

CMS TRANSPLANT PROGRAM QUALITY WEBINAR SERIES

Comprehensive Program and 5 Key Aspects



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Enhancing Quality Assessment and Performance Improvement Programs in Transplant Programs and Hospitals April 8, 2015

CMS Webinar Series Transplant Centers

- 1. Introduction to the Transplant QAPI: Regulatory Overview
- Worksheet Overview
- 3. Comprehensive Program and 5 Key Aspects of QAPI
- 4. Objective Measures
- 5. Performance Improvements
- 6. Adverse Events
- 7. Transplant Adverse Event "Thorough Analysis"
- 8. QAPI Tools (part 1)
- 9. QAPI Tools (part 2)
- 10. Data display
- 11. Writing an effective Plan of Correction and Other QAPI Resources
- 12. Interpretive Guidelines



Disclaimer

- This training consists of Quality concepts, foundational and historical perspectives of Quality Assessment and Performance Improvement methodologies as they were originally developed.
- Healthcare has not come to an agreement on any one definition of what quality is, the best method(s) to employ or the best tool(s) to utilize within quality assessment and process improvement activities. Today, many organizations blend several quality concepts and tools to provide for a more nimble and individualized quality program.
- CMS is not prescriptive. This training does not support or advocate any particular method or tool. This training fully supports that the QAPI process includes data driven decisions that will sustain improvement leading to improved patient outcomes.



Objectives

The purpose of this webinar training is to enhance Quality Assessment and Performance Improvement activities within Transplant Programs through increased knowledge of Quality regulations, methods, tools and documentation practices.

Upon completion of this session, the participant will be able to:

- Identify the CMS regulations applicable to a comprehensive, data driven transplant QAPI program
- Review the 5 Key aspects of a comprehensive transplant QAPI program
- Identify quality resources available for developing a successful transplant
 QAPI program



Concept of the FQAPI Survey

"Increasingly effective QAPI programs in hospitals and transplant centers will improve quality of care, increase safety of care and reduce costs associated with each local organization's high risk, problem prone areas of concern".

Source: Announcement from CMS Secretary Kathleen Sebelius on April 12, 2011



Concept of the FQAPI Survey

Focused QAPI surveys will ensure transplant programs maintain an effective QAPI program.

Survey considerations include that:

- A timely QAPI process was initiated when an appropriate concern was identified.
- The QAPI program identifies a method for discovery of issues, referral of issues for QAPI interventions and corrective action plans.
- High risk, high volume (extremely low volume), or problem-prone areas are identified and being addressed in the QAPI program.



Introducing: The 5 Key Aspects of Transplant Quality

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





Overview of the Transplant Quality Condition of Participation §482.96

§482.96 Condition of Participation: Quality Assessment and Performance Improvement (QAPI)

Interpretive Guidelines:

5 Key Aspects of Transplant
Quality

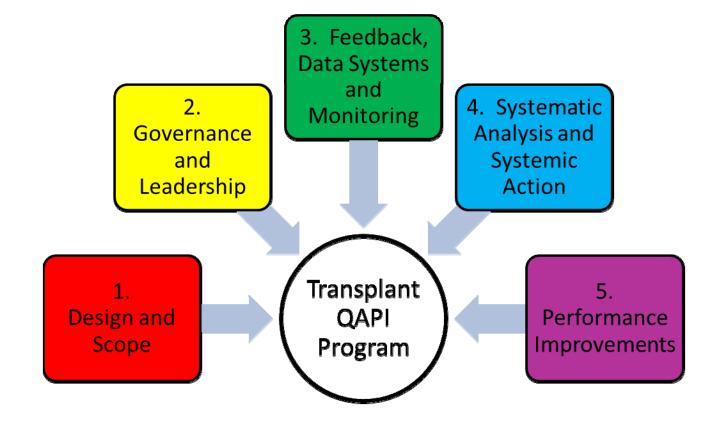
Transplant centers must develop, implement, and maintain a written, comprehensive, datadriven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

- 1. Design and Scope
- 2. Governance and Leadership
- 3. Feedback, Data System and Monitoring
- Systematic Analysis and Systemic Action
- 5. Performance Improvements





The 5 Key Aspects of Transplant Quality





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 care 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.



