



“Introduction to Transplant QAPI: A Regulatory Overview”

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QAPI Specialists/Quality Surveyor Educators (QSEs)/Transplant Surveyors

Centers for Medicare and Medicaid Services

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SOLID ORGAN TRANSPLANT CENTERS

2015



**Enhancing Quality Assessment and Performance Improvement
Programs in Transplant Programs and Hospitals (EQAPI)**

**CMS WEBINAR SERIES
TRANSPLANT PROGRAM QAPI**

**Introduction to Transplant QAPI
A Regulatory Overview**

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CMS WEBINAR SERIES

Transplant Programs

1. **Introduction to the Transplant QAPI: Regulatory Overview**
2. FQAPI Worksheet Overview
3. Objective Measures – Monitoring & Evaluating Services
4. Performance Improvement – Tools and Methods
5. Transplant Adverse Events
6. Transplant Adverse Events “A Thorough Analysis”
7. QAPI Tools (part 1)
8. QAPI Tools (part 2)
9. Data Display - Tools and Methods
10. Comprehensive Program and 5 Key Aspects
11. Interpretive Guidelines
12. Writing an effective Plan of Correction & Other QAPI Resources

PURPOSE AND OBJECTIVES



- The purpose of this training series is to enhance Quality Assessment and Performance Improvement activities within Transplant Programs through increased knowledge of QAPI, regulations, methods, tools, and documentation practices.
- Upon completion of this session, the participant will be able to:
 - Discuss the basis for the Transplant Focused Quality Assessment and Performance Improvement survey.
 - Understand the Conditions of Participation for a Transplant QAPI program and Hospital QAPI program and the relationship between the two sets of requirements.
 - Specify critical elements required from a Transplant QAPI Program.

DISCLAIMER

- This training series will contain Quality concepts, foundational and historical perspectives of Quality Assessment and Performance Improvement methodologies (as they were originally developed) and regulatory guidance to help transplant programs meet compliance with the Conditions of Participation.
- CMS understands that: 1) Healthcare has various definitions of what Quality is, 2) There are many methods that can be employed and 3) there are many tools that can be utilized within quality assessment and process improvement activities.
- CMS also understands that some organizations blend several quality concepts and tools together to provide for a more nimble and individualized QAPI program.
- CMS is never prescriptive to organizations in how to meet compliance. This training series does not support or advocate any particular QAPI method or tool. This training fully supports that QAPI activities include data driven decisions that lead to sustained improved performance and ultimately improved patient outcomes.



WHY IS THERE SUCH A FOCUS ON TRANSPLANT PROGRAMS?



REGULATIONS IMPLEMENTED

In **2007**, the Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants 42 CFR Parts 405, 482, 488, and 498 went into effect.

This training will focus specifically on the Condition of Participation for QA PI in Transplant Programs.

482.96 states: “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.”



A FOCUS ON QUALITY CAN IMPROVE OUTCOMES

In **2013**, Focused Quality Assessment and Performance Improvement (FQAPI) Survey process was created and piloted.

The Purpose: To fully evaluate if transplant programs have developed and implemented effective, integrated programs of internal quality assessment and performance improvement that are prioritized to address high-risk, high-volume or problem prone areas that affect health outcomes, patient safety, and quality of care as required in the Transplant QAPI Conditions of Participation (CoPs) (42 CFR 482.96).

What CMS found:

2013: 10 Pilot surveys conducted – 10 programs found to be at risk for Condition Level non-compliance
(Tag X099)

2014: 20 FQAPI surveys conducted – 10 programs found to be non-compliant at Condition Level
(Tag X099)

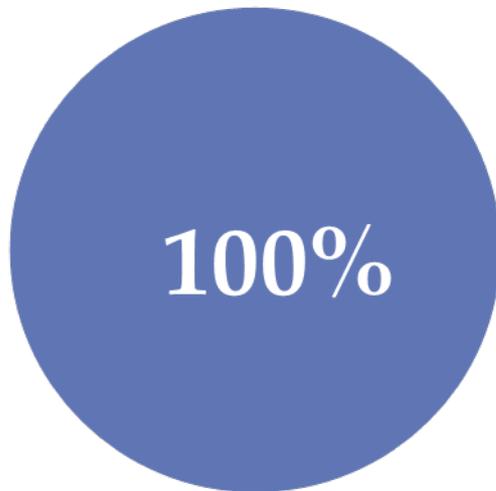


STATISTICAL VIEW

PILOT SURVEYS

10 PROGRAMS – 10 AT RISK

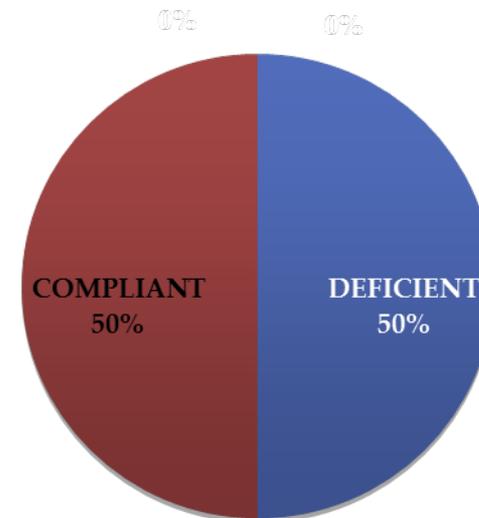
X099



FQAPI SURVEYS

20 PROGRAMS – 10 DEFICIENT

X099



QUALITY CAN IMPACT CARE



The following statistics provide an example of where healthcare can benefit from improvements within patient care and the impact efforts have achieved.

