"FQAPI Worksheet Overview"

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Centers for Medicare and Medicaid Services

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

Centers for Medicare & Medicaid Services (CMS)

TRANSPLANT PROGRAM QUALITY WEBINAR SERIES

Introduction to the Focused Quality Assessment and Performance Improvement (FQAPI) Survey Worksheet for Transplant Programs

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CMS Webinar Series
Transplant Centers

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

Disclaimer

- This training consists of Quality concepts, foundational and historical perspectives of Quality Assessment and Performance Improvement methodologies as they were originally developed.
- There are many definitions of healthcare quality and many methods and tools to address quality assessment and process improvement activities. Today, organizations often blend the best quality concepts and tools to provide for a more nimble and individualized quality program.
- CMS is not prescriptive. This training does not support or advocate any particular method or tool. This training fully supports that the QAPI process includes data driven decisions that will sustain improvement leading to improved patient outcomes.

Purpose and Objectives

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

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

1. Identify the key sections of the Transplant FQAPI worksheet;
2. Identify the characteristics of a written, comprehensive, implemented Transplant QAPI program as identified in the worksheet;
3. Discuss the integration and bi-directional communication needs between transplant and hospital QAPI programs.

Why the FQAPI Focus?

- Improving patient outcomes and patient safety is the fundamental goal of all QAPI regulations and the survey for compliance
- CMS identified the need to assist States in oversight of Transplant QAPI
- Review of transplant patient outcomes of mortality and graft failure of programs applying for mitigating factors since 2007, indicated the need to globally focus on transplant quality and patient safety

Worksheet Survey Process

Provides for a complete structured review that verifies a comprehensive quality program has been developed, implemented and is effective including:

- Identification of a method for discovery of issues, referral of issues for QAPI interventions and corrective action plans;
- Recognition of high risk, high volume, or problem-prone areas being addressed in the QAPI program;
- Initiation of a QAPI process when concerns are identified;
- Appropriate management of Adverse Events.

The Survey Process is Standardized by using the worksheet

- A 1 ½ to 2 day survey, “unannounced”
- Limited to the Conditions of Participation (CoPs) at §482.96, the condition and five related requirements
- CoP deficiencies other than QAPI in this survey are referred to the appropriate CMS RO
- Performed by CMS contractor according to CMS approved protocol
- Recently standardized to one contractor (HMS) for all 50 states/CMS regions
- Each organ program is surveyed separately
- Two types:
  - Focused QAPI survey only (two surveyors) or
  - “Joint” survey with Initial or Re-approval Transplant Survey (one or more surveyors additional depending on number of programs)

Survey Process

Criteria for program selection for Notification of full/actual FQAPI Survey

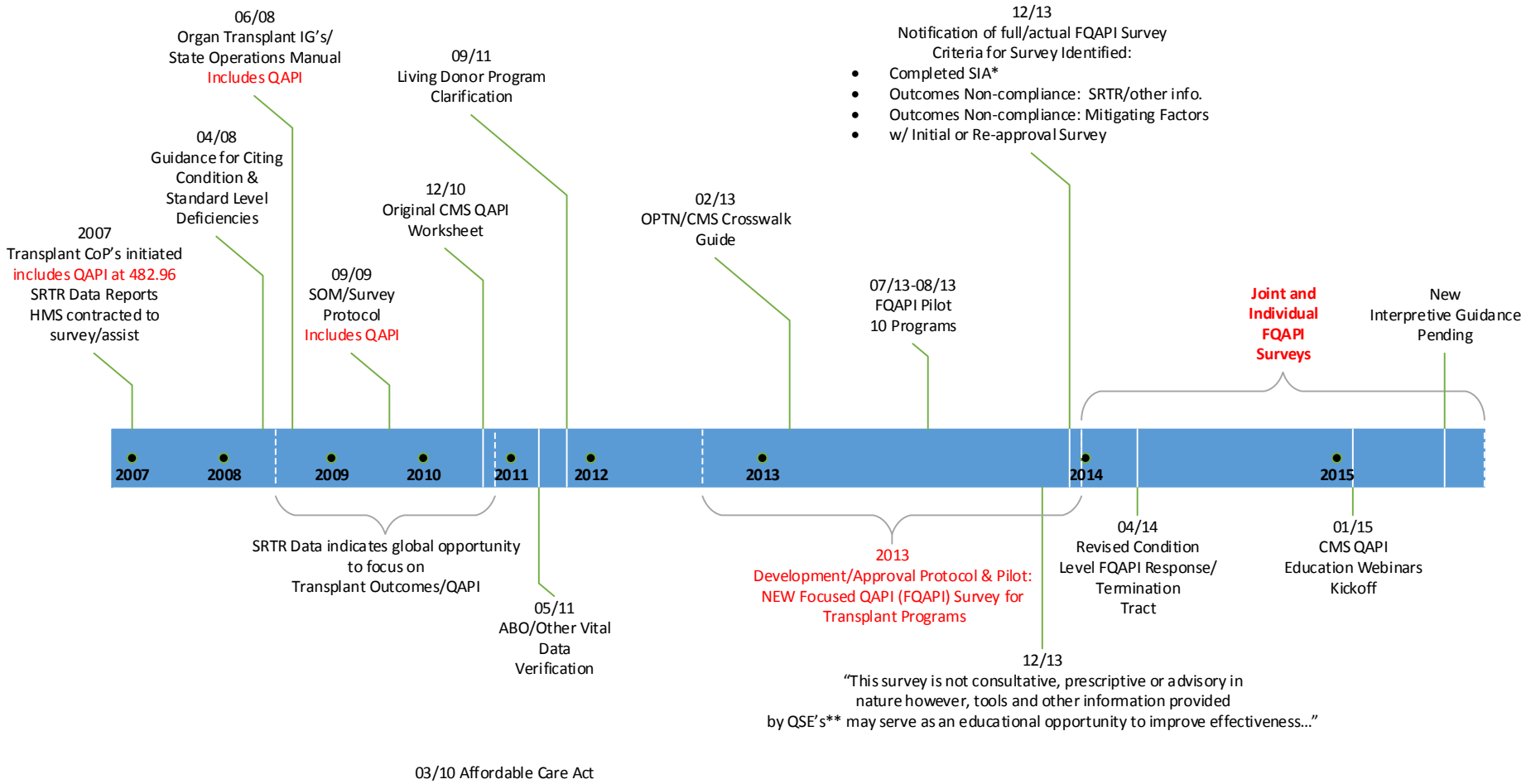
- Completed Systems Improvement Agreement (SIA)
- Outcomes Non-compliance: Scientific Registry of Transplant Recipient (SRTR)/other information
- Outcomes Non-compliance: Mitigating Factors
- In conjunction with Initial or Re-approval Survey
- Complaints