Aspect 1: Design and Scope

• The program includes methods for conducting analyses, implementing corrective actions, evaluating improvements, and assessing whether improvements are sustained. Is "Sustaining Improvement" addressed as a concept in your QAPI plan?

Similar terms may be:

"holding the gains",

"ensuring continued improvements"

"maintaining improved processes"

etc.



What Quality Method is Used?



Nash, D. (2012) Physician Training and the Culture of Quality. 11th National Quality Colloquium.

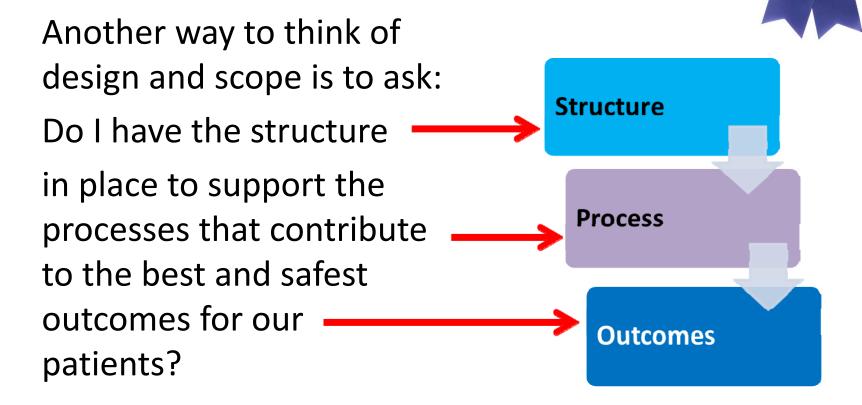
Aspect 1: Design and Scope

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.

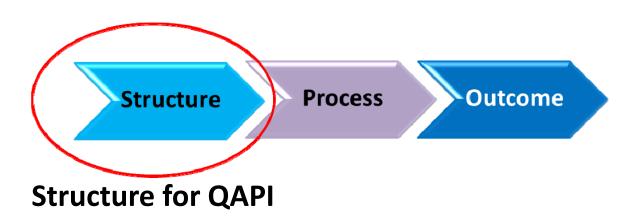


Design & Scope





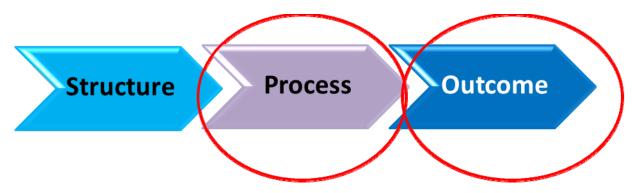
Design & Scope



- Written program
- Implemented (practice matches written program)
- Integrated with hospital quality
- Identifies high risk, high (or very low) volume, problem prone areas
- Methodology for conducting analyses, implementing corrective actions, evaluating improvements, assessing whether improvements are sustained

- Multidisciplinary
- Process and outcome objective measures
- Established frequencies for review of performance
- Identification of transplant specific adverse events
- Structured investigation processes
- Mechanisms for reporting between transplant and hospital programs.

Design & Scope



ONGOING PROCESS/OUTCOMES REVIEW Covering Full Range of Services:

ing I ull Natige of Services

- Patient Safety
- Clinical Care
- Quality of Life
- Contracted Services

DATA DRIVEN ... Reflecting:

- Complexity of Transplant Services
- All systems of transplant care
- All transplant management practices
- Multidisciplinary involvement
- Both process and outcome measures in all phases of transplant and living donor care



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.



Leadership/Governance Responsibilities

"Leadership engagement in patient safety and quality initiatives is imperative because 75% to 80% of all initiatives that require people to change behavior fail in the absence of leadership managing the change." Creating a culture of respect. Academic Medicine. 2012, Jul. 87(7): 853-858.

