Driving Quality Improvement & Safety Using Highly-Reliable Management Systems

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Key Points

As a result of this activity, learners should be able to:

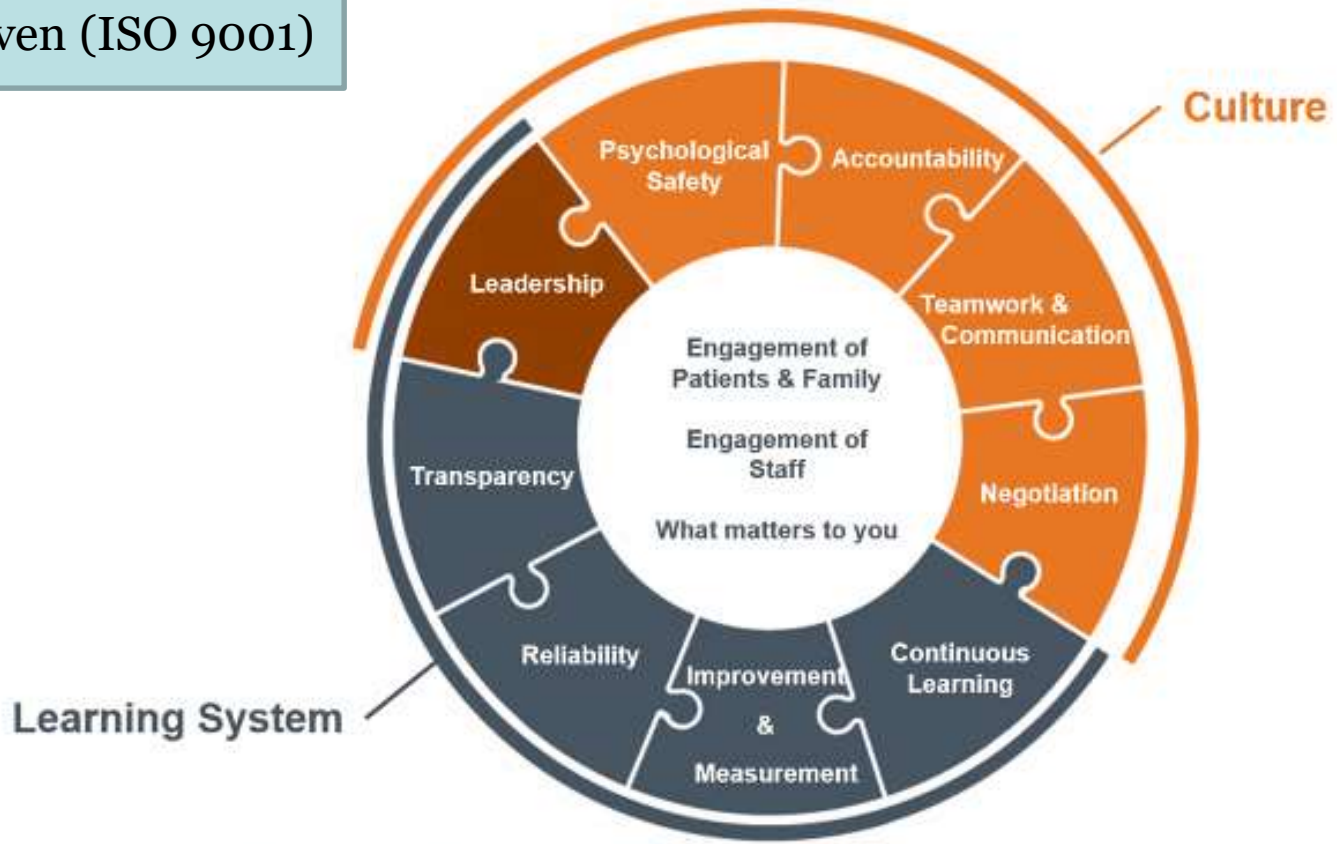
- Cite high reliability principles and discuss how they relate to healthcare quality and safety
- Explain the importance of accreditation bodies, like DNV, to healthcare quality and safety
- Explain how ISO 9001:2015 requirements support the creation of a Quality Management System
- Utilize basic improvement science methods to drive improvement

Acknowledgements

- Quality, Safety and Service Leadership
  - Mike Bettinger
  - Jackie Bishop
  - Renee Grayson-Eubanks
  - Brooke Horne
  - Eileen Shrum
- And the whole Quality, Safety and Service Team
- Erlanger Health System leaders and frontline
- UT College of Medicine

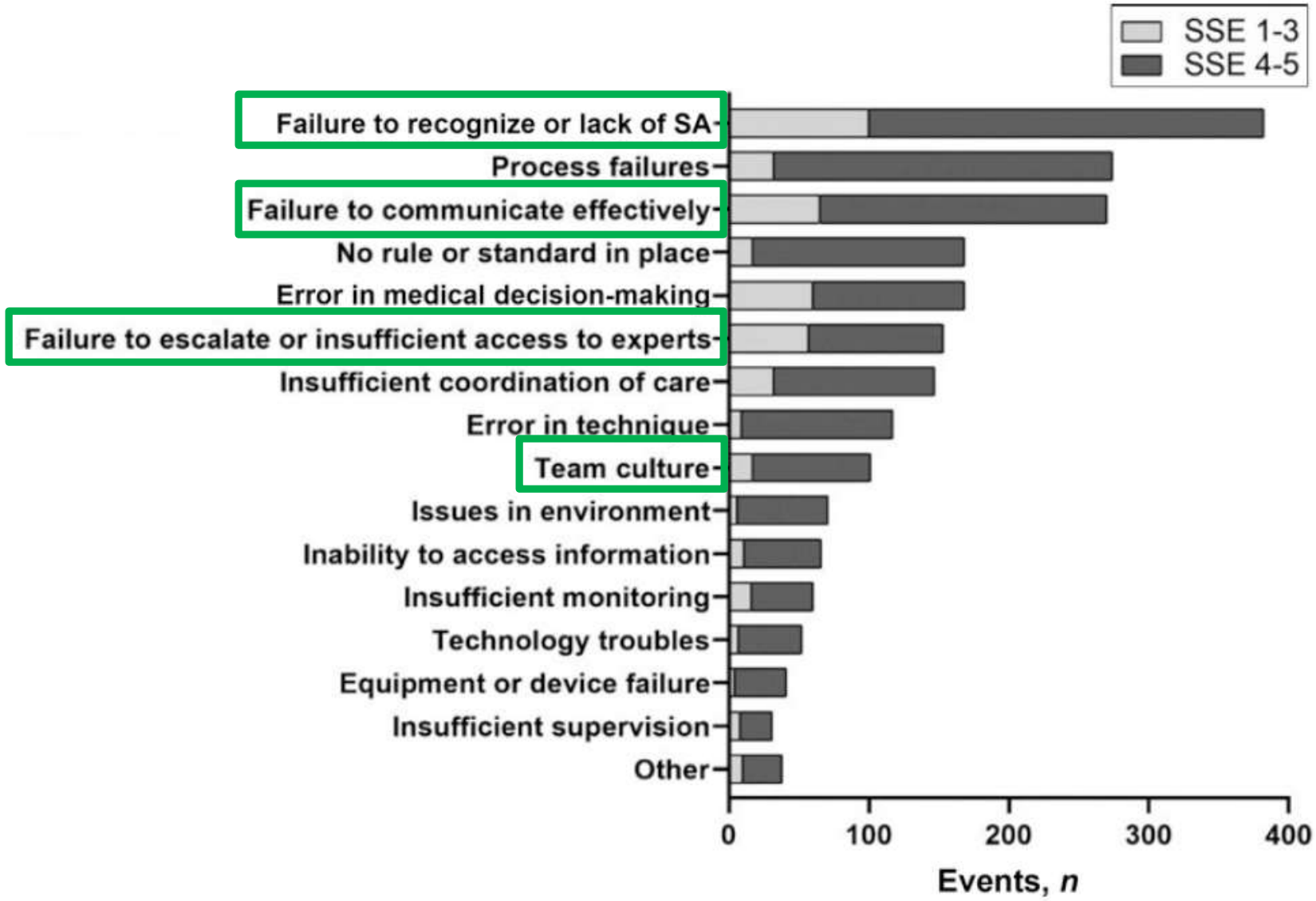
Framework for Safe, Reliable and Effective Health Care

Leader-driven (ISO 9001)



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)

Serious Safety Event Contributing Factors



Reference: Burrus, S. et al. Factors Related to Serious Safety Events in a Children's Hospital Patient Safety Collaborative. Pediatrics, 2021, 148 (3).

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."

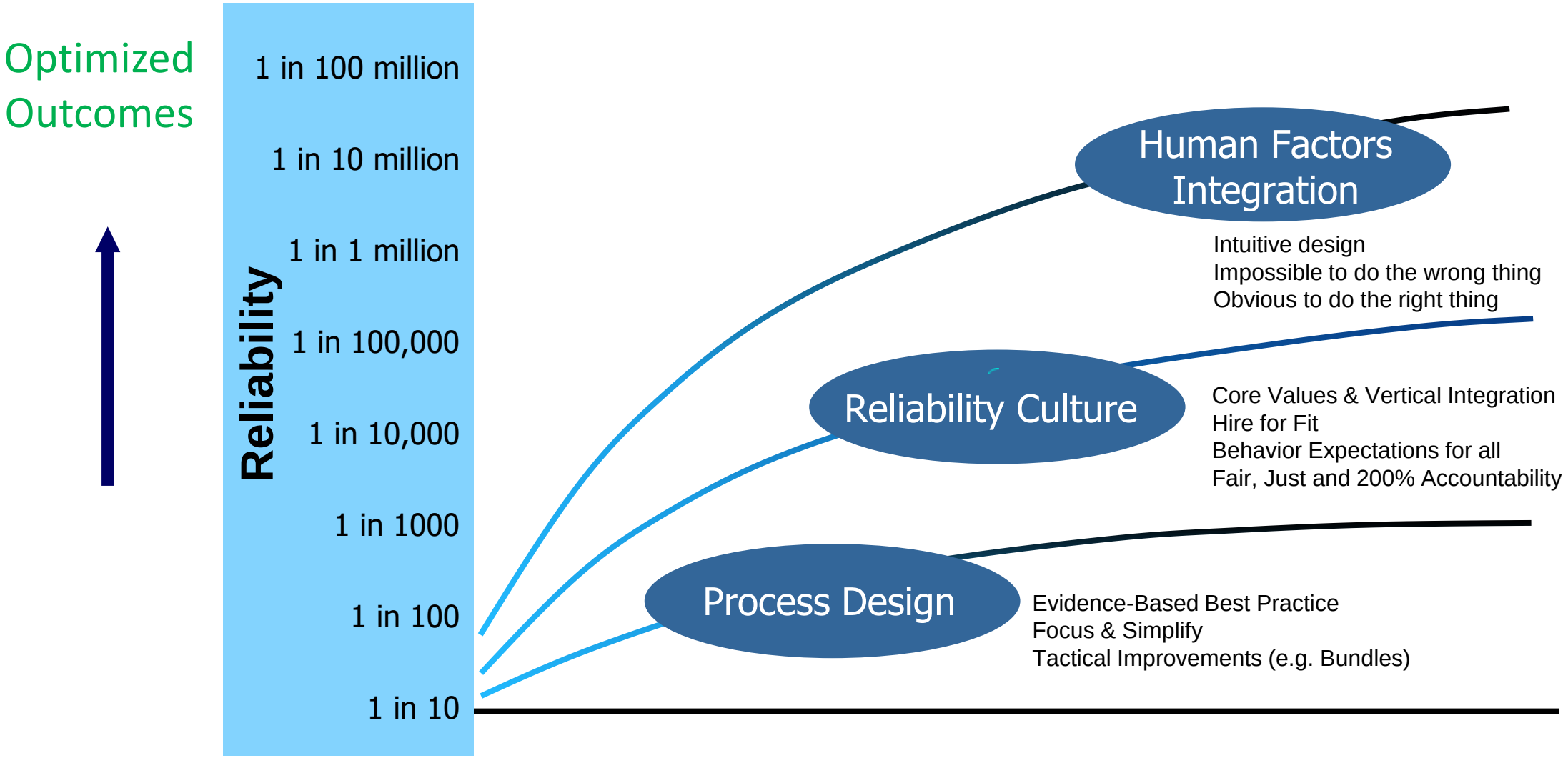
Risk is a function of **probability** and **consequence**. By decreasing the probability of an accident, HRO's recast a high-risk enterprise as merely a high-consequence enterprise. HROs operate as to make systems ultra-safe.

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

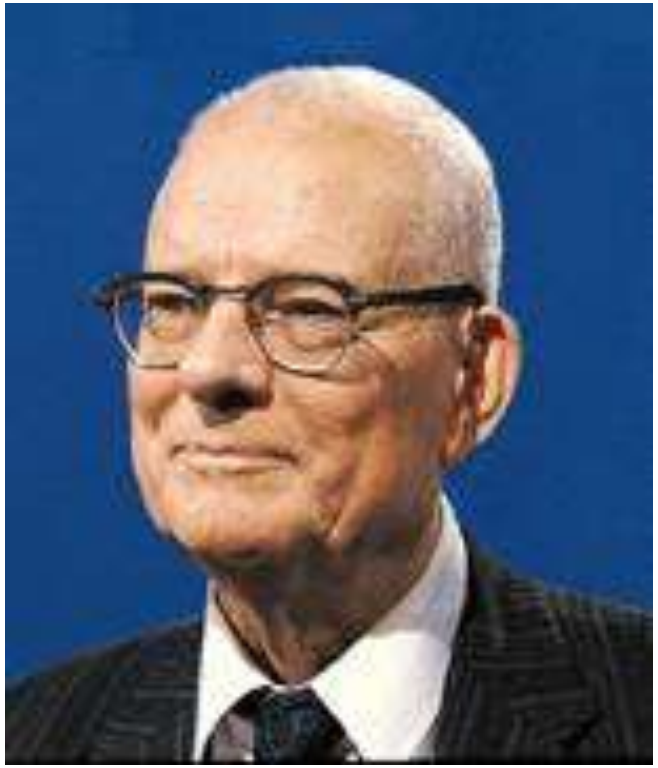
Relevant Metrics

What are the statistical goals of improvement?

