

**New York State Transplant Council
Minutes of the November 13, 2023 Meeting**

Council Members in Attendance for the Purpose of Determining Quorum:

Council Members: Lewis Teperman, MD - Acting Chairperson; Leonard Achan; Patricia Dahl; Jean Emond, MD; Andrew Flescher, Ph.D.; Milan Kinkhabwala, MD; Chris Kjolhede, MD; Naveed Masani, MD; Nancy Metzler; Michael Sosna.

Council Members in Attendance by Video Conference:

Barbara Breckenridge; Nancy Gallo; Liise Kayler, MD; Michael Kerr; Ernesto Molmenti, MD,

Invited Guests and Speakers:

Richard Formica, MD, UNOS President; Dr. Sumit Mohan, Columbia University Irving Medical Center

Meeting Attendees: Daryle Blackstock, Zina Cary, Bruce Gelb, Zena Kerry, Samantha DeLair, Samantha Taylor, Lily Lam, Vicki Lyons Eye Bank, Colleen O'Donnell Flores, Kristen Phillips, Aisha Tator, Amanda D'Ambrosio, Carrie Lindower, Karen Lindower, Darryl Blackstone, Donald Flores, Francis Queenie.

Staff: N. Agard; M. Hennessey; T. Irizarry; M. Kohn; M. Morelli; J. Morley; A. Nagy; J. Riegert; S. Shulman; J. Treacy; L Schillinger

Meeting Summary

1. Call to Order and Introductions

Dr. Teperman, Acting Chair for the NYS Transplant Council, called the meeting to order at 10:15 am. Council members invited guests and meeting attendees introduced themselves.

2. Report of the Chairperson

Dr. Teperman reviewed the meeting agenda and list of invited guests with members and meeting attendees.

Dr. Teperman announced the appointment of Dr. Liise Kayler, Chief of Transplant Surgery and Transplant Program Director at Erie County Medical Center and SUNY Buffalo, respectively.

3. Approval of Minutes

Dr. Teperman pointed member attention to the minutes of the May 23, 2023 meeting of the Council. There were no questions or concerns raised with the minutes as drafted. A motion to approve was made by Patricia Dahl, seconded by Nancy Gallo. The motion to approve the minutes was approved, no abstentions, no disapprovals.

4. Welcome and Remarks by Dr. John Morley, Deputy Commissioner, Office of Primary Care and Health Systems Management

Dr. Morley introduced himself and described his position in the Department. He stated he was attending Council meetings representing the Commissioner and Department Senior leadership. Dr. Morley recounted the Governor Hochul's nomination of Dr. James McDonald

to the position of Commissioner of Health, that Dr. McDonald had undergone a Senate confirmation Hearing and was confirmed the 18th Commissioner of Health shortly thereafter.

Dr. Morley reported to the Council that Dr. McDonald's and the Department's top priorities as being to increase access to healthcare and addressing the factors that contribute to disparities. The Department is working hard at carrying out its public health role in supporting health promotion and disease prevention for all New Yorkers and identifying the ways to address the health disparities that exist throughout the healthcare system. Increasing access to transplant services when needed is included in the Department's increasing access and addressing disparity initiative.

Dr. Morley conveyed the Commissioners and the Department's appreciation for the work and dedication of the Council and that he hopes be able to meet and catch up the Council himself as he familiarizes himself with the many aspects of the Department's work.

5. Review of Meeting Management Rules and Open Meetings Law Requirements

Ms. Agard reviewed the meeting slides dedicated to how the meeting will be managed, order of speakers, management of motions and reminders regarding the requirements of the Open Meeting Law.

6. Update on Federal, State and Departmental Activities –

Federal Update

Dr. Richard Formica, Vice President of the Organ Procurement and Transplant Network (OPTN) and United Network for Organ Sharing (UNOS) Board of Directors updated the Council on the HRSA OPTN Modernization Initiative, and UNOS Action Agenda responding to member questions when asked. See attached slides.

- HRSA Modernization Initiative:
- HRSA's goal of the modernization initiative is to improve the functioning of the OPTN and address public and legislative concerns about the inefficiencies and perceived failures of the OPTN as it is currently constructed under two contracts with UNOS and the Scientific Registry for Transplant Recipients (SRTR).
- HRSA plans break up the functions of the OPTN and contract them out to 5 different contractors. Contract will focus on one of the following: operations-including governance; IT systems and data continuity, maintenance and compliance; communications; research and evaluation including quality improvement and innovations; and general requirements.
- There will be a Transition Contract for Board Support and if a vendor wins the board support contract they cannot have any of the four others.

