

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
- | | | |
|--|--|--|
| <input type="checkbox"/> Adult kidney-only | <input type="checkbox"/> Adult liver | <input type="checkbox"/> Pediatric heart/lung |
| <input type="checkbox"/> Adult pancreas | <input type="checkbox"/> Adult intestinal and/or multivisceral | <input type="checkbox"/> Pediatric lung-only |
| <input type="checkbox"/> Adult heart-only | <input type="checkbox"/> Pediatric kidney-only | <input type="checkbox"/> Pediatric liver |
| <input type="checkbox"/> Adult heart/lung | <input type="checkbox"/> Pediatric pancreas | <input type="checkbox"/> Pediatric intestinal and/or multivisceral |
| <input type="checkbox"/> Adult lung-only | <input type="checkbox"/> Pediatric heart-only | |

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 <input type="checkbox"/> Transplant Surgeons _____ | 7 <input type="checkbox"/> Transplant Physicians _____ |
| 2 <input type="checkbox"/> Director of Transplant _____ | 8 <input type="checkbox"/> Transplant Clinic Nurse _____ |
| 3 <input type="checkbox"/> Living Donor Advocate _____ | 9 <input type="checkbox"/> Transplant Dietitian _____ |
| 4 <input type="checkbox"/> Transplant Pharmacist _____ | 10 <input type="checkbox"/> Transplant Social Worker _____ |
| 5 <input type="checkbox"/> Transplant Coordinators _____ | 11 <input type="checkbox"/> Dedicated QAPI Staff – How many FTEs? _____ |
| 6 <input type="checkbox"/> Transplant Floor Nurse _____ | 12 <input type="checkbox"/> 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

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

Patient Outcomes

	<i>Sample of objective measures: Pre-transplant, AKO- Mortality while on Waiting List; Post-Transplant, ALO – Acute Rejection</i>			
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). SUMMARY - 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

	<i>Sample of objective measure: Pre-donation, AKO- Completion of psychosocial evaluation</i>		
Pre-Donation			
Donation			
Post-Donation			

Living Donor Outcomes

	<i>Sample of objective measure: Donation, AKO- Conversion from laparoscopic to open nephrectomy</i>		
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-							

Notes-								
How?						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					Forms?		

	Part 5)					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.