

A photograph of a space shuttle in orbit above the Earth's surface. The shuttle is on the left, and the Earth's blue and white clouds are visible below. The text is overlaid on the image.

**Patient Safety:  
Challenges and Ways to  
Overcome Them with a  
Systems-Based Approach**

**It's Not Rocket Science**

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# Objectives

- Define Goal
- Identify Challenges
- Discuss Tools and Approaches to Achieve Goals to Evolve into a High Reliability Organization
  - Examples
- Identify the Role that Leaders at All Levels Must Play to Make a Culture of Safety Integral to the Fabric of the Organization



# Program Elements

- Goal – Prevent Inadvertent Harm To Patient While Under Our Care



## VIEWPOINT

# Crossing the Global Health Care Quality Chasm

## A Key Component of Universal Health Coverage

**Donald Berwick, MD**  
Institute for Healthcare  
Improvement (IHI),  
Editorial Affairs,  
Boston, Massachusetts.

**Megan Snair, MPH**  
Center for Populations  
Health Research,  
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**Sania Nishtar, PhD,  
FRCP**  
Heartfile, Islamabad,  
Pakistan.

**Despite years of investment** and research, the quality of health care in every country is much worse than it should be. Problems range from disrespect of people when they are interacting with the health care system, to preventable mistakes and harm, to high rates of incorrect and ineffective treatment.

Among low- and middle-income countries (LMICs) the exact burden of poor quality is difficult to quantify because of a dearth of data, lack of standard metrics, and insufficient research on quality interventions. But new estimates suggest that globally between 5.7 and 8.4 million people die every year from poor-quality care in LMICs.<sup>1</sup> These deaths, plus disabilities from poor-quality care, account for lost productivity totaling an estimated \$1.4 trillion to \$1.6 trillion dollars annually.<sup>1</sup>

Wealthier countries have similar experiences in terms of death, disability, and needless cost due to fragmented care, waste, and care organized around facilities instead of patients. One estimate suggests that 15% of all hospital costs in Organisation for Economic Co-operation and Development (OECD) countries can be attributed to patient harms from adverse events.<sup>2</sup>

In 2001, the Institute of Medicine published a landmark report on the quality of US health care: *Crossing the Quality Chasm: A New Health System for the 21st Century*. The report starkly documented major defects in 6 dimensions of quality: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. In the

fundamental principles of design and human factors. The route to improvement places the “user”—patient, individual, community—at the center. This report recommends design principles that include full transparency; co-design with users, staff, and communities; care that is anticipatory, not merely reactive; care reflective of societal values; and care that bases decisions on clear evidence, continuous feedback, and learning (Box).

Redesign like this is evident, for example, in Kenya's Clinical Information Network, which was developed in 2013 as a mechanism to promote continuing improvement. Their leaders understand that health care is a complex adaptive system that requires multidisciplinary work, soft skills, and flexibility for ongoing change.<sup>5</sup>

The NASEM report's idealized system empowers health care workers to solve problems at the front lines of care and integrates and coordinates care across the patient's “journey.” Adherence to these principles supports a “learning health care system”—one that learns from both successes and failures and encourages innovation. This culture of continuous learning demands strong leadership, commitment, cooperation, and feedback to continually update policies, protocols, and systems.

### Leveraging Universal Health Coverage

The path to achieving effective universal health coverage will be different for every country, but existing levers can be used in almost any setting to ensure and improve



# Where Healthcare Was/Is

- Cottage Industry Mentality
- Virtually Total Reliance on:
  - Professional/Individual Responsibility
  - Individual Perfection
  - Train and Blame
- Little Understanding of Systems Relative to People and Processes
  - Ignorance vs Arrogance

**Culturally Different!!!!**



# Typical Approach

- New Policies, Regulations, Reporting Systems, Training
- Good First Step But.....
  - Lack of Systems Insight
  - Superficial Solutions (?Answers)
  - Inadequate Follow-Up
  - Lost Opportunity



# Program Elements

- Goal – Prevent Inadvertent Harm To Patient While Under Our Care
- Culture Not Compliance
- Identify Barriers
- Reporting Systems



