

## **Adverse Events: Thorough Analysis**



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*Enhancing Quality Assessment and  
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in Transplant Programs and Hospitals*

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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 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

# Disclaimer



- This training series will contain concepts, tools and methods related to adverse events and patient safety systems (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 an Adverse Event is, 2) There are many methods that can be employed and 3) There are many tools that can be utilized to identify and analyze adverse events.
- CMS also understands that organizations have leeway to severity rank and define adverse events within their own organization in accordance to what their governing body has established, so long as the activities required under the CMS Adverse Event definition are fulfilled.
- This training series does not support or advocate any particular method or tool for analyzing adverse events. This training fully supports that patient safety activities include data driven decisions that lead to improved performance and ultimately the prevention of harm to patients.

# Purpose and Objectives



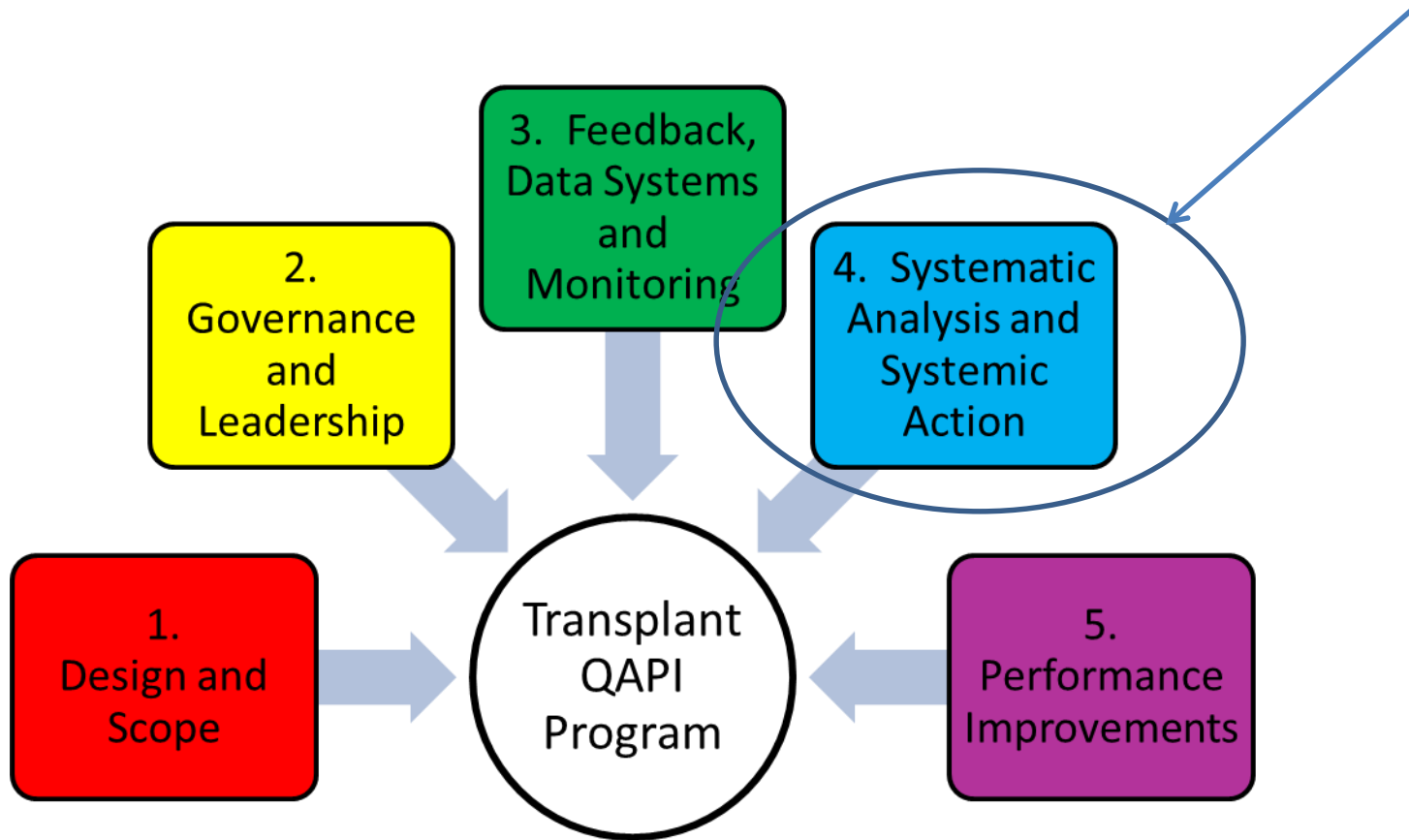
The purpose of this session is to enhance the safeguarding of recipients and living donors through:

- An increased understanding of regulations,
- An understanding of different analysis techniques & tools, and
- The use of results of a thorough analysis to prevent future re-occurrences.

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

- Discuss the meaning of a 'thorough analysis' as it applies to Transplant Adverse Events.
- Identify the requirements for Transplant programs in relation to the thorough analysis of Transplant Adverse Events.
- Specify critical elements of an Adverse Event Action Plan utilizing the results of a 'thorough analysis'.

# The 5 Key Aspects of Transplant Quality



# Adverse Events: Regulatory Language



A transplant center must:

- Establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.
- The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.
- Conduct a thorough analysis of and document any adverse event
- Utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.

# Aspect 4 - Systematic Analysis and Systemic Action



- Transplant adverse events must be **identified, tracked, investigated, analyzed,** and the **results used to prevent recurrence.**
- There must be **evidence** that the transplant QAPI program develops **system-based interventions** to improve quality of care and performance on an ongoing basis to reduce risk of harm to patients.
- Systemic actions look **comprehensively** across all involved systems to **prevent** future negative events and promote **sustained** improvement.
- The transplant QAPI program uses an identifiable **structure, policies and procedures** to address investigation of contributing and **root causes** of transplant quality issues and **document actions** taken toward correction and sustaining change.

## Regulation: 482.96(b)(2)



THOROUGH ANALYSIS



## §482.96(b)(2)

### **CONDUCT ANALYSIS of and DOCUMENT any ADVERSE EVENT**

(2) The transplant center **must conduct a thorough analysis of and document any** adverse event

# Interpretive Guidelines



A “thorough analysis” is expected to include (*but is not limited to*):

- a) A description of the key facts of the event **in enough detail** so that one can clearly understand what occurred, the severity of the event, and **how the patient was affected**;
- b) A review of whether or not similar events have occurred in the past; and
- c) An analysis of **related systems** and **processes** that contributed to the event’s occurrence

# IG's continued



*c) An analysis of **related systems** and **processes** that contributed to the event's occurrence*

Examples of systemic factors that may contribute to adverse events include:

- **Human:** communication, staff training, scheduling, the patient;
- **Environmental:** location of needed equipment, systems for organizing/labeling medication;
- **Equipment:** technology that does not warn of pending error;
- **Policies:** polices that may exist but are unclear, or where no policies exist;
- **Procedures:** there are no procedures for verification of blood type;
- **Organizational:** the transplant program may not be monitoring adherence to or reinforcing care protocols.

# Adverse Event Definition



*“Adverse event* means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended beneficiaries; and unintended transmission of infectious disease to a beneficiary..”

*Source: 42 CFR 482.70*

# Thorough Analysis



# Purpose



What is the purpose behind the requirement for a thorough analysis?

- In order to safeguard patients (*prevent future re-occurrences*) an in-depth review, investigation or analysis of the event will provide the means to detect process failure points, gaps in systems and other opportunities for improvement so that action may be planned and taken to prevent repeat incidents.
- The causes of/factors contributing to adverse events are often multi-factorial. In-depth review will increase the likelihood of identifying hidden causal or contributing factors.

# Goals

The goals of a thorough analysis are to:

- Understand the nature of the cause or contributing factors in relation to the event or identified problem,
- Ask deep enough questions to arrive at the underlying nature of the cause and not symptoms of the cause,
- Remove bias from the causal determination process to assist in uncovering ALL potential processes and system issues.

# Terminology



We must look past the terminology that may have different meanings (i.e., RCA) and focus on the intent of regulations.

