Quality Assessment and Performance Improvement (QAPI) Programs

A Resource Guide for Transplant Surveyors

Prepared for:
Survey and Certification Group
Center for Medicaid, CHIP and Survey & Certification
Centers for Medicare & Medicaid Services

Prepared by:
Catapult Consultants, LLC
2300 Clarendon Blvd., Suite 1005
Arlington, VA 22201
Phone: 703-849-0960
Fax: 703-852-2843
info@catapultconsultants.com
www.catapultconsultants.com

September 8, 2010

Quality Assessment and Performance Improvement (QAPI) Programs

A Resource Guide for Transplant Surveyors

TABLE OF CONTENTS

INTRODUCTION

Two additional tools have been developed to assist transplant surveyors in conducting transplant program surveys. Transplant surveyors already have an Organ Transplant Surveyor Workbook and a computer – based resource. The two new tools, *Quality Assessment and Performance Improvement (QAPI) Programs, A Resource Guide for Transplant Surveyors* and the "Surveyor Worksheet- Organ Transplant Program, Quality Assessment and Performance Improvement," will be incorporated into both the Organ Transplant Surveyor Workbook and computer-based resource online in the near future.
The *Quality Assessment and Performance Improvement (QAPI) Programs, A Resource Guide for Transplant Surveyors* was developed for the Centers for Medicare & Medicaid Services (CMS) to assist transplant surveyors with the completion of the "Surveyor Worksheet- Organ Transplant Program, Quality Assessment and Performance Improvement," also known as the QAPI Worksheet. The QAPI Worksheet is used by transplant surveyors to determine transplant programs' compliance with the Quality Assessment and Performance Improvement (QAPI) regulations.. The QAPI Worksheet was developed for three primary reasons:

1. The national need to ensure transplant surveyors understand the QAPI regulations and survey guidelines;
2. Further describe CMS expectations for a comprehensive transplant QAPI program; and
3. Provide surveyors with a tool that provides/promotes a consistent application of the QAPI regulation.

Use of the QAPI Worksheet

It is important that all surveyors complete the QAPI Worksheet. The information entered on the QAPI Worksheet will be used to further refine and develop not only the QAPI Worksheet and Resource Guide, but any other materials that might prove useful for transplant surveyors. CMS will also track the information so that at the end of September 2011 CMS will know in which areas the programs excel and which areas may need additional work.

It is CMS's expectation that all transplant surveyors applying the QAPI regulations will completely fill out and use the QAPI Worksheet. For the year October 2010 through September 2011, once the transplant surveyors have completed the 2567 for the transplant survey in ASPEN, the transplant surveyors will need to send the completed QAPI Worksheet to:

transplantproject@catapultconsultants.com

or

Catapult Consultants, LLC
2300 Clarendon Blvd., Suite 1005
Arlington, VA 22201,
Attention: CMS Transplant Project

A. COMPONENTS OF A QAPI PROGRAM IN TRANSPLANTATION

It is important for surveyors to have a basic understanding and conceptualization of a provider's purpose and practices. This is particularly true for transplant surveyors especially in the areas of Quality Assessment and Performance Improvement. This Resource Guide is organized to familiarize the transplant surveyor with basic concepts of QAPI and then walk through the transplant QAPI worksheet which will review and explain in more detail the specific regulatory expectations of a Transplant QAPI.

The Structure of a Transplant QAPI Program

Transplant QAPI programs oversee the overall quality management of the transplant program, which is typically comprised of two main components:

1. Quality Assessment
2. Performance Improvement

The structure of a transplant QAPI program is generally described in detail in the program's QAPI/ Quality Plan, which may also be known as the program description document or the policies and procedures. The QAPI Plan should be reviewed by transplant program QAPI personnel or the QAPI Committee/ Council on a regular basis. Topics commonly found in a QAPI Plan include:

- General QAPI program description and overview,
- Organization structure to include an Organization Chart and reporting lines,
- Goals, objectives and purpose of the QAPI program,
- QAPI Committee/ Council description and structure,
- Roles and responsibilities of the QAPI personnel,
- Reporting mechanisms,
- Process for activities relating to adverse events,
- List of indicators for monitoring Quality Assessment and Performance Improvement activities, and
- Methods for Quality Assessment and Performance Improvement activities and for monitoring compliance with regulations/ standards.

A transplant QAPI program usually contains a QAPI committee/ council. The transplant QAPI policies and procedures or the QAPI Plan should describe the QAPI committee/ council's:

- Regular members/ meeting attendees,
- Responsibilities,
- Quality Assessment and Performance Improvement procedures (including how improvements are tracked),
- Decision process concerning data collection and tracking,
- Decision process regarding indicators for monitoring Quality Assessment and Performance Improvement activities, and
- Frequency of the transplant QAPI meetings.

QAPI for transplant programs includes two processes, Quality Assessment and Performance Improvement; which incorporate the development of objective measures relating to transplant processes and patient outcomes; identifying acceptable benchmarks to measure quality; identifying gaps in performance with needed improvements/changes; providing assurance changes are effective, and the review of adverse events.

Transplantation includes three phases of transplantation (pre-transplant, such as evaluation, patient selection and waiting list management; transplant, such as surgical protocols, immunosuppression, cold ischemic times; and post-transplant, such as medication effectiveness, support services and health maintenance) and can include all three phases for both the transplant recipient and the living donor. This Resource Guide provides the transplant surveyor with different element of Quality Assessment and Performance Improvement as well as how they relate to the three phases of transplantation.

QAPI Methods

Quality Assessment and Performance Improvement methods include the identification and selection of data for analysis with the intent to create new processes or improve existing processes in order to improve the overall quality of the program procedures. The QAPI method used by the transplant program is often documented in the program's QAPI Plan, policies or procedures and may influence how the program performs its Quality Assessment and Performance Improvement activities. Many different QAPI methods are utilized by transplant QAPI programs.

Surveyors need to be aware that:

- Transplant QAPI programs may have adapted and re-named a more well-known method for their own use,
- There are often "hybrid" methods developed and tailored to fit transplant QAPI programs, and
- Often transplant QAPI programs confuse "Quality Assessment" and "Performance Improvement" methods and tools.

Examples of some QAPI methods are included in the table below so that surveyors will understand the possible QAPI methods that may be used. The inclusion of a method in this Resource Guide does not constitute a recommendation or endorsement that a program is expected to use a particular method. A transplant program may use any method that fulfills the requirements of the regulation. The QAPI regulations do not specify which particular method is to be used by a transplant program, but rather expects whatever method is chosen meets the needs of the transplant program and the intent of the QAPI regulations. Regardless of the method chosen, follow-up monitoring needs to also be documented to ensure that the process is operating as intended.

Some commonalities that exist among the more frequently used QAPI methods are usually seen in the method's discussion and/ or use of:

- Goals/ criteria, standards/measures,
- Data analysis/evaluation,
- Repetition of continuous cycle, and
- Roles/ responsibilities/interactions.

The following table includes some of the more frequently used QAPI methods. Note that the table does not include all available QAPI methods, but does include some of the more frequently used QAPI methods.

Table 1 – QAPI Methods

Acronym	Name of Method	Notes
PDSA	Plan-Do-Study-Act	• Continuous quality improvement method • Also known as Deming Cycle, Shewhart Cycle, Deming Wheel or Plan-Do-Check-Act
FADE	Focus, Analyze, Develop and Execute	• Continuous quality improvement method • Similar to PDSA
Six Sigma	Six Sigma	• Focuses on improving quality by reducing the number of errors/ incidents • Includes two methodologies, DMAIC and DMADV • Inspired by PDSA
DMAIC	Define Measure Analyze Improve Control	• Six Sigma method used to improve an existing process
DMADV	Define Measure Analyze Design Verify	• Six Sigma method used to create a new process, also known as DFSS
DFSS	Design For Six Sigma	• Six Sigma method used to create a new process, also known as DMADV
FMEA	Failure Mode and Effects Analysis	• Method of analysis of failures and the consequences within a system • Related method is HFMEA (Healthcare Failure Mode and Effects Analysis) which combines FMEA and HACCP (Hazard Analysis and Critical Control Points), a food safety method
TQM	Total Quality Management	• Focuses on improving quality by ensuring conformance with requirements
WIE	Wills-Ideas-Execution	• Framework for system-level improvement in healthcare
WSM	Whole System Measures	• System used to measure overall quality of a health system and to align improvement to work across a hospital or large healthcare system

QAPI Tools/ Instruments

To assist with data collection and analysis, some examples of QAPI tools are included in the table below. While this document describes tools used for capturing and documenting data, the examples presented do not replace or represent official QAPI regulations. The inclusion of a tool/ instrument in this Resource Guide does not constitute a recommendation or endorsement that a program is expected to use a particular tool/ instrument. A transplant program may use any tools/ instruments it wishes. . The QAPI regulations do not specify which particular tools/ instruments that a transplant program must use, but rather expects whatever tool/ instrument is

chosen meets the needs of the transplant program and the intent of the QAPI regulations. The following table does not include all available QAPI tools/ instruments, but does include some of the more frequently used tools/ instruments.

Table 2 - QAPI Tools / Instruments[1]

Name of Tool	Description	Purpose	Method
Flow Chart	Symbols to show steps in a process	Visual "feel" for the complexity involved	Layout process steps using standardized symbols
Check sheet	Form for entering data under predetermined categories	To collect data	Design form for clarity and ease of data collection
Checklist	List of items that are checked off upon completion	To record progress	Simple "To Do List" for checking off completion of tasks identified
Pareto Diagram	A bar chart with percent arranged so bars touch, bars are in descending order from the left	Helps identify what category is most significant	Frequencies are on the left and cumulative percent on the right
Histogram	Bar chart showing data set divided into classes (bars) of equal width, height of bar shows quantity	Shows patterns in dispersion of continuous data or large discrete data sets	Draw bars touching to show pattern as a whole not the individual classes
Fishbone Diagram (Cause-and-Effect Diagram)	Shows cause and effect relationships	Aids in identifying root cause	"Fish's head" (main activity) on the right, "ribs" contain major process steps
Scatter Diagram	Chart where data for "x" and "y" variables are entered as dots to see if they form a pattern	Shows if a casual relationship exists between variables	Suspected cause is on "x" axis and the effect on the "y" axis
Run Chart (Trend Graph or Line Graph)	A chart with "x" and "y" axes, data values are shown as points connected by lines	Shows direction (trend) and change over time	"X" axis shows time and "y" axis shows the measurement scale
Control Chart	A line graph with an average line and control limit lines	Monitors an ongoing process and detects changes in output	Separate types of charts for continuous and discrete data

[1] Peter Mears, Quality Improvement Tools & Techniques, (McGraw-Hill, 1995) 13 – 17.

