

# New York Center for Liver Transplantation

## Staff Report

### Annual Update 2014

The New York Center for Liver Transplantation, Inc. (NYCLT) is a not-for-profit created in 1988 under the direction of the Department of Health with a mission dedicated to ensuring that New Yorkers have access to high quality liver transplantation services. Its membership consists of the seven liver transplant programs in New York State. The NYCLT also monitors the quality of services at all centers authorized to perform liver transplantation in New York State and tracks the outcomes for all live adult liver donors in New York State. The goal is to promote collaboration and coordinate information sharing among its members, collect and review data on volumes and outcomes, and serve as a forum for program monitoring and peer review activities.

**Strategic Planning:** In 2013 the Board of Directors adopted the following long-term objectives for NYCLT: provide a forum for communication among liver transplant professionals; develop new programs through the increased use of data to improve liver transplantation and donation; assist members with regulatory compliance; increase and secure funding from grants and other sources; and strengthen relationships with other organizations, including OPOs.

The following key targets have been identified through 2016: reduce geographic disparities in access to liver transplantation; review/improve quality of liver transplantation in NYS; increase liver transplantation in NYS; expand revenue to include 20% funding from non-state resources. To meet these targets, NYCLT is committed to: continue advocacy efforts at the local and national levels for broader sharing of livers, either through mathematical redistricting or similar mechanisms; incorporate data driven mechanisms to improve and evaluate efforts related to liver transplant; evaluate use of NYLiver.org and its impact on import liver rates; build on and maintain the relationships established with key organizations to advocate for change in policy to promote/increase organ donation; continue OPO communication activities that improve and enhance donation and transplantation in New York; and maintain existing relationships with funders and diversify revenue through tenant and management services agreements, grant writing, donations and/or products/services offerings.

**Regional Disparities in Access to Liver Transplantation:** New York State patients experience some of the longest wait times for a liver in the country. Similar to California and New England, the average MELD score of a New Yorker at transplant is significantly higher than the majority of regions in the US. Current regional sharing in New York is not broad enough to mitigate the *national discrepancies* in patient access to liver transplant. Nationally, the OPTN Final Rule charges UNOS with instituting policies for the equitable allocation of organs among potential recipients. Since 2010, NYCLT has taken a leadership role with NYSDOH, the NYS liver transplant programs and other regions with liver shortages to promote broader sharing of organs nationally, so New Yorkers are not unfairly overlooked in the liver allocation process. NYCLT is working within UNOS through participation in its committees, public forums and educating the public about this issue in an effort to change practice to be more in line with the Final Rule.

As a result of the push for broader sharing, UNOS released a concept document related to liver distribution equity in July 2014 for public comment. NYCLT made comment to UNOS, but also wrote letters to the NYS Congressional Delegation, Senators and HHS Secretary Burwell to write in opposition of media reports that changes in liver distribution essentially resulted in disadvantages to African Americans.

A public forum was held in September 2014 to seek additional input and was attended by nearly 500 people from most of the liver transplant programs in the country. The vast majority of participants agreed the OPTN should seek to ensure that candidates have timely access to liver transplantation. Opinions varied on the best metrics and methods to use in identifying and reducing geographic disparities, as well as the potential effects such efforts may

have for transplant institutions in areas such as costs, logistics and practice. The utilization of available organs and optimization of organ donation was also discussed. The Liver and Intestinal Organ Transplantation Committee also met September 2014 and agreed that additional study and feedback is necessary to continue to evaluate the issues identified. It resolved to establish work groups to address key focus areas including: metrics to assess geographic disparity; logistical/transportation considerations; financial issues; and methods to optimize liver utilization.

This is only the first step in reducing regional liver transplant disparities, and one NYCLT will continue to support. However, a timetable has not been established for a policy proposal resulting from these discussions. As such, NYCLT has retained Manatt, Phelps and Phillips, LLC, a lobbying firm, to advocate for changes to current liver districting in the US. In addition to teaming up with GNYHA and HANYS to attend a congressional briefing in DC in October 2014, NYCLT is making personal visits to key congressional members in November 2014 to emphasize the urgency of the issue and to push HRSA to establish a timeline for change. NYCLT staff reached out and met with the CA hospital association to encourage their support in making changes to the current liver distribution system. The California congressional delegation is agreeable to joining our efforts.