Worksheet Guided by Survey Protocol

- Research & Development process
  - CMS CoPs and other precedents (Hospital, Long Term Care, etc.)
  - Best practices
  - Standardized worksheet based on protocol
- Computerized process
- Pilot (July/Aug. 2013)
- Implementation (Jan. 2014)

History: QAPI CoPs are not new…

An Eight Year Journey for Transplant QAPI *



*SIA=Systems Improvement Agreement
**QSE's=Quality Survey Educators

Worksheet Methodology

- Primarily retrospective review:
  - Transplant and Hospital QAPI documentation
  - Observational component as needed
  - "Tracer" methodology tracks improvement opportunities through the entire QAPI cycle as DEFINED BY THE ORGANIZATION
    - Improvement projects are "traced"
    - Adverse events are "traced"

Survey Worksheet Methods

Surveyor worksheet provides for:

- Review according to the INDIVIDUAL PROGRAM-specific plan, policies and procedure
- Documentation of “triggers” in written materials
- Observations and attendance during rounds or meetings
- Medical record reviews as needed (no set “sample” requirement)
- Patient interviews if needed
- Tracing of PI Projects and Adverse Events

REQUESTED ITEMS FOR REVIEW

Documents Requested Are Reflected in Worksheet Content

1. ☐ An organizational chart of the transplant program and how the transplant QAPI program fits within the hospital structure;
2. ☐ The written copy *(2 copies – 1 for each surveyor)* of the Transplant programs Quality Assessment and Performance Improvement (QAPI) plan;
3. ☐ The written copy *(2 copies – 1 for each surveyor)* of the Hospitals Quality Assessment and Performance Improvement (QAPI) plan;
4. ☐ QAPI policies, processes and procedures if different than above (*review how they are created and maintained*);
5. ☐ Identification of the responsible staff over the QAPI program and their qualifications;
6. ☐ Any QAPI reports, records and minutes of QAPI committee meetings, or consultation reports about the QAPI program;
7. ☐ Log of Patient Complaints/Concerns/Grievances for the past 24 months and corresponding documentation of investigation;
8. ☐ Log of any reported adverse events for the past 24 months and documentation of the investigation, analysis of events, and any follow-up action taken;
9. ☐ All indicators, measures , monitored items and items under surveillance for the past 3 years (all 3 phases of transplant / living donations);
10. ☐ Quality Reports: a) dashboards; b) scorecards; c) benchmarks; d) comparative national reports ; e) data resources utilized;
11. ☐ Policy / Protocol on complaints, adverse events and other occurrence or variance reporting issues *(2 copies – 1 for each surveyor)*;
12. ☐ All QAPI related documents (*investigations, corrective action plans, performance improvement projects, education curriculum, indicator selection criteria, hospital executive leadership involvement in program functions)*;
13. ☐ List of all transplant associated professional personnel and their titles;
14. ☐ List of and copy of any contracts with external parties that the hospital or transplant program have for services relevant to transplantation;

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

12/18/13

SURVEY WORKSHEET

PART 2: QAPI DESIGN AND SCOPE

***CONDITION Level 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. (**Tag X099**)*

Elements to be Assessed		Yes / No	Surveyor Notes
2.1 Does the Transplant program have a written comprehensive QAPI program:	2.1a Is there a written QAPI program?	Choose an item.	List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):
	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 (*activities*) **processes and outcomes**?	Choose an item.	
	2.1d Is the program implemented?	Choose an item.	
	2.1e Has the QAPI program defined what Quality methods / tools will be used for QAPI activities?	Choose an item.	Identify the methods / tools identified in the program:
2.2 Does the QAPI program include evaluation of all 3 phases (Continuum of Care) for transplant and living donation? *(pre, procedure, post) (as appropriate)*		Choose an item.	
2.3 Does the QAPI plan contain the 5 key elements of a Quality structure:	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.	

SURVEY WORKSHEET

2.4 Is the program Data Driven?	Choose an item.	
2.5 Are Benchmarks and Goals established using evidence based practices, nationally recognized materials or the most current medical knowledge?	Choose an item.	

Elements to be Assessed	Yes / No	Surveyor Notes
2.6 Are QAPI activities focused on process improvement*(s)* and patient outcomes?	Choose an item.	
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.	
2.8 TRANSPLANT QAPI COMMITTEE: **Does the written program identify the existence of a committee, list committee membership by staff role/responsibility and identify the purpose of the committee?**	Choose an item.	List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):
2.9 Does the QAPI committee meet according to programs policy and procedures? ☐ **Monthly** ☐ **Quarterly** ☐ **Other** _____	Choose an item.	