Leape, L. et al. A culture of Respect, part 2: Creating a culture of respect. *Academic Medicine* 2013. Jul.87(7): 853-858





Aspect 2: Governance and Leadership

- 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.



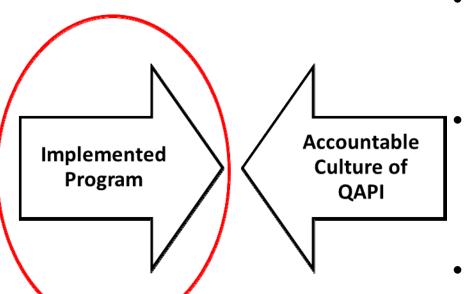
Aspect 2: Governance and Leadership

- 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.



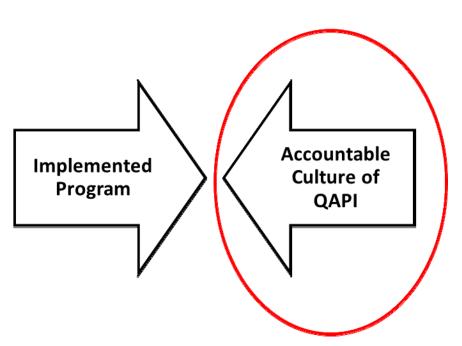
Leadership/Governance Responsibilities: QAPI Oversight

Implemented Program



- Ongoing, comprehensive, effective, resourced, operating in a continuous manner with evidence of sustained improvement
 - Clear expectations with written policies for quality and safety, quality care, and patient rights for transplant recipients and living donors
 - Bi-directional communication and reporting to ensure risk/harm reduction and reinforce lessons learned

Leadership/Governance Responsibilities: QAPI Oversight



Accountable Culture of QAPI

- Includes input from all stakeholders (staff/leaders/patients/families)
- Multidisciplinary team with roles/responsibilities
- Comfortable atmosphere where staff identify/reporting quality problems, opportunities for improvement
- QAPI education, developing leadership and hospital-wide training
- Staff time, equipment, technical training as needed

Culture of 'QUALITY'

The core of Quality is in the Organizations Culture

- Culture is a simple way of saying how an organization expresses itself, defining relationships both internally and externally.
- Culture is driven by values and leadership, whether by purpose or default.
- These drivers determine how an organization responds to all things, both good and bad. As a matter of fact, there isn't a part of an organization that isn't influenced or affected by the type of culture that has either been developed or allowed to exist.

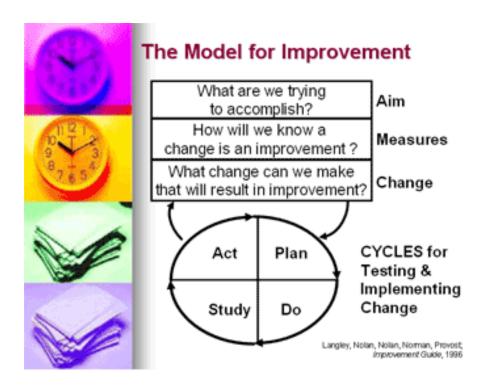


Aspect 3: Feedback, Data Systems and Monitoring

- 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.



Simple Data and Feedback Questions





Aspect 3: Feedback, Data Systems and Monitoring

- 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.
- 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.



Aspect 4: Systematic Analysis and Systemic Action

- 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.

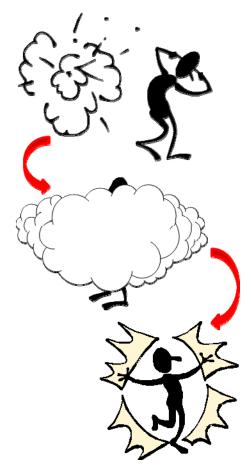


Aspect 4: Systematic Analysis and Systemic Action

Note:

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 unintended transmission of infectious disease to a beneficiary.