- A **‘Thorough Analysis’** is a planned, systematic investigative process (*a method of problem solving*) that tries to identify the root cause or contributing factors of a problem.
- A **‘Thorough Analysis’** encompasses the entire continuum of care around a given adverse event. (*Point of Event all the way back to the Point of First Contact with the patient*)
- The scope and depth of analysis should be scaled in proportion to the scope and severity of the harm experienced and/or the risk involved. (*see next slide*)



# Terminology continued



- Adverse events that resulted in, or had the potential to result in death, graft loss or other very serious harm warrant use of a more elaborate and in-depth thorough analysis process.
- Less elaborate and time-intensive methods that nonetheless allow for the collection and analysis of essential facts about systems factors (event details, staff, equipment, policy, environmental concerns and procedures) may be sufficient to thoroughly analyze adverse events that resulted in, or had the potential to result in less serious harm.

# Components



A thorough analysis includes:

- Determination of human and other factors most directly associated with the event;
- Analysis of direct processes and systems related to the event (including policies);
- Analysis of underlying / secondary systems and processes (including policies);
- An inquiry into all areas appropriate to the event;
- An identification of risk points and their potential contributions to the type of event;
- A determination of potential improvements that will likely decrease future events.

# Determining the Level



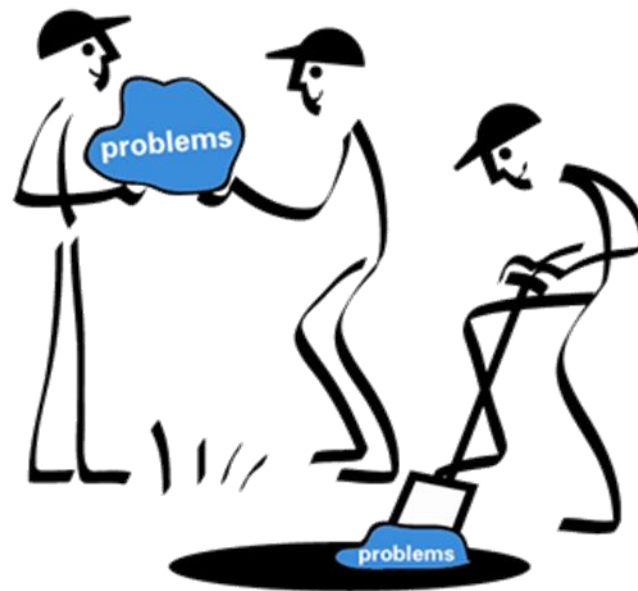
- The organization's Risk Management Department or Patient Safety Department should have a screening algorithm or harm severity ranking system that will be beneficial in determining the level of '**thorough analysis**' to be performed for a given transplant adverse event.
- There are many methods to severity rank an adverse event; transplant programs will want to align with the hospital system for ease of integration and reporting.
- Surveyors will look for what has been defined as a '**thorough analysis**' in the adverse event policy and then ensure that this process was followed for any adverse event within the transplant program.

# Professional Resources

**\*Not required or endorsed by CMS\***



- National Quality Forum: Serious Reportable Events
- HPI Safety Event Classification
- Joint Commission Patient Safety Event Taxonomy
- World Health Organization International Classification for Patient Safety
- IHI Global Trigger Tool for Measuring Adverse Events
- The Clavien-Dindo Classification of Surgical Complications
- Institute for Safe Medication Practices (ISMP)
- Midas+ (Midas+ AHRQ PSO Acute Care Data Collection and Extraction Toolkit )
- AHRQ Common Formats (Agency for Healthcare Research and Quality)



Dig Deep

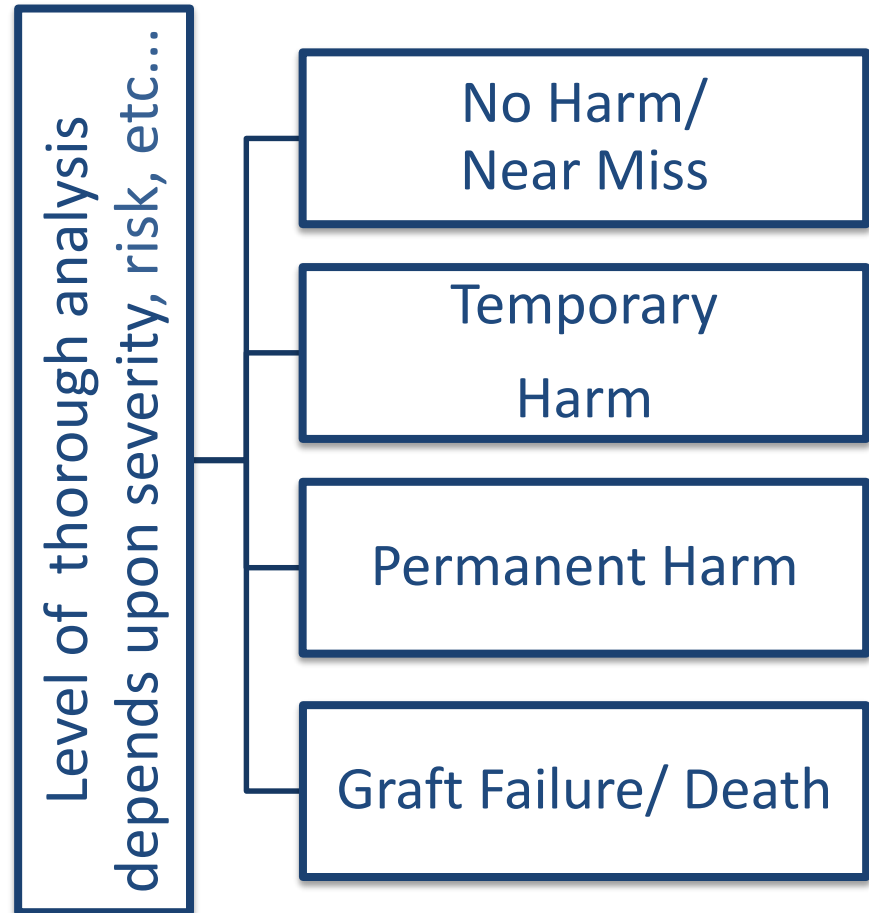
# Survey Application - Examples



- Surveyors are not focusing on the specific details of the event. The focus in the survey process is to determine that the **components of a thorough analysis** were present in order for actions to be developed to prevent repeat events.
- Surveyors are validating the transplant program responded appropriately to a given adverse event ensuring the protection and safeguarding of all potential recipients, recipients, potential living donors and living donors.

# Adverse Event Determination

- **Event Awareness** (*reported, recognized, identified, discovered*)
- **Event Report** initiated (*incident report, occurrence report, event report*)
- Determination of event **severity or harm** by organization's ranking system
- **Investigation and Analysis** of event
- **Disclosure** (per policy – *patient, family, external agencies*)
- **Actions** developed and sustained to prevent repeat incidents
- Sharing **lessons learned** (*Reporting throughout program and organization*)



# Gathering and Analyzing the Facts



A thorough analysis will have answered these questions:

- **What happened?** (*full detailed description of events*)
- **When did it occur?** (*time or shift and related factors*)
- **Where did it occur?** (*location of the event - transplant unit, transplant clinic, hospital unit and related factors in the environment*)
- **Who was involved?** (*identify all staff involved: nursing, ancillary, or contracted vendors and related factors such as distraction, communication, fatigue, training, culture, supports*)
- **What equipment and information technology, if any, were involved?** (*factors such as design, usability, safeguards, maintenance, information display, “work-arounds”*)
- **What policies, procedures or processes were involved?** (*assessment of policies/procedures/processes and their effectiveness, usability, implementation, acceptance, adherence*)
- **Why did it happen?**
- **Was it preventable or avoidable?** (*go beyond the patient’s current medical condition*)
- **Is there a risk of harm to others if the process / systems are not addressed?**





# Analysis of Adverse Event #1 (as found on survey)



Missed Medications

During record review – note of missed medication was discovered

Surveyors asked for the details of the event

Tacrolimus

Hospital brought an online occurrence report that had been completed by the unit nursing manager for review

and Mycophenolate Mofetil

Interview with Hospital Risk Manager revealed that the event was no harm to the patient and the information was sent to P&T committee

