

**The AAMI Foundation's National Coalition to
Promote the Safe Use of Complex Healthcare
Technology
Presents:**

Fail Safe Use of Complex Medical Devices

**Patricia Hercules, BSN, MS, RN-BC
Director, System Clinical Programs**

**Teresa Ryan, RN, BSN, CPHRM
Manager, Risk Mgmt, MH Southeast Hospital**

**M. Michael Shabot, MD, FACS, FCCM, FACMI
Executive Vice President, System Chief Clinical Officer**

AAMI FOUNDATION

AAMI Foundation

Mission

The AAMI Foundation drives reductions in preventable patient harm and improvements in outcomes associated with the use of health technology.

- *National Coalition for Alarm Management Safety*
- *National Coalition for Infusion Therapy Safety*
- *National Coalition to Promote Continuous Monitoring of Patients on Opioids*
- *National Coalition to Promote the Safe Use of Complex Healthcare Technology*

AAMI FOUNDATION

A Special Thanks



AAMI FOUNDATION

Thank You to Our Industry Partners!

DIAMOND



human connections



Medtronic

Further, Together

Platinum




Gold



bringing technology to life

LinkedIn Questions

Join our group ™

Please post questions on the
[AAMI Foundation's LinkedIn page.](#)

OR

Type a question into the question box on the webinar
dashboard.

AAMI FOUNDATION

Speaker Introduction

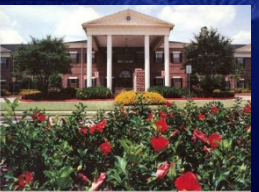
**Patricia Hercules, BSN, MS, RN-BC
Director, System Clinical Programs**

**Teresa Ryan, RN, BSN, CPHRM
Manager, Risk Mgmt, MH Southeast
Hospital**

**M. Michael Shabot, MD, FACS,
FCCM, FACMI**

**Executive Vice President, System
Chief Clinical Officer**

AAMI FOUNDATION



Fail Safe Use of Complex Medical Devices

AAMI Foundation Seminar

December 4, 2017

Patricia Hercules, BSN, MS, RN-BC
Director, System Clinical Programs

Teresa Ryan, RN, BSN, CPHRM
Manager, Risk Mgmt, MH Southeast Hospital

M. Michael Shabot, MD, FACS, FCCM, FACMI
Executive Vice President, System Chief Clinical Officer

MEMORIAL
HERMANN

V1

High Reliability in Healthcare

How is healthcare different from many other industries?