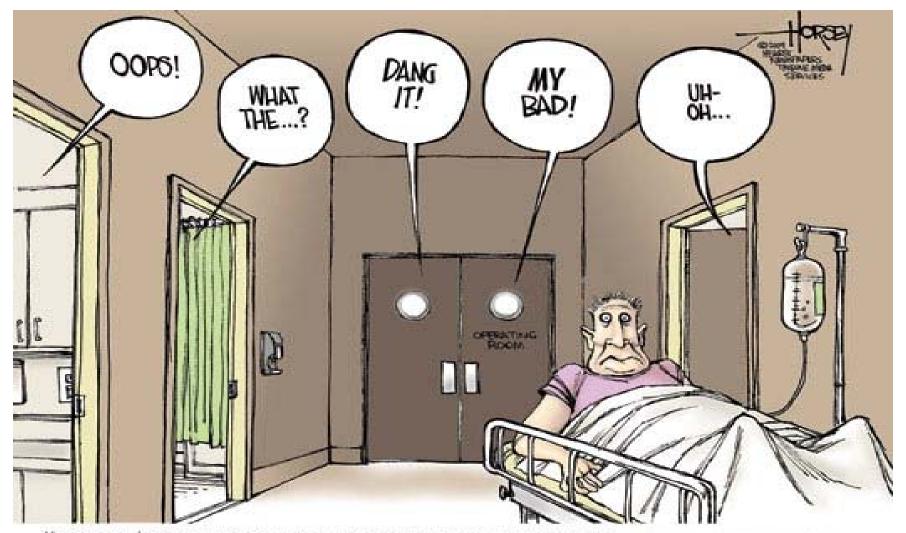




Aspect 4: Systematic Analysis and Systemic Action

- Transplant adverse events 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.





HOSPITAL MEDICAL ERRORS KILL 98,000 AMERICANS EACH YEAR. -- HEARST NEWS INVESTIGATION



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.



Aspect 5: Performance Improvements

- 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.



Understanding QA / PI Activities

QUALITY ASSESSMENT

The systematic act of appraisal - the process of gathering and discussing information from multiple sources in order to better understand a situation.

QA = Assessing Opportunity

PERFORMANCE IMPROVEMENT

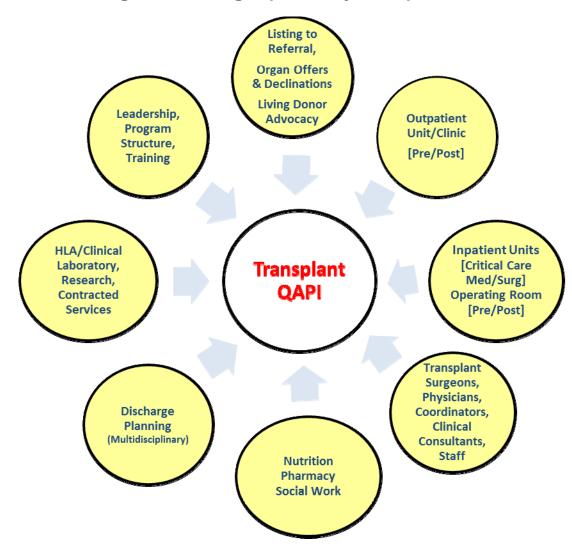
The concept of measuring the output of a particular process or procedure, then modifying the process or procedure to increase the output, increase efficiency, or increase the effectiveness of the process or procedure.

PI = Action



Thinking Transplant QAPI?

Consider: What is High Risk, High (or Very Low) Volume, Problem Prone?





QA/PI Activities: Examples

PI = ACTION

- Corrective action plans and changes to identified negative trends, problems facing the program or outliers in expected outcomes.
- Monitoring of changes made to:
 - ABO verification form
 - Informed consent process
 - Receipt of organ
 - Discharge planning process
 - Education process
 - Other program specific process changes
- Projects that change any step within a process related to the recipient or living donor



Overview of the Transplant Quality Condition of Participation §482.96

§482.96 Condition of Participation: Quality Assessment and Performance Improvement (QAPI)

Transplant centers must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.