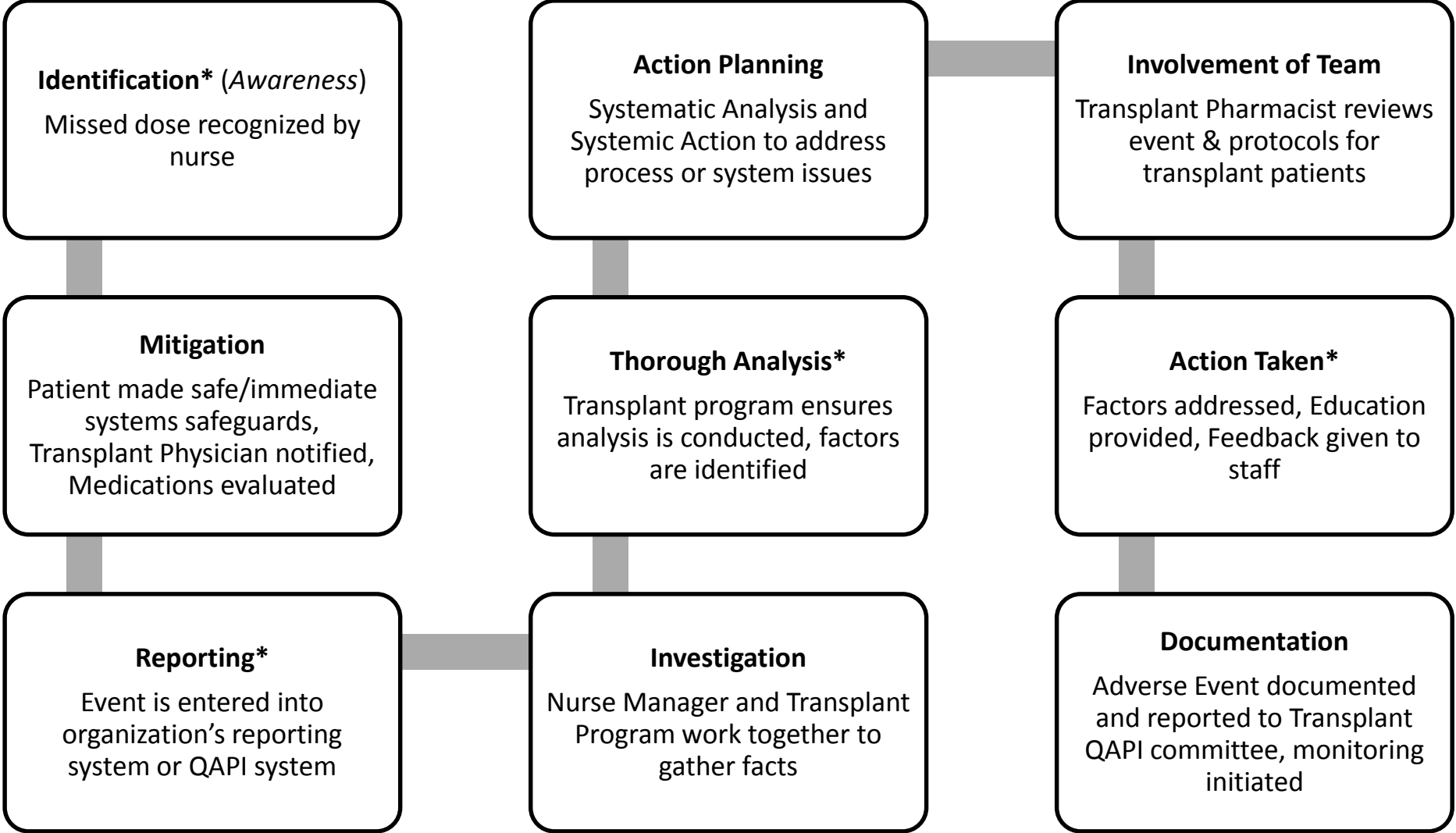
Review of the occurrence report showed that protocols were not followed and education would be provided to the unit

There was no evidence that Transplant was involved in the completion of the occurrence report or education to nursing

There was no evidence of this event in Transplant documents, QAPI meetings or objective measures



# Thorough Analysis Adverse Event #1



\* Indicates items required in the Adverse Event Policy and Transplant Regulations



# Adverse Event #2 (as found on survey)



## Falls on Nursing Unit involving Transplant Recipients

During survey there was **no evidence** that the Transplant program had included patient falls into their QAPI activities

Surveyors asked the Hospital for fall information for the nursing floor that Kidney Recipients were sent after the procedure

Hospital brought a log that showed 8 falls (3 with injury) for the nursing unit

Interview with Transplant Administrator revealed that patient falls were handled through the Hospital's fall program

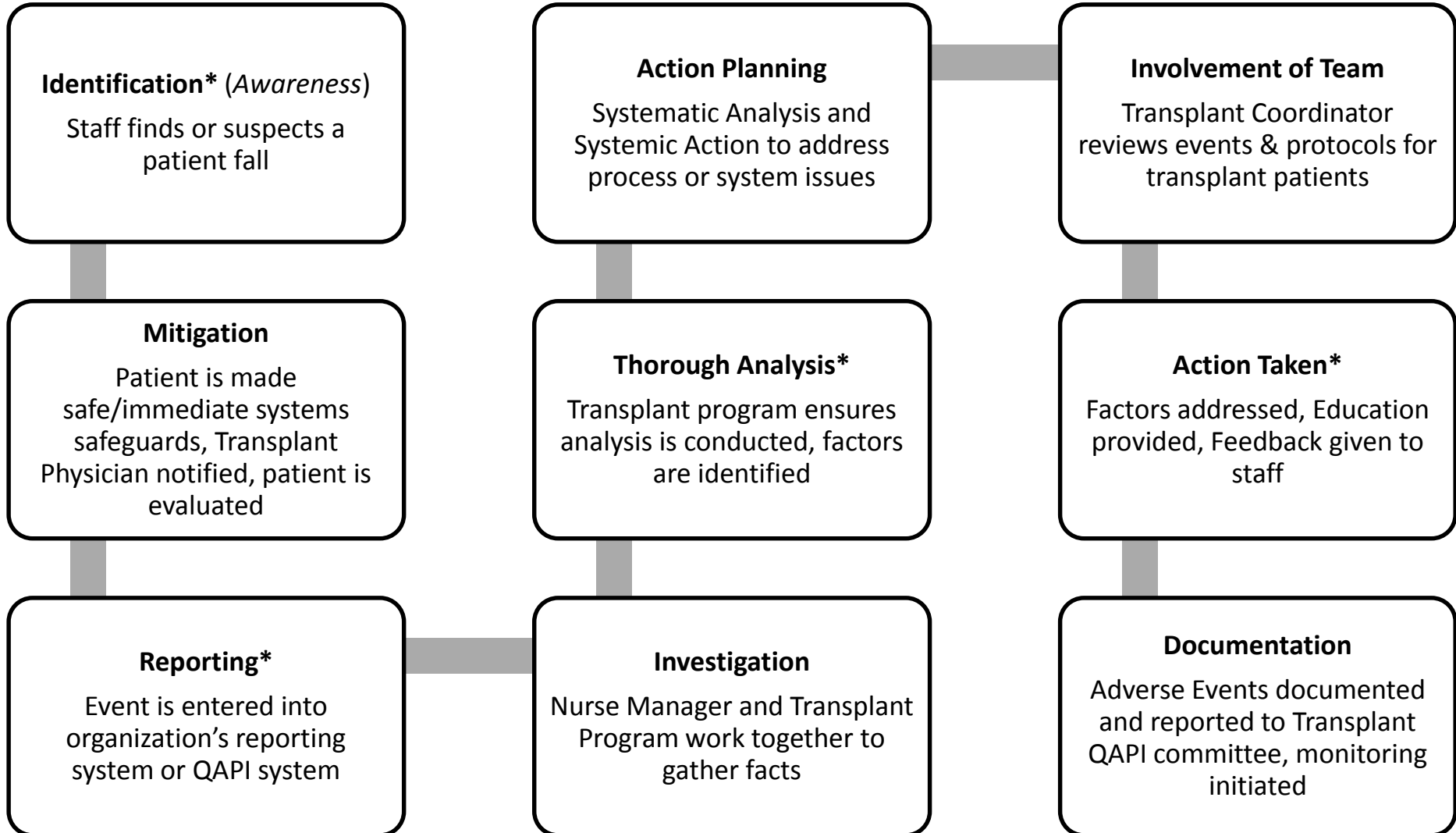
Review of the Fall log revealed that 5 of the 8 patients listed were Transplant Recipients