**Expanded Criteria Donor (ECD) Project:** The ever-increasing disparity between the need for and the availability of donor livers has made it necessary to increasingly widen the boundaries of useable organs. Current allocation algorithms, geographic limitations, programming constraints and inherent obstacles of organ notification have particularly impacted the expedited placement of expanded criteria livers. NYCLT has worked with the NYS DOH to allow real-time notification of the availability of an open liver offer to all liver transplant decision-makers where expedited review and allocation of livers is essential to avoid liver discards. To this end, NYCLT created a web application that provides over 100 users at 7 transplant centers and the NYODN with equal access to liver offers that originate out of state.

The pilot project went live in November 2012 and has gone through a series of modifications to address issues such as allowing for enhanced communication between the NYODN and the liver transplant programs; adding a prompt box to require users to input a recipient sequence number in the case there is interest in a liver offer for a given waitlist candidate; and in the event of a direct call from an offering OPO allowing a transplant program to accept a liver for patient X, but also specifying NYODN will back up the offer and submit it through NYLiver.org. NYCLT also provided additional training in the summer 2014 to new users and to refresh veteran users. CPC members remain committed to the principal of broader sharing as a means to enhance the collective ability to give more NYS patients the transplant opportunity.

During the two years since implementation, one major trend has emerged – the quality of livers offers from out of state have remained low, resulting in no NYS interest in 75% of liver offers through NYLiver.org. On average, there are 20-25 notifications per quarter with 1-2 transplants resulting. The average transplant center response time to an offer is 9 minutes. A few transplant programs continue to report that the majority of imported organs have come through DonorNet.

**Simultaneous Liver-Kidney Transplantation Project:** In November 2014, Dr. Gaglio presented the *Utilization of Simultaneous Liver-Kidney Transplants Continues to Vary Dramatically by UNOS Region* at the annual meeting of the American Association for the Study of Liver Disease. As the NYCLT President, Dr. Gaglio spearheaded a project to look at the utilization of simultaneous liver-kidney transplants (SLK) by UNOS region. Over the last several years, the number of SLK has increased. However, guidelines for SLK, including when these combined transplants are appropriate based on serum creatinine, underlying liver and renal disease, etiology of renal dysfunction and time on dialysis, are contentious. Inappropriate SLK removes an organ from the donor pool which would more appropriately be utilized for a patient awaiting kidney transplantation. Failure to provide SLK to a patient who requires prolonged dialysis and kidney transplantation following isolated LT is similarly inappropriate.

Utilizing data provided by UNOS, a retrospective review of all SLK performed from 2002-2012 was done, analyzing the percentage of SLK performed in each region based on total number of liver transplants (LT) performed, the ratio of % SLK performed to mean MELD at the time of transplantation, and assessed rate of change in number of SLK by year by region.

Findings show that utilization of SLK varies significantly when comparing UNOS regions. The increased utilization of SLK does not appear to correlate to increased wait list MELD score at the time of transplantation in regions performing the highest % of SLK. In fact, lowest utilization of SLK is occurring in regions with some of the highest wait list MELD scores. These findings suggest that a uniform policy related to utilization of SLK should be adopted.

### **Living Liver Donation (LLD) Objectives:**

**LLD Data Deliverables to NYSDOH:** There is a regulatory requirement in New York State to track the post-donation quality of life of living liver donors. NYCLT provides a centralized, standardized process to achieve that goal. NYCLT has been surveying living liver donors since 2004, after it received DOH approval to use the surveys to fulfill the regulatory requirement for tracking these individuals and subsequently, NYCLT has shared the surveys with the transplant programs. NYCLT's Data Use Agreement with UNOS continues to provide a mechanism to access living liver donor and recipient data for review by the CPC and subsequent reporting to DOH. In April 2014, NYCLT completed the living donor surveys for all 2004-2013 donors and provided the results to the NYS DOH. Hard-copy surveys were sent to the respective centers for use in educational tools and to help comply with the regulatory requirement to track donors for life.