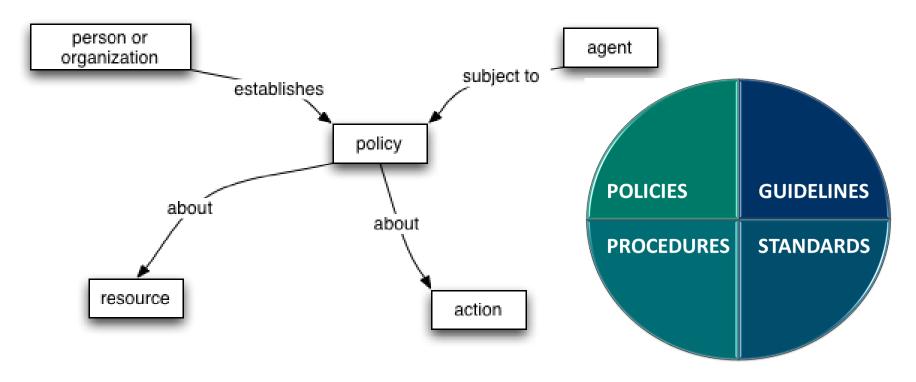


Written

- There must be a written transplant QAPI program, whose plan clearly defines the QAPI program purpose, structure, and operations.
- The QAPI program must either include or reference the program's patient safety plan to identify, prioritize, and address adverse events.
- Programs may maintain a separate adverse event or "patient safety" plan or they may incorporate the identification and management of adverse events into one unified QAPI program.
- The transplant QAPI program must include its structure including how it is organized and integrated into the organizational (hospital-wide) QAPI program, and must also identify the program leadership and management.
- The QAPI program must also have written specifications for data collection, analysis and use.



What's in a Program



CMS transplant regulations do not differentiate between "program", "plan", "policy", "procedure", "guidelines", "standards".
YOUR transplant center must define what the program is.



Comprehensive

- A comprehensive transplant QAPI program includes proactively-identified, transplant-specific indicators across all phases of transplant, transplant services (including those provided under contract or arrangement), for the transplant candidate/recipient and potential LD/LD.
- This includes off-site departments and remote locations (other inpatient campuses) providing care to the transplant candidate/recipient and potential LDs/LDs.



Comprehensive

- Since the transplant QAPI program is separate from the hospital's QAPI program, there must be clear evidence that information and findings from the transplant QAPI program are communicated to the hospital's QAPI program and that the transplant program incorporates appropriate hospital-wide QAPI activities.
- The hospital governing body must be aware of priority areas of the transplant QAPI program, including findings from thorough analyses in order to appropriately resource the QAPI program and individual projects.



Comprehensive:

- The scope of the transplant survey does not include a full assessment of the hospital QAPI program, but it does include tracing transplant identified issues to the hospital QAPI program and leadership attention.
- The hospital QAPI program must have documentation of these issues and support activities to improve services that are provided potential transplant candidate/ transplant recipients.



A comprehensive QAPI program is expected to include the following:

- Individual members identifiable by title, role, and responsibilities;
- Objective measures consisting of outcome and process measures for all phases of transplantation and living donation for which quality-related data will be collected and analyzed (including the measures described in §482.80 and §482.82);
- 3. Data-driven...(next slide)



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- 3. Data-driven: The program must clearly specify:
 - 1. The data to measure various aspects of quality of care and patient safety;
 - The frequency of data collection and how the data will be collected, analyzed and used;
 - 3. Proactively-defined indicators for systematic data collection in regular intervals;
 - 4. A comprehensive system to identify adverse events, and after identifying an adverse event, collect additional qualitative and/or quantitative information in preparation for root cause analyses; and
 - 5. How the program utilizes data analysis to drive continuous improvement.



- 4. Established frequencies for review of program performance, and reporting to the QAPI Committee and to the hospital-wide QAPI program;
- 5. Evidence of performance improvement initiatives including identifying high risk, problem prone areas in need of improvement, and of tracking and implementing recommendations for improvement;
- 6. Evidence of ongoing compliance with changes implemented as a result of recommendations by the QAPI Committee; and
- 7. Broad representation of staff and transplant program issues relevant for the disciplines represented in the multidisciplinary team (e.g., surgery, nursing, social services). This means that the QAPI program would not solely be focused on a single discipline (e.g., surgery) but would include performance measures relevant for other disciplines.