Surveyors requested the event reports/QAPI program documentation for the 5 transplant recipients; there was no evidence of involvement by the transplant program

Review of the 5 event reports showed that none of the recipients were on fall precautions and 3 recipients had injuries from the fall



# Thorough Analysis Adverse Event #2



\* Indicates items required in the Adverse Event Policy and Transplant Regulations



# Adverse Event #3 *(as found on survey)*



## Patient Death

Review of Medical Records showed one death

Surveyors requested the review of the Death to see how the Transplant program handled the event

Transplant program provided a Hospital Root Cause Analysis that contained a timeline of events and identified causal factors; review suggested an equipment malfunction

Review of the surgical case did not identify anything of concern with the surgical care

The hospital was able to provide evidence that the equipment involved had been the subject of an FDA recall several years prior

There was no evidence that the death review, hospital RCA or even a death summary was included in transplant QAPI activities



# Thorough Analysis Adverse Event #3



## Identification\* (*Awareness*)

Patient death identified by external report to facility

## Action Planning

Systematic Analysis and Systemic Action to address process or system issues

## Preventable Event?

Analysis indicated the equipment used were part of an FDA recall, but could not determine how the equipment remained in supplies

## Reporting\*

Transplant program reported death as required to external agencies

## Involvement of Team

The analysis was conducted by the hospital with transplant surgeon, physician and administrator involved

## Action Taken\*

Review of Recall process was conducted, no other actions were identified in the Root Cause Analysis

## Thorough Analysis\*

Death reviewed by Transplant Program, RCA conducted and Surgical Case Peer Review was conducted by hospital

## Investigation

Transplant program reviewed patient chart, selection criteria and follow up was according to policy

## Documentation

Mortality documented as part of objective measures, Summary report to Transplant QAPI to monitor

\* Indicates items required in the Adverse Event Policy and Transplant Regulations

# Thorough Analysis Process



# Investigative Process within a Thorough Analysis

## A typical investigative process includes:

- Adverse event awareness (notification / discovery / identification)
- Form team or assign responsible staff to gather facts
- Gather facts (what happened, when, where, why, how, who was involved: patient, staff, family)
- Document any equipment involved or care environment concerns
- Develop a timeline as far back as possible to capture all relevant facts
- Conduct interviews with relevant internal staff
- Conduct interviews with relevant external groups
- Identify the process(es) that may be involved
- Identify policy / procedures that may be involved
- Report facts and details to Analysis team

how  
where  
when  
why  
what  
whose  
who



# Analysis Process



## A typical Thorough Analysis includes:

- Reviews related systems and processes
- Identifies system-related cause(s) and explains their potential role in the event
- Outlines a plan to address opportunities to improve or explains why the organization isn't addressing those opportunities
- Explains : when improvement plans are justified, who will carry out the plan, when that person(s) will carry out the plan; and, the methods for measuring results
- Involves people closely associated with all aspects of the systems and processes under review (internal and external parties including contracted service agencies)
- Considers all relevant literature, policies and protocols
- Reported to all levels of leadership (findings are consistent and conclusions are endorsed by all)
- Promotes learning - distributed to anyone who can benefit from the findings

# Team Response & Decision



# Team Response



- After an event has occurred, responding to an event from a team approach is important to prevent repeat incidents (CMS does not specify particular disciplines for such analyses, however).
- The adverse event policy should identify a **timeframe** of when the multi-disciplinary team should conduct a first meeting in response to an event notification.
- Normally, within 72 hours is an acceptable timeframe for a thorough analysis to begin. The quicker an analysis begins allows for details to be captured while they are still fresh in the memories of those involved.

# Team Decision



- Consider: Including as many relevant staff as appropriate and possible from the multi-disciplinary team, floor nurses, ancillary staff, others.
- An analysis team that consists of 2 or 3 people may not be enough staff to analyze the data, understand the full processes involved or be able to make effective recommendations for improvement.



# Documenting Any Adverse Event

# Documenting Adverse Events



## Methods of Documenting Adverse Events

Event Reporting System

Log Books

Patient Safety Meetings

Transplant QAPI Meetings

QAPI Meetings

Adverse Event Spreadsheets

Transplant AE Meetings

Transplant Event reports

Surveyors are looking for Transplant specific evidence that adverse events were identified, reported, analyzed and acted upon within the transplant program.

# Section 1 Summary

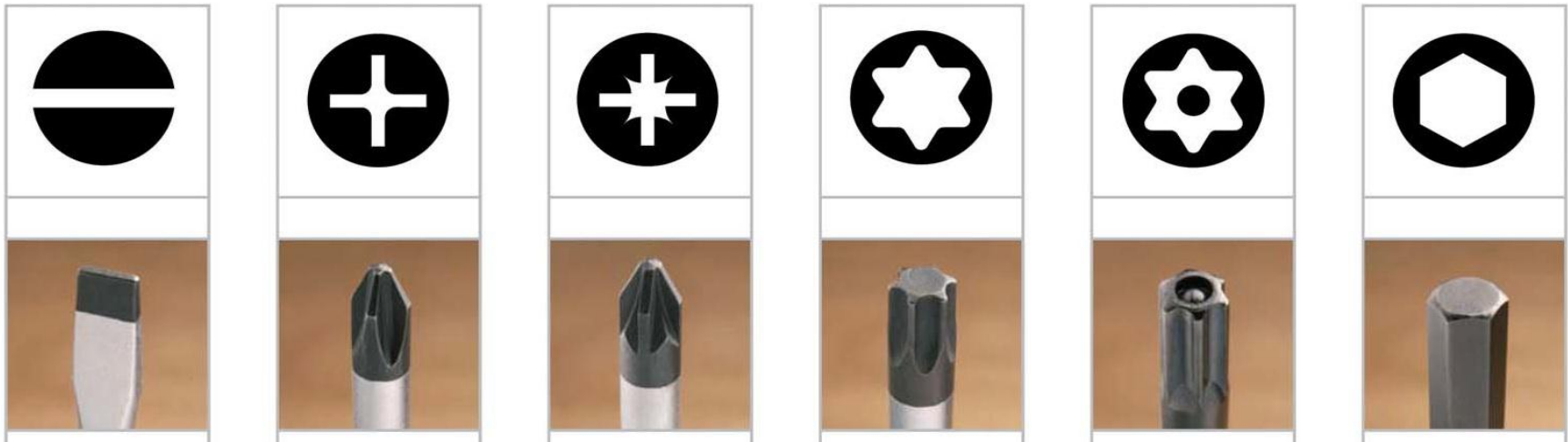


The primary focus of a thorough analysis is:

- 1) To determine what happened,
- 2) Why did it happen, and
- 3) What can we do to prevent it from happening again.

Documenting any adverse event is the ability of a transplant program to provide evidence that a transplant adverse event has been identified, reported (internally within the transplant program and externally where required), analyzed and acted upon.

