

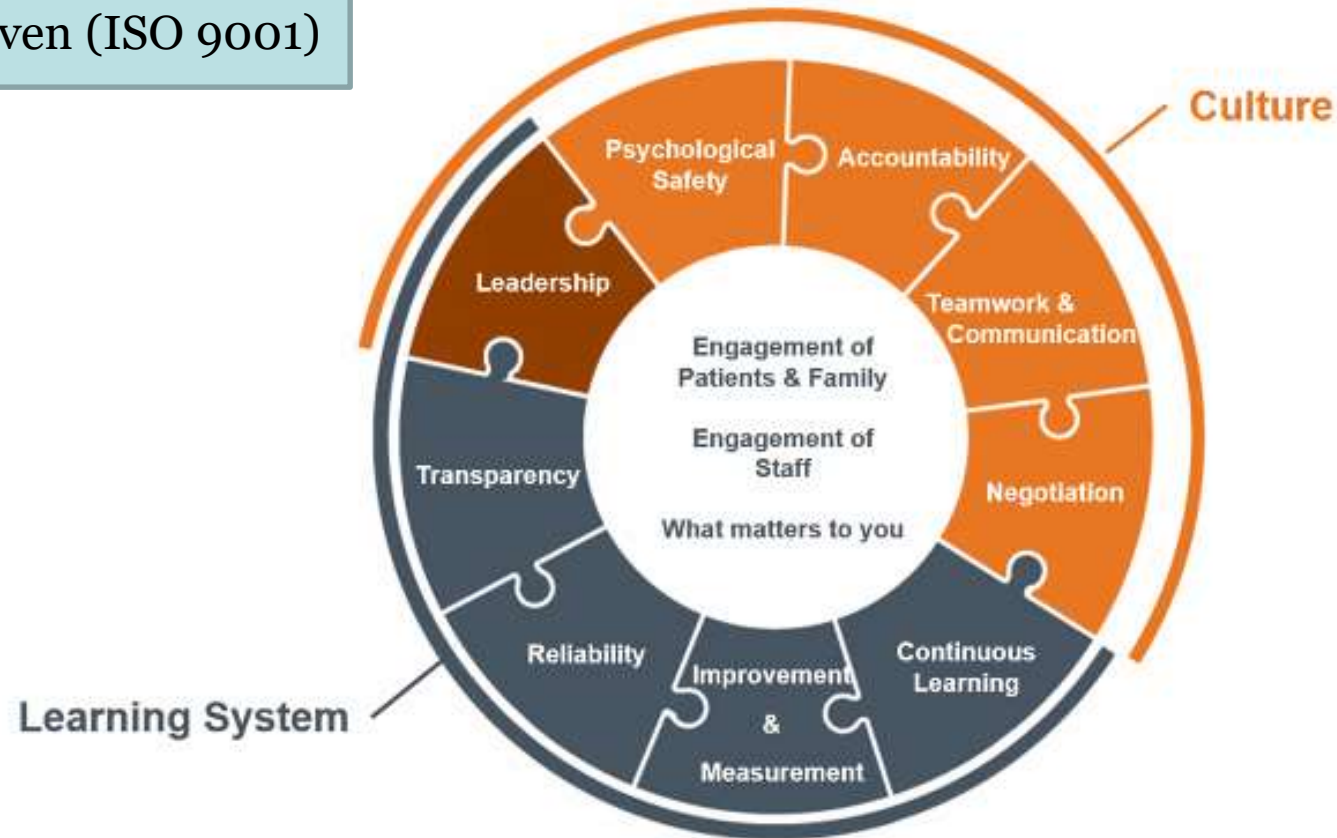
**Driving Quality Improvement & Safety Using  
Highly-Reliable Management Systems**

***“Adverse Event Reporting – eSafe, and  
Root Cause Analysis (RCA)”  
Healthcare Principles in Practice  
August 9, 2022***

**Adam M. Campbell, PhD  
Vice President, Patient Safety and Quality  
Erlanger Health System**

# Framework for Safe, Reliable and Effective Health Care

Leader-driven (ISO 9001)



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Source: Frankel A, Haraden C, Federico F, Lenoci-Edwards J. A Framework for Safe, Reliable, and Effective Care. White Paper. Cambridge, MA: Institute for Healthcare Improvement and Safe & Reliable Healthcare; 2017. (Available at [ihi.org](http://ihi.org))

# Hudson Model of Safety Maturity



# High Reliability Organizations

## Naval Aviation



## Commercial Aviation



## Nuclear Power



# Variability

## Aircraft Carrier

- Jet speed and characteristics
- Level of carrier
- Visibility
- Sea conditions
- Training of crew
- Equipment functionality in jet and on carrier
- Pilot condition



## Healthcare

- Health of patient
- Equipment functionality
- Training of staff
- Staff condition
- Medication accuracy
- Room setup and cleanliness
- Patient information (ID, registration, insurance)
- Language
- Health literacy
- Time of day
- Census/volume



# High Reliability Organizations

“operate under very trying conditions all the time  
**and yet manage** to have fewer  
than their fair share of accidents.”

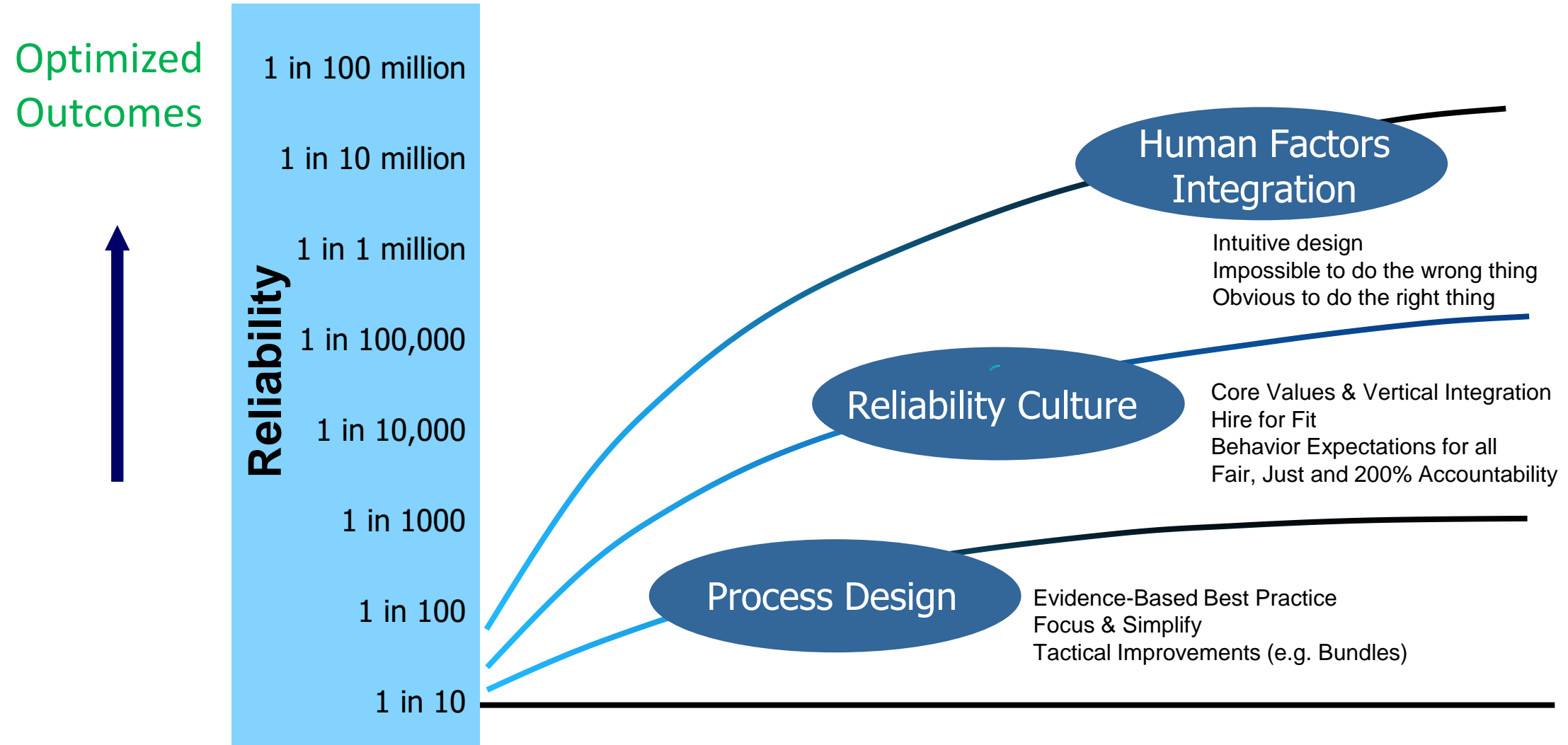
**Risk** is a function of **probability** and **consequence**.  
By decreasing the probability of an accident, HRO's  
recast a high-risk enterprise as merely a high-  
consequence enterprise. HROs operate as to make  
systems ultra-safe.

# Definition of *Reliability* for Health Care

The capability of a process, procedure or health service to perform its intended function in the required time under existing conditions.

**“...it is not possible in such dynamic settings to anticipate and write a rule for every circumstance....(we need) to foster real-time problem solving and...institute safety systems that incorporate a knowledge of human factors....”**

# Journey to improving reliability





# How do we measure quality and safety levels in healthcare?

**In industry** this is called [reduction of nonconformities](#), and [increasing yield](#)

**In healthcare, we:**

- Reduce infections
- Reduce falls
- Reduce untimely documentation
- Reduce readmissions
- Increase patient flow efficiency
- Many more...

[Improvement Science Methods \(like Lean Six Sigma\)](#) is a “non-conformity” and variation reduction strategy, increasing effectiveness and efficiency of services and products

# How do we know we have improved?

**Process capability:** Ability of a process, based on how it is resourced and structured, to meet your intended goal

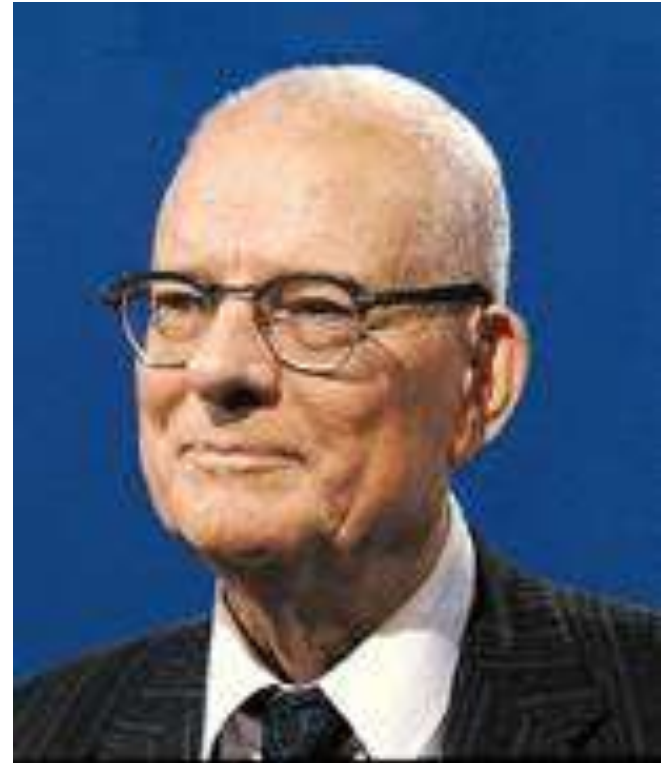
**Process reliability:** The consistency of your process or system over time

**Process improvement:** Increasing the process capability and reliability

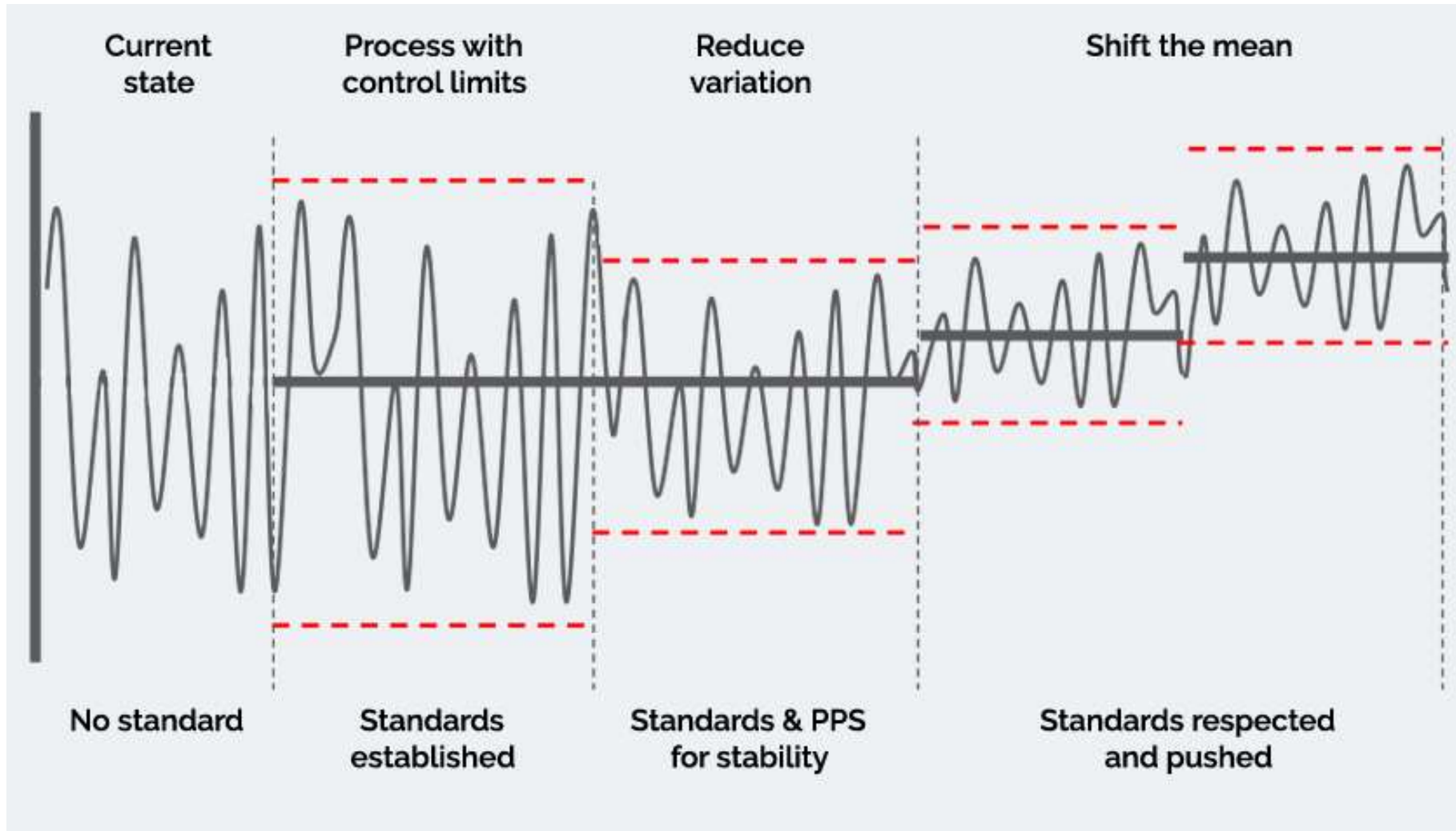
**Relevant Metrics**

*"If I had to reduce my message for management to just a few words, I'd say it all had to do with reducing variation."*

