ENHANCING QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT
PILOT FOCUSED QUALITY SURVEYOR WORKSHEET

PROGRAM ANALYSIS WORKSHEET

Survey Agency Name: _____

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.

PART 1: QAPI PROGRAM INFORMATION

1. Transplant Hospital Name: _____
2. Transplant Hospital Address: _____
3. City / Zip: _____
4. State: _____

5. Transplant Hospital Provider Number: _____

6. Survey Type: ___ Focused QAPI

7. Region: _____

Surveyor Name(s):_____ Survey date(s): ____/____/____(mm/dd/yyyy)

8. 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 2: QAPI DESIGN AND SCOPE

***Regulation**: Transplant programs must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement. (**X099**)*

Elements to be Assessed		Yes / No	Surveyor Notes
2.1 Does the Transplant program have a written detailed QAPI program? **Yes: ____ No: _____**	2.1a Is there a written QAPI plan?	Choose an item.	Documents Reviewed: Interviews: Transplant QAPI Director (or designee): Date/Time: Comments:
	2.1b Is there a clear linkage between the transplant program's QAPI program and the hospital's QAPI program?	Choose an item.	
	2.1c Are policies, procedures, QA measures and PI activities focused on transplant **processes** and **outcomes**?	Choose an item.	
	2.1d Is the program implemented?	Choose an item.	
	2.1e Describe the QAPI programs Quality methods / tools.	Choose an item.	Description:
2.2 Does the QAPI program include evaluation of all 3 phases for transplant and living donation? *(pre, procedure, post) (as appropriate)*		Choose an item.	Comments:
2.3 Does the QAPI plan contain the 5 key elements of a Quality structure? **Yes:_____ No:_____**	2.3a Design and Scope	Choose an item.	
	2.3b Executive Responsibilities	Choose an item.	
	2.3c Feedback and Data Systems	Choose an item.	
	2.3d Analyses of Data	Choose an item.	
	2.3e Performance Improvement Activities	Choose an item.	
2.4 Is the program Data Driven? *(has there been any action(s) taken in response to the analyzed data)*		Choose an item.	Comments:

Elements to be Assessed	Yes / No	Surveyor Notes
2.5 Are Benchmarks and Goals established using evidence based practices, nationally recognized materials or the most current medical knowledge?	Choose an item.	Comments:
2.6 Are QAPI activities focused on process improvement*(s)* and patient outcomes?	Choose an item.	Comments:
2.7 Is there MONITORING and EVALUATION of contracted services connected to the transplant program? *(enter N/A if there are no contracts)* List all transplant connected contract services below: **1)**_____ **2)**_____ **3)**_____ **4)**_____ *(add more if necessary - determined at entrance conference)*	Choose an item.	Comments:
2.8 TRANSPLANT QAPI COMMITTEE: **Does the written plan identify the existence of a committee, list committee membership by staff role and identify the purpose of the committee?**	Choose an item.	Comments:
2.9 Does the QAPI committee meet according to programs policy and procedures? **Monthly** **Quarterly** **Other** _____	Choose an item.	Comments:
2.10 Is there multi-disciplinary team participation? (Check all areas in the box below to identify staff who are actively involved in committee meetings and functions; active participation should be defined by program policy on acceptable participation) Multi-Disciplinary Team __Transplant Surgeons __Transplant Physicians __Director of Transplant __Transplant Clinic Nurse __Living Donor Advocate __Transplant Dietitian __Transplant Pharmacist __Transplant Social Worker __Transplant Coordinators __Dedicated QAPI Staff __Transplant Floor Nurse __Transplant Administrator	Choose an item.	Comments:
2.11 If there are multiple transplant QAPI committees or QAPI sub-groups, is there a description of group's purpose and is the communication between the group's defined? *(enter N/A if question does not apply)*	Choose an item.	Comments:

Elements to be Assessed		Yes	No	Surveyor Notes
2.12 Describe how the transplant program's QAPI information is communicated to the hospital's QAPI program. (*i.e. meetings, memos, emails, reports, etc.)*		Choose an item.		Description:
2.13 Describe how the hospital's QAPI information is communicated to the transplant QAPI program. *(i.e. meetings, memos, emails, reports, etc.)*		Choose an item.		Description:
2.14 Describe how the transplant program's QAPI information is communicated to the transplant staff. *(i.e. meetings, memos, emails, reports, letters, etc.)*		Choose an item.		Description:
2.15 Is there a process to determine what objective measures the transplant QAPI program will look at on a regular basis? **Yes:____ No:_____**	2.15a Are the selected measures **OBJECTIVE**? *(i.e., not financial in nature, logistical in nature or required by regulation to be maintained)* (see Resource Guide for more information)	Choose an item.		Comments:
	2.15b Are the **OBJECTIVE** measures based on internally identified, high risk, high volume, or problem prone issues?	Choose an item.		
	2.15c Do the **OBJECTIVE** measures include externally identified benchmarks? *(best practice, professional standards, evidenced based science)*	Choose an item.		
	2.15d Are the **OBJECTIVE** measures focused on improving patient outcomes?	Choose an item.		
2.16 Is there a defined process to identify and track performance improvement? *(is there a system to identify issues within the program that may need improvement related to patient outcomes or program performance)*	2.16a What process has been determined? *(what method of reporting adverse events, occurrences, incidents, etc. will be utilized)*	Choose an item.		Comments: *(document any and all methods chosen: computer, paper, hotline, other)*
	2.16b Discuss how this connects to the QAPI philosophy and organizational culture?	Choose an item.		Discussion:

PART 3: GOVERNANCE AND LEADERSHIP

Elements to be Assessed		Yes	No	Surveyor Notes
3.1 Has the formal Transplant QAPI program been-approved by the Governing Body? *(including written policies and procedures, budgeted resources, and clearly identified responsible staff)* **Yes: ____ No: _____**	3.1a Has the hospital / transplant program maintained and made available for surveyor evidence of its QAPI program and other requested materials?	Choose an item.		Documents Reviewed: Interviews: Title: Date/Time: Comments:
3.2. Is there evidence of hospital leadership's involvement with and knowledge of the transplant QAPI program?		Choose an item.		Description:
3.3 Can the transplant leadership provide evidence of QAPI monitoring for each service related to clinical care? (*Business only contracts not required*)		Choose an item.		Comments:
3.4 Is there evidence that the hospital's governing body is involved in QAPI activities? *(evidence may be found in QAPI meeting minutes, MEC minutes or hospital leadership reports)* **Yes: _____ No:_____**	3.4a Approved the QAPI program indicators selected and the frequency of data collection?	Choose an item.		Comments:
	3.4b Ensures the QAPI program annually determines the number of distinct QAPI performance improvement projects to be conducted in the coming year?			
	3.4c Actively reviews the results of QAPI data collection, analyses, activities, projects and makes decisions based on such review?			
3.5 Describe how hospital leadership allocates resources to the transplant program to conduct QAPI activities. (*i.e., staff training, time away from normal duties for QAPI activities, administrative assistance***)**		Choose an item.		Comments:

PART 4: FEEDBACK, DATA SYSTEMS AND MONITORING

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

Step 1: Identify a measure/indicator for each phase of transplant care for recipients and living donors (if the program has living donation services). Fill in the grid below to ensure that measures/indicators have been implemented in relation to each phase of transplant care.

Step 2: Select one (1) indicator from the grid below for each phase (for a total of 3) and conduct tracer activities to answer the following multipart questions.

Focus on indicators that have been in place long enough for most questions to be applicable. *The **TRACER** methodology will allow for an in-depth review of the indicator from dashboard/scorecard reports back to and through indicator measurement and development.*

TRACER INDICATOR SELECTION (PROCESS AND OUTCOME MEASURES)

PROCESS MEASURES (measures that reflect sequential steps to complete a task)			
PATIENT TYPE	PRE-TRANSPLANT / EVALUATION	PROCEDURE	POST PROCEDURE (DISCHARGE PLANNING)
RECIPIENT			
LIVING DONOR (*if applicable*)			
OUTCOME MEASURES (measures that relate to a result or end of care)			
PATIENT TYPE	PRE-TRANSPLANT / EVALUATION	PROCEDURE	POST PROCEDURE (DISCHARGE PLANNING)
RECIPIENT			
LIVING DONOR (*if applicable*)			