# Analysis Tools and Methods

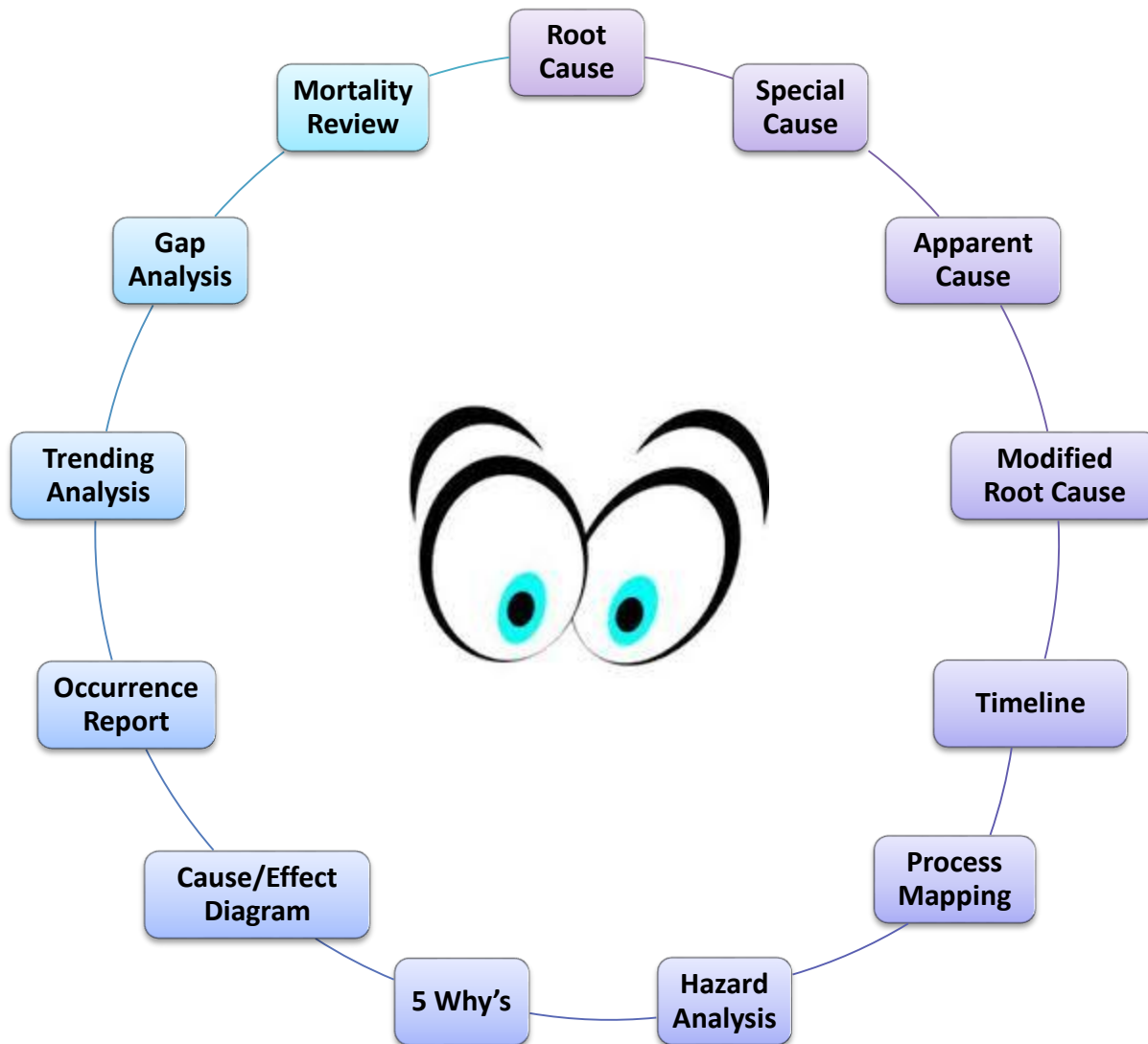


**SELECTING THE PROPER TOOL / METHOD IS IMPORTANT**



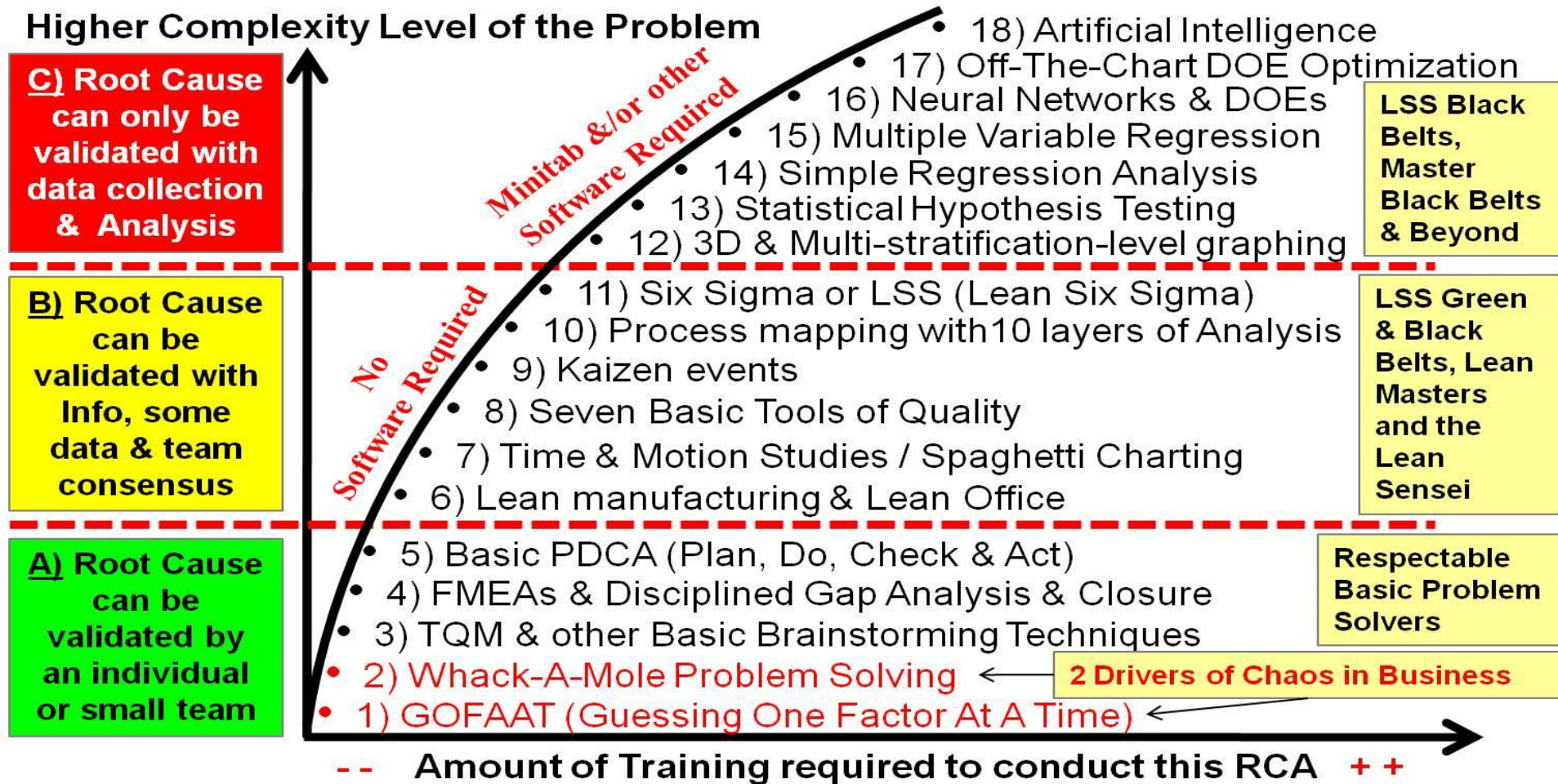


# Potential Tools and Methods

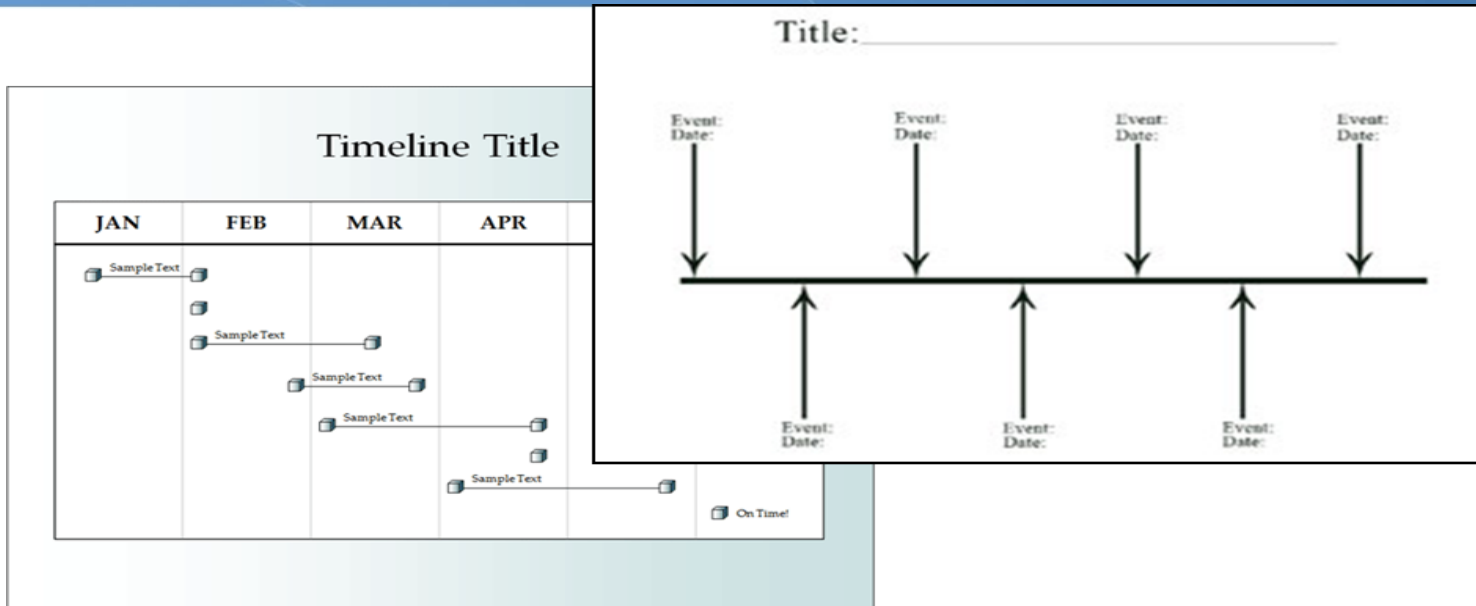


# Examples of Root Cause Tools and Methods

## Some of the Popular Root Cause Analysis & Problem Solving Techniques



# Timeline example

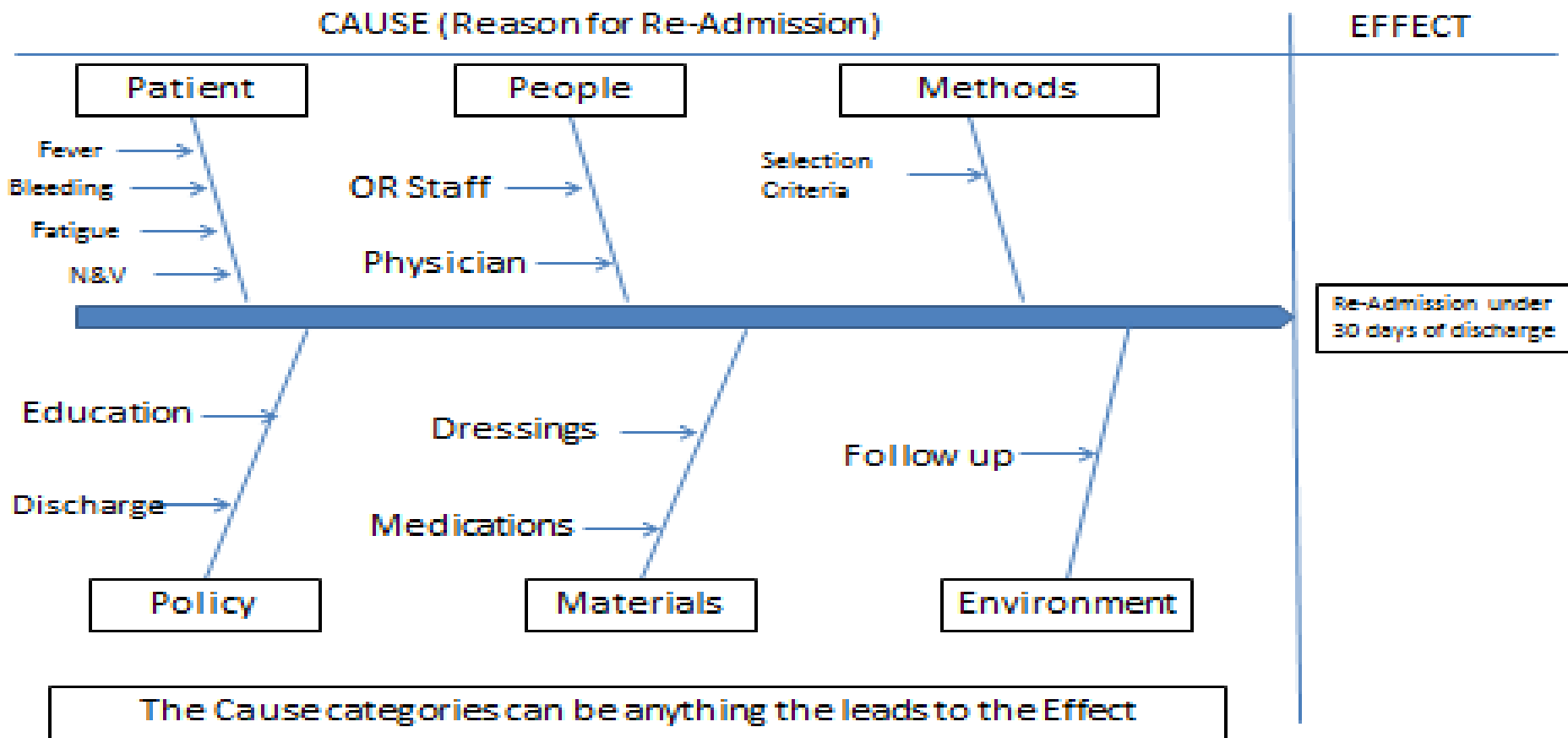


## Serious Safety Event Timeline Example

Date	Time	Issue	Team Member	Comments
		Request for Evaluation	Pre Coord. A	No issues identified
		Evaluation Complete	Pre Coord. A	No issues identified
		Wait Listed	Pre Coord. A	No issues identified
		Organ Offer	Coordinator B	ECD [Extended Criteria Donor]
		[Issue here]	[Health care team member]	
		[Issue here]	[Health care team member]	
		[Issue here]	[Health care team member]	
		Event Occurred (specify)		

# Fishbone Example

## Cause and Effect Diagram



# 5 WHY's example

## 5 Why Analysis

Define the problem

Delayed Immuno-suppressive treatments post-transplant

**Why is this happening?**

1. Treatment is based on late lab results

**Why are lab results late?**

2. Labs are drawn and processed on nursing floor timely

**Why are lab results late?**

3. Labs are sent to lab timely as directed by policy

**Why are lab results late?**

4. Labs are placed into the normal processing cycle

**Why is that?**

5. Policy does not consider these labs as needing to be processed rapidly like other Critical Labs with Critical Values

# Section 2 Summary



- Some tools and methods are a better fit at uncovering cause or contributing factors in relation to the effect or problem being reviewed.
- Ensure that the staff have been trained on the tool or method selected (or at least ensure that the staff leading the analysis has experience with the tool and review process).