# Patient Safety System Design

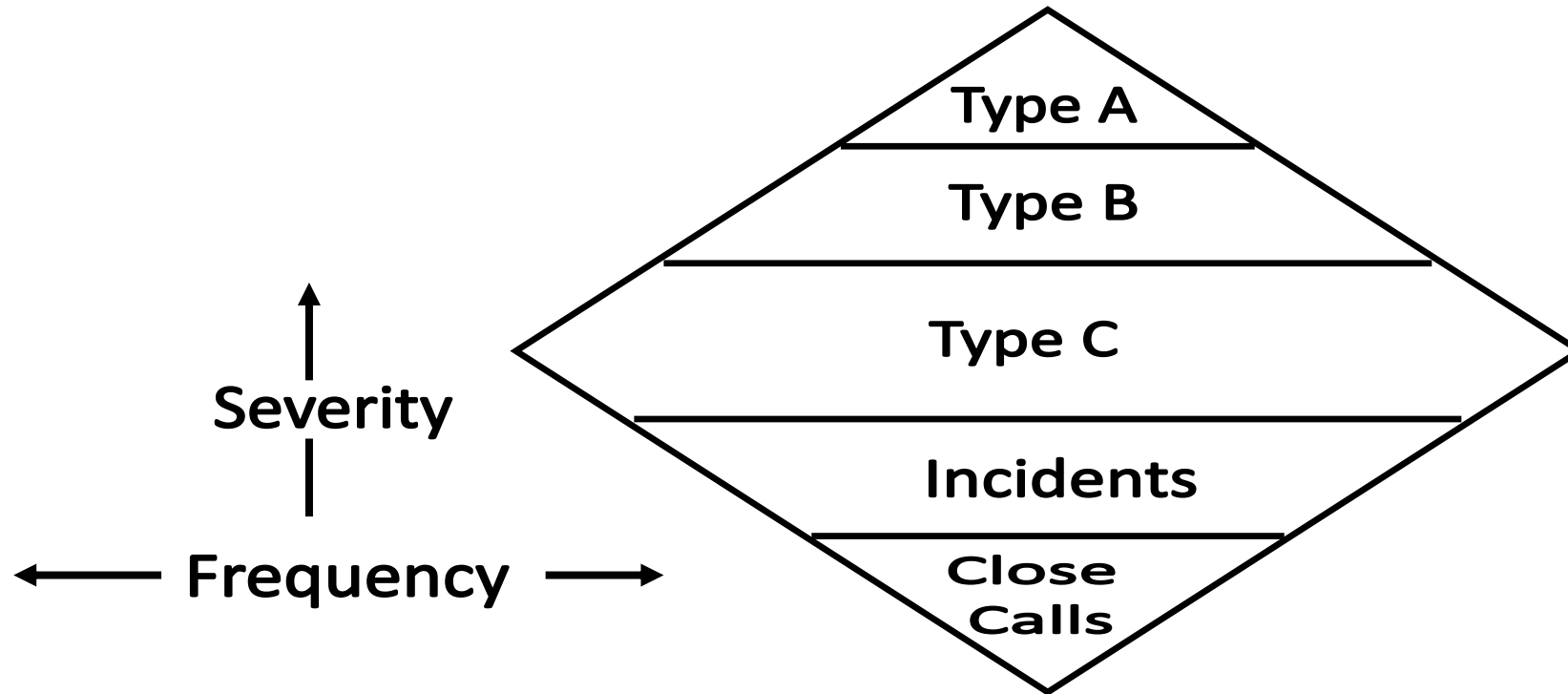
- High Reliability Organizations
- Role of Reporting
  - Learning, **NOT** Accountability
- Systems-Based Solutions
  - Patient Centered – DUH!!!!
- Importance of Close Calls





