Objective Measures

James Ballard, MBA, CPHQ, CPPS, HACP
Eileen Willey, MSN, BSN, RN, CPHQ, HACP

QAPI Specialist/ Quality Surveyor Educators (QSE's)/ Transplant Surveyors

Enhancing Quality Assessment and Performance Improvement Programs in Transplant Programs and Hospitals

May 13, 2015

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. Writing an effective Plan of Correction and Other QAPI Resources
12. Interpretive Guidelines

Disclaimer

- This training consists of Quality concepts, foundational and historical perspectives of Quality Assessment and Performance Improvement (QAPI) methodologies as they were originally developed.

- Healthcare has not come to an agreement on any one definition of what quality is, the best method(s) to employ or the best tool(s) to utilize within quality assessment and process improvement activities. Today, many organizations blend several 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.

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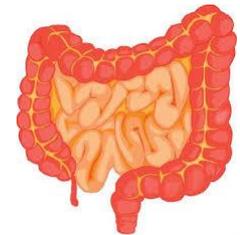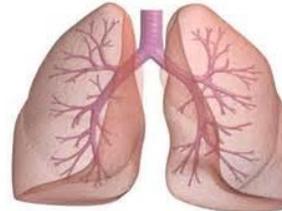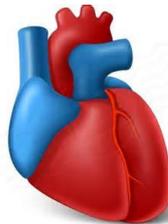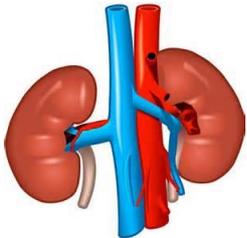
Upon completion of this session, the participant will be able to:

- Identify the CMS regulations applicable to activity/process and outcomes measures for Transplant QAPI programs.

- Differentiate between "Process" and "Outcome" objective measures.

- Discuss strategies for selecting objectives measures appropriate for individual transplant programs (high risk, high or very low volume, problem prone…).

Determining Objective Measures

§482.96(a) Standard: Components of a QAPI Program

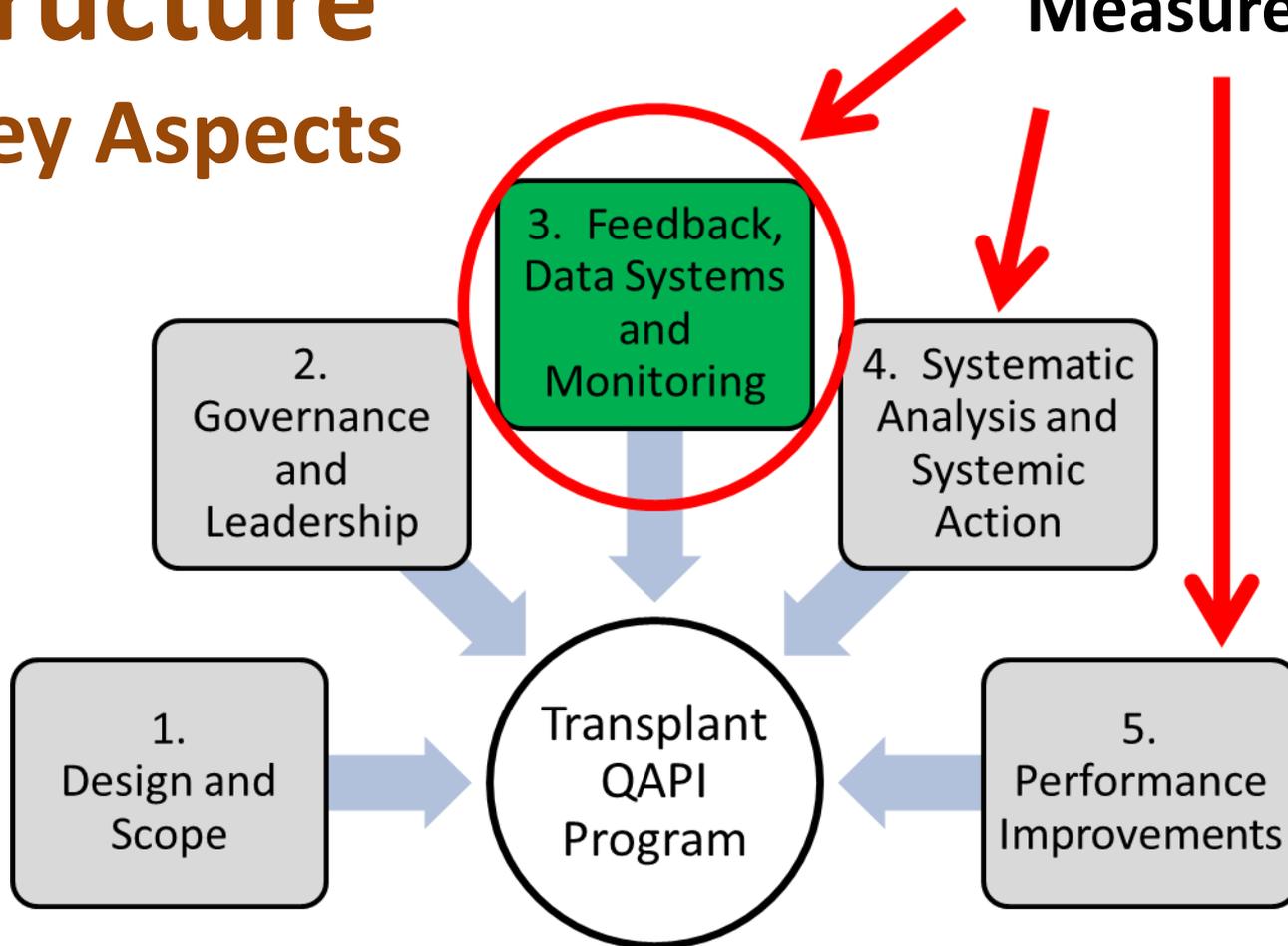*(a) The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes.*

Program Structure

5 Key Aspects

Objective Measures...