Quality Assessment

Definition

Quality Assessment is one of the two main components of the overall quality management of the transplant program. Quality Assessment and Performance Improvement are separate processes that have activities which are related to and influence the activities of the other process.

Quality Assessment is defined as a "process for ensuring compliance with specifications, requirements or standards and identifying indicators for performance monitoring and compliance with standards."[2]

Objective Measures

Integral to Quality Assessment are the development and use of objective measures. Objective measures are specific attributes that are the basis for assessing quality in a particular area, have to be measureable/ observable and constrained by a timeframe. Both Quality Assessment and Performance Improvement need objective measures. A transplant QAPI program must use objective measures to evaluate the transplant center's activities and outcomes.

In building an understanding of a successful QAPI, the surveyor needs to take note of the difference between a "transplant activity/ process" and a "patient outcome" as distinguishing these two elements is essential when evaluating the scope of the program's objective measures. There are numerous transplant processes and patient outcomes within each of the three phases of transplantation (pre-transplant, transplant and post-transplant) for both the recipient and the donor when surveying a Transplant QAPI Program.

- **Transplant Activity/ Process –** Defined as a series of actions (e.g.. informed consent by transplant patient) or functions (e.g. cold ischemic time of organ) during the delivery of patient care within the program's system that result in an organ transplant.

- **Patient Outcome –** Defined as either a measurement (e.g. serum creatinine) or an event (e.g. death or need for dialysis) that is the result of the transplant process and directly affects the length or quality of a person's life. An outcome is potentially modifiable by a defined intervention

The regulation requires that the QAPI program be comprehensive. The transplant program must have objective measures for transplant processes/activities and outcomes for each phase of transplantation (pre-transplant, transplant and post-transplant) relating to transplant recipients and also for living donors. Table 3 in this QAPI Resource Guide contains several examples for relating objective measures to transplant processes and patient outcomes for each of the three phases of transplantation (pre-transplant, transplant and post-transplant) for both the recipient and the donor.

[2] Elizabeth R. Ransom, et al., The Healthcare Quality Book Vision, Strategy, and Tools Second Edition (Chicago, IL: Health Administration Press and Washington, DC: AUPHA Press, 2008) 331.

Table 3 - Examples of Objective Measures in Each Phase of Transplantation for Recipient and Living Donors

*Note: To assist the surveyor in organizing all the Transplant QAPI program materials and information, the QAPI Worksheet contains charts and checklists. Table 3 is to be used to document the Quality Assessment measures being used for both the transplant recipient and living donor in the three phases of transplantation: pre-transplant, transplant, and post-transplant. In this Resource Guide, examples of what the surveyor **may** find are given, but under **no** circumstances is it the expectation that these are the **only** possibilities. The transplant program does not need to have <u>all</u> the measures listed – these are just examples of measures for each category.*

Transplant Recipient	
<u>Transplant Activities/ Process</u>	**<u>Patient Outcomes</u>**
Pre-transplant ABO Prior to listing Referral to Waitlist time Updating UNET info Donor Acceptance Rates Adherence to Policies/ Procedures (P&P) (e.g., Informed Consent, Education, Re-evaluation)	**Pre-transplant** Mortality on the Waiting List Health Maintenance while on the waiting list
Transplant Cold ischemic time Surgical protocols Involvement by multidisciplinary team	**Transplant** Unplanned return to the OR Transplant rate vs. Expected Infection rates while hospitalized Stay in ICU or Step-down Length of Stay Dialysis within 7 days
Post-Transplant Documentation of follow-up visits Adherence to P&P (e.g., discharge planning) Immunosuppression	**Post-Transplant** Infection Rates survival Complications Readmission within 90 days Acute rejection rates 30-day patient/graft Patient satisfaction Emergency Rm visits
Living Donor	
<u>Transplant Activities/ Process</u>	**<u>Patient Outcomes</u>**
Pre-donation Nutritional Screening in Medical Record (MR) of potential donor candidates Medical/psychosocial evaluation conducted Adherence to Policies/ Procedures (P&P) (e.g., Informed Consent, Education)	**Pre-donation** Percentage of donors who met weight loss recommendations prior to donation
Donation Surgical protocols Involvement by multidisciplinary team Documentation by Living Donor Advocate	**Donation** Conversion from Laparoscopic to Open Nephrectomy Length of Stay Stay in ICU or Step Down
Post-donation Documentation of follow-up visits Adherence to P&P (e.g., discharge planning)	**Post-Transplant** Infection Rates Patient satisfaction Complications Readmission within 90 days

The transplant program is expected to clearly define the objectives for both transplant process and patient outcome measures tracked and monitored during the QAPI process. Clear and precise definitions help ensure consistency in the way the transplant program collects the data to evaluate the measure, as well as consistency in the analysis over time. The transplant program's measures are typically included on the program's Dashboard, the QAPI Plan and/ or in the transplant QAPI policies and procedures. While all measures need clear and precise definitions, examples of measures that are broad and could have different interpretations if clear and precise definitions are not provided include:

- Adherence to Policies and Procedures (which policies and procedures are included),
- Complication Rates (what types of complications are included),
- Environmental Factors,
- Infection Rates, and
- National Patient Safety Goals.

Quality Assessment Activities

A transplant program's Quality Assessment program includes all activities that ensure compliance with regulations and requirements, such as identifying outcomes, establishing benchmarks and the monitoring performance. Quality Assessment often involves the coordinated efforts of staff with multiple skills and from different specialties/ disciplines working together to improve transplant quality of care. Personnel involved in Quality Assessment may identify the processes and outcomes integral to the program, develop objectives, select indicators and benchmarks for the processes and outcomes, and analyze the program results on a regular basis. Quality Assessment activities may include both regularly scheduled analyses of established outcomes and data collection and completion of specific projects.

Quality Assessment, and the related methods and tools, may also be referred to as:

- Performance Measurement/ Assessment/ Assurance,
- Program Measurement/ Assessment/ Assurance, or
- Quality Measurement/ Assurance.

Monitoring of the transplant program's performance is important for the transplant program to ensure successful outcomes for their patients. Without a coordinated effort by all transplant staff, this goal may fall short. Well thought out Quality Assessment activities combined with careful selection of performance improvement activities will lead to improved transplant services.

Surveyors, through observations and interviews, are expected to ensure that different levels of staff are involved with the Transplant QAPI program; that the QAPI Program had adequate dedicated staff to do the job well and accurately, and that communication of QAPI objectives, benchmarks and discoveries are shared with Transplant staff.

Benchmarks

Benchmarks are quantitative points of reference by which a program's objective measures can be assessed, monitored and compared. Benchmarks may also be known as standards or targets. Each objective measure must have an associated benchmark for determining acceptability of performance. Programs need to regularly assess the benchmark or level of acceptable performance on each objective measure.

Possible benchmark sources the transplant QAPI program may use to review, compare, monitor and evaluate the program activities include:

- Best practices of different disciplines/ professions, which may include practice guidelines, protocols, care maps, appropriations criteria, credentialing requirements and checklists;
- Research;
- Compliance with regulations;
- National benchmarks/ industry standards;
- The program's own findings, data and/ or independent discovery;
- Various decision aids, such as checklists, reminders, alerts and prompts;
- Outcomes of the analysis of adverse events/ sentinel events/ accident reports;
- Clinical variances from standards of care;
- Funding sources;
- Response to complaints;
- Results of complaint investigations; and
- Participation in national transplant registries/databases.

Table 4 gives an example of benchmarks related to Quality Assessment objectives for both process and outcome.

Table 4 - Relating Benchmarks with Objective Measures

Type of Measure	Focus of Assessment	Example of Objective Measure	Example of Benchmark
Process	Treatment of patients hospitalized for heart attack	Percentage of post-heart attack patients prescribed beta-blockers upon discharge	At least 96% of heart attack patients receive a beta-blocker prescription upon discharge
Patient Outcome	Blood pressure of patients with diabetes	Percentage of patients with diabetes whose blood pressure is at or below 130/85	At least 50% of patients with diabetes have blood pressure at or below 130/85

System for Collection/ Analysis

For benchmarks to be useful, a documented data-driven method to collect the results of the program's designated measures is required. The transplant surveyor must identify data collection processes, record review (manual or computer), observations, staff reporting, protocol adherence, incident analysis, and random spot checks and any other techniques that may be used by a QAPI program. As with data collection, the surveyor would expect to find a description of how the collected data will be analyzed, compared to previous data, aggregated, averaged or graphed, and who will analyze the data. After the data has been collected and analyzed it needs to be reviewed and discussed by the QAPI committee/ council who should decide if the results of the analyses, as well as any identified trends are significant and warrant further assessment and/ or the development of performance improvement activities. The transplant program's system for collection and analysis for objectives may be documented in the QAPI Plan or in the policies and procedures.

Ensuring Measures are Valid

As a final note, the transplant program must ensure that the actual monitoring and data collection activities are accurate and timely. Some examples of evaluation and monitoring activities include sampling, parallel collection, spot checks (e.g. reviewing one record and checking if results are repeated), and data queries.

Performance Improvement

Definition

Performance Improvement is the second component of the overall quality management of the transplant program. Quality Assessment and Performance Improvement are separate processes that may have unique activities.