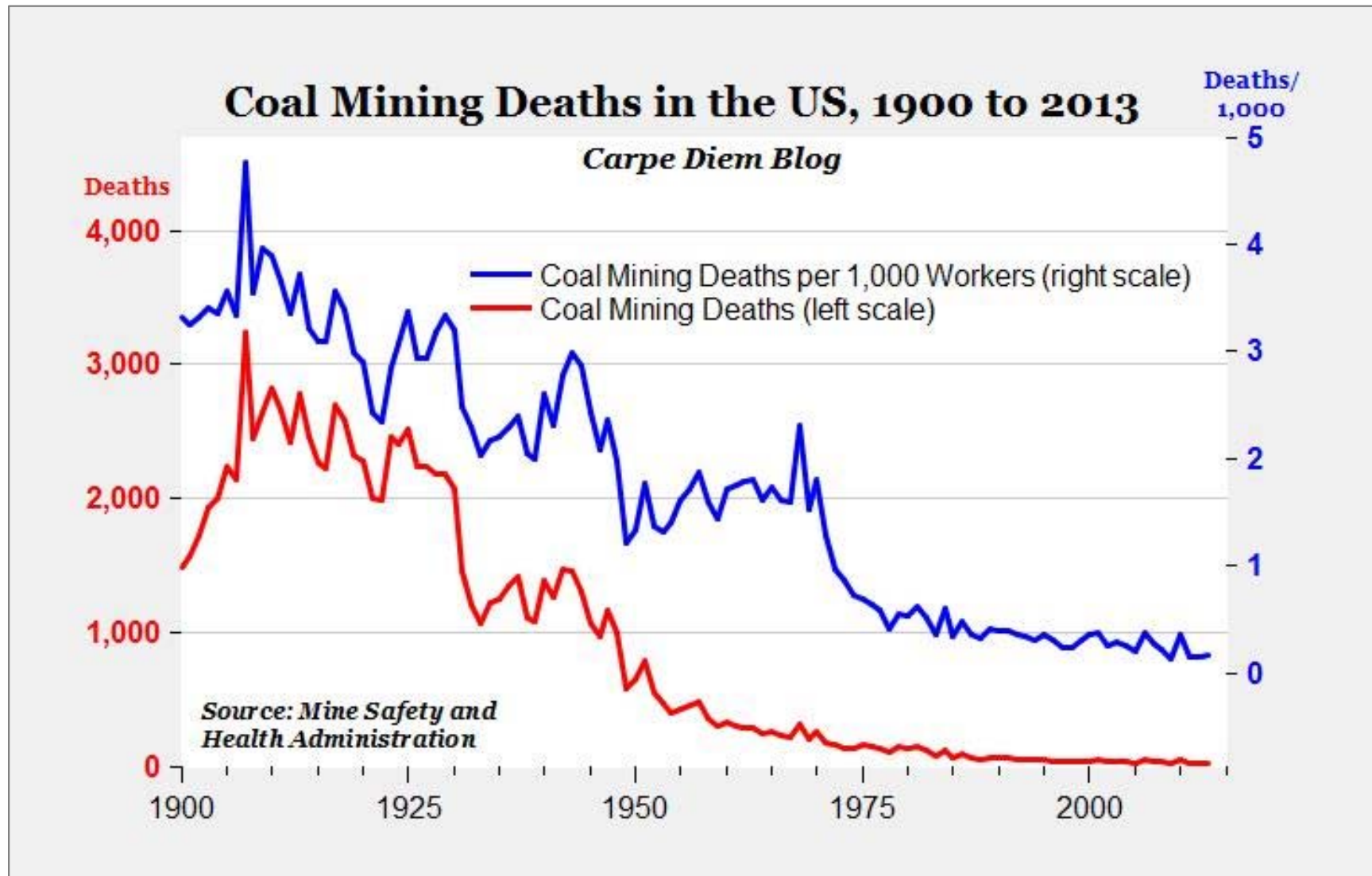


High Reliability in Healthcare

How is healthcare different from many other industries?



U.S. Coal Mining Deaths



Hospital Patient Harm

Question: How many avoidable deaths occur in U.S. hospitals each year?

- 25,000
- 50,000
- 100,000
- 200,000

Hospital Patient Harm

Question: How many avoidable deaths occur in U.S. hospitals each year?

- 25,000
- 50,000
- 100,000
- 200,000



Equivalent to a fully-loaded Boeing 737 crashing **every 7 hours**

Hospital Patient Harm

Question: How many avoidable deaths occur in U.S. hospitals each year?

BMJ 2016

ANALYSIS

Medical error—the third leading cause of death in the US

Medical error is not included on death certificates or in rankings of cause of death. **Martin Makary** and **Michael Daniel** assess its contribution to mortality and call for better reporting

Martin A Makary *professor*, Michael Daniel *research fellow*

Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD 21287, USA

251,454

Hospital Patient Harm



Question: How many avoidable deaths

Memorial Hermann's Goal

The graphic features the BMJ 2016 ANALYSIS logo. The main text reads '0 (Zero)' in large red font, with '251,454' in red font below it. The background text is faded and includes the following:

Medical error—the third leading cause of death in the US

Medical errors included 251,454 deaths in a kind of care of death. Martin Makary and Michael Daniel assess its contribution to mortality and call for better reporting.

Martin A Makary *professor*, Michael Daniel *research fellow*

Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD 21287, USA

Source: James JT. A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care. *Jol Patient Safety* 2013;9:122-128.

737 crash every 5.5 hours

How Can Memorial Hermann Get to Zero?



New Nursing Staff?

New Doctors?



All New Execs?

