RECOMMENDATIONS:

2.0 PHYSICIAN ASSESSMENT:

- Recruit and hire 2.0 FTE Transplant Hepatologists
- Recruit and hire 2.0 FTE Mid-level Providers (MLP)
- Immediately change the staffing ratios in the ICU for fresh Liver transplant recipients
- Institute absolute & relative exclusion criteria for liver transplant candidates

2.1 SURGEON ASSESSMENT:

- Increase the stringency of the evaluation & selection process.
- Define specific relative and absolute exclusion criteria for liver transplant candidates
- Design and disseminate Protocols for both Pre and Post Liver Transplant patients
- Push forward with Transplant Database acquisition
- Fully participate in Hospital Quality Process

2.2 ROOT CAUSE ANALYSIS:

- Include all disciplines in Root Cause Analysis reviews
- Include all disciplines' input at Liver Selection Committee

2.3 QAPI PROGRAM

- Need a governance structure that integrates transplant with the hospital and corporate with clear bidirectional information sharing. Transplant is not currently included as it is considered a department not a service line.
- Considering participating in an outcome reporting group such as Vizient for benchmarking and awareness of program status compared to competitors. This will provide a resource of indicators for current state of service-line or department. This will also provide information for the C-suite to know if a program needs more resources.
- The transplant QAPI program must be adequately resourced. There should be dedicated QAPI support from the hospital PI department as well.
- The culture of QAPI for long term success is dependent upon hospital and transplant leadership commitment and involvement. It is clear there is no alignment of hospital

leadership and the transplant center QAPI activities. It is recommended that hospital leadership prioritize efforts in ensuring there is transparency in QAPI activities and support from the hospital including the PI department.

- All members of the transplant team should be engaged in the activities of QAPI in all meetings, selection of quality indicators, and performance improvement activities. It was apparent that not all of the members of the transplant team were actively involved in QAPI activities. All members of the transplant team and representatives with direct impact when indicated should participate in QAPI activities. This minimizes variation, creates consistency, prevents duplicative and sometimes confusing multiple approaches to the same problem. QAPI meetings should be viewed as mandatory.

- QAPI PI projects are limited, the transplant quality director makes great efforts to drive PI projects but she cannot be the sole owner. Champions need to be identified for PI projects the ownership on a small team for that specific PI project. Rather than applying quick fixes, thorough analysis needs to be performed to identify all the potential contributing factors, following the hospital methods for performance improvement, and implementing meaningful effective, sustainable change.

- The "RCA" process currently being utilized is ineffective to identify the contributing factors. A true RCA is a system approach to identify problems that contribute to adverse events and a multidisciplinary team approach and presence is required to effectively identify the contributing factors. Ultimately the goal is to prevent future harm. The "RCA's" performed had limited attendance and not multidisciplinary. CMS Transplant COP's Tag X103 states "The transplant center must conduct a thorough analysis of and document any adverse event." True RCA's should be referred to hospital patient safety/risk management to perform. Thorough analysis should be utilized within the transplant for the less than 1-year graft and patient losses incorporating all potential representation.

- The CMS Survey conducted 5/8/18-5/10/18 the transplant programs were cited for TagX104 "The transplant center must utilize the adverse analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents." The finding indicated there was no evidence of documentation to support that the staff utilized the results of an analysis or took actions that could prevent repeat incidents.

- There are Patient Safety PI (PSQI) meetings for many service lines, but transplant does not have one. It is recommended to institute this for the transplant services at least every 2 weeks initially.

- For bi-directional sharing of information and transparency the following meetings that are occurring should include transplant. A weekly SSE meeting with coders, stroke coordinator, AMI coordinators, and sepsis coordinator. A quarterly system meeting for SSE data and trending for the prior quarter. Lessons learned in other areas of the hospital can then be applied and vice versa. Best practices should be standardized across all applicable areas.

- Education of QAPI for the hospital staff, transplant staff, and QAPI chairs and MDs can provide a base to have effective, facility-wide comprehensive program that has transparency and open exchange of ideas and information. QAPI should be non-punitive and focus on processes not people.

