Maine Medical Center
Maine Transplant Program
Policies and Procedures
Adverse Event Policy

Purpose
To outline the process for identifying and responding to adverse events within the transplant and living donor programs.

Policy
It is the Policy of the Maine Transplant Program to actively identify, report and review any adverse event involving a transplant recipient or living donor during any phase of care. This Policy will be implemented in accordance with CMS 42 CFR §482.70 OPTN Policies 15 and 18, and Maine Health (MH) Policy ""Adverse Event Reporting"

Definition
Transplant adverse events are defined, per CMS guidance, as "an untoward, undesirable and usually unanticipated event that causes death or serious injury, or the risk thereof". As applied to transplant recipients or donors, events include but are not limited to serious medical or surgical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; or transmission of infectious disease to a recipient.

Identification and Internal Reporting
Adverse events may be identified by any team member via reporting to transplant program medical and administrative leadership, and entry into the online Safety Report System, RL Solutions. Entry into the RL Solutions will initiate a review by the Maine Medical Center (MMC) Risk Management. All events are reviewed within RL Solutions by any departments involved in the event, either directly or indirectly. In consultation with transplant program leadership, Risk Management will determine the extent of their involvement in any further intensive review or Root Cause Analysis. Any event involving a transplant patient (any organ) or living donor will be automatically forwarded to the Transplant Director for comment and/or review in the RL Solutions system.

Analysis of Events
The Transplant QAPI Committee and Living Donor QAPI Committees will be responsible for the thorough analysis of adverse events involving any kidney transplant recipient or living donor. The QAPI Committee will determine the appropriate format for this review based on the severity of the event. This analysis may occur in conjunction with the MMC Risk Management team, and will include all relevant clinical and non-clinical parties. In addition, the Department of Surgery has a robust analysis process through its Morbidity and Mortality review structure. Any serious complication or event arising during or from a transplant or donor surgery will be reviewed through this process.

Corrective Actions
All adverse events will be analyzed with a focus on root causes and actions to prevent a recurrence of a similar event in the future. Action plans will be documented with timelines and reviewed periodically to determine the need for additional actions or modifications to the action plan. Corrective Actions may involve a change in policy and/or procedure, reeducation of team members, changes in organizational structure, or work flow modifications. The QAPI Committees and program leadership will be responsible to assure ongoing compliance with any active action plans and to update and close action plans as appropriate.

Reporting, Investigating, and Analyzing Events:
The Transplant Program will follow the Maine Health Policy, "Adverse Event Reporting" in regard to internal procedure for adverse events. Both policies outline reporting requirements to the Joint Commission and State of Maine.

External Reporting
The Transplant Program will comply with all relevant event reporting required by the OPTN for both living donors and transplant recipients, including Policies 15 and 18.Required reporting to state and federal agencies is outlined in the MH Policy, "Adverse Event Reporting".

References
Maine Transplant Program Policy: QAPI Program
MH Policy "Adverse Event Reporting"
OPTN Policies 15 and 18

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Policy Champion: John P. Vella, MD, FACP, FRCP, FASN, FAST – Director of Nephrology and Transplantation