SURVEY WORKSHEET

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.	List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):
2.11 If there are multiple transplant QAPI committees, QAPI sub-groups or a QAPI Steering committee / council:	2.11a Is there a description of group's purpose?	Choose an item.	List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):
	2.11b Is the communication (*reporting structure*) between the QAPI group's defined?	Choose an item.	

Elements to be Assessed		Yes / No	Surveyor Notes
(enter N/A if question does not apply)	2.11c Do the group's meet as defined in the written program? ☐ Monthly ☐ Quarterly ☐ Other	Choose an item.	
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.)*		Description:	
2.13 Describe how the hospital's QAPI information is communicated to the transplant QAPI program. (*i.e. meetings, memos, emails, reports, etc.)*		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.)*		Description:	
2.15 QUALITY ASSESSMENT	2.15a Are the selected measures	Choose an	List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):

SURVEY WORKSHEET

2.15 QUALITY ASSESSMENT **Is there a process defined to determine what objective measures the transplant QAPI program will look at on a regular basis?**	2.15a Are the selected measures **OBJECTIVE**? *(i.e.,* fact based related to patient care processes and outcomes*; not financial in nature, logistical in nature or ONLY the minimum required by regulation to be maintained)*	Choose an item.	List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):
	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 across the transplant continuum of care?	Choose an item.	
2.16 PERFORMANCE IMPROVEMENT **Is there a defined process to identify and track performance improvement opportunities?**	2.16a What process has been determined?	*(document the process / methods chosen: computer, paper, hotline, chart audits, data analysis, etc.)*	
	2.16b Discuss how this process/method connects to the QAPI philosophy and organizational culture?	Discussion:	

Survey Application

Interpretive Guidelines

X099 §482.96 Condition: **DEVELOP, IMPLEMENT & MAINTAIN** WRITTEN COMPREHENSIVE DATA-DRIVEN QAPI PROGRAM

The transplant program's portion of the QAPI program must:

Specifically address the individual components of the transplant program; and

- **Include the participation of the transplant program's key personnel** (Director, primary transplant surgeon, primary transplant physician, clinical transplant coordinator, and nursing personnel). Examples of their participation include participation in QAPI committee meetings, presenting topics to the QAPI committee, authoring reports or updates for the QAPI committee about the program's status.

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

Potential Findings

- Participation of key team members is not evident
- Surgeon or Physician rarely attend
- Key members are not present when specialty materials are discussed
- Meeting minutes do not reflect member attendance
- There are no minutes of meetings ("but we have email evites")
- Committee meetings are frequently cancelled and never re-scheduled
- QAPI activities do not cover all aspects of the team members involvement (pharmacy, social services, etc.)

Note: If a given discipline is not specifically addressed, do not cite as a deficiency as long as: (1) the overall intent is still met that the QAPI program is comprehensive; and (2) there is no evidence in the survey that would identify this area as problematic.

SURVEY WORKSHEET

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?		Choose an item.	List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):
3.1a Has the hospital / transplant program maintained and made available for surveyor evidence of its reviewed QAPI program and other requested materials, including date(s) of review?		Choose an item.	
3.2. Is there evidence of hospital leadership's involvement with and knowledge of the transplant QAPI program?		Choose an item.	
3.3 Can the transplant leadership provide evidence of QAPI monitoring for each service related to clinical care across the Continuum of Care? *(including: inpatient, outpatient, etc.)*		Choose an item.	
3.4 Is there evidence that the hospital's governing body is involved in QAPI activities?	3.4a Approved the QAPI program indicators selected and the frequency of data collection?	Choose an item.	List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):
	3.4b Ensures the QAPI program annually determines the number of distinct QAPI performance improvement projects to be conducted in the coming year?	Choose an item.	
	3.4c Actively reviews the results of QAPI data collection, analyses, activities, projects and makes decisions based on such review?	Choose an item.	
3.5 Describe how hospital leadership allocates resources to the transplant program to conduct QAPI activities.		Description:	

GOVERNANCE & LEADERSHIP

I – CORPORATE ACCOUNTABILITY
- SENIOR LEADERSHIP
- MIDDLE MANAGEMENT
- FRONT LINE STAFF

II – OWNERSHIP
- QAPI COMMITTEE
- QAPI CHAIRPERSON
- CLINICAL STAFF
- SUPPORT STAFF
- CUSTOMER

III - CULTURE
- CONTINUOUS IMPROVEMENT FOCUS
- ORGANIZATIONAL ETHICS
- ORGANIZATION FUNCTIONS
- COMMUNICATION
- TRANSPARENCY
- MANAGING CHANGE