Performance Improvement is defined broadly as "an organized, structured process used to identify parts of the transplant program that need addressing due to failure to meet Quality Assessment expectations and/ or results of adverse events. Often, transplant program staff may identify processes, policies, protocols that need changes or refinement analyzing, or at the very least further study".

Performance Improvement Activities

Performance Improvement activities includes all activities related to the achievement of improvement within the transplant program. Performance Improvement projects that have been implemented within the transplant program need to be effective and sustainable.

Performance Improvement, and the related methods and tools, may be also be referred to as:

- Quality Improvement,
- Process Improvement, or
- Program Improvement.

Performance Improvement activities include:

1. A review transplant performance compared to established benchmarks (identified during Quality Assessment activities) to determine areas where changes may be needed to improve operations or services, and
2. Identification and prioritization of special activities/ studies that will lead to changes to improve services.

The transplant program is expected to address in their policies and procedures how the QAPI committee/ council/ staff determine the topics/ areas of concern for performance improvement. Some of the most common techniques used by QAPI programs to determine the topics/ areas of concern for performance improvement are:

- Prioritizing results from the program's Quality Assessment activities;
- Brainstorming;,
- Determining the impact on operations and the bottom line;

- Responding to complaints;
- Use of nationally established priorities; and
- Leveraging the resources available.

The policies and procedures for Performance Improvement need to also detail:

- The process used to analyze the selected issue;
- How possible solutions are generated;
- How recommendations for changes are determined; and
- How the impact of the changes will be monitored for durability.

The CMS transplant regulations do not dictate how the four above-mentioned activities will be accomplished, but rather expect the program to develop a method that best works for themselves.

Consider the following questions when conducting a review of a transplant QAPI program's Performance Improvement activities:

1. How does the QAPI program assure that once a change is implemented that the program maintains its effectiveness of the change?
2. Does the QAPI program have a way to double check the accuracy of the data/ information collected as part of their PI activities/ projects?
3. If staff training is the designated corrective action or is necessary for performance improvement, how does the QAPI program assure that the training is effective?
4. How is staff throughout the transplant program notified of changes/ modifications?

A well-established framework for ensuring compliance will not, in itself, guarantee success. A QAPI program's success will also depend on strong execution.

Adverse Events

The transplant program must have a clear description of what constitutes an adverse event during any of the three phases of transplantation (pre-transplant, transplant and post-transplant), and must have a process to identify, report, analyze and prevent adverse events.

The transplant regulations define an adverse event as: "an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, 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."[3]

The transplant program may share or have the same definition of adverse event as the hospital. Regardless, it must be **at least** as stringent as CMS's definition, which defines an adverse event as "an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, 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." It is acceptable for a transplant program to use the same adverse event processes as the hospital as long as the surveyor is able to verify that all adverse events related to transplant services follow these processes QAPI

[3] Department of Health and Human Services, Centers for Medicare & Medicaid Services 42 CFR Part 482.70 Definitions

policies and procedures must establish and manage through consistent standards of documentation and reporting, a mechanism to react to remediation requirements and provide a communication channel for the transplant staff. Additionally, the QAPI policies and procedures must include a description of how adverse events related to transplant services are communicated to the transplant QAPI staff.

Root Cause Analysis

A Root Cause Analysis (RCA) is one of the most universally used set of steps during the investigation of an adverse event and is often used to identify performance issues, related causes and needed improvements. RCA's strength is that when done correctly, it leads to the identification of the primary cause of the problem and related secondary causes.

The CMS regulation states that 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. The policies must address at a minimum, the process for the identification, reporting, analysis and prevention of adverse events. (X102)

The transplant program may be part of the hospital's adverse event analysis team/ committee/ council, but it is expected that any adverse event impacting transplant services is also reviewed and becomes part of the transplant QAPI program. The below chart is provided as a summary of the purpose of a RCA and as a reference point for transplant program surveyors.

Table 5 - Purpose of a Root Cause Analysis

Questions	Actions
What happened?	• Description of events/ activities/ actions that caused the adverse event
Why did it happen?	• Identify contributing factors to the adverse event
What follow-up and/or performance improvement projects need to done?	• Develop a plan to prevent repeat incidences or after the analysis determine that no opportunities for improvement exist

A Root Cause Analysis may be performed by:

- Transplant QAPI personnel that report directly to hospital QAPI staff,
- The hospital's QAPI personnel,
- The hospital and transplant's QAPI personnel working together,
- The hospital's or transplant program's Human Resources (HR) personnel, or
- Other personnel specifically designated to handle investigation of adverse events.

A RCA performed by Transplant QAPI personnel that report to the transplant program could constitute a potential conflict of interest as the personnel cannot be considered an independent party. Different techniques can be used for analyzing adverse events and for tracking and incorporating changes in the program's policies and procedures dealing with transplant adverse events. Examples of tools to assist in the analysis of an adverse event are displayed in the table below. This table does not include all available tools used in the analysis of an adverse event, but does list some of the more commonly used tools. It is important to note that CMS does not subscribe or advocate for a particular type of tool, provided that there is a thorough analysis.

Table 6 - Tools to Assist in Analysis of an Adverse Event

Name	Notes
Cause and Effect Charting	• Simple tool to identify many possible causes for an effect or a problem
Fishbone Diagram	• Used to identify many possible causes for an effect or a problem • Also known as Ishikawa or Cause and Effect Diagram
5 Whys	• Question-asking tool used to explore cause and effect and discover a root cause of a problem

Example 1 - Fishbone Diagram[4]

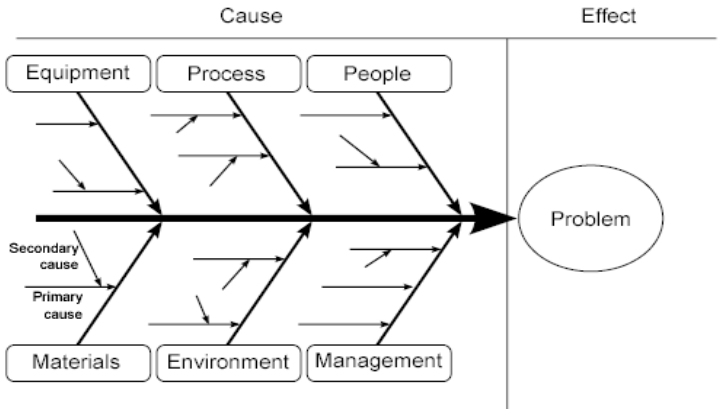
Use the fishbone diagram to systematically sort all of the contributing causes for problems being analyzed. Typical cause categories include: people, equipment, methods/process, materials, policies, environment & measurement.

Step 1. Define the problem in a brief statement at the 'head' of the fish.

Step 2. It is often useful to organize the possible causes into major cause categories and write at the end of each 'large bone' of the fish. A commonly used format it to categorize causes as equipment, process, people, materials, environment or management causes.

Step 3. Brainstorm all possible causes within the major cause categories on each 'small bone' of the fish.

Step 4. Once all the causes have been identified brainstorm solutions for each of possible causes. If there are a significant number of causes identified, prioritize the causes then brainstorm solutions.



[4] http://www.projectsmart.co.uk/pdf/cause-and-effect-diagrams.pdf

Example 2 - Root cause analysis utilizing '5 Whys' Tool[5]

The '5 Whys' tool lends itself to a more narrative version when examining adverse events. One of the benefits derived from using this tool is the ability to drill down to the problem's root cause by peeling away peripheral data and focusing the reasons the adverse event occurred. However, once defined the steps leading to the adverse event can be scrutinized.

How to Complete the '5 Whys'

1. Write down the specific problem. Writing the issue helps you formalize the problem and describe it completely.
2. Ask Why the problem happens and write the answer down below the problem.
3. If the answer you just provided doesn't identify the root cause of the problem that you wrote down in step 1, ask Why again and write that answer down.
4. Look back to step 3 until the team is in agreement that the problem's root cause is identified. Again, this may take fewer or more times than five Whys.

Assuring Effectiveness of Changes

The Root Cause Analysis (or any other form of analysis) generally results in specific recommendations/ action steps to correct or prevent repeat occurrences of the adverse event. If there are no specific recommendations/ action steps a sound rationale for not making any changes to the transplant program policies, procedures, and protocols, must be documented. A surveyor may find that specific recommendations/ action steps are recorded by the transplant program in any of the following:

- Adverse Events Log,
- Performance Improvement Log,
- Completed Root Cause Analysis Form (or any other type of analysis form),
- Quality/ Safety/ QAPI Meeting Minutes, or
- Dashboard.

Identifying needed changes does not assure that changes have been made and are effective. The transplant program must have procedures in place to assure that change is implemented and communicated to all applicable staff. Once changes are implemented, they need to be measured in terms of its continued effectiveness. Quality Assessment and Performance Improvement is a continuous process. Once QAPI personnel know that change has been implemented they also need to assess whether the change has resulted in a performance improvement. The transplant program needs to continuously monitor changes and additional improvements should be considered as needed.

[5] *www.therenalnetwork.org/qi/qi_QAPI_home.php*

B. COMPLETING THE QAPI WORKSHEET

The "Surveyor Worksheet- Organ Transplant Program, Quality Assessment and Performance Improvement," also known as the QAPI Worksheet, has been developed to assist transplant surveyors when performing a review of transplant QAPI programs. The QAPI Worksheet is used by transplant surveyors to determine transplant programs' compliance to the QAPI regulations, tags and survey guidelines.

QAPI Worksheet General Program Information

The surveyor needs to ensure that the completed QAPI Worksheet includes:

- The full names of the hospital and transplant center being surveyed, and
- All of the transplant programs covered by the QAPI program.

If there are more than one transplant QAPI program at the transplant program a QAPI Worksheet must be completed for each distinct transplant QAPI program. A distinct transplant QAPI program will have separate QAPI policies, procedures and plan.

During the entrance conference, surveyors must request a copy of the transplant QAPI policies, procedures and plan including those describing:

- The structure of transplant QAPI program,
- How the transplant QAPI program operates,
- The handling of adverse events, and
- The process for using objective measures and performance improvement activities,
- Log of adverse events.