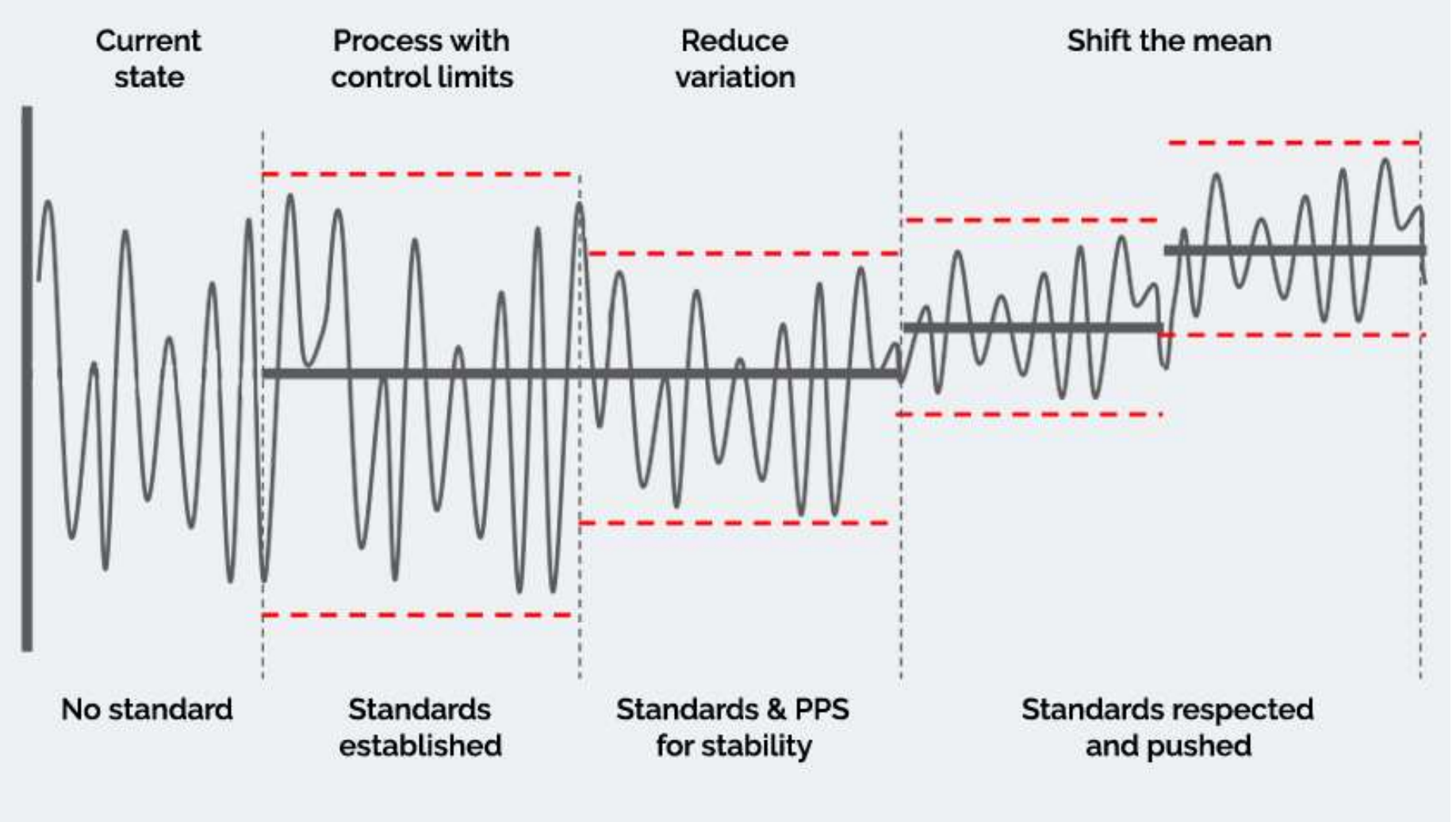
- Shifting performance
- Reducing variation