OPPORTUNITIES FOR IMPROVEMENT

- Potentially preventable medical errors that occur during or after surgery cost nearly \$1.5 billion a year;
- Healthcare Associated Infections affect approximately 5% of hospitalized patients. (145 per 1000);
- 32.9 million re-admissions occur annually; (Mar 2012 – AHRQ);
- 14.1% of those needing care never received care; (AHRQ – 2010 report)
- Institute of Medicine (IOM) estimates there are 44,000 to 98,000 preventable deaths each year; (*To Err is Human, 1999*)

RESULTS OF QUALITY EFFORTS

- The Partnership for Patients and other efforts to improve patient safety are estimated to have helped **avoid 15,000 deaths** and more than **560,000 patient harms** over the past two years.
- Patient safety efforts and new payment incentives for hospitals are estimated to have helped avoid **150,000 readmissions** to hospitals during 2012 and 2013.
- Of the National Quality measures being monitored – over **80% have seen improvement** from 2006 to 2012.

SECTION SUMMARY

- The Conditions of Participation for Transplant Programs are not new, they have been in effect since 2007.
- Progress has been made over the past 8 years, but some programs are still at risk of non-compliance and deficient with the QAPI Condition of Participation.
- CMS understands that a focus on Quality Assessment and Performance Improvement activities can lead to improved patient outcomes.



CONDITIONS OF PARTICIPATION



To qualify for Medicare certification and reimbursement, providers and suppliers of health services must comply with **MINIMUM** health and safety standards.

CONDITION OF PARTICIPATION QAPI

INTEGRATED

42 CFR 482.21 (Hospital)

The hospital must develop, implement and maintain an effective, ongoing, **hospital-wide, data-driven** quality assessment and performance improvement program. The hospital's **governing body must ensure** that the program **reflects the complexity of the hospital's organization and services; involves all hospital departments and services** (including those services furnished under contract or arrangement); and **focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors**. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

DISTINCT

42 CFR 482.96 (Transplant)

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.



FQAPI SURVEY FINDINGS



TAG X099 – CITED 50% OF THE TIME

482.96 Condition: DEVELOP, IMPLEMENT & MAINTAIN WRITTEN COMPREHENSIVE DATA-DRIVEN QAPI

- No active, implemented, comprehensive, data-driven QAPI program.
- Documentation for QAPI plan, minutes, reports, and dashboard did not reflect active QAPI program.
- QAPI plan not accepted or reviewed by leadership or Governing Body.
- Plan did not state role & responsibilities.
- No inclusion of all phases of transplantation or donation.
- Contract services not identified in Performance Improvement measures.
- No methodology, measures, meetings, analyzed data, Governing Body involvement, Multi-disciplinary Team involvement, or Board representative.
- Not functioning as their plan stated for meeting frequency and membership, selection and monitoring of objective measures, communication of PI initiatives.
- No documented mechanism for communication of PI information reflecting the entire cycle of QAPI from identification of opportunity to sustained improvement.

A COMPREHENSIVE QAPI PROGRAM IS **EXPECTED TO INCLUDE THE FOLLOWING:**



1. Individual members identifiable by title, role, and responsibilities;
2. QAPI methods of operating and decision-making (e.g., by committee, sub-committee, other);
3. Objective measures by which the quality-related data will be collected and analyzed (including the measures described in §482.80 and §482.82);
4. Established frequencies for review of program performance and reporting to the QAPI Committee and to the hospital-wide QAPI program;
5. Method by which key findings and recommendations are reported to QAPI transplant members, to the hospital-wide QAPI, and to individuals determined by the QAPI program as instrumental to action on important analyses, findings, and recommendations;

A COMPREHENSIVE QAPI PROGRAM IS **EXPECTED** TO INCLUDE THE FOLLOWING continued:

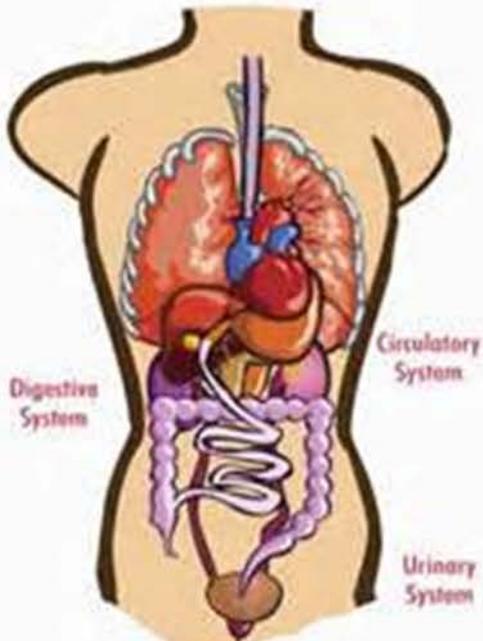
6. Designation of an individual who will be responsible for monitoring the transplant program's QAPI program (i.e., QAPI coordinator);
7. Evidence of tracking and implementing recommendations for improvement;
8. Evidence of ongoing compliance with changes implemented as a result of recommendations by the QAPI Committee; and
9. Broad representation of transplant program issues relevant for the disciplines represented in the multidisciplinary team (e.g., surgical, nursing, social services). This means that the QAPI would not solely be focused on a single discipline (e.g., the surgeon) and would include performance measures relevant for other disciplines.

