New York Center for Liver Transplantation
Staff Report
Annual Update 2011

Strategic Planning: In January 2009 the Board of Directors conducted its first Strategic Planning meeting and in June adopted a Strategic Plan for 2009-2011. After a SWOT (strengths, weaknesses, threats, opportunities) review, the following long-term objectives of the NYCLT were identified: 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 were identified to meet the long-term objectives identified above and have been achieved by NYCLT through 2011: develop and implement a statewide research project to look at 1 year graft and patient survival in the HCV patient population (see attached abstract); create an entity capable of meeting new DOH deliverables in the development of a cardiothoracic consortium which operates independently of NYCLT, but shares resources, management and administration (NYCTC incorporated March 2011); and expand grant funding by 20% (funding increased by 60%). One key target that has continued to be a challenge is increasing liver donation by 20%. While NYCLT's relationship with the OPOs in NYS continues to remain collaborative, its ability to directly impact the rate of liver donation is somewhat limited. NYCLT has worked to improve OPO donor management to increase donor yield, created effective communication to help ensure donor organ placement is expedited to prevent unnecessary discards, and strongly championed broader sharing of livers than currently exists. There have been some small incremental changes proposed to decrease the disparities in access to liver transplantation; however it is not enough to help waiting New Yorkers. Therefore, a key initiative for NYCLT in the future is to continue to pursue broader changes to the liver allocation policy in the United States.

Regional Disparities in Access to Liver Transplantation: New York State patients experience some of the longest wait times for a liver in the country. Our patients are much sicker here when transplanted than in most parts of the country – the average MELD score of a New Yorker at transplant is 27, 23% higher than three-quarters of 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. NYCLT has teamed up 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 public forums and educating the public about this issue in an effort to change this policy.

As a result of the push for broader sharing, the national Liver-Intestine looked at interim proposals related to expedited placement of livers that are currently being turned down or discarded by other regions in the US. As the national committee has debated, the NYCLT has moved ahead with the development of a liver visualization project that may help expedite placement of those livers turned down in the OR by the recovering surgical team and the OPO is under pressure to quickly place the liver or end up discarding it. The plan is to expedite the placement of these livers by providing each surgeon in the state with an image of the liver real-time to aid in clinical decision-making

Collaborative Research – Study of Liver Disease Burden in NYS and Throughout the US: Discussions of possible liver allocation schemes at the UNOS Forum raised the issue of differences in need for liver transplantation throughout the US. For example, we know that viral hepatitis is a significant risk factor for severe liver disease that varies across populations. In particular, we believe that the population of New York State's has a higher prevalence of viral Hepatitis, due to the 1) high proportion of residents who are immigrants from high prevalence countries and 2) high proportion of residents with risk factors for viral hepatitis. For example, New York has a higher prevalence of HIV/AIDS infection (29.5

cases per 100,000 residents compared to 17.4 cases per 100,000 residents in the United States as a whole), a disease that shares many risk factors with viral hepatitis.

Dr. Tom Schiano, the Liver-Intestine Committee representative from Region 9 in 2010, approached the NYSDOH about access to data to study the pattern of liver disease in NYS. NYCLT was asked to participate and subsequently committed resources to the project. A review of the Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample, a representative sample of all inpatient admissions in the United States, and the New York State Department of Health Statewide Planning and Research Cooperative System (SPARCS) , which includes all inpatient discharges from non federal acute care hospitals in New York, was done to compare the prevalence of chronic viral hepatitis in New York to the United States. The expected number of hospital admissions for chronic viral hepatitis in New York was calculated based on the rate of hospital admissions in the United States. The indirect standardization method was used to adjust the expected number for age and gender of the population.

The expected number of hepatitis admissions for New York was 20,612 for 2007 and 20,450 for 2008. The observed number of admissions, however, was 24,522 for 2007 and 26,722 for 2008. This is a 20 to 30% excess number of admissions in New York compared to the expected number based on the admission rates for the entire United States. The actual number of excess admissions was 3,909 for 2007 and 6,072 for 2008. *This calculation shows that the burden of hepatitis in New York is substantially higher than in the United States.* This increased burden likely accounts for some of the differences in waiting time and supports the argument that changes to the national allocation scheme must be made to ensure equitable access to liver transplantation.

Collaborative Research - Liver Transplantation in the HCV Patient Population:
A 5-Year Retrospective Review: As part of its strategic planning process in 2009, the NYCLT Board members identified an excellent opportunity to make an important contribution to the field of liver transplantation by using the programs' combined data to study and report outcomes in liver transplant recipients with pre-existing hepatitis C. NYCLT released an RFP in April 2009 inviting faculty and/or graduate students from the Schools of Medicine, Nursing, Public Health and/or Epidemiology to apply for funding to collect, analyze and report data to the NYCLT related to 1 and 3-year patient and graft survival rates for patients transplanted as a result of HCV.