Robust Process Improvement: *Path to Quality Outcomes*

Lean



Six Sigma



Change Management



Robust Process Improvement: *Changing Standard Work*



**Standard Work =
What we do every day**

***What we do every day =
CULTURE!***

Robust Process Improvement: High Reliability Standard Work



| | 16-Jan | 14-Dec | 14-Nov | 14-Oct | 14-Sep | 14-Aug | 14-Jul | 14-Jun | 14-May | 14-Apr | 14-Mar | 14-Feb |
|---|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Blood Stream Infection Prevention Bundle | | | | | | | | | | | | |
| Central Line Insertion | | | | | | | | | | | | |
| MD Hand Hygiene | 97.83% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |
| Chlorhexadine | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |
| MD gown, gloves, hat & mask | 100.00% | 97.37% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 97.14% | 100.00% | 95.24% | 100.00% | 100.00% |
| Drape patient head to toe | 100.00% | 97.37% | 100.00% | 100.00% | 96.43% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |
| Sterile field maintained during procedure | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |
| Assistant Hand Hygiene | 100.00% | 100.00% | 100.00% | 97.50% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |
| Assistant gown, gloves, hat & mask | 97.83% | 100.00% | 96.88% | 97.50% | 100.00% | 100.00% | 96.00% | 100.00% | 100.00% | 100.00% | 95.24% | 96.88% |
| Insertion Bundle Compliance | 95.65% | 94.74% | 96.88% | 97.50% | 96.43% | 100.00% | 96.00% | 97.14% | 100.00% | 95.24% | 95.24% | 96.88% |
| % Femoral Lines | 8.70% | 0.00% | 0.00% | 2.50% | 0.00% | 0.00% | 0.00% | 2.86% | 2.78% | 0.00% | 0.00% | 0.00% |
| % Femoral Lines justified by careful site selection | 100.00% | | | 100.00% | | | | 100.00% | 100.00% | | | |
| Ultrasound Guidance | | | | | | | | | | | | |
| % Ultrasound Guided CVC Insertions | 100.00% | 100.00% | 92.31% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |



Central Line Sterile Insertion Bundle

Ultrasound Guidance for Central Line Punctures



OR Surgical Safety Checklist



High Reliability Hand Hygiene

Hospital Acquired Infections, Conditions and Patient Safety Indicators

Central Line Associated Bloodstream Infections

Ventilator Associated Pneumonias

Surgical Site Infections

Retained Foreign Bodies

Intraoperative Trauma

Pressure Ulcers and Burns

Medication Errors & IV

Associated Injuries

Thrombosis and/or Pulmonary Embolism

Deaths Among Surgical Inpatients with

Serious Treatable Complications

Birth Traumas

Serious Safety Events

What if?

Hospital Acquired Infections, Conditions and Patient Safety Indicators



Central Line Associated Bloodstream Infections
Ventilator Associated Pneumonias
Surgical Site Infections
Retained Foreign Bodies
Iatrogenic Pneumothorax
Accidental Punctures and Lacerations
Pressure Ulcers Stages III & IV
Hospital Associated Injuries
Deep Vein Thrombosis and/or Pulmonary Embolism
Deaths Among Surgical Inpatients with
Serious Treatable Complications
Birth Traumas
Serious Safety Events

High Reliability *Certified Zero Award*



1. Zero Events



2. 12 Consecutive Months

3. Certified Zero Category

2016


MEMORIAL
HERMANN


High Reliability Certified Zero Award


To: TIRR Memorial Hermann
**Zero Central Line Associated Bloodstream Infections
Hospital-wide for 24 months**