*W. Edwards Deming*



# Process Control and Reliability



## Bundle Reliability

- CLABSI
- CAUTI
- SSI
- Unplanned Extubation
- Pressure Injury

ISO 9001: 2015-Quality Management Systems

# **ORGANIZATIONAL OVERSIGHT**

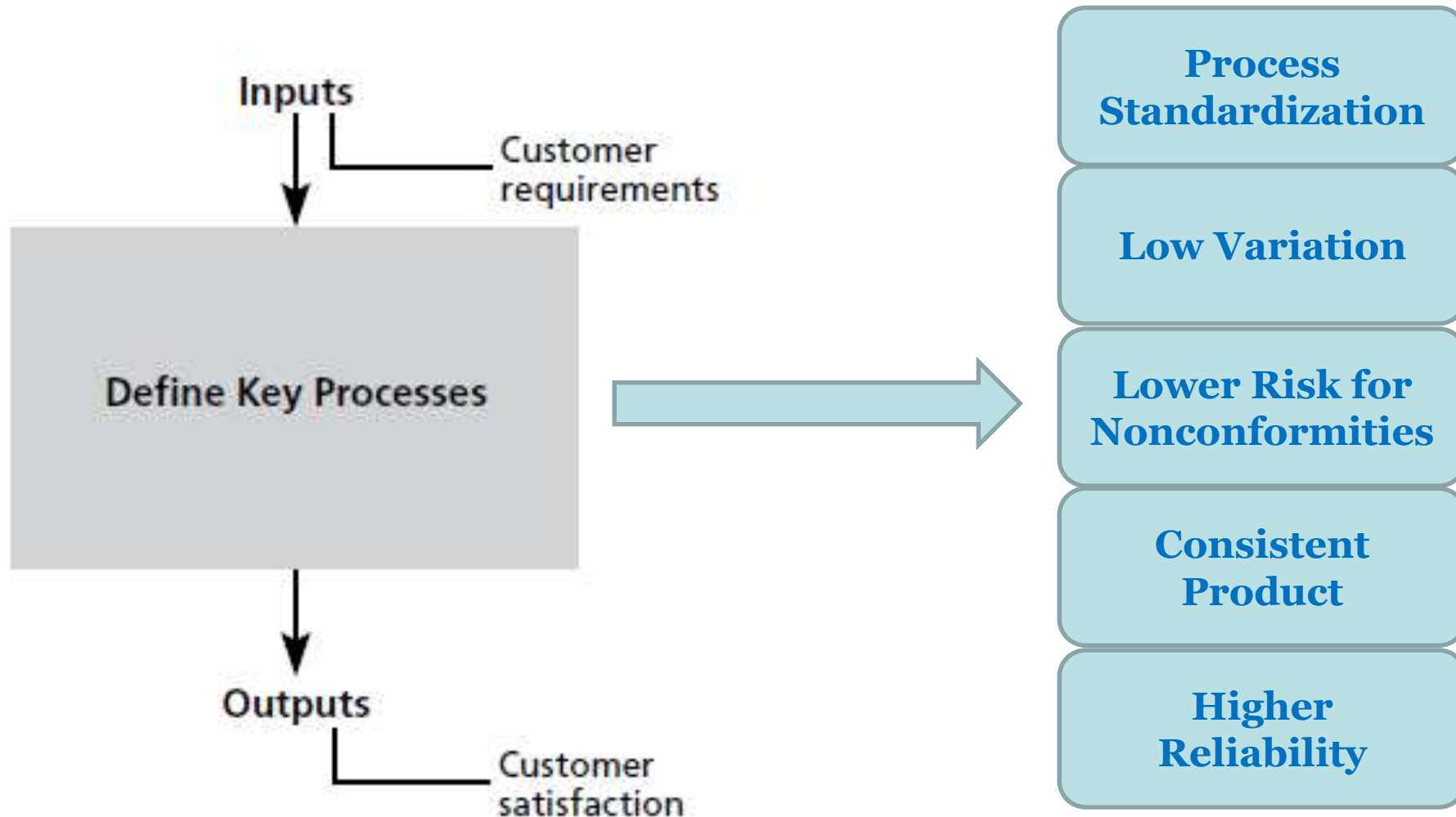
# Quality Management Systems: DNV and ISO 9001:2015

ISO 9001: 2015 is defined as the international standard that specifies requirements for a **quality management system (QMS)**

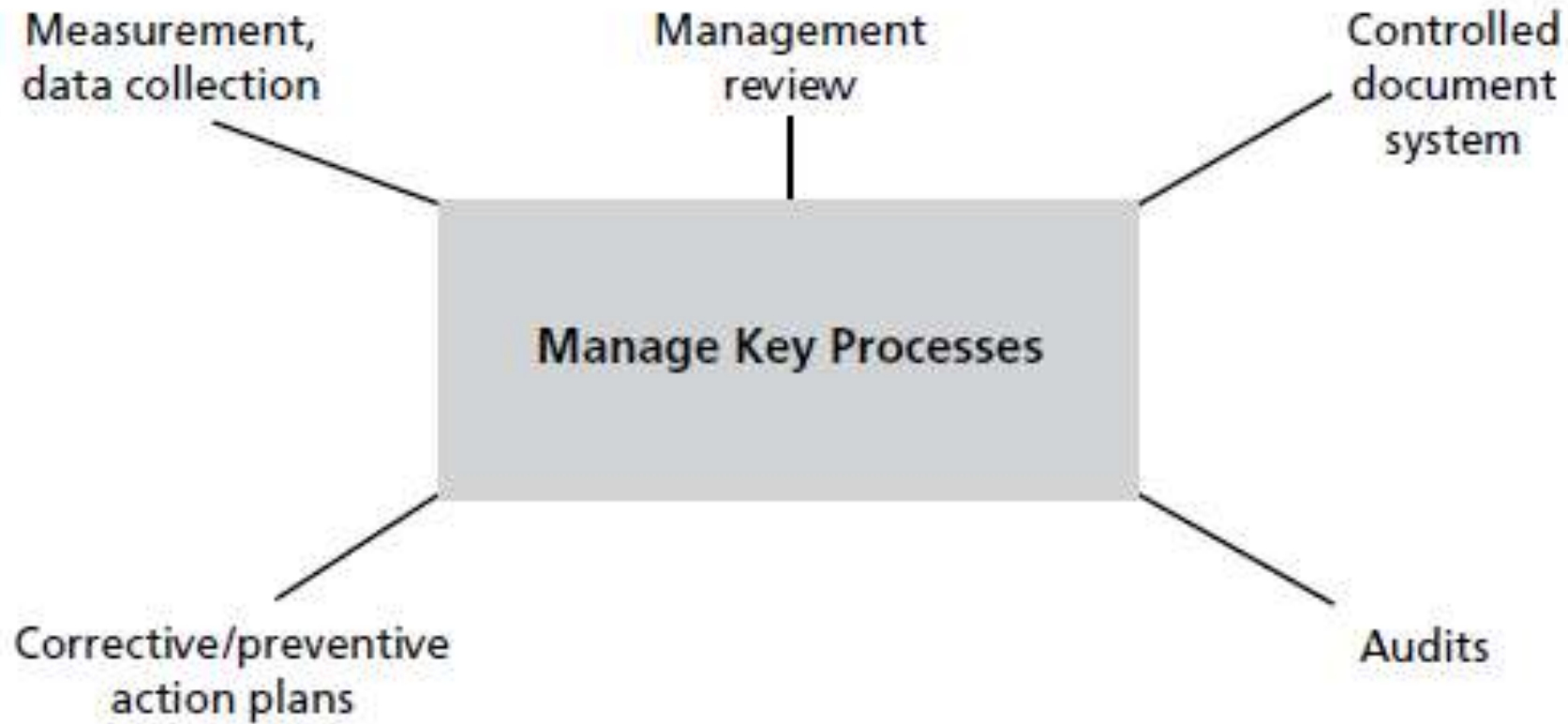
A **quality management system (QMS)** is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives

Organizations use the standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements

# Defining Key Processes

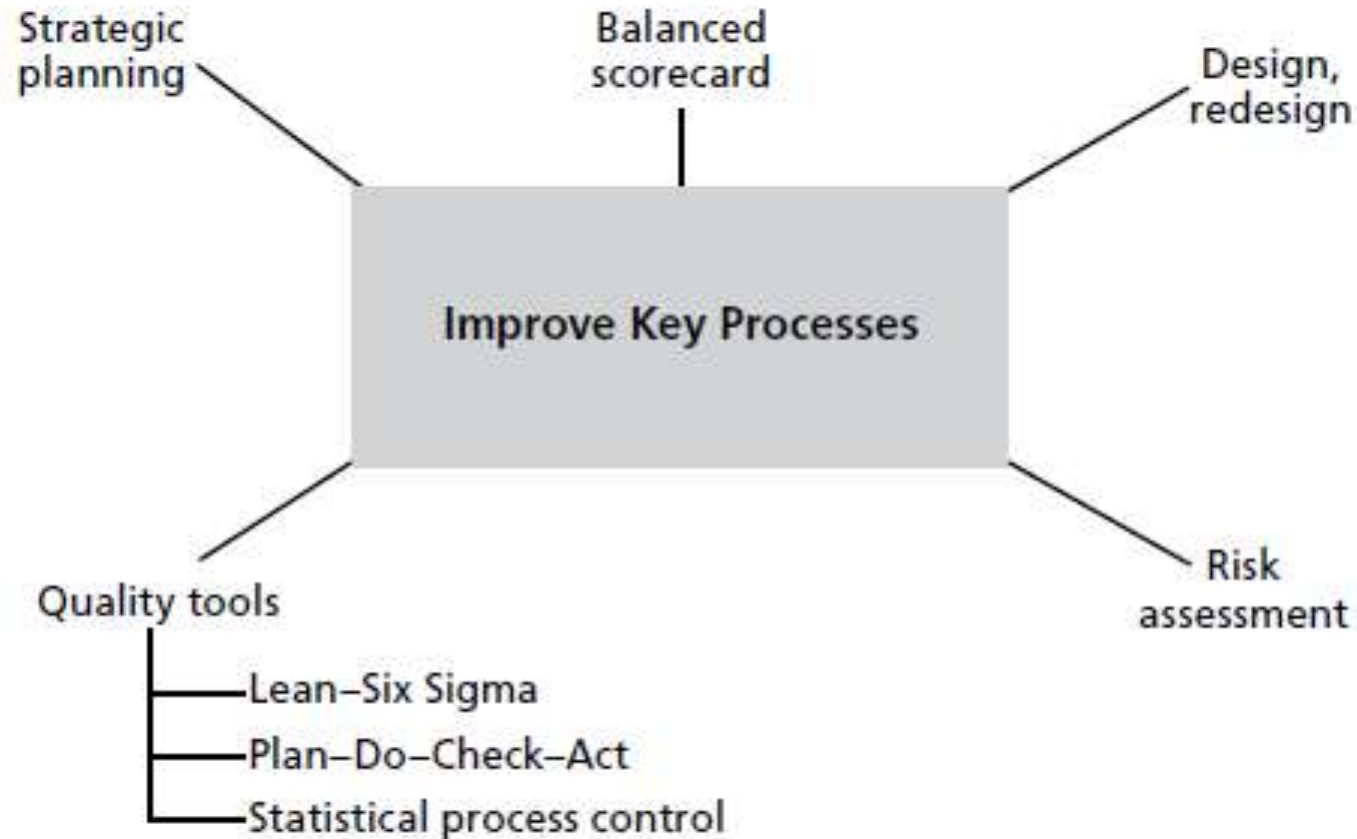


# Managing Key Processes





# Improving Key Processes



# QMS Engine

## System Inputs

Voice of the Patient and Family

Unit/Department Top 10 Problem Lists (Risk-based Management)

Opportunity Identification by Frontline (Rounds/Audits)

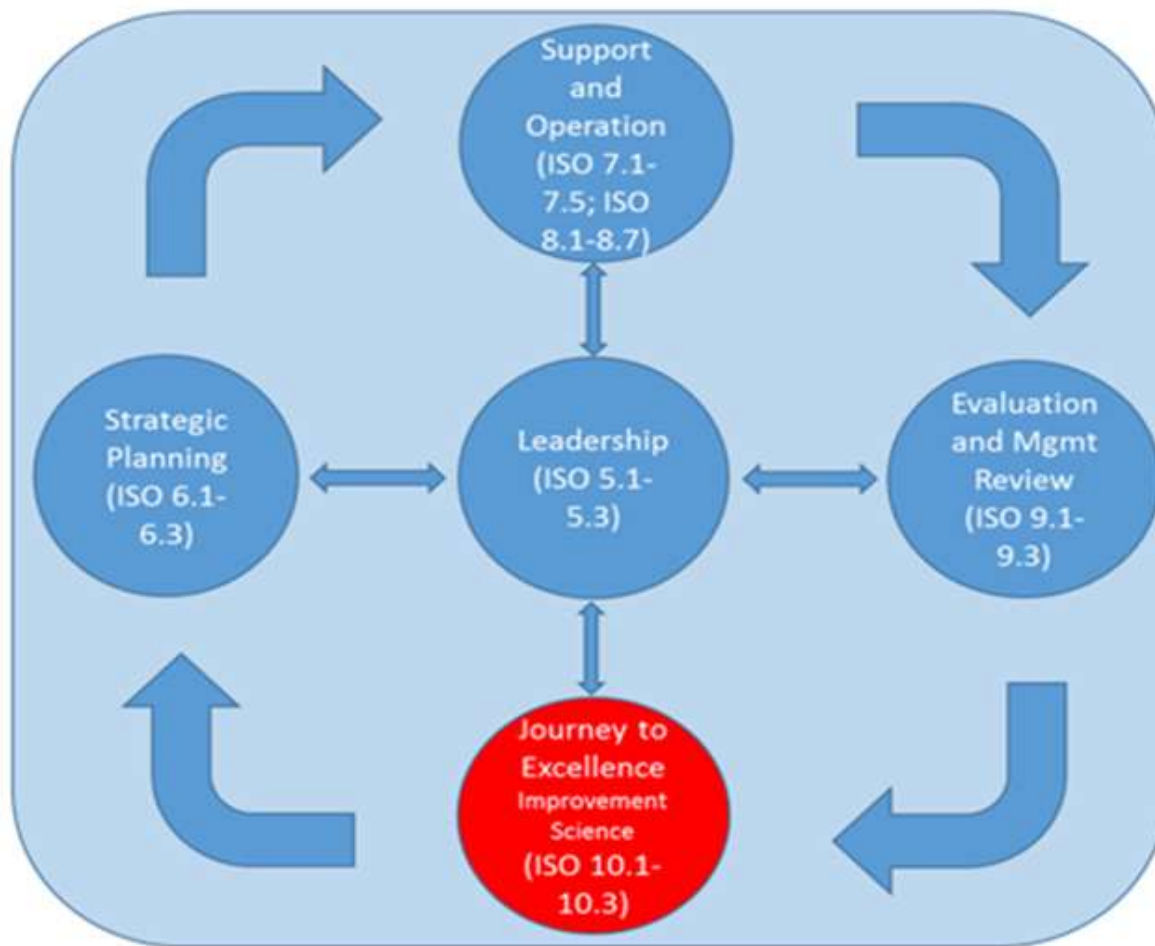
Regulatory Expectations

Staff Expectations

Community Responsibilities

Organizational Values

Best Practices



## System Outputs

Patient/Family Satisfaction

Quality Outcomes

Zero Harm (Patients and Staff)

Regulatory Compliance

Staff Satisfaction and Retention

Community and Financial Value



**1. Rear Jack 2. Rear Tyre Off 3. Tyre Gunner 4. Rear Tyre On 5. Stabiliser 6. Front Tyre On 7. Tyre Gunner 8. Front Tyre Off/Stop Marker 9. Front Wing Adjuster 10. Backup Front Jack 11. Front Jack 12. Front Wing Adjuster 13. Front Tyre Off / Stop Marker 14. Tyre Gunner 15. Lollipop Man 16. Front Tyre On 17. Stabiliser 18. Rear Tyre Off 19. Tyre Gunner 20. Rear Tyre On 21. Driver**