NYCLT has also worked with Dr. LaPointe-Rudow to compile two abstracts which summarize the living donor self-reports on follow-up quality-of life post-donation. IRB approval has been obtained and NYCLT is awaiting approval from the NYS DOH to submit to ATC for presentation in 2015.

**LLD State Regulatory Work:** NYCLT is represented on the NYS Transplant Council Regulation Review Workgroup by Samantha DeLair. Since 2006, NYCLT has fulfilled its contractual obligations and provided feedback and experiential input to the DOH and to its regulation review committee over several iterations of the revised regulations. Membership on the committee allowed for an assessment of the existing regulations developed by the NYS Committee on Quality Improvement in Living Liver Donation. NYCLT provided focused review to the informed choice process, the role of the independent donor advocate team (IDAT), the educational materials and the follow up requirements for living liver donors. Due to its regulatory compliance work, including the living liver donor peer review process, focus groups and follow-up surveys, NYCLT's recommended changes to the regulations were well-received in 2011 and many of them have been incorporated into the final version enacted in September 2014. NYCLT has distributed the revised transplant regulations to the leadership and administration at each transplant program. The DOH plans to focus its attention next on the Certificate of Need regulations as they apply to transplant.

**OPO Communication Initiative:** NYCLT conducted a meeting with the OPO leadership in NYS on October 8, 2014 to review NYCLT initiatives related to regional disparities in liver distribution, collaborative research projects and compliance with liver biopsy guidelines; to discuss the regional review board and its communication process; to look at acceptance/declination practices by center in NYS; to determine the best use of NYLiver.org as it relates to local vs imported organs; to review ongoing OPO data collection and multi-organ allocation policies; and to identify ways in which NYCLT can help the OPOs in their efforts to increase organ donation. The Buffalo OPO indicated a problem with the unavailability of stat serology testing in NYS, resulting in delays in organ recovery and subsequent organ discard. As a first step, NYCLT is surveying NYS OPO, eye and tissue banks to determine the potential number of samples NYS facilities might offer to a lab willing to offer the more expensive stat services.

**OPO Data Review:** OPOs continue to share quarterly data related to liver donors including DCD and splits, discards and exports. The OPOs have provided NYCLT with ongoing donor-specific data, including information related to the organ offer and acceptance patterns at each transplant program. In turn, NYCLT has shared with its members, recipient outcome data in an effort to learn from the successes and challenges other programs have with the use of extended criteria donors. This unique initiative has helped identify problematic trends in liver placement, allocation and processes. The ultimate goal is to make maximum use of the donor livers available to patients on the liver transplant waiting list in New York State.

**DCD Recovery and Preservation:** Given the critical shortage of deceased donor livers in New York State, NYCLT members have increasingly considered expanded criteria donor livers, including those recovered through donation after cardiac death (DCD). Several NYS OPOs report as high as 45% DCD donor potential within their DSAs. Despite the high DCD potential and the critical need for liver transplantation demonstrated by the large liver waiting list in New York, currently the utilization of DCD livers is low due to mixed recipient outcomes. In May 2014, NYCLT met with the Medical Director of the NYODN to discuss the use of DCD livers and explore the use of a number of techniques in the recovery, preservation and preparation of DCD livers for transplant to attempt to provide better outcomes for liver transplant recipients. Although the use of different recovery and preservation techniques was determined to be dependent on center-based decision making, transplant programs continue to evaluate and expand the use of DCD organs whenever possible.

**OPO Donation Initiatives:** As New York programs face the lowest donation and transplant rates in years, the Center has initiated discussions with the NYS OPOs on ways in which NYCLT can aid in OPO donation initiatives, particularly in NYC. With one of the lowest donation rates in the US, the NYS OPOs are working with a statewide consortium to enhance the NYS Donate Life Registry and create a united message to raise public awareness regarding the need for organ donation. In early 2013, NYCLT wrote letters of support to the NYS Assembly and Senate Health Committee Chairs regarding legislation allowing a non-profit to run the NYS donor registry, rather than remain as a state-run registry. Large states such as California, Illinois and Florida have contracted management of their registries to outside entities and are far better registrant performers than NYS. In Spring 2014, the NYS budget bills and Article VII language allowed for the NYS Donate Life Registry to be put out for public-private partnership management. Hopefully this will allow the registry to be more technologically nimble, and responsive to changes in social media.