- 1. Design and Scope
- 2. Governance and Leadership
- 3. Feedback, Data Systems and Monitoring
- 4. Systematic Analysis and Systemic Action
- 5. Performance Improvements
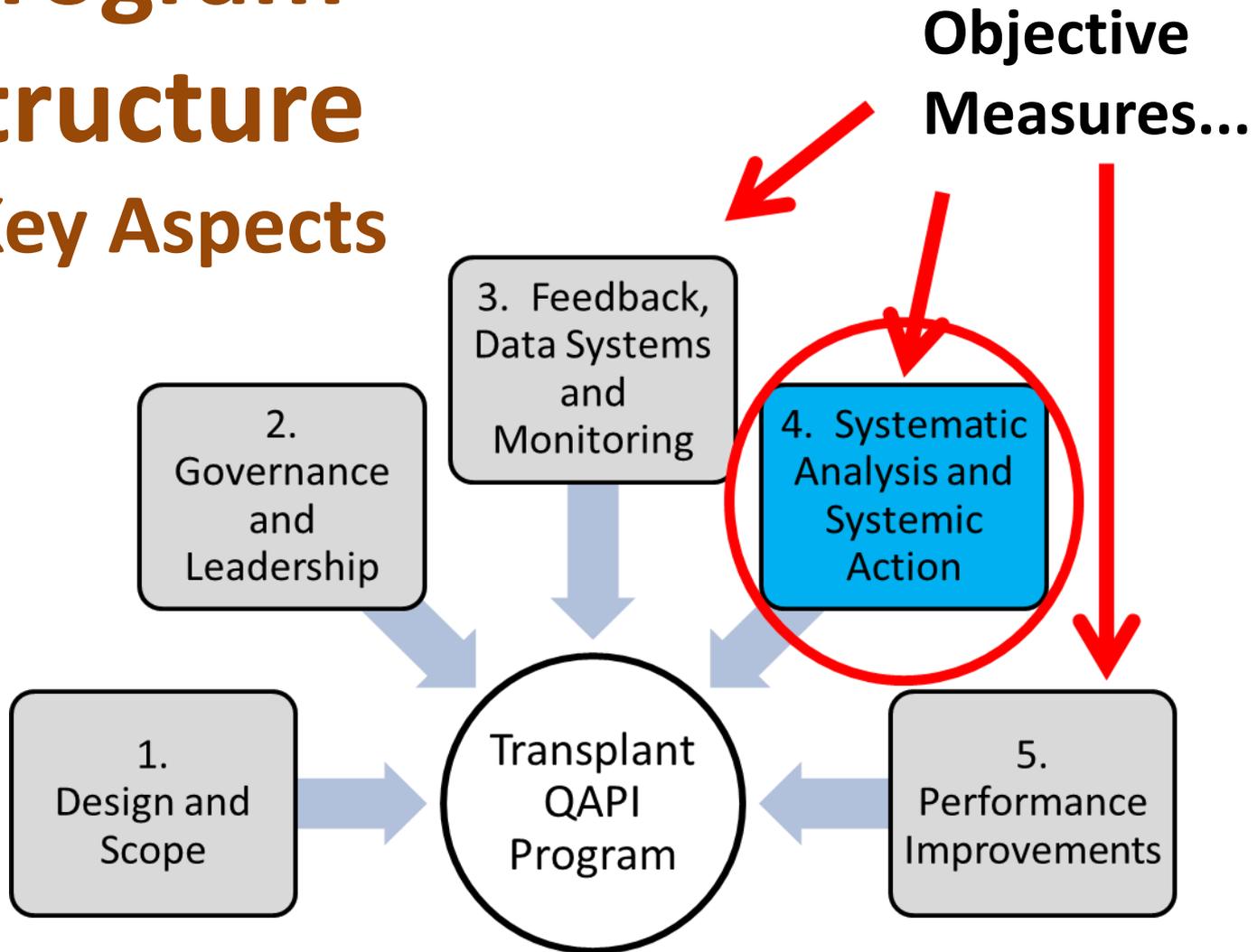- Transplant QAPI Program

Aspect 3: Feedback, Data Systems and Monitoring

- The transplant program must have systems in place to <u>monitor care and services in all phases and settings</u> of transplant and living donation, drawing from multiple sources;

- <u>Process and outcome indicators reflecting the complexity</u> of services within the program are <u>defined, measured, analyzed and tracked</u>;

- <u>Applicable benchmarks or targets</u> are established by the program to measure performance.

Program Structure

5 Key Aspects

Objective Measures...

3. Feedback, Data Systems and Monitoring

2. Governance and Leadership

4. Systematic Analysis and Systemic Action

1. Design and Scope

Transplant QAPI Program

5. Performance Improvements

Aspect 4: Systematic Analysis and Systemic Action

- The transplant QAPI program must <u>analyze collected data</u>.

- Analyses must include, but are not limited to, analysis of data related to <u>proactively defined quality indicators</u> and the ongoing use of systemic methods to assess and analyze adverse events....

- Systemic actions look comprehensively across all involved systems to prevent future negative events and promote <u>sustained improvement.</u>

Systems Issues

- Focus is on the system of related processes
- Understand the process, identify all the steps in a process
- Evaluate and anticipate points of failure
- Select solutions that improve the process
  - Prevent Miscommunication
  - Streamline
  - Reduce handoffs
  - Reduce human error
  - Eliminate failure points
- Communicate the results

