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FINAL DRAFT REPORT

University Hospital, Methodist
Adult Liver Transplant Program
Memphis, Tennessee
INDEPENDENT PEER REVIEW – Conducted October 22-23, 2018

The members of the Independent Peer Review Team were:

Transplant Surgeon:	John Roberts, MD
Transplant Physician:	Robert Brown, MD
Transplant Administrator:	Pamela Gillette, MPH, RN, FACHE
Transplant QAPI:	Kristine Browning, RN
Transplant Social Worker:	Evonne David, MSW

In Attendance from CENTER for General and/or Individual Interview Sessions:

[redacted]

James Eason, MD, Program Director
Satheesh Nair, MD, Medical Director

[redacted]

EXECUTIVE SUMMARY

During the onsite comprehensive review conducted on October 22 & 23, 2018 at the Methodist Memphis Liver Transplant Program ("Program"), the multi-disciplinary Independent Peer Review ("IPR") Team identified positive findings, particularly the dedication and willingness to make all changes necessary to improve its quality and outcomes.

While not minimizing these positive findings, this report follows the standard peer review root cause analysis process. It identifies factors that could or have contributed to the Program's suboptimal outcomes over the past several years as well as issues that are preventing or inhibiting the Program from attaining or maintaining full compliance with the Medicare Conditions of Participation for transplant programs. This report also proposes recommendations for Program changes/adjustments based on the IPR findings.

Lastly, it is the position of the Independent Peer Review Team that the Program can be successful and have the required outcomes if it is able to fully implement the recommendations set forth below.

FINDINGS

1.0 PHYSICIAN ASSESSMENT:

The Methodist Transplant Program has the overall structure and essential pieces it needs to succeed, but requires targeted investment, restructuring of several jobs, and an openness to collaboration between both team members and between the transplant programs and outside consultants. The hospital investment must increase staffing both within the transplant program as well as within the hospital (e.g. ICU). Finally, there needs to be a change in a culture which is driven largely by a perceived need to value transplant volume over quality which leads to errors, largely in recipient selection. This culture appears to be fueled among the staff by a perception, based in large part on fact/observation, that the Medical and Surgical Directors are the only ones whose opinion matters and that they will accept for listing all potential candidates regardless of relative or even absolute medical or psychosocial contraindications.

Liver Transplant leadership is under the direction of Satheesh Nair, MD, who is listed as the Primary Physician in UNOS. Currently the staffing has adequate surgical Attendings but only three transplant hepatologists, due to staff departures. I would suspect a minimum of five hepatologists are needed. The morale among the junior hepatologists seems low. The

coordinators are shared between liver and kidney transplantation and only support transplant candidates and recipients. The Hepatologists report that the program does not have any absolute contraindications to transplantation. In Selection Committee, they report that their professional opinions are over-ruled by the Surgeons. There is a need for NP's dedicated to the hepatology practice to allow the transplant physicians to see more new patients, which would increase list size while being able to maintain reasonable rigor in selection. The increased referral base and more attentive care of the hepatology and pre-transplant patients is the best way to preserve volume and improve quality concurrently. Looking at the UNOS staffing guidelines there is a need for additional social workers. Not only is staffing inadequate, many of the providers are working below their degree with RN's and NP's doing work that could be done by clerical staff. I would recommend an increase in the number of NP's and PA's to see patients pre and post-transplant and have nurses doing refills, wait list management and leave clerical people to do faxing, etc. There is also a need for data entry personnel and people dedicated to data analysis for quality. This should be linked to a high-quality database either investing in TeleResults/Presidio with direct bridges to LabCorp, Quest and Cerner, or investing in Otter. I would avoid any "home-grown" systems as these are less costly upfront but costlier and less functional in the long-run. The liver and kidney programs and their functions should be separated as they are each of adequate size for independence. This one will lead to more functional autonomy and a sense of dedication, more interaction with the medical specialists who do not cross between liver and kidney (hepatologists and nephrologists) and make multidisciplinary meetings more inclusive and time efficient for the non-surgical Attendings.