- Utilize the most appropriate tool or method that will allow the analysis to dig deep enough and across all phases of transplantation so that the true nature of the cause is understood and that the analysis is not capturing mere symptoms of a larger issue.
- A specific tool or method is not mandatory – what is necessary is that transplant programs have a consistent and thorough methodology defined that will dig deep enough into the events and relationships between variables that will aid in the determination of cause(s).

# Taking Action

think  
rethink  
respond  
react  
act  
action

# Transplant Regulation

## Tag X104



### **§482.96(b)(2)**

**Utilize the ANALYSIS to EFFECT CHANGE (ADVERSE EVENTS)**

- and must utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.



# Importance of an Analysis



- An analysis helps understand the relationship between an event (the cause) and a second event (the effect), where the second event is understood as a consequence of the first.
- Understanding cause helps to identify and predict future effects from interactions of people and systems.
- A transplant program's ability to understand causes and effects within their processes and systems enables improvement.
- When looking at adverse events (those that caused harm and those with the potential to cause harm) the analysis must dig deep enough into the cause, causal relationships, agents and mechanisms that had an impact on the effect or outcome.
- The results and recommendations from a thorough analysis should provide enough information or data that can become knowledge for a program to take action towards improvement.

# Action Planning



Once a thorough analysis has been completed, it should clearly contain the components listed in previous slides and include enough data for analysis. The action coming from an analysis may be similar to those seen from PI activities.

