



CMS TRANSPLANT PROGRAM QUALITY WEBINAR SERIES

Performance Improvement Tools and Methods



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

June 10, 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 Improvement Tools and Methods**
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

Purpose and Objectives



The purpose of this session is to enhance the Quality Assessment and Performance Improvement (QAPI) activities within Transplant Programs through increased knowledge of QAPI regulations, performance improvement techniques / tools and sustaining improvements.

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

1. Discuss the basis for Performance Improvement within Transplant Programs.
2. Identify the tools, methods and components within Performance Improvement.
3. Specify critical elements required from a Transplant QAPI program.

Disclaimer



- This training series will contain concepts, foundational and historical perspectives of Performance Improvement methodologies (as they were originally developed) and regulatory guidance to help transplant programs meet compliance with the Conditions of Participation.
- CMS understands that: 1) Healthcare has various definitions of what Quality is, 2) There are many methods that can be employed and 3) There are many tools that can be utilized within quality assessment and process improvement activities.
- CMS also understands that some organizations blend several quality concepts and tools together to provide for a more nimble and individualized QAPI program.
- CMS is never prescriptive to organizations in how to meet compliance. This training series does not support or advocate any particular QAPI method or tool. This training fully supports that QAPI activities include data driven decisions that lead to sustained improved performance and ultimately improved patient outcomes.

Take Action



IF YOU REALLY WANT TO KNOW WHO YOU ARE...



**KEEP TAKING ACTION
- IT'S YOUR ACTIONS THAT DEFINE YOU!**

Transplant Regulation

Tag X101



§482.96(a) TAKE ACTION and TRACK PERFORMANCE for SUSTAINABILITY.

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

FQAPI SURVEY FINDINGS



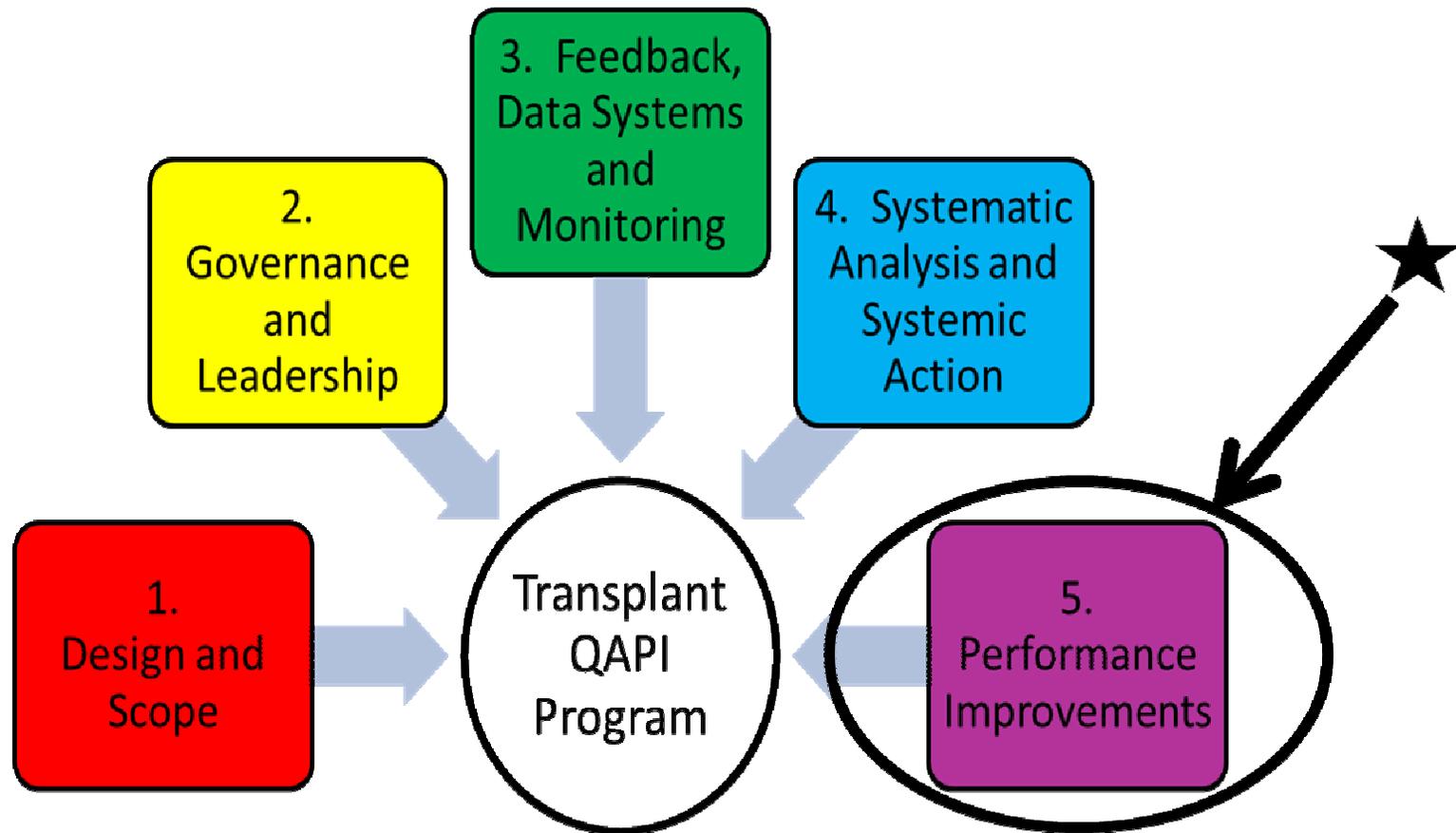
482.96(a) TAKE ACTION AND TRACK PERFORMANCE FOR SUSTAINABILITY

- No mechanisms to ensure problems were handled promptly.
- No documentation of actions or sustainment.
- Did not address complete continuous Performance Improvement process.
- No evidence of entire scope of quality continuum identified problems, aggregated data, analysis, appropriate action taken, improvements made, or evidence of sustained compliance.
- No evidence of actions to improve on 26 of 28 measures.
- QAPI plan did not include any stage related to control or monitoring of actions taken that led to sustainable improvements.
- No evidence the last step of QAPI process to monitor and collect data was done.
- QAPI plan did not address a QAPI process that addressed how improvement was evaluated or sustained.
- QAPI plan did not include mechanism to ensure problems were promptly identified or how long term measures were implemented and evaluated to ensure continuous compliance.