"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

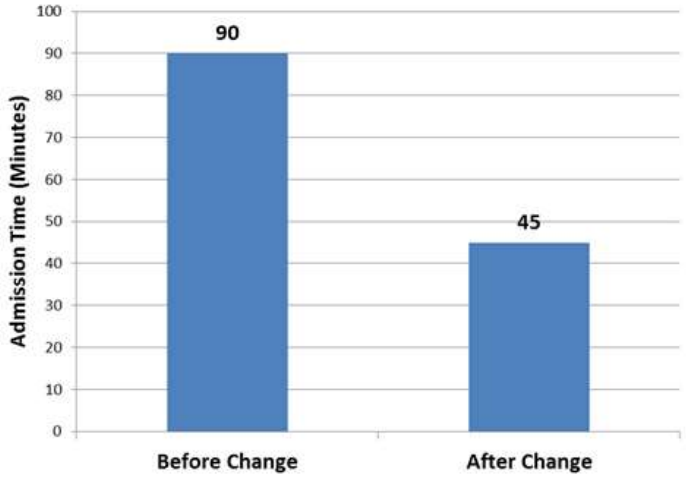


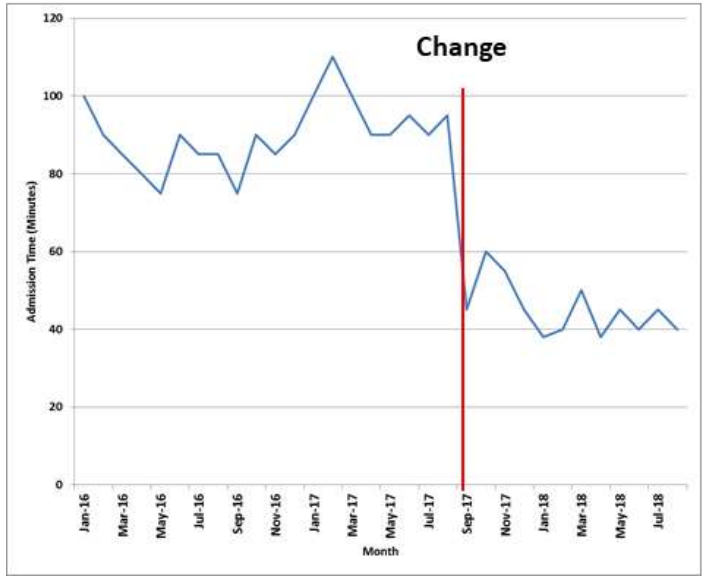
Process Control and Reliability

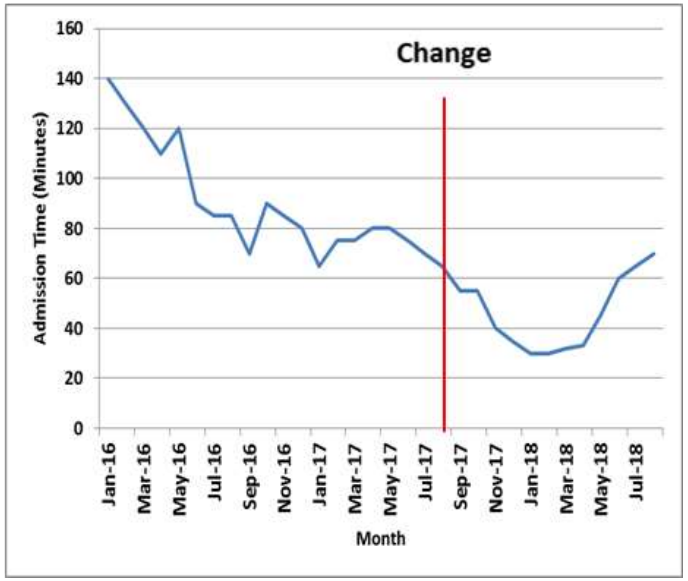


Bundle Reliability
-CLABSI
-CAUTI
-SSI
-Unplanned Extubation
-Pressure Injury

Before Change Mean = 90
After Change Mean = 45

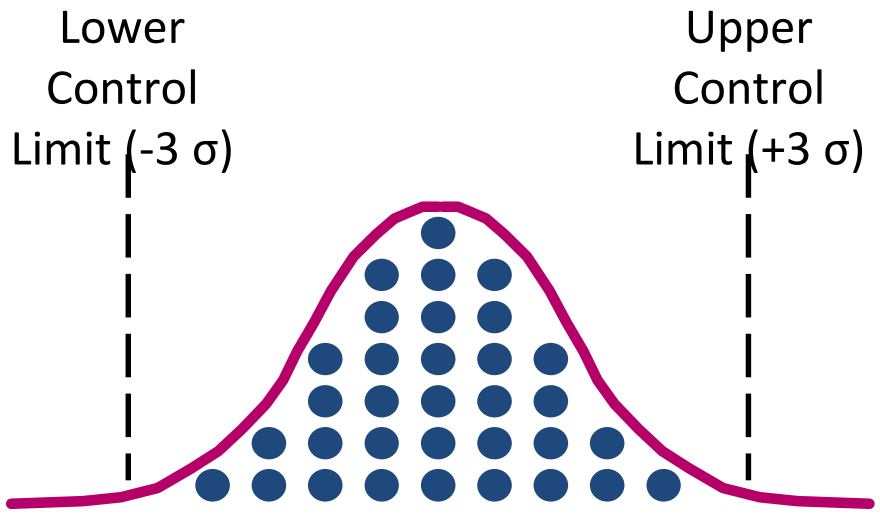




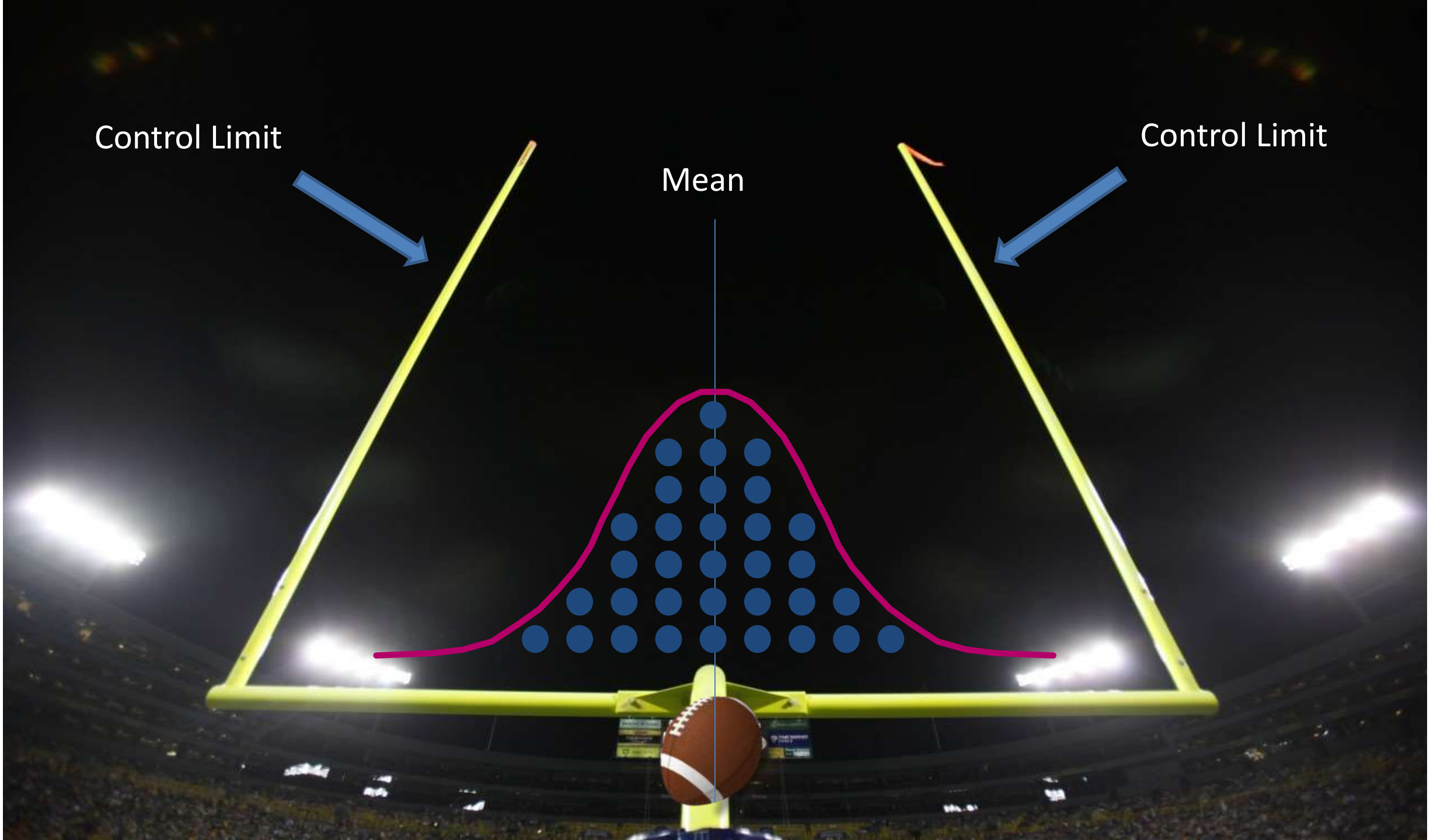


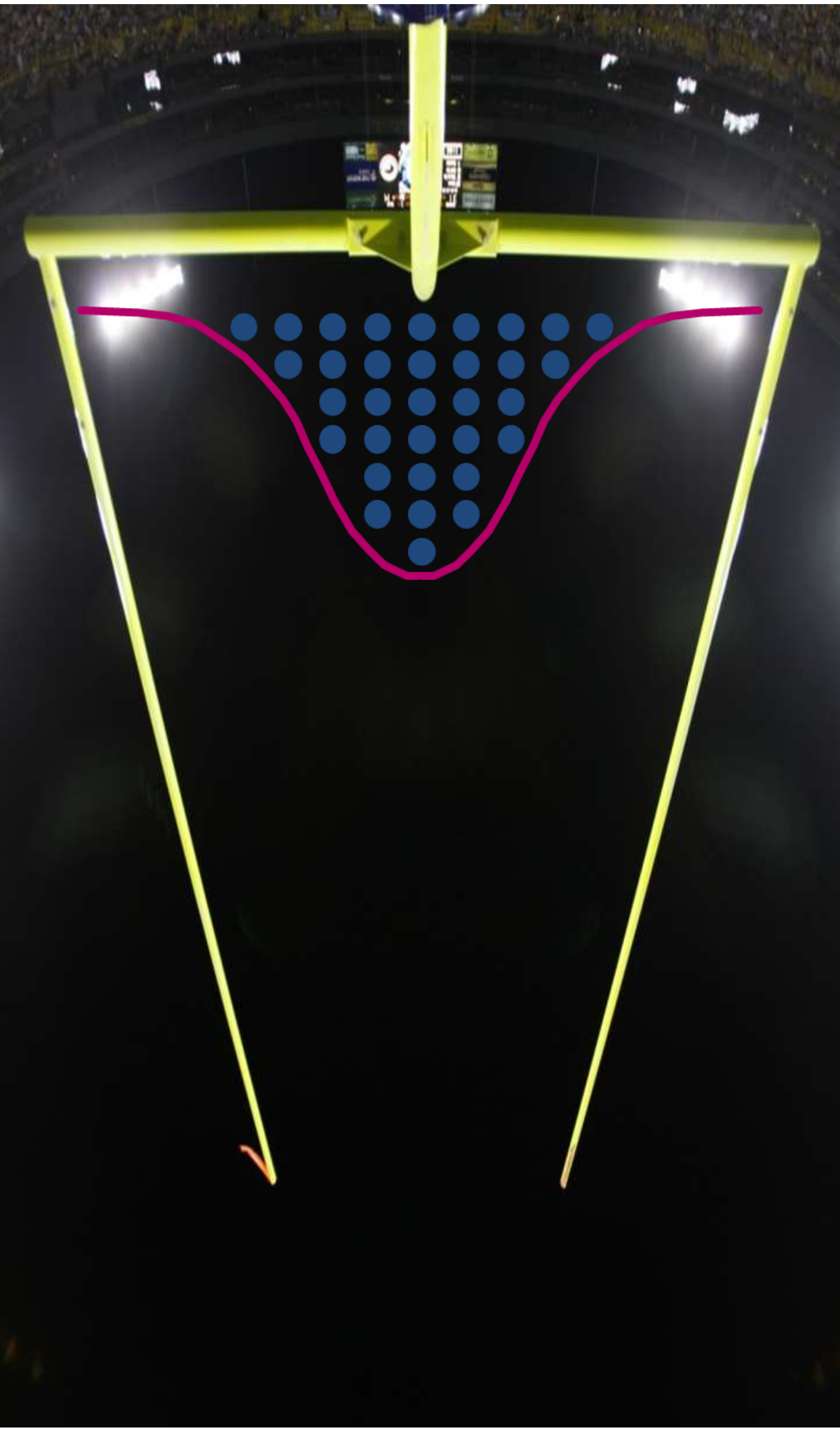
Statistical Process Control

- Statistically looking at trends to analyze baselines and effects of change
- Follows specific rules looking for common and special causes of variation
  - **Common cause:** variation inherent in a system
  - **Special cause:** variation caused by a change from outside the normal system

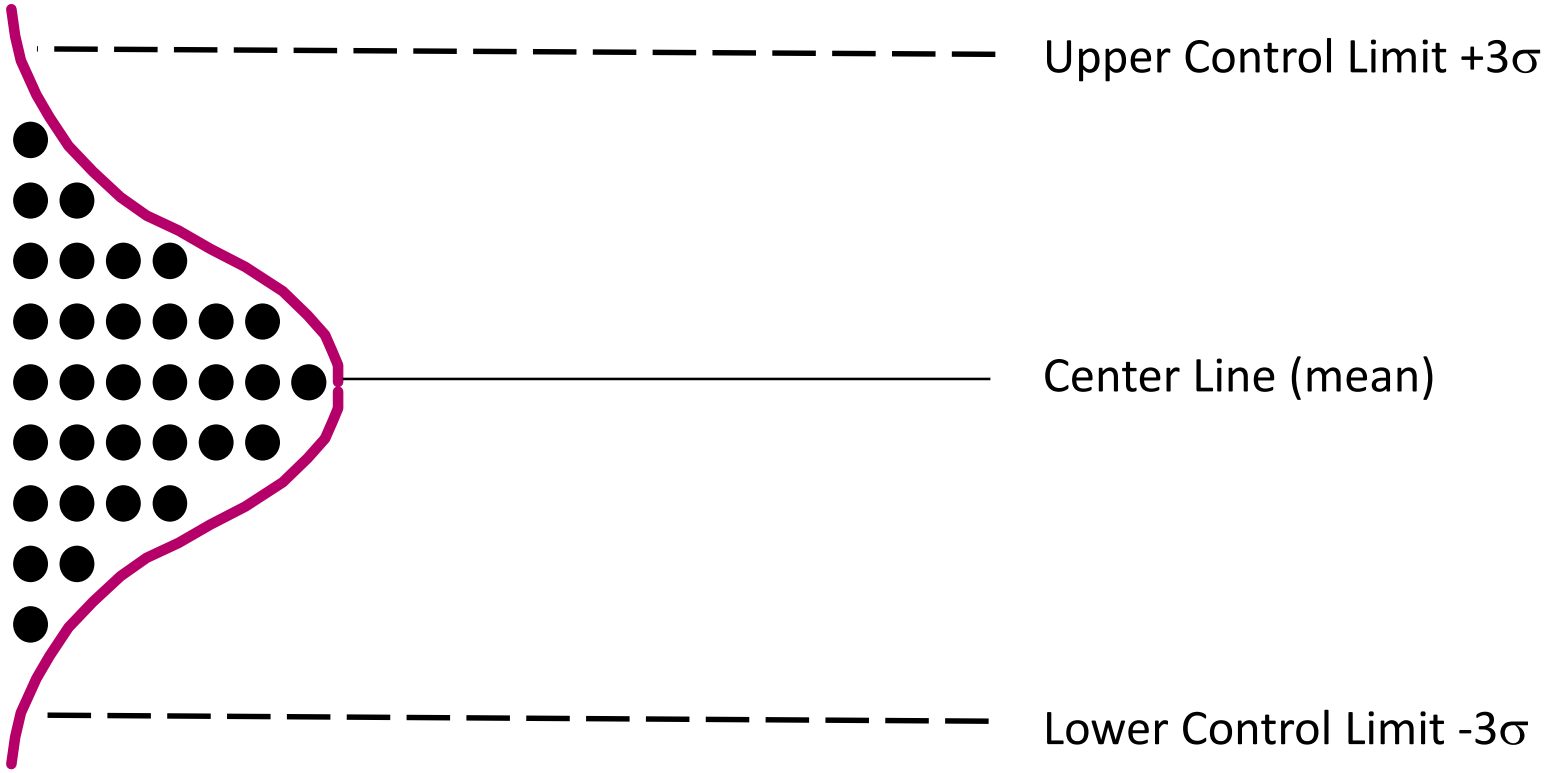


Control limits tell us where the measurements in a stable process should fall

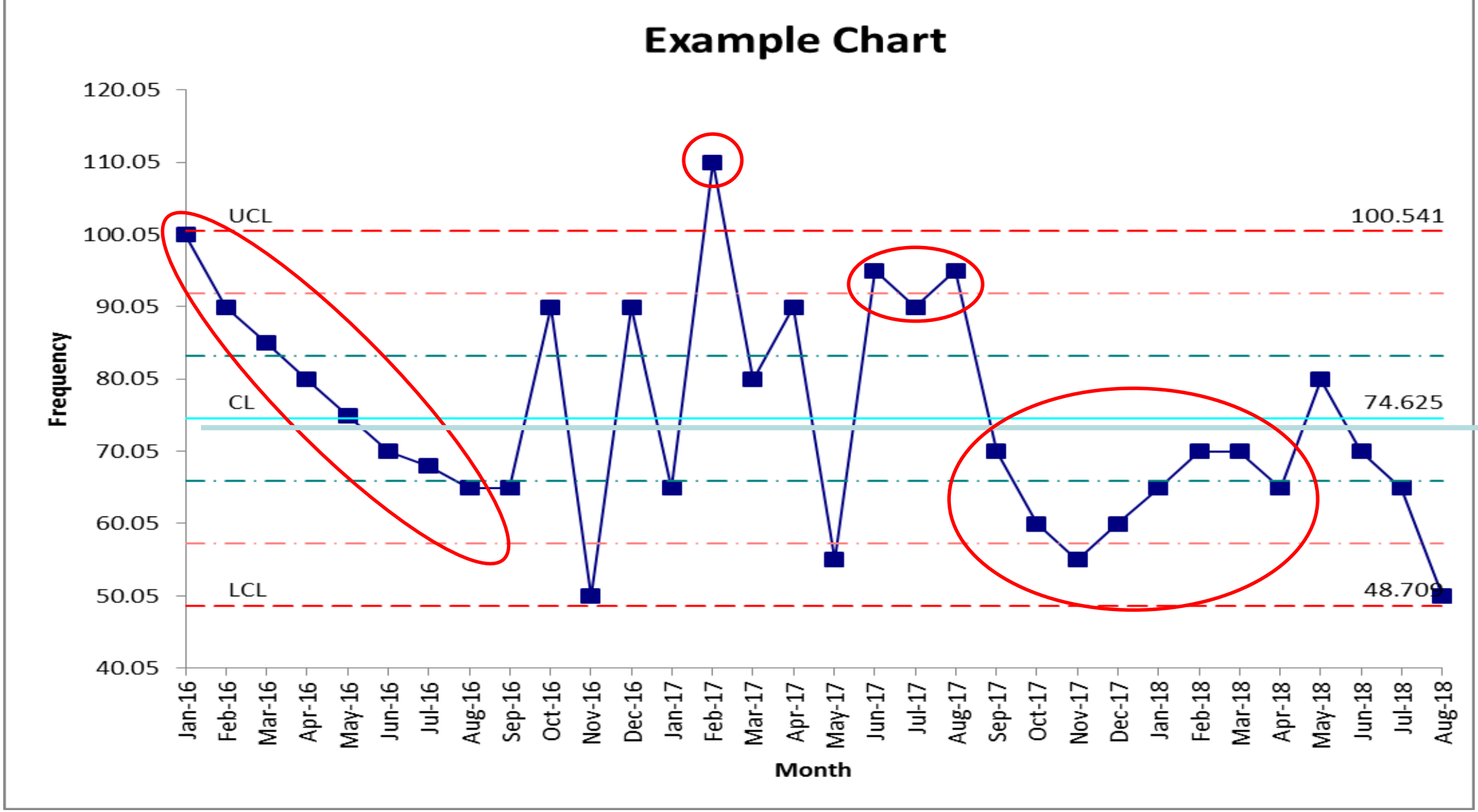

Control Limit
Mean
Control Limit



Creating a control chart using control limits



Turn the distribution on its side


Example Chart
120.05
110.05
100.05
90.05
80.05
70.05
60.05
50.05
40.05
Frequency
UCL
100.541
CL
74.625
LCL
48.709
Jan-16
Feb-16
Mar-16
Apr-16
May-16
Jun-16
Jul-16
Aug-16
Sep-16
Oct-16
Nov-16
Dec-16
Jan-17
Feb-17
Mar-17
Apr-17
May-17
Jun-17
Jul-17
Aug-17
Sep-17
Oct-17
Nov-17
Dec-17
Jan-18
Feb-18
Mar-18
Apr-18
May-18
Jun-18
Jul-18
Aug-18
Month