The RN staffing on both the transplant floor and in the ICU is largely inadequate. It is standard to be able to provide 1:1 nursing for the first 24 hours in the ICU post-liver transplantation, followed by 1:2 in the step-down and 1:3-4 on the floor for liver patients. The largest inadequacy is in critical care medicine staffing. There is only a critical care NP, Monday to Friday. There are no Critical Care Fellows or Critical Care Attendings at any time, and no on-site advanced practice NP/PA or Attending on-site on nights and weekends. Thus, much of the Critical Care Management is done remotely by the Surgical Fellows and Surgical Attendings. Currently, virtually all hospitals are transitioning to systems where Critical Care Management is done by trained board-certified or eligible critical care professionals on-site 24/7/365. Compounding this, there appears to be a reluctance of the transplant team to have any outside consultants; for example, patients who have significant pulmonary disease pre-transplant or pulmonary complications post-transplant have no pulmonary consultation or ongoing pulmonary attending input. Similarly, cardiology and infectious disease consultation are underutilized, and there is no transplant ID service. There are only two PharmD's covering both liver and kidney and they have multiple other responsibilities. There is no outpatient PharmD and this likely affects medication compliance as well.

Overall, it seems that both the Junior Hepatology Faculty, the coordinators and social workers do not feel empowered to express opinions, especially those that lead to a candidate being excluded from transplant. For example, social work recommendations on patients with an obvious contraindication to transplant (e.g. still with actively drinking) will write in their note "final recommendations to be made post multidisciplinary meeting". The lack of support from the medical and surgical directors for the social work team is clear. They have no full-time psychiatrist which is clearly needed for both patient care and to support the social workers.

There is also a clear need for more protocolized and random drug and urine screening and these tests must carry weight with patients either not being listed, being made inactive, or delisted when positive tests occur. At Weill-Cornell, we do urine ethyl glucuronide and urine drug screens universally at the time of initial evaluation and randomly with required participation in rehabilitation programs for all patients with prior addiction. Similarly, the financial coordinators evaluation is not valued, and there is not a requirement for adequate insurance at the time of listing. Many patients are listed with inadequate supplemental coverage and this then stresses the service and likely contributes to inadequate outcomes.

The hepatologists currently see large numbers of non-transplant hepatology patients without any support from NP's or PA's. The Junior Hepatologists clearly do not feel that Dr. Nair is able to adequately advocate for their needs and feel unsupported vis a vis the service and their clinical activities. The liver transplant potential candidates often have Medicare, they are older, many of them are on disability. The Monday morning multidisciplinary meeting is an excellent meeting with all the groups represented but, it should not be joint between liver, kidney and pediatrics. Most of the hepatology staff is only interested in one-third of the activity (and similar for pediatrics and renal) and thus attention among the non-surgeons is diminished. This leads to inadequate time and attention for important medical issues. During the observed meeting, I saw obvious non-candidates with relative or absolute medical or psychosocial contraindications are still viewed as viable candidates; for example, a patient with pulmonary hypertension had no pulmonary consult and left AMA and was considered to be a reasonable candidate. Similarly, high MELD patients with questionable insurance were still active on the waiting list instead of being Status 7 or on "internal hold". They have a high-risk list for post-transplant patients, it is not clear how that high-risk list is made, and they have no high-risk list for their pre-transplant patients. At Weill-Cornell, we use a top 50 list to manage pre-transplant patients and discuss how to manage issues like portal vein thrombosis and who should be selected for extended criteria donors on the list weekly. The lack of medical input into management leads to over-utilized trips back to the OR and under-utilization of interventional radiology. The overemphasis of the multidisciplinary meeting also leads to relatively radical immunosuppressant changes that are made not at the bedside in a multidisciplinary manner between the hepatologist and surgeon on call during rounds but rather by the surgical director at the multi-disciplinary meeting.