What is Performance Improvement?



The 5 Key Aspects Transplant Quality



Aspect 5: Performance Improvements



- The transplant program **conducts activities** to examine and improve care or services in areas that the transplant program identifies as needing attention (**high risk, high (or very low) volume and problem prone areas**).
- Areas that need attention will **vary** depending on the **organ type**.
- Documentation of transplant performance improvement interventions should **reflect** utilization of the program's defined **performance improvement model or methodology**.
- The **bi-directional reporting** of these activities between staff, the transplant program, and hospital leaders, promotes a culture of continuous learning and improvement.

Understanding QA / PI



QUALITY ASSESSMENT

The systematic act of appraisal - the process of gathering and discussing information from multiple sources in order to better understand a situation.

QA = Assessing Opportunity

PERFORMANCE IMPROVEMENT

The concept of measuring the output of a particular process or procedure, then modifying the process or procedure to increase the output, increase efficiency, or increase the effectiveness of the process or procedure.

PI = Action

PI Activities: Examples



Performance Improvement = ACTION

- Corrective **action plans and changes** to identified negative trends, problems facing the program or outliers in expected outcomes.
- **Changes** made as a result of Monitoring:
 - ABO verification process
 - Informed consent process
 - Receipt of organ process
 - Discharge planning process
 - Patient education process
 - Transplant specific patient practice process changes
- Activities that **change any step** within a process related to transplant patients (*recipient, potential recipient, living donor, potential living donor*)

Process Improvement



Performance Improvement has become interchangeable with **Process** Improvement; if process variation can be eliminated and controlled – performance can be improved.

The essence of making positive change includes:

- 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.

Project Structure

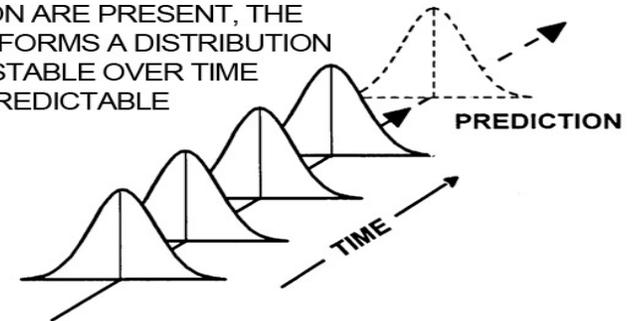
- Project Structure**
- Problem Identification**
- Team**
- Define Problem**
- Define Goals**
- Select PI Improvement Tool**
- Select Data to be collected**
- Data Collection**
- Implement Feedback loops**
- Data Analysis**
- Improvement Action**
- Improvement Testing**
- Improvement Implementation**
- Improvement Data Collection**
- Improvement Data Analysis**
- Improvement Reporting**
- Project Follow Up**

All projects should have a foundation established at the start – these categories will apply no matter what method or tool is utilized.

The desired goal of any project should be the establishment of a stable process and sustainable performance.

A Stable Process

IF ONLY COMMON CAUSES OF VARIATION ARE PRESENT, THE OUTPUT FORMS A DISTRIBUTION THAT IS STABLE OVER TIME AND IS PREDICTABLE



Where does Performance Improvement come from?



P.I. Origins



- **Objective measures monitoring** (*negative trends or undesired performance of measure*),
- **Identified opportunity for improvement** (*High Risk, High Volume, Low Volume, Problem Prone*),
- **Planned re-design of a patient care process** (*Ideal State, Eliminate Waste, Efficiency, New Service*).

All of these may lead to Performance Improvement

Evaluation of Services



Objective Measures evaluate program services and outcomes as part of the Quality Assessment activities within a program.

- Objective Measures may have negative or undesired trend patterns that need action to improve the performance of a given process.
- Objective measures provide a means of performance comparison to National, State and other sources, indicating superior, comparable or poorer performance.
- Patient Care processes may not be meeting expectations when looking at an 'Ideal State' of performance – processes may need re-designed to meet these expectations.

All action taken towards improving a patient's health outcome is considered Performance Improvement and should be documented within QAPI activities.