ISO 9001: 2015-Quality Management Systems

ORGANIZATIONAL OVERSIGHT

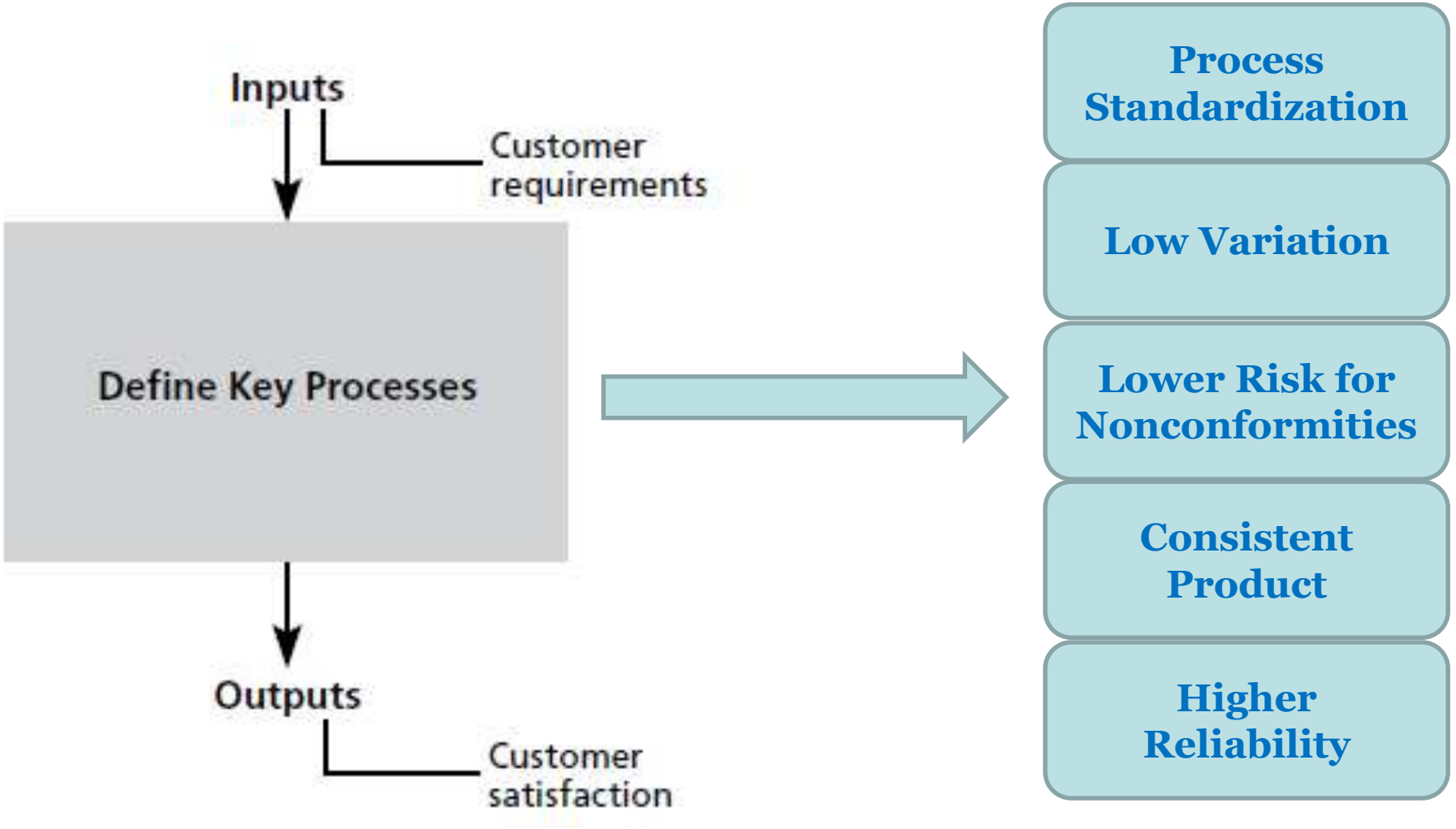
Quality Management Systems

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

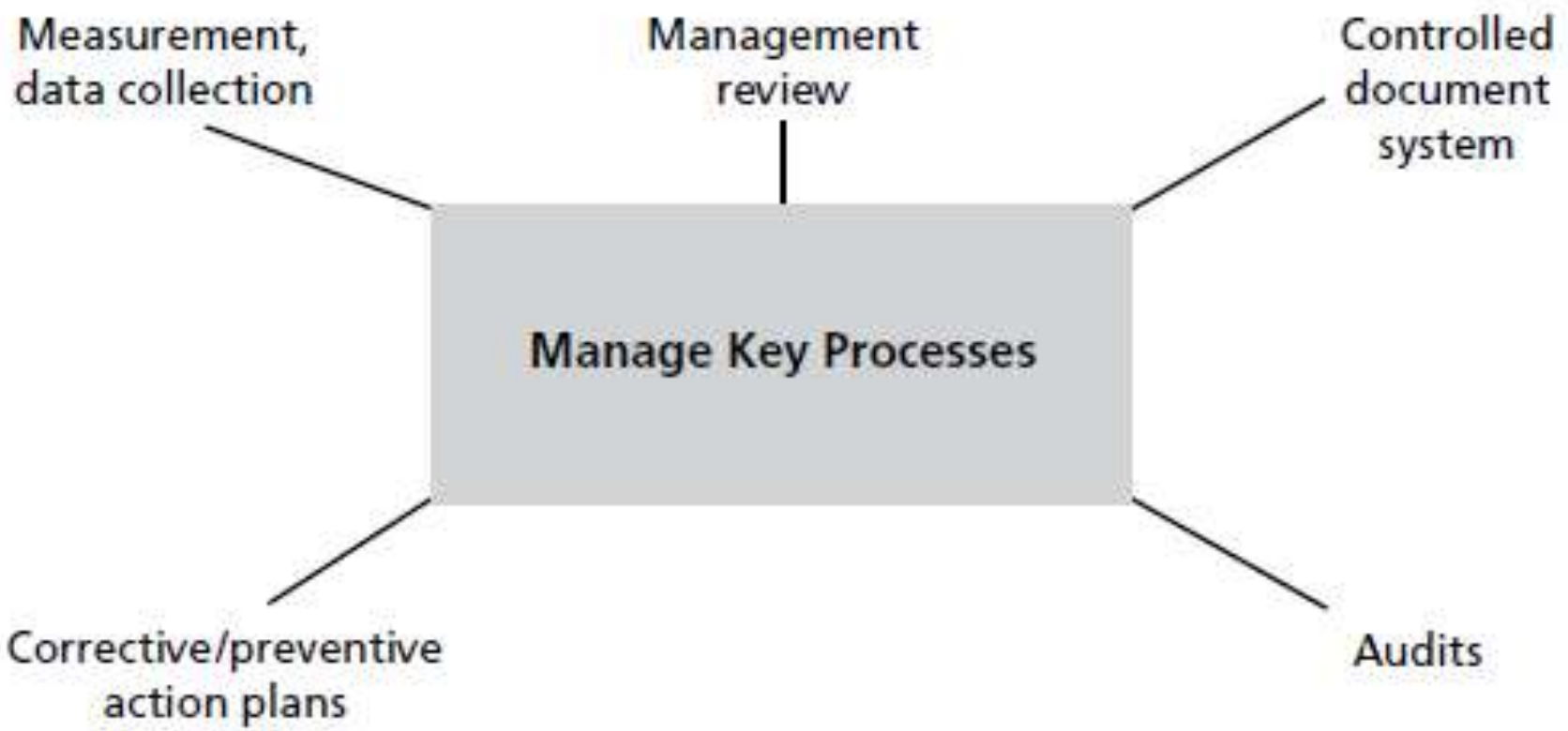
Organizations use the standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements

Defining Key Processes

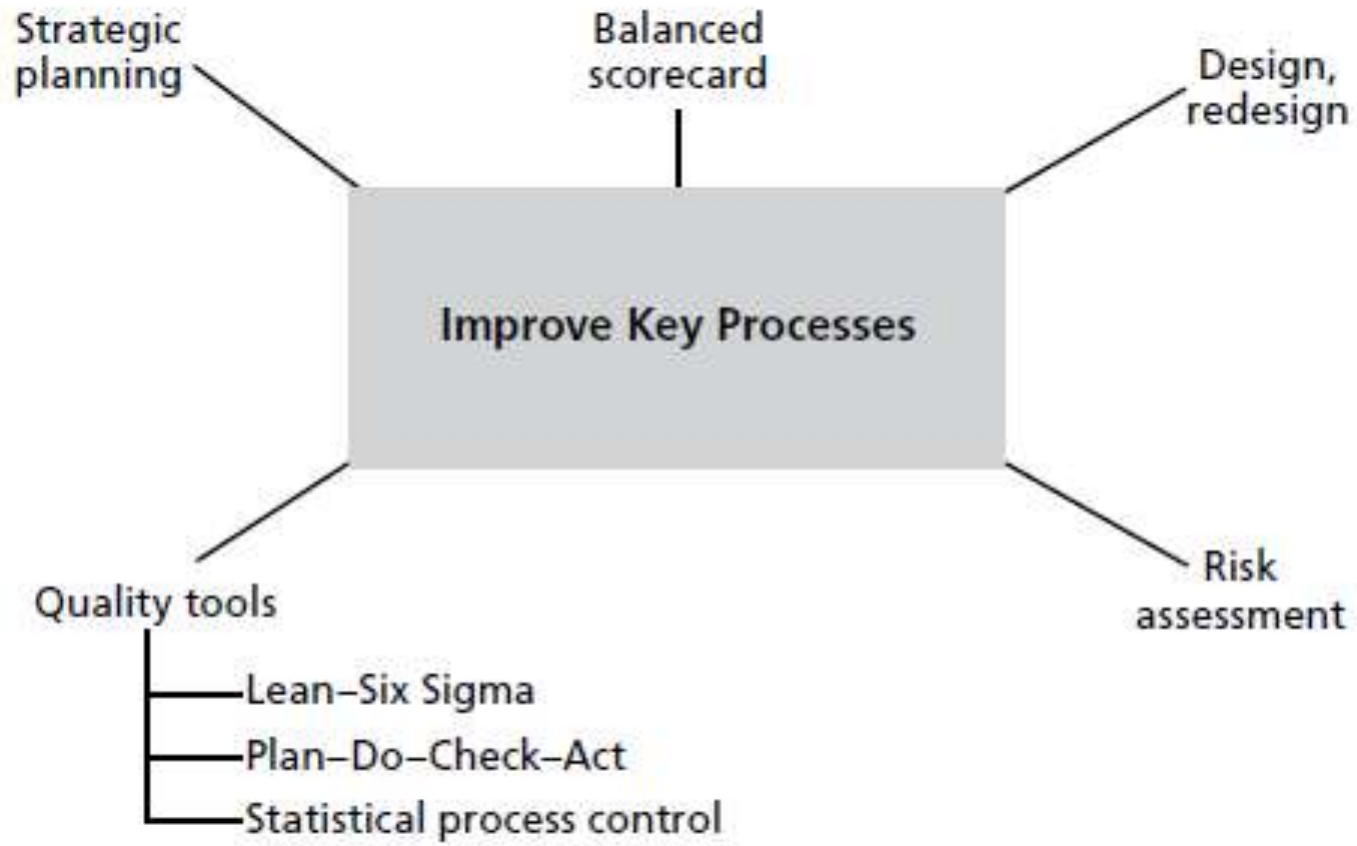


Reference: Levett, JM and Burney, RG. Using ISO 9001 in Healthcare: Applications for Quality Systems, Performance Improvement, Clinical Integration and Accreditation, 2011.

Managing Key Processes



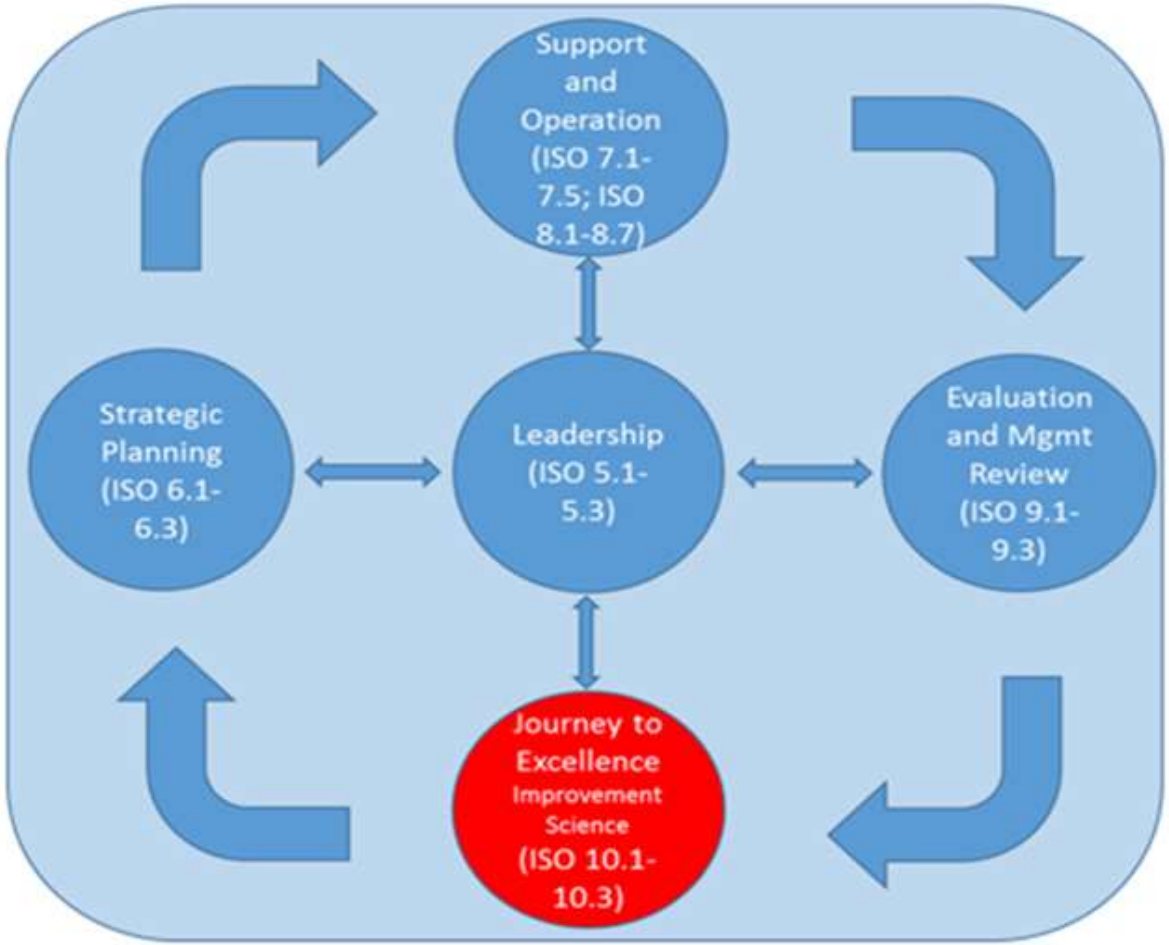
Improving Key Processes



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

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

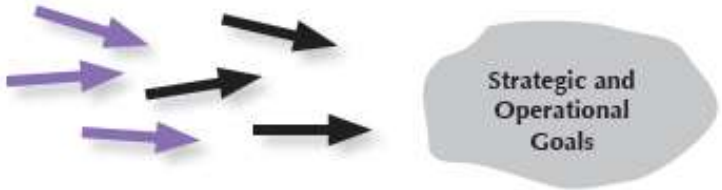
Source: Frankel A, Haraden C, Federico F, Lenoci-Edwards J. A Framework for Safe, Reliable, and Effective Care. White Paper. Cambridge, MA: Institute for Healthcare Improvement and Safe & Reliable Healthcare; 2017. (Available at ihi.org)

DNV and ISO 9001: 2015 Goal: Process Maturation

Reacting to Problems (0–25%)

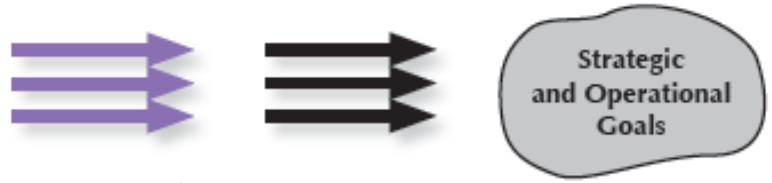
Operations are characterized by activities rather than by processes, and they are largely responsive to immediate needs or problems. Goals are poorly defined.

Early Systematic Approaches (30–45%)



The organization is beginning to carry out operations with repeatable processes, evaluation, and improvement, and there is some early coordination among organizational units. Strategy and quantitative goals are being defined.

