

**New York State Transplant Council
Minutes of the April 9th, 2025, Meeting**

Council Members in Attendance for the Purpose of Determining Quorum:

Chair-Lewis Teperman, MD; Patricia Dahl; Andrew Flescher, PhD; Nancy Gallo; Milan Kinkhabwala, MD; Chris Kjolhede, MD; Naveed Masani, MD; Nancy Metzler; Michael Sosna; Vincent Tilson.

Council Members in Attendance by Video Conference:

Liise Kayler, MD

Council Members Not in Attendance:

Leonard Achan; Barbara Breckenridge; Jean Emond, MD; Aaron Glatt, MD; Kevin Gramlich, Ernesto Molmenti, MD.

Invited Guests and Speakers:

Dr. Douglas Fish, Deputy Commissioner, NYS DOH; Larissa Wilberschied, Program Manager, Hepatitis B & C Surveillance Unit NYS DOH; Samantha Delair, Executive Director of the NY Center for Liver Transplantation; Colleen Flores, Director of Quality, Northwell Health; and Katie Dokus, Director of Transplant Operations, University of Rochester Strong Memorial Medical Center.

Staff: N. Agard, M. Glannon, M. Hennessey, T. Irizarry, L. Mosher, A. Wager; J. Riegert, T. Wallace, V. Murray, W. McKenna, L. Schillinger, A. Nagy

Meeting Summary

1. Call to Order and Introductions

Dr. Teperman, Chair of the NYS Transplant Council, called the meeting to order at 1:05 pm and reviewed the meeting agenda.

Dr. Teperman reminded members and guests that April is Donate Life month and commends all the great work that is being done to promote organ, eye and tissue donation. Dr. Teperman informs the group that this is Tammy Irizarry's last meeting and before retirement recognizing her dedicated support of the Council for many years.

2. Report of the Chairperson

Dr. Teperman acknowledged that a quorum had been met and reviewed recent appointments and resignation(s) from the Council. Dr. Teperman reported that he had been appointed as Chairperson of the council, having served as Acting Chairperson for several years. He noted that Vincent Tilson is newly appointed to former council member Michael Kerr's position to a recipient and advocate position on the Council.

At this time, he encouraged Mr. Tilson to introduce himself. Mr. Tilson gave background that he is a retired police officer and is now 14 years post-transplant. Dr. Teperman extended welcome to the transplant council.

Dr. Teperman addresses the transplant council's vice chair vacancy. The position requires the individual to work closely with the chair and government, specifically the Department of Health. Dr. Teperman stresses the importance of being present and active for council meetings, also noting the many active issues facing transplantation. Those interested in the vice chair position were directed by Dr. Teperman to email Tammy regarding their interest, names to be to department by April 29th.

3. Welcome and Remarks by Dr. Douglas Fish, Deputy Commissioner, Office of Health Care Delivery, New York State Department of Health

Dr. Fish introduced himself to Council members, he led with thanking the council for their thoughtful, and dedicated work on behalf of New York State. Dr. Fish addresses Donate Life month, he acknowledged it as a time to celebrate donors, their families, and to thank them for their selfless gifts while also educating the public about becoming organ donors. He shared a personal story of how organ donation has impacted him.

Dr. Fish highlighted that the Department of Health (DOH) has recently gone under reorganization noting that the new Office of Health Care Delivery houses the Office of Primary Care Health Systems Management and the Division of Hospitals and Diagnostic and Treatment Centers which is where the Bureau of Organ Donation and Transplantation sits. Dr. Fish further expanded on the many responsibilities that fall to the state's Department of Health.

Dr. Fish addressed federal level changes, their current and anticipated impacts. He highlighted that the state's role is becoming increasingly important and, through all the current uncertainty, that the state will remain focused on its mission.

4. Approval of 09/18/2024 Minutes

Dr. Teperman asked Council members to review the minutes of the September 18, 2024, meeting and questioned if there was a motion to approve. A motion to approve was made by Patricia Dahl, seconded by Michael Sonsa. The minutes approved unanimously.