QAPI Worksheet Part 1: Policies and Procedures for QAPI Program

Regulation: 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. (X099)

The surveyor may utilize a variety of collection techniques in order to determine whether the transplant center has a written, comprehensive, data-driven QAPI program that has been implemented and maintained. To make this determination the surveyor must request documentation and ask questions during the entrance conference, review the program's policies and procedures, review documented evidence of QAPI meetings, interview staff and patients/ living donors and observe operations at the transplant program.

Policies and Procedures

When reviewing transplant QAPI policies and procedures surveyors must determine if, as a whole, they describe the big picture as well as day-to-day operations as the surveyor has observed or learned. The transplant QAPI policies and procedures are expected to lay out for the program's transplant personnel exactly how the transplant QAPI program works.

During the QAPI record review the surveyor must confirm that:

1. The various points contained in the QAPI Worksheet are reflected in the transplant program's QAPI policies and procedures, and
2. The policies and procedures match what the surveyor has learned first-hand through observations and interviews.

While comparing the various points in the QAPI Worksheet to the transplant program's QAPI policies and procedures, the surveyor may find:

1. The members of the transplant QAPI committee/ council,
2. The expectations of the transplant QAPI committee/ council,
3. Support personnel that are designated as QAPI personnel,
4. The responsibilities of the transplant QAPI personnel,
5. Whether the transplant program's QAPI meets the different components detailed in Part 4 of the Worksheet for performance improvement activities, and
6. Whether there are definitions for different parts of the QAPI program defined to be at least as stringent as CMS's definitions.

When confirming that the transplant program's policies and procedures match what the surveyor has learned first-hand through observations and interviews, the surveyor needs to confirm that:

- Patients are aware of the informed consent process, that they know exactly what they have signed and for what they gave permission. Patients have been provided with the program's most recent transplant outcomes' data, expressed patient needs are being addressed by the program and patients know who and how to contact help when needed.
- Standard level deficiencies cited in the last survey have been researched and discussed by the transplant program's QAPI personnel and necessary changes have been made to the policies, procedures, protocols, other written materials and staff and/ or patient behavior.

QAPI Meetings

Seek evidence of:

- Meeting agendas, minutes and summaries from transplant QAPI meetings which specifically reflect the points discussed, results of the discussion, next steps with possible due dates and responsible person identified, or
- Reports and/ or presentations created by transplant QAPI staff, which may summarize data/ statistics and show compliance with pre-set benchmarks/ targets/ goals.

Peer-protected Information

Certain QAPI documentation may be designated as peer-protected information, and as such is kept confidential from entities outside the hospital and/ or transplant program. These peer protections do not apply to surveys of the provider's compliance or the Conditions of Participation

Examples of peer-protected information may include the discussions about and work products associated with:

- Root Cause Analyses,
- Peer reviews, and
- Adverse event investigations

A Comprehensive QAPI Program

CMS has defined a "comprehensive" transplant QAPI program to mean the inclusion of the three phases of transplantation (pre-transplant, such as evaluation, patient selection and waiting list management; transplant, such as surgical protocols, immunosuppression, cold ischemic times; and post-transplant, such as medication effectiveness, support services and health maintenance) for both the recipient and the donor. It is expected that the transplant QAPI program will have objective measures (see page 8 for a discussion of objective measures) to evaluate performance with respect to transplant activities/ processes and outcomes for each phase of transplantation for both the recipient and the donor.

When using the QAPI Worksheet, the surveyor will review thoroughly the transplant QAPI program's objective measures for transplant activities/processes and outcomes for each phase of transplantation (pre-transplant, transplant and post-transplant) relating to transplant recipients and also for living donors. ***For each organ transplant program*** that is surveyed the surveyor needs to document at least six objective measures, for transplant recipients (one transplant activity/ process measure and one outcome measure for each phase of transplantation, pre-transplant, transplant and post-transplant) and six objective measures for living donors (one transplant activity/ process measure and one outcome measure for each phase of transplantation, pre-transplant, transplant and post-transplant).

Take note of the difference between a "transplant process" and a "patient outcome" when documenting the program's objective measures. There are several transplant processes and patient outcomes within each of the three phases of transplantation (pre-transplant, transplant and post-transplant) for both the recipient and the donor.

- **Transplant Process –** Defined as a series of actions or functions during the delivery of patient care within the program's system that result in an organ transplant.

- **Patient Outcome –** Defined as either a measurement (i.e. serum creatinine) or an event (i.e. death or need for dialysis) that is the result of the transplant process and directly affects the length or quality of a person's life. An outcome is potentially modifiable by a defined intervention. Outcome measures capture whether or not a benchmark/ target was achieved.

Linking with the Hospital's QAPI Program

As part of the transplant QAPI program structure there must be a clear, documented link between the hospital's QAPI program and the transplant QAPI program which may be documented in the transplant program's policies and procedures, organization chart or QAPI Plan. To confirm this link, review the evidence that describes:

- How information flows to and from the hospital and transplant QAPI programs,
- How often the hospital and transplant QAPI programs communicate,

- What the reporting line is from the transplant QAPI program to the hospital QAPI program, and
- Whether a member of the hospital QAPI program with the authority/ power to make/ dictate change is part of the transplant QAPI committee/ council.

QAPI Worksheet Part 2: Evaluation and Monitoring the Transplant Program by the QAPI

Regulation: The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. (X100)

The program's measures used to evaluate performance must:

1. Be objective,
2. Address activities/ processes and outcomes throughout the three phases of transplant relating to the ***recipient*** (pre-transplant, transplant and post-transplant), and
3. Address activities/ processes and outcomes for all three phases of the donation process relating to the ***living donor*** (pre-donation, donation and post-donation).

   ****** As stated previously in this Resource Guide, ***for each organ transplant program*** that is surveyed the surveyor needs to document six objective measures, for transplant recipients (one transplant activity/ process measure and one outcome measure for each phase of transplantation, pre-transplant, transplant and post-transplant) and six objective measures for living donors (one transplant activity/ process measure and one outcome measure for each phase of transplantation, pre-transplant, transplant and post-transplant).

The transplant program must have a documented data-driven method to collect the results of the program's designated measures. A data-driven methodology includes:

1. Which specific data will be collected,
2. How often the data will be collected,
3. Where the data will come from (records, observations, etc.),
4. Who is responsible for the data collections,
5. How the data will be analyzed (tallied and compared, charted for trends, tracked over identified time periods),
6. How often updates to the QAPI Committee/ Council (or others) is expected.

The results of the measures must be monitored and evaluated on a regular basis, and be a part of the program's data-driven description. The results of the program's data-driven measures are often tracked and monitored on the program's Dashboard. Dashboards may monitor the program's measures monthly, quarterly or any other designated time frame. A Dashboard may also be known as:

- Transplant Quality Assessment Dashboard,
- Performance Measurement Report,
- Performance Assessment,
- Quality Measurement Report or
- Quality Assessment.

The surveyors will seek evidence that the transplant QAPI staff and committee/ council members are reviewing and discussing the results of the objective measures through written documentation like:

- QAPI committee/ council meeting agendas,
- QAPI committee/ council meeting minutes,
- QAPI presentations, and/or
- QAPI progress notes.

If a transplant program is having difficulties in a given area, review the objective measures to ensure that the issue is being tracked. For example, if the program does not meet the 1-year post transplant outcomes, confirm that this issue is one of the tracked measures.

Table 7 - Sample of a Dashboard

Quality Measure	Year-End Benchmark/ Target	Performance				
		Q1	Q2	Q3	Q4	2009 YTD
Transplant Volume						0
Living Donor transplants		10	8	11	9	38
Deceased donor transplant		17	15	18	16	66
Total Transplants		**27**	**23**	**29**	**25**	104
Regulatory Indicators						
Two ABOs prior to listing	100%	87%	92%	91%	94%	91%
Patient Notification Letters	100%	98%	97%	99%	98%	98%
At Recovery- Completion of ABO Form for ABO compatibility & UNOS ID	100%	84%	87%	91%	89%	88%
In OR- Completion of ABO Form for ABO compatibility & UNOS ID	100%	81%	85%	92%	88%	87%
Patient removal from wait list within 24 hours of transplant or death	100%	94%	96%	98%	96%	96%
Multidisciplinary rounds	100%	79%	83%	86%	83%	83%
Communication with Dialysis Centers	100%	90%	95%	98%	97%	95%
Performance Indicators						
Median Time from referral to listing	170	185	182	176	178	180.25
Median hospital LOS	8	14	12	9	11	11.50
Waitlist management	35%	37	35	33	31	3400%
Return to surgery within 30 days	10%	14%	15%	12%	11%	13%
30 Day rejection rates	12%	15%	14%	10%	11%	13%
Dialysis<7 days of transplant	17%	17%	18%	16%	18%	17%
Dialysis on day 7 or more of transplant	20%	16%	17%	16%	17%	17%
SRTR Tracking						
1 yr graft survival	87%	89%	90%	91%	92%	91%
3 yr graft survival	76%	78%	77%	76%	80%	78%
1 yr patient survival	90%	90%	91%	92%	93%	92%
3 yr patient survival	82%	84%	83%	84%	85%	84%

QAPI Worksheet Part 3: Review of Objective Measures

Review of Objective Measures – Transplant Recipients

The transplant program's measures must address transplant activities/ process and outcomes throughout the three phases of transplantation (pre-transplant, transplant, and post-transplant). Below are samples of completed charts from Part 3 of the "Surveyor Worksheet- Organ Transplant Program, Quality Assessment and Performance Improvement." This chart represents a transplant center with two organ transplant programs for Adult Kidney Only (AKO) and Adult Liver (AL).