Aligned Approaches (50–65%)



Operations are characterized by repeatable processes that are regularly evaluated for improvement. Learnings are shared, and there is coordination among organizational units. Processes address key strategies and goals.

Integrated Approaches (70–100%)

Operations are characterized by repeatable processes that are regularly evaluated for change and improvement in collaboration with other affected units. The organization seeks and achieves efficiencies across units through analysis, innovation, and the sharing of information and knowledge. Processes and measures track progress on key strategic and operational goals.

DNV and ISO 9001: 2015 Goal: Learning Organization

Learning is an essential attribute of high-performing organizations. Effective, well-deployed organizational learning can help an organization improve from the early stages of reacting to problems to the highest levels of organization-wide improvement, refinement, and innovation.

1

Reacting to the problem (0–5%)

Run with the hose and put out the fire.

2

General improvement orientation (10–25%)

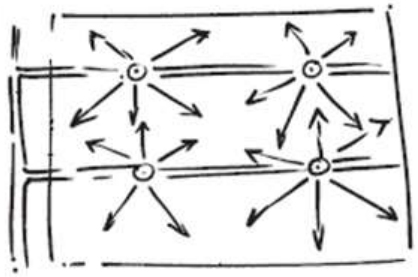
Install more fire hoses to get to the fires quickly and reduce their impact.

3

Systematic evaluation and improvement (30–45%)

Evaluate which locations are most susceptible to fire. Install heat sensors and sprinklers in those locations.

4



Learning and strategic improvement (50–65%)

Install systemwide heat sensors and a sprinkler system that is activated by the heat preceding fires.

5

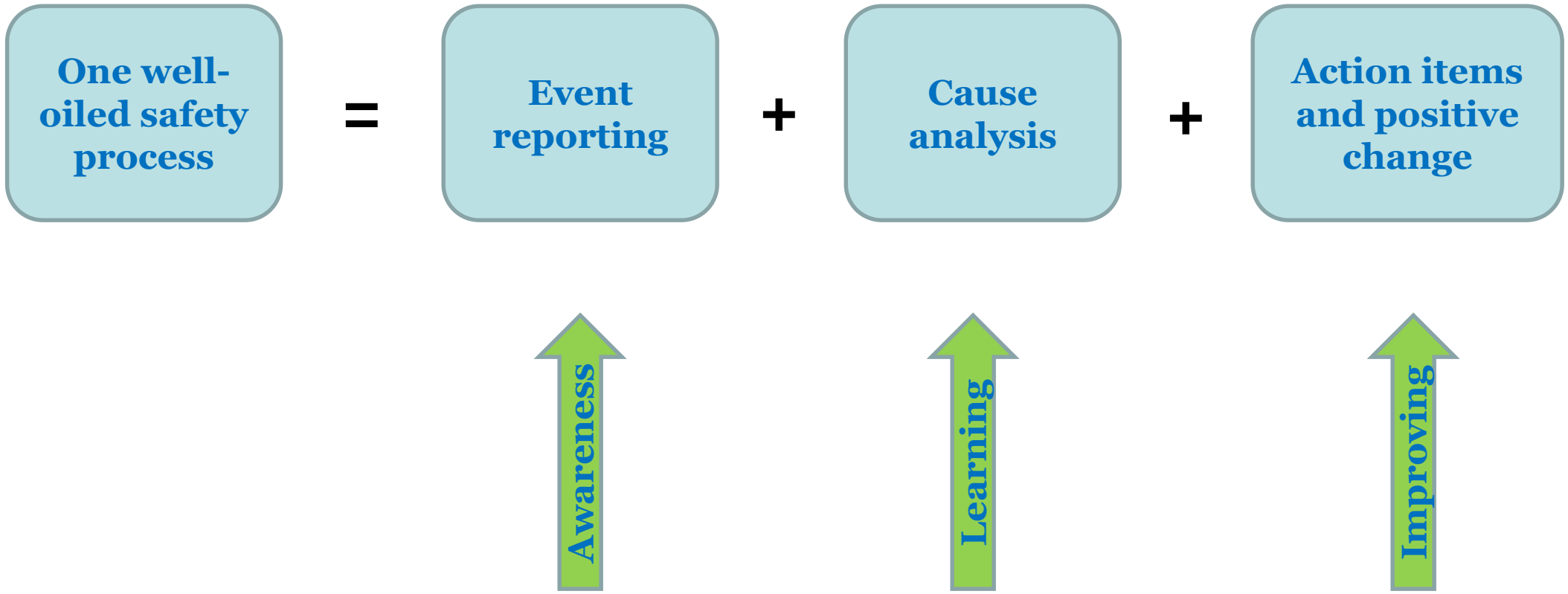
Organizational analysis and innovation (70–100%)

Use fireproof and fire-retardant materials. Replace combustible liquids with water-based liquids. Prevention is the primary approach for protection, with sensors and sprinklers as the secondary line of protection. This approach has been shared with all facilities and is practiced in all locations.

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



Event Reporting

How?

Record occurrence in eSafe

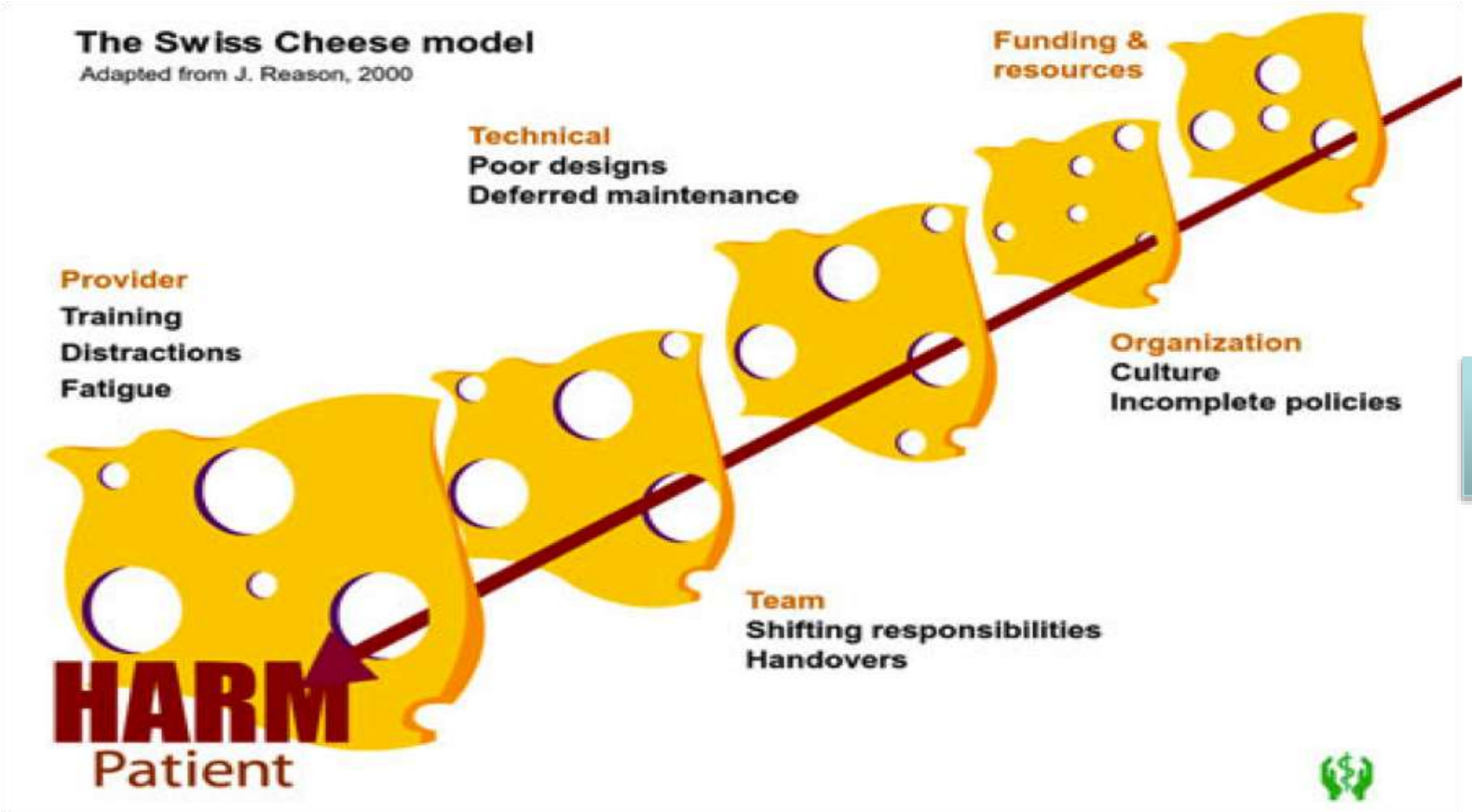
Why?

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



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

Reference: Reason, J. Human error: models and management. BMJ, 320 (7237), 2000.

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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Decentralization to the frontline

IMPROVEMENT SCIENCE METHODS

QMS Engine

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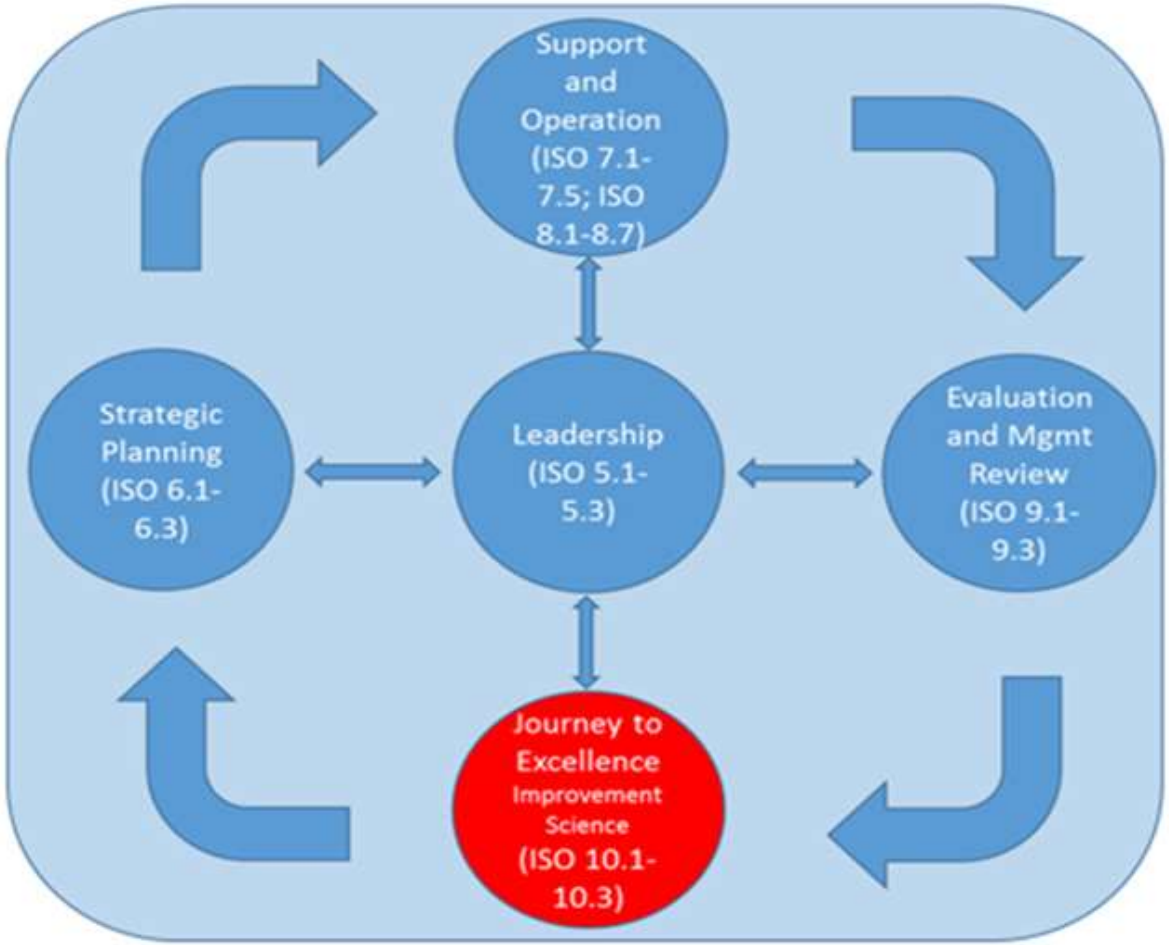