# Patient Safety System Design

## THE "MISHAP DIAMOND"

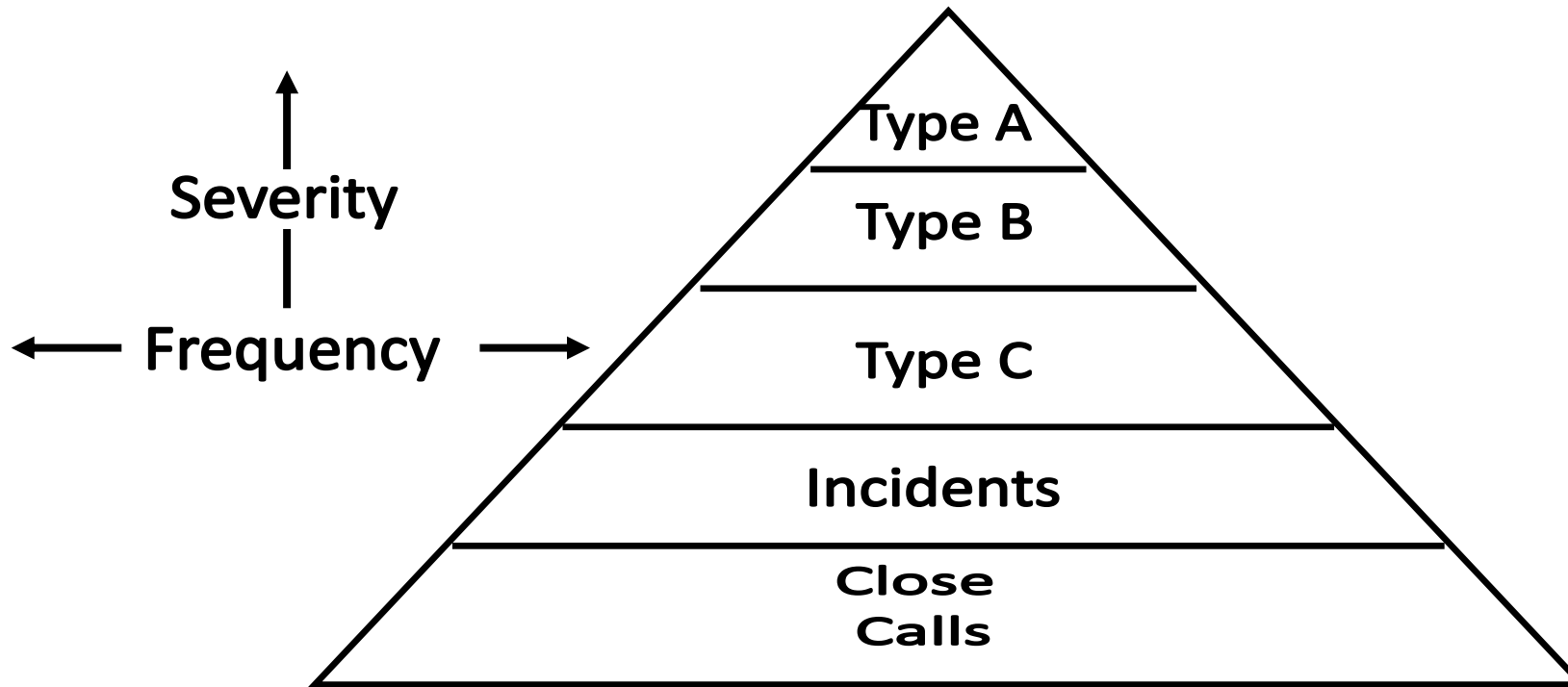


Weak Program Model



# Patient Safety System Design

## THE "MISHAP PYRAMID"



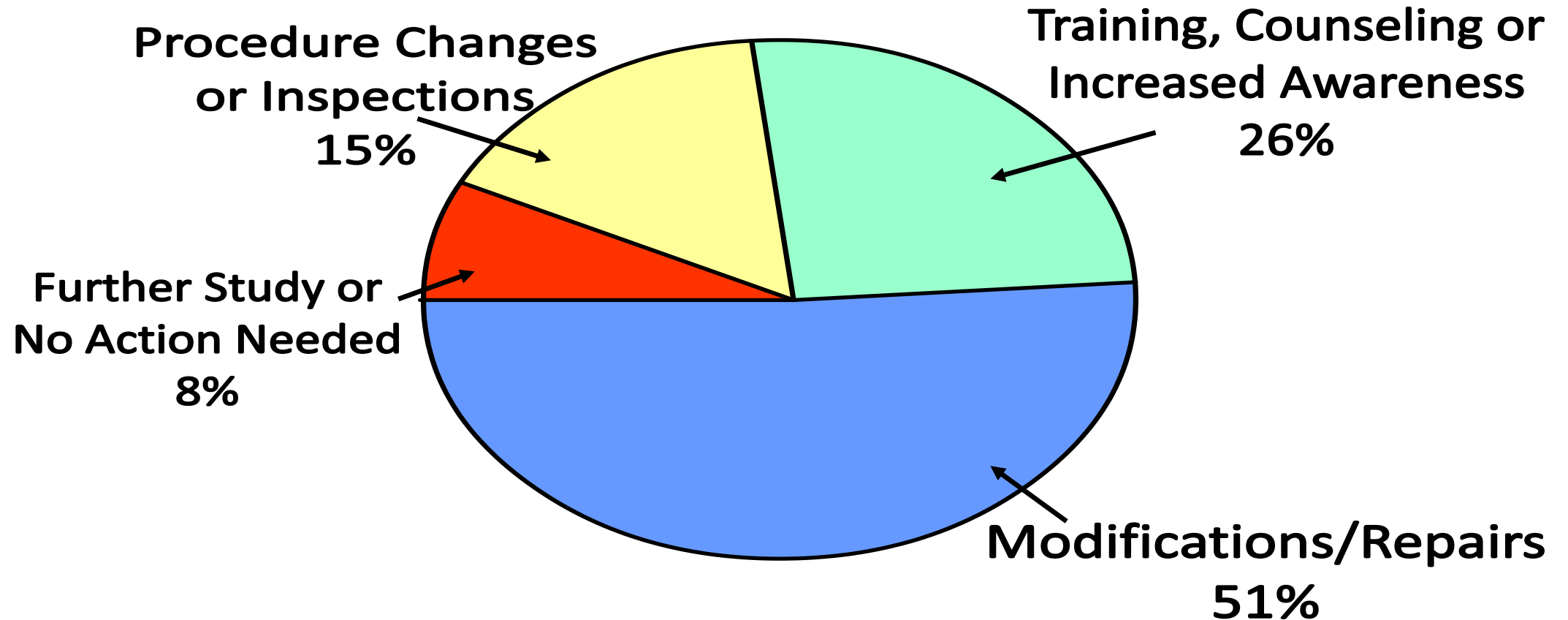
Strong Program Model



# Patient Safety System Design

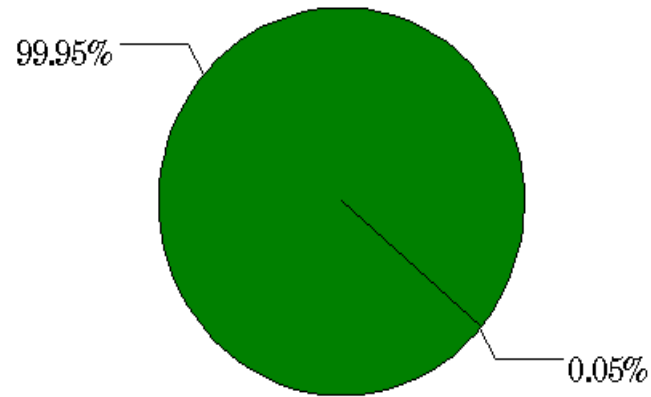
## NASA Experience

### Corrective Actions from Close Call Reports

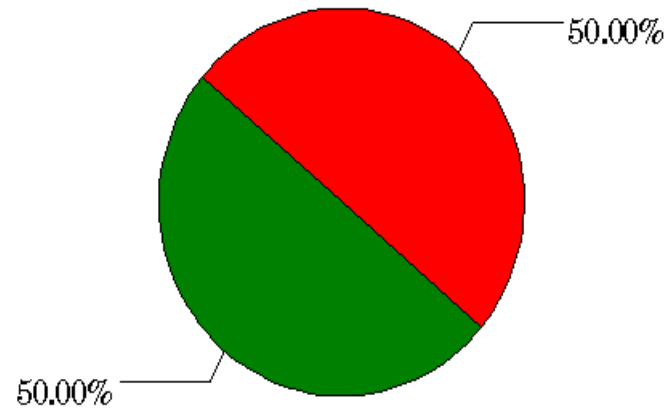




# Root Cause Analysis Reports

RCA Reports 1998 through 1999



RCA Reports 2000 through 2006



-  RCA Close Calls
-  RCA Actual Events



# Program Elements

- Goal – Prevent Inadvertent Harm To Patient While Under Our Care
- Culture Not Compliance
- Identify Barriers
- Reporting Systems
  - Learning, Not Accountability
  - Identify Vulnerabilities, Not for Counting
  - *Transparency, Meaningful Feedback, Resulting Actions*
- Systems-Based Solutions



# Safety & Human Error: Challenges

- Healthcare Views Errors as Failings Which Deserve Blame - Fault
- Train and Blame Mentality vs Systems-Based
- Blind Adherence To Rules
- Corrective Actions Focusing on Individual
- No Blood No Foul Philosophy