Table 8 - Transplant Activities/ Process

	Review Objective Measures. For each box, identify the program type and an example of *at least one* measure for each of the 3 categories. *Examples: Pre-transplant: AKO-Completion of psychosocial evaluation; Transplant: ALO – ABO Verification* **Note: Can combine adult/pediatric program types if they're using the same measures.**			
Pre-Transplant	**AKO-ABO Prior to listing**	**ALI-Referral to wait list time**		
	AKO-Updating UNET info	**ALI-ABO prior to listing**		
Transplant	**AKO-Cold ischemic time**	**ALI-Surgical protocols**		
		ALI-Cold ischemic time		
Post-Transplant	**AKO-Graft survival**	**ALI-Documentation of follow-up visits**		
	AKO-Patient survival	**ALI-Pharmacy discharge planning**		

Table 9 - Patient Outcomes

	Review Objective Measures. For each box, identify the program type and an example of *at least one* measure for each of the 3 categories. *Examples for Pre-transplant: AKO- Mortality while on Waiting List; Post-Transplant: ALO – Acute Rejection* **Note: Can combine adult/pediatric program types if they're using the same measures.**			
Pre-Transplant	**AKO-Health maintenance on wait list**	**ALI-Mortality on wait list**		
Transplant	**AKO-Length of stay**	**ALI-Infection rates while in hospital**		
	AKO-Dialysis within 7 days			
Post-Transplant	**AKO-Complications**	**ALI-Immunosuppression**		
		ALI-Readmission within 30 days		

The below chart has both "Yes" and "No" sample answers.

Table 10 - Summary in Reviewing Measures for Transplant Recipients

<u>SUMMARY</u> - IN REVIEWING MEASURES FOR TRANSPLANT RECIPIENTS:
1. Are there benchmarks? If no, how does the program evaluate performance? **Yes, the benchmarks are on the program's dashboard. / No, the program evaluates data quarterly at QAPI meetings.**
2. Is data missing from any indicators? If yes, why? **Yes, program doesn't have a transplant-specific QAPI program. The only data reported is in the hospital quality meeting minutes and this data is incomplete. / No data is missing.**
3. Are any instances where other survey information (e.g., interview, records) show something different than what the program is reporting in the indicators (i.e., indicators aren't valid)? **Yes, the program's Data Manager reported during an interview that she collects data / No differences.**
4. Is there agreement/ consistency between the measures how they are being measured and the analysis? (i.e. The program is measuring what it says it will be measuring and the list of indicators is consistent throughout the QAPI process.) **Yes, there is consistency. / No. The list of indicators is different on the Dashboard than in the QAPI Plan.**

Review of Objective Measures – Living Donors

The program's measures must address transplant activities/ process and outcomes throughout the three phases of the donation process (pre-donation, donation, and post-donation). Below are samples of completed charts from Part 3 of the "Surveyor Worksheet- Organ Transplant Program, Quality Assessment and Performance Improvement." This chart represents a transplant center with two organ transplant programs for Adult Kidney Only (AKO) and Adult Liver (AL).

Table 11 - Transplant Program Activities/ Process

	Review Objective Measures: Specify program type and example of measure for each category. **Note: Can combine adult/pediatric program types if they're using the same measures.** *Example for pre-donation: AKO- Completion of psychosocial evaluation*			
Pre-Donation	**AKO-Nutritional screening in MR**	**ALI-Selection Committee Forms** **ALI-Informed Consent**		
Donation	**AKO-Documentation by Living Donor Advocate**	**ALI-ABO verification in OR**		
Post-Donation	**AKO-Documentation of follow-up visits**	**ALI-Multi-disciplinary team documentation** **ALI- OPTN follow-up forms completed**		

Table 12 - Living Donor Outcomes

	Review Objective Measures: Specify program type and example of measure for each category. **Note: Can combine adult/pediatric program types if they're using the same measures.** *Example for Donation: AKO- Conversion from laparoscopic to open nephrectomy*			
Pre-Donation	**AKO-% of donors who met weight loss recommendations prior to donation**	**ALI-Pharmacological assessment to include over-the-counter medications/products**		
Donation	**AKO-Conversion from laparoscopic to open nephrectomy**	**ALI-Length of stay**		
Post-Donation	**AKO-Complications**	**ALI- Infection** **ALI-Death of Donor**		

Table 13 - Summary in Reviewing the Measures for Living Donors

The below chart has both "Yes" and "No" sample answers.

SUMMARY - IN REVIEWING THE MEASURES FOR LIVING DONORS:
1. Are there benchmarks for each measure? If no, how does the program evaluate performance? **Yes. / No, the program reviews data twice a year and looks at whether or not numbers are increasing or decreasing.**
2. Is data missing from any measures? If yes, why? **Yes. The QAPI Plan states that the program's Dashboard will track 12 measures, but the Dashboard only shows tracking of 10 measures. / For the measures being tracked, none of the data is missing.**
3. Are any measures that are inaccurate based on other information? **Yes. The transplant program defines "multidisciplinary" as involvement of surgical personnel and only one other discipline. / No.**
4. Is there consistency in the specific measures that the program identifies are being tracked? (i.e. What the written policy says the program is tracking and the listing of indicators is the same.) **Yes, they are consistent. / No, the QAPI personnel stated during the interview that a different set of measures are tracked than what is identified in the program's policies and procedures.**

QAPI Worksheet Part 4: Performance Improvement Actions/ Activities and Prior Non-Compliance, Complaints and Adverse Events

Regulation: The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained. (X101)

Part 4 of the QAPI Worksheet is related to the surveyor's review of the transplant QAPI program's Performance Improvement actions/ activities and non-compliance, complaints and adverse events identified during a prior survey. Surveyors will confirm that standard level deficiencies cited in the last survey have been researched and discussed by the transplant program's QAPI personnel to determine exactly what is needed to correct the issue and maintain the correction. If QAPI personnel determine that a Performance Improvement project is necessary, the specific item to be improved needs to be described, as well as how the program expects the change will happen. The applicable Performance Improvement project needs to be monitored on a Performance Improvement log, the Dashboard or in the QAPI meeting minutes. There needs to be evidence with a description of the Performance Improvement project, the actions taken and the effect of the actions taken.

Below is an explanation of the columns on the charts entitled "Program Actions/ Activities" and "Resolution of Prior Enforcement Identified Problems" located on the "Surveyor Worksheet- Organ Transplant Program, Quality Assessment and Performance Improvement."

Table 14 - Examples of Documentation Needed

Chart Column Heading	Explanation/ Example of Documentation Needed
Program Type	Three letter abbreviation, such as "AKO" for an Adult Kidney-only program.
Program Actions/ Activities chart only - Issue/ need for change identified? (How? When?)	QAPI meeting agenda, minutes, progress notes, presentation or report
Resolution of Prior Enforcement Identified Problems chart only - SRTR Data/ 2567 Issues/ Complaint Issues	For follow-up survey visits, confirmation that all issues/ problems identified during prior survey(s) have been resolved/ addressed by the transplant program
Tracked as part of objective measures?	Dashboard, QAPI Plan and/or policies and procedures
Was issue analyzed? (Yes/ No)	Root Cause Analysis form or other type of analysis form
Specific action items to correct?	Adverse Events Log, Performance Improvement Log, QAPI meeting minutes, agenda or

Chart Column Heading	Explanation/ Example of Documentation Needed
	progress notes
Corrective action implemented? (Yes/ No)	Corrective Action form, Adverse Events Log, Performance Improvement Log, QAPI meeting minutes, agenda or progress notes, training logs
Negative outcomes from delays? (If yes, describe)	Dashboard, Adverse Events Log, Performance Improvement Log, QAPI meeting minutes, agenda or progress notes
Forms are changed? (Eff. Date)	Copies of forms/ templates used, Adverse Events log, Performance Improvement Log, QAPI Plan, policies and procedures, QAPI meeting minutes, agenda or progress notes
Staff trained? (When?)	QAPI meeting minutes, agenda or progress notes, training logs, sign in sheets, computerized list of users
Policies and procedures revised? (Eff. Date)	Copies of policies and procedures and QAPI meeting minutes
Improvements tracked? (How?)	Dashboard, Adverse Events log, Performance Improvement Log, QAPI meeting minutes, agenda or progress notes
Evidence improvement not sustained?	Dashboard, Adverse Events log, Performance Improvement Log, QAPI meeting minutes, agenda, progress notes, presentation or report, data results

Program Actions/ Activities

Below is an example of a completed Program Actions/ Activities chart located in Part 4 of the "Surveyor Worksheet- Organ Transplant Program, Quality Assessment and Performance Improvement." This chart represents a transplant center with two organ transplant programs for Adult Kidney Only (AKO) and Adult Liver (ALI). One organ program is recorded in each row of the chart.

Table 15 – Example of a Completed Program Actions/ Activities Chart

Program Type	**Issue / need for change identified (How? When?)**	**Tracked as objective measures? (Yes/No)**	**Was issue analyzed? (Yes/No)**	**Corrective action items implemented? (Yes/No)**	**Negative outcomes from delays? (Yes/No) (If Yes, describe.)**	**Confirm that Corrective Action Fully Implemented**	**Improvements tracked? (Yes/No) (How?)**	**Evidence improvement not sustained? (Yes/No)**
AKO	How? By QAPI Committee When? 10/10/09	**Yes**	**Yes**	**Yes**	**Yes** Delay in ID, lower graft survival for longer time	Forms? Yes, Eff. Date-11/09/09 Staff Training? Yes, 11/01/09 P&P? Yes, Eff. Date-11/09/09	**Yes** How? On Performance Improvement Log	**No**
ALI	How? By Chief Medical Officer When? 08/09/09	**Yes**	**Yes**	**Yes**	**No**	Forms? **Yes**, Eff. Date-9/15/09 Staff Training? **Yes**, 9/12/09 P&P? Yes, Eff. Date 9/15/09	**Yes** How? Patient chart review	**Yes**

Resolution of Prior Non-Compliance, Complaints and Adverse Events

Below is a sample Resolution of Prior Identified Problems chart located in Part 4 of the "Surveyor Worksheet- Organ Transplant Program, Quality Assessment and Performance Improvement." This chart is used by transplant surveyors to track previous non-compliance issues, investigations and adverse events. The purpose is to ensure that the transplant program incorporated improvements into their QAPI program that are associated with the prior identified problems. This chart represents a transplant program with two organ transplant programs for Adult Kidney Only (AKO) and Adult Liver (ALI). One organ program is recorded in each row of the chart.