INDICATOR TRACER	**PRE PHASE Indicator #1**	**PROCEDURE PHASE Indicator #2**	**POST PHASE Indicator #3**
Insert the selected indicator from the grid above to be reviewed: *(ensure numerator and denominator is rational)*			

Elements to be Assessed	**Yes or No**		**Yes or No**		**Yes or No**	
4.1 Is the program using objective measures to evaluate the program's performance related to activities and outcomes? *(programs should have indicators related to pre-transplant / living donor evaluation phase, procedure phase and post procedure / discharge planning phase)*	Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.
	Comments		Comments		Comments	

Elements to be Assessed	Yes or No	Yes or No	Yes or No
4.2 Is the indicator defined and understood by all transplant staff?	Choose an item. / Choose an item. Comments	Choose an item. / Choose an item. Comments	Choose an item. / Choose an item. Comments
4.3 Describe what the indicator is based upon. (*high risk, high volume, problem prone issues, best practices or benchmarks, guidelines from a nationally recognized research organization, hospital specific evidence, peer-reviewed research, internal targets/goals, etc.*)	Description:	Description:	Description:
4.4 Is the scope of the indicator specific to transplant patients and not general hospital patients? (e.g., falls, surgical site infections, medication errors).	Choose an item. Comments	Choose an item. Comments	Choose an item. Comments
4.5 Is appropriate data being captured for selected indicator? (data sources, frequency, type and unit of measure, method of collection) *(does the data answer/fit the indicator)*	Choose an item. Comments	Choose an item. Comments	Choose an item. Comments
4.6 Is there evidence of late, incomplete, or incorrect data collection? *(example: missing data on dashboards, gaps in graphs/charts)*	Choose an item. Comments	Choose an item. Comments	Choose an item. Comments
4.7 How does the program ensure data reliability? (if more than one person is collecting) *(is there cross training, cross coverage, provided education)*	Choose an item. Comments	Choose an item. Comments	Choose an item. Comments
4.8 Did the program collect the data they said they were going to? *(look for raw data ; something more substantive than charts and graphs)*	Choose an item. Comments	Choose an item. Comments	Choose an item. Comments
4.9 Are the collected data analyzed to explain improvements, deficits, or other conclusions?	Choose an item. Comments	Choose an item. Comments	Choose an item. Comments

Elements to be Assessed	Yes or No	Yes or No	Yes or No
4.10 *When feasible*, **are aggregated data broken down into subsets that allow comparison of performance within the program?** *(i.e., individual surgeon graft loss, graft loss by patient age/sex, waitlist denials by age/sex/demographics)*	Choose an item.	Choose an item.	Choose an item.
	Comments	Comments	Comments
4.11. Is there evidence that the program took action based on the analysis of collected data?	Choose an item.	Choose an item.	Choose an item.
	Comments	Comments	Comments
4.12 Are interventions or actions evaluated for success?	Choose an item.	Choose an item.	Choose an item.
	Comments	Comments	Comments
4.13 If interventions taken were not successful, were new interventions developed?	Choose an item.	Choose an item.	Choose an item.
	Comments	Comments	Comments
4.14 If interventions were successful, how does the program determine the improvement was sustainable?	Choose an item.	Choose an item.	Choose an item.
	Comments	Comments	Comments

PART 5: PERFORMANCE IMPROVEMENT ACTIVITIES TRACER

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

Elements to be Assessed	Yes	No	Surveyor Notes
5.2 Can the program provide evidence that its improvement activities focus on areas that are high risk (severity**), high volume (**incidence or prevalence**), or problem-prone?**	Choose an item.		Documents Reviewed: Interviews: Title: Date/Time: Comments:
5.1 Can the program provide evidence that it conducts transplant specific performance improvement projects?	Choose an item.		Documents Reviewed: Interviews: Title: Date/Time:

Elements to be Assessed		Yes	No	Surveyor Notes
				Comments:
5.3 Do the performance improvement projects reflect the scope and complexity of the transplant program's services and operations? *(do the projects seem appropriate for the program size and the number of issues the program is dealing with)*		Choose an item.		Comments:
5.4 Does the project include multi-disciplinary team members, transplant leadership members and *where feasible***, hospital leadership members?**		Choose an item.		Comments:
5.5 Can the program provide evidence showing why each project was selected?		Choose an item.		Documents Reviewed: Interviews: Title: Date/Time: Comments:
5.6 Do performance improvement projects (PIPs) include the core components necessary for the transplant program to take action and sustain improvement? **Yes:____** **No: _____**	**5.6a** Is there documentation that a problem or opportunity for improvement was identified and defined?	Choose an item.		Documents Reviewed: Interviews: Title: Date/Time: Comments:
	5.6b Is there documentation that goals were established for the project?	Choose an item.		
	5.6c Is there evidence that QAPI tools were selected and utilized as defined by the program?	Choose an item.		
	5.6d Is there documentation that data was selected and a method for collection defined?	Choose an item.		
	5.6e Is there evidence that data was collected as defined?	Choose an item.		

Elements to be Assessed		Yes	No	Surveyor Notes
	5.6f Was the data analyzed as defined?	Choose an item.		
	5.6g Is there evidence that improvement actions were implemented?	Choose an item.		
	5.6h Is there documentation that monitoring of improvement actions occurred?	Choose an item.		
	5.6i Is there documentation that follow-up analysis of implemented actions and data were conducted to determine if the improvements were sustained?	Choose an item.		

PART 6: ADVERSE EVENT (AE) TRACER

Regulation*: A transplant program 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 programs, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; and unintended transmission of infectious disease to a recipient."*

Elements to be Assessed	Yes	No	Surveyor Notes
6.1 Are there written adverse event (AE) policies and procedures specific to transplant? *(transplant programs often follow the hospital process and definition. If so, determine how AE policies are specific to transplant and ensure communication between hospital and transplant is defined)*	Choose an item.		Documents Reviewed: Interviews: Title: Date/Time: Comments:
6.2 Are AEs evaluated according to policies and procedures?	Choose an item.		Comments:
6.3 Can transplant staff describe what is meant by an adverse event (AE) in transplant?	Choose an item.		Interviews: Title: Date/Time: Comments:

Elements to be Assessed		Yes	No	Surveyor Notes
6.4 Can transplant staff explain how and/or to whom they report an adverse event (AE)?		Choose an item.		Interviews: Title: Date/Time: Comments:
6.5 Does the hospital/program employ methods, *in addition to staff incident reporting***, to identify possible adverse events?**		Choose an item.		Comments:
6.6 Can the program provide evidence that adverse events identified through staff reports are being addressed?		Choose an item.		Documents Reviewed: Comments:
6.7 Does the written adverse event policy address the following communication and reporting structures?	**6.7a** For each organ type. (*approved and being surveyed*)	Choose an item.		Comments:
	6.7b Staff reporting and communication methods within the transplant program and hospital.	Choose an item.		
	6.7c Process for disclosure of AE's to the patient(*s*) (*or family*).	Choose an item.		
	6.7d Process and timeline for reporting adverse events to required public, state and federal agencies. (*OPO, OPTN, State, CMS, etc.*)	Choose an item.		
	6.7e Is there evidence that the transplant program has adopted policies supporting a non-punitive approach to staff reporting of events and situations they consider unsafe?	Choose an item.		
6.8 Does the written policy address/categorize the severity of events that are tracked and analyzed? (**all events** outside of normal and routine care, *no matter the definition*, should have a minimal screening		Choose an item.		Comments:

Elements to be Assessed		Yes	No	Surveyor Notes
to determine if a full causal analysis shall be conducted – *events may range from falls, surgical conversions to open, medication events, infections and death within 1 year of transplant*)				
6.9 Does the program have a defined analysis method / process for adverse events (AE)? (*Verify the policy or list of those events that will be reviewed include: death, patient harm, loss of function or any item that has the POTENTIAL to cause death, loss of function or harm to a patient.*)	**6.9a** Who is responsible for conducting the AE analysis.	Choose an item.		Comments:
	6.9b What types of events that will be reviewed.	Choose an item.		
	6.9c Actions taken to prevent similar adverse events.	Choose an item.		
	6.9d Method for follow up and evaluating actions taken.	Choose an item.		
6.10 Describe which method(s) will be utilized to analyze adverse events (AE's).		Description of tools:		
6.11 Has the program/hospital conducted any causal analyses in the past 24 months? *If yes – complete causal analysis tracer below*		Choose an item.		Comments:
6.12 Did the analysis of the adverse event address all appropriate areas across the continuum of care? Causal Analysis *(i.e., no unanswered questions or unresolved conflicting information - the findings were explained, and the program considered underlying systems, processes and review of literature)*		Choose an item.		Comments:

Elements to be Assessed	Yes	No	Surveyor Notes
6.13 Has the program/hospital reviewed or compared completed adverse event analysis to similar past events in an attempt to identify links or causal relationships to event outcomes?	Choose an item.		Comments:

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

Instructions: If the answer to Question 6.11 is "YES", select three (3) (*or as many as available*) causal analyses the program has completed for adverse events or near misses (close calls) during the last 24 months. Analyses may be of a single event or a group of similar types of events. **ANSWER EACH QUESTION FOR EACH ANALYSIS**

CAUSAL ANALYSIS TRACER

Elements to be Assessed		Yes / No	Yes / No	Yes / No
CAUSAL ANALYSIS TRACER		**Causal Analysis #1**	**Causal Analysis #2**	**Causal Analysis #3**
Write in selected causal analysis. (*use a identifier code or other means to avoid capturing PHI or identifiable information on this worksheet*).				
6.14 Did the analysis identify: *(select all that may apply)*	**6.14a** Primary root cause(s).	Choose an item.	Choose an item.	Choose an item.
	6.14b Special or underlying cause(s).	Choose an item.	Choose an item.	Choose an item.
	6.14c Contributing factors to the event. *(ensure that the entire continuum of care was considered in the review)*	Choose an item.	Choose an item.	Choose an item.
6.15 Did the program thoroughly document the causal analysis? **Yes:____** **No: _____**	**6.15a** Specific chronology of the incident.	Choose an item.	Choose an item.	Choose an item.
	6.15b Interview with all relevant staff involved.	Choose an item.	Choose an item.	Choose an item.
	6.15c Interview with relevant external parties. (e.g., OPO, referring physicians)	Choose an item.	Choose an item.	Choose an item.
	6.15d Review of all relevant policies	Choose an item.	Choose an item.	Choose an item.

Elements to be Assessed		**Yes / No**	**Yes / No**	**Yes / No**
	and procedures and identification of any variation that occurred.			
	6.15e Any contextual factors related to the environment. *(e.g., staff schedules, bed availability, equipment, systems, other human factors)*	Choose an item.	Choose an item.	Choose an item.
	6.15f Rate of occurrence and common factors for the same / similar event(s)?	Choose an item.	Choose an item.	Choose an item.
	Comments for 6.15	Comments	Comments	Comments
6.16 Did individual(s) with authority to make decisions about the transplant program participate in the analysis of the adverse event?		Choose an item.	Choose an item.	Choose an item.
		Comments	Comments	Comments
6.17 Are there specific recommendations/action steps that resulted from the analysis?		Choose an item.	Choose an item.	Choose an item.
		Comments	Comments	Comments
6.18 Were potential areas to prevent repeat incidences identified? *(if after analysis it was determined that no opportunities for improvement exist – describe why)*		Choose an item.	Choose an item.	Choose an item.
		Description:	Description:	Description:

Elements to be Assessed	**Yes / No**	**Yes / No**	**Yes / No**
6.19 Has the program developed and implemented preventive actions based on the analysis in at least one area?	Choose an item.	Choose an item.	Choose an item.
	Comments	Comments	Comments
6.20 Has the program evaluated the impact of the preventative actions, including tracking re-occurrences of similar events? *(did the actions or results of the analysis generate a QA / PI measure or indicator – closing the QA loop)*	Choose an item.	Choose an item.	Choose an item.
	Comments	Comments	Comments
6.21 If intervention(s) did not meet established goals; did the program implement a revised intervention / action?	Choose an item.	Choose an item.	Choose an item.
	Comments	Comments	Comments
6.22 Has the program implemented preventative actions determined to be effective utilizing similar processes / at similar risk? *(was the actions included in the QA/PI plan, risk assessment or program evaluation)*	Choose an item.	Choose an item.	Choose an item.
	Comments	Comments	Comments