TRANSPLANT PROGRAMS NEED TO BE **INTEGRATED** WITH HOSPITAL QAPI ACTIVITIES WHILE ALSO CONDUCTING **DISTINCT** ORGAN SPECIFIC QAPI ACTIVITIES

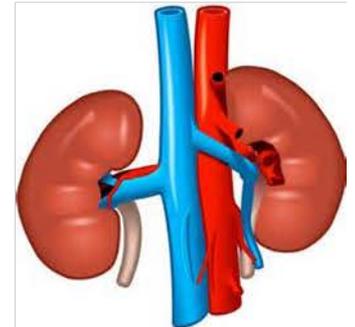
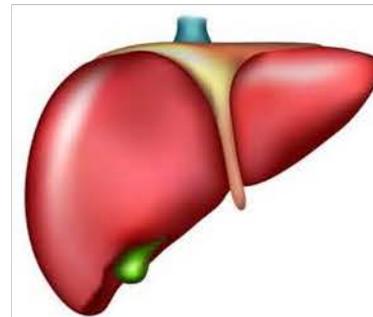
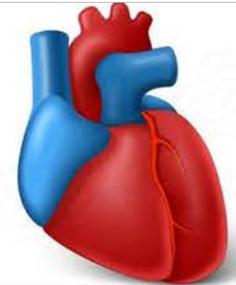
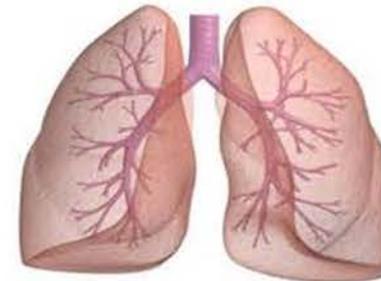
HOSPITAL QAPI

COMMUNICATION

TRANSPLANT QAPI



INTEGRATED ACTIVITIES



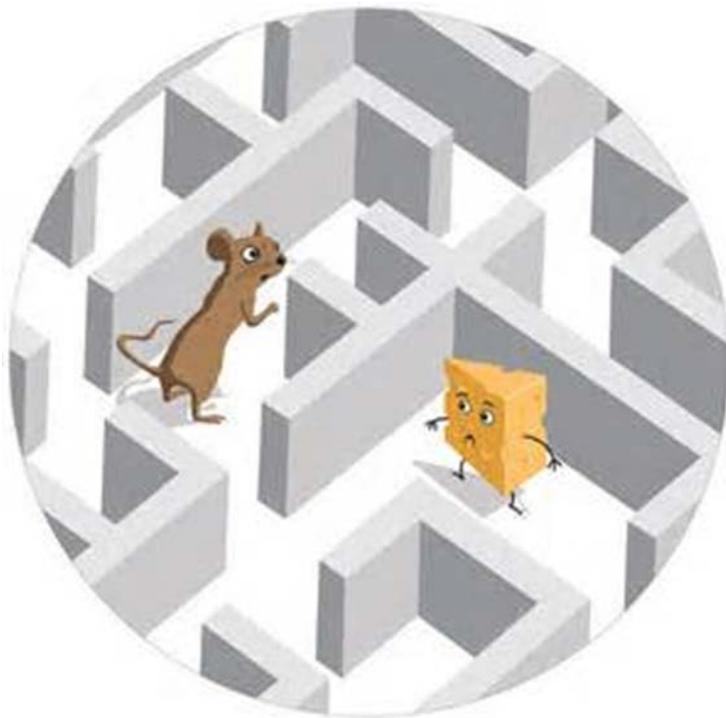
DISTINCT FUNCTIONS

OBJECTIVE MEASURES

Are you still chasing
objective measures?

OR

Have you taken a
'SMART' approach



STANDARD: COMPONENTS OF A QAPI PROGRAM

INTEGRATED

482.21(a)(1) - The program must include, but not be limited to, an ongoing program that shows measurable improvement in **indicators** for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

482.21(a)(2) - The hospital must **measure, analyze, and track quality indicators**, including adverse patient events, and other aspects of performance that assess processes of care, hospital service, and operations.

DISTINCT

482.96 (a) Standard: Components of a QAPI Program

The Transplant Program's QAPI program **must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes.**

Outcome measures *may include, but are not limited to:*

- patient and donor selection criteria,
- accuracy of the waiting list in accordance with the OPTN waiting list requirements,
- accuracy of donor and recipient matching,
- patient and donor management,
- techniques for organ recovery,
- consent practices,
- patient education,
- patient satisfaction,
- patient rights.

FQAPI SURVEY FINDINGS X100

X100 CITED 57% OF THE TIME

482.96(a) Standard: Components of a QAPI Program

- No process measures for pre donation and no outcome measures for pre donation, and post donation phases.
- Measures were not consistently identified by process, outcomes, or by phases.
- No rationale used for identification.
- No evidence of data analysis, aggregated data, and appropriate action taken or implemented presented.
- Not all measures were in all phases.
- The QAPI Plan did not include Living Donation in selection of objective measures.
- Did not identify measures in all programs in all phases as stated in plan.