5. Update on Federal, State and Departmental Activities

Federal Update:

Dr. Teperman noted the uniqueness of this meeting, while it's typical to have someone from the Organ Procurement Transplant Network (OPTN) and/or United Network for Organ Sharing (UNOS) to provide insight and updates at a federal level, there will be no one from these entities speaking at today's meeting. He reports that federal officials, including those from UNOS and OPTN, were instructed not to attend or speak at such meetings at this time.

Dr. Flescher, Chair of the both the Transplant Council and OPTN Ethic Committee, expressed concern over potential privatization and the issue of out of sequence allocation. Dr. Flescher referenced an article by Sumit Mohan in the American Journal of Transplantation discrediting the claimed benefits of out of sequence allocation, i.e., increased utilization and expeditious transplantation. Dr. Flescher went on to further

raise concerns related to out of sequence allocation. There is a growing percentage of kidneys being allocated outside of the waitlist order (up to 25%). This raises issues of fairness, transparency, and could damage public trust in the system.

Group discussion highlighted concerns over the lack of Organ Procurement Organization (OPO) oversight without sufficient transparency or accountability. Only 11 of 55 OPOs responded to a recent data survey, raising concerns about compliance and willingness to collaborate.

During the allocation out of sequence discussion a concern was raised that wealthier centers, patients or those with certain insurance plans may be more likely to receive organs due to the potential increased availability of expensive machine preservation technologies, e.g., normothermic regional perfusion, that are not widely reimbursed. Machine preservation, though helpful in extending organ viability and increasing the donor pool, is expensive and unevenly adopted. There was concern voiced that access to such technologies might influence allocation decisions.

As the members brainstormed potential solutions to issues raised, it was stated that current New York State law (Public Health Law §4363) is outdated, making it unclear what authority the state has over New York OPOs and whether DOH could request data from them. The potential need for legislative updates was raised. Jason Riegert, Deputy Director, Bureau of Program Council, acknowledged that oversight of OPOs primarily lies with the Center for Medicare and Medicaid Services (CMS), noting, however, there was Public Health Law that grants the Department some authority that could likely be leveraged to support Departmental request for comprehensive data from OPOs. Existing public health law regarding NYS licensed tissue banks regulations were discussed as a potential route to obtain data. There was an overall group consensus that although federal oversight may be lacking or disrupted, state-level monitoring is still necessary to protect New Yorkers.

A motion recommending that the New York State Department of Health (DOH) request detailed data from OPOs regarding out-of-sequence organ allocations, use of bypass codes, time from organ availability to allocation, recipient center information, and other relevant data as deemed necessary by the DOH was introduced by Dr. Teperman. The motion was seconded by Patricia Dahl and was approved unanimously. The DOH will determine how best to request and potentially enforce data collection, especially from OPOs with existing regulatory ties to the state.

State and Department Update:

Nancey Agard MS, RN, Director, DOH Bureau Organ Donation and Transplantation, provided an update on Department and Program matters.

Department Updates included the appointments of:

- Dr. Douglas Fish to Deputy Commissioner of the Office of Health Care Delivery and
- Tina Kim to Deputy Commissioner of the Office of Health Equity and Human Rights;

Program Updates:

1. Transplant Center Licensure, Survey and Surveillance
 - The Department completed the pre-opening survey for LIJ's Cohen's Children's Medical Center and approved their pediatric heart transplant program. The first transplant was recently and successfully performed.
 - New Certificate of Need (CON) applications for transplant programs have been received from:
 - NYU Brooklyn applying for a kidney transplant program and
 - North Shore University Hospital seeking to establish an adult pancreas transplant program.
2. Implementation of New Laws Establishing New Registry Enrollment Sources
 - The Department has been working to implement Health and Insurance Law that required the addition of the "Lauren's Law Question" to health insurance enrollment, renewal and portal establishment forms. The number of insurance plans impacted is unclear but could be up to 200–300 insurance plans. Data transfer methods for submission of the data to the Registry (secure file transfer and API) are being finalized. Rollout will be staggered to manage the logistics. The effective date of these laws is January 1, 2026.
 - A new bill will require hospital Electronic Health Record (EHR) vendors to include the Lauren's Law organ donor question on patient portals.
3. Update on NYS Registry
 - A Request for Proposals (RFP) for operating the donor registry was issued. Bids were received, reviewed, and scored. The contract award process is ongoing with the Department being the legally mandated quiet period. In response to Council member questions, it is emphasized that there can be no further public details disclosed until the process concludes.
4. NYS Hepatitis C Organ Transplant Surveillance