Program Structure
5 Key Aspects

Objective Measures...
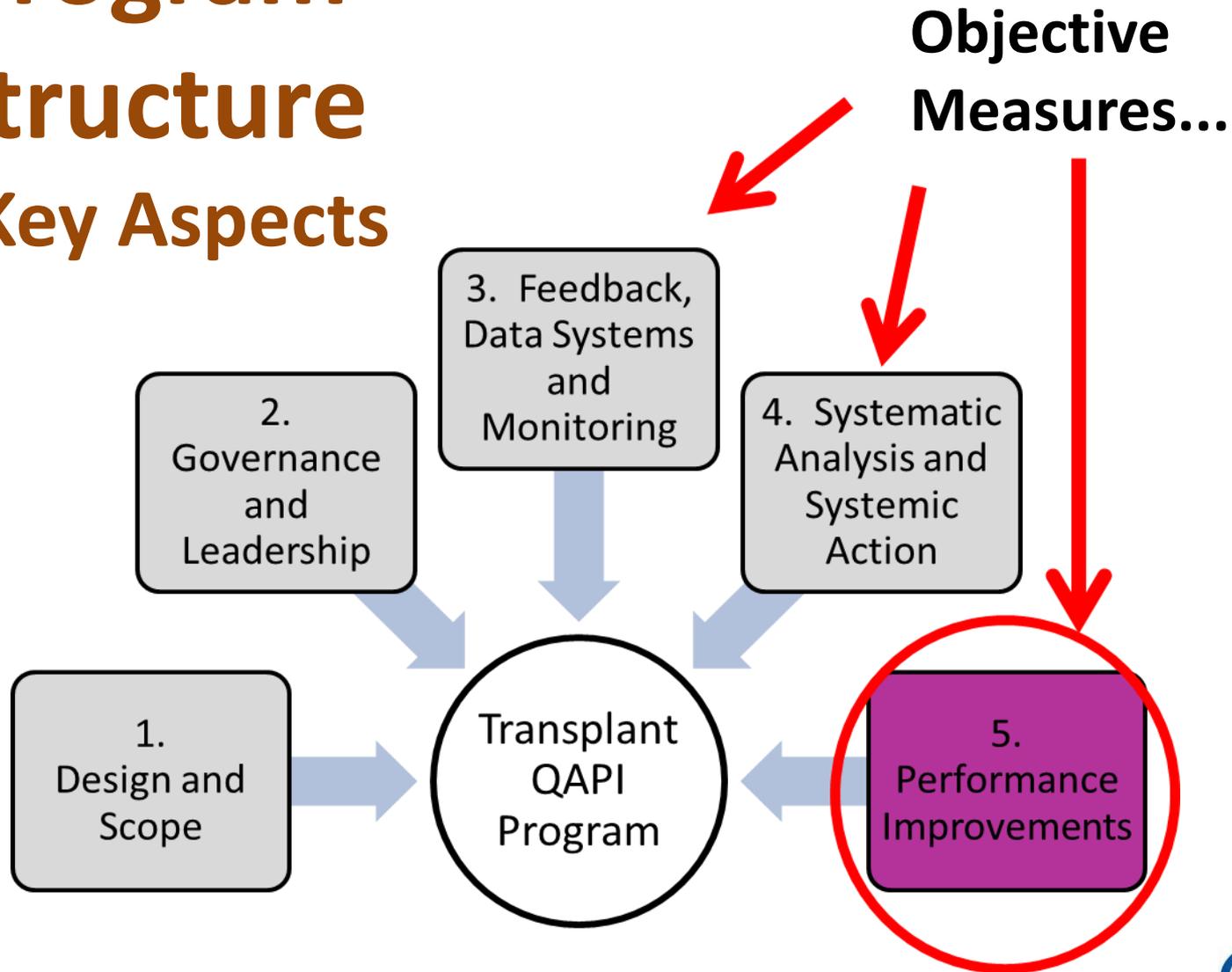
Aspect 5: Performance Improvements

- The transplant QAPI program must define, implement, and evaluate performance improvement interventions with the objective of improving quality of care;

- Once implemented, the interventions are later evaluated for success or continued need for improvement;

- Evidence of evaluation and sustained improvement is communicated to all stakeholders.

- Areas that need attention will vary depending on the organ type.

Basic Questions to Ask:

What are we trying to accomplish? (more of something, less of something?)

How will we know a change is an improvement?

What change can we make that will result in improvement?

How do you identify YOUR objective measures?

How do we choose objective measures?

- Clinically Relevant – making a difference for patient care?
  - High risk
  - High volume (or of such LOW volume it's an issue!)
  - Problem prone
- Financially Important (caution - where is your quality outcomes monitoring related to this…)
- Meaningful to Audience
- "Controllable" (Within your Scope…)
- Feasible to Collect the Data
- Is it a "pertinent negative"? (see next slide)
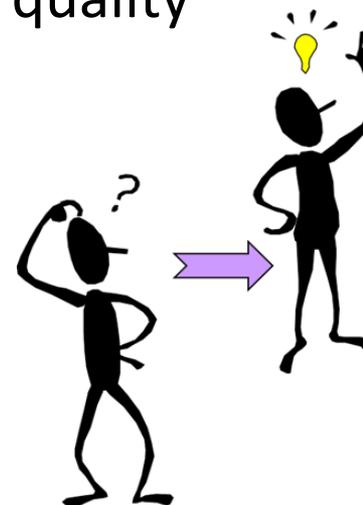
"Pertinent Negative"

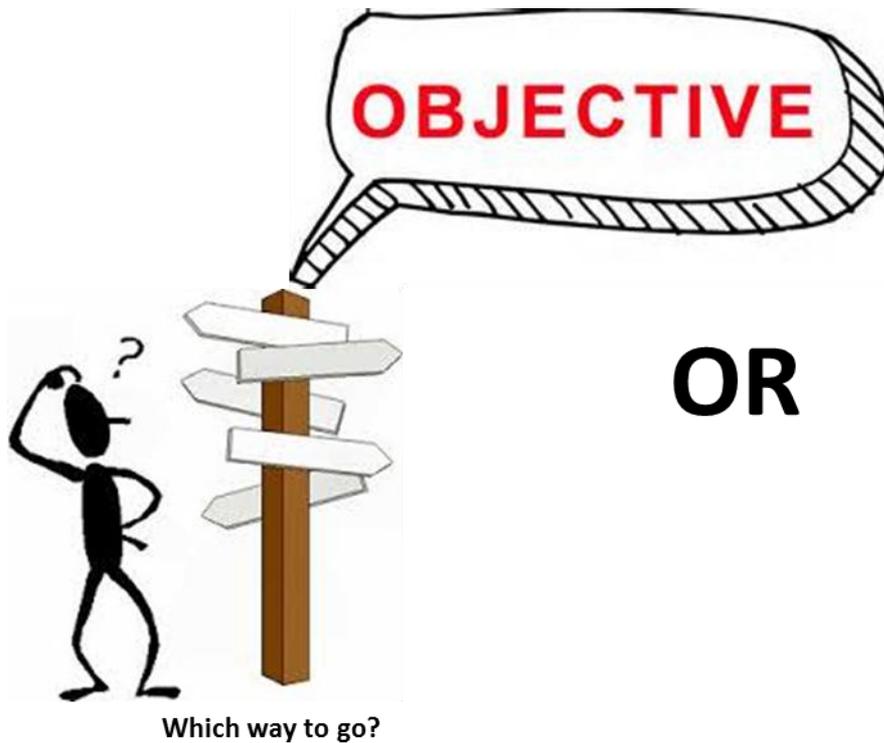What are those things so critical to your program, that it is important to know if they DON'T happen?

Objective Measures

Do you struggle with objective measures or have you taken a smart approach?

OBJECTIVE

Which way to go?