COMPONENTS OF OBJECTIVE MEASURES



- Objective measures should be used to evaluate the center's performance in regards to transplant activities and outcomes.
- Objective measures are **fact based** monitors over processes and outcomes in **each phase** of transplantation or living donation.
- Objective measures are more than transplant volumes, transplant rates and survival rates.
- Objective measures evaluate processes that impact patient outcomes.
- Effective objective measures have included: measure definition, numerator, denominator, data source, reason the measure exists, triggers for action plans, reporting requirements, and timeframes for retirement.

§482.21(b) STANDARD: PROGRAM DATA

INTEGRATED

482.21(b)(1) - The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

482.21(b)(2) - The **hospital must use the data collected** to—

- (i) **Monitor the effectiveness and safety of services and quality of care;** and
- §482.21(b)(2)(ii) - **Identify opportunities for improvement and changes that will lead to improvement.**
- §482.21(b)(3) - The frequency and detail of data collection **must be specified by the hospital's governing body.**

DISTINCT FUNCTION

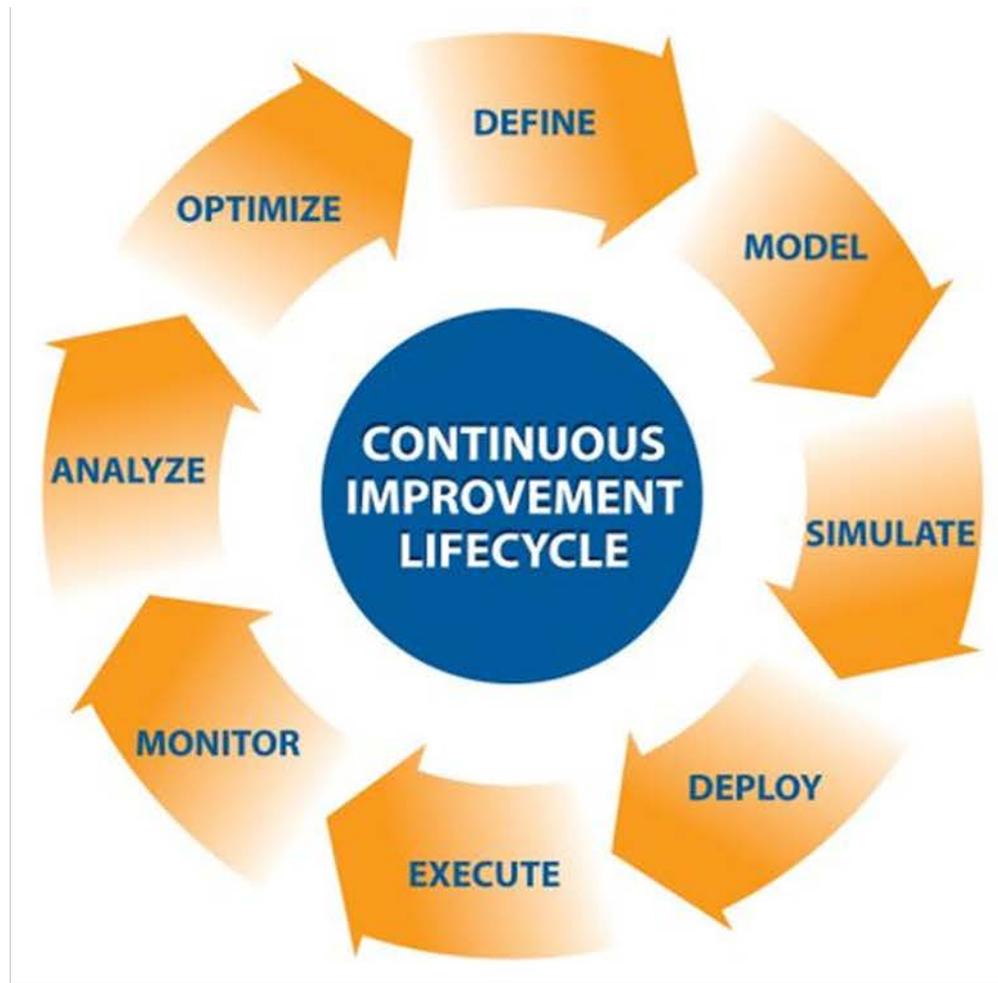
482.96(a) **TAKE ACTION AND TRACK PERFORMANCE FOR SUSTAINABILITY**

The Transplant Center **must take actions** that result in performance improvements and **track performance to ensure that improvements are sustained.**

TAKING ACTION AND ENSURING SUSTAINABILITY

How do you develop actions toward improvement?

Have you developed follow-up methods for actions taken?



Was the action taken a one time correction or something that requires continuous monitoring?

How do you determine if the actions taken have been sustained?