June 2014 to May 2016



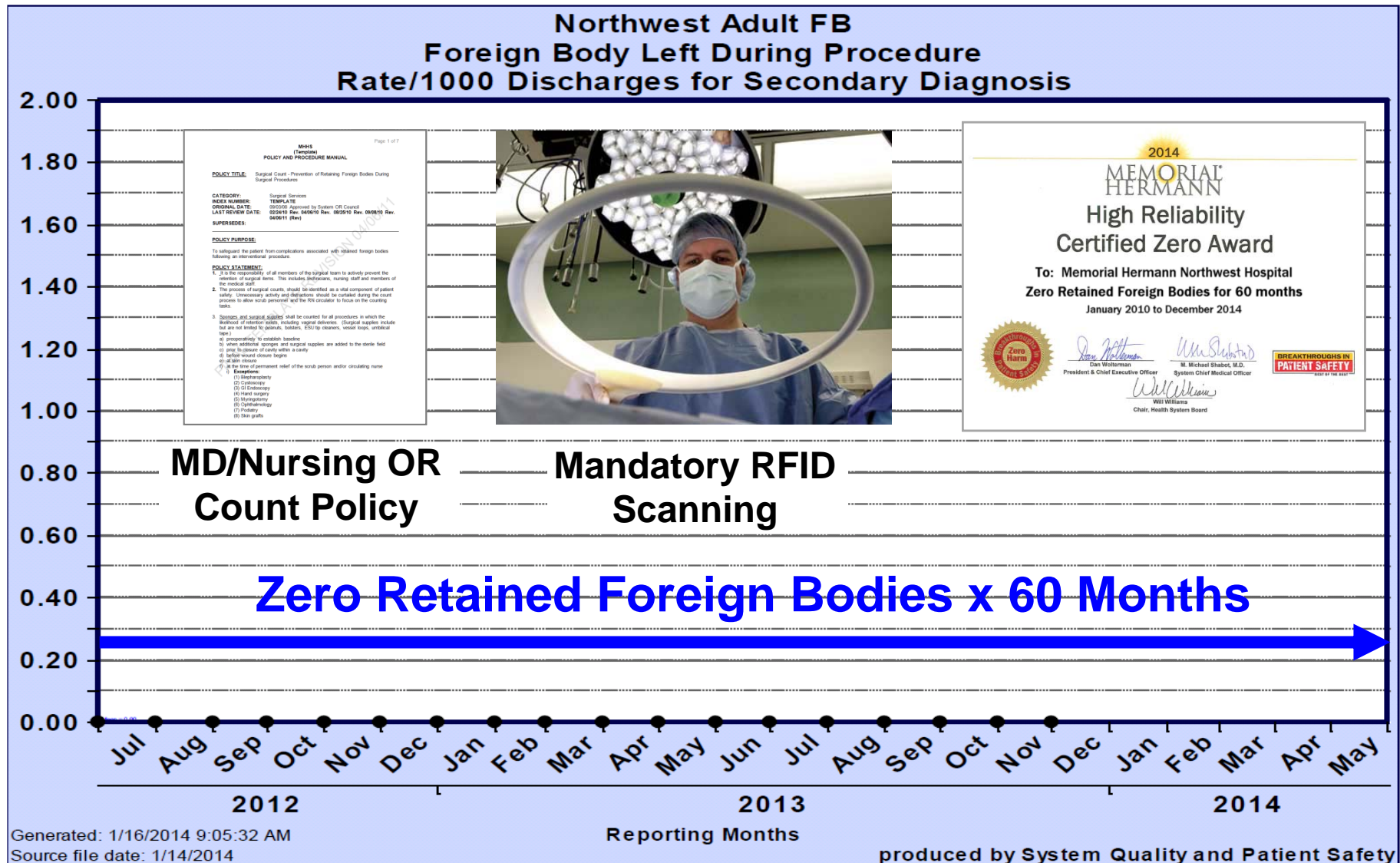

Benjamin K. Chu, M.D.
President & Chief Executive Officer


M. Michael Shabot, M.D.
System Chief Clinical Officer


Will Williams
Chair, Health System Board



MH Northwest: Zero Retained Foreign Bodies



Hospital Acquired Conditions

“Never Events”