OR

S SPECIFIC

M MEASURABLE

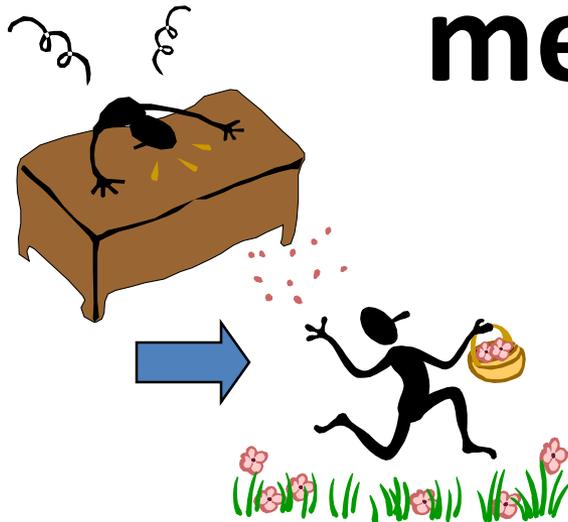**A** ATTAINABLE
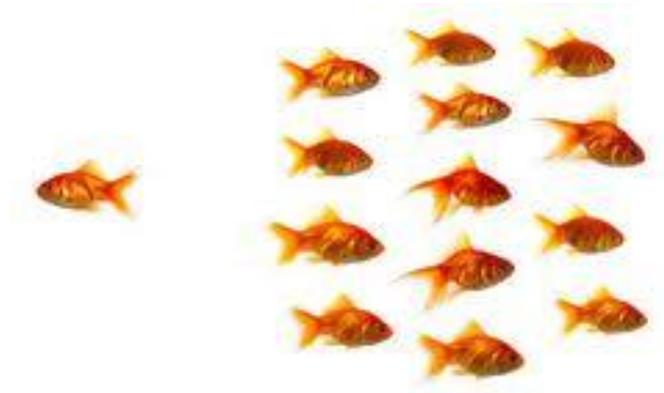
R RELEVANT

T TIME-BOUND

OBJECTIVE MEASURES

Will someone just tell me what I have to do?

NO – each program is <u>unique!</u>

"If you've seen <u>one</u> transplant program, you've seen <u>one</u> transplant program"...

Where do I go from here?
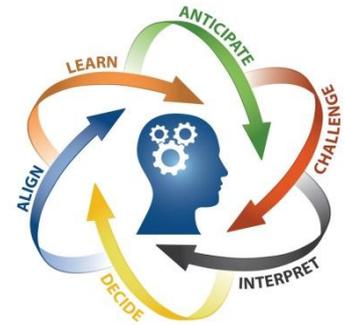
QAPI PLANNING

Prioritization of activities should be based on risk analyses of the severity affecting patients (**eg. High volume, High Risk, Problem Prone areas)**

Identify Patient Flow Processes

Identify Information Flow Processes

Identify Material Flow Processes

Identify QAPI Information flow

Identify Resource Management

STRATEGIC GOALS

The organization should have strategic goals of improving patient outcomes and patient safety, increasing efficiency and promoting preventative health measures.   Strategic goals give direction to organizational QAPI efforts.

Where do I go from here?

(continued)

ALIGNMENT
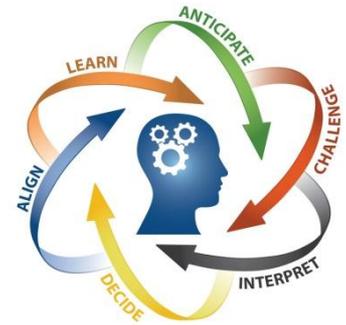
Transplant QAPI Planning activities should align with the Hospital QAPI plans as well as the organizations strategic plans, vision and mission

PATIENT FOCUSED

Patients are customers, with individual needs and expectations. Patients and their families must be actively engaged in health care decision-making and options for treatment

CUSTOMER ORIENTED

An organization can improve patient care quality by assessing and improving the governance, managerial, clinical, and support processes that most affect customers

Objective Measures:
Fundamental Concepts

- Objective measures are defined data elements that are selected to reflect program activities and outcomes.
- "Objective" means being able to be reviewed in an unbiased manner, strictly identified by a numerator and denominator. Measures selected should be sufficiently defined for program staff so that all members understand their meaning.
- Activities or processes must relate to the core transplant processes across all phases of transplant and living donation as mandated by CMS, the OPTN and all other applicable standards and regulations and as described in the program's policies and procedures.
- Outcome measures must relate to the intended and unintended effects resulting from the care provided.
- The objective measures must be defined, collected and analyzed and result in recommendations that are communicated to the transplant program decision-makers.

What are you measuring?

- **Structure:** the context for delivery of care, including finance, staffing, environment, equipment

- **Process:** the activities or procedures leading to outcomes

- **Outcome:** the effects, results or consequences of a process

[Example derived from A. Donabedian (1966) not required by CMS]

Objective measures evaluate processes that impact patient outcomes

Process Measure

- reflecting steps ['process'] to complete a task

Outcome Measure

- relating to the results or end point of care

Improving PROCESSES

Structure → Leads to → Processes → Which leads to → Outcomes
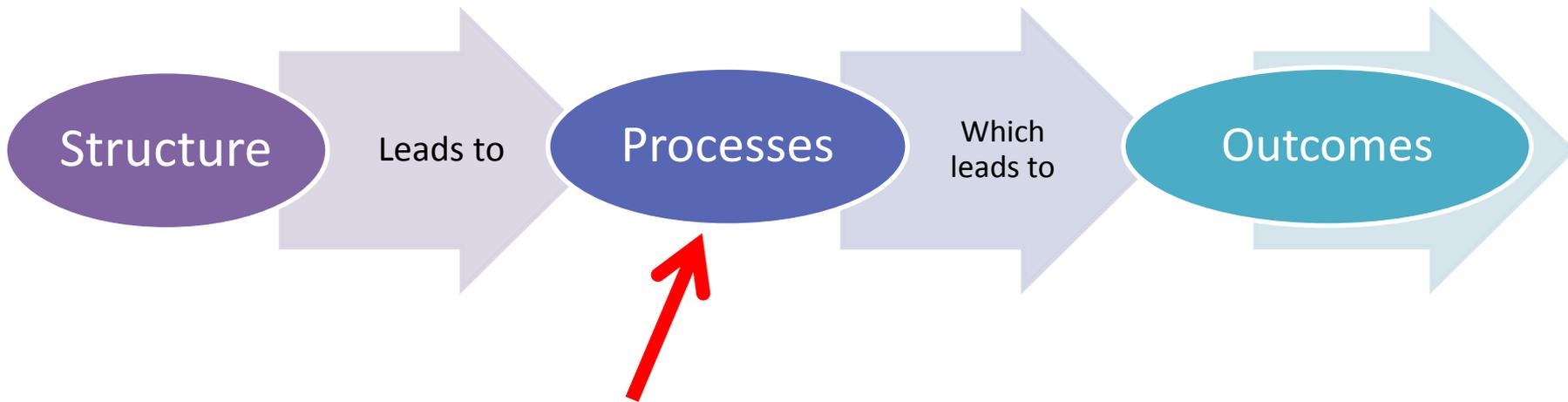
A process is a series of actions or steps taken in order to achieve a particular end.