- UNOS Action Agenda
- Includes:
 - o Governance – making the OPTN Board independent.
 - o Transportation – reducing risk of organ delay, damage or loss in transport.
 - o Equity –Improving equity in access to transplant health care system for patients with end stage organ failure.
 - o Attaining Efficiency in Allocation and improve organ utilization.

- Data Collection and Accountability – to enhance organ procurement organization (OPO) performance monitoring identifying complimentary performance metrics to those used by CMS.

Questions, concerns and comments were made including:

- HRSA's timelines for various planned actions and whether or not the plan was do-able-if extensions were going to be allowed.
- Impact that multiple contracts would have on bifurcating government at the regulatory level being a big concern.
- The roles of CMS and the OPTN's Membership and Professional Standards Committee (MPSC) being different, one regulatory and one quality improvement and patient safety.
- Concerns about the potential impact of for-profit companies being allowed to become contractors vs the not for profit orientation of the field.
- Whether or not performance metrics had been or would be identified for/required of contractors.
- Concerns regarding the impacts of changes on OPO performance and stability.
- Lack of transparency of contractors a concern
- Within the federal government the OTAG – Organ Transplant Affinity Group was established. This group includes HRSA CMS, and possibly the FDA; they meet regularly to work toward harmonizing the agencies requirements.
- Concern for how HRSA management for 4-5 contractors will go. There are concerns. They will need more staff.
- Question raised about implementation of continuous distribution with some organs not started yet.
- Changes in how organs were allowed to be transported on airplanes in the cargo hold must be addresses as this is contributing to injuries and delays. The point was made that there are unintended consequences of good ideas.
- Broader distribution is working as there are more transplants in sicker individuals. Larger distribution of organs went into effect and one month later new OPO regs. Rate of recovery went up dramatically. In 2022 there were 7,455 kidneys recovered but not transplanted. 2023 on tract for approx. 8,000. Clearly something needs to be looked at. We need to ensure that organs get to people who will use them and reduce disparities.
- Need for additional reimbursement from insurance companies was identified if we are going to use livers and organs that need profusion devices.
- Concern was voiced about manipulation of pre-transplant metrics and alignment and the need for everyone to abide by the metrics.

State and Departmental Update

Ms. Agard updated the Council on Dr. McDonalds confirmation as Commissioner of health and appointment of Johanne Morne as Acting Executive Deputy Commissioner. Ms. Morne previously led the AIDS institute and the new office of Human Rights and Health Equity prior to taking on the acting executive deputy commissioner role.

Ms. Agard reported that the department is continuing its focus on health equity and reduction of health disparities.

Program Update

Ms. Agard updated the Council on the following:

- Living Donor Support Program (LDSP):
 - Program planning and background work is being done; meetings are being held with various stakeholders.
 - Recruitment and hiring of staff is underway.
 - Plans include appointing an Advisory Committee.
 - Dr. Teperman volunteered to serve on the Committee.
- Adding enrollment sources to the Registry
 - Working with Department of Environmental Conservation (DEC) and Registry Contractor (DLNYS) to add the Lauren's Law questions to the fishing and hunting licenses. Planning for implementation of the secure file transfer of DEC enrollments to the Registry is in progress.
 - Also, working to implement the law requiring insurance plans to add the Lauren's Law donor designation question to their applications and determine which method of transmission of data works best for them.
 - In response to a question about MyCharts, Ms. Agard discussed Registry Partners and how they have the option of implementing a trackable link or embedding the Registry Enrollment Form on their websites—some partners that are hospitals have chosen to put these in their patient portals to their electronic health records (EHR). She went on to explain that currently there are 8 hospitals/health care systems that are Registry Partners and that there is a bill making its way through the Legislature that would require a method of direct enrollment in the Registry via general hospital EHR systems.
 - Ms. Agard went on to explain that currently approximately 47% of NY State's eligible population is enrolled in the Registry and that the rates of enrollment per county vary greatly. The primary registration source of enrollees in the Registry is the Department of Motor Vehicles. NYS is the only states that uses the voter registration to ask for donation. Bronx has 28% of the population enrolled.
- Licensure, Survey and Surveillance of Transplant Programs
 - Ms. Agard briefly reviewed the role of the program in review of Certificate of Need applications for new transplant programs and frequency of CMS recertification surveys for these programs.
 - Ms. Agard notes the importance of hospitals working with OPO's on maximizing donations especially in light of the new CMS OPO performance measures.
 - The Organ Donation and Transplant Program also works with the hospital program in support of their survey, surveillance and oversight responsibilities related to organ donation and procurement.