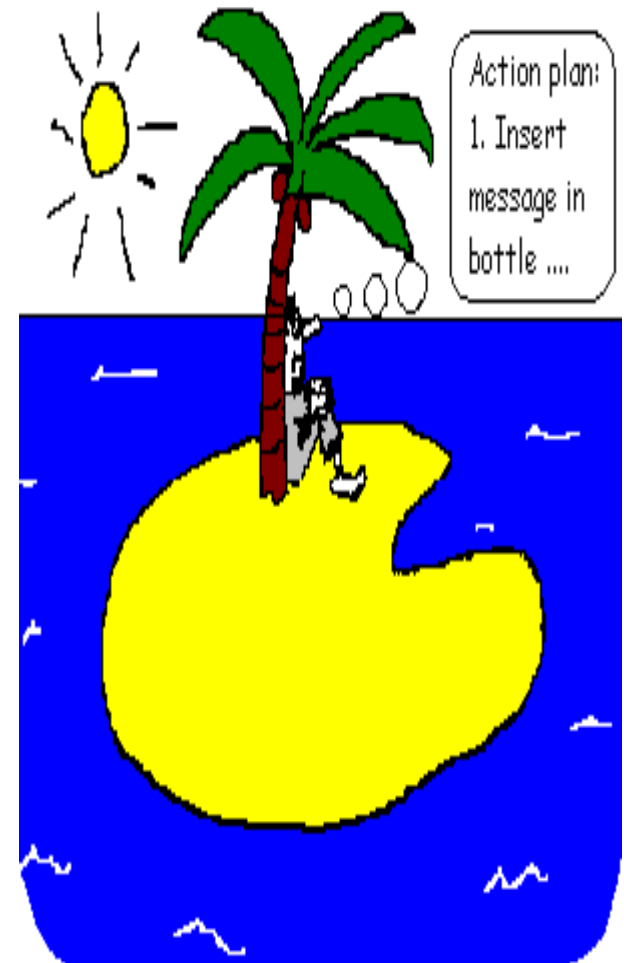
The action implemented from an analysis should include:

- Identification of barriers that prevent effective implementation
- Identify all countermeasure options available
- Evaluate all alternative options available
- Contain actions that address the cause(s), do not cause detrimental effects, and have understandable consequences if implemented and if not implemented

All actions implemented must have a defined follow up time documented with a responsible person and reporting mechanisms of the follow up findings. Follow up review reports should be contained or referenced in QAPI meeting minutes (although not required in CMS regulations).

# Action Plans

- 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 (including transplant staff: physicians and administrators).



# Action Plan example



## Adverse Event Action Plan

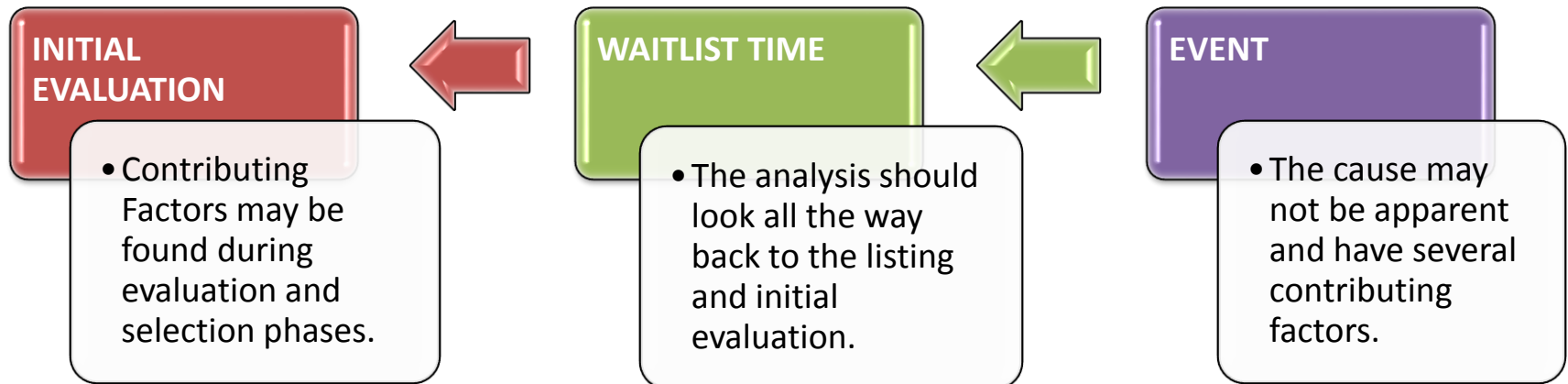
Name of Agency/Hospital/Program: St. Elsewhere Date Form Completed/Updated: 4/4/2024  
 Goal #1: Improve Patient Outcomes through better selection criteria utilization Date Begun: 1/4/2022  
 Goal # 2: Follow patients more closely after discharge Date Begun: 2/6/2022

Objectives: To prevent graft failures we will follow patients weekly after discharge for the first 6 months to ensure treatment plans are understood and being followed. In addition we will apply selection criteria more consistently to decrease the risk of graft failure with the expanded criteria we used in the past

Intervention	Intended Outcome	Individual(s) Responsible	Resources Required	Start Date	End Date	Measurement of Success
Call patients weekly post discharge for first 6 months.	Better compliance	Cathy Coordinator	1) Telephone 2) Email 3) Letter / Mail 4) Coordinator Time	2/6/22		1) Total number of patients reached each week 2) Zero graft failures

# Survey Application - Analysis

Surveyors will review if an organization's thorough analysis (*cause and effect*) was thorough enough to actually determine the cause or contributing factors of the adverse event in which **improvements can be made to prevent** similar events from occurring.



AN ANALYSIS SHOULD INCLUDE THE ENTIRE CONTINUUM OF CARE

# Trending & Comparative Data



# Trending

Recall from the IG's: A *“thorough analysis”* is expected to include:

*b) A review of whether or not similar events have occurred in the past;*

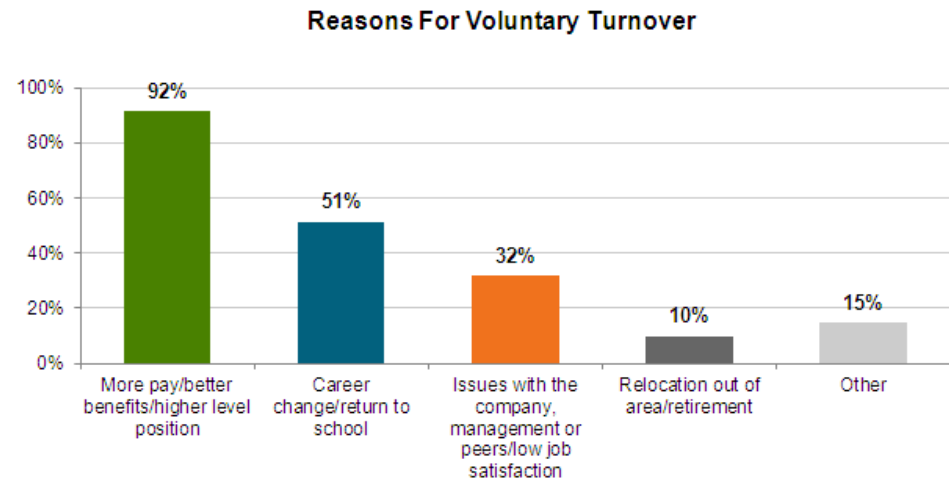
- Adverse Events are often not isolated in nature.
- **Transplant programs should always take into account previous thorough analysis conducted or event trends** to identify if the current event is **unique or connected** to something larger within the system.

# Trending vs. Analyzing

**Trending** (collecting and monitoring data over time) is different than **analyzing** (using data over time to draw conclusions about an issue).