A healthcare process refers to the procedures, methods, means or sequence of steps for providing patient care and producing clinical outcomes.

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Processes are sequentially related steps intended to produce specific outcomes: Transplant Example

Selection of a process measure as part of Performance Improvement activities needs to ensure the measure contains a sequence of related steps that produce a desired outcome

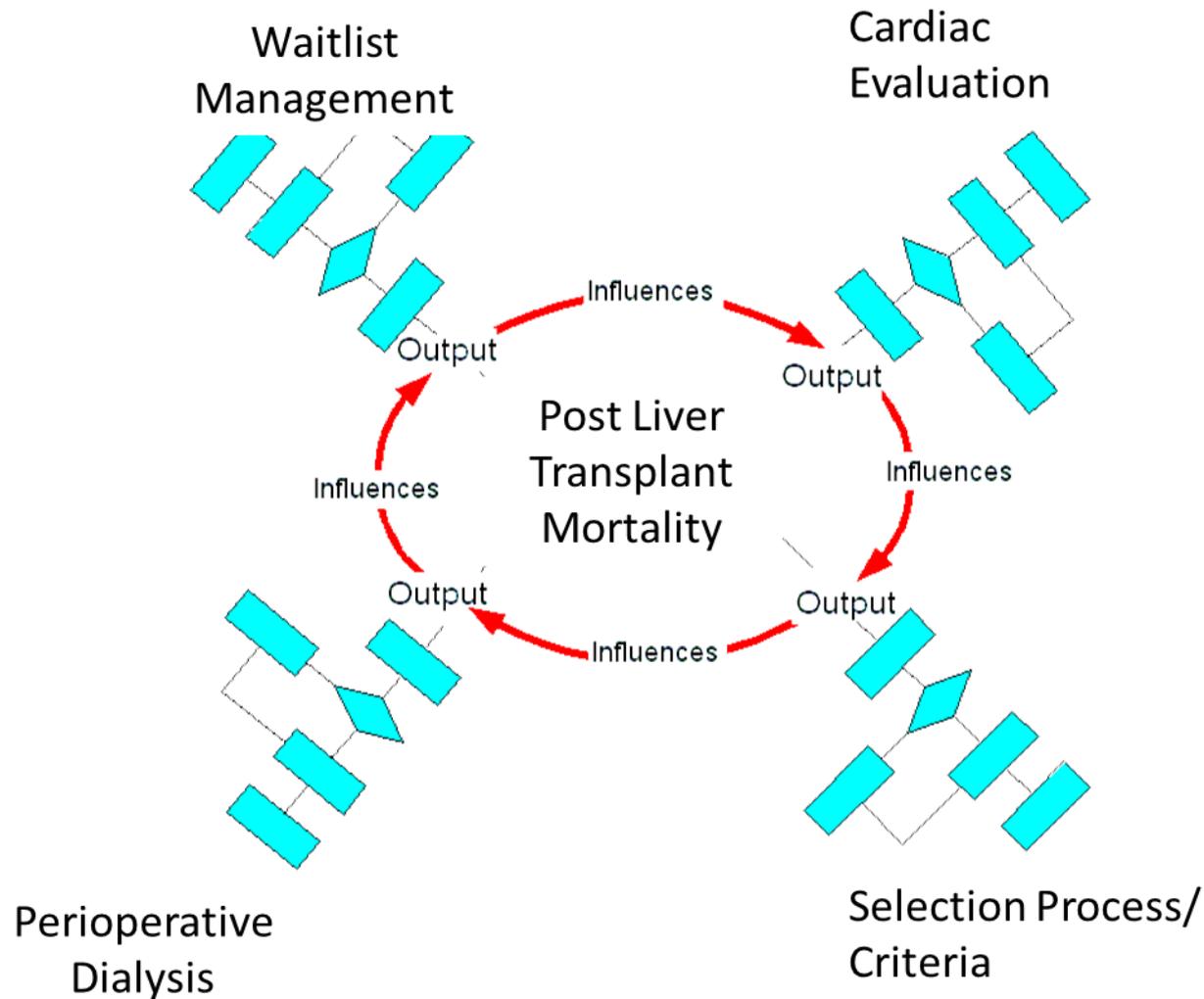| PRE-TRANSPLANT	TRANSPLANT	POST -TRANSPLANT
ABO Prior to listing	Cold Ischemic Time	Critical Care Protocols
Referral to Waitlist time	Blood Type Verification	Immunosuppression
Adherence to Treatment Plan	Surgical Time Out adherence	Individualized Patient Care Plan
Updating UNET information	Involvement of multidisciplinary team members	Involvement of Multi-disciplinary team members (follow-up care)
Donor Acceptance Rates	Surgical Protocols	Nutritional Support
Informed Consent	Surgical Skin Prep adherence	Pharmacy Support
Education	OR Staff Traffic Control	Discharge Planning
Patient Re-evaluation	Recovery Room Protocols	Protocol / Policy Adherence
Patient Flow (continuum)	Critical Care Bed Availability	Follow Up visits / evaluations
PRE-DONATION	DONATION	POST-DONATION
Nutritional Screening in record	Surgical Protocol Adherence	Adherence to Protocols
Medical / Psychosocial Evaluation	Involvement of multidisciplinary team	Documentation of Follow up visits
Adherence to Protocols (Informed Consent, Education)	Documentation by Living Donor Advocate	