IV – INTEGRATED DELIVERY SYSTEM
- CONTINUUM OF CARE
- PATIENT CENTERED
- PURSUIT OF EXCELLENCE

SURVEY WORKSHEET

PART 4: FEEDBACK, DATA SYSTEMS AND MONITORING

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

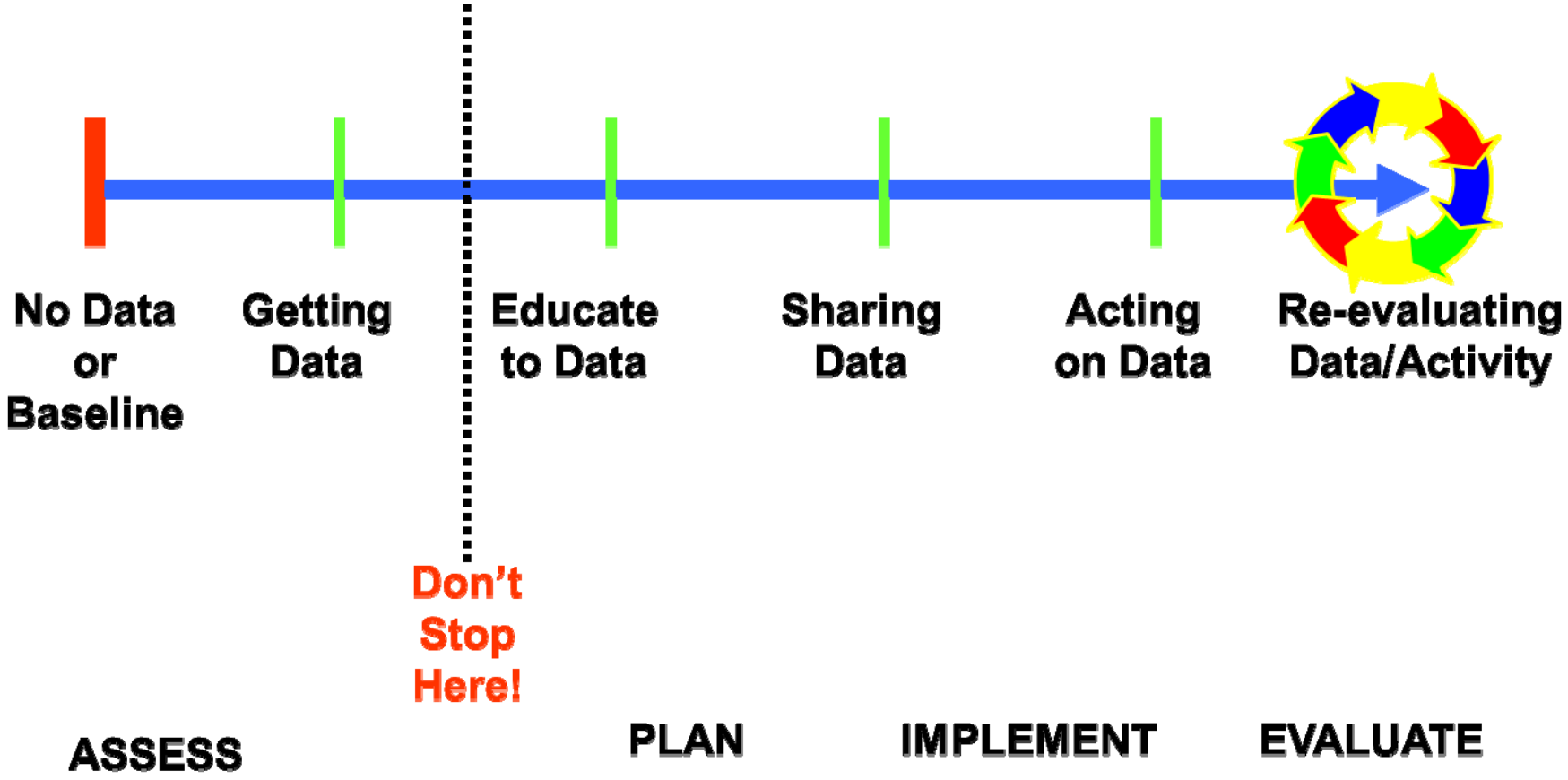
Focus on indicators that have been in place long enough for most questions to be applicable. *The TRACER methodology will allow for an in-depth review of the indicator from dashboard/scorecard reports back to and through indicator measurement and development.*

TRACER INDICATOR SELECTION (PROCESS AND OUTCOME MEASURES)

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

INDICATOR TRACER	**Indicator #1**	**Indicator #2**	**Indicator #3**
Insert the selected indicator from the grid to be traced: *(ensure numerator and denominator is rational)*			

Where is the program in the process of tracking outcomes & quality issues?



Survey Application:

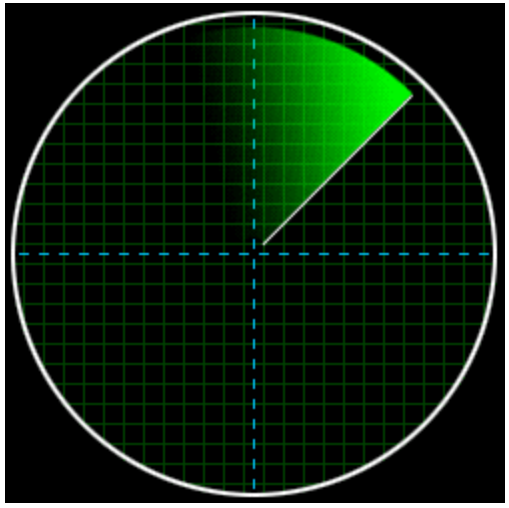
The program needs defined data systems, methods of monitoring and reporting, to include :