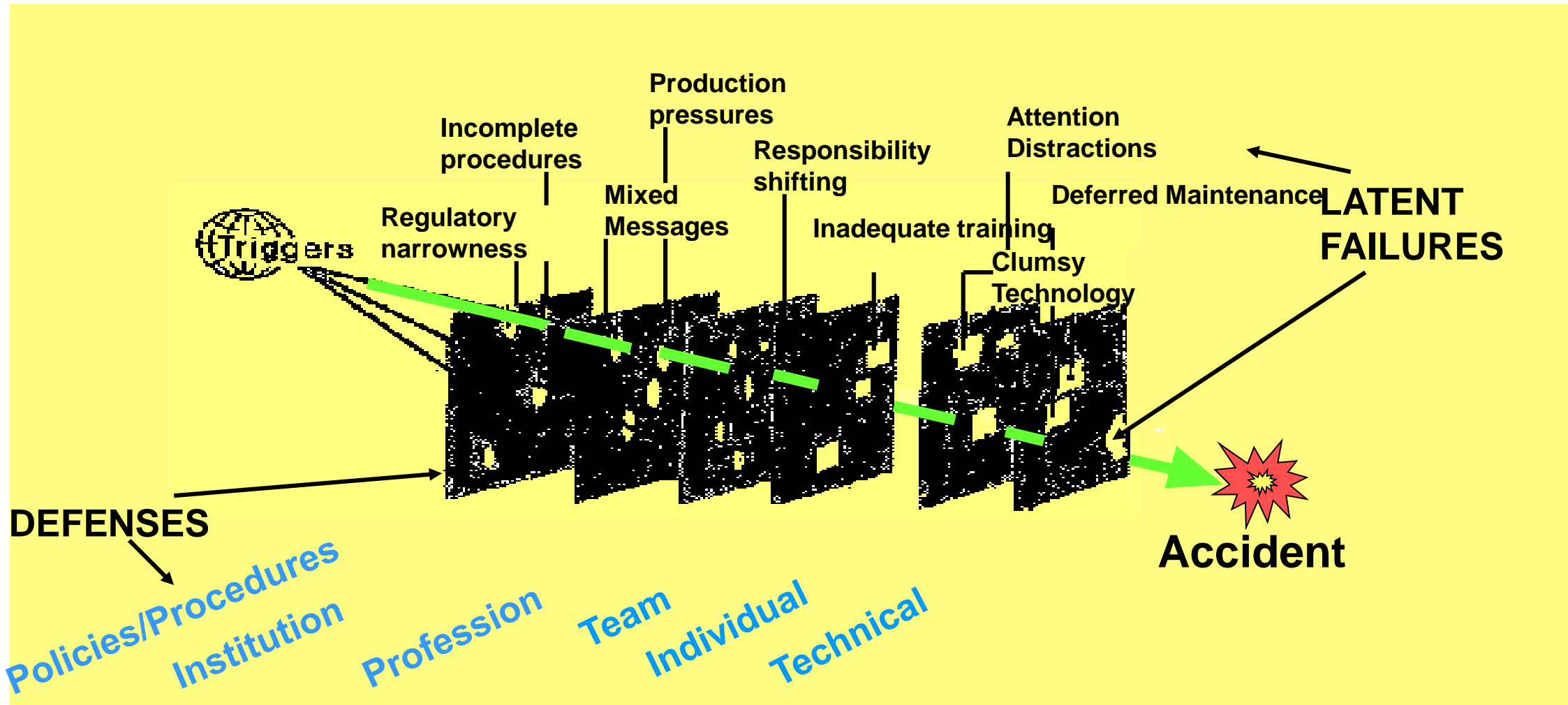


# Safety & Human Error: Cornerstones

- People Don't Come to Work to Hurt Someone or Make a Mistake
- Must Keep Asking "Why?"



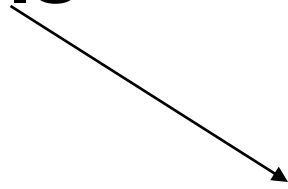
# Safety – Human Error



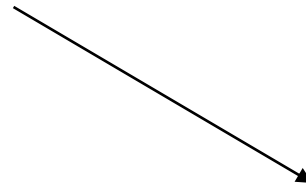


# Changing Culture

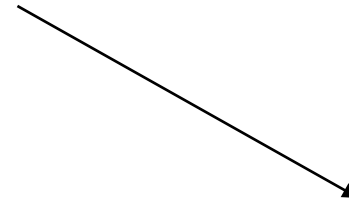
**Tools**



**Behavior**



**Attitude**



**CULTURE!!!**



# Causation/Actions: Who vs. What & Why

- Who
  - ‘Whose Fault Is This?’
  - Actions focused on correcting individual
  - ‘Corrects’ only after problem occurs
  - Limited scope of action and generalizability
- What & Why
  - Actions focus on systems level causation
  - Widespread applicability
  - Stronger preventive strategy