Improving OUTCOMES

Structure → Leads to → Processes → Which leads to → Outcomes
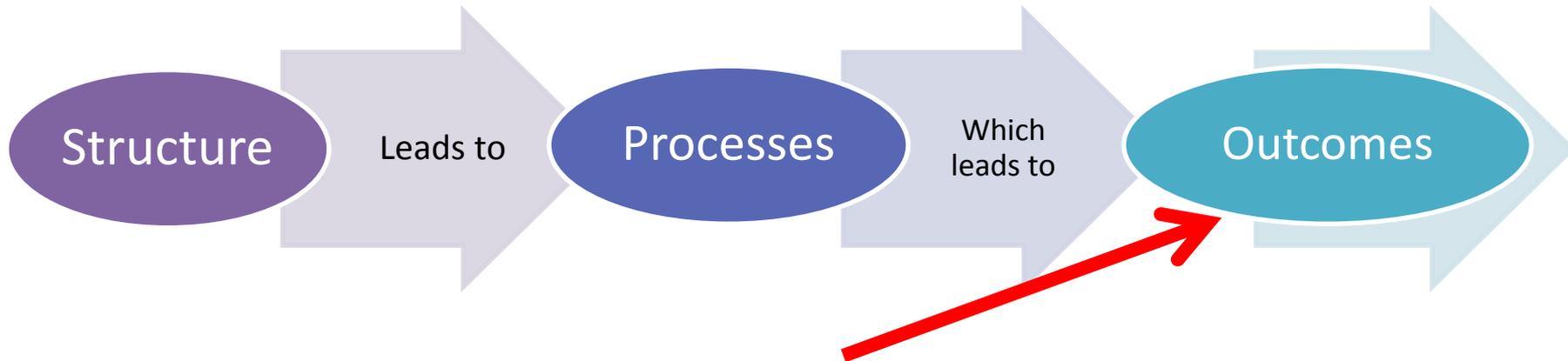
Outcome is defined as: An end result; a consequence. Something that follows from an action or a final product.

In healthcare, Outcomes refer to the results of care (*the end*), they can be positive (example: a full recovery) or negative (examples: death, infection, or injury).

Managing Outcomes includes:

- Reliance on Standards and Guidelines
- Measurement of the functioning and well-being of patients
- Pooling of Clinical and Outcome data
- Analysis and Dissemination of outcome results

OUTCOME-Focused Measures   Examples Only

Outcome focused measures monitor the results of care and do not involve processes.
Outcome measures do not include financial or logistical items, they should be focused on the delivery or result of care provided to patients.

PRE-TRANSPLANT	TRANSPLANT	POST -TRANSPLANT
Mortality on Waiting List	Unplanned Return to OR	Infection Rates
Health Maintenance on Waiting List	Transplant Rate vs. Expected	Diabetes (new onset post procedure)
Diabetes (existing condition)	Infection rate while hospitalized	Mortality
	Length of Stay in ICU / Step Down Critical Care units	Complications / Adverse Events (graft survival, etc.)
	Overall Length of Stay	Readmission within 90 days
	Complication / Adverse Events	30-day patient/graft
	Dialysis within 7 days	Emergency Room visits
		Patient Satisfaction
PRE-DONATION	DONATION	POST-DONATION
Percentage of donors who met weight loss requirements	Conversion rates from Laparoscopic to Open	Infection Rates and Follow Up Care
Health Maintenance after evaluation	Length of Stay – ICU / Step Down ; Overall	Complications / Adverse Events
	Infection Rates	Patient Satisfaction

Do your efforts demonstrate the bi-directional communication of hospital and transplant initiatives*?

Integrated

- LOS Management
- Readmissions
- Falls
- Patient Safety Goals
- Medication Errors
- Medication Safety
- Infection Prevention and Control:
  - CLABSI (Central Line Associated BSI)
  - CAUTI (Catheter Associated UTI)
  - SSI (Surgical Site Infections)
- Core Measures (Heart Failure and Pneumonia)
- Stroke Outcomes
- Restraint Utilization
- Customer Satisfaction/Perception of Care

Distinct

- Patient Flow: referral to evaluation, evaluation to listing, waitlist management
- Transplant-specific readmissions issues
- Graft to host transmission: infection prevention management
- Blood utilization in OR
- Transplant- specific surgical complications
- Others?

*Intended as examples only, not required regulation

Why am I doing this?

STOP COLLECTING NUMBERS IF YOU'RE NOT DOING ANYTHING WITH THEM!

Data
Rich
Information
Poor

You must educate your audience to transplant "nuances"

| Hospital: Familiar & Understood... | Transplant: Opportunity to Educate .... |

INTEGRATED

- Regulatory/accrediting standards for hospitals
- Referral Volumes/growth
- Clinic Volumes/growth
- Transplant Volume
- LOS
- Cost per case
- Readmissions

DISTINCT

- "Dedicated" transplant CoP's including QAPI
- Program competition within region
- OPO relationships
- Waitlist patients & responsibilities
- Critical Outreach activities
- Living Donor program

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Critically analyze what you "borrow" from others.
Is it high risk, high volume, or problem prone for YOUR program?
Is it important enough for YOU to measure?

"Borrowing" from best practices

- Be careful when using "best practices" for measures

- Other programs "opportunities" for improvement might not be the same as yours;

- Example: are you monitoring how many patients get swans and A-lines peri-operatively when this hasn't been an issue for you?

- Critically evaluate others' thresholds & targets

Best Practice Process:

"Borrowing" from others....

1. In Excel file, consider putting "N" sample sizes with your data, especially with small patient volumes
2. Adding cell comments (Highlight cell, select "Review" from toolbar and add "New Comment" or "Edit Comment")

FQAPI Survey Findings

(X100 CITED >50% of 2014 surveys)

482.96(a) Standard: Components of a QAPI Program

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

Considerations for Objective Measures

$$\frac{2}{3}$$

- Define your measure
    - Numerator (top number)
    - Denominator

      (bottom number; "out of how many" is important!)
    - Data source
    - Reason the measure exists
    - Triggers for action (threshold/benchmark)
    - Abstraction done by whom?
    - Evaluation of measure (?annual review vs. other)
    - The process for consideration of retirement of measures

- Put these in your QAPI Plan!
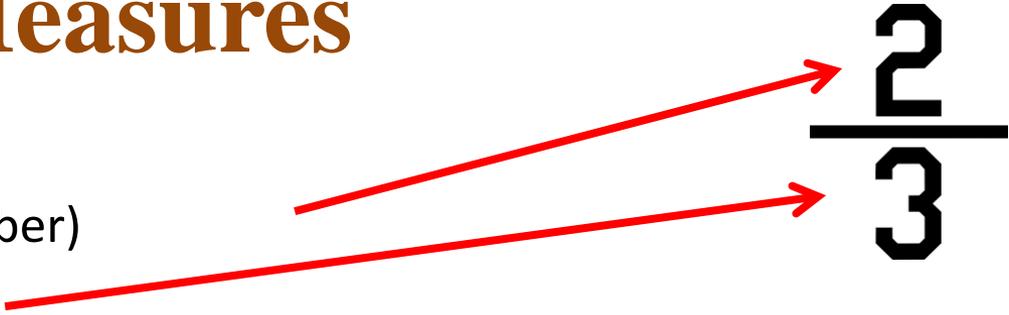
Retiring a Measure

- Are your objective measures still important for your program?