Acute Hemolytic Transfusion Reactions

Transfusion Events Jan 2007 - Dec 2016

PSI 16 Transfusion Reaction - Per 1000

2,617,000 Adjusted Admissions

14,234,000 Adjusted Pt Days

1,240,000 Transfusions

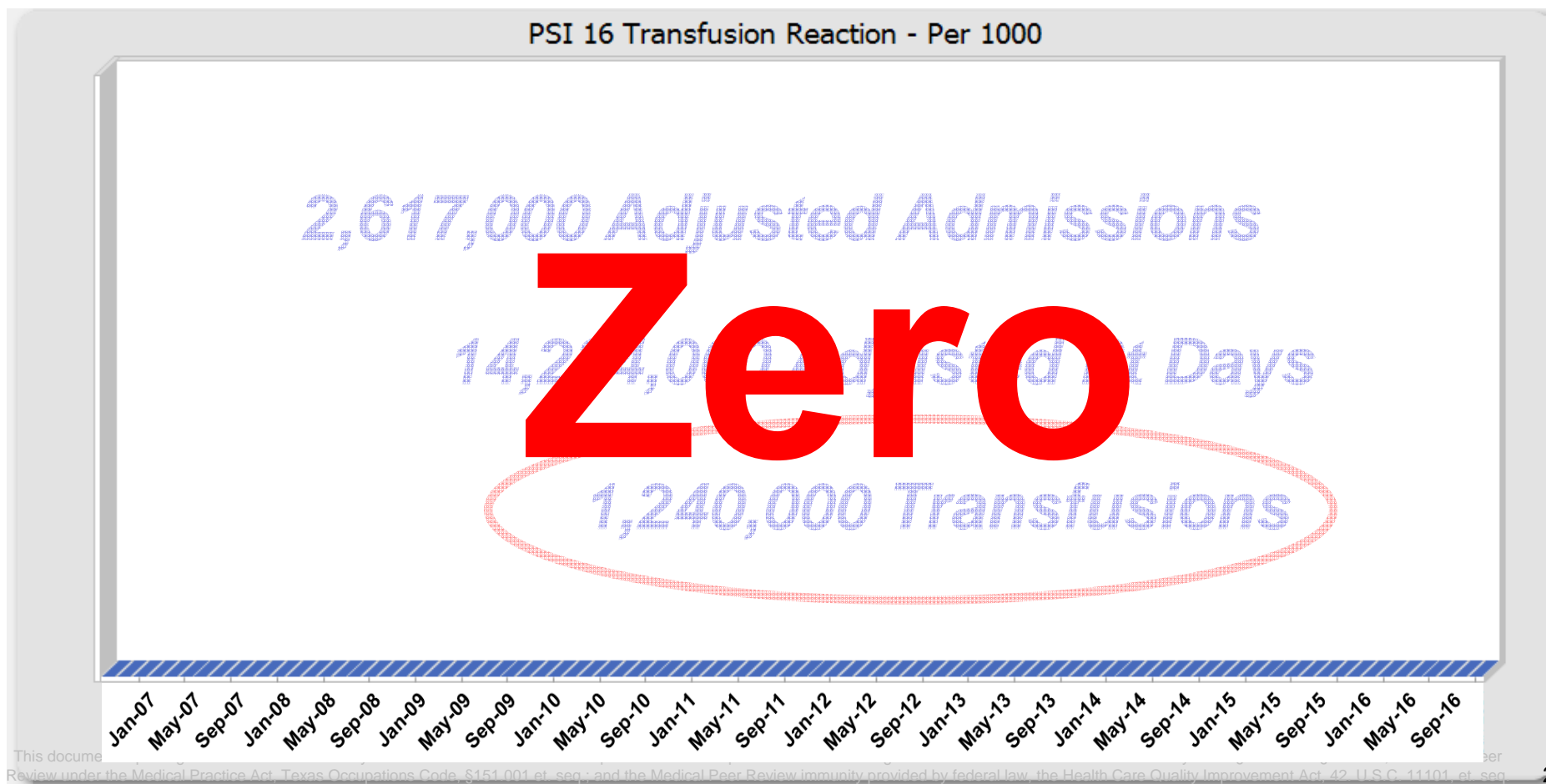
Jan-07 May-07 Sep-07 Jan-08 May-08 Sep-08 Jan-09 May-09 Sep-09 Jan-10 May-10 Sep-10 Jan-11 May-11 Sep-11 Jan-12 May-12 Sep-12 Jan-13 May-13 Sep-13 Jan-14 May-14 Sep-14 Jan-15 May-15 Sep-15 Jan-16 May-16 Sep-16