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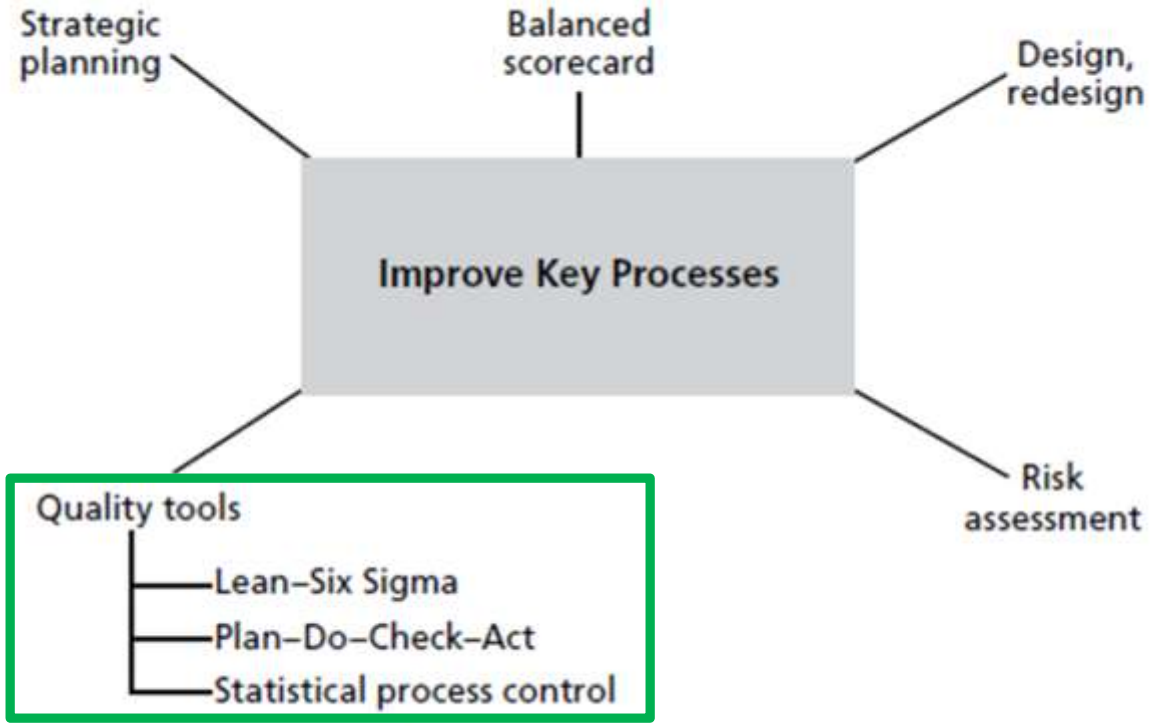
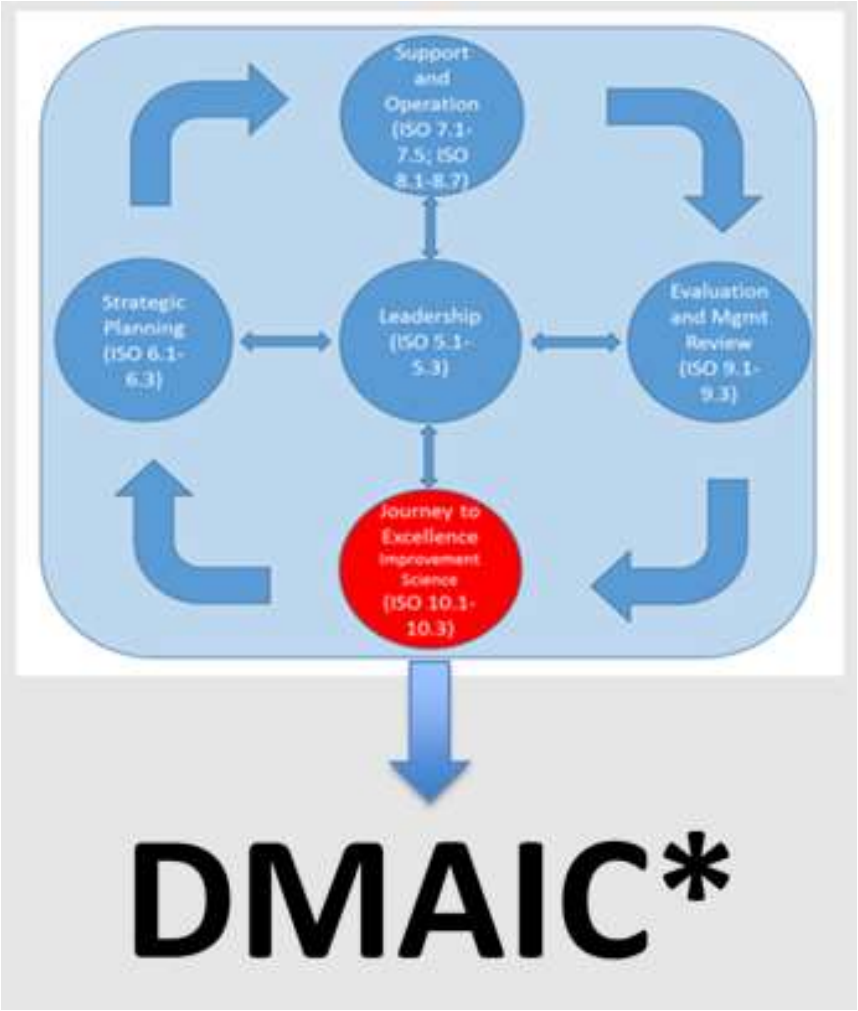




Reference: Levett, JM and Burney, RG. Using ISO 9001 in Healthcare: Applications for Quality Systems, Performance Improvement, Clinical Integration and Accreditation, 2011.

Identifying the Opportunity

Opportunities often occur in your daily work, found on leader rounds as well as through other collaborative methods. When you identify an opportunity, share it with unit/departmental leadership. Discuss the need for an improvement, and how it should be addressed.

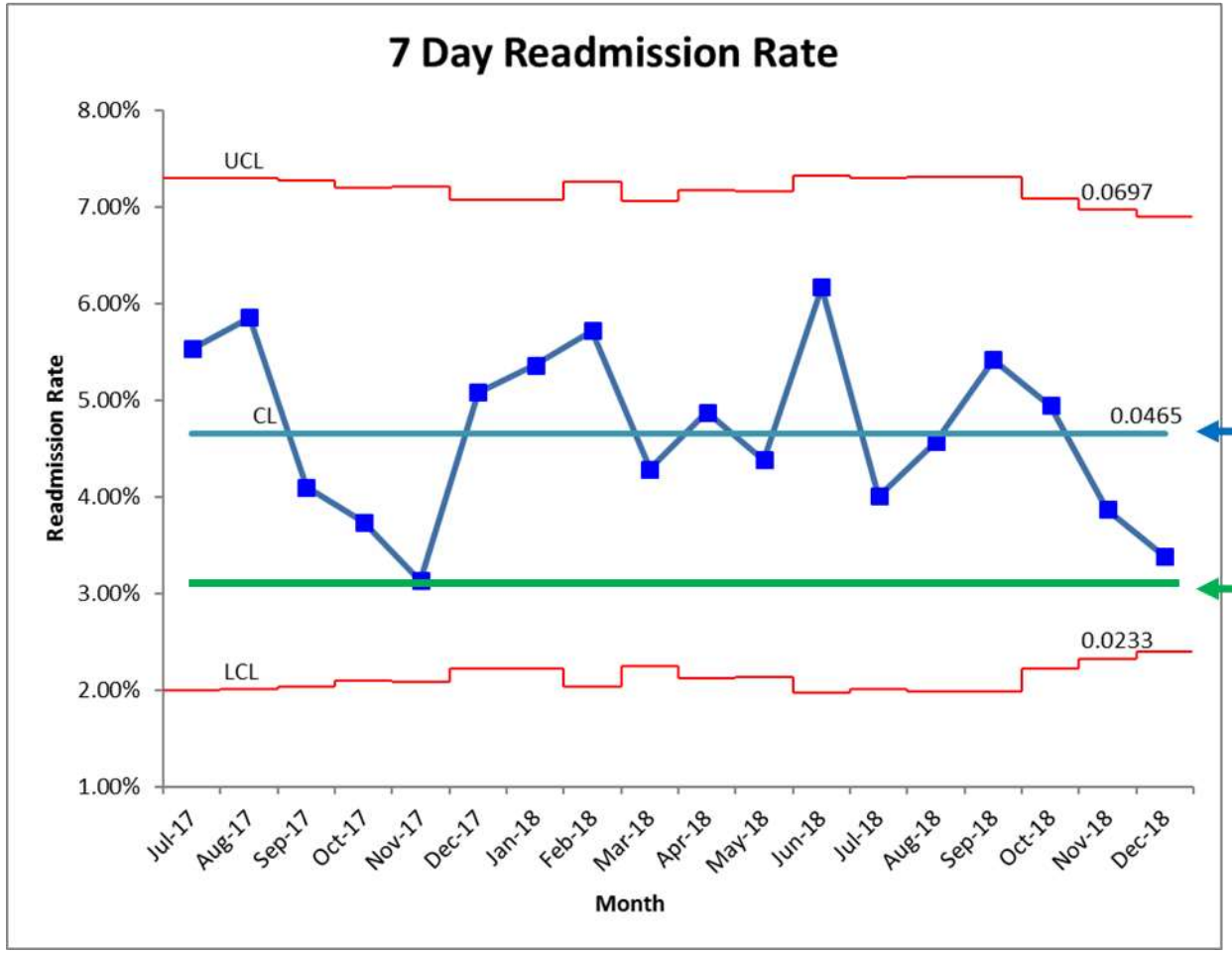
What are we trying to accomplish?

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.