Example of a continuous improvement cycle

FQAPI SURVEY FINDINGS X101



X101 CITED 71% OF THE TIME

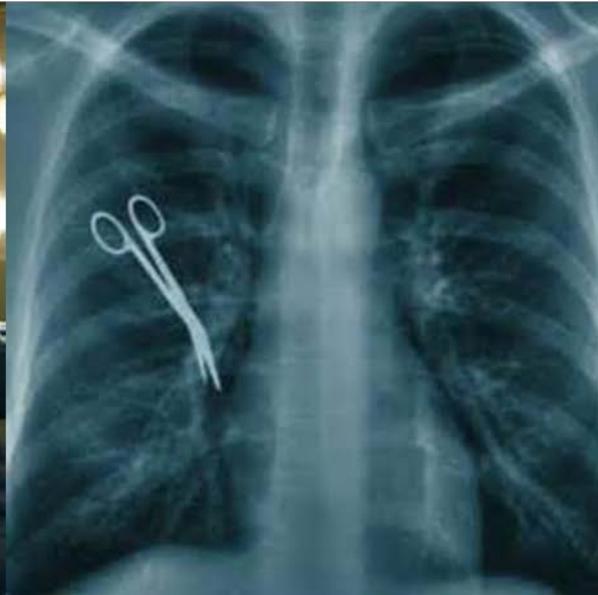
482.96(a) TAKE ACTION AND TRACK PERFORMANCE FOR SUSTAINABILITY

- No mechanisms to ensure problems handled promptly.
- No documentation of actions or sustainment.
- Did not address complete continuous PI process.
- No evidence of entire scope of quality continuum identified problems, aggregated data, analysis, appropriate action taken, improvements made, or evidence of sustained compliance.
- No evidence of actions to improve on 26 of 28 measures.
- QAPI plan did not include any stage related to control or monitoring of actions taken that led to sustainable improvements.
- Last step of QAPI process was to monitor and collect data.
- QAPI plan did not address a QAPI process that addressed how improvement was evaluated or sustained.
- QAPI plan did not include mechanism to ensure problems were promptly identified or how long term measures were implemented and evaluated to ensure continuous compliance.

TAKE ACTION AND TRACK PERFORMANCE FOR SUSTAINABILITY

- Effective programs have defined when and how actions will be developed and taken toward improvement.
- Once actions are taken, the plan should include follow-up periods to determine if the actions led to improvement and have been sustained over time.
- Action plans often contain time periods for when actions taken will be monitored after sustained improvement has been achieved.
- There are many tools available to help develop action plans – the component often missed is communicating actions taken to ALL staff who come in contact with transplant patients (multi-D team, floor nurses, leadership).

ADVERSE EVENTS



ADVERSE EVENT DEFINITION

Adverse Event Definition 482.70-

- **“Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.”**
- As applied to transplant programs, **examples** of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; and unintended transmission of infectious disease to a recipient.

INTEGRATED

482.21(c)(1) - The hospital must set priorities for its performance improvement activities that-

- (i) **Focus on high-risk, high-volume, or problem-prone areas;**
- (iii) **Affect health outcomes, patient safety, and quality of care.**

482.21(c)(2) - Performance improvement activities **must track medical errors and adverse patient events,...**

482.21(c)(2) (C) **implement preventive actions** and mechanisms that include feedback and learning **throughout the hospital.**

DISTINCT FUNCTION

482.96(b)(1) STANDARD:
IMPLEMENT WRITTEN
POLICIES TO ADDRESS
ADVERSE EVENTS

- A Transplant Center **must establish and implement written policies to address and document** adverse events that occur **during any phase of an organ transplantation case.**
- (1) The policies must address, at a minimum, the process for the **identification, reporting, analysis, and prevention** of adverse events.

FQAPI SURVEY FINDINGS X102



X102 CITED 43% OF THE TIME

482.96(b)(1) STANDARD: IMPLEMENT WRITTEN POLICIES TO ADDRESS ADVERSE EVENTS

- Had no Adverse Event policy.
- Policy did not address the process for identifying, reporting, analysis, and prevention of AE.
- Did not define adverse events that can occur during any phase of organ transplantation or living donation.
- Policy was not transplant-specific.
- Policy did not address the process for identification, analysis, prevention of Adverse Events.
- Policy did not define what would be considered AE during any phase of transplantation or living donation.

THE POLICIES SHOULD ADDRESS:

1. Procedure for reporting an adverse event by transplant program personnel, the hierarchy of reporting, and for conducting analysis based on the reports;
2. The required timeframe for reporting, investigating and analyzing adverse events;
3. The corrective action process after the completion of the analysis and the timeframes for the action;
4. Use of analysis of reported adverse events in prevention;
5. External reporting of events to OPTN, ESRD Network, and States, etc. as required and applicable.

THE POLICIES SHOULD ADDRESS (cont.):

6. Reporting to, or inclusion of, Institutional Review Board (IRB)/Western Institutional Review Board (WIRB) if the adverse event occurred within the context of an approved study;
7. For suspected medical device-related deaths or serious injury, reporting to the Food and Drug Administration (FDA) and the device manufacturer as required by federal law.
8. Reporting to the OPTN if the adverse event caused, or may have caused, transmission of an infectious disease, and reporting to the Centers for Disease Control (CDC), if CDC requires such reporting to them.
9. Reporting to the OPO if the adverse event was related to an infectious disease present in a recovered organ from a deceased donor that could have been transmitted to other recipients who received organs from that same donor, or an otherwise compromised organ that was not detected either through the donor screening or organ transport processes.

A 'THOROUGH' ANALYSIS



THOROUGH ANALYSIS



INTEGRATED

482.21(a)(2) - The **hospital** must measure, **analyze**, and track quality indicators, **including adverse patient events**, and other aspects of performance that assess processes of care, hospital service and operations.