Objective Measures



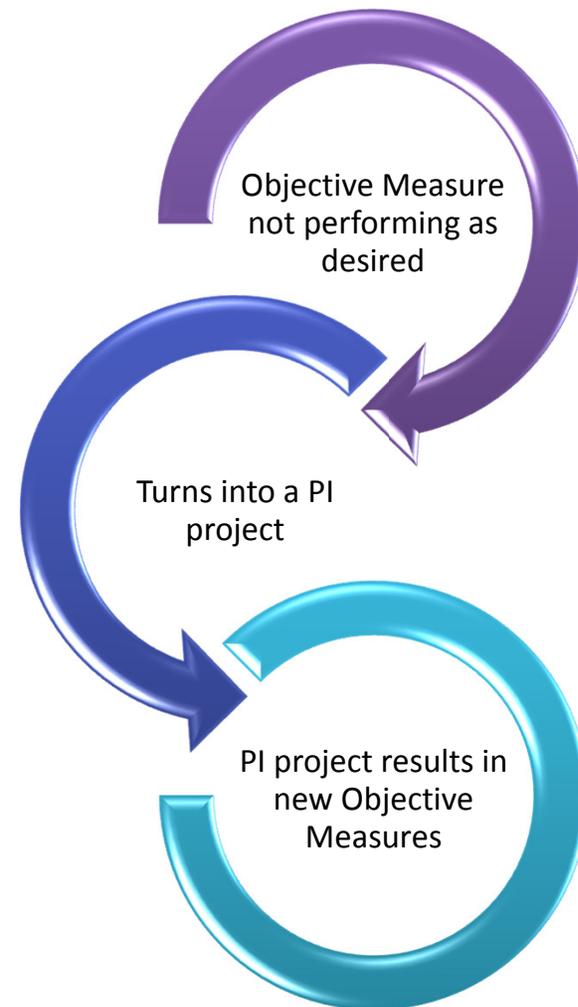
- Objective measures are fact based data elements that should address problems/issues within a program.
- The concept of having a data-driven QAPI program is to ensure that the data being collected is meaningful and measures the performance of the transplant centers activities and outcomes.
- Goals, targets or thresholds should be established for objective measures data elements.
- In order to improve processes or patient outcomes, the goals must be realistic and attainable.

Objective Measure Example



Patient Survival – Post Transplant

- 1) **Processes Reviewed:** Cardiac Evaluation, Selection Criteria, Perioperative Dialysis, Waitlist Management.
- 2) **PI Action:** Require Cardiac work-ups on all evaluations and include Cardiologist review immediately prior to surgery.
- 3) **QA / PI monitors:**
 - a) Completed Cardiac Evaluations (Process : Pre-Phase)
 - b) Cardiologist review prior to surgery (Process : Transplant Phase)
 - c) Survival Rates (Outcome : Post Phase)



Opportunity for Improvement

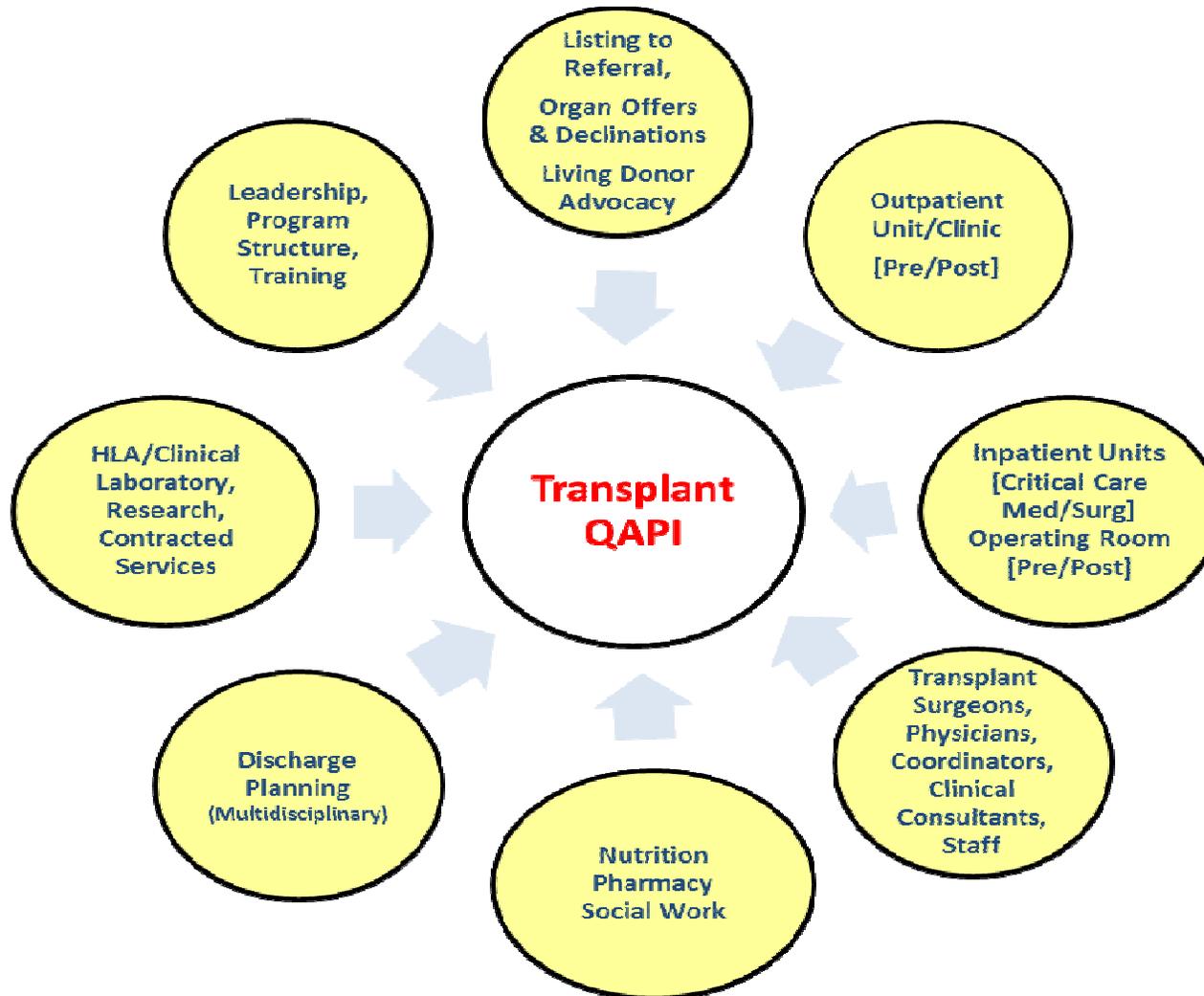


Opportunities for improvement may come from anywhere:

- Gap Analysis
- Risk Assessment
- Adverse Events
- Undesired Data Trend
- Staff Recommendation
- Program Evaluation
- Policy or Protocol Review



Think Transplant Specific



Re-Design / Ideal State



Health care re-design involves making systematic changes to care practices and health systems to improve the quality, efficiency, and effectiveness of patient care.