Larissa Wilberschied, MS Program Manager in the Hepatitis B & C Surveillance Unit gave a presentation of the Hepatitis C Organ Transplant Surveillance and Evaluation Project. This project is a collaborative effort between the CDC, New York State Department of Health, NYC Department of Health and Mental Hygiene, and transplant centers across NY State. The aim is to assess the public health impact of hepatitis C (HCV) infections resulting from organ transplants involving HCV-positive donors.

Ms. Wilberschied reports that currently all NYS transplant centers that transplanted HCV-positive organs responded to data requests and that data analysis is ongoing. NYS and NYC DOHs will report their aggregated and de-identified data to CDC for them to combine with data from other jurisdictions and assess national trends. Data submission is expected by this June, with follow-up meetings to follow.
5. Living Donor Support Program Update

Ms. Agard identified that three staff members were hired to support the program. A dedicated phone line is being established, and a website is planned to support program operations. Greater detail was given at the special session held earlier

today and documents pertaining to the Living Donor Support Program are one the Transplant Council web page.

Living Donor Support Program (LDSP) staff reviewed the status of proposed program regulations and guidance developed to educate the public and transplant centers regarding program eligibility and reimbursement.

- Ms. Agard highlighted that regulations have been drafted based on a “minimum necessary” model, focusing on what’s required by law. She reviewed the regulatory process as required by the State Administrative Procedures Act including publication in the State Register and an open comment period for 60 days. Comments received will be evaluated, proposed regulations may be revised and re-published if needed be, and a program launch date determined after the completion of this process. The Departments hope is to launch the program in later summer or early fall.
- Ms. Wager gave an overview of the program’s eligibility criteria and application process noting that eligibility for the Living Donor Support Program is based on New York State residency for both the living donor and ultimate recipient, not income.
- Ms. Mosher outlined the reimbursement process and guidelines. She noted the Department’s intent to reimburse legacy donors, those living donors who meet program eligibility and donated between April 1, 2023 and prior to program launch, as well as future eligible living donors. She reported the Department’s plan for program oversight and fraud prevention

Dr. Teperman encouraged members and attendees to review the material and provide feedback to the Department in the next two weeks.

6. Report of Special and Standing Committees

1. Ethics Committee Update and Discussion:

Dr. Flescher, Chair of the Ethics Committee, reviewed the membership and charge of the Ethics Committee and reported on the work of the committee to date.

Normothermic Regional Perfusion (NRP)

Dr. Flescher reviewed a draft paper of the Ethics Committee on NRP. The papers focus is an ethical analysis of NRP, presenting both the pro and con perspectives on its use, particularly as it relates to the dead donor rule and recommends the issue be referred to the Academy of Medicine for final arbitration. Council member reviewed the draft paper identifying only minor edits and typos to be addressed. The council voted to endorse the paper and approved posting it publicly on the Department’s website providing an opportunity for broader feedback to be gained. Once feedback is received and any final revisions are made, the council may revise the paper and determine its final recommendation(s).

Analysis of the 2023 American Academy of Neurology (AAN), Pediatric and Adult Brain Death/Death by Neurologic Criteria Consensus Guidelines

Ms. Agard reminded the Council of the background of this undertaking. The Council was asked to assess the new guidelines relative to existing New York State regulations and policy, including those in Part 400.6 and prior Task Force on Life and the Law guidelines and make a recommendation as to whether the Department could endorse them.

Ms. Agard indicated that the guidelines contained both clinical recommendations and recommendations addressing topics of special consideration and that though discussed at the last meeting of the Council, no action was taken. Ms. Agard reminded the group that the Ethics Committee fully endorsed the clinical recommendations in the AAN consensus guidelines and that there was extended discussion regarding a number of the recommendations addressing topics of special considerations.