- 8. Method by which key findings and recommendations are reported to transplant QAPI program members, to the hospital-wide QAPI program, and to individuals determined by the QAPI program as instrumental to act on important analyses, findings, and recommendations and sustained improvements;
- 9. The program must conduct an appropriate, thorough analysis of any adverse event and utilize the analysis to effect changes in policies and practices to prevent repeat incidents.



- 10. Documented process/policy for identification, reporting, analysis and prevention of adverse events (AE) including written definition of transplant specific adverse events as an "untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof" including all phases of transplant and donation (pre-transplant, transplant, post-transplant; pre-donation, donation and post-donation);
- 11. The program must conduct an appropriate, thorough analysis of any adverse event and utilize the analysis to effect changes in policies and practices to prevent repeat incidents.



Comparison

Survey Procedure

Program Content







Survey Procedure

Review transplant program QAPI policy and documents to ensure the presence of the following:

- 1. Multidisciplinary team participation, with individuals identifiable by title, role, and responsibilities;
- 2. QAPI methods for developing objective measures, consisting of outcome and process measures for all phases of transplantation and living donation.

Comprehensive Program Content

A comprehensive QAPI program is expected to include the following:

Individual members identifiable by title, role, and responsibilities;

Objective measures consisting of outcome and process measures for all phases of transplantation and living donation for which quality-related data will be collected and analyzed (including the measures described in §482.80 and §482.82);



Survey Procedure

Demonstration of how quality-related data is collected, analyzed, and utilized;

Comprehensive Program Content

Data-driven: The program must clearly specify:

- 1. The data to measure various aspects of quality of care and patient safety;
- 2. The frequency of data collection and how the data will be collected, analyzed and used;
- Proactively-defined indicators for systematic data collection in regular intervals;
- 4. A comprehensive system to identify adverse events, and after identifying an adverse event, collect additional qualitative and/or quantitative information in preparation for root cause analyses; and
- 5. How the program utilizes data analysis to drive continuous improvement.





Comprehensive Program Content

 Established frequencies for review of program performance, and reporting to the QAPI Committee and to the hospital-wide QAPI program;

Survey Procedure

5. Designation of an individual who will be responsible for monitoring the transplant program's QAPI program (i.e., QAPI coordinator)

Established frequencies for review of program performance, and reporting to the QAPI Committee and to the hospital-wide QAPI program;

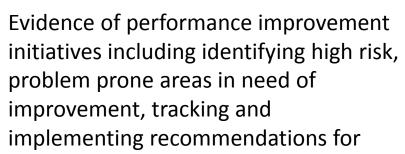


improvement;

Survey Procedure

- improvement initiatives including identifying high-risk, high-volume and problem-prone areas in need of improvement, tracking and implementing recommendations for improvement;
- 7. Evidence of ongoing compliance with changes implemented as a result of QAPI activities;

Comprehensive Program Content



Evidence of ongoing compliance with changes implemented as a result of recommendations by the QAPI Committee; and



Survey Procedure

8. Specific issues relevant to each of the disciplines represented in the multidisciplinary team (e.g., surgical, nursing, social services, dietary, and pharmacy), as warranted;

Comprehensive Program Content

Broad representation of staff and transplant program issues relevant for the disciplines represented in the multidisciplinary team (e.g., surgery, nursing, social services). This means that the QAPI program would not solely be focused on a single discipline (e.g., surgery) but would include performance measures relevant for other disciplines.



Survey Procedure

- 9. Participation of the transplant program's personnel (director, transplant surgeon(s), transplant physician(s), clinical transplant coordinator(s), and nursing personnel). Examples of their participation include being a member of QAPI committee/ sub-committees and project improvement teams, presenting topics to the QAPI committee, authoring reports or updates for the QAPI committee about the program's status.
- 10. An internal communication structure to ensure that information is communicated up through the organization and back to front line staff.