After identifying HCV data points and receiving IRB approval; NYCLT contracted with the University of Rochester to provide complete analysis of the data and with a medical editor to aid in preparation for publication. NYCLT also formed a small subcommittee which met four times in 2011. At its August meeting, the NYCLT HCV Subcommittee discussed the most recent analyses of the combined HCV dataset and decided to delve further into reasons for severe recurrence of HCV and to determine what, in addition to donor age, had an impact on recipient survival outcomes. For example, literature shows donor age is associated with bad outcomes, but what about putting an older donor liver in a low MELD patient, or a young donor liver in a high MELD patient? It would be incredibly beneficial to find a cut point at which we see a decrease in outcomes based on donor age x recipient MELD. When the NYCLT dataset was mined, the variable MELD by donor age (*MELDage*) was indeed a strong predictor for the survival outcome and a set of reasonable cut points appeared to be: <400; 400-1200; 1200-2400; >2400. The risk of graft failure did increase as the score of this combination increased. We further looked at the effect of donor age on the survival outcome for each of the four categories of *MELDage*. Donor age less than 60 remained a strong predictor for a better outcome in all categories except for *MELDage*<400 category, where there were only two patients with donor age less than 60. On the other hand, if we looked at the MELD score effect (e.g. >=20 vs. <20) on the outcome by donor age, the effect of MELD score was not significant for either donor age>=60 group nor donor age<60 group. All these analyses seem to suggest that although *MELDage* was a strong predictor, donor age appeared to be the main drive for this phenomenon. MELD score may still have some effects on the outcome but it is limited comparing to donor age.

The HCV Subcommittee and NYCLT staff looked at a number of variables that might predict outcomes of transplant in the HCV positive patient population and are working on a manuscript to make the results public, particularly the

finding that imported organs and local organs appear to be equal in terms of outcomes within the patient population studied.

NYCLT members agree one purpose of the HCV project is to create a database that all NYS liver transplant programs will be able to access. NYCLT will create a process to review requests for data and provide access on a case-by-case basis.

Expanded Criteria Donor (ECD) Project: Over the past several years, NY liver transplant programs have seen a significant increase in the number of liver discards in New York, further reducing the pool of livers available for transplant. NYCLT looked to expanded criteria donors (ECD) to bridge the gap. The CPC focused its ECD project efforts to have the greatest impact in increasing the donor yield. In an effort to avoid wasting donor livers, DOH agreed in 2008 to support digital pathology technology to improve the liver placement process. The ongoing statewide problem in the digital pathology process is a lack of real time, high-quality images of the gross appearance of the liver. In cases where there is a high risk of liver discard (in the OR setting at organ recovery), back up surgical teams are reliant on "oral reports" of the quality/condition of the donor liver. The current process raises a number of questions: is the liver pink, yellow, brown; how much fat is estimated with this liver; is the liver transplant team truly interested for the next recipient on the list; does the team need a biopsy to make a final decision? To help answer these questions and provide a statewide solution to the problems with liver visualization, NYCLT has provided each liver transplant surgeon in the state with a tablet PC with WiFi and 3G service for 24/7 access, allowing a high resolution image of the liver to be delivered directly to the decision-maker for each liver offer made. NYCLT contributed in-kind to provide each OPO with similar devices. Each OPO has agreed to have their procurement staff image livers at the time of procurements.

NYCLT engaged a software programmer to provide a web interface (NYLiver.org) that allows OPO recovery coordinators to upload images to a specific site that automatically forwards the images to all liver transplant surgeons in the state electronically (regardless of whether or not their center has a potential recipient at that time). NYCLT is able to track surgeon access to the images and requires each surgeon who accesses the image to fill out a brief survey (e.g., based on the image, how much fat do you estimate with this liver; based on the image, would you use this liver for transplant). This data has been correlated with actual biopsy results from the transplanting center and recipient outcome.

While this project does not have any impact on the actual OPO allocation of the organ, the process does provide surgeons with additional information (such as procurement injuries and anatomic abnormalities that are imaged real-time) that enhances decision making to expedite placement, especially when the procuring team does not want a given organ for an intended recipient.

NYCLT plans to utilize this new capability to approach OPOs outside Region 9 to consider expedited liver placement to NY State transplant centers as an adjunct to UNET. Currently, UNET programming is not capable of offering an organ to more than 4 centers and the delays in OPO placements, particularly when the liver has already been procured, leads to considerable discard rates which this process may be able to alleviate. Further logistical details need to be addressed to allow Regional sharing of imported livers, which has been a longtime goal for NYCLT. Finally, there are many research and even compliance (UNOS/CMS documentation requirements at time of procurement) that could potentially be addressed with the tablet PC format.