- The transplant quality director is utilizing the SRTR expected survival models to predict future survival outcomes. This information is not shared beyond the team and should be incorporated into reporting up to hospital leadership. The data should be graphed in ways that are clear for hospital leadership as meaningful data (see graph A below). CUSUM reports are difficult to interpret and not best served to be the stand-alone report. In February 2018 the CUSUM report for liver graft failure reached the 5% threshold 3 times 1 ½ years (see graph B below). SRTR recommends when the threshold a program may need to consider a formal process review. The CUSUM chart resets to zero to essentially start the monitoring process over. It is recommended as there are rapid trending period moving upward, then the program should perform reassess their program for potential contributing factors far before the threshold is it. The trending upward indicates the program is having higher than expected event rates and should be concerning. The goal is to maintain a steady state indicating the program is having as expected events or less than expected events. Given the 3 rapid rises in the CUSUM over the 1 ½ year period of time, the program did not take into consideration the concern for more than the expected events. The transplant quality coordinator is exceptionally knowledgeable and has the skills to utilize these tools to provide analysis and support when there is early concern. This includes utilizing the SRTR excepted survival model to predict future release expected survival based on current model (see Figure C below). It is recommended to value these offerings to assist the program in being fully aware of the programs current and future outcomes.

- Going forward, the Program must conduct Root Cause Analysis on all graft losses and deaths, initially within the first-year post-transplant, utilizing a process that includes the full multidisciplinary transplant team to facilitate a thorough assessment of contributing factors across the continuum of care leading up to the adverse event. Having all disciplines in the same room to conduct the RCA lends to educational opportunities between disciplines in understanding respective risk factors.

- In determining psychosocial aspects related to identification of patient death or graft failure, identification of non-adherence is multi-factorial; to simply state non-adherence in an RCA does not investigate the underlying cause(s): social support system, psychological stability and psychopathology, lifestyle and effect of substance use/misuse/dependence, compliance, overall readiness, motivation and understanding of transplant (patient education).

- In the analysis of outcomes, tracking of psychosocial data needs to be included. For example, the Program team selects and transplants a candidate who is assessed as having an absolute contraindication or relative contraindications and is a "poor," "high risk" or

"minimally acceptable candidate" and the patient experiences graft failure and/or patient death, to what extent did psychosocial risk factors contribute to poor outcomes. The QAPI program needs ability to define baseline quality measures in effort to assess psychosocial data that contributes to outcomes. Active membership of TSW on the Quality Committee is essential.

2.4 DONOR SELECTION:

- Develop written donor selection criteria.

2.5 SELECTION CRITERIA/SELECTION COMMITTEE:

- In concert with an independent review and analysis of the literature, consider a query of other liver transplant programs with respect to their established surgical, medical and psychosocial minimal listing and exclusion criteria including absolute and relative contraindications.

- Consistent use of an objective tool to measure frailty - http://newswise.com/articles/simple-frailty-test-predicts-kidney-transplant-outcome.

- Consider the inclusion of "inadequate social support," "non-adherence with treatment," "active illicit substance use," "active alcohol dependence," "active nicotine abuse," active psychotic symptoms that may impair adherence with treatment," "dementia," "a history of multiple suicide attempts," as absolute psychosocial contraindications.

- Consider classifying psychosocial risk in absolute and relative terms in its own category separate from medical and surgical contraindications. This effort would aide in upholding the Selection criteria in consistent fashion as each patient is individually considered will lend to a more objective, evidence-based model in the consideration of psychosocial factors.

- Include the Social Worker assessments as part of the decision-making process for candidacy.

2.6 TRANSPLANT PSYCHOSOCIAL EVALUATION:

- A risk severity score such as the SIPAT score can assist in tracking outcomes in your QAPI, future M&M, and RCA efforts. The culture with medical and surgical leadership has to want to change current ideology and practice in order for any tool to be useful.

- Consider implementing use of validated screening tools (BDI & BAI or PHQ-9, GAD-7 for depression and anxiety, AUDIT for alcohol use and DAST for drug use) that will objectively identify risk related to the CMS defined possible risk factors that are disclosed as part of informed consent. A list of these tools in addition to measures for social support and adult literacy in medicine tools has been provided to the TSW's via email.

- TSW needs to be supported by the Team in the use and enforcement of the Abstinence and Primary Caregiver Agreements via respectful and objective discussion in Selection; otherwise their use becomes perfunctory.

- If recommended, random toxicology screens need to be executed and documented on consistent basis.

- Lack of mental health and chemical dependency services across the transplant continuum is a critical issue facing many transplant programs nationally. The transplant community is charged with creative thinking and a dedication of financial and other resources to secure adequate mental health and chemical dependency providers. Assertive recruitment is needed within the larger community and nationally. Potential organization for recruitment is the Academy of Psychosomatic Medicine https://www.clpsychiatry.org.

- Create an algorithm of when to refer for evaluation for transplant.

- Consider adding an Addiction Medicine specialist – an MD, Ph.D. or LCSW to your team.