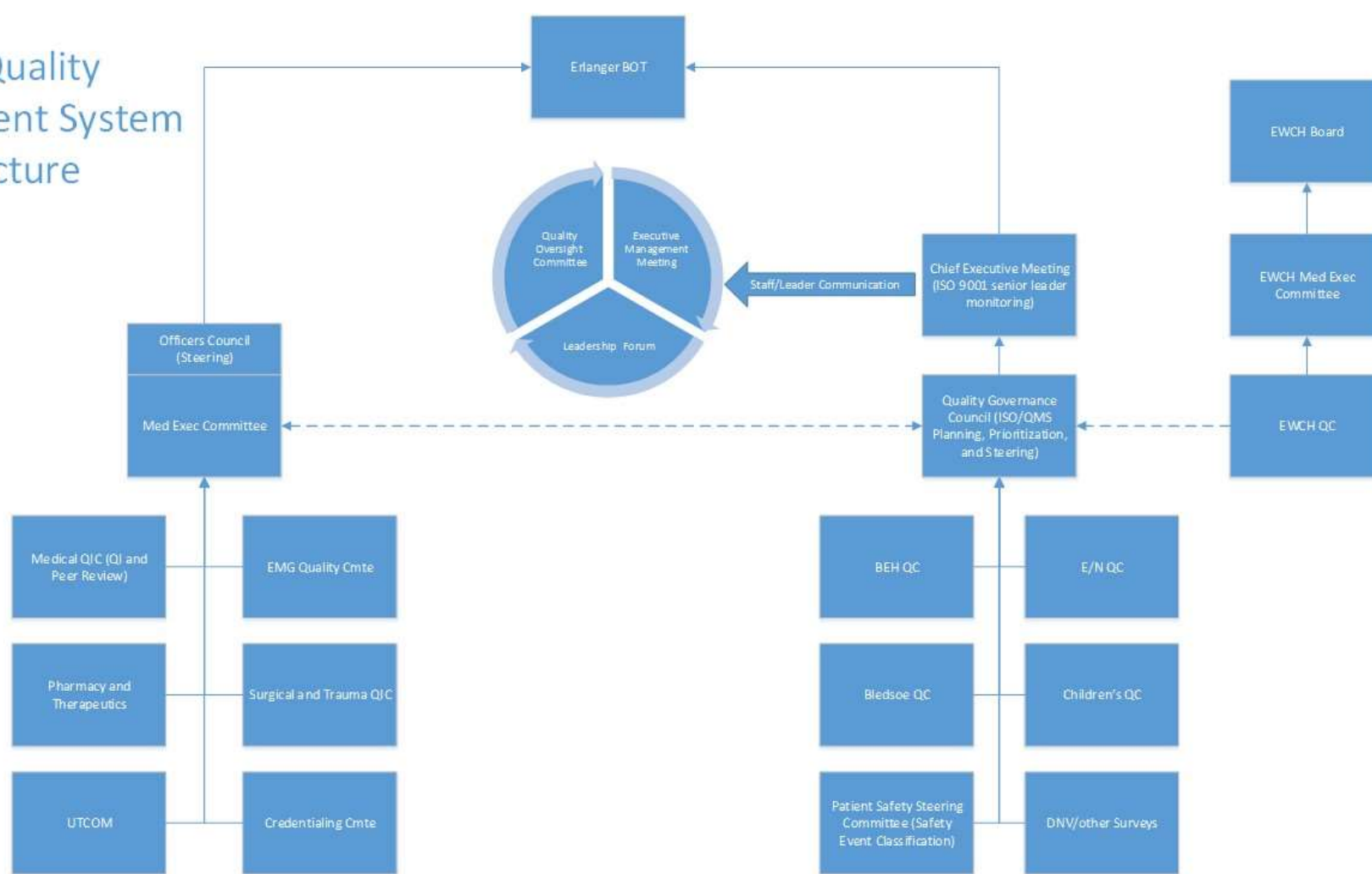
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# EHS Quality Management System Structure



Version 0.3  
Date: 3/22/2022  
Patient Safety and Quality/Medical Staff



Event Reporting Root Cause Analyses

# **BECOMING A LEARNING SYSTEM**

# Driving the Mission, Vision and Values



# Framework for Safe, Reliable and Effective Health Care

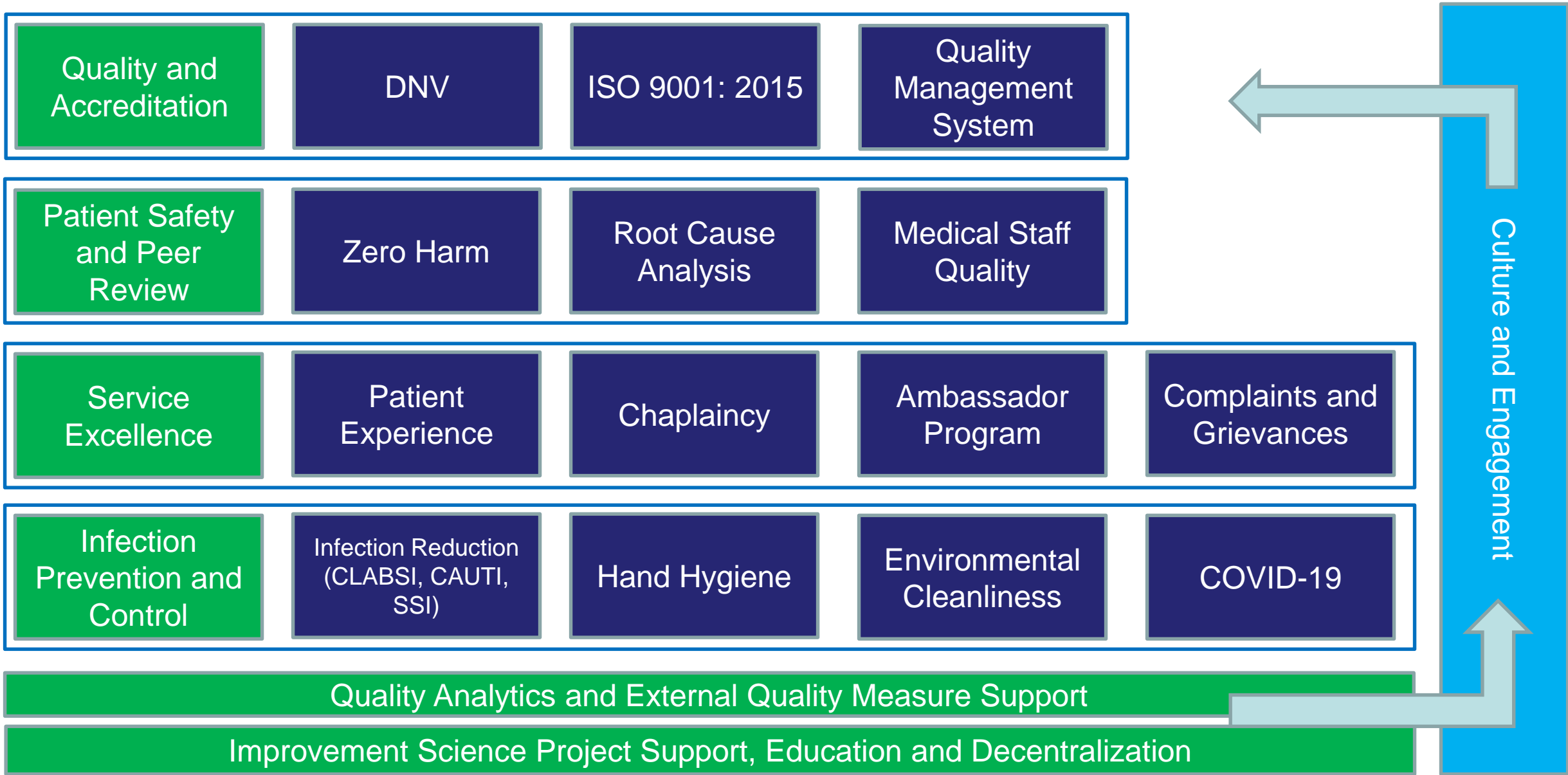
Learning System



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Source: Frankel A, Haraden C, Federico F, Lenoci-Edwards J. A Framework for Safe, Reliable, and Effective Care. White Paper. Cambridge, MA: Institute for Healthcare Improvement and Safe & Reliable Healthcare; 2017. (Available at [ihi.org](http://ihi.org))

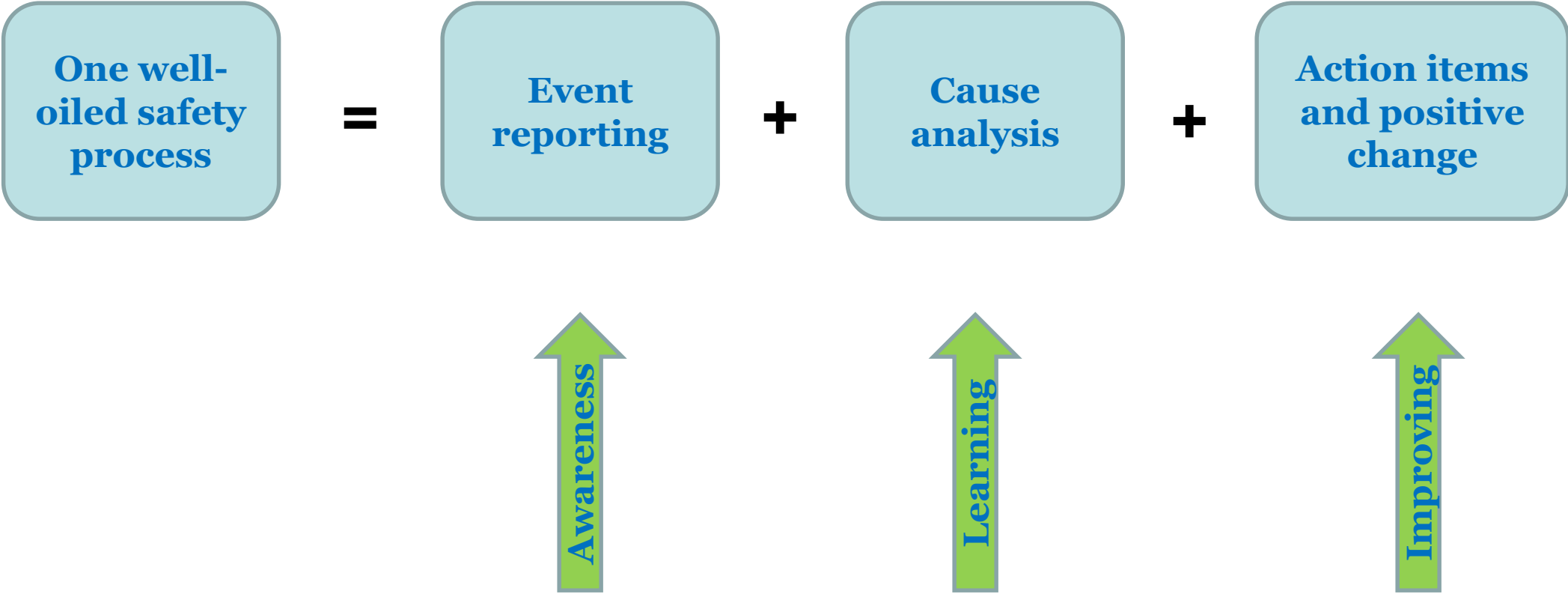




# Culture of Safety

- Defined by IHI as:
  - “an environment in which providers can discuss errors, near misses, and harm openly, knowing that they won’t be unfairly punished and have confidence that **reporting safety events** will lead to improvement”

# Awareness and Learning



# Causal Analysis

- A systematic approach to analyze the *factors (or errors)* that lead to a safety event.
- Goal: Reduce the risk of the same, or similar, event from occurring again
- Apparent Cause Analysis (ACA) and Root Cause Analysis (RCA), are the most common forms of systematic analysis used for identifying the factors that bring about a patient safety event.