# Systematic (5 Rules of Causation)

- Cause and Effect
- *Human Error **Must** Have Preceding Cause*
- *Failure to Follow Procedure By Itself Is **NOT** a Root Cause*
- Negative Descriptors Aren't Actionable
- Failure To Act Is **Not** A Cause Without Pre-existing Requirement To Act


**Why, Why, Why, Why, Why, Why.....**



# Human Factors Engineering and “Actions”

- **Warnings and labels** (watch out!)
- **Training** (don't do that)
- **Procedure changes** (work around that)
- **Interlock, lock-in, lock-out, etc** (design it so you cannot do that – forcing functions)
- **Is there one right action???**

**Weaker**



**Stronger**



# Action Hierarchy

*Less memory or  
reliance on individual  
performance*



*Greater reliance on  
memory and  
individual  
performance*

<b>Stronger Actions</b>	<ul style="list-style-type: none"><li>Architectural/physical plant changes</li><li>New devices with usability testing before purchasing</li><li>Engineering control or interlock (forcing functions)</li><li>Simplify the process and remove unnecessary steps</li><li>Standardize on equipment or process</li><li>Tangible involvement and action by leadership in support of patient safety</li></ul>
<b>Intermediate Actions</b>	<ul style="list-style-type: none"><li>Redundancy</li><li>Increase in staffing/decrease in workload</li><li>Software enhancements/modifications</li><li>Education using simulation-based learning with a competency assessment completed on a recurring basis</li><li>Eliminate/reduce distractions (sterile medical environment)</li><li>Checklist/cognitive aid</li><li>Eliminate look and sound-alikes</li><li>Repeat-back/Read-back</li><li>Enhanced documentation/communication</li></ul>
<b>Weaker Actions</b>	<ul style="list-style-type: none"><li>Double checks</li><li>Warnings and labels</li><li>New procedure/memorandum/policy</li><li>Traditional training</li><li>Additional study/analysis</li></ul>

# Action Assessment

- Characteristics of Actions
  - Temporary vs. Permanent
  - Procedural vs. Physical
- Action Evaluation
  - Process
  - Outcome



Cause/Contributing Factor (CCF) Statement #1:	<i>The lack of a ferromagnetic detection system at the entrance into the MR magnet room increased the likelihood that the patient's oxygen cylinder would be permitted in the room resulting in the cylinder being drawn into the bore of the magnet, the magnet being quenched, and the MR room being out of service for 5 days.</i>
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Action 1	<i>Install a ferromagnetic detection system at the entrance to all four MRI magnet rooms.</i>
Action Due Date	April 30, 2015
Date Action Completed	Pending
Responsible Person:	Ms. B, Facility Engineer

Process/Outcome Measure 1 (Each Process/Outcome Measure needs to include: what will be measured; how long it will be measured; and the expected level of compliance.)	<i>Five ferrous objects including an oxygen cylinder will be passed by the ferromagnetic sensors of each detector and 100% will result in alarms sounding in the adjacent MR Control Room.</i>
Date To Be Measured:	May 10, 2015
Responsible Person:	Dr. A, MRI Safety Officer
Was the Compliance Level Met?	To be determined

Management concurs with this Action and Process/Outcome Measure	Yes
If No, why not? (Answered by Management)	
Is the identification of another action required?	To be determined