DISTINCT FUNCTION

482.96(b)(2) CONDUCT ANALYSIS OF AND DOCUMENT ANY ADVERSE EVENT.

The Transplant Center **must conduct a thorough analysis of and document ANY adverse event.**

FQAPI SURVEY FINDINGS X103

X103 CITED 57% OF THE TIME

482.96(b)(2) CONDUCT ANALYSIS OF AND DOCUMENT ANY ADVERSE EVENT

- No policy.
- QAPI process was not specified in hospital policy or transplant policy.
- QAPI plan stated they would follow the hospital's policies, but no evidence of process for conducting analysis and documenting AE for all phases of transplantation or living donation.
- No AE presented to indicate if any AE other than unexpected nature that were identified, documented or analysis conducted.

A “**THOROUGH ANALYSIS**” IS EXPECTED TO INCLUDE

(but is not limited to):

- a. A description of the key facts of the event in enough detail so that one can clearly understand what occurred, the severity of the event, and how the patient was affected;
- b. A review of whether or not similar events have occurred in the past; and
- c. An analysis of related systems and processes that contributed to the event’s occurrence.

AN ANALYSIS OF RELATED SYSTEMS AND PROCESS THAT CONTRIBUTED TO THE EVENTS OCCURRENCE



Examples of systemic factors that may contribute to adverse events include:

- Human Factors (for example, communication procedures, staff training, scheduling)
- Environment (for example, location of needed equipment, systems for organizing/labeling medication)
- Equipment (for example, technology that does not warn of pending error)
- Policies (for example polices that may exist but are unclear, or where no policies exist)
- Procedures (for example, there are no procedures for verification of blood type)
- Organizational (for example, the transplant program may not be monitoring adherence to or reinforcing care protocols)

UTILIZE THE ANALYSIS

INTEGRATED

482.21(c)(2) (C)

- **implement preventive actions** and mechanisms that include feedback and learning throughout the hospital.

DISTINCT FUNCTION

482.96(b)(2) UTILIZE THE ANALYSIS TO EFFECT CHANGE (ADVERSE EVENTS)

- and **must utilize the analysis** to effect changes in the Transplant Center's policies and practices **to prevent repeat incidents.**

FQAPI SURVEY FINDINGS X104

X104 CITED 60% OF THE TIME

482.96(b)(2) UTILIZE THE ANALYSIS TO EFFECT CHANGE (ADVERSE EVENTS)

- No policy.
- Policy did not define how analysis would be utilized for prevention of repeat incidents of AE.
- No evidence that results of analysis were to be taken to prevent repeats.
- No evidence of any method or process in place to monitor or follow-up on actions taken as result of analysis to determine if improvements made or actions taken led to prevention of repeat incidents.
- No evidence of process to utilize the results of AE analysis in order to take actions that could prevent repeat incidents.
- No evidence that action plans or recommendations by the programs were discussed or part of the council's meeting minutes.
- Documents did not indicate any analysis or action plans taken to prevent repeat incidents.
- No process to utilize the results of AE analysis to take action to prevent repeat incidents.
- No evidence of follow-up or monitoring of any actions that may have been taken was conducted to prevent repeat incidents.

UTILIZING THE ANALYSIS

- Just like developing action plans for objective measures, action plans generated from a thorough analysis should include: actions taken, timeframe for completing action, responsible party for the action, timeframe for follow-up and timeframe for monitoring.
- Utilizing the results of a thorough analysis should lead to ‘learning’.
- Learning is information communicated to ALL staff who come into contact with transplant patients.
- Communication is only effective when it is a complete cycle, clear, timely and allows for feedback.

HOSPITAL EXTRA'S



§482.21(d) STANDARD: PERFORMANCE IMPROVEMENT PROJECTS

As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

§482.21(d)(1) - The number and scope of distinct improvement projects conducted annually **must be proportional to the scope and complexity of the hospital's services and operations.**

§482.21(e) STANDARD: **EXECUTIVE RESPONSIBILITIES**

The **hospital's governing body** (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

- **§482.21(e)(1) - That an ongoing program for quality improvement ... is defined, implemented, and maintained.**
That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

§482.21(e) STANDARD: EXECUTIVE RESPONSIBILITIES

§482.21(e)(2) - That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care...and **that all improvement actions are evaluated**. That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