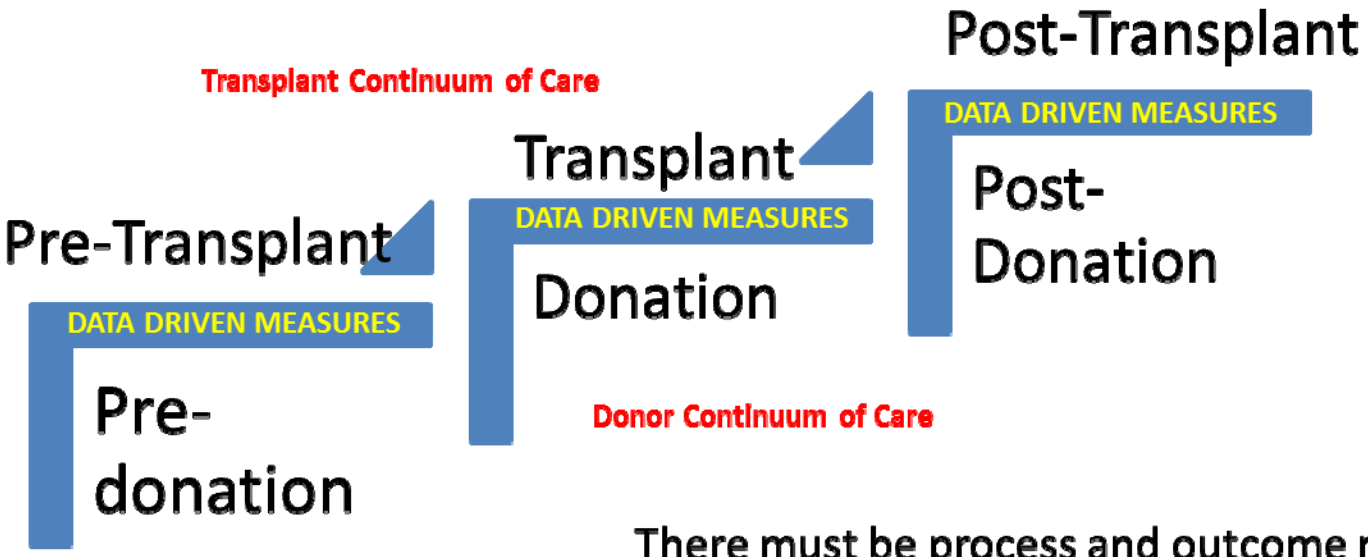
- Bi-directional communications structure (transplant/hospital; hospital/transplant)
- Proactive identification of quality indicators
- Effective surveillance to identify and respond to adverse events
- Ongoing data collection, tracking, and analysis across the continuum
- Data driven, defined and meaningful measures
- Benchmarks
- Targets/goals

WHAT'S ON THE RADAR

CURRENT IMPORTANT ISSUES IN THE WORLD OF TRANSPLANTATION

- IMMUNOSUPPRESSION
- SELECTION CRITERIA
- GRAFT SURVIVAL
- CARDIAC EVENTS
- INFECTIONS
- TECHNICAL COMPETENCY OF HARVEST TEAM
- PROPHYLAXIS RELATED TO IMMUNOSUPPRESSION
- SEROLOGY TESTING
- DELAYED GRAFT FUNCTION
- PATIENT EDUCATION
- FOLLOW UP VISITS
- RE-ADMISSIONS
- WAITLIST MANAGEMENT
- NUTRITION
- BLEEDING – QUALITY OF ORGAN
- TEAM STRUCTURE AND TRAINING





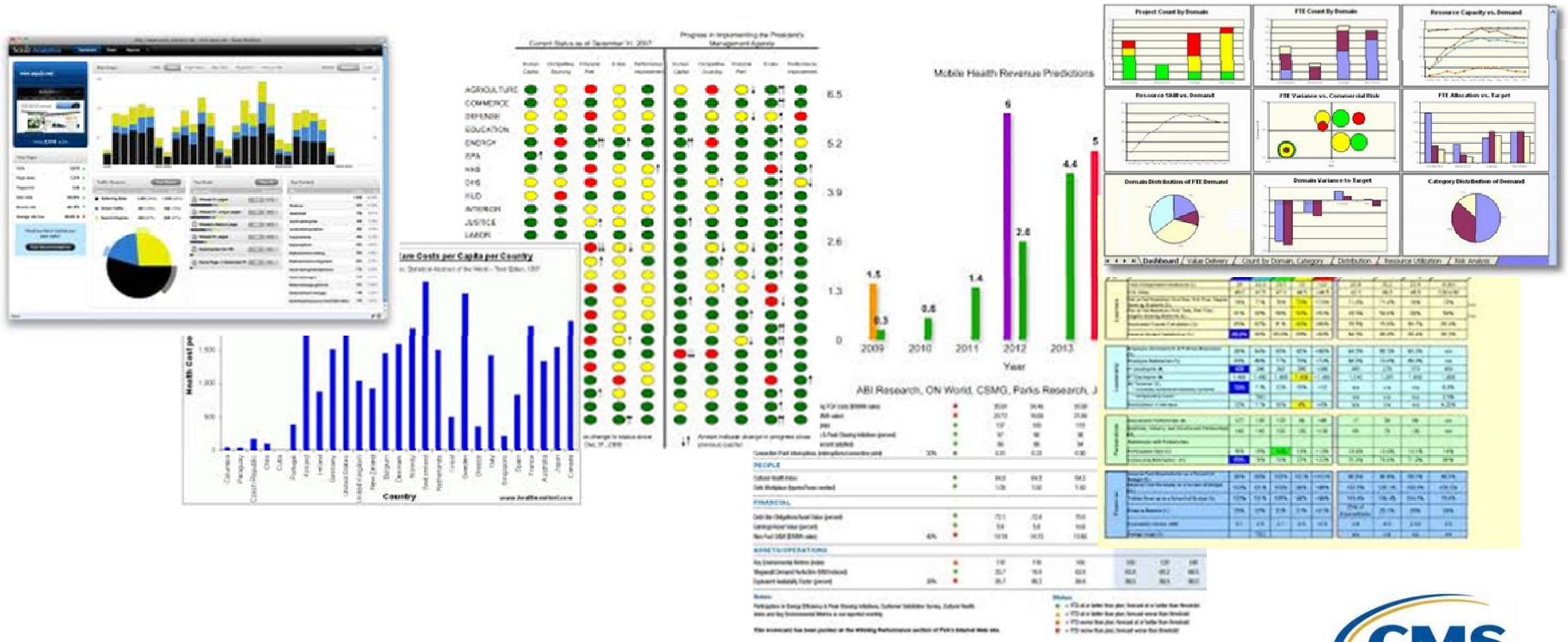
There must be process and outcome measures in all phases of transplant and living donation