**Palliative Care Initiative:** Palliative Care has become an increasingly used service during a patient's end-of-life in the hospital setting and can have a substantial impact on decision making at that time. However, organ donation is not a routine part of palliative care training and NYCLT members indicated a need for education and statewide discussion between leaders in the transplant and palliative care communities. NYCLT is collaborating with the NYS DOH to create a statewide conversation regarding organ donation with the palliative care community. Funding for such a conference will likely occur in the late spring of 2015. –

In the meantime, NYCLT has worked with the NYS OPOs to modify the MOLST (Medical Orders for Life Sustaining Treatment) that was primarily created for EMS, but has been increasingly adopted in health care systems and distributed those recommendations to the NYS DOH.

NYCLT also partnered with the Albany Lions Eye Bank to distribute a short survey to the palliative care community to determine their knowledge regarding donation, their comfort level in discussing it with patients, etc. Results of the survey show that half the palliative care community feels inadequately prepared to discuss organ donation and in fact, do not discuss it with patients. Although many palliative care professionals felt that their patients are not candidates for organ donation, survey participants had a number of suggestions as to the best way to educate their colleagues about organ donation and the best way to reach their patients to discuss organ donation. The input garnered from the surveys will be used to aid our discussions with the palliative care

community and identify the best method to disseminate outcomes from a statewide conference on the intersection between palliative care and organ donation.

**New York Cardiothoracic Transplant Consortium (NYCTC):** In December 2008, the NYS Transplant Council made a unanimous recommendation to pursue the creation of a heart/lung transplant consortium, similar to NYCLT. As a result, the DOH staff approached NYCLT in January 2009 to assist in the development of a cardiothoracic transplant consortium as part of the deliverables attached to the existing state contract with NYCLT. Together with DOH, NYCLT met with the NYS heart and lung transplant programs in June 2009 to work on the development of bylaws, a governing structure, and a draft budget with dues and worked with the NYS OPOs to identify programmatic goals. The NYCTC was launched in March 2010 and has an ongoing relationship with NYCLT to obtain management services, where costs related to staff, space, and equipment are shared to achieve internal economies of scale. However, the two organizations remain separate and distinct, with separate bylaws, boards of directors, budgets, financials, etc.

NYCLT received a 60% increase in its state grant contract, partially to fund the activities of the NYCTC. As such, NYCLT has continued to provide the NYSDOH with reports on the progress of the NYCTC. In summary, the NYCTC has participated in the following objectives:

**Organizational Development:** The NYCTC underwent its annual audit to maintain appropriate oversight and control over organizational finances. An independent auditor prepared annual financial statements which were presented to both the Finance Committee and the Board of Directors.

NYCTC submitted an application to UNOS to be a Public Organization member. The application was reviewed by the Membership and Professional Standards Committee (MPSC) and then approved by the OPTN/UNOS Board of Directors at their June 23-24 meeting. NYCTC's two-year term began with the MPSC's initial recommendation for interim approval on February 26, 2014, and will conclude on February 25, 2016.

In May 2014, NYCTC staff met with members from each member program to begin the process of strategic plan development. Discussions on program development and organizational strategies led to the creation of a Strategic Plan for the organization which was presented at the August 4 Board of Directors meeting and approved. In addition to the Strategic Plan, project outline sheets were developed and discussed to be used as guidelines for project completion.

In response to the Non-Profit Revitalization Act of 2013 NYCTC staff worked with the corporate attorney to update the bylaws so that the organization is in compliance with the new law. A majority of the new requirements were already included in the NYCTC bylaws. Included changes are: wording allowing meeting notification via email, fax, or phone; elaboration of requirements surrounding actions of the Board taken outside of a meeting; audit-oversight duties for the Board; and language referencing rules for handling of Conflicts of Interest and Related Party Transactions. Proposed changes were reviewed and approved at the August 4 Board of Directors meeting.