# SEC Pyramid

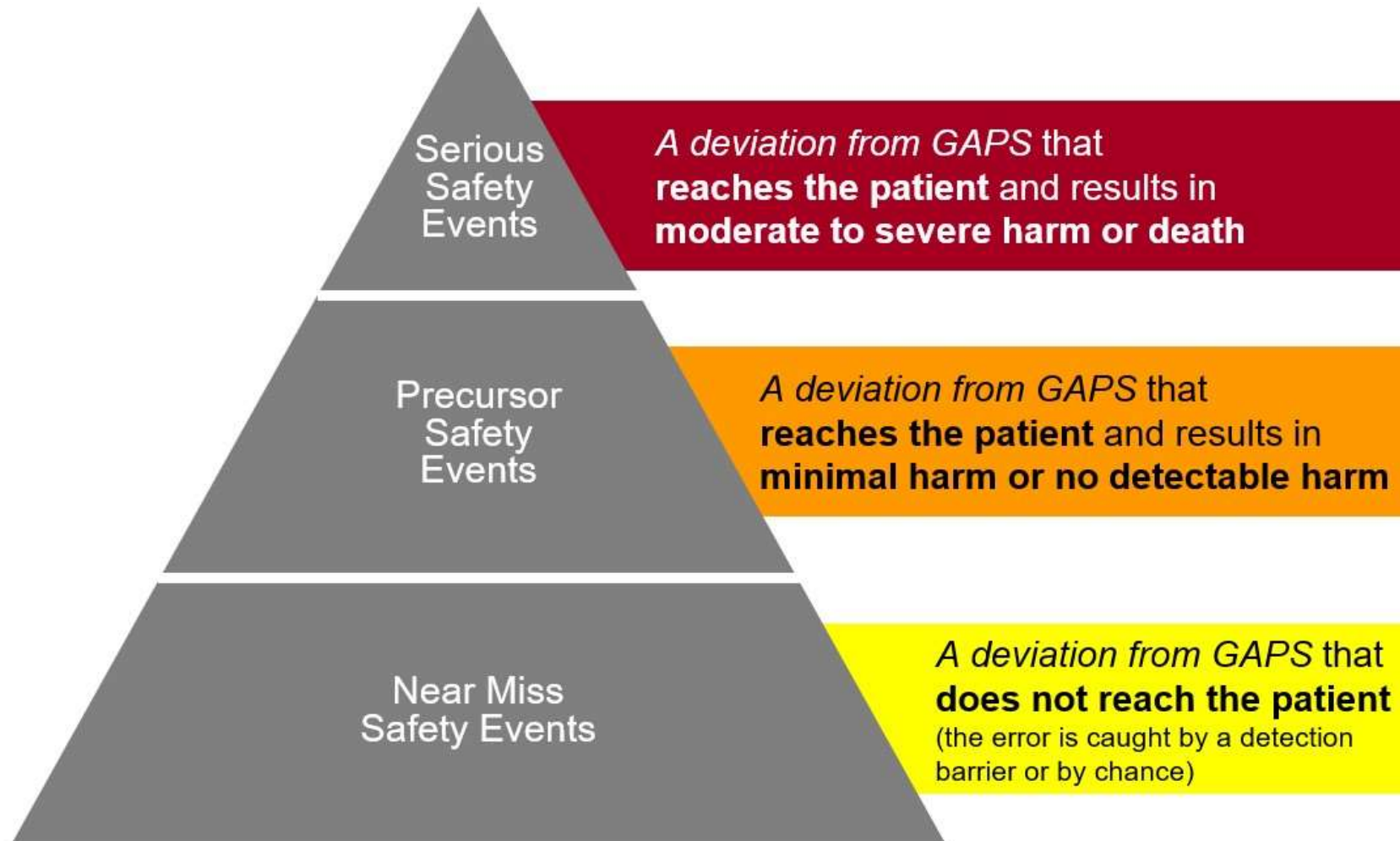
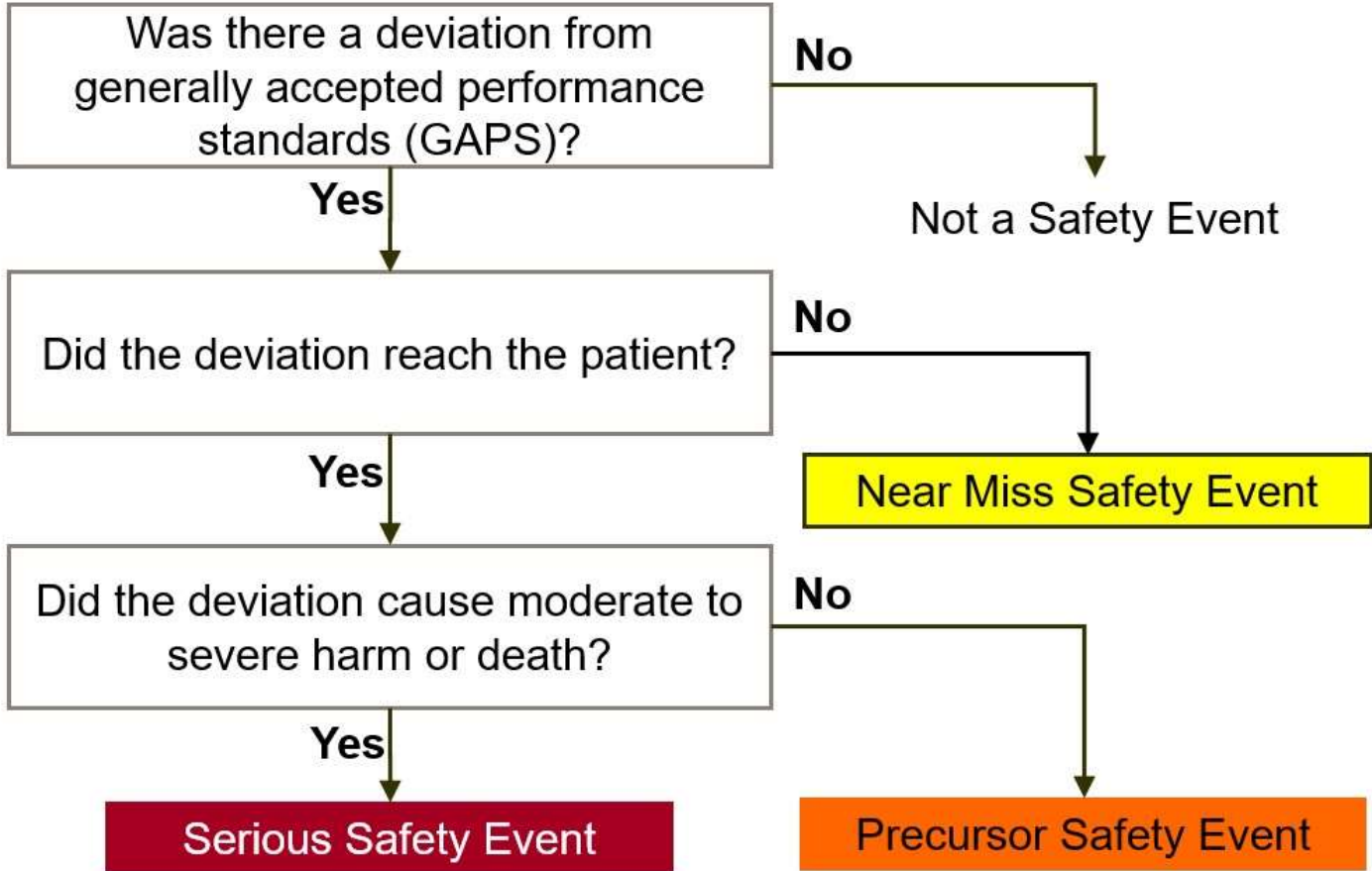


Figure 1. Safety Event Classification Pyramid

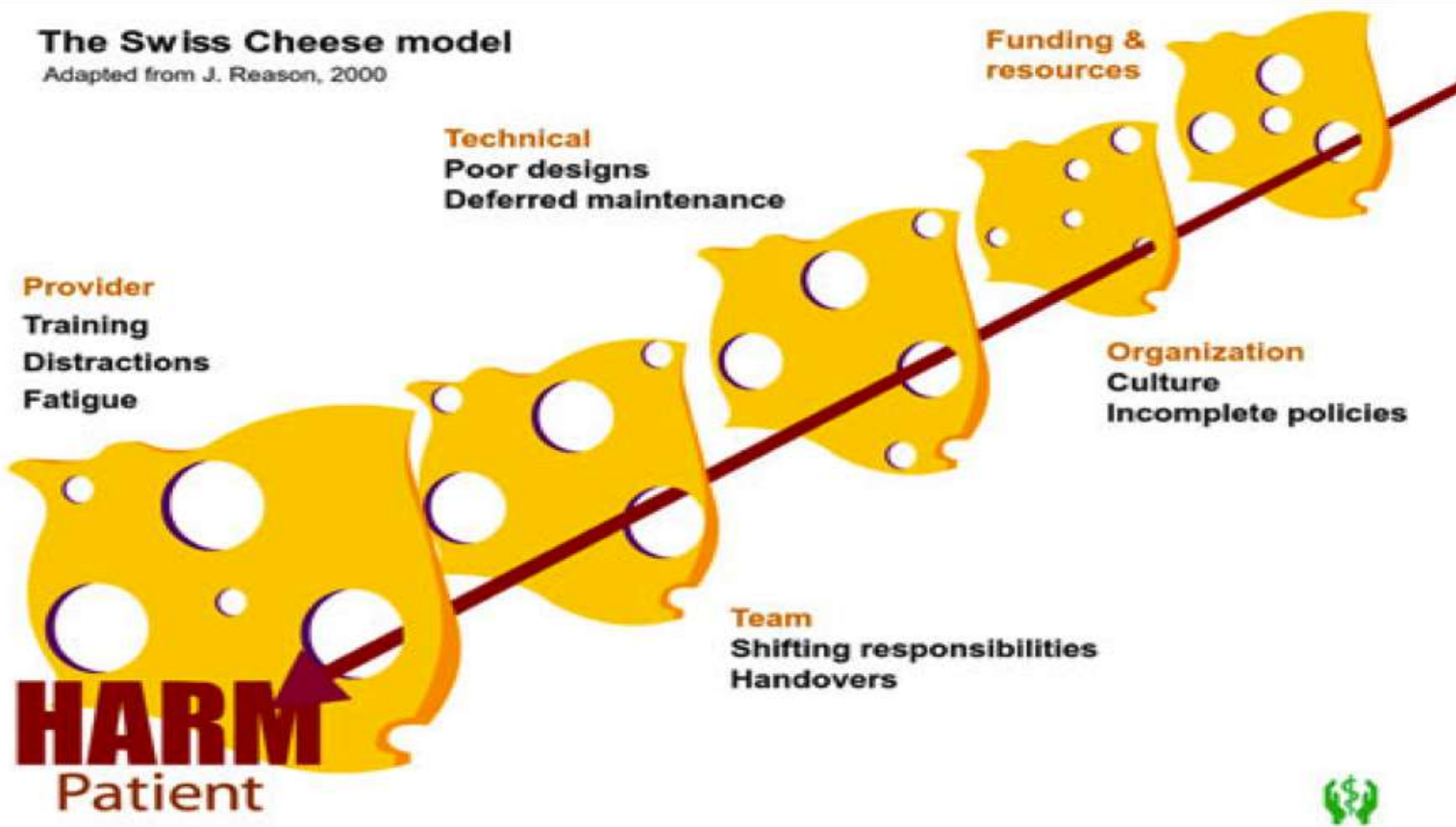
# SEC Algorithm



HPI SEC	Code	Level of Harm
<b>Serious Safety Event (SSE)</b>	<b>SSE 1</b>	Death
	<b>SSE 2</b>	Severe Permanent Harm
	<b>SSE 3</b>	Moderate Permanent Harm
	<b>SSE 4</b>	Severe Temporary Harm
	<b>SSE 5</b>	Moderate Temporary Harm
<b>Precursor Safety Event (PSE)</b>	<b>PSE 1</b>	Minor Permanent Harm
	<b>PSE 2</b>	Minor Temporary Harm
	<b>PSE 3</b>	No Detectable Harm
	<b>PSE 4</b>	No Harm
<b>Near Miss Safety Event (NME)</b>	<b>NME 1</b>	Unplanned Catch
	<b>NME 2</b>	Last Strong Barrier Catch
	<b>NME 3</b>	Early Barrier Catch

## The Swiss Cheese model

Adapted from J. Reason, 2000



Root Cause Analyses (RCA) identify system issues that lead to events



# Event Reporting

## How?

Record occurrence in eSafe

## Why?

Error reduction through analysis and process improvement

Reduction/elimination of same type error in same location

Reduction/elimination of same type error in other areas

Reduction/elimination of errors of related type before they occur

RL software for safer healthcare

ERLANGER HEALTH SYSTEMS  
eSAFE

ERLANGER NETWORK

Username

Password

LOGIN

Submit Anonymously

# eSafe

## Access/Training/Clinical Questions?



### Access/Training?

Dia Perry, MSQI, eSafe System Coordinator

[dia.perry@erlanger.org](mailto:dia.perry@erlanger.org)

### Clinical Questions, ACA/RCA Meetings?

Jackie Bishop, RN, MSQI Director

[jackie.bishop@erlanger.org](mailto:jackie.bishop@erlanger.org)

Dean Burse, RN, Patient Safety Coordinator

[deanna.burse@erlanger.org](mailto:deanna.burse@erlanger.org)

### Patient Safety/Culture, Causal Analysis

Dr. Adam Campbell, PhD

VP, Patient Safety & Quality

[adam.campbell@erlanger.org](mailto:adam.campbell@erlanger.org)

# PATIENT EXPERIENCE AND SERVICE EXCELLENCE

# Key Inpatient Experience Domains, By Unit of Discharge

Percentile Rank versus All Press Ganey Participating Hospitals (11/01/2021 - 04/30/2022)

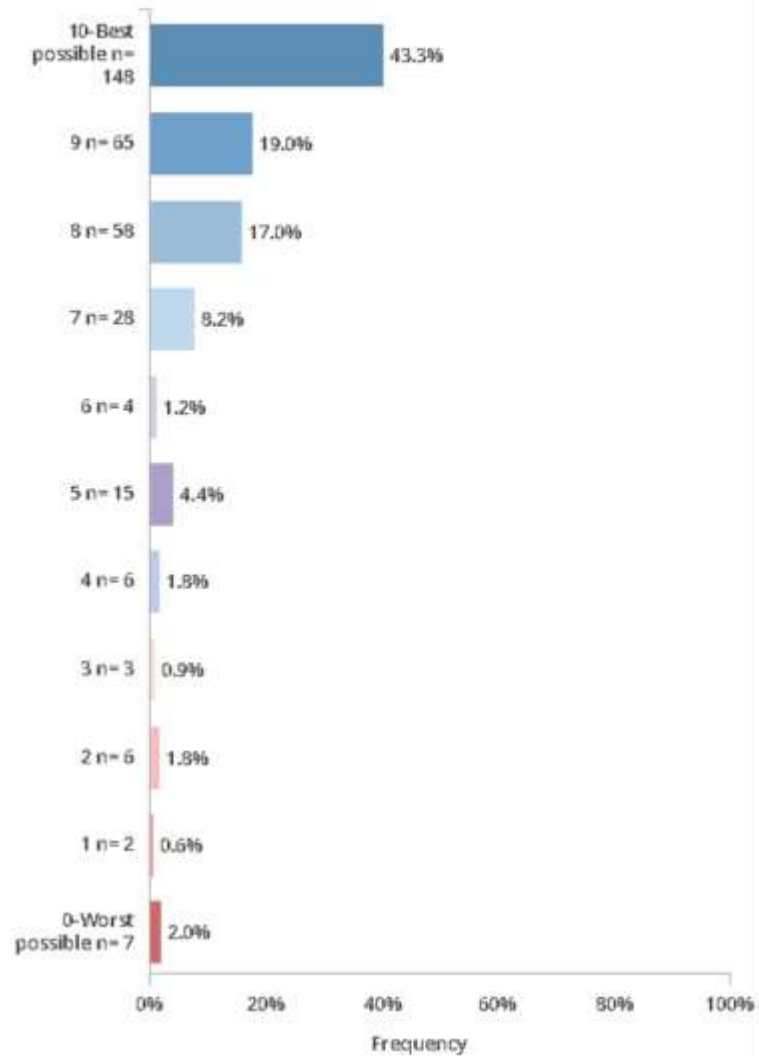
Discharging Unit	Responses	Recommend the hospital	Rate hospital at Least 9 on 0-10 Scale	Communicate w/ Nurses	Responsive Hospital Staff	Communicate w/ Doctors	Cleanliness	Quietness	Communicate About Meds	Discharge Information	Care Transitions	Meals Overall (not HCAHPS)
Total	2283	38	22	27	58	72	8	41	58	30	61	7
Baroness Total	1324	22	12	15	41	58	6	24	53	27	44	4
3000 MS	55	4	1	1	1	3	1	1	7	2	5	1
WW3	44	1	1	1	1	1	2	1	3	4	13	1
CSDU	97	62	41	34	77	73	25	21	47	80	48	1
CV-SSU	28	57	57	11	84	80	23	26	44	8	45	7
CWW6	157	77	90	92	96	96	66	96	90	98	81	9
NW6	121	25	9	7	15	88	2	13	49	50	46	4
NW7	45	7	1	1	3	9	3	3	7	41	10	1
NW8	147	22	15	10	23	43	21	38	49	30	58	7
NW9S	60	28	3	4	8	62	34	41	31	81	10	10
E-STAR	52	14	23	87	82	88	1	1	88	4	11	1
BEH ER	126	1	1	1	1	2	1	1	1	1	1	1
BEH Surg	20	56	9	78	83	81	85	37	99	20	83	1
GYN ONC	41	15	11	36	50	82	30	97	88	6	37	13
WW7 Oncology	98	40	25	39	58	95	6	54	76	47	91	4
BEH Mother-Baby	111	20	9	61	83	65	2	73	85	15	65	18
HRPU	36	51	41	77	97	58	10	89	99	10	97	23
East Total	786	71	47	58	86	91	7	78	75	38	89	16
East W2	184	51	26	19	23	67	4	69	60	24	51	8
East W3	220	50	32	12	27	68	5	80	29	17	63	11
East Mother-Baby	364	87	70	92	98	98	12	77	95	62	97	25
EWCH Total	117	13	8	43	9	18	25	8	42	25	6	15

- Targeted approach
- Specificity of unit and metric
- Mining of comments to understand patient perception
- Collaboration with physicians, vendors and other stakeholders
- Work consistent with CMS and payer focus areas