This project has truly allowed the transplant programs to work cooperatively to enhance the collective ability to give more of NYS patients the transplant opportunity. With nearly 1 out of every 9 people awaiting liver transplantation in the United States living in NYS and one of the highest mortality rates on the waiting list, this represents the continued and unique Region 9 tradition of true broader sharing as NYCLT has done for greater than 20 years.

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. The Center provides a centralized, standardized process to achieve that goal. The Center 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, the Center has shared the surveys with the transplant programs. The Center'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. The Center completed the living donor surveys for all 2004-2010 donors, data reports and annual review by the CPC, and forwarded the full report to the NYSDOH.

LLD State Regulatory Work: The Center is represented on the NYS Transplant Council Regulation Review Workgroup by Samantha DeLair. Since 2006, the Center has fulfilled its contractual obligations and provided feedback and experiential input to the DOH and subsequently 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, the Center's recommended changes to the regulations were well-received and many of them have been incorporated into the draft changes currently being considered by the NYS Department of Health. The DOH plans to focus its attention next on the Certificate of Need regulations as they apply to transplant.

OPO Communication Initiative: NYCLT has participated in several OPO/CPC conference calls, and meetings between NYS liver transplant professionals and OPO representatives from Region 9:

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). Despite 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. As such, NYCLT has worked with the OPOs in NYS to 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. The collaborative approach has helped to streamline the recovery of DCD livers and aided in OPO and transplant center logistics and communication with other organ transplant programs, all in an effort to utilize DCD livers that might otherwise be wasted. This year, members have pursued IRB approval so NYCLT is able to communicate its outcomes with the donation and transplant community at large.

New York Cardiothoracic Transplant Center (NYCTC): In December 2008, after hearing a report from Dr. Sheiner on the recent activities of the NYCLT, 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. Given the positive response by the programs, NYCLT staff

began development of bylaws, a governing structure, a draft budget with dues and worked with the NYS OPOs to identify programmatic goals. The relationship between NYCLT and NYCTC is to provide management services, where costs related to staff, space, and equipment are shared to achieve internal economies of scale. However, the two organizations will remain separate and distinct, with separate bylaws, boards of directors, budgets, financials, etc.

NYCLT has received a 60% increase in its 2011-2012 state contract, partially to fund the start up 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: As part of its start up activities, the NYCTC initiated legal paperwork this quarter for the organization's application for tax-exempt status. A design firm was identified to work on informational materials, and a logo for the consortium to develop recognition of the organization in the transplant and donation communities.

At its May Board of Directors meeting, the NYCTC created a Policy and Operations Committee (POC). The POC will focus on policy work, including data sharing, research projects, best practices and other specific projects as deemed important by the members.

OPO Collaboration: OPO leaders and NYCTC members agreed to review Donor Management Goals and work together toward a standardized protocol for all 4 OPOs in the state. The objective of standardization is to improve organ viability for transplant, allocation and recipient outcomes. Several current protocols have not been updated in a number of years and OPO leadership requested input from the transplant professionals to provide the most relevant information and foundation for a standardized protocol.

UNOS requires a point person to be identified at each transplant program to be contacted with donor/recipient disease transmission communications. OPO representatives requested each program be sure they had provided that information to each OPO in the state. NYCTC staff worked with the heart/lung programs to provide contact information to the OPOs.

OPO representatives also requested a call rotation be organized 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.

Out-Of-Sequence Heart Allocation: Out-of-sequence heart allocation for sensitized patients was identified as an issue where a region-wide policy would help to formalize the process. Review of UNOS policy (3.7.1.1) revealed a provision allowing the creation of such a policy. NYCTC staff worked with the New England Organ Bank (NEOB) to obtain a copy of the New England Center for Heart Transplantation's (NECHT) policy. In discussing the possibility of adapting the protocol for use in Region 9, the POC members agreed to share the number of out of sequence occurrences at each center as well as each center's desensitization protocols for better determination of further data collection necessary, and to identify next steps.

Data Collection: NYCTC members agreed to collect and share data on a quarterly basis. Data reported by each center include the number of deaths on the waiting list, the number of adult heart transplants performed, retransplants, and the number of pediatric heart transplants, stratified by patients on ventricular assist devices (VADs) and non-VAD patients, reported by status on the waiting list. Imported organs are also being tracked. Historical data was requested from UNOS to provide comparative information. The 4 NYS OPOs have provided data on the allocation of the local organs consented, noting turndowns, discards and organs used for research. Future data reporting will include a category for delisted patients, and data on heart multi-organ transplants.