- Is your scorecard of data all "green"?

- What about "permission" to STOP monitoring something?

- Have you consistently met the target or threshold for more than three measurement periods?

- Consider:
  - moving monitoring to less frequently (monthly to quarterly; quarterly to semi-annually; semi-annually to annually)
  - "Spot checking" with a periodic audit of a sample of patients
  - Changing sample size from 100% to a smaller but valid sample size (consult your hospital QAPI program)

Process Improvement: Change

The essence of making positive change includes the steps of:

- Discovery (identify problem, define problem, map the process)

- Data (define, collect, analyze, utilize)

- Implement Change

- Monitor and Evaluate Changes made

- Continue cycle until desired outcome is achieved and sustained

Objective measures evaluate change!

Clarification:

CMS does NOT require that each objective measure has a related PI Project.

However, it makes logical sense that at least some of your objective measures will have documentation of activity related to improvement activity. Monitoring them provides evidence of how you are tracking sustained improvement…..

For Example:

Examples of objective outcome measures could include:

- Survival rate (graft and patient) over a designated period of time, including sub-group analyses;
- Number of blood type compatibility errors over a designated period of time;
- Number of post-transplant or post-living-donation infections and other complications;
- Percentage of organ rejection over a given period of time; and
- Measurements of the effectiveness of the transplant candidate/recipient and potential LD/LD and family education.

Examples Related to PI (continued)

Examples of objective process measures could include:

- Frequency of the use of criteria exceptions in the patient/donor selection process;
- The extent to which OPTN rules for removal from the wait list are adhered to;
- Number of the transplant candidate/recipient and potential LD/LD or family complaints that were received, investigated, and resolved;
- Number of complaints related to consent practices;
- Returns to OR in a specified period; and,
- Extent of adherence to patient evaluation steps.

How Do I Measure A Process or Outcome?

- How Do I Know What Is Good Enough?

- Compare data to a target or benchmark

- How Do I Find A Benchmark
  - Literature and Internet Searches
  - Another Hospital
  - Other Professionals
  - "Internal Benchmark" (historical data, experience...)
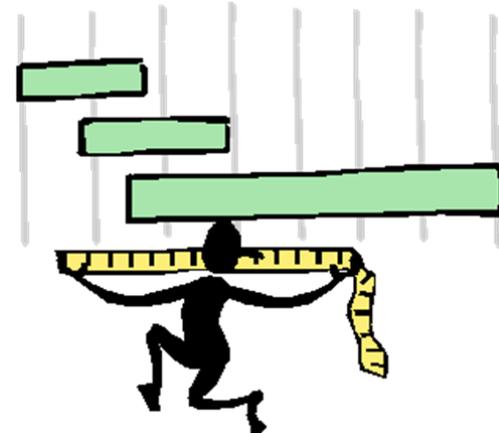
Measures Selection & Management

- Avoid "scope creep", pick a reasonable topic
- Appropriate methodology to look at issue
- Appropriate sample size
  ("5% or 30-50 per timeframe" rule – check with Hospital Quality…)
- Baseline
- Look at data over time to document improvement
- True process improvement is not indicated by one data point in time
- Implement identified activity consistently without "tinkering" with process
- (More Education to come re: PI Methods & Tools)

Questions to Ask About Objective Measures
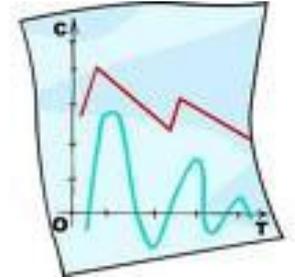
- Is Your Data "**Clean**"
  - identify incomplete, incorrect, inaccurate, irrelevant parts of the data and then replace, modify or delete the *dirty data*
- Source Data Reliability
- Numerator/Denominator Correct/Valid?

- Cost Effective to Capture?

- Inter-rater reliability:
  - Will different people come up with the same results/outcomes

- Does it need to be:
  - Risk/Severity Adjusted?
  - Stratified by Group?

Not Required by Regulation but Useful: Objective Measures Matrix

- Includes all required information
- Useful for "snapshot" overview for leaders (and regulators!)
- Provides detail of required work necessary for compliance (for resource considerations!)
- Program Specific!

Transplant Quality Measures: XYZ Program

Phase		Benchmark	Cohort	P/O/S	Data Source	Data Entry	Data Mining	Data Definition
	Transplant Volume	CY Budget	monthly rolling year	S	OTTR	Coordinator A	OTTR Data Admin	Monitor transplant volume by month (actual # procedures)
	% WL Growth	CY Budget (>/=10% target)	monthly rolling year	S	OTTR	Listing Coordinator	OTTR Data Admin	(Program specific definition here) Monitor additions to the waiting list each month to assess performance to target of 10% increase from prior year. Calendar year by month.
	Overall ALOS	Internal Benchmark	monthly rolling year	S	OTTR	Coordinator A	OTTR Data Admin	(Program specific definition here)
	Dialysis dollars saved (for AKO programs)	N/A	monthly rolling year	S		Txp. Manager		(Program specific definition here: conversion to functioning kidney from chronic dialysis..)

Process

Phase		Benchmark	Cohort	P/O	Data Source	Data Entry	Data Mining	Data Definition
PRE	Referral/Intake to Eval Start < 30 days	100% review outliers	monthly rolling year	P	OTTR	Intake Coord/ Pre-Transplant Coordinator	OTTR Data Admin	Monitor the number of patients with REFERRALS ENDED with end reason "Evaluation Started" >30 days and review for PI opportunities; 1 month previous.
PRE	Evaluation Length - (All End Reasons) < 30 days	100% review outliers	monthly rolling year	P	OTTR	Pre-Transplant Coordinator	OTTR Data Admin	Monitor the number of patients with EVALUATIONS ENDED with ALL end reasons >30 days and review for PI opportunities; 1 month previous.
PRE	Social Work Assessments (outpatient)	100% compliance CMS Requirement	point-in-time	P	OTTR	Social Worker	OTTR Data Admin	Compliance with UH Transplant Institute SW Guidelines as required by CMS Regulation. Point in time of listed patients as of "today" % that have a Psycho social update within the last 12 months; SW to review outliers
PRE	Two ABOs Prior to Listing	100% compliance CMS/UNOS Requirement	monthly rolling year				Consider eliminating this one due to current computer process "fail-safe" - cannot list without them!	