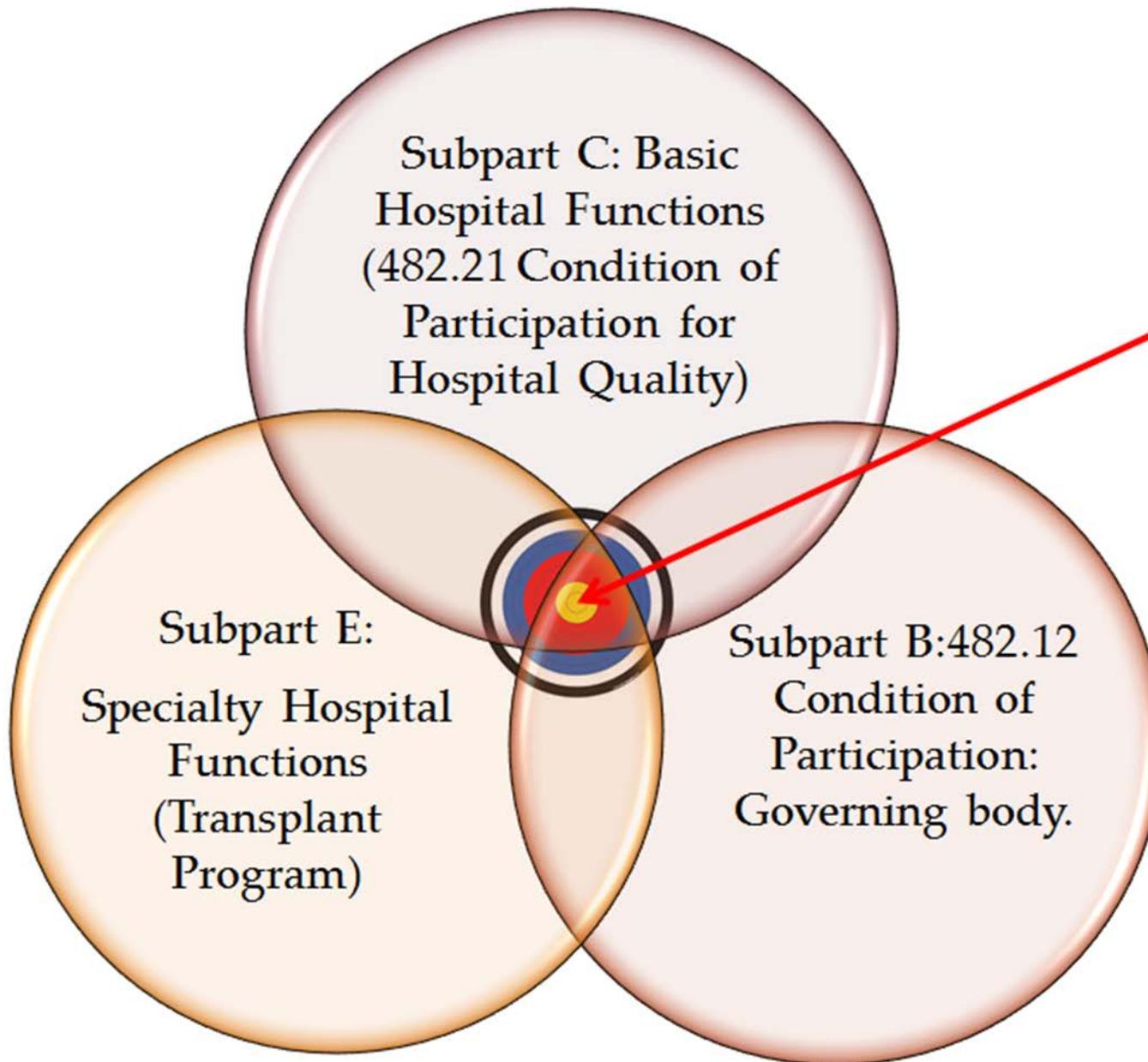
§482.21(e) STANDARD: **EXECUTIVE RESPONSIBILITIES** cont.

§482.21(e)(3) - That **clear expectations for safety are established.**

§482.21(e)(4) - **That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance** and that adequate resources are allocated for **reducing risk to patients.**

§482.21(e)(5) - **That the determination of the number of distinct improvement projects is conducted annually.**