Improving a system by intentional change is also called “re-design.” Re-designed systems have the potential to have broad impact to improve the way things work.

Some models for re-design include: Six Sigma, Toyota Production System (Lean), and Quality by Design.

How is Performance Improvement accomplished?



The QAPI Cycle



Quality Assessment Activities

EVALUATION of Program Services

- Objective Measures
- Gap / Risk Analysis
- Adverse Event Analysis
- Organization Initiatives
- Committee Recommendations
- Strategic Planning
- Planning New Services
- Outreach Programs



QA PI Activities

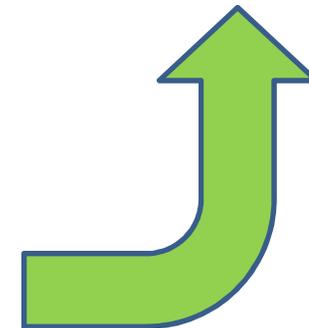
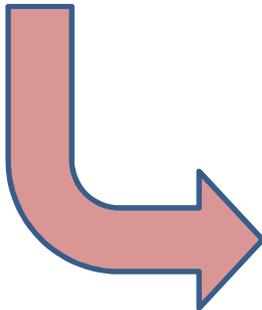
MONITOR the Actions

- New / Updated Objective Measures
- Monitor of process to cover gaps in care
- Monitor Adverse Event Action Plan
- Integrated reporting for initiatives
- Gather and Validate Data for EBM findings
- Monitor Referral to Evaluation times

Performance Improvement Activities

ACTION based on Evaluations

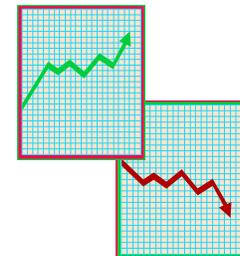
- Review processes related to undesired trends
 - Gaps in Care / Services
 - AE Analysis Recommendations
 - HAI Initiatives, Core Measures
 - Evidence Based Medicine Findings
- Decrease Referral to Evaluation time by adding new Provider



Selection & Management

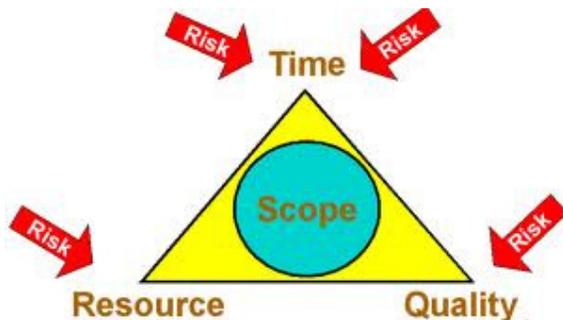


- Avoid “scope creep”, pick a reasonable topic.
- Need appropriate methodology to look at issue.
- What can be measured about the opportunity?
- Need a baseline to compare against improvements made.
- Need to look at data over time to document improvement .
- True process improvement is not indicated by one data point in time.
- Need an appropriate sample size (“5% or 30-50 per timeframe” rule – check with Hospital Quality...).



“Scope Creep”

- Uncontrolled changes or continuous growth in a project scope;
- Project drift from original purpose morphing into a larger; (previously unplanned) focus;
- Forces longer timelines and increased resources.
- Scope Creep results is an ‘Overwhelmed’ feeling (“cure world hunger” analogy)



Project's found on Survey



- Cardiac Protocol change
- Selection Criteria change
- ABO verification process change
- Laboratory Assay controls changed
- Initial evaluation process changed to a single day of appointments
- Blood specimen testing for transplant patients made into STAT orders

- Coordinator's desk reorganized for efficiency
- Organ delivery site changed to Surgery Department only
- Emergency Room communication process changed to notify transplant providers of any transplant patient arriving for care
- Rejection episodes confirmed by biopsy only
- "Organ Offer" declination review

Is your project Transplant Specific?



Hospital Integration

- Hand Hygiene
- Hospital Acquired Infections (HAI)
- Central Line Associated Blood Stream Infection Prevention (CLABSI)
- Ventilator Associated Pneumonia (VAP)
- Venous Thromboembolism Prevention (VTE)
- Stroke Treatment/Prevention
- Sepsis (Prevention, Expediting Diagnosis/Treatment...)
- CMS Core Measures (Heart Failure, Pneumonia, Surgical Infection Prevention)

Transplant Specific

- Referral to Evaluation
- Health Maintenance while on waitlist
- ABO verification process
- Living Donor Follow up
- Conversion rates (evaluated to selected)
- Selection Criteria
- Cardiac Protocols
- Organ acceptability

QAPI Tools and Methods



**KEEP
CALM**

AND

**use the right tool
for the right job**

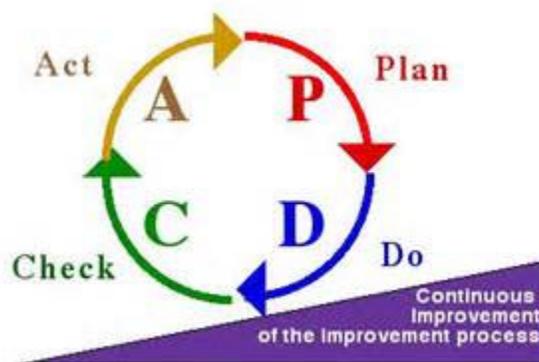
Methods and Tools for documenting improvements