**Trust Everyone  
But Always Cut the Cards**

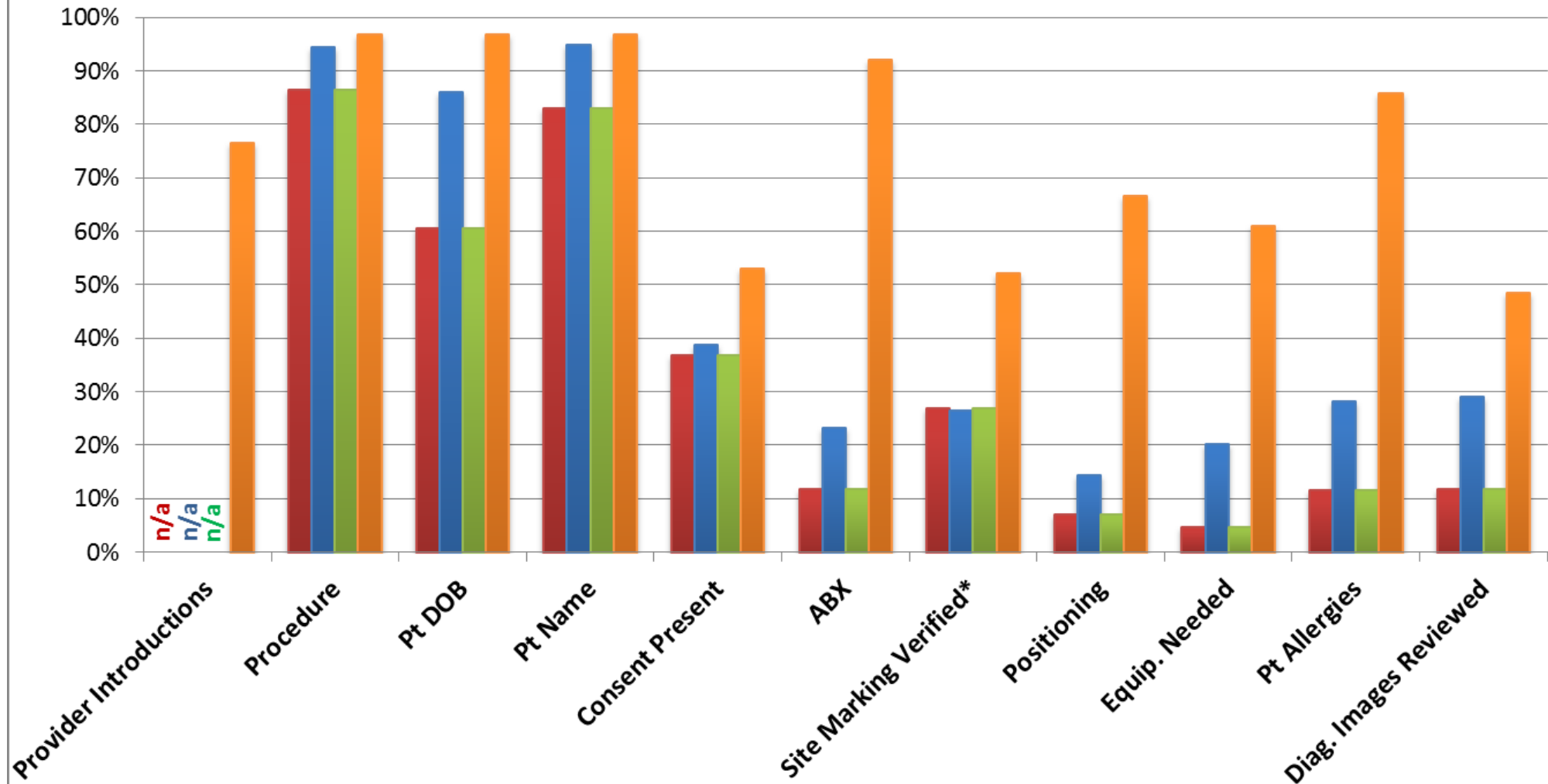




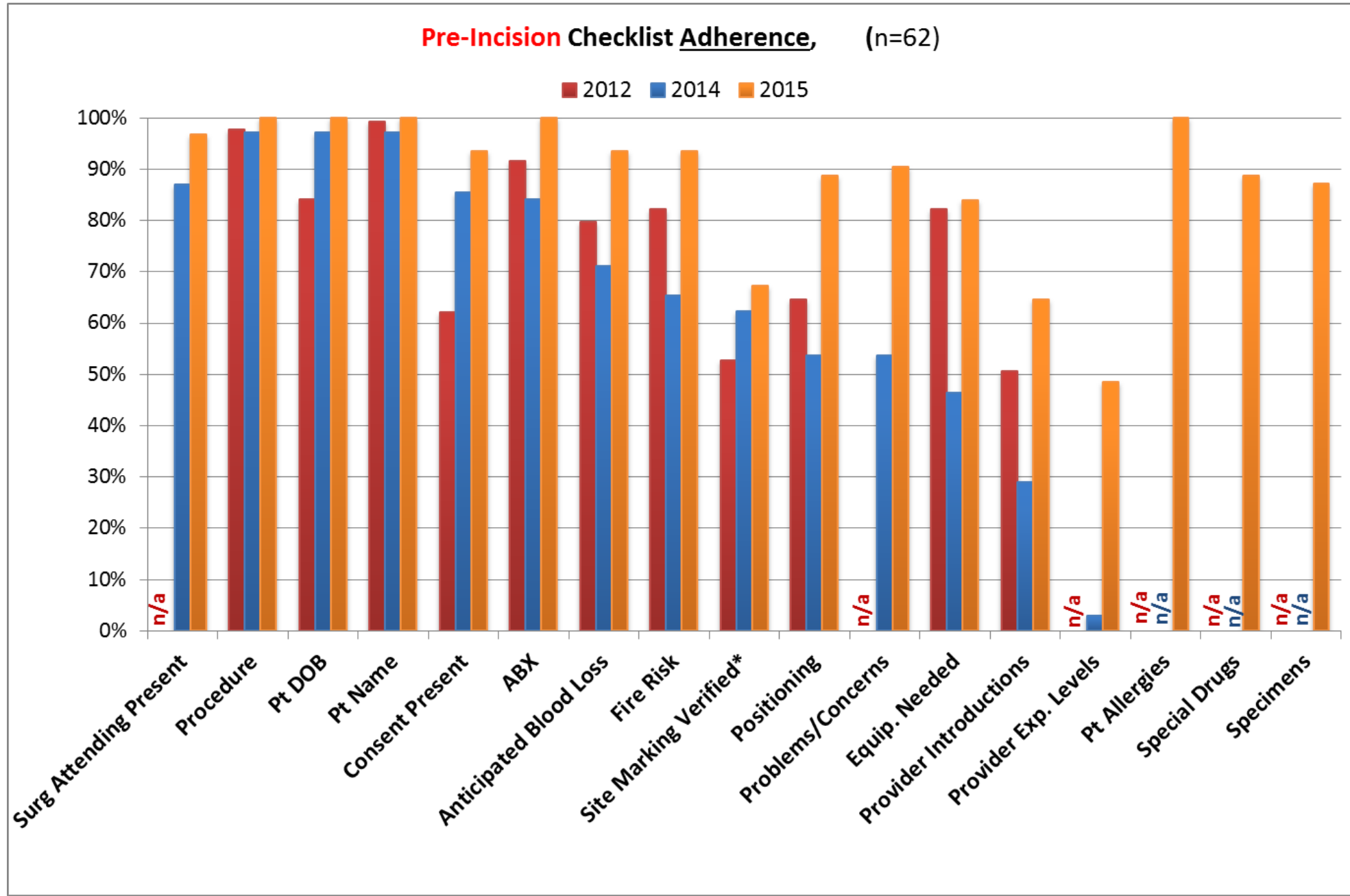
# Pre-induction

Pre-Induction Checklist Adherence, (n=64)

2011 2012 2014 2015



# Pre-incision



# RCA<sup>2</sup>

Improving Root Cause  
Analyses and Actions  
to Prevent Harm



# Endorsing Organizations



Children's Health Queensland



AAMIFOUNDATION



A conversation can change an outcome.  
A conversation can change a life.™



Risk Management Foundation  
of the Harvard Medical Institutions, Inc.



# Is There A Business Case?

- **YOU BET!!!**
- **Examples:**
  - “Easy CAP” CO<sub>2</sub> Detector
    - \$125/detected esophageal intubation
  - Ventilator Humidification System
    - \$114k/facility/yr and reduced risk
- RCA/45person-hrs X 12RCA/yr =

**0.25FTEE**



# Leadership - What Can Be Done Right Now?

- ***Lead by Example***
- Relentless Drumbeat
- Eliminate ‘Whose fault is it?’
- Encourage Skepticism
  - Devil’s Advocate is Valued
- Distinguish **Real** Priorities From Official Priorities
- Part of Every Agenda
- ***What Happened?, What Should Have Happened?, What Usually Happens?***



# Leadership - Key Points

- Transparent Risk-Based Prioritization Methodology
- Non-Punitive Approach – Blameworthy Definition
- Emphasize Systems-Based Solutions
  - Determination of Real Underlying Causes
  - Seek Out Stronger Solutions
- Emphasize Formal Scrutiny of Close-Calls
- Verify that work as imagined is the same as the work as actually performed – Robust QA Processes
- ***Interventions Must Go Farther Than Simply Training and Policy***



# Closing Thoughts

- It's Everyone's Job
- Not About Errors!!!
- Counting reports **is not** the objective, identifying Vulnerabilities **is**
  - Hope they increase
  - **Analysis, Action, & Feedback are the key**
- Prevention NOT Punishment
- Cultural change is the key
- ***Safety is the Foundation Upon which Quality is Built***







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