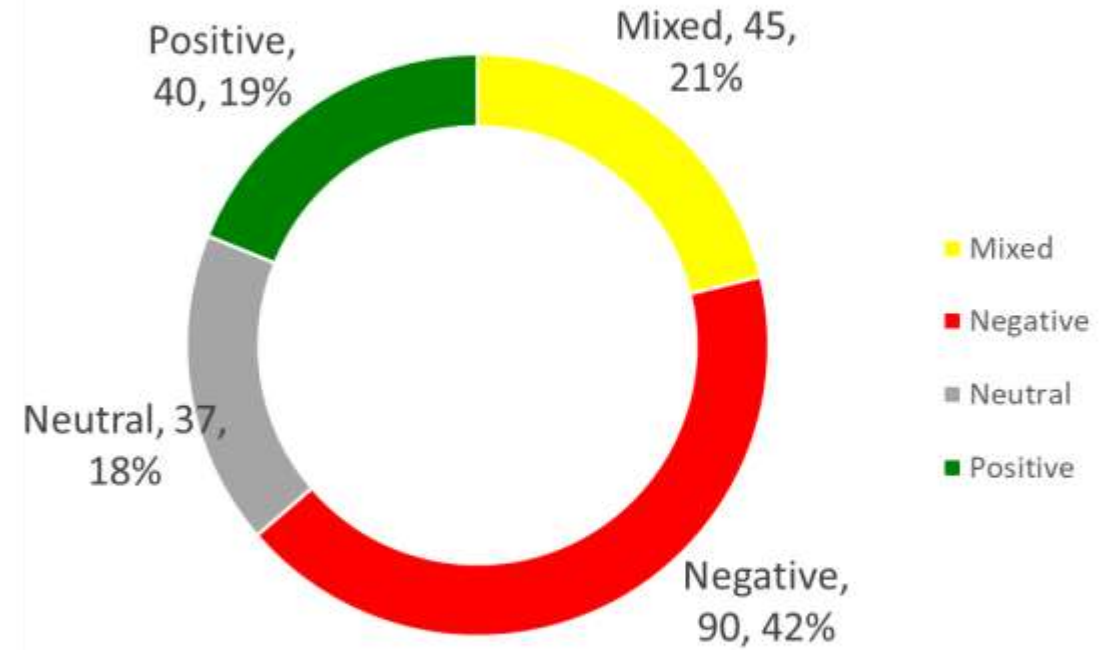
# Inpatient Overall Question & Comments Distribution (Rolling 3 months)

## Distribution of Responses ⓘ

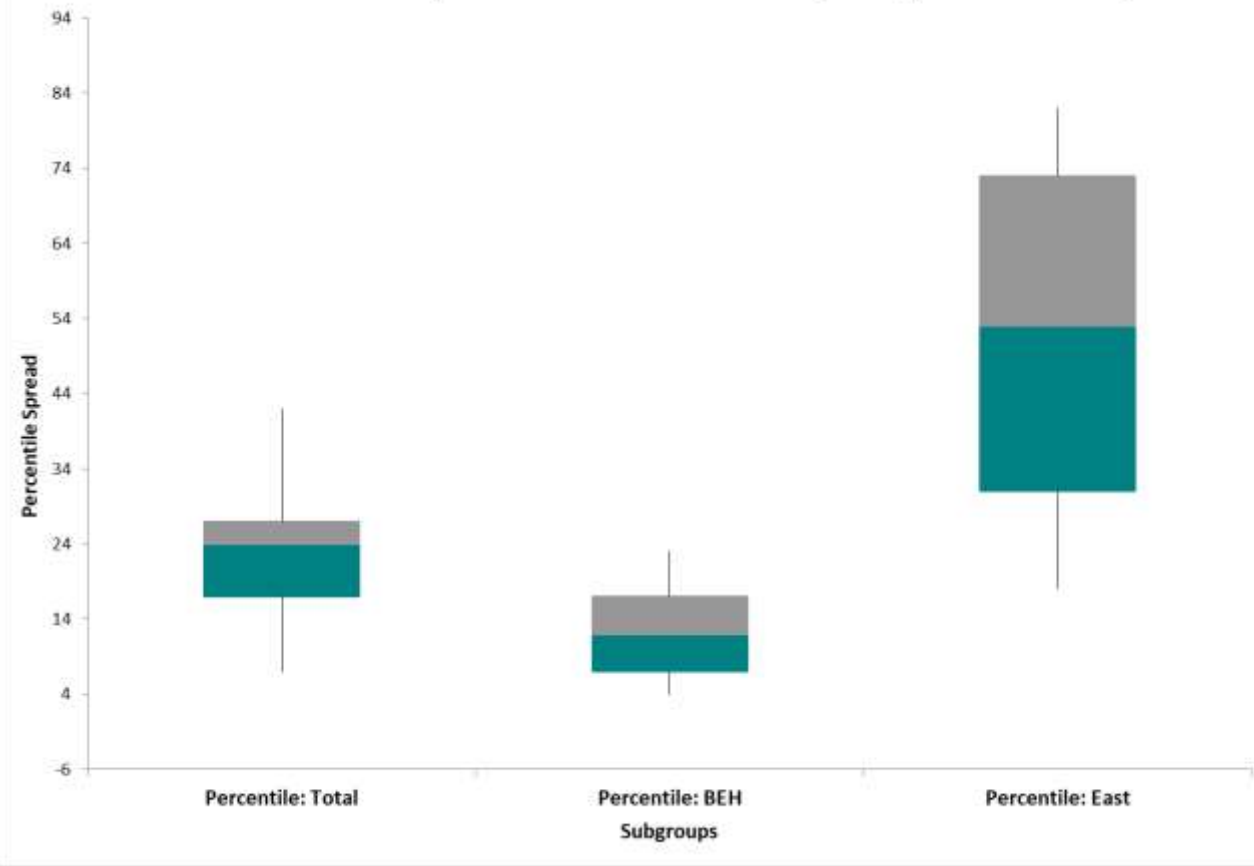
CAHPS Rate 0-10



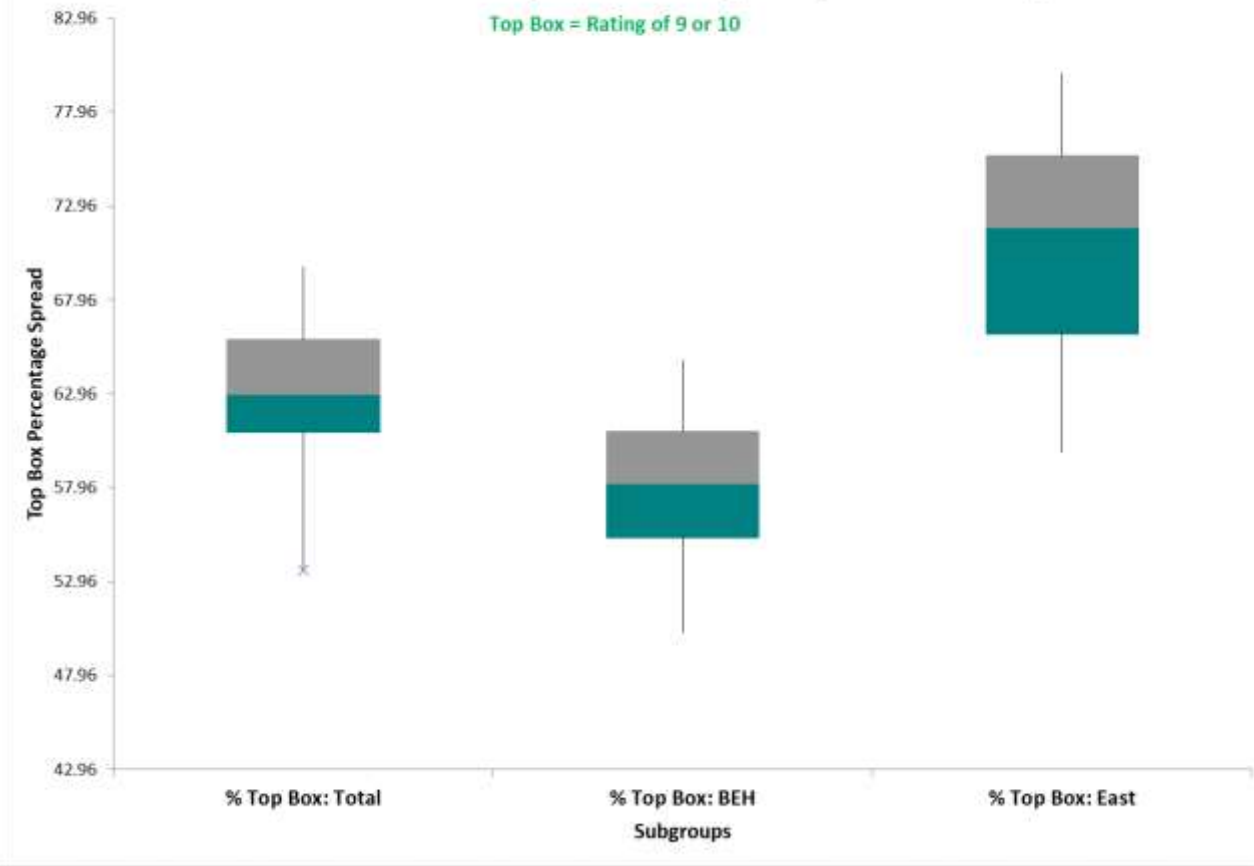
## Comments from Respondents that Choose '8'



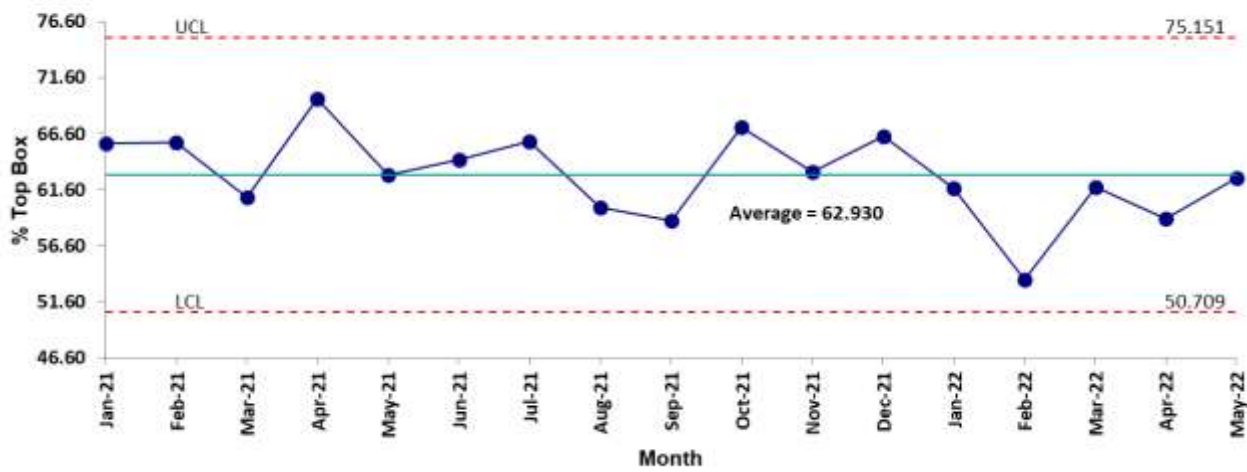
Box and Whisker Comparisons: Percentile Rank Spread (Jan '21-current)



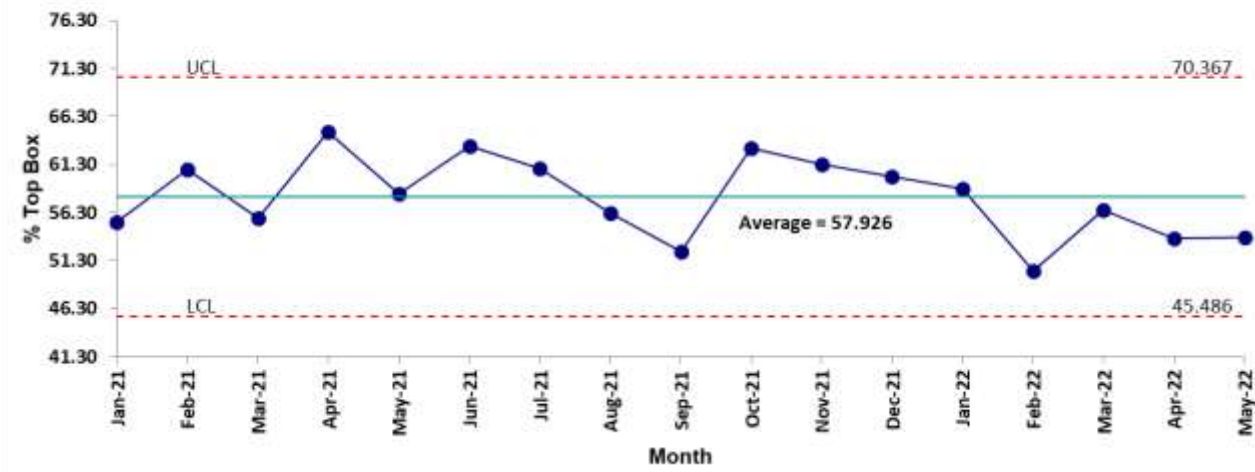
Box and Whisker Comparisons: % Top Box (Jan '21-current)