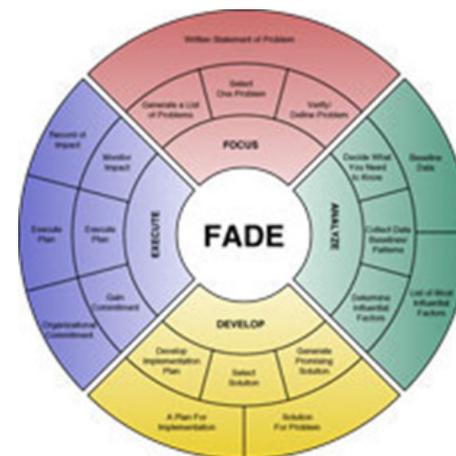
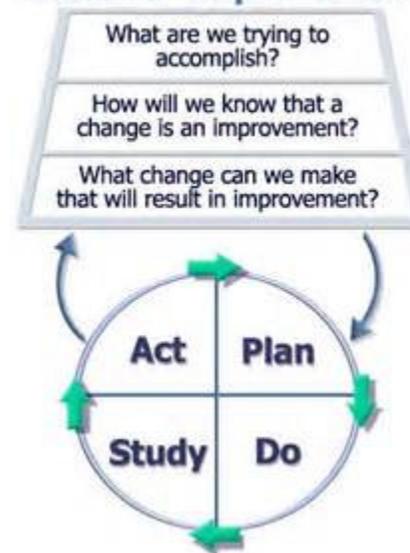
- All methods and tools are a means to the same goal = **Improvement**
- Different methods and tools achieve different results in different timeframes.
- All methods may be employed as long as the method provides the desired results.
- Improvement may focus on Clinical Variation or Process Variation.
- The goal of any model is to use the best knowledge available today to improve performance through the elimination of **special cause(s)** and **common cause(s)** in processes and then ensure that performance is sustained over time.

Method Examples

- Plan-Do-Study-Act (PDSA/PDCA)
- Model for Improvement (MFI)
- Focus, Analyze, Develop and Execute (FADE)
- Define, Measure, Analyze, Improve, Control (DMAIC)
- Define, Measure, Analyze, Design, Verify (DMADV)
- Identify, Measure, Prioritize, Research, Outline, Validate, Execute (IMPROVE)
- Assess, Plan, Implement, Evaluate (APIE)
- Identify, Determine, Establish, Act (IDEA)
- Failure Mode and Effect Analysis (FMEA)



Model for Improvement



Project Charter example



Team Specific Process and Performance Improvement Projects

Team: _____

Date: _____

| | | |
|---|------------------------|-----------------|
| Performance Improvement TOPIC: | | |
| How did you decide this is important (what baseline data are being used)? | | |
| Specific Aim or Purpose | | |
| Desired Outcome or Improvement Target | | |
| Plan to Achieve Target - Action Steps (who, will do what, by when) | | |
| What will be done? (brief description) | Who will do it? | By When? |
| | | |
| | | |
| | | |
| | | |
| How will you measure success and continue to monitor the process? | | |

PDSA Template Example



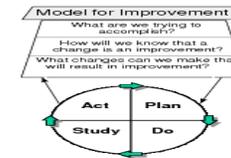
PDSA Cycles Report

Project:
Team/Site:
Aim:

Change Idea:

Date begun:

Date finished:



| | |
|--------------|--|
| PLAN | <p>Describe the objective of the cycle?</p> <p>What do you predict will happen?</p> <p>What is the plan? (What are we testing? Who are we testing the change on? When? Where?)</p> <p>What measure(s) will you use to assess the success of this test? (What data do we need to collect? Who will collect the data? When? Where? How?)</p> |
| DO | <p>What was actually tested?</p> <p>What happened? What observations did you make?</p> <p>Were there any problems?</p> |
| STUDY | <p>What were the results of the test, and how did they compare with your prediction?</p> |
| ACT | <p>Based on what you learned, what will you do next?</p> |
| PLAN | <p>Objective of next cycle:</p> |

DMAIC Template example



BB DMAIC Tool Template



| Phase/Activity | Target Date | Comp Date |
|------------------------------------|-------------|--------------------------|
| Define | XX-XX-XX | XX-XX-XX |
| • Schematic | | <input type="checkbox"/> |
| • Team Charter | | <input type="checkbox"/> |
| • Benchmarking | | <input type="checkbox"/> |
| • "AS-IS" Process Map | | <input type="checkbox"/> |
| • VOB/VOC to CTQ's | | <input type="checkbox"/> |
| • Cause-n-Effect Diagram | | <input type="checkbox"/> |
| • Quick Wins Identified | | <input type="checkbox"/> |
| Measure | XX-XX-XX | XX-XX-XX |
| • Data Collection Plan | | <input type="checkbox"/> |
| • Measurement Operation Definition | | <input type="checkbox"/> |
| • Source of Variation Study | | <input type="checkbox"/> |
| • Sigma Analysis | | <input type="checkbox"/> |
| • Process Capability | | <input type="checkbox"/> |