**Regulatory Compliance:** Revisions to the NYS regulations related to transplant went into effect on September 10, 2014. These regulations were revised as part of a Transplant Council Subcommittee over 4 years ago. The regulations were shared with members at the November 10 Policy and Operations Committee meeting. Scheduling of a roundtable between Transplant Administrators at the member programs and DOH representatives to review the revisions is pending approval of the Board.

Increasingly this year, NYCTC staff have been contacted by transplant administration at several programs to address issues raised by CMS during on-site reviews. NYCTC peer-review has aided the programs in

demonstrating compliance with CMS Conditions of Participation (CoP), particularly quality assurance. NYCTC program activities have also been included in one program's quality plan to demonstrate the collaborative state process in reviewing many different elements of quality, such as organ offers. A general statement outlining the purpose of the organization, the structure, the committees and general information about data review was shared.

**OPO Collaboration:** At the March 24 NYCTC Board of Directors meeting, members discussed the use of software and website systems that allow OPOs to share donor medical images such as Echocardiograms, Cardiac Caths, Chest X-Rays, Ultrasounds, and CTs with transplant center staff. Staff reported that NYODN was continuing to use E-Mix for file sharing.

Dr. Eduardo Rodriguez presented information on hand and face transplants at the March 24 Board of Directors meeting. Dr. Rodriguez is a part of NYU and opened the hand/face transplant program there in Spring 2014. The presentation and following discussion highlighted recovery issues, timing, and consent, and their impacts on the heart and lung allocation process.

In late 2011/early 2012 at the request of OPO representatives a call rotation of cardiologists whom they can reach out to for real time consults in donor cases, particularly to help with requesting tests and/or procedures when working with donor hospital intensivists was organized and distributed. Personal cell phone and other relevant contact information was shared by the members for inclusion in the rotation. The call schedule was reviewed by the members in November 2013 and is distributed to the OPOs monthly. One OPO has reported being approached by two different national companies whose purpose is remote interpretation of echocardiograms. NYCTC staff will reach out to the 4 NYS OPOs individually to remind them that the members are offering this service at no cost.

At the March 24 Board of Directors meeting NYCTC staff reported that Montefiore indicated their center was being bypassed on a number of potential donor offers for "Expedited Allocation". Having analyzed data from UNOS, a letter was sent from Montefiore to Lifelink of Georgia, one of the OPOs that was noted for a significant number of 'bypasses', in order to request a partnership to avoid this situation in the future. NYCTC staff provided a copy of the data request to members interested in obtaining center specific data from UNOS.

**Data Collection:** NYCTC members and the 4 NYS OPOs continue to share and review data on a quarterly basis allowing them to review specific cases if issues arise and observe the donation and transplantation climate in NYS. During this review at the March 24 Board of Directors meeting members discussed the status definitions for Status 1A patients and the need for revision of those definitions or a modification of the allocation system. The UNOS Thoracic Organ Transplantation Committee has been reviewing SRTR mortality data and are working on redistributing the allocation scheme. Members expressed interest in continuing to monitor the Committees progress and further discuss the issue to determine next steps in assisting UNOS with these efforts.

The NYCTC Board of Directors approved the addition of a data query feature to the Members section of the NYCTC website ([www.nycardiothoracic.org](http://www.nycardiothoracic.org)). This area is password restricted to retain confidentiality of the data shared, and allows members to query the data shared between members on a quarterly basis. NYCTC staff worked with the selected website developer to create and test the data input and search features. Work to reformat previously submitted data for upload into the system is anticipated to be completed by the end of the year at which point the query feature will be usable by the members.

The Retrospective Data Project was expanded to include 2010-2013 data. Further analysis of the data found that of the 320 hearts that were procured in NYS, 245 were transplanted at one of the 5 member programs, 15 were transplanted out of region as primary offers, and 60 were turned down in the region and exported. Of the

60 exports, 43 were turned down for donor-related “quality” reasons. Members discussed the findings and determined additional data on these 43 exports would be valuable. Members reached out the transplant programs to obtain follow up data on the exports, and additional donor data was collected. At the August 4 Board of Directors meeting members agreed they would like to develop an abstract from the findings, for submission to ISHLT. Following analysis of the additional data collected, NYCTC staff collaborated with members to write the abstract, and submitted it to ISHLT on November 3.