The special consideration recommendations that were specifically discussed revolved around when to discontinue life support for persons that have been declared brain dead or have met the criteria for determination of death by neurologic criteria. Existing policy in New York requires that hospitals have policies and procedures in place about allowing families reasonable time for emotional adjustment after the determination of brain death, but there is no option to continue life support long term beyond the determination of brain death. The Ethics Committee discussed whether families should be allowed to object to brain death determinations and continue life support. This would be contrary to existing policy and the Ethics Committee was not in favor of allowing this—thus supporting the AAN recommendation regarding this issue. The discussion referenced the one state (New Jersey) that allows families to object to the brain death determination and maintain life support but acknowledged it is rarely used.

Dr. Flescher added that one member of the Ethics Committee proposed consideration of an accommodation similar to New Jersey's, for the rationale that the number of instances when it would likely be used would be low enough not to rouse objection. The idea of allowing an exception was not supported by the group for a number of reasons including but not limited to financial, ethical, and logistical concerns. A motion was made to recommend to the Department that it endorses the AAN consensus guidelines on the determination of brain death, the motion included adoption of the 2023 AAN Consensus Guidelines on the determination of death by neurologic criteria. This motion to endorse was made by Dr. Flescher and seconded by Michael Sosna. The motion was unanimously approved.

2. NYS National Academy of Science, Engineering and Medicine (NASEM) Report Review Committee Update and Discussion:

Nancy Metzler, Chair, requested that Samanta Delair give the report to the Council on the activities of the NASEM Report Review Committee.

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

- The Performance Measure Workgroup report was given by Katie Dokus. Ms. Dokus indicated that committee members were surveyed on performance metrics respondents' thought were of most importance in gaining an objective picture of the performance of the donation and transplant system. There was a 50% response rate to the survey. She shared the top 5 donor/OPO scoring metrics as well as the top 5 transplant center metric scores and reported that initial analysis of the data suggests that donor/OPO metrics received higher impact scores than those associated with transplant centers. Ms. Dokus noted that the next steps for this group would be further review and analysis of the data and collaboration with

the other workgroup leads. In addition, the feasibility of data collection (cost and effort considerations) needs to be determined before methods to make this data publicly available can be determined. Dr. Teperman reported that the NASEM Committee co-chair, Leonard Achan, resigned and that this position will need to be filled. He asked that interested parties reach out to the Department.

- The Improve System Performance Workgroup is chaired by Bruce Gelb and Carrie Lindower with report given by Ms. DeLair. A focus of this group is on equitable access to transplant. There was much discussion on eliminating New York's ban on in-state multiple listing for transplants. It was noted that most states allow multiple listings, NY is currently an outlier in this regard. A number of pros, cons and potential unintended consequences were discussed by the group. Dr. Flescher spoke on a paper written by the OPTN Ethics Committee that raised concerns about multi-listing, ultimately suggesting that it should only be allowed in certain circumstances. After much discussion the Council asked the workgroup to write up a thorough evaluation of the pros, cons and unintended consequences for the Council's consideration at its next meeting so they could make a recommendation to the Department about the matter.
- The report of the Increase Use of Donated Organs Workgroup was given by Colleen Flores. She reported that this workgroup surveyed their members and other members of the committee and Council. The results of survey analysis resulted in the identification of 5 recommendation themes. These include: facilitating partnership, sharing data, and education and development of donation and transplant professional. Next steps include determination of how to accomplish these recommendations.

Ms. DeLair closes in noting that the need to improve relationship and communication between OPOs and transplant centers was highlighted by all workgroups as it relates to their specific topics.

3. Organ Recovery Taskforce:

Update on this item was brief and given by Dr. Teperman. The Council voted to establish this taskforce to address concerns raised regarding the training and competency of those involved in organ procurement. There has been difficulty in recruitment of membership for the Organ Recovery Taskforce, further work is needed to get these efforts up and running.

7. New and Other Business

Dr. Teperman opened the floor to new and other business. No new business was raised.

8. Adjourned

A motion to Adjourn the meeting was made and seconded. The meeting adjourned at 3:30 p.m.