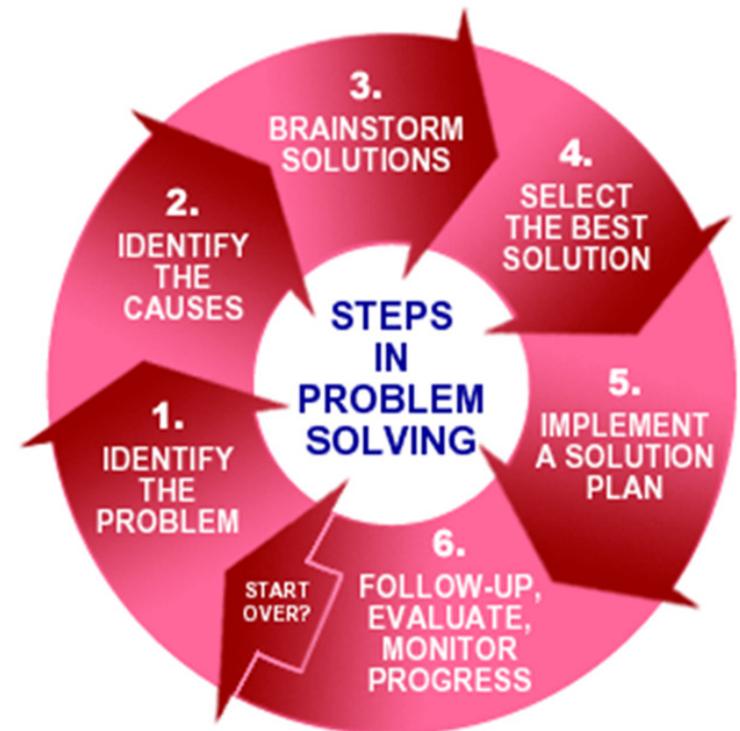
| Phase/Activity | Target Date | Comp Date |
|--------------------------------------|-------------|--------------------------|
| Analyze | XX-XX-XX | XX-XX-XX |
| • Pareto Analysis and Stratification | | <input type="checkbox"/> |
| • Regression Analysis | | <input type="checkbox"/> |
| • Root Cause Analysis | | <input type="checkbox"/> |
| Improve | XX-XX-XX | XX-XX-XX |
| • Cost Benefit Plan | | <input type="checkbox"/> |
| • Alternative Solutions Identified | | <input type="checkbox"/> |
| • "SHOULD BE" Process Map | | <input type="checkbox"/> |
| • Change Plan | | <input type="checkbox"/> |
| • Pilot Plan and Results | | <input type="checkbox"/> |
| Control | XX-XX-XX | XX-XX-XX |
| • Digitization Plan | | <input type="checkbox"/> |
| • Standardization/Adoption Plan | | <input type="checkbox"/> |
| • Lessons Learned and Feedback | | <input type="checkbox"/> |

- ACTIVITY COMPLETED
- ACTIVITY STARTED
- PHASE COMPLETED
- PHASE STARTED
- PHASE STARTED BUT MISS COMP DATE
- PHASE COMPLETED BUT MISS COMP DATE

Problem Solving

All methods contain similar components for problem solving:

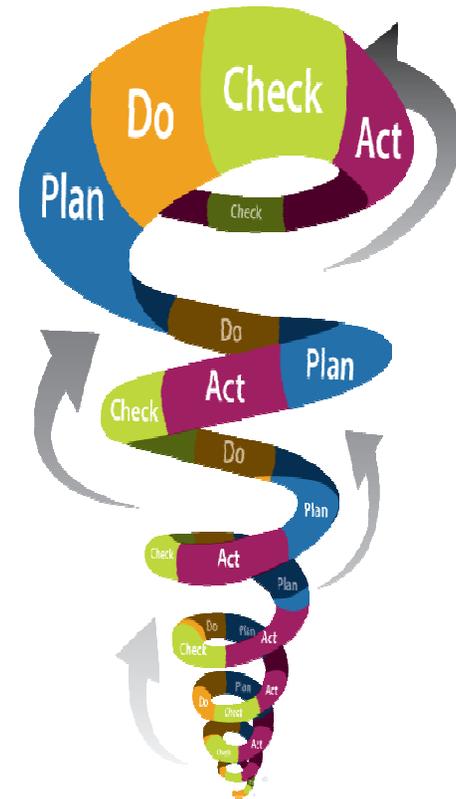
- 1) An Opportunity for Improvement exist,
- 2) Data is collected, analyzed and turned into information (*data helps identify the causes*),
- 3) Actions / Solutions are identified,
- 4) Actions / Solutions are tested,
- 5) Actions / Solutions are implemented,
- 6) Implemented items are monitored for success to determine if improvements are sustained or are sustainable.



Continuous Improvement

All models focus on
CONTINUOUS improvement
cycles.

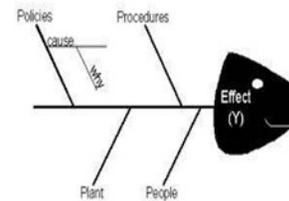
Cycles should be considered a
three dimensional (spring) process where excellence is
continually pursued.