Overall my impression is that this is a "closed system" where the transplant program functions autonomously in all aspects both clinical care and quality. The staff is extremely dedicated but feel powerless to make change due to resistance of leadership, lack of resources or an impression that "nothing changes or changes for a short period of time and then reverts". The impression is that volume is king. All of the people I spoke with appeared afraid that any decrease in volume will lead to a decrease in allocated resources. The best way to increase volume while maintaining quality would be to do better outreach into the community but this would need adequate staffing with an outreach coordinator, this could be shared between the transplant programs or with other service lines.

I think with a dedicated staff, a structure that promotes collaboration with joint offices, a single ward and joint rounds, all the pieces are there to make this program succeed. Investment in full-time intensive care services, identifying trusted consultants in pulmonary, infectious disease and cardiology and collaboration among all the team members with each of their opinions carrying

weight, and increasing the staffing in social work, nursing, administrative assistant, data analysis, and NP/PA support particularly of the hepatology side with recruitment of two to three hepatologists would increase the evaluation volume and listing to a point where potential recipient selection could be tighter without decreasing volume. Otherwise, a volume decrease would be needed in the short run to improve outcomes.

1.1 SURGEON ASSESSMENT:

The curriculum vitae of the surgeons involved with the liver transplant program were reviewed. Several of the CVs were out of date. All the CVs suggested that the surgeons have adequate training to perform liver transplantation. It was noted in the course of the discussion, that one surgeon [redacted] is only doing organ recoveries and not liver transplants.

Four surgeons: [redacted] were interviewed as a group. James Eason was interviewed separately. James Eason, MD, is designated as the Program Director, with [redacted] listed as the Primary Surgeon for the Liver Program.

60 patients who had either graft loss or death or both were reviewed.

The outcomes of the surgeons were tabulated. Although not risk adjusted, there did not appear to be increased risk of graft loss or death by surgeon. The Program Director's results trended high, but he was asked to do the more difficult cases with the most difficult apparently reserved for him.

[redacted]

An evaluation was made regarding whether the graft loss or death was related to a surgical/technical issue. 31 out of the 60 cases appeared to have a death that was related to a surgical/technical issue. 21 of these 31 cases the death or graft loss occurred within 30 days of the initial transplant. 8 of the deaths occurred intraoperatively. 3 of the intra-operative deaths were identified by the program as having a pre-operative problem that contributed to the intra-

operative death, 1 additional intra-operative death appeared to be related to undiagnosed cardiac disease.

The program assessed that 21 of the 60 deaths or graft losses were related in some fashion to an issue at evaluation. Nine of these deaths were considered to be related to a surgical/technical issue, such as intraoperative arrest or hepatic artery thrombosis (HAT) or other. 12 of the 21 did not appear to have a direct surgical/technical cause.

The program must have from a tighter evaluation process to eliminate some of the transplants where there was an inadequate evaluation. The issues regarding inadequate evaluation were primarily cardiac and social. The program needs to have strict criteria regarding which patients undergo cardiac catheterization and patients with significant coronary artery disease that cannot be corrected should be excluded from transplantation. Of greater concern, is the ignoring of the concerns of the team regarding the ability of the patient and/or family to care for them in the postoperative period. This would include transplant patients without financial support where the out-of-pocket cost of medications would be too high. The transplant center has been providing pharmaceutical support to those patients who cannot afford their medications. There should be very clear-cut financial and social exclusions for transplantation. There should be delisting for alcohol related issues such as lack of compliance to the program's protocols. There should be a protocol for drug and alcohol screening prior to transplantation. Consideration should also be given to monitoring post-transplant. Use of ethyl glucuronide urine testing is considered to be best practice. The monitoring of patient's compliance in the pre-transplant setting is complicated by the relatively short time between listing and transplantation. There should be careful consideration given to having a defined period of time were compliance be assessed. Though the patient could be listed transplantation would be deferred until compliance was completely assessed.

Is of concern that the team appears to be trying to maximize the number of transplants by disregarding flags in the evaluation process. This is the result of relatively fluid and not carefully defined selection criteria. The team should recognize that the volume of transplants will probably end up decreasing with the flagging of the programs results by the OPTN. There should not be an attempt to transplant patients, who would not benefit from transplant, in order to make up for this decrease in volume.