Outcomes

Phase		Benchmark	Cohort	P/O	Data Source	Data Entry	Data Mining	Data Definition
Pre	Deaths on Waitlist	100% review	monthly rolling year	O	OTTR	Listing Coordinator	OTTR Data Admin	Monitor the number of deaths on the waiting list each month and ensure that each one is discussed; Calendar year by month; semi-annual comparison to the latest release of the SRTR Region Deaths on the wait list during the previous calendar year.
Pre	Referrals to Hospice	Internal Benchmark	monthly rolling year	O	OTTR	Listing Coordinator	OTTR Data Admin	Program specific definition here
PRE	Total Ischemic Time <12 Hours (Cross Clamp Time-Donor to Recipient Unclamp Time)	100% review outliers	monthly rolling year	O	OTTR	On-Call Coordinator	OTTR Data Admin	Review all transplants cases each month with donor organ total ischemic time >12 hours
PERI	Blood Products (Median Per Case) - PRBC Intraoperative	TBD	monthly rolling year	O	OTTR	Inpatient Coordinator	OTTR Data Admin	Monitor the median usage of intraoperative PRBC blood products per month against prior months and review outliers
PERI	Organ Offer Refusals	100% review	monthly rolling year	O	UNET/ EXCEL	Surgical Director	Surgical Director	Review the all organ refusals each month; 1 month
PERI	Blood Products (Median per Case) - PRBC SICU 24 hrs post-op	TBD	monthly rolling year	O	OTTR	Inpatient Coordinator	OTTR Data Admin	Monitor the median usage of PRBC blood products on a monthly basis against prior months and review

NOT A REQUIREMENT BUT USEFUL
Objective Measures Matrix

XYZ Transplant Program Quality Measures Tracking Grid							
Phase	Type (structure, process, outcome)	Measure	Target	Data Definition	Source	Responsible Person	Benchmark/ References
	(Structure)	Transplant Volume					
Pre Txp.	Process						
Pre Txp.	Outcome						
Txp.	Process						
Txp.	Outcome						
Post Txp.	Process						
Post Txp.	Outcome						
	(Structure)	Living Donor Volume					
Pre LD	Process						
Pre LD	Outcome						
Donation	Process						
Donation	Outcome						
Post LD	Process						
Post LD	Outcome						

Special Issue:
Tracking transplant patients….

- Can you identify your transplant patients throughout the entire patient encounter from Referral to Listing to Admission, Transplant/Donation, to Outpatient?

- Are they flagged in your system somehow for every encounter (visit, admission)?

- If you can flag your VRE/MRSA patients in your lifetime electronic medical record, you can flag Transplant Recipients!

Common Transplant Issues & Concerns

Bleeding – Quality of Organ
Cardiac Evaluation/Events
Delayed Graft Function
Follow-up Visits
Graft Survival
Immunosuppression Prophylaxis
Immunosuppression Therapy
Infections/Infectious Disease
Nutrition
Organ Offer Declinations
Patient Education
Re-Admissions
Selection Criteria
Serology Testing
Team Structure and Training
Technical Competency of Team
Waitlist Management

Objective Measures: Sample Topics

30 day, 90 day, 1 yr. mortality

30 day, 90 day, 1 yr. graft failures

ABO Prior to listing

Adherence to Treatment Plan

Adverse Events

Blood Utilization

Cold Ischemic Time

Complications

Conversions to Open from Laparoscopy

Critical Care Bed Availability

Critical Care Protocols

Diabetes (new onset post procedure)

Discharge Planning

Donor Acceptance Rates

ED visits

Education

Follow Up visits / evaluations

Health Maintenance on WL

Immunosuppression

Individualized Patient Care Plan

Infection Rate while hospitalized

Infection rates

Informed Consent

Involvement of multidisciplinary team members

Involvement of Multi-disciplinary team members (follow-up care)

Left OR on support device

LOS in ICU/Step Down

Overall LOS Mortality

Mortality on WL

Nutritional Support

OR Staff Traffic Control

Patient Flow (continuum)

Patient Re-evaluation

Pharmacy Support

Post Op Thrombosis

Protocol / Policy Adherence

Readmission w/I 90 days

Recovery Room Protocols

Referral to Waitlist time

Surgical Protocols

Surgical Skin Prep adherence

Surgical Time Out adherence

TEIDI Form Completion

Transplant rate vs. expected

Unscheduled Returns to OR

Updating UNET information

Additional Examples

- Mechanical Ventilation time
- Re-intubations
- Seizures
- Infection: requiring IV therapy within first year
- Postoperative liver failure
- Dialysis within "X" days of transplant
- Patient Grievances
- Patient Satisfaction
- Death on Waitlist; Status at Time of Death
- Percent (%) of "Status 7" on Waitlist
- CMV (Cytomegalovirus) rate

- Rejections requiring IV therapy
- PTLD (Post transplant Lymphoproliferative Disorder)
- Skin Cancer post transplant
- "Donor Declination" Quality Review (organs accepted/ transplanted by other programs after initial program refusal)
- Living Donor conversion rates
- Living Donors lost to follow-up
- Living Donor health maintenance from first evaluation to donation
- Living Donor lost to "change of mind"

Summary: Survey Considerations

- Is the QAPI program using objective measures for a comprehensive evaluation of the performance of the transplant program, including services provided under contract or arrangement.

- Measures should cover all components of the program and all transplant and LD phases.

- Are the indicators appropriate to local organizational needs?

- How and why were the measures selected? (high risk, high or very low volume, problem prone)

- Are measures relating to adverse events being monitored to prevent evidence of re-occurrence?

- Is data collected in accordance with a clear plan?

- Is data analyzed to produce actionable information?

- Is there action taken in response to the evaluation of data?

- How is this information communication up to leadership and down to staff?

Q&A

Contact Information

Michele G. Walton RN, BSN
Nurse Consultant

Centers for Medicare & Medicaid Services

Center for Clinical Standards and Quality

Survey & Certification Group

Phone 410-786-3353

Email michele.walton@cms.hhs.gov