**System % Top Box Over Time: XmR Chart**

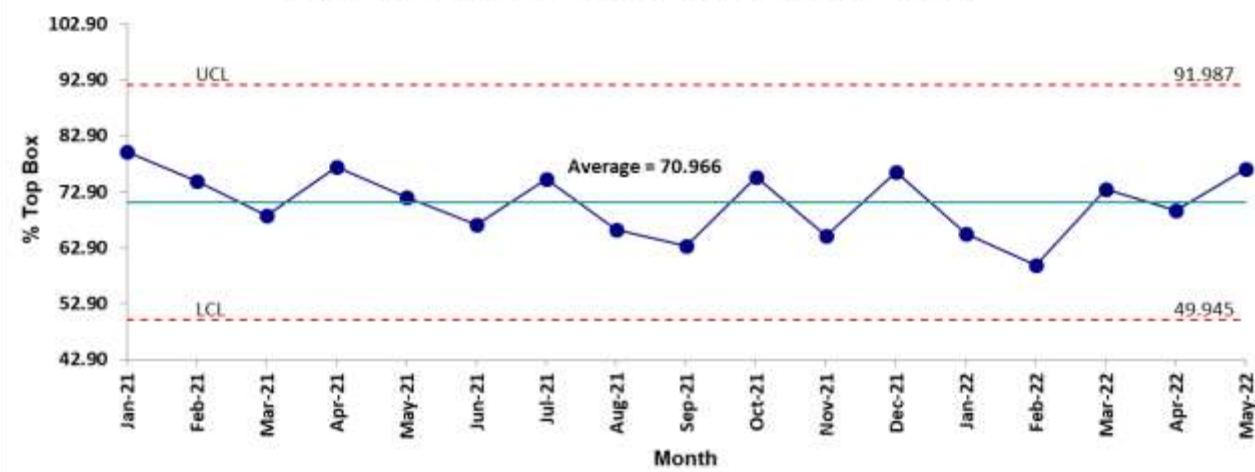


**BEH % Top Box Over Time: XmR Chart**

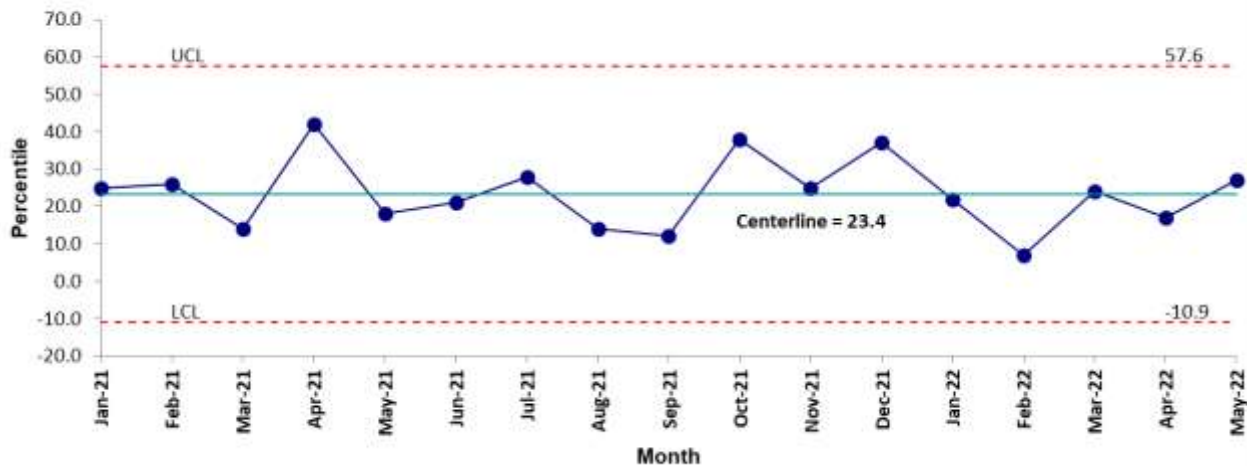


**Statistical Process Control Charts:  
% Top Box Over Time**

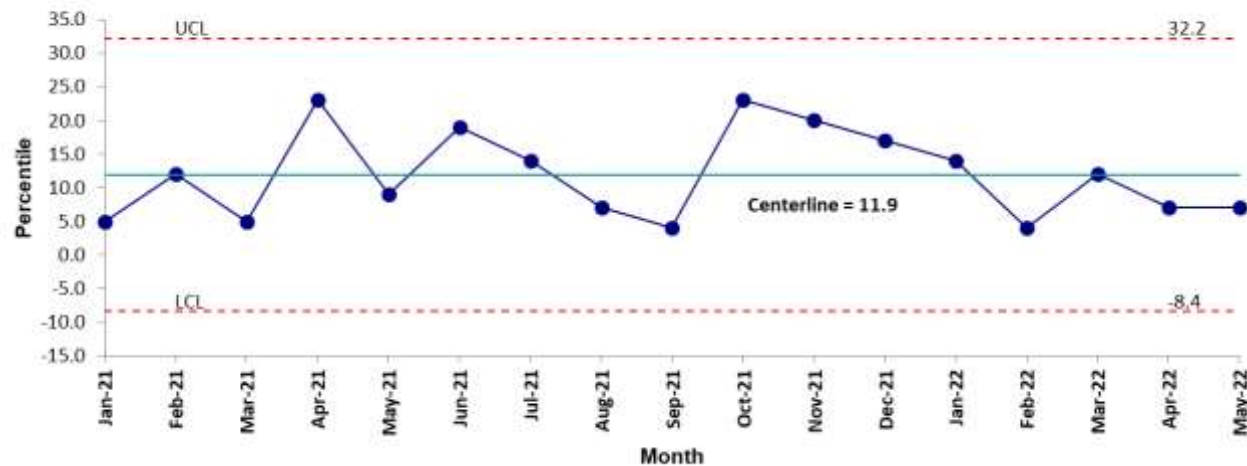
**East % Top Box Over Time: XmR Chart**



**System Percentile Rank Over Time: XmR Chart**

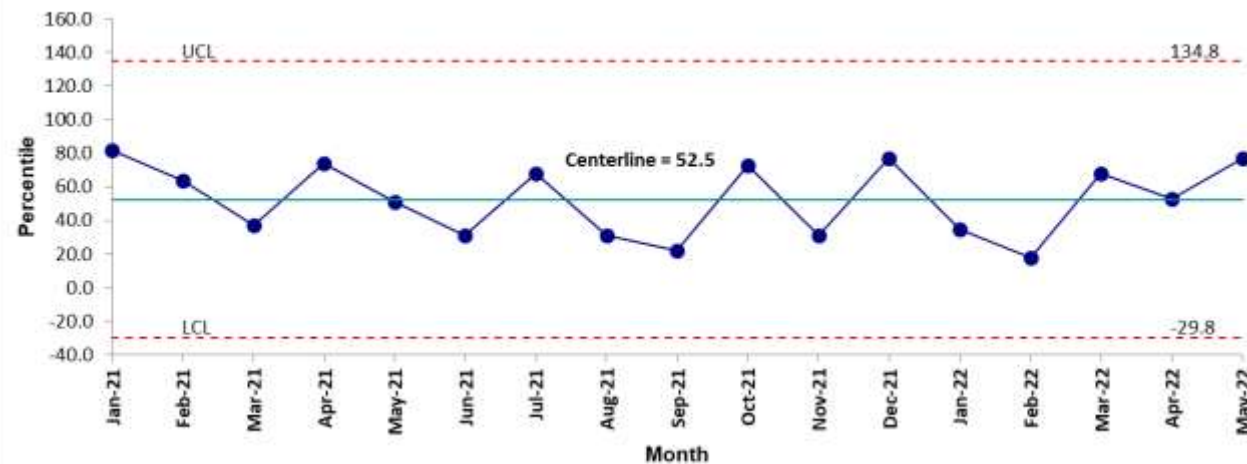


**BEH Percentile Rank Over Time: XmR Chart**



**Statistical Process Control Charts:  
Percentile Rank Over Time**

**East Percentile Rank Over Time: XmR**





Decentralization to the frontline

# **IMPROVEMENT SCIENCE METHODS**

# Inpatient Survey Comments from 8's

Discharge Unit	Comment	Survey Section	Reaction
Beh Nw8	Mandy on the 8th floor worked on night shift. She was awesome! She had wonderful bedside manners. She was on top of it and helped keep me as comfortable as she could just by being kind. Both my daughter and husband were very thankful for her help as well. Thank you Mandy.	Nurses	Positive
Beh Cv Sdu	CVicu the nurse is Rebecca and Jackie and levana if you are a shadow and a few others I don't know their names they were awesome the sweetest ladies I could have ever met in a while they helped me a lot	Intensive/ Critical Care	Positive
Beh Nw9s	The cleaning staff were excellent and very polite. I was glad to be able to set my room temperature, since I felt very hot.	Room	Positive
Beh Cw5 Ob/Gyn	I was surprised at how quick I was able to receive an epidural after I requested it. When we found out I needed to have an unplanned c-section they were very quick to get my into the OR. Everyone in the OR was so nice and explained everything to me. It was just me and my husband so I am grateful some nurses took my husbands phone to snap some pictures of us as a family of three.	Doctors	Positive
Beh 3000	I would like to expressly commend a nurse *Audrey (nurse extender) who was attuned to what I need. She anticipated my needs. *Audrey seemed to be very experienced in how she cared for my needs.	Overall Assessment	Positive

# QMS Engine

## System Inputs

Voice of the Patient and Family

Unit/Department Top 10 Problem Lists (Risk-based Management)

Opportunity Identification by Frontline (Rounds/Audits)

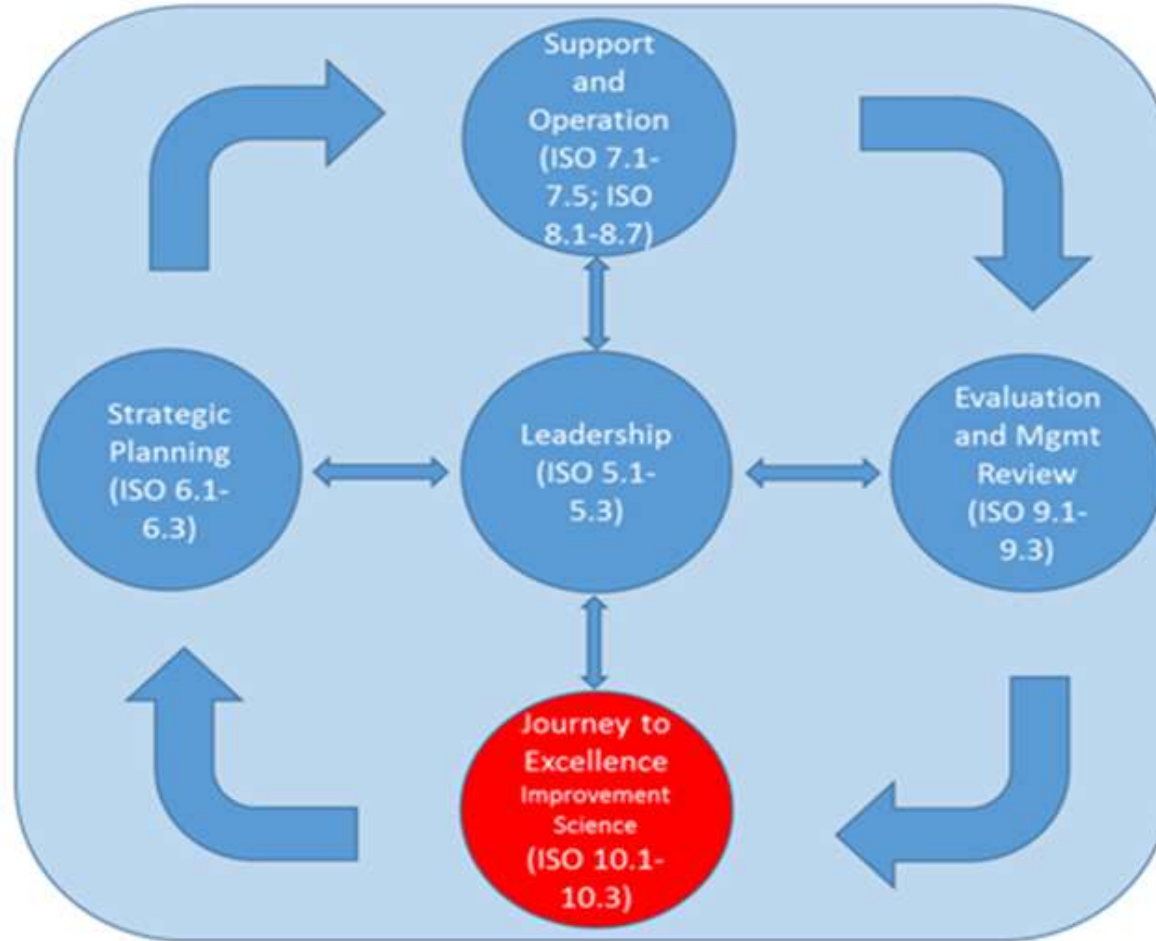
Regulatory Expectations

Staff Expectations

Community Responsibilities

Organizational Values

Best Practices



## System Outputs

Patient/Family Satisfaction

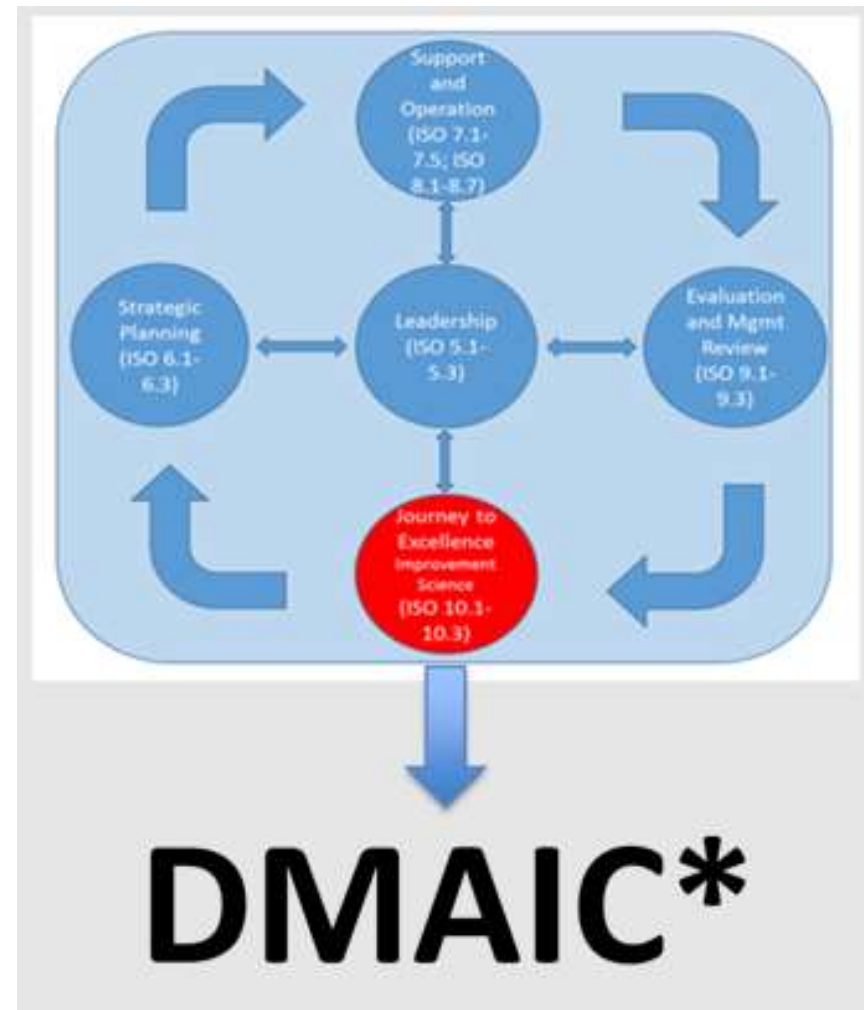
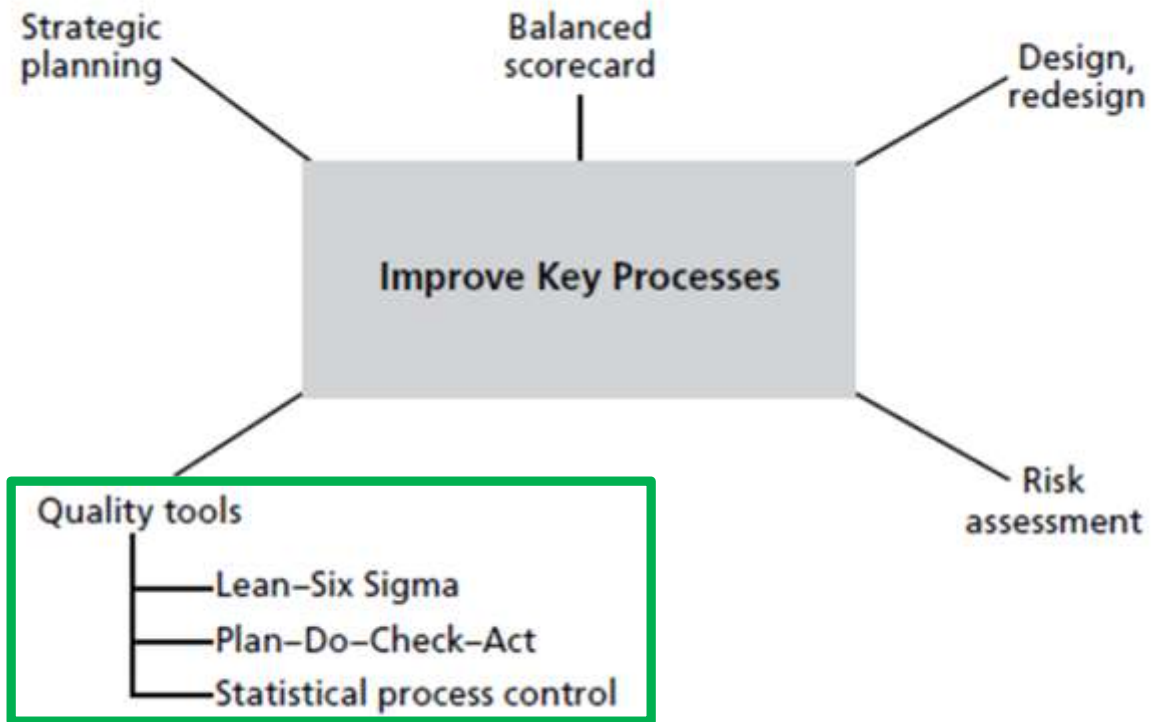
Quality Outcomes

Zero Harm (Patients and Staff)