Table 16 – Sample of Resolution of Non-Compliance, Complaints and Adverse Events Chart

Program Type	SRTR Data/ Patient Care/ Complaint Issues	Tracked as objective measures? (Yes/No)	Was issue analyzed? (Yes/No)	Corrective action items implemented? (Yes/No)	Negative outcomes from delays? (Yes/No) (If Yes, describe.)	Confirm that Corrective Action Fully Implemented	Improvements tracked? (Yes/No) (How?)	Evidence improvement not sustained? (Yes/No)
	SRTR Data					Forms? Staff Training? P&P?	How?	
	Notes-							
						Forms? Staff Training? P&P?	How?	
	Notes-							
	Quality of Care					Forms? Staff Training? P&P?	How?	
	Notes-							
						Forms? Staff Training? P&P?	How?	
	Notes-							
	Substantiated Complaints					Forms? Staff Training? P&P?	How?	
	Notes-							
	Adverse Event (see Part 5)					Forms? Staff Training? P&P?	How?	
	Notes-							

QAPI Worksheet Part 5: Transplant Program's Adverse Event Policies/ Procedures and Analysis

Adverse Event Policies/ Procedures

Regulation: 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. The policies must address at a minimum, the process for the identification, reporting, analysis and prevention of adverse events. (X102) The transplant regulations define an adverse event as: "an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, 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."

The transplant program's Adverse Events Policy will most likely be found as part of the program's QAPI Plan or Policies and Procedures or in the hospital's Adverse Events Policies and Procedures, if not the surveyor needs to ask for a copy of the Adverse Events Policy.

The transplant program's definition of an adverse event must be specific to transplant and describe in detail what constitutes an adverse event during any of the three phases of transplantation (pre-transplant, transplant and post-transplant).

If the transplant program does not use the term "adverse event," the surveyor will need to ask what term the program uses that is equivalent to the CMS definition. The transplant program may also refer to an adverse event as:

- An incident,
- A critical incident,
- A safety incident,
- A safety event,
- A critical event, or
- A sentinel event**.

*** Please Note: The Joint Commission has a different definition for "Sentinel Event" than for "Adverse Event," however the surveyor may find that the transplant program uses the terms synonymously.*

Adverse Event Analysis

The transplant center must conduct a thorough analysis of and document any adverse event. (X103) The transplant center must utilize the analysis to effect changes in the Transplant Center's policies and practices to prevent repeat incidents. (X104)

A Root Cause Analysis is the most common way to investigate an adverse event. CMS does not dictate that a specific type of Root Cause Analysis be used when the transplant program conducts an analysis of an adverse event, the program may use any form of analysis that is thorough and is used to effect change in the transplant center's policies and procedures in order to prevent repeat incidents.

Using Analysis to Effect Change

To use the findings from the investigations of adverse events to effect change the transplant program must have documentation that shows that the program has:

1. Analyzed the adverse event.
2. Identified the specific recommendations/ action steps needed to correct or prevent repeat occurrences of the adverse event or develop a sound rationale for not making any changes to the transplant program.
3. Determined how the effectiveness of the change will be evaluated.
4. Updated the transplant program policies and procedures.
5. Provided training or education to staff regarding the change in policies and procedures.
6. Implemented the change to the transplant program.
7. Monitored the effectiveness of the change and track the measure on the program Dashboard (or other tracking method).

The following is one example of a sequence of actions by a transplant program and how the program used analysis to effect change is related to the problem of a sponge left in the kidney cavity during surgery:

1. There was an unexplained death of a transplant recipient.
2. The transplant QAPI personnel performed a root cause analysis that determined that the surgical protocols were not specific enough.
3. The QAPI Committee decided to proceed with a Performance Improvement project that would revise and add more detail to the surgical protocols.
4. The transplant program hired an outside consultant to review the surgical protocols.
5. The consultant recommended specific changes/ additions to the surgical protocols.
6. The QAPI Committee reviewed the consultant's recommendations and finalized revisions to the surgical protocols.
7. The revised surgical protocols were presented to the transplant surgery staff with an implementation plan, which included staff training and surgical oversight.
8. QAPI personnel collected monthly data for six months and quarterly data for a year to track and monitor the improvement and ensure that is was effective and sustainable.

C. SURVEYING TECHNIQUES

Entrance Conference/ Written Materials

During the entrance conference, request copies of all written materials within the transplant QAPI program which describe:

- The structure of transplant QAPI program,
- How the transplant QAPI program operates,
- The handling of adverse events, and
- The process for using objective measures and performance improvement activities.

These written materials may include some or all of the following:

- Hospital and/or transplant program policies,
- Hospital and/or transplant procedures,
- Transplant QAPI Plan,
- Transplant QAPI meeting agendas, minutes and summaries, as well as
- Report or presentations created by transplant staff.

The transplant program written materials and the collection of the materials has been discussed in more detail in this Resource Guide in "B. Completing the QAPI Worksheet, Part 1: Policies and Procedures for QAPI Program."

Observations

When it comes to determining QAPI compliance, observations are tricky. A surveyor has to be attuned to what is happening and if what they see could reasonably be expected to impact the transplant QAPI program. A few examples of situations that have been observed which might impact the transplant QAPI program are:

- The suggestion/comment box in the transplant outpatient clinic had no top;
- The quarterly training schedule on the bulletin board didn't have any transplant specific topics;
- The brochures in the waiting room about becoming a living donor were from another hospital;
- The patient records in the transplant step-down unit were left unattended on the nurses' station counter for 40 minutes;
- A couple waiting at the door with a suitcase (one of whom is in a wheelchair) commented to each other that they didn't know where to go for the first follow up clinic visit next week and couldn't find it on the paper they just got;
- An elderly woman slipped and fell to the floor in the waiting room and was helped into a chair by two people one of which went to the registration desk and told the receptionist about the fall. Although the woman didn't appear to be or act injured, no one came to talk to her for the 55 minutes she was observed.

Of course, in every one of the above examples an interview would be the optimal action to be taken by the surveyor. The results of the observation in conjunction with the information gleaned from the interview(s)

would determine whether questions specific to the observation would be brought up during the QAPI interviews.

Interviews

Interviewing QAPI Personnel

Interview the individual primarily responsible for day-to-day operations of the transplant QAPI program, usually the transplant program's QAPI director, administrator, manager or coordinator. There are five primary questions whose answers are basic to the understanding of the transplant QAPI program and will provide guidance to surveyors as they review the policies and procedures.

The five primary interview questions are:

1. What is the transplant QAPI organizational structure and to whom do the transplant QAPI personnel report?
2. Would you walk through the process your QAPI program uses to determine and monitor objective measures for quality assessment activities including establishing benchmarks, collection of data and steps used in analyzing the results? (If preferred, a specific outcome measure can be used as an example.)
3. What is an example of an adverse event that precipitated a change in operations and how did it happen?
4. How do you identify which performance issues need improving and assure the implemented improvements work?
5. How are transplant QAPI results communicated up the ranks to hospital administration and down to the day-to-day support staff?

Additional questions for clarification and further information will be necessary depending on the answers or explanation given to any of the primary questions. During interviews staff may respond with simple "Yes" or "No" answers which will prompt the surveyor to inquire further with follow-up questions. For example if the surveyor asks if there have been any adverse events and the QAPI staff simply answers "No," then the surveyor could follow-up by asking if any deaths have occurred.

Interviewing Non-QAPI Personnel

Most of the interviews conducted by the surveyors regarding the transplant QAPI program will likely be done with personnel directly involved with QAPI activities; however, good information can be collected from non-QAPI personnel involved with the transplant program. When interviewing non-QAPI personnel, give the personnel time to walk through the process, and then ask them the outcome of their actions.

A sampling of questions the surveyor could ask of non-QAPI personnel are:

1. Where/ when did you learn about the adverse events processes/ actions?
2. When was the last time you were trained or made aware of changes to processes because of a QAPI Committee recommendation?
3. How would you report an adverse event or accident?

4. Have any non-QAPI transplant personnel ever been invited or participated in a QAPI activity such as task analysis, opinions of specific activities success or lack thereof?

Additional questions for clarification and further information will be necessary depending on the answers or explanation given to any of the questions. During interviews staff may respond with simple "Yes" or "No" answers which will prompt the surveyor to inquire further with follow-up questions.

Interviewing Patients/ Living Donors

As part of interviews conducted with various patients, include questions directly related to QAPI.

A sampling of questions the surveyor could ask of a patient are:

1. What would you do if you witnessed something at the transplant program you thought was inappropriate or unsafe?
2. Have you ever been in a situation where you have witnessed something at the transplant program that was inappropriate or unsafe? What did you do? What happened next?
3. If you had a problem with any part of your transplant experience what would you do?

Additional questions for clarification and further information will be necessary depending on the answers or explanation given to any of the questions. During interviews patients/ living donors may respond with simple "Yes" or "No" answers which will prompt the surveyor to inquire further with follow-up questions.

Conclusion/ Exit Conference

To conclude the survey visit the surveyor needs to hold an exit conference with transplant program personnel to provide an opportunity for the transplant program to share any other information not previously discussed and explain the next steps in the process.

BIBLIOGRAPHY

American Society for Quality, Accessed 13 April 2010 http://www.asq.org.

Baldrige National Quality Program, Accessed 16 June 2010 http://www.nist.gov/baldrige/.

Charles Conway, Successful Software Management: Find Hidden Project Risks, Accessed 12 July 2010 http://www.charlesconway.com/articles/find_hidden_project_risks.htm

Columbia University Medical Center Department of Surgery, Accessed 22 April 2010 http://www.columbiasurgery.org/.

The Commonwealth Fund, A Private Foundation Working Toward a High Performance Health System, Publications, Accessed 21 April 2010 http://www.commonwealthfund.org/.