TRANSPLANT	PHASE
	PROCESS – PRE Transplant
	OUTCOME – PRE Transplant
	PROCESS – Transplant
	OUTCOME – Transplant
	PROCESS – POST Transplant
	OUTCOME – POST Transplant

Living Donation	PHASE
	PROCESS – PRE Donation
	OUTCOME – PRE Donation
	PROCESS – Donation
	OUTCOME – Donation
	PROCESS – POST Donation
	OUTCOME – POST Donation

DRIP, DRIP, DRIP

Consider if the program is
Data **R**ich **I**nformation **P**oor (**DRIP**)
or are they actually using the
information to make improvements?



Tracking Improvements

A means to track improvements IS required

Benchmarking, Dashboards and Scorecards are <u>not</u> interchangeable terms/items.
Is there <u>analysis, evidence of actions</u> taken in response and sustained activity?

SCORECARD EXAMPLE

Tabular Format, compares to target/benchmark, often color coded to "stoplight" format (Green=target met; Yellow=caution; Red=Target not met)

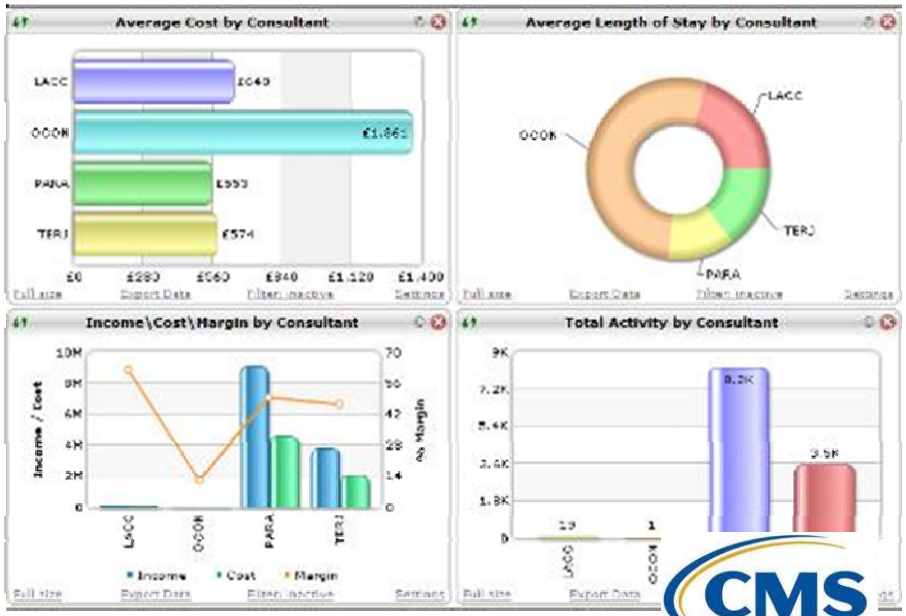
Exhibit 2

National Scorecard on U.S. Health System Performance, 2011:
Scores on 42 Key Performance Indicators

	Indicator	U.S. Average Rate*	Benchmark	Benchmark Rate*	Score: Ratio of U.S. to Benchmark
	OVERALL SCORE				**64**
	HEALTHY LIVES				
1	Mortality amenable to health care, deaths per 100,000 population	96	Top 3 of 16 countries	57	60
2	Infant mortality, deaths per 1,000 live births	6.8	Top 10% states	4.7	69
3	Healthy life expectancy at age 60, years (average of two ratios)	Various	Various	Various	88
4	Adults ages 18–64 limited in any activities because of physical, mental, or emotional problems	18.4	Top 10% states	11.5	63
5	Children ages 6–17 missed 11 or more school days because of illness or injury	5.8	Top 10% states	3.8	66
6	Adults who smoke	17.0	Top 10% states	12.2	72
7	Children ages 10–17 who are overweight or obese	32	Top 10% states	23	72
	QUALITY				
8	Adults received recommended screening and preventive care	51	Target	80	64
9	Children received recommended immunizations and preventive care (average of two ratios)	Various	Various	Various	88
10	Adults and children needed mental health care and received treatment (average of two ratios)	Various	Various	Various	75
11	Chronic disease under control (average of two ratios)	Various	Various	Various	81
12	Hospitalized patients received recommended care for heart attack, heart failure, and pneumonia	96	Top hospitals	100	96
13	Surgical patients received appropriate care to prevent complications	96	Top hospitals	100	96
14	Adults ages 19–64 with an accessible primary care provider	56	65+ yrs, high income	77	73
15	Children with a medical home	58	Top 10% states	68	85
16	Care coordination at hospital discharge (average of three ratios)	Various	Various	Various	80
17	Nursing homes: hospital admissions and readmissions among residents (average of two ratios)	Various	Various	Various	61
18	Home health care: hospital admissions among home health patients	29	Top 25% agencies	17	60
19	Sicker adults reported medical, medication, or lab test error	32	Best of 8 countries	16	50
20	Unsafe drug use (average of three ratios)	Various	Various	Various	62
21	Nursing home residents with pressure sores (average of two ratios)	Various	Various	Various	68
22	Hospital-standardized mortality ratios, actual to expected deaths	73	Top 10% hospitals	68	94
23	Risk-adjusted 30-day hospital mortality rates for heart attack, heart failure, and pneumonia (average of three ratios)	Various	Various	Various	85
24	Sicker adults able to see doctor on same/next day when sick or needed medical attention	43	Best of 8 countries	81	53
25	Sicker adults reported very/somewhat easy to get care after hours without going to the emergency room	37	Best of 8 countries	72	51
26	Adults whose health providers always listened carefully, explained things clearly, respected what they had to say, and spent enough time with them	57	90th %ile health plans	77	75
27	Sicker adults with chronic conditions received self-management plan	66	Best of 8 countries	66	100
28	Patient-centered hospital care (average of three ratios)	Various	Various	Various	88
29	Home health care patients whose ability to walk or move around improved	47	Top 25% agencies	58	81