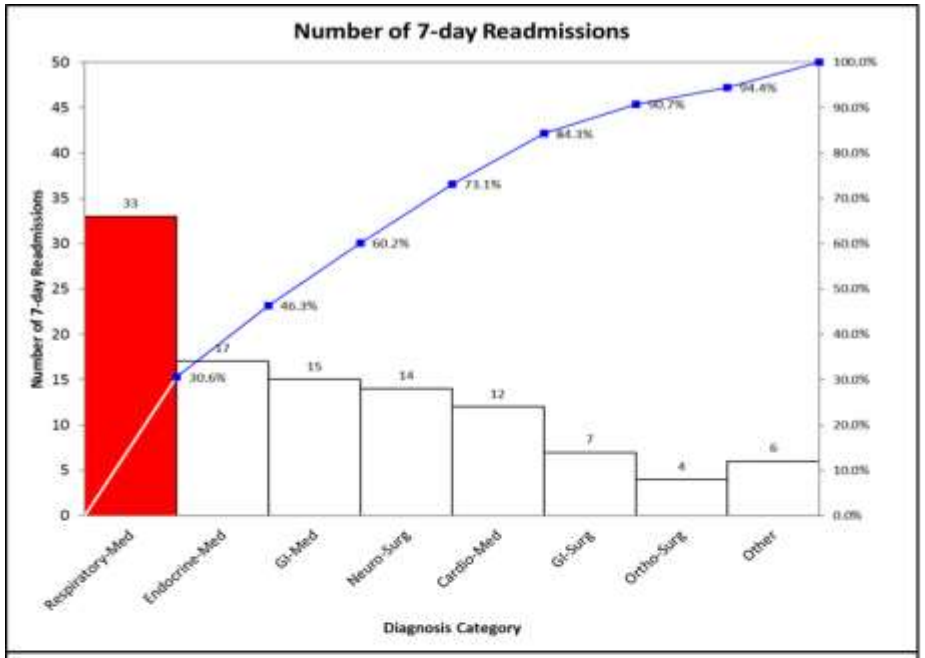
Understand the Opportunity

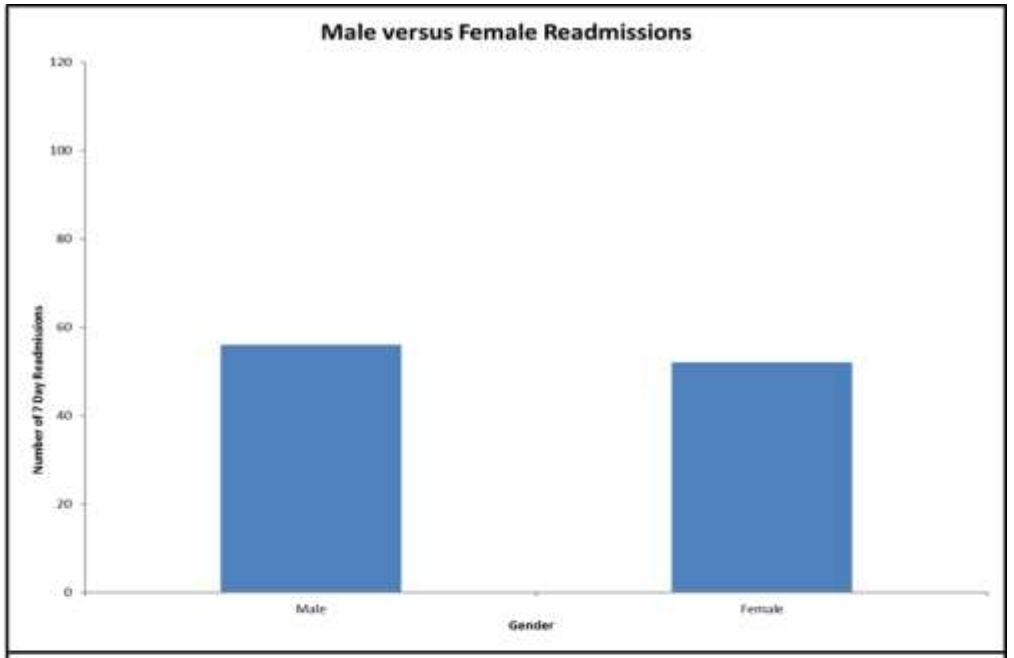
Review Available Data

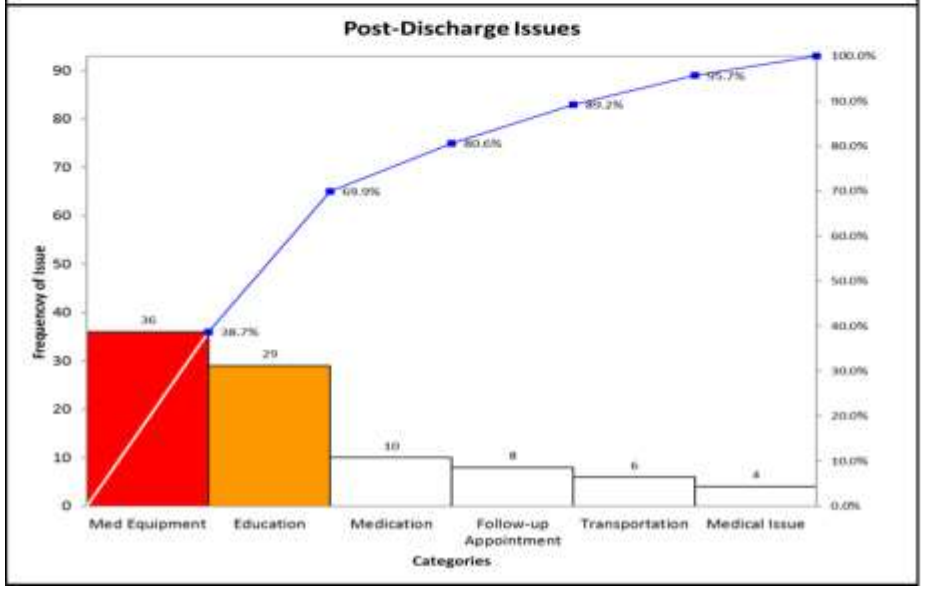


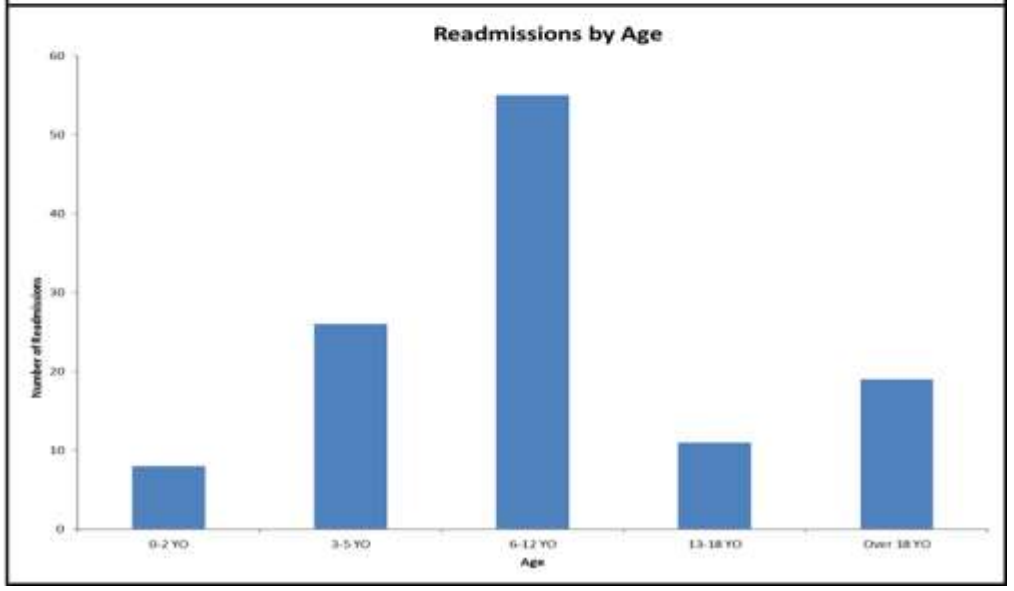
Our Average Performance

Other Pediatric Hospital Performance

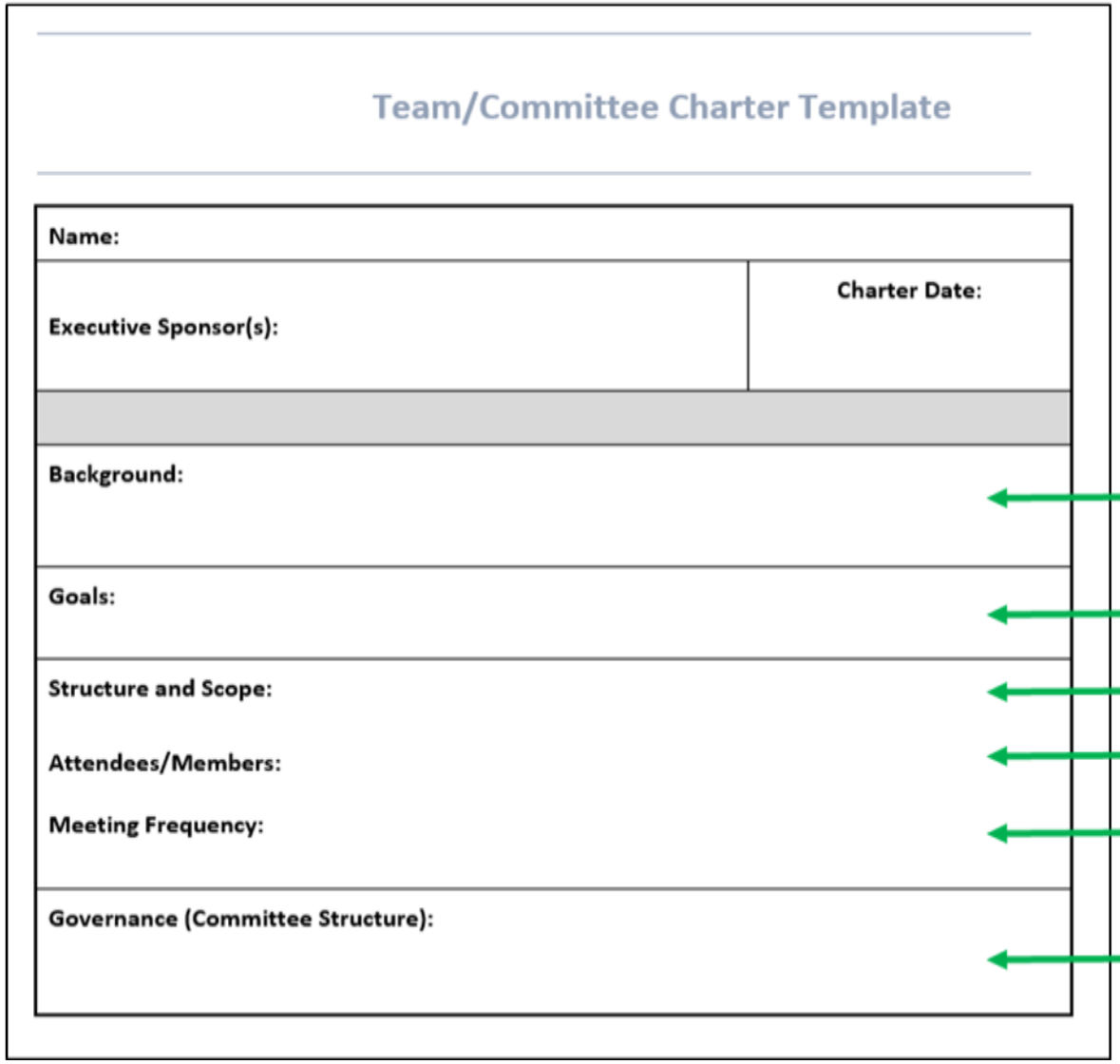

Number of 7-day Readmissions
Number of 7-day Readmissions
Diagnosis Category
Respiratory-Med
Endocrine-Med
GI-Med
Neuro-Surg
Cardio-Med
GI-Surg
Ortho-Surg
Other
33
17
15
14
12
7
4
6
30.6%
46.3%
60.2%
73.1%
84.3%
90.7%
94.4%


Male versus Female Readmissions
Number of 7 Day Readmissions
Gender
Male
Female


Post-Discharge Issues
Frequency of Issue
Categories
Med Equipment
Education
Medication
Follow-up Appointment
Transportation
Medical Issue
36
29
10
8
6
4
38.7%
69.9%
80.6%
89.2%
95.7%


Readmissions by Age
Number of Readmissions
Age
0-2 YO
3-5 YO
6-12 YO
13-18 YO
Over 18 YO

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

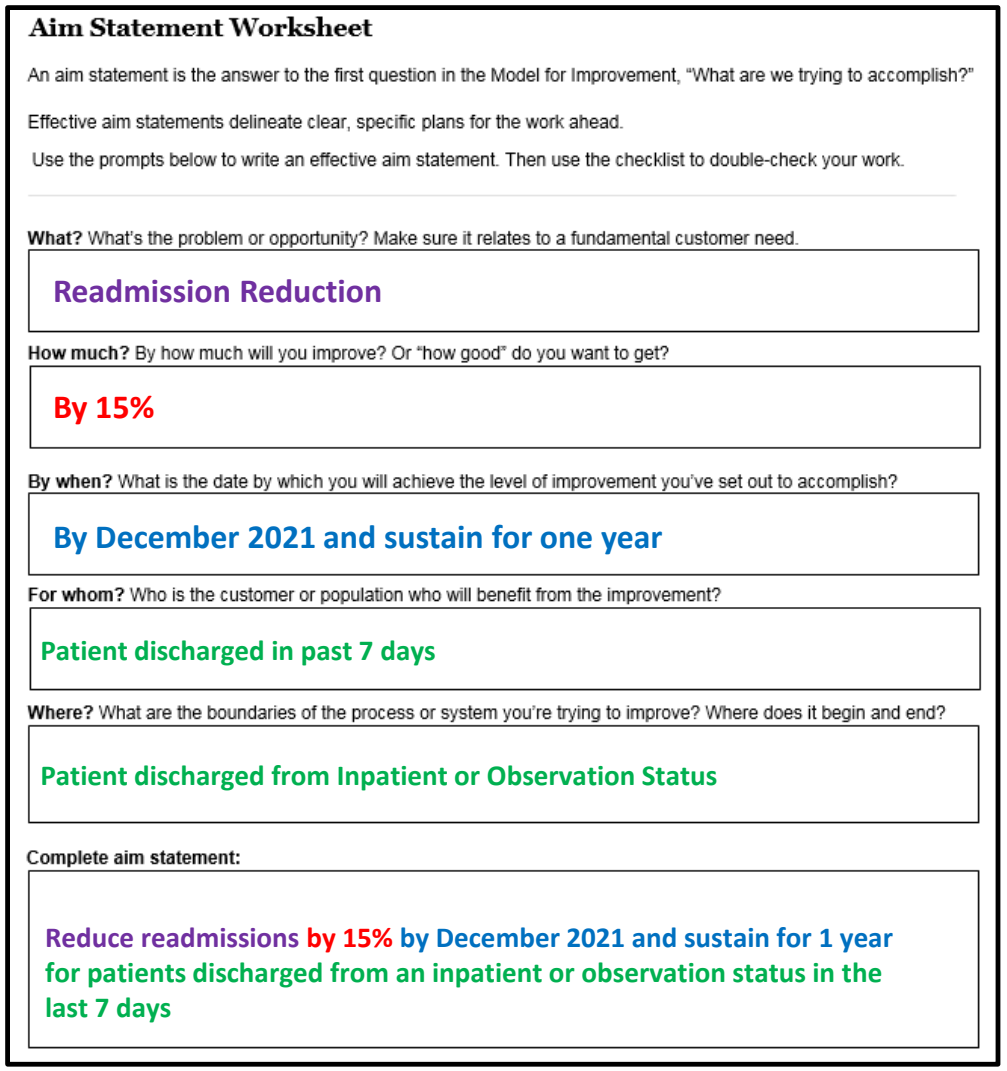
Who is on the improvement team?

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?

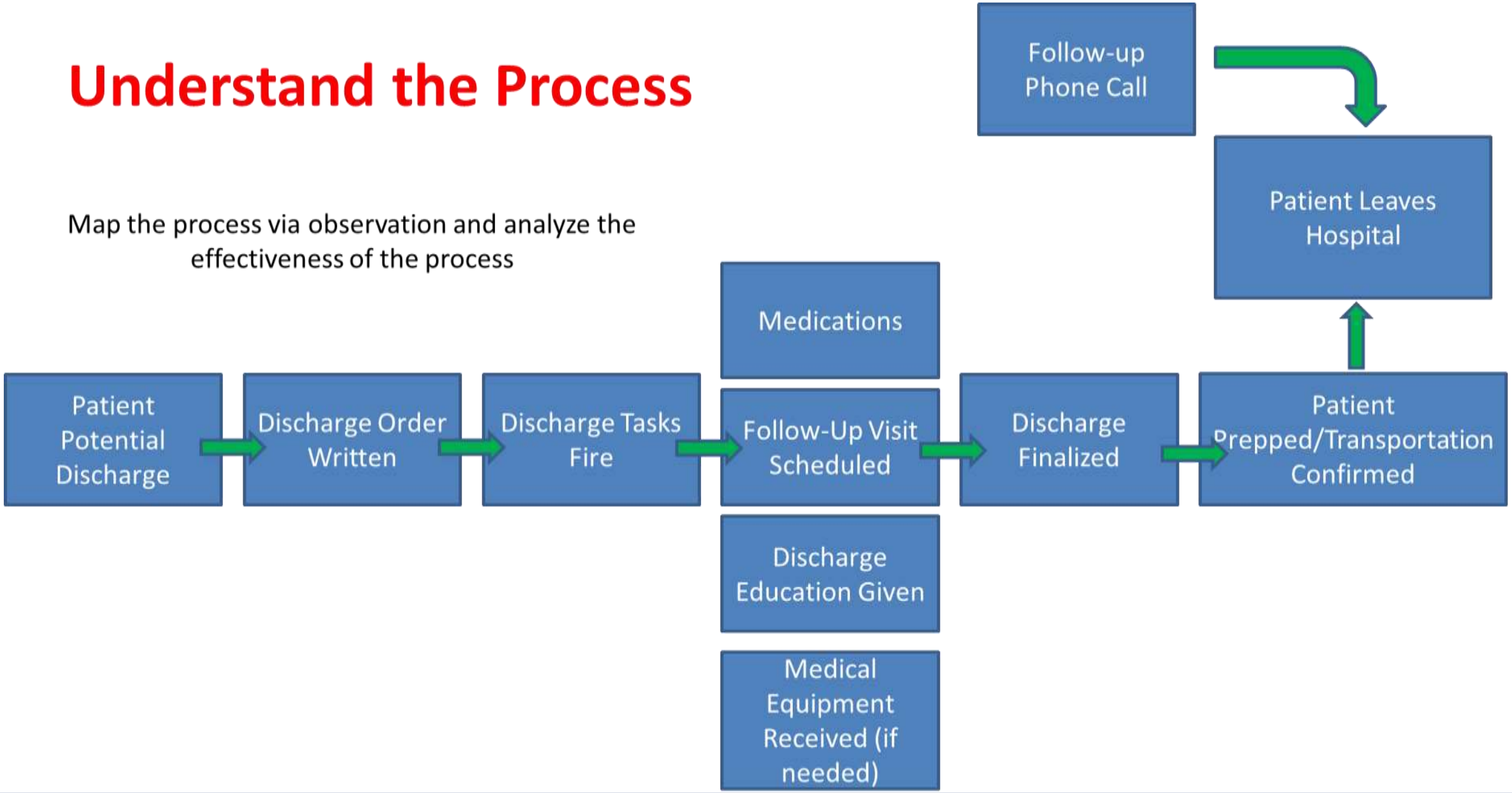
Patient discharged from Inpatient or Observation Status

Complete aim statement:

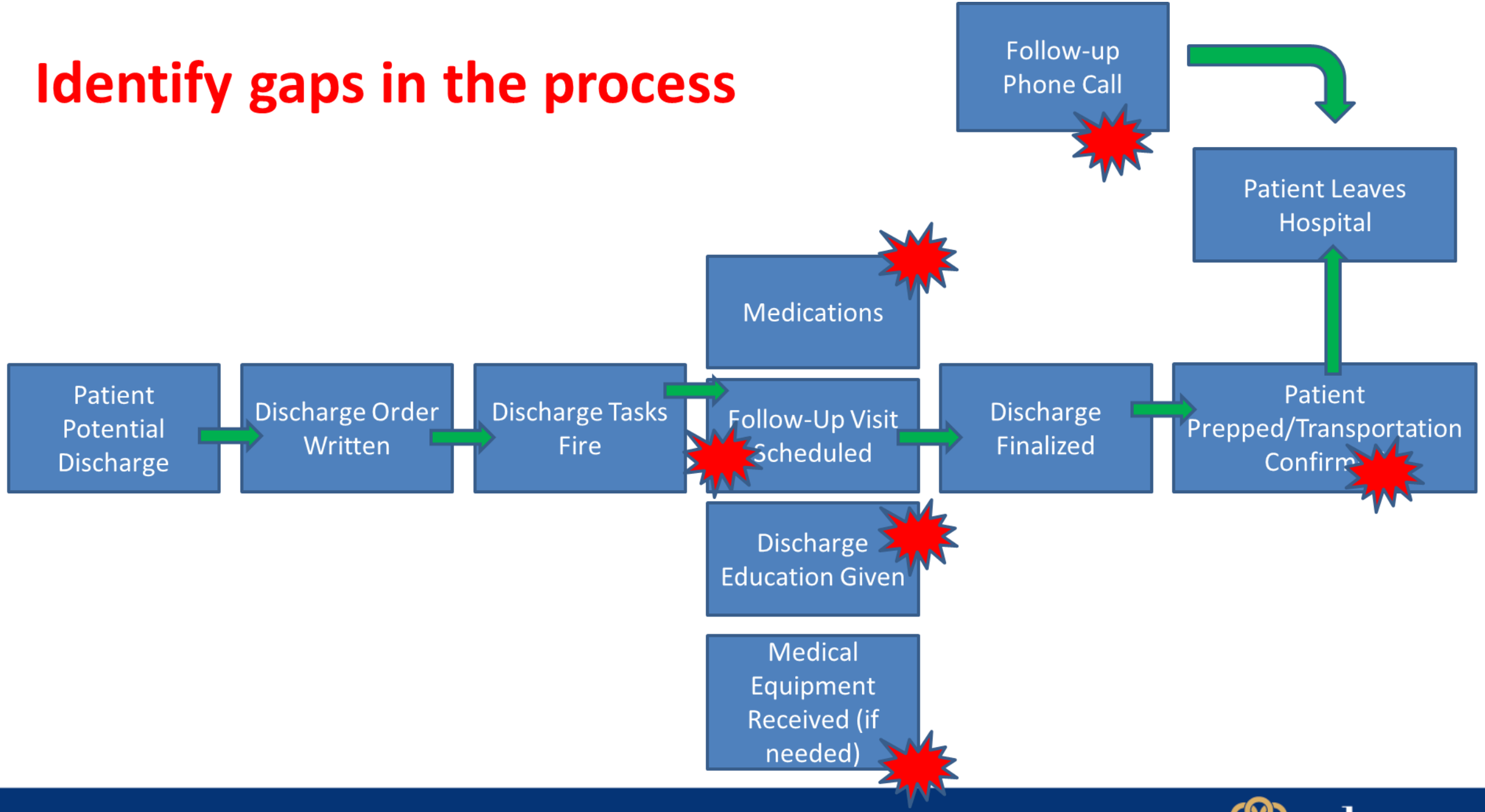
Reduce readmissions by 15% by December 2021 and sustain for 1 year for patients discharged from an inpatient or observation status in the last 7 days

Understand the Process

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



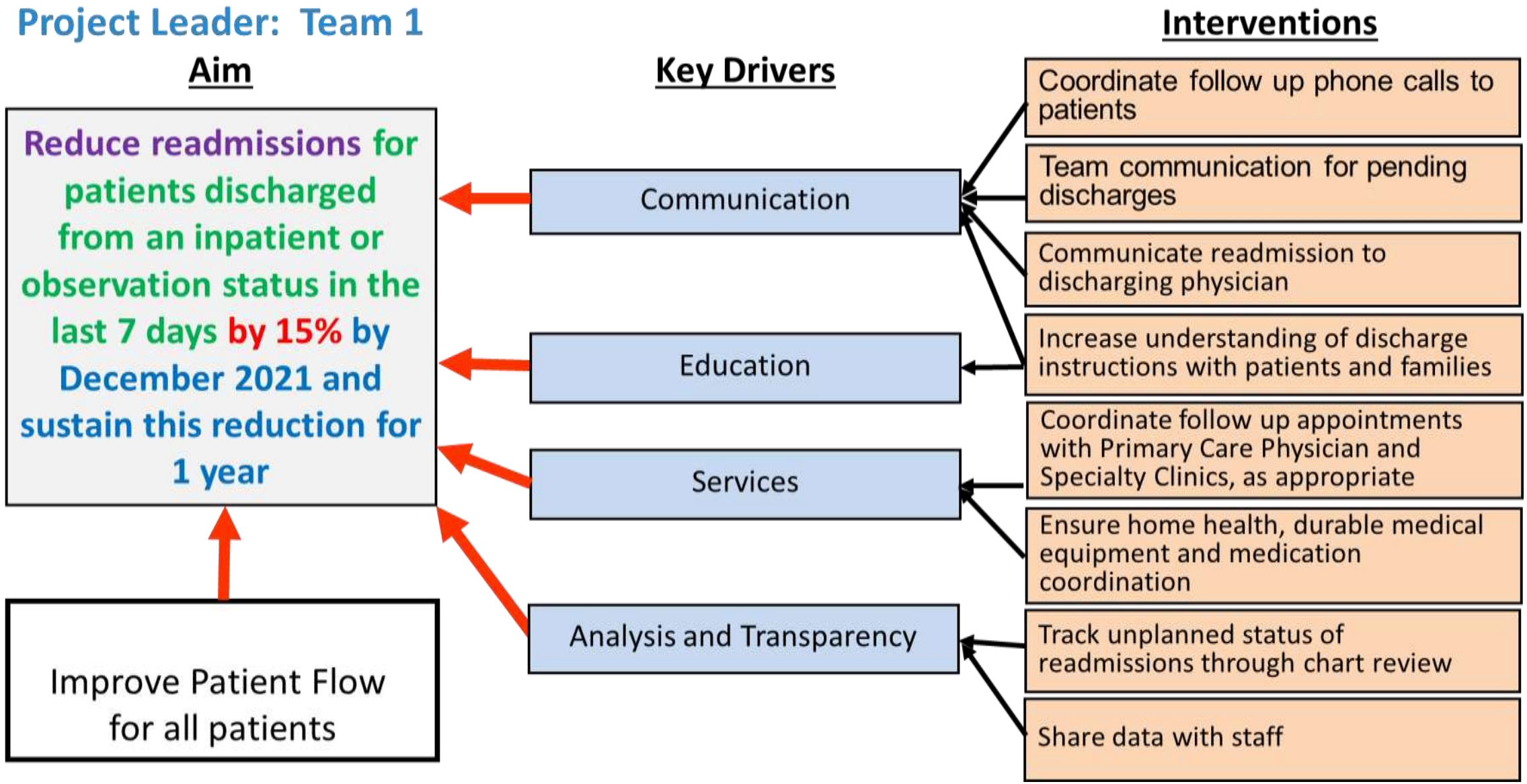
Identify gaps in the process



Project Title: Readmission Reduction

Project Leader: Team 1

Key Driver Diagram (KDD)

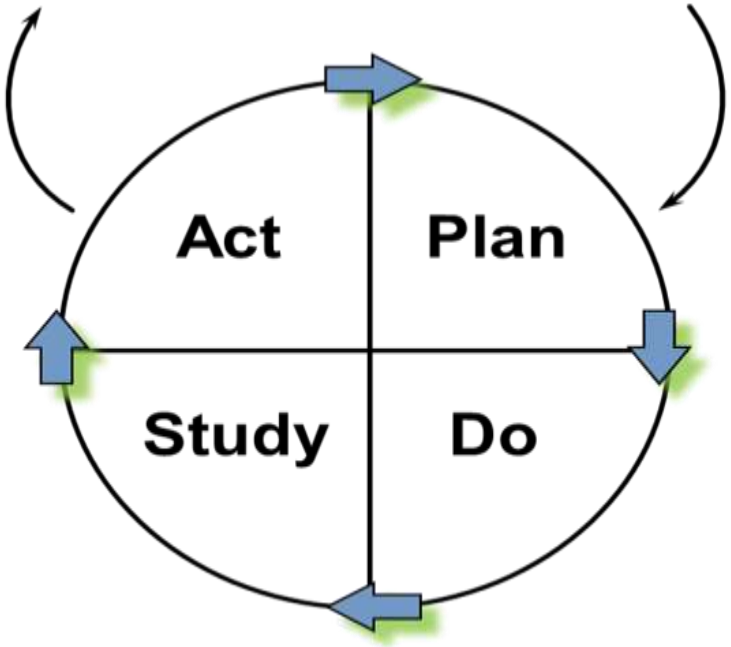


Model for Improvement

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):

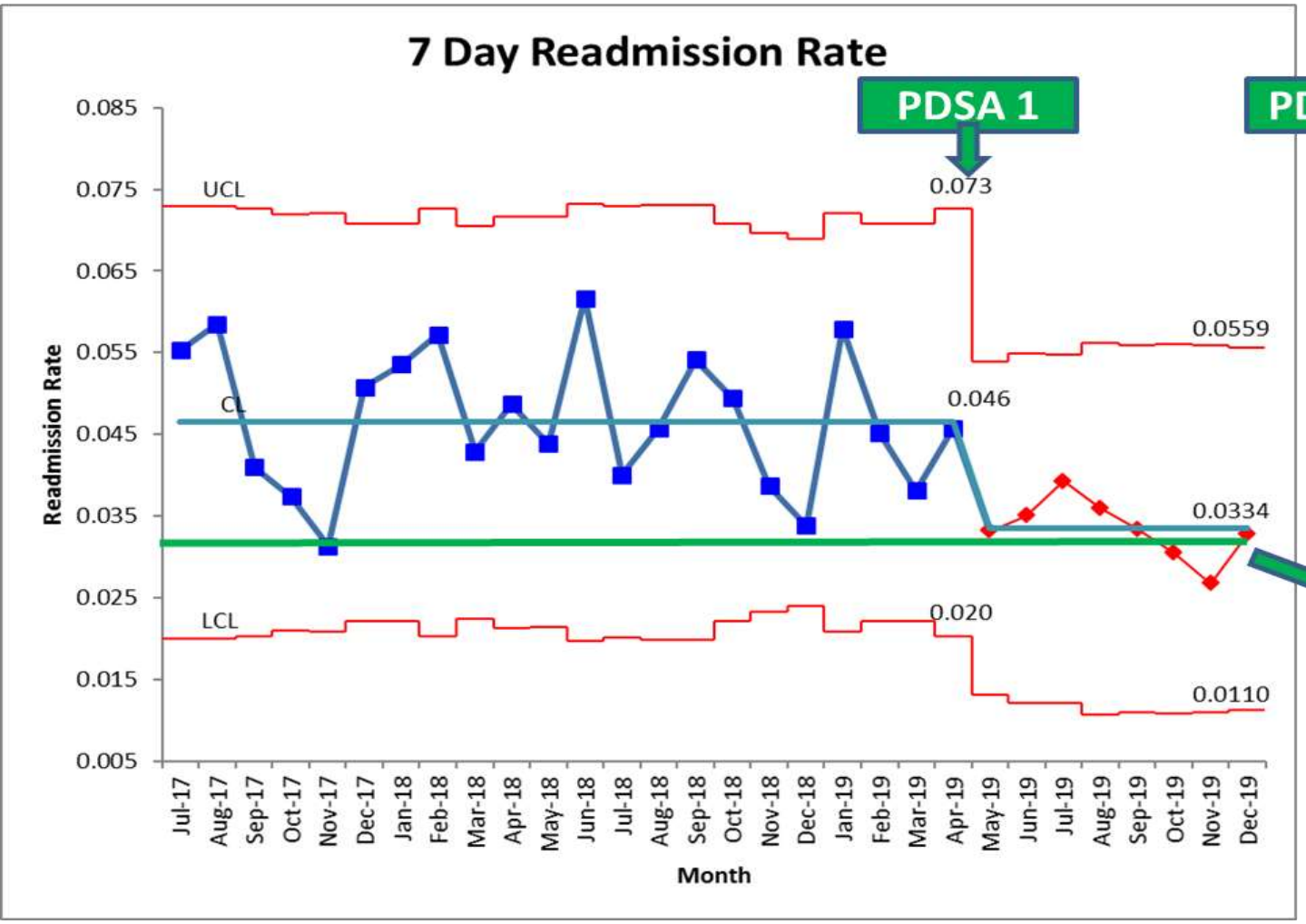
Do:
Carry out the change or test; Collect data and begin analysis.

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



Further Improvement

Institute for Healthcare 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

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Continuing education credits and certificates »

children's
Hospital at Erlanger

"Never"

HARM

Common

PERFECT: Process prevents defects ("pokayoke")

"WORLD CLASS" MANAGEMENT SYSTEM

- Process focus engrained in system culture
- Data and personnel systems aligned at "zero harm"
- Impact demonstrated in organizational bottom line; budgets reflect commitment to continuous improvement

PREVENT: Inspection before shipping; defect detection at source

"SAFETY CONTINUUM"

- Event tracking reaches external stakeholders
- Shared commitment to harm reduction emerges
- Process focus emerges
- Trust and QI partnerships develop in pockets across continuum; local ROI may develop
- Metrics reflect process performance (Leading Metrics)

PROTECT: Inspection before delivery; "near misses"

"LOCAL SAFETY CULTURE"

- "Hero" ethic is reinforced
- Local vigilance is primary barrier to harm
- Limited connection to defect source; blame still common
- Metrics reflect local reporting/tracking of events (Lagging Metrics)

LAMENT: Harm is "expected"/not always recognized


Thank
you