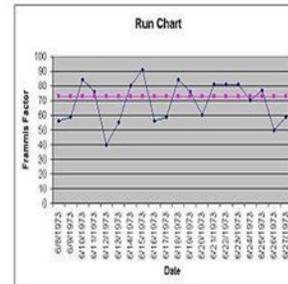
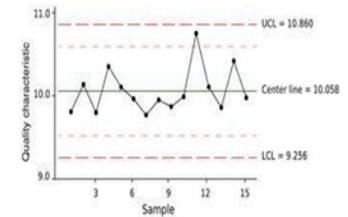
Tools

| 7 BASIC STATISTICAL TOOLS |
|---------------------------|
| Check Sheet |
| Flowchart |
| Histogram |
| Pareto Chart |
| Scatter Diagram |
| Fishbone Diagram |
| Control Chart |

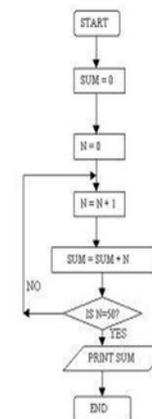
Cause and Effect Diagram



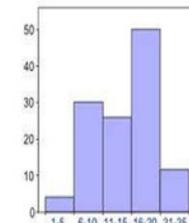
Control Chart



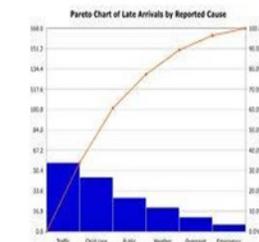
Run Chart



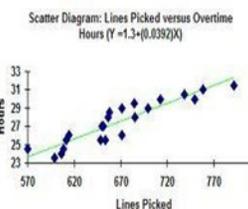
Flowchart



Histogram



Pareto Chart



Scatter Diagram

7 Basic Statistical Tools



- Most statistical tools are neither difficult nor complicated to master.
- The Seven Basic Tools of Quality is a designation given to a fixed set of graphical techniques identified as being most helpful in troubleshooting issues related to quality.
- They are called basic because they are suitable for people with little formal training in statistics and because they can be used to solve the vast majority of quality-related issues.

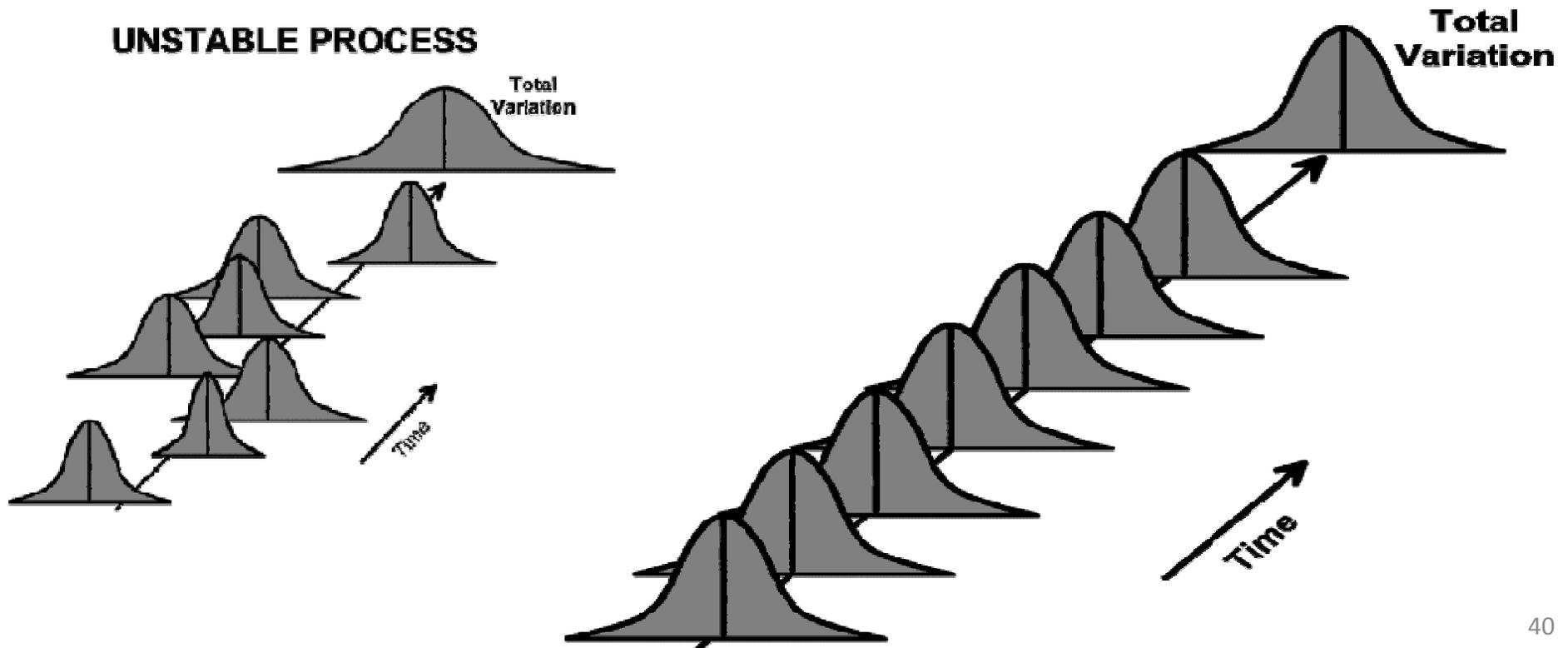
Thoughts from W. Edwards Deming (The Deming Management Method 1986) on why statistical methods are important; helping organizations understand, utilize and apply data analysis appropriately.



Action Planning

The ultimate GOAL of action planning is to achieve a
STABLE & PREDICTABLE process over time.

STABLE PROCESS



Action towards improvement



1) How do you develop actions toward improvement?

Answer:

- Identify barriers to effective implementation.
- Identify countermeasures available.
- Evaluate alternatives.
- Contain actions that address the root cause and are not detrimental if implemented.
- Action plans should be tested as would be done in any performance improvement project.
- Action plans must establish timeframes for completion and follow-up.
- Action plans must identify responsible individuals to oversee the implementation.

2) Was the action taken a one-time correction or something that requires continuous monitoring?

Answer:

- A one-time correction may be monitored by exception – will the event or undesired performance ever appear again?
- Something that requires continuous monitoring should become a QA measure and tracked along with all the other objective measures.