Regulatory Compliance

Staff Satisfaction and Retention

Community and Financial Value

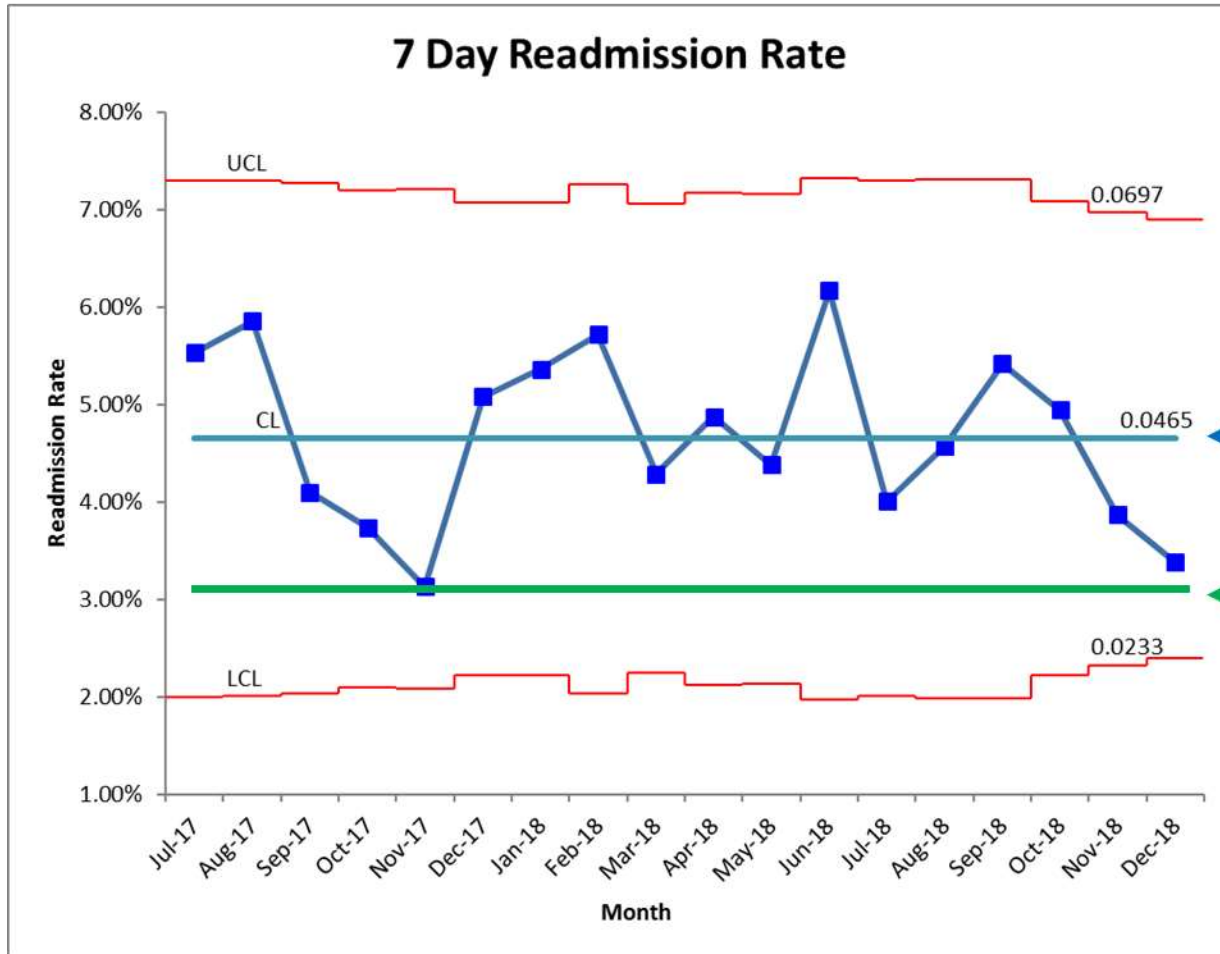


# Problem Statement

If a child is readmitted to the hospital after being recently discharged, it leads to family dissatisfaction and stresses the system clinically. Our 7-day readmission rate is higher than other similar pediatric hospitals. As part of providing safe and quality care to all patients and families, we would like to reduce our readmission rate.

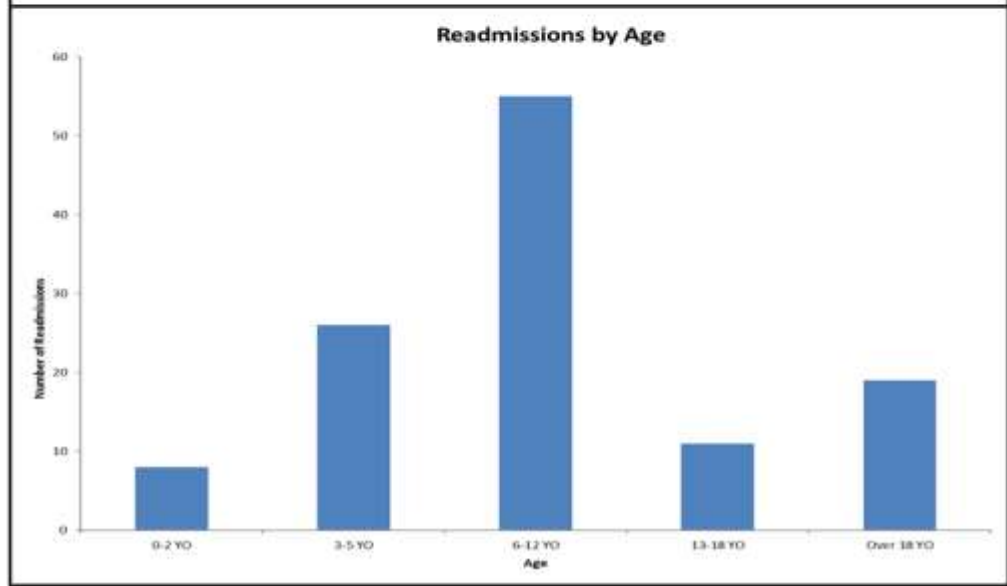
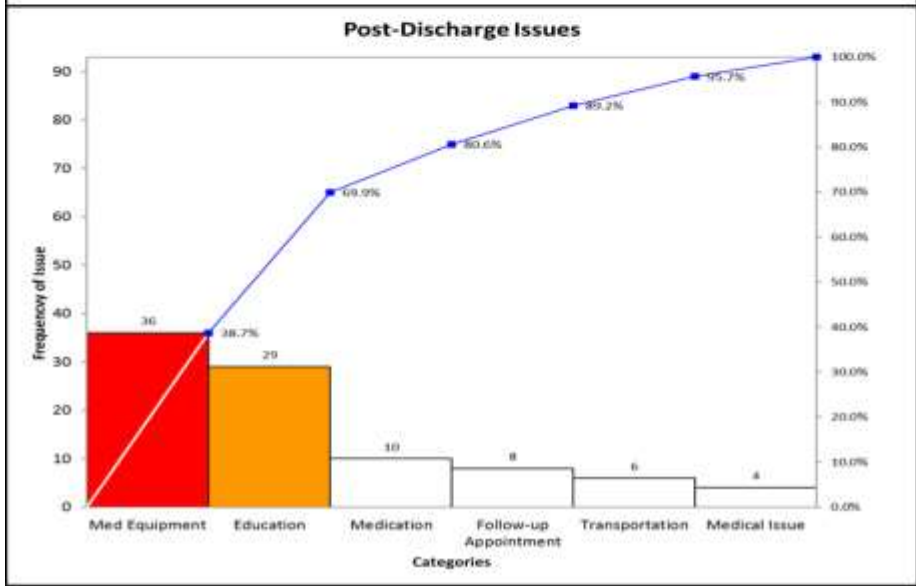
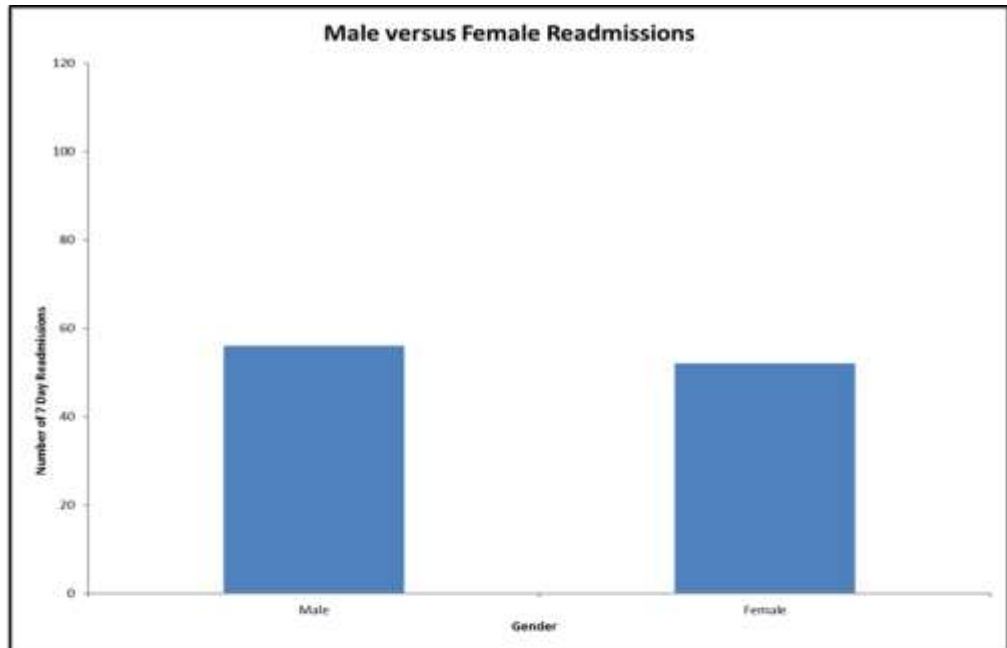
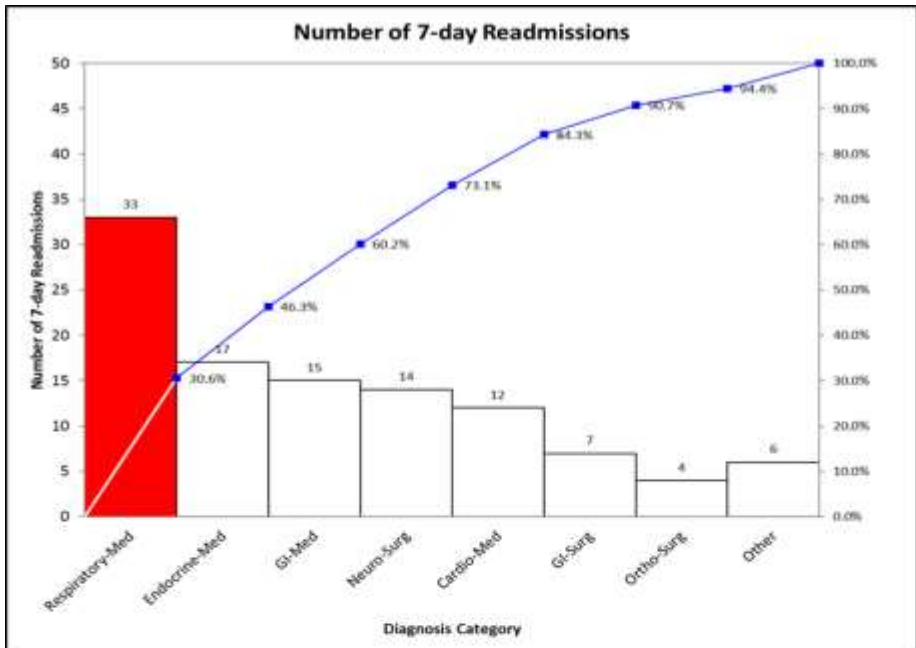
**Understand the Opportunity**

# Review Available Data



Our Average Performance

Other Pediatric Hospital Performance



# Project Charter: Formalizing the Team and Project

Team/Committee Charter Template	
Name:	
Executive Sponsor(s):	Charter Date:
Background:	
Goals:	
Structure and Scope:	
Attendees/Members:	
Meeting Frequency:	
Governance (Committee Structure):	

- ← What is the purpose of the group?
- ← SMART AIM goals for the group
- ← Size and strategic integration of work
- ← Who is on the improvement team?
- ← How often will the team meet?
- ← To whom does the group give updates?



# SMART AIM: What + How Much + By When + For Whom + Where

## Aim Statement Worksheet

An aim statement is the answer to the first question in the Model for Improvement, "What are we trying to accomplish?"

Effective aim statements delineate clear, specific plans for the work ahead.

Use the prompts below to write an effective aim statement. Then use the checklist to double-check your work.

**What?** What's the problem or opportunity? Make sure it relates to a fundamental customer need.

Readmission Reduction

**How much?** By how much will you improve? Or "how good" do you want to get?

By 15%

**By when?** What is the date by which you will achieve the level of improvement you've set out to accomplish?

By December 2021 and sustain for one year

**For whom?** Who is the customer or population who will benefit from the improvement?

Patient discharged in past 7 days

**Where?** What are the boundaries of the process or system you're trying to improve? Where does it begin and end?

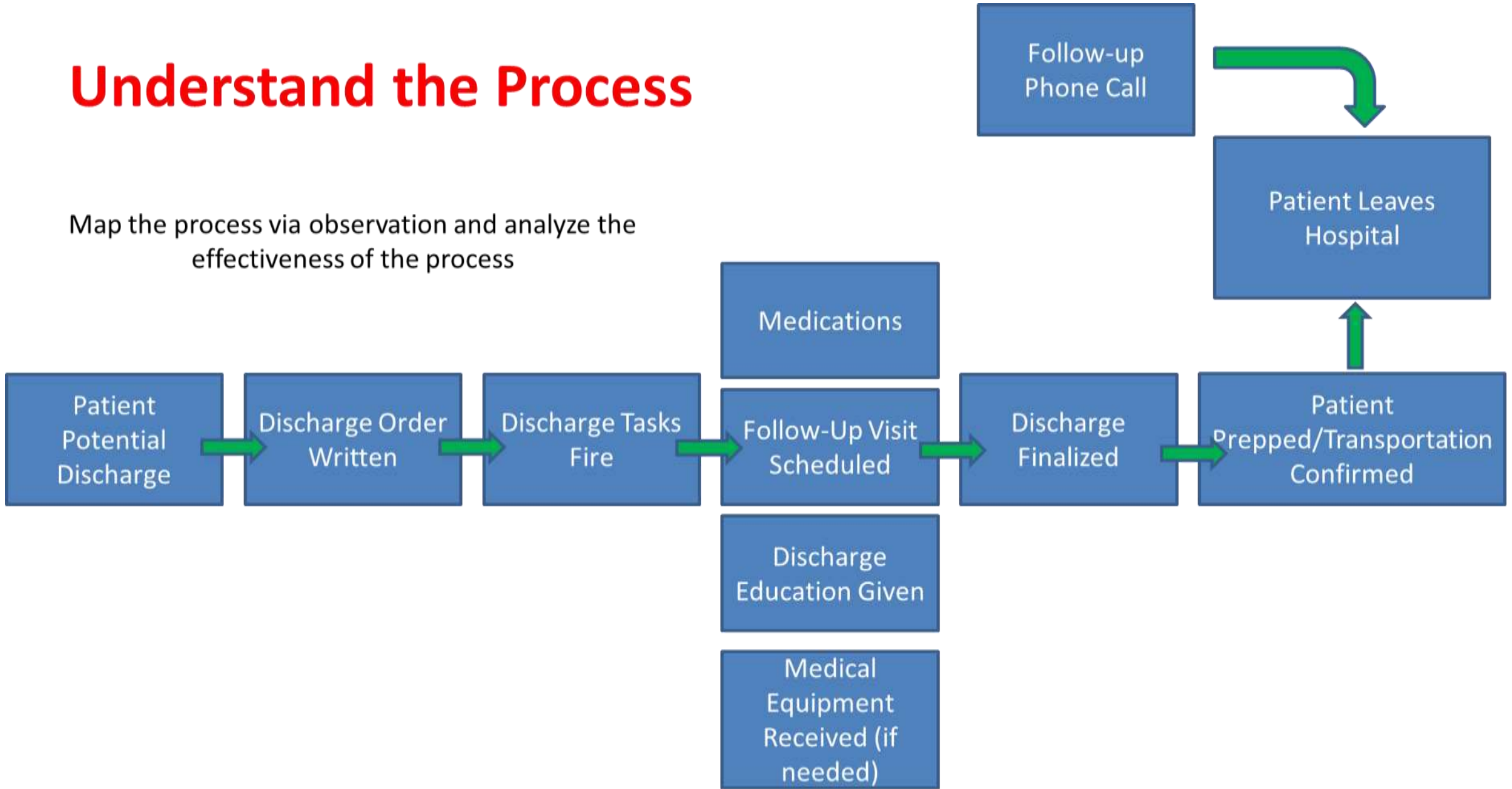
Patient discharged from Inpatient or Observation Status