Department of Health and Human Services, Centers for Medicare & Medicaid Services 42 CFR Parts 405, 482, 488 and 498, Medicare Program; Hospital Conditions of Participation : Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Final Rule

Experimental and Clinical Transplantation, Accessed 11 May 2010 http://ectrx.org

FMEA Info Centre, Accessed 13 April 2010 http://www.fmeainfocentre.com/.

Healthcare Quarterly, Accessed 29 April 2010 http:www.longwoods.com/publications/healthcare-quarterly.

Henry Ford Health System, Accessed 5 April 2010 http://www.henryford.com.

Hospital Council of Northern & Central California, Quality Initiatives, Accessed 30 April 2010 http://www.hospitalcouncil.net/.

iSix Sigma, Quality Resources for Achieving Six Sigma Results, Accessed 13 April 2010 http://www.isixsigma.com/.

Institute for Healthcare Improvement, Accessed 5 April 2010 http://www.ihi.org.

Institute of Medicine of the National Academies, Accessed 30 April 2010 http://iom.edu/.

Interactive Cardio Vascular and Thoracic Surgery, Accessed 29 April 2010 http://icvts.ctsnetjournals.org/.

International Journal for Quality in Health Care, Accessed 6 May 2010 http://intqhc.oxfordjournals.org/.

The Joint Commission, Helping Health Care Organizations help patients, Accessed 2 June 2010 http://www.jointcommission.org/.

Journal of the American Pharmacists Association, Accessed 10 May 2010 http://japha.metapress.com/.

Maine Network for Health, Accessed 5 April 2010 http://www.mainenetwork.org.

Massachusetts General Hospital, Quality and Safety, Accessed 20 April 2010 http://www.massgeneral.org/.

Mears, Peter. Quality Improvement Tools & Techniques. McGraw-Hill, Inc., 1995.

NATCO The Organization for Transplant Professionals, Accessed 4 May 2010 http://www.natco1.org/.

National Center for Biotechnology Information, Accessed 30 April 2010 http://www.ncbi.nlm.nih.gov/.

National Patient Safety Foundation, Accessed 21 April 2010 http://www.npsf.org/.

The New England Journal of Medicine, Accessed 28 April 2010 http://content.nejm.org/.

New Hampshire Department of Health and Human Services, Accessed 9 April 2010 http://www.dhhs.state.nh.us.

New York State Office of Mental Health, Office of Quality Management, Accessed 5 April 2010 http://www.omh.state.ny.us/omhweb.

OrganDonor.Gov, Access to U.S. Government Information on Organ & Tissue Donation and Transplantation, Accessed 5 May 2010 http://organdonor.gov/.

Quality Digest, Accessed 21 April 2010 http://www.qualitydigest.com/.

Ransom, Elizabeth R., Maulik S. Joshi, David B. Nash, and Scott B. Ransom, eds. The Healthcare Quality Book Second Edition Vision, Strategy, and Tools. Chicago, IL: Health Administration Press and Washington, DC AUPHA Press, 2008.

The Renal Network, ESRD Networks 4, 9 & 10, "Quality Improvement Overview." Accessed 17 December 2009 www.therenalnetwork.org/qi/qi_QAPI_home.php.

Respiratory Care, The Science Journal of the American Association for Respiratory Care, Accessed 30 April 2010 http://www.rcjournal.com/.

United States Department of Homeland Security, United States Coast Guard District Eight Performance Management Branch, Accessed 16 June 2010 http://www.uscg.mil/d8/performance/.

United States Department of Veterans Affairs, VA National Center for Patient Safety, Accessed 22 April 2010 http://www.patientsafety.gov/.

United States Department of Health & Human Services, Centers for Medicare & Medicaid Services, Accessed 2 June 2010 http://www.cms.gov.

University of California San Diego Medical Center, Accessed 8 April 2010 http://medinfo.ucsd.edu.

University of California Los Angeles Health System Transplantation Services, Accessed 26 May 2010 http://transplants.ucla.edu/.

University of Michigan Health System, Accessed 28 April 2010 http://www.med.umich.edu/.

University of Pennsylvania Health System, Accessed 23 April 2010 http://www.pennmedicine.org/.

Wyszewianski, L. Clinics in Family Practice, Volume 5, "Defining, Measuring, and Improving Quality of Care," 2003.

ATTACHMENT 1 – QAPI WORKSHEET

SURVEYOR WORKSHEET- ORGAN TRANSPLANT PROGRAM
QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT

Instructions: This worksheet is to be used during the survey to document the evidence obtained by the surveyor. Answer all questions and completely fill in all charts. Do not include any HIPAA sensitive data on this worksheet. Complete one worksheet for each of the hospital's transplant QAPI programs being surveyed. A transplant program may have many different organs under one QAPI program, which would require the completion of only one QAPI Worksheet. If there is more than one transplant QAPI program (i.e. thoracic and abdominal QAPI programs), then more than one QAPI Worksheet will need to be completed. Separate transplant QAPI programs will have their own policies and procedures, staff and processes.

General Program Information

1) Transplant Hospital Name: _____ Transplant Hospital Provider Number: _____ Surveyor Name(s): _____ Survey date(s): _____ (mm/dd/yyyy)
2) Types of transplant program(s) covered by this Quality Assessment and Performance Improvement program

- ☐ Adult kidney-only
- ☐ Adult pancreas
- ☐ Adult heart-only
- ☐ Adult heart/lung
- ☐ Adult lung-only
- ☐ Adult liver
- ☐ Adult intestinal and/or multivisceral
- ☐ Pediatric kidney-only
- ☐ Pediatric pancreas
- ☐ Pediatric heart-only
- ☐ Pediatric heart/lung
- ☐ Pediatric lung-only
- ☐ Pediatric liver
- ☐ Pediatric intestinal and/or multivisceral

Part 1- Policies and Procedures for QAPI Program(s)

Regulation: 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. (X099)

3) a. Transplant hospital has a written detailed QAPI program with policies and procedures focused on transplant data and outcomes?
   1 ☐ Yes 2 ☐ No
   b. Is the program implemented? 1 ☐ Yes 2 ☐ No
4) Written QAPI program covers the following:
   a. All organ types? 1 ☐ Yes 2 ☐ No
   b. Is it elsewhere? 1 ☐ Yes 2 ☐ No Where: _____
   c. Who serves on the Transplant QAPI committee? (Check all identified and, if needed, write notes)
      - 1 ☐ Transplant Surgeons _____
      - 2 ☐ Director of Transplant _____
      - 3 ☐ Living Donor Advocate _____
      - 4 ☐ Transplant Pharmacist _____
      - 5 ☐ Transplant Coordinators _____
      - 6 ☐ Transplant Floor Nurse _____
      - 7 ☐ Transplant Physicians _____
      - 8 ☐ Transplant Clinic Nurse _____
      - 9 ☐ Transplant Dietitian _____
      - 10 ☐ Transplant Social Worker _____
      - 11 ☐ Dedicated QAPI Staff – How many FTEs? _____
      - 12 ☐ Other: _____

d. QAPI committee meets (or will meet if the program is not yet implemented)?
1☐ Monthly 2☐ Quarterly 3☐ Annually 4☐ Other ____

e. If there are multiple QAPI committees or quality subgroups, the scope and communication between these groups are defined?
1☐ Yes 2☐ No

f. The process to determine what objective measures the transplant QAPI program will look at on a regular basis. 1☐ Yes 2☐ No ____

g. The process to identify and track performance improvement activities. 1☐ Yes 2☐ No

5) The hospital's QAPI program must cover all areas of the hospital (42 CFR 482.21). Is there a clear linkage between the transplant program's QAPI program and the overall hospital's QAPI program? 1☐ Yes 2☐ No

a. Describe the level of involvement between the transplant program QAPI and the hospital's QAPI. ____

b. Describe how the transplant QAPI's information is going up to the hospital's QAPI program. (i.e. meetings, memos, e-mails, reports, etc.) ____

c. Describe how the hospital's QAPI information is going from the hospital's QAPI program to the transplant QAPI program. ____

Part 2 – Evaluation and Monitoring of the Transplant Program by the QAPI

Regulation: The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. (X100)

6) Is there evidence (e.g., meeting agendas, presentations, minutes, progress notes) that the QAPI staff and committee members are reviewing and discussing the results of the objective measures? (Please note this is different than a case review of an adverse event.)
1 ☐ Yes 2☐ No

7) Is there evidence that individuals with authority to make decisions about the transplant program's policies and practices are routinely participating in the QAPI meetings or process? (Check all that apply.)
1☐ Transplant Director
2☐ Primary Transplant Surgeon
3☐ Primary Transplant Physician

Part 3 – Review of Objective Measures: *Transplant Recipients* - Do the transplant program's objective measures address transplant activities and outcomes throughout the 3 phases of transplantation (pre-transplant, transplant, and post-transplant)?

Instructions: Document QAPI objective measures for Transplant Recipients on charts below:

- One organ transplant program per column
- Include organ type with sample objective measure
- List one objective measure per transplant phase up to three
- Objective measures are either process or outcome

Transplant Activities/ Process

	Sample of objective measures: Pre-transplant, AKO-Completion of psychosocial evaluation; Transplant, ALO – ABO Verification			
Pre-Transplant				
Transplant				
Post-Transplant				

Patient Outcomes

	Sample of objective measures: Pre-transplant, AKO- Mortality while on Waiting List; Post-Transplant, ALO – Acute Rejection			
Pre-Transplant				
Transplant				
Post-Transplant				
List any measures (either process or outcomes) which were not significant to the Transplant program (e.g. tracking expenditures of surgical suite,; tracking patient satisfaction with the onsite food café):				

8). **<u>SUMMARY</u> - IN REVIEWING OBJECTIVE MEASURES FOR TRANSPLANT RECIPIENTS:**
a) Are there benchmarks? If not, how does the program evaluate performance for each objective measure?
b) Is data missing from any of the objective measures? If yes, why?
c) Are there any instances where other survey information (e.g., interviews, records) show something different than what the program is reporting in the objective measures?
d) Is the program measuring what it says it will be measuring and is the list of indicators consistent throughout the QAPI process?