Sustainability of Actions



3) How do you determine if the actions taken have been sustained?

Answer:

- Sustainability means the process has become stable (without variation).
- Stable means variation does not appear over an extended period of time – normally 4 measure periods.

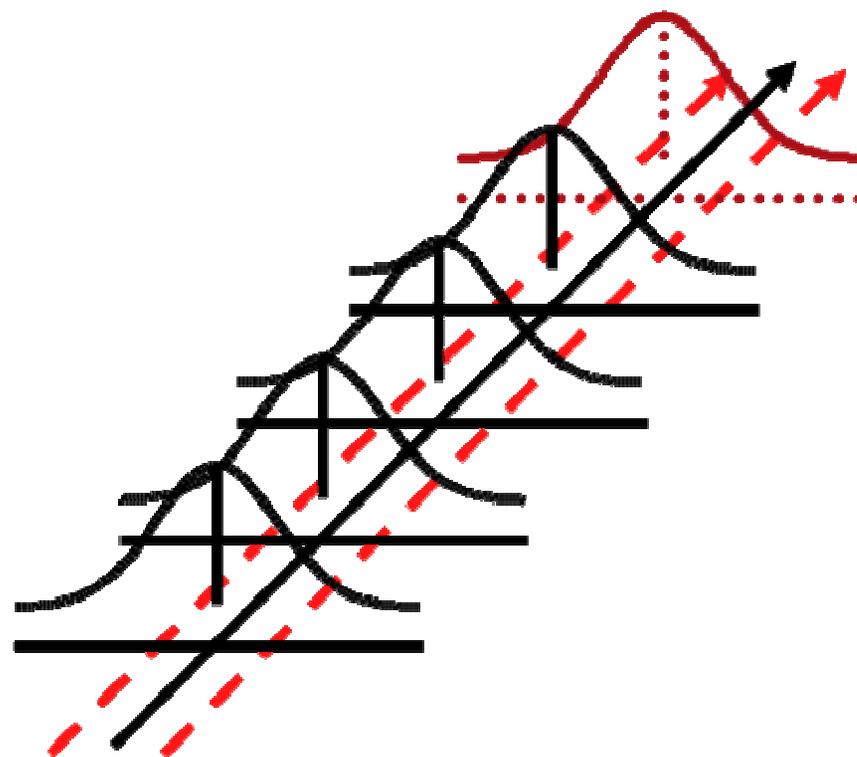
4) Have you developed follow-up methods for actions taken?

Answer:

- Follow up methods may be continued surveillance, continued monitoring, or spot checking at select intervals.
- Follow up all depends on the nature of the process and the actions taken.

Stable and Predictable Process

- Effective QAPI programs define when and how actions are developed and taken toward improvement prior to negative trends, undesired performance or opportunities for improvement are identified.
- Once actions are taken, the plan should include follow-up periods to determine if the actions led to improvement and sustained over time; normally 4 periods of measurement is adequate.
- A stable and predictable process is one without variation present, ensuring the process is functioning at its expected and desired level of performance.



Action Plan example



There are many formats for reporting improvement activity.

A simple action plan assists in documenting actions taken in response to identification of opportunities.

| Issue/ Opportunity | Discussion & Analysis | Interventions | Whom | Target Date | Comments |
|-----------------------|--------------------------|---------------|------|----------------|----------|
| 1. | | | | | |
| 2. | | | | | |
| 3. | | | | | |

Survey Application



- The Hospital and Transplant Conditions of Participation require improvements to be **sustained** over time.
- All projects, action plans or QAPI activities should have a defined method to monitor or follow up actions taken **completing the cycle** prior to the start of any action being taken. All QAPI cycles should be **closed** or **return to the planning stage** for further actions to be developed.
- Surveyors focus on the sustainability of actions and if actions taken led to improvements that were sustained over time.

Project Termination



- Some projects come to full completion and the improvements are sustained.
- Some projects morph into something totally different than what the initial opportunity indicated. It is acceptable to make changes to a project's scope, AIM or Goals as new information becomes available.
- Programs should have processes in place to terminate a project if solutions will not lead to sustainable improvements or if the solutions create negative consequences in other areas.



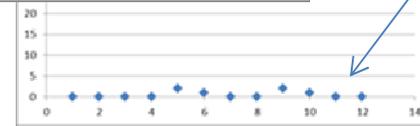
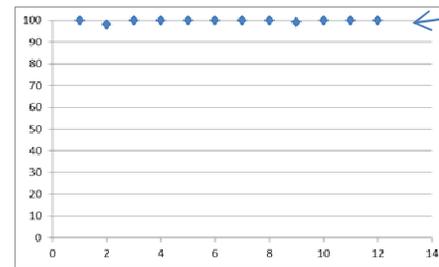
Closing

HIGH RISK



HIGH VOLUME*

*or very LOW VOLUME



PROBLEM PRONE



PI Summary



Performance Improvement is:

- the planned, systematic approach to identify, understand and make changes to a process making that process more effective or efficient.
- the concept of measuring the output of a particular process or procedure, then modifying the process or procedure to increase the output, increase efficiency, or increase the effectiveness of the process or procedure.
- the action taken when an opportunity for improvement has been identified.

Closing Summary



- A comprehensive integrated improvement program needs to be fueled by a vision of the future state and by a pipeline of specific projects that will help close the gap between the current state and future (*ideal*) state.
- It does not matter what QAPI methodology is utilized by the program/organization – the goal is the same: CLEARLY Define the problem, Analyze the Data APPROPRIATELY and Test the improvements prior to implementation to determine SUSTAINABILITY.

Questions



Contact Information



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