The post-transplant management process seems somewhat fragmented. First off, the inpatient service appears to be fragmented by time post-transplant. Patients who are status post-transplant may be admitted to non-transplant services and transplant physicians and surgeons may or may not be consulted. In general, the best process is to combine all the post-transplant patients on a single service. All patients from the emergency room should be admitted to this service unless they have very clear issues, such as myocardial infarction, that should benefit from them being on a non-transplant service.

The outpatient post-transplant care in the first 6 months is managed by a nurse with support from surgeons or hepatologist. On consideration should be changing to an advanced health practitioner to care for the patients in the early postoperative period. The advantages to using an advanced health practitioner is that this staff member can function relatively independently in terms of patient orders such as medication changes. Protocols can be developed to allow for standardization of care by the advanced health practitioners. Currently, important clinical

decisions bottleneck to 2 physicians. This makes the management of these patient's difficult and would be improved by having an advanced health practitioner who could be more independent than a nurse. Alternatively, there could be development of detailed protocols that would allow the nurse to function but typically these protocols are still bottlenecked by the need for physicians to sign orders in the electronic medical record.

It is surprising to learn that patient critical issues such as Coumadin therapy are not managed by a Coumadin clinic. There is very clear need for a pharmacist in the post-transplant clinic and to be involved in post-transplant management of the patient's in conjunction with the surgeons or hepatologist.

Of greatest concern, is the lack of a transplant database system. Although the hospital apparently owns the rights to a transplant database system, this has lain fallow, apparently because of issues with funding. The lack of a database system results in many of the nurses/coordinators working below their licensing, doing such tasks as data entry, faxing, and manipulating paper orders. There is great risk to the patients of not having a database system that can allow for timely access of current medications, laboratory, and other data that is crucial for taking care of the post and pre-transplant patients. There has been a decision by the hospital to pursue the acquisition of an electronic medical record for the transplant patients. It is important that the true cost of ownership of this system be factored into the allocation of funding. The true cost of ownership would include the hospital information technology work hours needed to create and maintain interfaces to all relevant internal and external systems to allow function by the transplant electronic medical record. This would include interfaces to outside laboratories, such as Lab Corp that would allow for seamless resulting of outside laboratory records without the need for manual data entry into the system. Some of these funding cost would be recovered by having personnel work at the top of their license rather than below. It is crucial to the financial success of the transplant program that nurses do nurse tasks and the not the work of MAs.

The evaluation of complications such as death and graft loss have been completed by a root cause analysis process. Unfortunately, this process appears to be limited to the transplant service and the root cause analyses provided were superficial. For example, there have been deaths related to aspiration in the post-transplant period. The surgeons recognize that aspiration is occurring in the post-transplant at a significant rate. There has not been any involvement in the hospital root cause analysis process to determine the factors that are leading to the relatively high rate of aspiration. The hospital is aware of the issue and the institution of a different type of feeding tube was trialed but without a detailed root cause analysis. There appears to be a wall between the hospital's QA/PSQI process and that of the transplant services processes. It is important that the transplant efforts be incorporated within the hospital effort regarding quality improvement.

ANESTHESIA SUPPORT

The anesthesia team supporting the Transplant Program is led by [redacted] who is the primary anesthesiologist for the Liver Program. He is part of a team of 6 anesthesiologists who manage the liver recipients in the Operating Room. [redacted] reports that the Liver Program does not utilize any CRNAs in the OR.

Per [redacted] there are no current coagulation protocols for the Liver Transplant Program. MUH utilizes rotational thromboelastometry (ROTEM) to guide coagulation practice.

[redacted] reports that in his opinion, the Liver Program is currently accepting less than ideal donor organs for transplantation. He attends Selection and QAPI meetings and reports that there has been an inconsistent acceptance process for candidates with alcohol abuse issues, past or current.

No recommendations for Anesthesia.

[redacted]