Comprehensive Program Content



Method by which key findings and recommendations are reported to transplant QAPI program members, to the hospital-wide QAPI program, and to individuals determined by the QAPI program as instrumental to act on important analyses, findings, recommendations and sustained improvements.

Survey Procedure

11. An Adverse Event Policy, see section §482.96 (b).

Comprehensive Program Content

The program must conduct an appropriate, thorough analysis of any adverse event and utilize the analysis to effect changes in policies and practices to prevent repeat incidents.

Documented process/policy for identification, reporting, analysis and prevention of adverse events (AE) including written definition of transplant specific adverse events as an "untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof" including all phases of transplant and donation (pre-transplant, transplant, post-transplant; pre-donation, donation and post-donation).

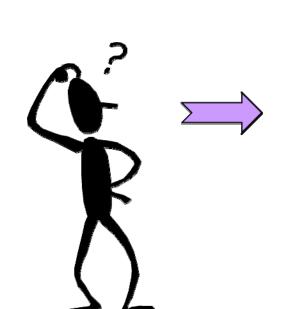
The program must conduct an appropriate, thorough analysis of any adverse event and utilize the analysis to effect changes in policies and practices to prevent repeat incidents.



5 Key Aspects of Quality

- 1. Design and Scope
- Governance and Leadership
- 3. Feedback, Data Systems and Monitoring
- 4. Systematic Analysis and Systemic Action
- 5. Performance Improvements

Consider starting with the Hospital QAPI Plan as a resource....





QAPI Process

Quality starts with planning. Organizations must determine through a risk analysis what measures they want to improve or need to improve. Prioritization of activities should be based on the severity towards patients (high volume, high risk, problem prone areas). In order to effectively prioritize measures, organizations need to identify patient flow processes, information flow process and material flow processes

QAPI PLANNING

 Prioritization of activities should be based on Risk analyses of the severity towards patients (eg. High volume, High Risk, problem prone areas)

Identify Patient Flow Processes
Identify Information Flow Processes
Identify Material Flow Processes

STRATEGIC GOALS

 The organization should have strategic goals of improving patient outcomes, increasing efficiency and promoting preventative health measures.

<u>ALIGNMENT</u>

- Transplant QAPI Planning activities should align with the Hospital QAPI plans as well as the organizations strategic plans, vision and mission

PATIENT FOCUSED

- Patients are suppliers; unique processors; and the immediate customer of the same processes, with needs and expectations.

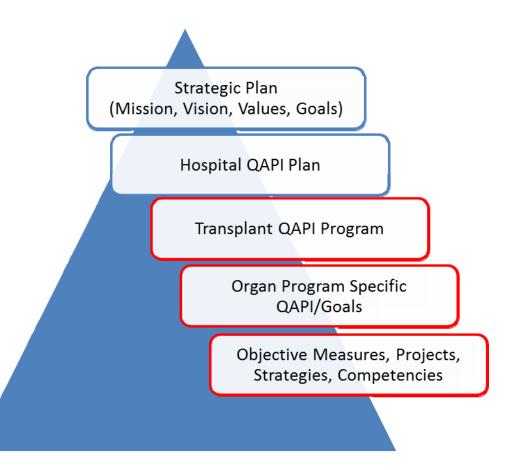
CUSTOMER

- An organization can improve patient care quality by assessing and improving the governance, managerial, clinical and support processes that most affect customers.



Cascading Goals for QAPI

Not required by regulation but common sense!





Hospital Annual Strategic Goals Generic example

INTEGRATED

- Information Systems
- LOS Management (including unnecessary readmissions)
- Infection Prevention
- Volume growth

DISTINCT

- Data validity (source codes, diagnosis codes, etc.)
- Transplant specific database needs
- Referral to listing systems issues
- Long term clinic follow up
- Immunocompromised hosts have different risks...
- Critical management of transplant staffing related to program growth



Quality "Opportunities" Identified, in your HOSPITAL Plan...

Wording similar to:

"Organizational improvement opportunities are selected by reviewing the hospital's strategic plan, organizational dashboard and report card data, care management initiatives, regulatory requirements and recommendations from the following:..."