Trending Staff Turnover by Quarters



Analyzed Data - Turnover by Reason



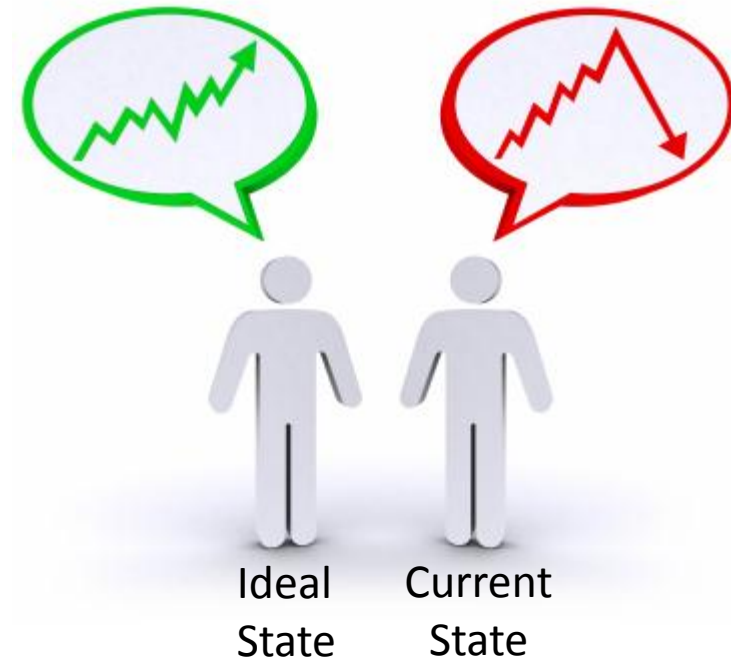
# Analyzed Trends

## *Examples of analyzed trends:*

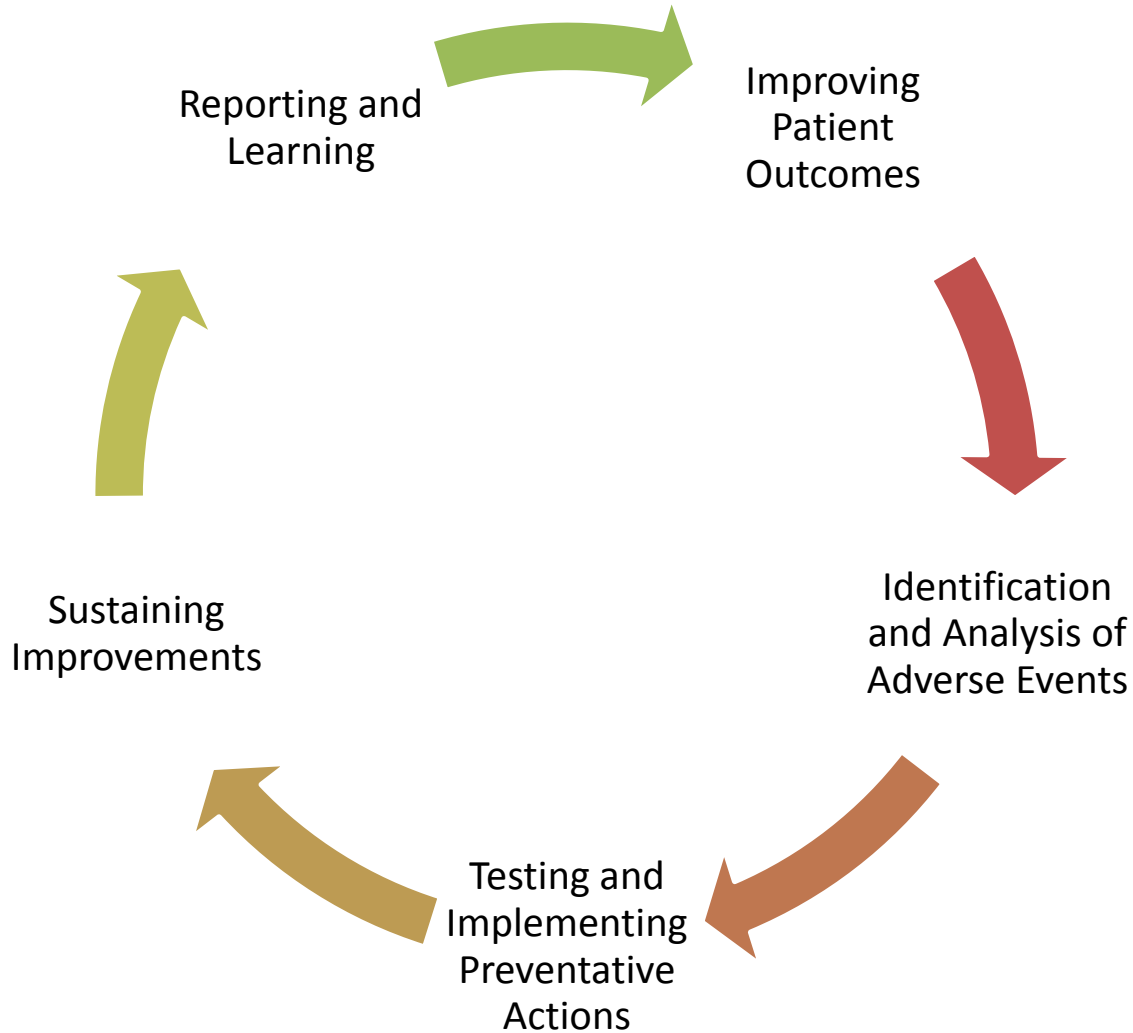
- Mortality by age or donor type;
- Graft failure by reason;
- Unplanned return to the O.R. by surgeon / complication / reason;
- Falls – transplant vs. hospital / medication protocols for recipients or donors / age / ambulation issues;
- Medication Errors by phase / staff / unit.

# Comparative Data

- Causes and Effects may be correlated to a process or connected to one another that is not easily identifiable without a comparative analysis.
- There are many methods to compare data. The goal is to look at data from as many different views as possible. Then comparing these data view points that may not appear to be connected but may have similar factors or components (i.e., patient demographics).
- When comparing data or trending, understanding what the 'Ideal State' for a process is will help determine if 'Current State' is functioning as desired.



# Completing the Cycle



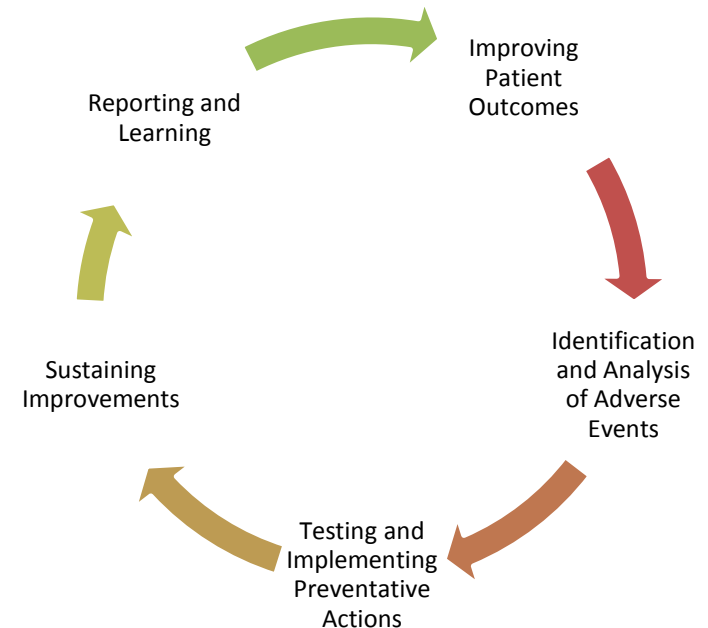
# Follow Up Activities



- The most overlooked component of action planning is to design / define follow up and monitoring activities of those actions taken towards improvement.
- Programs must always define the timeframes for when an action will be followed up to determine if improvement occurred or something different needs to occur.
- The overall goal of action planning is to develop effective actions and **sustain improvement** over time that leads to improved patient outcomes.

# Closing the Loop

- Regardless of the method – closing the loop in all activities is paramount to ensuring an effective program is in place.
- If the actions taken led to improvement and have been sustained, ensure all staff have been educated, learning has been passed through the organization and the improvements have been documented / reported to the highest levels of leadership.
- If actions taken did not lead to improvement, other actions are necessary. These activities should all be documented and reported to the highest levels of leadership – as the actions necessary for improvement may require higher levels of decision making than transplant programs have control over or access to.





# Closing Summary



- Transplant programs **MUST** have a **policy** that includes the process for identification, reporting, analysis and prevention of adverse event.
- Transplant programs **MUST** conduct a **thorough analysis** on **ANY** adverse event in **ANY** phase of transplantation or living donation.
- Transplant programs **MUST utilize the results** of the thorough analysis to effect changes to policies and practices.

# Outstanding Work in Transplant Programs



Thorough analysis of adverse events has resulted in various improvements, for example:

- Changes to Lab controls.
- Improvements to organ delivery logistics and processes to ensure timely delivery to correct OR.
- Consideration of frailty scoring in selection criteria.
- Improvements to endotracheal tube care protocol.
- Better implementation of patient fall precautions protocols.



# Questions



# Contact Information



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