Complete aim statement:

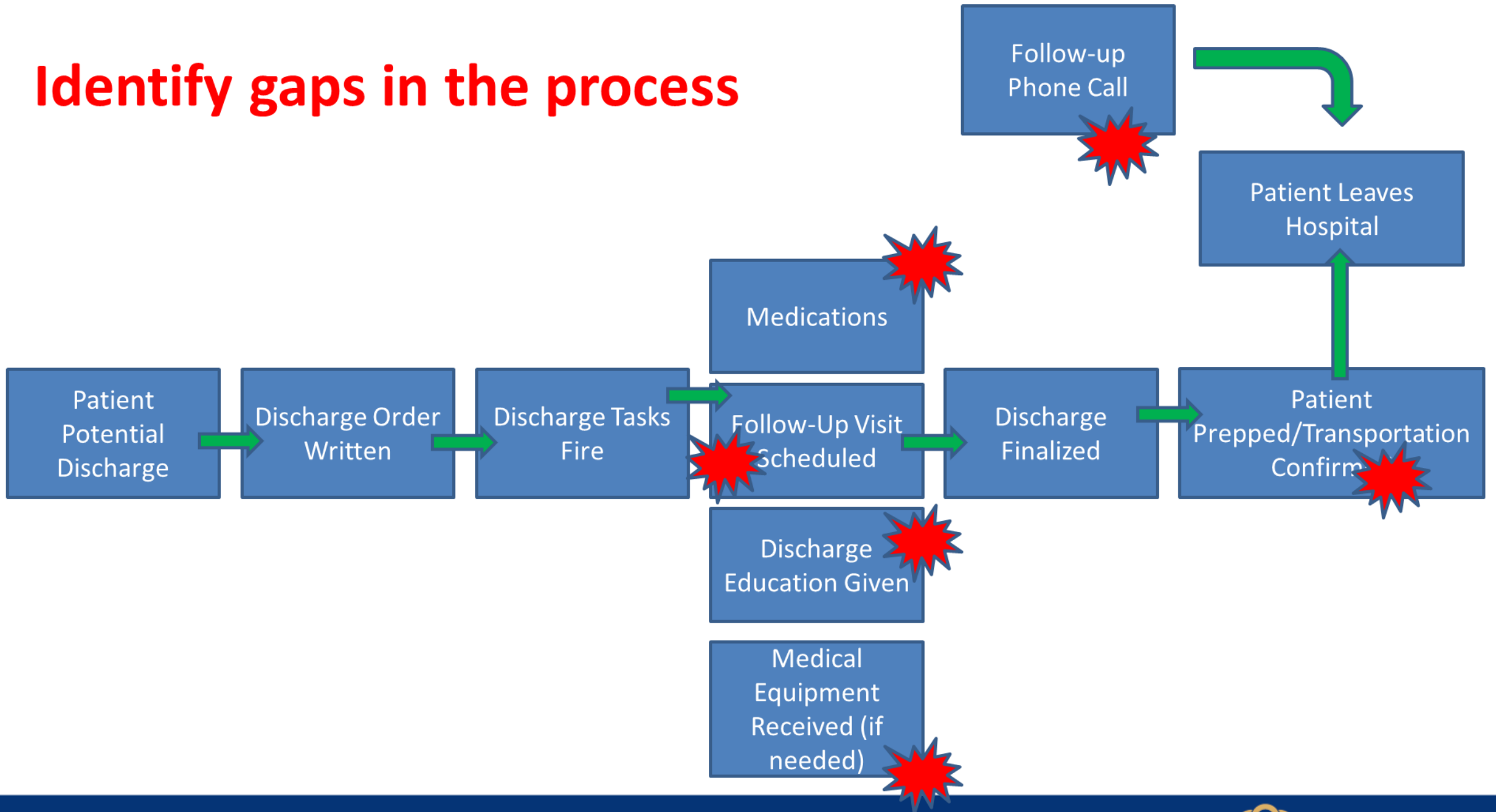
Reduce readmissions by 15% by December 2021 and sustain for 1 year for patients discharged from an inpatient or observation status in the last 7 days

# Understand the Process

Map the process via observation and analyze the effectiveness of the process



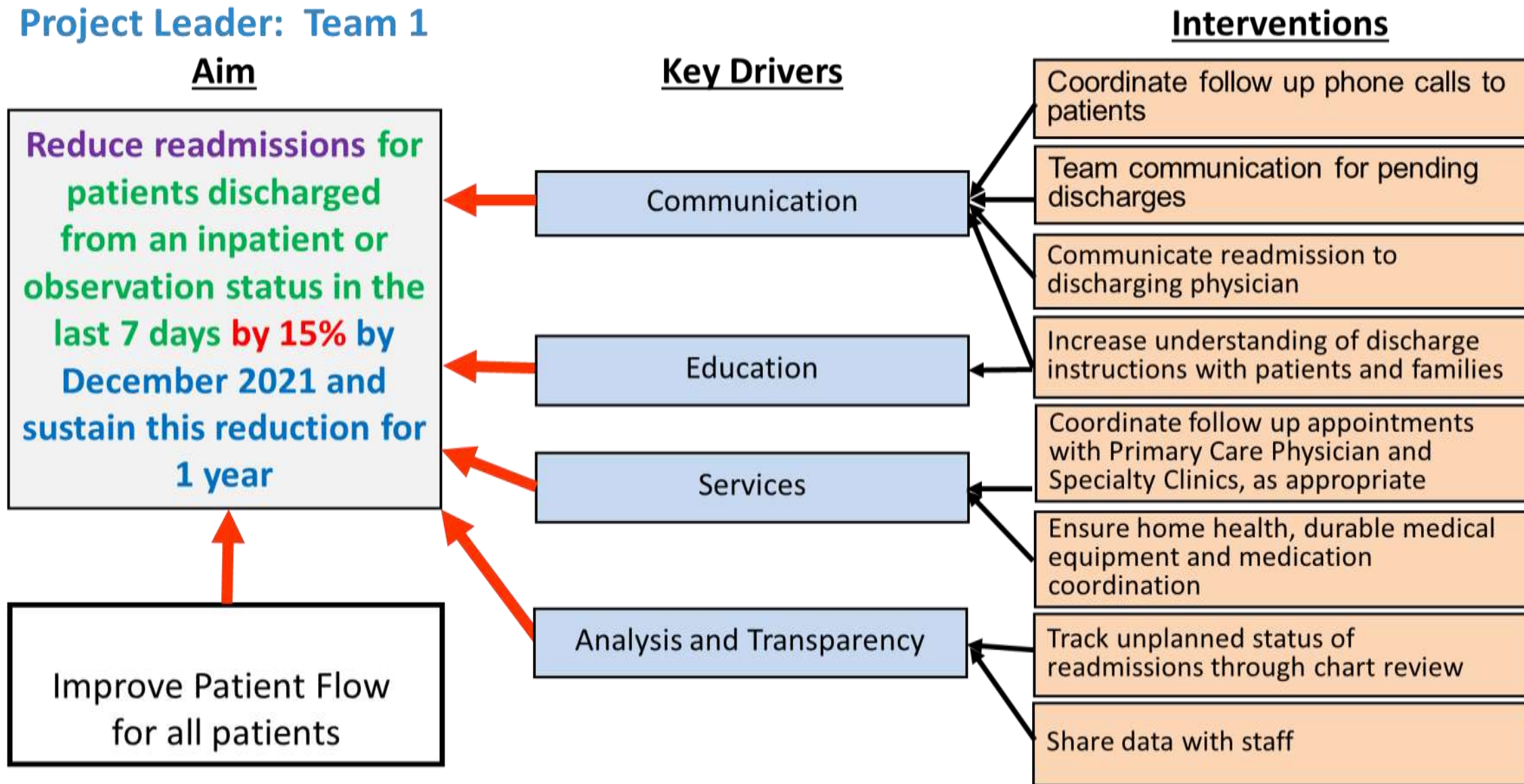
# Identify gaps in the process



# Project Title: Readmission Reduction

Project Leader: Team 1

## Key Driver Diagram (KDD)

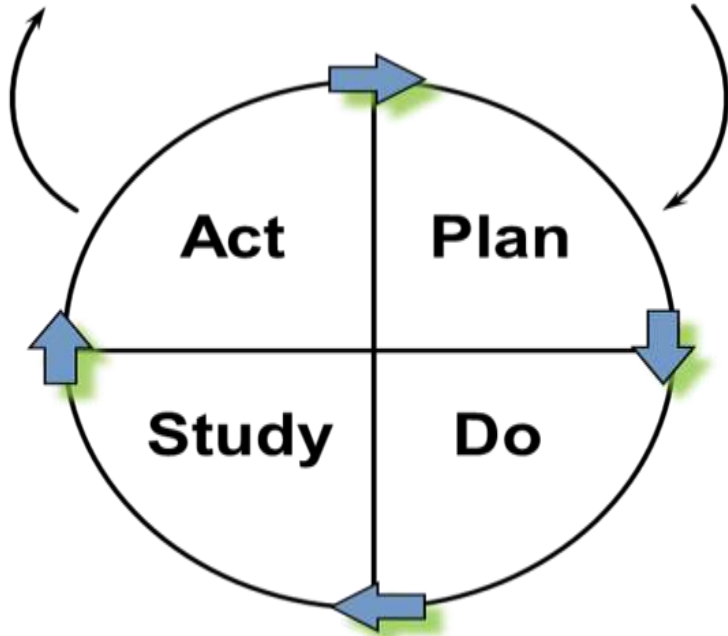


## Model for Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?



# PDSA Form



PDSA Short Form    DATE \_\_\_\_\_

Objective for this PDSA Cycle:

Is the use of this cycle to develop, test, or implement a change?

What question(s) do we want to answer on this PDSA cycle?

---

**Plan:**

*Plan to answer questions: Who, What, When, Where*

*Plan for collection of data: Who, What, When, Where*

Predictions (for questions above based on plan):

**Do:**

*Carry out the change or test; Collect data and begin analysis.*

**Study:**

*Complete analysis of data;*

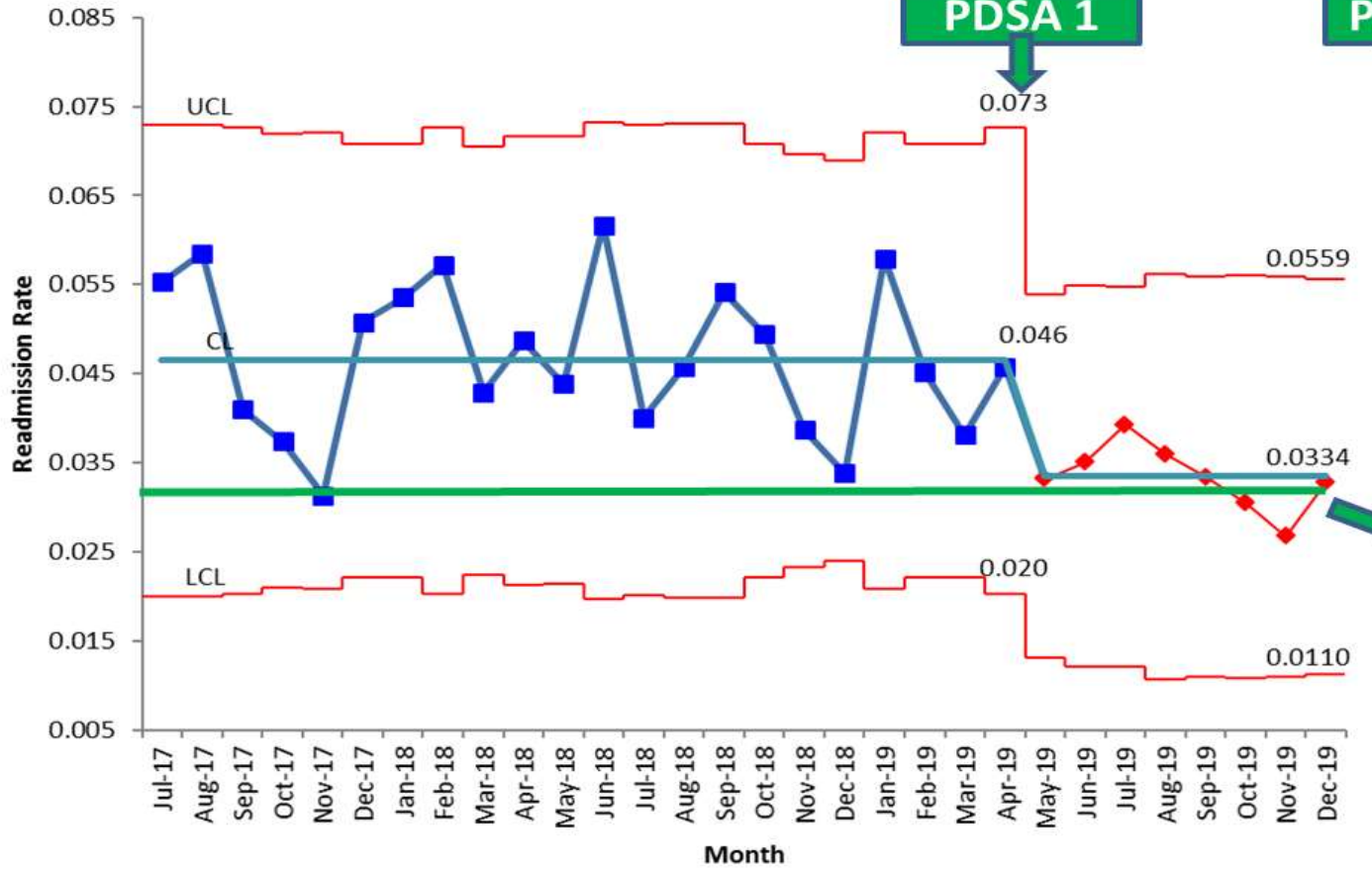
*Compare the data to your predictions and summarize the learning*

**Act:**

*Are we ready to make a change? Plan for the next cycle*

# Effects of Changes

## 7 Day Readmission Rate



**Further Improvement**

## QI Essentials Toolkit

- [Cause and Effect Diagram](#)
- [Driver Diagram](#)
- [Failure Modes and Effects Analysis \(FMEA\)](#)
- [Flowchart](#)
- [Histogram](#)
- [Pareto Chart](#)
- [PDSA Worksheet](#)
- [Project Planning Form](#)
- [Run Chart & Control Chart](#)
- [Scatter Diagram](#)

## Ready to start improving?

With dozens of online courses and thousands of local Chapters around the world, the IHI Open School is here to support you and your team in providing the best possible health care.



Take a Course

## Credits and Certification



The complete catalog of online courses includes more than **35 continuing education credits** for nurses, physicians, and pharmacists as well as a **Basic Certificate in Quality and Safety**. A selection of courses has been approved for Maintenance of Certification (MOC) Part 2 Activity points.

[Continuing education credits and certificates »](#)

*Thank  
you*



Adam.Campbell@Erlanger.org