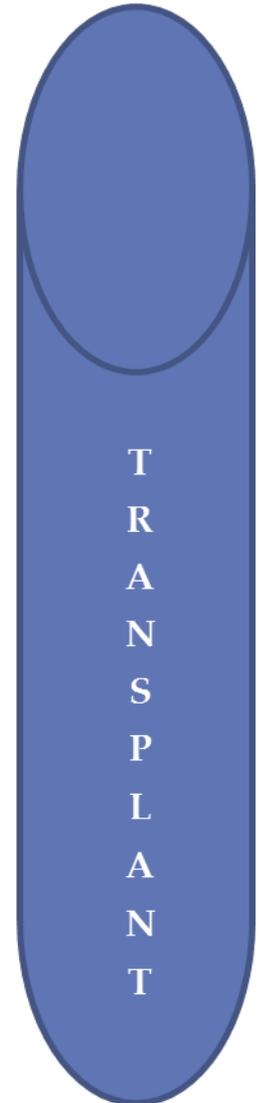
CONCLUSION



482.96
Transplant
QAPI
Condition of
Participation

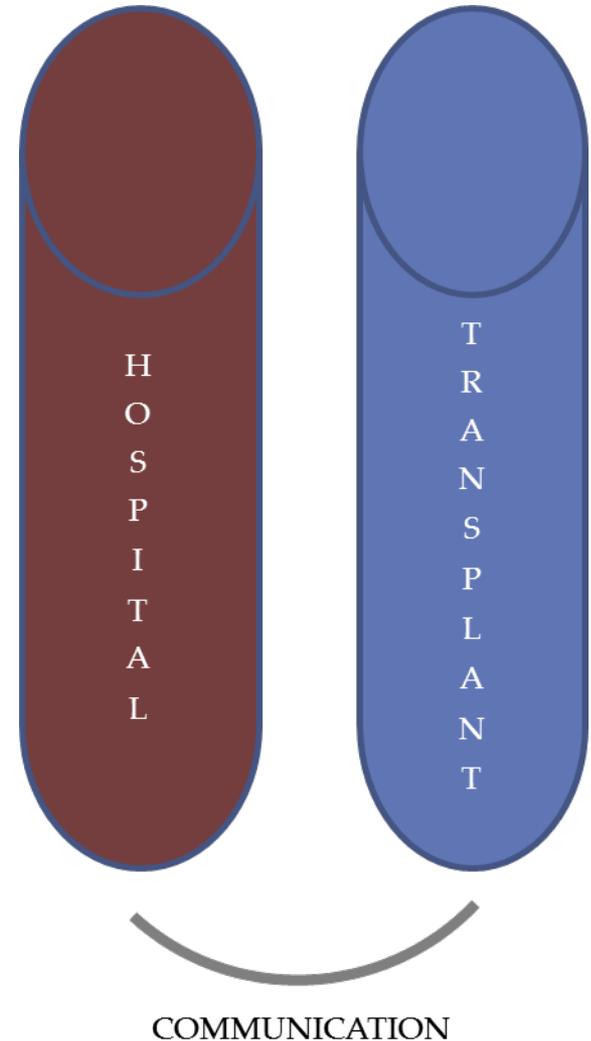
DISTINCT FUNCTIONS SUMMARY

- Transplant Programs have specific Conditions of Participation that **MUST** be adhered to in order to be eligible to participate in Medicare programs.
- Transplant Programs **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.
- Transplant Programs **MUST** establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.



INTEGRATION SUMMARY

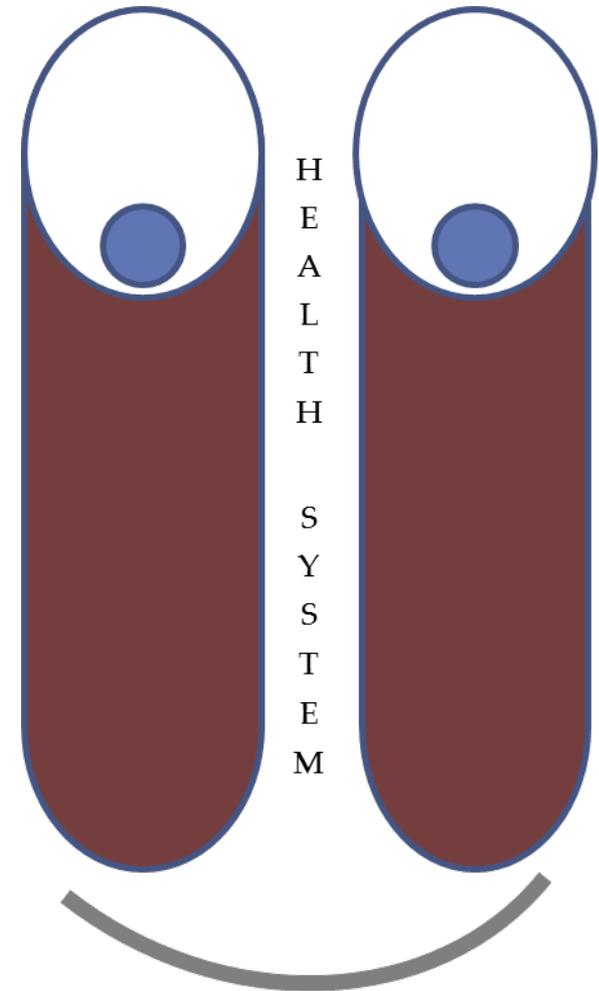
- Transplant Programs (Organ Specific Programs) are service lines and departments within the hospital which subject them to the Hospital Conditions of Participation (CoP's).
- The Hospital CoP's signify the need for and level of integration that must exist between Transplant Programs and Hospital activities.
- All QAPI programs must reflect the complexity of services offered within an organization.
- All QAPI programs must be data-driven with the ultimate goal of improving patient outcomes and reducing medical errors.



INTEGRATED QAPI ACTIVITIES

Effectively integrated QAPI activities include:

- A bi-directional communication system.
- Interaction and Involvement from hospital leadership over the transplant QAPI program, measures and resource allocation.
- Transplant Program participates in Hospital QAPI activities.
- Hospital participates in Transplant QAPI activities.
- Frequent evaluation of transplant services and reporting of these evaluations and actions taken to Hospital Committees.



TAKE AWAYS

- Transplant Programs have requirements to be integrated with the overall Hospital QAPI program as well as conduct distinct QAPI activities to meet the Condition of Participation found at 482.96.
- Transplant Programs are under the authority and control of the Hospital's Governing Body; who must ensure that QAPI programs are developed, implemented and resourced appropriately.
- Effective QAPI programs are continuously striving to improve processes that may have a positive impact on patient outcomes, involve all staff and develop effective lines of communication throughout the organization.
- Transplant Programs and Hospitals are charged with reducing medical errors (adverse events) in all phases of a patient's care.

RESOURCES

Agency for Healthcare Research and Quality (AHRQ)

<http://www.ahrq.gov/>

Patient Safety Network – (PSNet) <http://psnet.ahrq.gov>

Institute for Healthcare Improvement (IHI) <http://www.ihl.org/>

National Patient Safety Foundation <http://www.npsf.org/>

National Quality Forum (NQF) <http://www.qualityforum.org/>

World Health Organization (WHO) <http://www.who.int/>

American Society for Quality (ASQ) <http://asq.org>

Q&A

You have

Questions

We have

Answers

Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives.

William A Foster