DASHBOARD EXAMPLE

Multiple copies of "data over time" graphs with snapshot analysis, often with action/evaluation noted



SURVEY WORKSHEET

INDICATOR TRACER	Indicator #1	Indicator #2	Indicator #3
Insert the selected indicator from the grid to be traced: *(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?	Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.
	Surveyor Notes:		*Surveyor Notes:*		*Surveyor Notes:*	
4.2 Is the indicator defined and understood by all transplant staff?	Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.	Choose an item.
4.3 Describe what the indicator is based upon.	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.		Choose an item.		Choose an item.	
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.		Choose an item.		Choose an item.	
4.6 Is there evidence of late, incomplete or incorrect data collection? *(example: missing data on dashboards, gaps in graphs/charts)*	Choose an item.		Choose an item.		Choose an item.	

SURVEY WORKSHEET

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.	Choose an item.	Choose an item.
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.	Choose an item.	Choose an item.
4.9 Are the collected data analyzed to explain improvements, deficits, or other conclusions?	Choose an item.	Choose an item.	Choose an item.
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.

• SURVEY WORKSHEET

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.
4.11a Is there evidence that the action(s) taken towards improvement were communicated (*education provided*) to staff throughout the entire continuum of care (inpatient, outpatient) as appropriate?	Choose an item.	Choose an item.	Choose an item.
4.12 Are interventions or actions evaluated for success?	Choose an item.	Choose an item.	Choose an item.
4.13 If interventions taken were not successful, were new interventions developed?	Choose an item.	Choose an item.	Choose an item.
4.14 If interventions were successful, how does the program determine the improvement was sustainable?	Choose an item.	Choose an item.	Choose an item.

• SURVEY WORKSHEET

PART 5: PERFORMANCE IMPROVEMENT ACTIVITIES TRACER

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

Elements to be Assessed	Yes	No	Surveyor Notes
5.1 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.		List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):
5.2 Can the program provide evidence that it conducts transplant specific performance improvement projects?	Choose an item.		

Elements to be Assessed	Yes	No	Surveyor Notes
5.3 Do the performance improvement projects reflect the scope and complexity of the transplant program's services and operations?	Choose an item.		
5.4 Does the project include multi-disciplinary team members, transplant leadership members and *where feasible,* hospital leadership members?	Choose an item.		
5.5 Can the program provide evidence showing why each project was selected?	Choose an item.		

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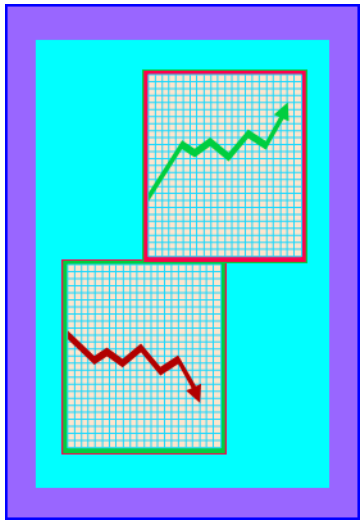
5.6 Do performance improvement projects (PIPs) include the core components necessary for the transplant program to take action and sustain improvement:	**5.6a** Is there documentation that a problem or opportunity for improvement was identified and defined?	Choose an item.	List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):
	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.	
	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.	

Elements to be Assessed		Yes / No	Surveyor Notes
	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.	

Did the program Define the Opportunity?

Types of Opportunities

- Defects/Errors
- Time/Delays
- Cost/Re-Work/Waste



Did the project want to increase or decrease occurrence?

482.96(a) Actions to Improve Performance/Tracking

"The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained."

Interventions must be evaluated and monitored for sustained change:

- How is success being measured?
- What is being measured?
- How are measures defined?
- Reported to (whom/where)?

482.96(a) Actions to Improve Performance/Tracking

- What does the written program say about sustaining improvement?
- Is there a documentation method to capture baseline performance, actions taken in response to analysis of performance and monitoring of sustained performance to target?
- Does the program use this method?
- Are there opportunities identified that do not have any follow up or data or associated QAPI activity?

SURVEY WORKSHEET

PART 6: ADVERSE EVENT (AE) TRACER

STANDARD Level 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. **(Tag X102)

Elements to be Assessed		Yes / No	Surveyor Notes
6.1 Are there written adverse event (AE) policies and procedures specific to transplant?		Choose an item.	List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):
6.2 Are AE evaluated according to policies and procedures?		Choose an item.	
6.3 Can transplant staff describe what is meant by an adverse event (AE) in transplant?		Choose an item.	
6.4 Can transplant staff explain how and/or to whom they report an adverse event (AE)?		Choose an item.	
6.5 Does the hospital/program employ methods, *in addition to staff incident reporting*, to identify possible adverse events?		Choose an item.	
6.6 Can the program provide evidence that adverse events identified through staff reports are being addressed?		Choose an item.	
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.	
	6.7b Staff reporting and communication methods within the transplant program and hospital.	Choose an item.	