Hospital Acquired Conditions “Never Events”



Acute Hemolytic Transfusion Reactions

Transfusion Events Jan 2007 - Dec 2016



High Reliability 2011-2017 Certified Zero Awards



ICU Central Line Associated Bloodstream Infections (18)

ICU Catheter Associated Urinary Tract Infections (16)

Hospital-Wide Central Line Associated Bloodstream Infections (7)

Hospital-Wide Catheter Associated Urinary Tract Infections (5)

Ventilator Associated Pneumonias (23)

Surgical Site Infections

Retained Foreign Bodies (46)

Iatrogenic Pneumothorax (24)

Accidental Punctures and Lacerations (3)

Pressure Ulcers Stages III & IV (37)

Hospital Associated Injuries (7)

Deep Vein Thrombosis and/or Pulmonary Embolism (2)

Deaths Among Surgical Inpatients with Serious Treatable Complications (1)

Birth Traumas (16)

Obstetric Trauma in Natural Deliveries with Instrumentation (4)

Serious Safety Events 1&2 (21)

Serious Safety Events 1 & 2 for 1000 Days (2)

All Serious Safety Events (1)

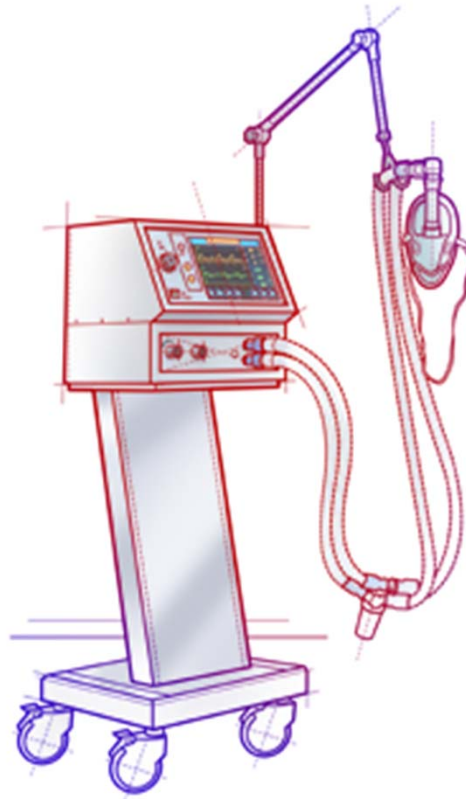
Early Elective Deliveries (9)

Manifestations of Poor Glycemic Control (21)