Wadsworth Update

Dr. Matthew Kohn, Director of Tissue Services, Wadsworth Laboratory, updated the Council on tissue donation related issues including:

- Dr. Kohn discussed the need for changes and corrections to NYCRR Part 52 regulations with the Council. Proposed language changes are currently being reviewed internal. When the proposed amended language is available for public comment he will share them with the Council for their feedback. The changes affect the non-transplant anatomic banking regulations which date back to 2007 and several other sections Part 52 which were last amended in 2000.

7. Report of Special and Standing Committees

Report of the Ethics Committee:

The report of the Ethics Committee was given by Dr. Flescher, ethicist, Member of the Transplant Council and former Chairperson of the OPTN/UNOS Ethics Committee. He explained that the convening of the Committee resulted from an action of the Council, that seven members had been identified and they had begun their work.

Dr. Flescher reported that the Committee had been charged with reviewing the state's Determination of Brain Death Guidelines, last published in 2011 and making recommendations for updating as needed and performing an ethical analysis of normothermic regional perfusion (NRP).

Questions were asked including the following:

Q. What is the goal of NRP review?

A. A comprehensive ethical analysis. The OPTN/UNOS paper stopped short of prescription. Our ethical analysis may lead to recommendations and not limited in the way that the OPTN paper was. This may be a way to impact and advance the national conversation.

Q. How will patient and public engagement occur in the NRP process?

A. OPTN and UNOS process directly involved patient and public input in their analysis. This group is informed by that. The Committee plans to be "extra-committee" comment on their analysis, with or without recommendations, with a discussion a one or more Transplant Council meetings, which are open to the public and patients. There is patient representation among Council membership. Before anything is finalized there will be presentation and discussion with the Council and others.

Q. Brain Death regulation. Hospital based bylaws.

A. With NRP it is designed to be tabular offset. We are only revising the brain death document. NRP and the carotid arteries is the critical question.

Q. Does any of the Ethics Committee have NRP experience.

A. Yes, and we have consulted with surgeons that have NRP experience as well. The membership of the committee was specifically constructed to include members with known positions of being in favor or and in opposition to NRP, in order to facilitate robust discussion.

Council members voice continued concerns about the potential that NRP advocates are not adequately represented on or to the Committee in their deliberations. Others questioned whether there were members of the NYS transplant community and whether OPOs were represented on the Committee.

Report of the Council's NASEM Committee:

The report of committee charged to review the recommendations of the National Academy of Sciences, Engineering and Medicine (NASEM) 2022 report and identify related opportunities of improvement in NYS was given by Ms. Metzler, Co-Chair of the Committee.

Ms. Metzler explained that after review of the report, Ms. Metzler and Mr. Achan, Co-Chair of the NASEM Committee, met with Council Chair Dr. Teperman and DOH staff and determined that it would be expeditious to establish three workgroups to focus and hopefully expedite the work. The workgroups were to be focused around developing performance metrics and goals, improving system performance to increase access and equity and improve use of donated organs.

The report of the workgroups to date were given by their leads as follows:

1. Develop Performance Metrics and Goals: Led by Mr. Achan and Dr. Sumit Mohan reported a meeting scheduled for this week.
2. Improve System Performance to Increase Equity and Access: Led by Dr. Bruce Gelb and Carrie Lindower reported that this workgroup has met. Upon review of their scope of work the Leads determined that of their work could be broken down into 6 different categories of challenges. At their meeting each person on the Workgroup was asked to work with the Leads and then the rest of the group on two of those categories of challenge. The plan is for the Workgroup to meet again in the next few weeks and proceed from there.
3. Improve Use of Donated Organs: Led by Dr. Liise Kayler and Colleen Flores reported that their group had met, and each member was assigned a question related to their area of work. Workgroup members were asked to write a one-page response. Information from these write-ups will be assessed and presented later. In addition, Workgroup members were surveyed and asked to rank their opinions of the importance of each recommendation included in the NASEM report. Survey responses will be tabulated, ranked, and evaluated for further action.

8. New and Other Business

Dr. Teperman raised his concerns about the training and competence of persons procuring organs for transplantation and the effect new technology was having on this arena. After a brief discussion during which other members of the Council voiced similar, Dr. Teperman moved to:

- Create a task force to address credentialing of all organ procurement providers, including but not limited to training and education requirements, and evaluation/competency criteria for those providers.

Motion seconded by Michael Sosna. Council members voted on the motion with zero opposed, zero sustained and all members approved. Motion passes.

Meeting Summary is not final until approved by the Transplant Council

Nancy Gallo announced that after 45 years the New York Firefighters Skin Bank was closing due to financial burdens. As a result, Nancy will not be working with the Skin Bank and would hope to stay on the Council.

Adjourned

- A motion to Adjourn the meeting was made and seconded.
- The meeting adjourned at 1:03 p.m.

DRAFT