- Patients with a history of heroin abuse and who are on a Methadone Maintenance Program (MMP) should be required to have consult with a transplant psychiatrist to assess proper MMP dosing in setting of transplant.

2.7 WAIT LIST MANAGEMENT:

- Wait list management policy and processes needs to be reassessed with respect to adequate surveillance of the psychosocial and financial risk factors with culture change in consensus to defer a patient to listing with absolute or multiple relative psychosocial contraindications.

2.8 PROGRAM POLICIES and PROCEDURES:

- Using evidence-based data from national standards and best practices create a policy that defines indications for re-transplantation, the re-evaluation process and surgical, medical and psychosocial absolute and relative contraindications to re-transplantation.

- Consider recidivism to alcohol, illicit &licit drug and tobacco abuse as absolute contraindications for re-transplant in addition to documented non-adherence that contributed or was root cause of graft failure.

- Create a Substance Use Policy that is consistent with your Selection criteria.

- Update and change your protocols, policies and procedures accordingly.

2.9 POST-TRANSPLANT FOLLOWUP:

- For transplant patients who are less than one-year post-transplant, consider providing scheduled time in clinic for TSW to meet with patient and/or support person(s) in order to assess coping and overall adaptation to the post-transplant course from a psychosocial point of view. In addition, consider using objective measurement tools to assess for anxiety and depression for those patients in active psychological distress and/or with known history of anxiety, depression or PTSD.

- Similarly, those patients considered at risk with respect to past alcohol or drug abuse and/or dependence (in particular those with less than one-year sobriety) should be under proactive surveillance.

2.10 PERFORMANCE of the MULTI-DISCIPLINARY TEAM ("MDT"):

- CMS requires MDT rounding and participation in the peri-operative phase and discharge event, of all disciplines including TSW, pharmacy and dietitian with appropriate interventions and documentation.

- Schedule programmatic meetings with MDT clinical providers to review, revise existing Policy, Procedures and Protocols that were created without MDT input.

- Need for culture change among the transplant team to increase a multidisciplinary and interdisciplinary approach, mutual professional respect and to increase lines of communications and liaison.

- Surgical and medical directors in concert with the program and hospital leadership must be able to cooperatively work towards mutually established and agreed upon vision and goals in the context of exemplary patient care, improving outcomes and strengthening the Program.

- Disruptive, disrespectful, non-collaborative individuals who work in silos and in the past of "how it's always been" and who are resistant to the changing culture of transplantation put the Program and its patients in a constant state of risk and erode the morale of all Team members.

- The Joint Commission issued a "Sentinel Event Alert" on July 9, 2008 regarding behaviors that undermine the culture of safety (http://www.jointcommission.org/assets/1/18/SEA_40.pdf). This Alert contains existing Joint Commission requirements as to addressing this problem along with other suggested actions to systematically confront this challenging issue that has far reaching implications.

- Consider hiring a professional team that provides services and interventions to improve and optimize Team morale, culture and dynamics.

- Invite transplant clinical providers from all disciplines to present a lecture at transplant grand rounds.

- In the spirit of development and growth in the rapidly changing field, step outside your institution to examine your clinical and team practices in the greater context of national and international specialization in the field of transplantation.
- Create program development working groups represented by all disciplines to accomplish your goals and track your progress.

- Continue to include consultants from ID, nephrology, psychiatry /psychology, cardiology, and other appropriate providers at every phase of the transplant process, in addition to attendance at program development working groups.

- As a process improvement project, consider the TFC creating a packet of written information related to insurance and financial aspects in transplantation, to be given to patient and support(s) at time of evaluation. The TFCA is an excellent resource with respect to "proven" or "best" practice towards standardization and consistency. http://www.tfcassociation.com

2.11 PROGRAMMATIC REVIEW – STAFFING:

- Recruit and hire 2.0 FTE nurse auditors
- Recruit and hire 1.0 FTE Quality Coordinator
- Recruit and hire 1.0 FTE Clinical Manager
- Recruit and hire 1.0 FTE Transplant Pharmacist
- Only Transplant trained Pharmacists to round & educate transplant recipients
- Move patient assistance with medications to the Transplant Social Worker Team
- Recruit and hire 1.0 FTE pre-transplant Coordinator
- Recruit and hire 1.0 FTE post-transplant Coordinator
- Recruit and hire 1.0 FTE Coordinator Assistant for all clerical tasks
- Recruit and hire 1.0 FTE Transplant Financial Coordinator
- Recruit and hire 1.0 FTE TSW to increase focus of service on the post-transplant population.

- Move the 1.0 FTE from In-Patient (Case Management) to the Transplant Cost Center to facilitate continuity of communication within the team.