SURVEY WORKSHEET

Elements to be Assessed		Yes	No	Surveyor Notes
	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?		Choose an item.		
6.9 Does the program have a defined analysis method / process for adverse events (AE) including:	6.9a Who is responsible for conducting the AE analysis.	Choose an item.		List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):
	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.		

SURVEY WORKSHEET

6.10 Describe which method(s) will be utilized to analyze adverse events (AE's).	Description of methods/tools:	
6.11 Has the program/hospital conducted any adverse event analysis in the past 24 months? *If yes – complete adverse event analysis tracer below* *If no – determine if the program had any deaths or graft failures. Is there another type of investigation / analysis performed for these events? (proceed with tracer to determine if deaths and graft failures attempt to identify the cause of the event)*	Choose an item.	
6.12 Did the analysis of the adverse event address all appropriate areas across the continuum of care? Adverse Event 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.	
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.	List Documents Reviewed (*Title, Approval Date and Date/Time reviewed*):

SURVEY WORKSHEET

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

ADVERSE EVENT TRACER ANALYSIS

Elements to be Assessed	Yes / No	Yes / No	Yes / No
ADVERSE EVENT TRACER	**Investigation #1**	**Investigation #2**	**Investigation #3**
Write in the selected investigation. (*use a identifier code or other means to avoid capturing PHI or identifiable information on this worksheet*).			

Elements to be Assessed		Yes / No	Yes / No	Yes / No
6.14 Did the thorough analysis identify: *(select all that may apply)*	6.14a Primary root cause(s).	Choose an item.	Choose an item.	Choose an item.
		Surveyor Notes:	*Surveyor Notes:*	*Surveyor Notes:*
	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.

SURVEY WORKSHEET

6.15 Did the program thoroughly document the root causes to include:	**6.15a** Specific chronology of the incident/event covering the entirety of the Continuum of Care.	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 and procedures and identification of any variation that occurred.	Choose an item.	Choose an item.	Choose an item.
	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.

SURVEY WORKSHEET

Elements to be Assessed	Yes / No	Yes / No	Yes / No
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.
6.17 Are there specific recommendations/action steps that resulted from the analysis?	Choose an item.	Choose an item.	Choose an item.
6.18 Were potential areas to <u>prevent</u> repeat incidences identified?	Choose an item.	Choose an item.	Choose an item.
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.

SURVEY WORKSHEET

6.20 Has the program evaluated the impact of the preventative actions, including tracking re-occurrences of similar events?	Choose an item.	Choose an item.	Choose an item.
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.
6.22 Has the program implemented preventative actions determined to be effective utilizing similar processes / at similar risk.	Choose an item.	Choose an item.	Choose an item.

Quality means doing it right when no one is looking.

Henry Ford

Lance Corporal Myles Kerr with 9 y.o. Brandon Fuchs finishing the Jeff Drenth Memorial 5K in Charlevoix, Michigan. The marine sacrificed his leading spot in the race after seeing the child was struggling to keep up. 200,000 twitter hits later, his response was, "I was just doing what any man would do." ABC News 08/01/13

QAPI Resources...

Contact/Organization			
Agency for Healthcare Research and Quality	Delmarva Foundation	MedWatch (FDA Safety Information and Adverse Event Reporting System)	Thomson Reuters top 100 hospitals
Agency for Health Care Research and Quality (AHRQ) patient safety information	FDA Patient Safety News	Missouri Center for Patient Safety	University Health System Consortium
AHRQ Health Care Innovations Exchange	Georgia Hospital Association Partnership for Health and Accountability	National Committee for Quality Assurance	United Network for Organ Sharing (UNOS)
Agency for Health Care Research and Quality Web M&M	Healthgrades	National Patient Safety Foundation	US News & World Report
American Hospital Association	Hospitals Compare	National Quality Forum (NQF)	USP Center for Advancement of Patient Safety (CAPS)
American Society of Healthcare Risk Management	Institute for Healthcare Improvement	National Safety Council	U.S. Pharmacopeia
PSNet - Patient Safety Network	The Institute for Safe Medication Practices	National Transportation Safety Board	Urgent Matters (Hospital Patient Flow)
American Society of Health-System Pharmacists	The Leapfrog Group for Patient Safety	New Jersey Patient Safety Newsletters, Alerts and Summary Reports	US Dept. of Veterans Affairs (VA) National Center for Patient Safety
The Anesthesia Patient Safety Foundation	Johns Hopkins University Quality & Safety Research Group	Oregon Patient Safety Commission	World Health Organization World Alliance for Patient Safety
Aviation Safety Reporting System	The Joint Commission	Organ Procurement and Transplantation Network (OPTN)	World Health Organization Surgical Checklist & Toolkit – Safe Surgery Saves Lives
California Hospital Patient Safety Organization	Joint Commission Collaborating Center for Patient Safety Solutions	Pennsylvania Patient Safety Authority	
Centers for Medicare & Medicaid Services	Maryland Health Care Commission	Premier	
Consumers'CHECKBOOK (Health and Healthcare)	Maryland Hospital Association	Quality Indicators Project	
Dartmouth Atlas of Health Care	Massachusetts Coalition for the Prevention of Medical Errors	Foundation for Health Care Quality	