Review of Objective Measures: *Living Donors* - Do the program's objective measures address transplant activities and outcomes throughout the 3 phases of the donation process (pre-donation, donation, and post-donation)?

Instructions: Document QAPI objective measures for Living Donors on charts below:

- One organ transplant program per column
- Include organ type with sample objective measure
- List one objective measure per transplant phase
- Objective measures are either process or outcome
- Use "N/A" to indicate the transplant program (AKO, ALI, PKO, PLI) does not use Living Donors

Transplant Program Activities/ Process

	Sample of objective measure: Pre-donation, AKO- Completion of psychosocial evaluation			
Pre-Donation				
Donation				
Post-Donation				

Living Donor Outcomes

	Sample of objective measure: Donation, AKO- Conversion from laparoscopic to open nephrectomy			
Pre-Donation				
Donation				
Post-Donation				

9). SUMMARY - IN REVIEWING THE OBJECTIVE MEASURES FOR LIVING DONORS:
a) Are there benchmarks for each objective measure? If not, how does the program evaluate performance?
b) Is data missing from any of the objective measures? If yes, why?
c) Are there any instances where other survey information (e.g., interviews, records) show something different than what the program is reporting in the objective measures?
d) Is the program measuring what it says it will be measuring and is the list of indicators consistent throughout the QAPI process?

Part 4 - Performance Improvement Actions/ Activities and Resolution of Prior Non-Compliance, Complaints and Adverse Events

Regulation: The transplant program must take actions that result in performance improvements and track performance to ensure that improvements are sustained. (X101)

Instructions: Document the transplant program's actions/ activities on the chart below:

- One organ transplant program per row
- Program type indicated by a three letter abbreviation (e.g. AKO for Adult Kidney Only)
- At a minimum complete all boxes/ cells for one row, which indicates a review of one organ transplant program being surveyed
- Space has been provided to indicate a review of seven organ programs

Describe Transplant Program's Actions/ Activities

Program Type	Issue / need for change identified (How? When?)	Tracked as objective measures? (Yes/No)	Was issue analyzed? (Yes/No)	Corrective action items implemented? (Yes/No)	Negative outcomes from delays? (Yes/No) (If Yes, describe.)	Confirm that Corrective Action Fully Implemented	Improvements tracked? (Yes/No) (How?)	Evidence improvement not sustained? (Yes/No)
	How? When?					Forms? Staff Training? P&P?	How?	
	Notes-							
	How? When?					Forms? Staff Training? P&P?	How?	
	Notes-							
	How? When?					Forms? Staff Training? P&P?	How?	
	Notes-							
	How? When?					Forms? Staff Training? P&P?	How?	
	Notes-							
	How? When?					Forms? Staff Training? P&P?	How?	
	Notes-							
	How? When?					Forms? Staff Training? P&P?	How?	
	Notes-							
	How? When?					Forms? Staff Training? P&P?	How?	
	Notes-							

Instructions: Document the resolution of prior non-compliance, complaint or adverse events on the chart below:

- One organ transplant program per row
- Program type indicated by a three letter abbreviation (e.g. AKO for Adult Kidney Only)
- At a minimum complete all boxes/ cells for one row, which indicates a review of the resolution of one prior issue for one program being surveyed
- Space has been provided to indicate a review of the resolutions of seven prior issues for a variety of organ programs being surveyed

Resolution of Prior Non-Compliance, Complaints and Adverse Events

Program Type	SRTR Data/ Patient Care/ Complaint Issues	Tracked as objective measures? (Yes/No)	Was issue analyzed? (Yes/No)	Corrective action items implemented? (Yes/No)	Negative outcomes from delays? (Yes/No) (If Yes, describe.)	Confirm that Corrective Action Fully Implemented	Improvements tracked? (Yes/No) (How?)	Evidence improvement not sustained? (Yes/No)
	SRTR Data					Forms? Staff Training? P&P?	How?	
	Notes-							
						Forms? Staff Training? P&P?	How?	
	Notes-							
	Quality of Care					Forms? Staff Training? P&P?	How?	
	Notes-							
						Forms? Staff Training? P&P?	How?	
	Notes-							
	Substantiated Complaints					Forms? Staff Training? P&P?	How?	
	Notes-							
						Forms? Staff Training? P&P?	How?	
	Notes-							
	Adverse Event (see Part 5)					Forms? Staff Training? P&P?	How?	
	Notes-							
						Forms? Staff Training? P&P?	How?	
	Notes-							

Part 5 –Transplant Program's Adverse Event Policies/Procedures and Analysis

Regulation: 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. The policies must address at a minimum, the process for the identification, reporting, analysis and prevention of adverse events. (X102) The transplant regulations define an adverse event as: "an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, 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."

10) a. Are there transplant hospital written adverse event policies and procedures specific to transplant? 1☐ Yes 2☐ No
b. Are policies and procedures implemented? 1☐ Yes 2☐ No

11) Does the written adverse event policy address the following:

a.	All organ types	1☐ Yes 2☐ No
b.	Process for identification of adverse events	1☐ Yes 2☐ No
c.	Severity of events that are tracked and analyzed	1☐ Yes 2☐ No
d.	Reporting of adverse events	
	i. Within the hospital	1☐ Yes 2☐ No
	ii. To the local or state agency	1☐ Yes 2☐ No
	iii. To the Organ Procurement and Transplantation Network	1☐ Yes 2☐ No
	iv. To the Organ Procurement Organization	1☐ Yes 2☐ No
e.	Disclosure of adverse events to the patient(s)	1☐ Yes 2☐ No
f.	Analysis of the adverse event	
	i. How will the event be analyzed	1☐ Yes 2☐ No
	ii. Who is responsible for conducting the review	1☐ Yes 2☐ No
	iii. What types of events will be reviewed and by whom	1☐ Yes 2☐ No
g.	Actions taken to prevent of similar adverse events	1☐ Yes 2☐ No

Regulation: The transplant center must conduct a thorough analysis of and document any adverse event. (X103) The transplant center must utilize the analysis to effect changes in the Transplant Center's policies and practices to prevent repeat incidents. (X104)

12) Did the analysis of the adverse event address all appropriate areas (i.e., questions were not left unanswered, no unresolved conflicting information, the findings were explained, and the program considered underlying systems and processes and relevant literature)?
1☐ Yes 2☐ No

Instructions: Using the transplant program's list/ log of transplant adverse events select at least one event to conduct an in-depth review, which entails the review of the patient's medical records, the complete root cause analysis, any recommendations, and all corrective actions. Based on the in-depth review, the surveyor should answer questions 13 through 16 of the QAPI Worksheet.

13) Did the program identify:
   1 ☐ Primary root cause(s)
   2 ☐ Contributing factors to the event
   3 ☐ Potential areas to prevent repeat incidences, or after analysis determined that no opportunities for improvement exist.

14) Did the program thoroughly document all adverse events including:

a.	Specific chronology of the incident	1 ☐ Yes 2 ☐ No
b.	Interview with all relevant staff involved	1 ☐ Yes 2 ☐ No
c.	Interview with relevant external parties (e.g., OPO, referring physicians)	1 ☐ Yes 2 ☐ No
d.	If available, interviews with the transplant patient/living donor	1 ☐ Yes 2 ☐ No
e.	Review of all relevant policies and procedures and identification of any variation that occurred	1 ☐ Yes 2 ☐ No
f.	Any contextual factors related to the environment (e.g., staff schedules, bed availability, equipment, systems)	1 ☐ Yes 2 ☐ No
g.	Rate of occurrence and common factors for the same/similar events	1 ☐ Yes 2 ☐ No

15) Did individual(s) with authority to make decisions about the transplant program participate in the analysis of the adverse event?
   1 ☐ Yes 2 ☐ No

16) Are there specific recommendations/action steps that resulted from the analysis? 1 ☐ Yes 2 ☐ No
   If not, is there a sound rationale for not making changes? 1 ☐ Yes 2 ☐ No

If there are specific recommendations/action steps, refer to Part 4 (page 6) to track implementation of these activities.

Check below the deficiency that will be cited:

☐ X099 QAPI COP
☐ X100 Components of QAPI program
☐ X101 QAPI – actions/tracking to improve & sustain performance
☐ X102 Adverse events
☐ X103 Analysis/Documentation of adverse events
☐ X104 Effect changes to prevent repeat incidents

TRANSPLANT CONDITION OF PARTICIPATION (COP) QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI) DECISION – MAKING

Consider citing a QAPI **condition- level deficiency** for **any** of the following evidence:

1. There is no transplant specific QAPI
2. There are no QAPI transplant specific policies and procedures
3. Performance issues related to outcomes, volume and substantiated complaints are not addressed by QAPI activities
4. No objective measures or limited to only mortality and morbidity reviews
5. If they have a living donor program and there are no living donor objective measures
6. There are no transplant decision-makers on the QAPI committee/group/council
7. The transplant program has no performance improvement actions/activities
8. There are no transplant specific adverse events policies and procedures
9. There is no analysis or action related to transplant adverse events
10. The transplant program is not following its own policies and procedures for adverse events
11. Majority of outcome measures do not match survey findings

Consider citing QAPI **standard- level deficiency** (SLD) for **any** of the following evidence:

1. Communication about transplant QAPI activities and outcomes is not integrated into the hospital's operations
2. System is not in place and implemented for communicating changes, updates and activities related to transplant QAPI
3. Transplant QAPI policies and procedures are incomplete
4. Performance improvement activities not implemented by the documented date(s)
5. Incomplete transplant adverse events policies and procedures
6. Incomplete transplant adverse events root cause analysis, recommendations or corrective actions
7. Sporadic information about performance data

This document should be used by the survey team during Task 11 – Pre-Exit Conference –to determine if the team has enough evidence to cite the QAPI - COP or SLD.