



*A Conceptual Framework for Medicare Requirements for
Quality Assessment and Performance Improvement in
Solid Organ Transplant Programs*

Five Aspects

Aspect 1: Design and Scope

An effective transplant quality assurance and performance improvement (QAPI) program is ongoing and comprehensive, dealing with the full range of services offered by the transplant program, including patient safety, clinical care, quality of life, and those services provided under contract or arrangement. The program is data-driven, reflects the complexity of transplant services, and addresses all systems of care and management practices relevant to transplantation. The program is therefore multi-disciplinary and covers all phases of transplant and donation in a continuous cycle of review and improvement. Transplant QAPI is connected or integrated with the hospital quality program and includes processes to identify high risk, high (or very low) volume, and problem prone areas. The program includes methods for conducting analyses, implementing corrective actions, evaluating improvements, and assessing whether improvements are sustained. Transplant programs have a written QAPI program that is implemented and includes active multi-disciplinary participation, methodologies to fulfill hospital and federal requirements, process and outcome objective measures, established frequencies for review of performance, identification of transplant specific adverse events, structured investigation processes and mechanisms for reporting between transplant and hospital programs.

Aspect 2: Governance and Leadership

The hospital leadership and governing body must be clearly engaged in QAPI oversight. The governing body ensures that the QAPI program is implemented, ongoing, comprehensive, effective, and that adequate resources are applied to conduct QAPI efforts and operate in a continuous manner. The governing body sets clear expectations for quality and safety. The transplant program administration, in conjunction with the hospital leadership and the governing body, develop a culture of quality assessment and performance improvement utilizing input from transplant program staff, transplant recipients, living donors, and their families or representatives. Hospital leadership and transplant administration ensure that written policies are developed to sustain QAPI by setting expectations for safety, quality care, and patient rights for transplant recipients and living donors. They create an atmosphere where staff are comfortable identifying and reporting quality problems as well as opportunities for improvement. QAPI education is part of the accountable culture. The transplant program must identify members of the multidisciplinary QAPI team and specify their roles and responsibilities. This includes designated staff to be accountable for QAPI; developing leadership and hospital-wide training on QAPI; and ensuring that staff time, equipment, and technical training are provided as needed. Transplant QAPI reports are provided to the hospital leadership and the governing body and are used to assess, improve and sustain quality of care and performance, reduce risk of harm to patients and utilize lessons learned.

Aspect 3: Feedback, Data Systems and Monitoring

The transplant program must have systems in place to monitor care and services in all phases and settings of transplant and living donation, drawing from multiple sources. Feedback systems include input from staff, transplant recipients, living donors and families or representatives as well as bidirectional communication between hospital and transplant quality programs. Process and outcome indicators reflecting the complexity of services within the program are defined, measured, analyzed and tracked. Applicable benchmarks or targets are established by the program to measure performance. The program includes effective surveillance to identify and respond to adverse events, additionally tracking and monitoring implemented improvement activities to prevent reoccurrence.

Aspect 4: Systematic Analysis and Systemic Action

The transplant QAPI program uses a methodical approach to determine when in-depth analysis is needed to fully understand improvement opportunities, causes, and implications of change for care and services delivered. Transplant programs must develop policies and procedures and demonstrate proficiency in conducting a thorough analysis. The transplant QAPI program must analyze collected data. Analyses must include, but are not be limited to, analysis of data related to proactively defined quality indicators and the ongoing use of systemic methods to assess and analyze adverse events. Transplant adverse events¹ must be identified, tracked, investigated, analyzed, and the results used to prevent recurrence. There must be evidence that the transplant QAPI program develops system-based interventions to improve quality of care and performance on an ongoing basis to reduce risk of harm to patients. Systemic actions look comprehensively across all involved systems to prevent future negative events and promote sustained improvement. The transplant QAPI program uses an identifiable structure, policies and procedures to address investigation of root causes of transplant quality issues and document actions taken toward correction and sustaining change.

Aspect 5: Performance Improvements

The transplant QAPI program must define, implement, and evaluate performance improvement interventions with the objective of improving quality of care. Performance improvements are concentrated efforts that involve systematic gathering of information to identify issues or problems, and subsequent development of interventions to prevent recurrences. Once implemented, the interventions are later evaluated for success or continued need for improvement. Evidence of evaluation and sustained improvement is communicated to all stakeholders. The bi-directional reporting of these activities between staff, the transplant program, and hospital leaders, promotes a culture of continuous learning and improvement. The transplant program conducts activities to examine and improve care or services in areas that the transplant program identifies as needing attention (high risk, high (or very low) volume and problem prone areas). Areas that need attention will vary depending on the organ type. Documentation of transplant performance improvement interventions should reflect utilization of the program's defined performance improvement model or methodology.

¹ As defined in CMS regulations at 42 CFR 482.70, an “*adverse event* means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.” Examples of adverse events include (but are not limited to) graft failure, serious medical complications or death, donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended beneficiaries; and unintentional transmission of infectious disease to a beneficiary.