Recommendations From...

INTEGRATED (Hospital)

- Senior Executive Council and Governing Body
- Hospital Performance Improvement Council
- Medical Executive Committee
- Root Cause Analysis investigations
- Failure Mode Analysis and other chartered teams
- Institute of Medicine
- Agency for Healthcare Quality
- Institute of Healthcare Improvement
- State and Federal Agencies including Centers for Medicare & Medicaid Services (CMS)
- Deemed Status Organization (Joint Commission, Det Norske Veritas, etc.)
- Internal Healthcare System Benchmarks
- External Healthcare System Benchmarks (i.e. University Health System Consortium)

DISTINCT (Transplant Program)

- UNOS/OPTN
- CMS
- Organ Donation and Transplantation Alliance
- Professional Transplant
 Organizations
- Others



Example of Cascading Goals

Strategic Goal: Control and reduce the cost of providing care

INTEGRATED

Decrease Hospital Length of Stay (LOS)



DISTINCT TRANPLANT SPECIFIC!

Decrease ICU LOS for (specify organ) transplant patients

- Focus project: Perioperative Dialysis
- Focus project: LVAD "Bridge" management

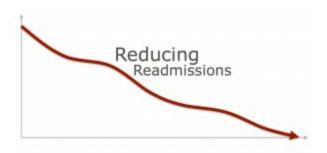


Example of Cascading Goals

Strategic Goal: Control and reduce the cost of providing care

INTEGRATED

Decrease Unnecessary Hospital Readmissions



DISTINCT

TRANPLANT SPECIFIC!

Decrease unnecessary (specify organ) transplant readmissions

- Focus project: Inpatient to Outpatient medication management
- Focus project: Clinic visit compliance



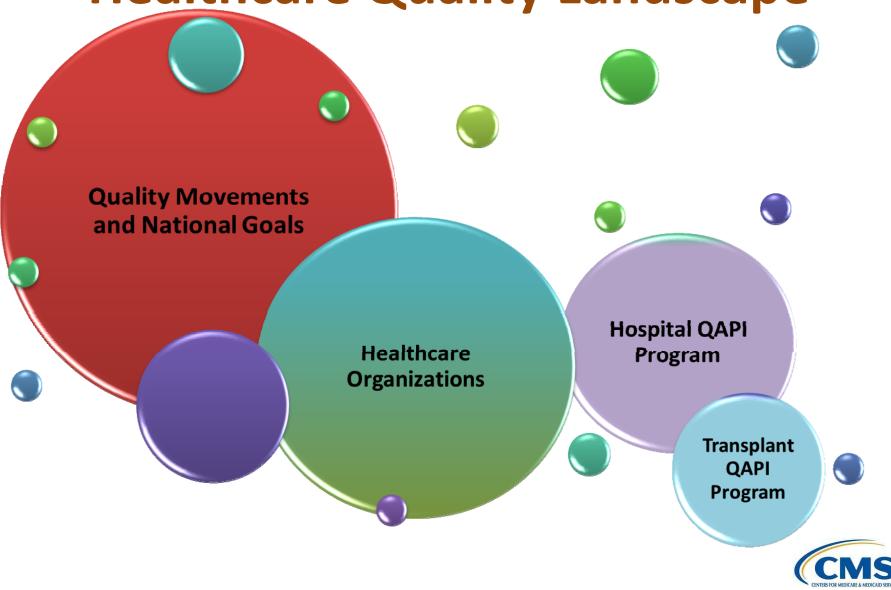
"Scope Creep"

- Uncontrolled changes or continuous growth in a project scope
- Project drift from original purpose morphing into a larger (previously unplanned) focus
- Forces longer timelines and increased resources.
- Result: Overwhelmed ("cure world hunger" analogy)

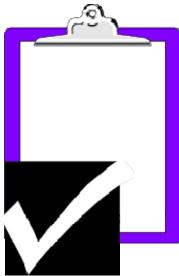




Healthcare Quality Landscape



Get "CREDIT" for it..... PUT IT IN YOUR QAPI Program





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