263

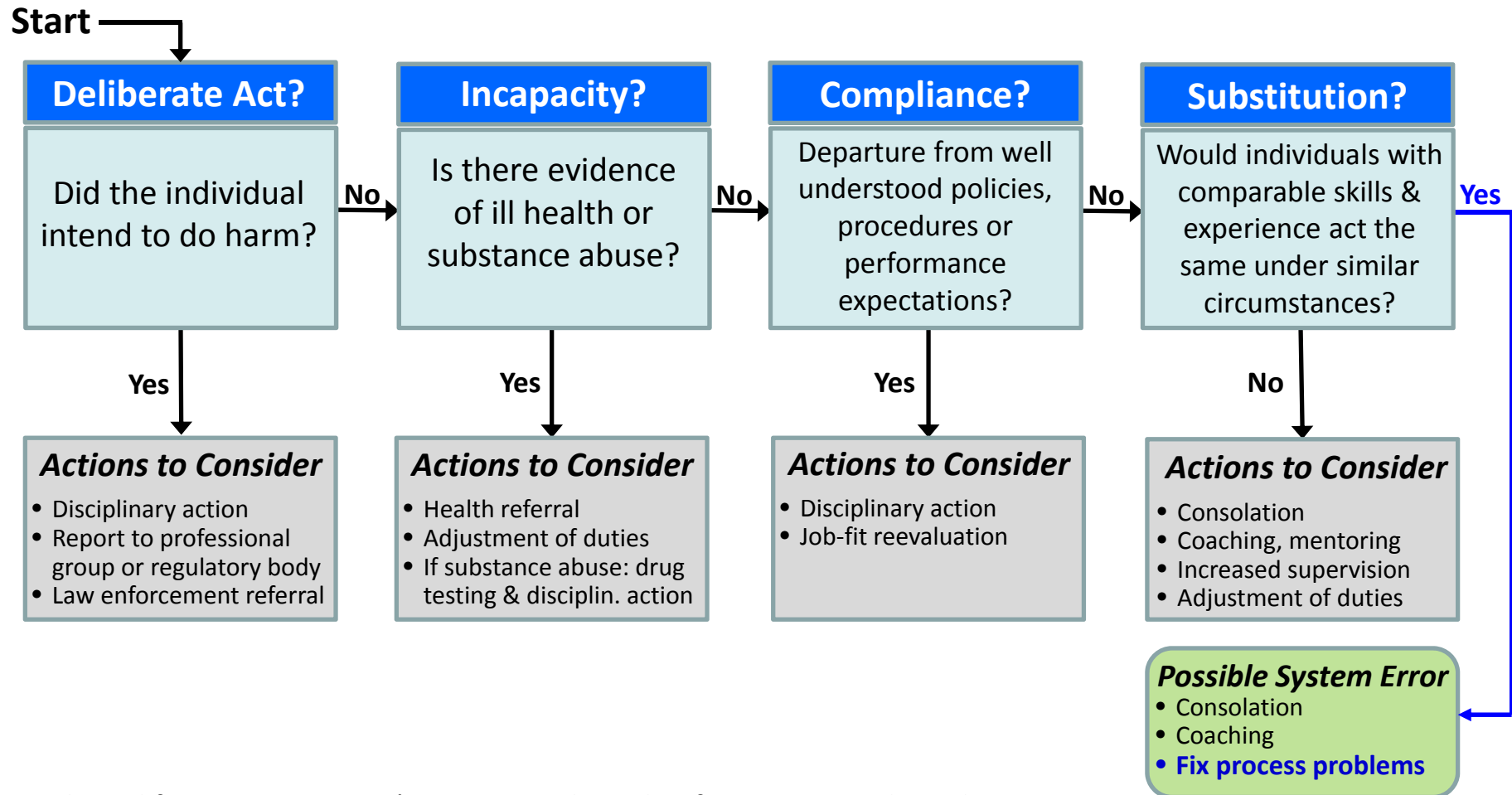


Complex Device Case Scenario



ICU Ventilator

Just Culture Performance Management Decision Guide



Adapted from James Reason's *Managing the Risks of Organizational Accidents*

The Process Challenge

Process that assures that new critical life safety and monitoring devices are not placed into service on nursing units until nurses and other care givers who use these devices on patients have received **formal in-service training** and this training is **documented in writing** for each.

Process includes a requirement of **100% compliance** with individual caregiver education prior to rolling out the equipment onto the unit.

“Fail Safe” Project Team

Charge-Streamline a “Fail Safe” Process -ultimate goal of zero harm

Six Sigma –Process Work Flow Design

- Time efficient
- Cost Effective

Executive Sponsor

Interdisciplinary Project Team

- Quality and Safety
- Risk Management
- Education Management and Specialists– Nursing and Other
- Clinicians
- Supply Chain



Fail Safe Project & Team Charter



Executive Sponsor: Dr. Shabot

Project Champion: Pat Hercules

Problem Statement

Patients may be harmed if staff does not receive training on all new equipment and devices, especially critical life support or monitoring devices such as ventilators and physiological monitors. Clinicians and caregivers must be sufficiently trained on these devices in a timely manner, and must be able to demonstrate competency prior to using equipment / devices.

Currently, there is no standardized process to ensure adequate and timely training for clinicians and caregivers using critical equipment so that they do not suffer the consequences of informal training.
(October 2013)

Customers

Primary: Patients
Key Stakeholders: Clinicians and Caregivers
MHHS & Facility Leaders
Risk Management

Project Alignment with Strategic Plan

Quality & Safety
Customer Satisfaction

Project Scope

In scope:

New Equipment with risk assessment of high risk (critical).
Memorial Hermann Patient units and procedural areas
Clinicians and caregivers that touch patients

Out of scope:

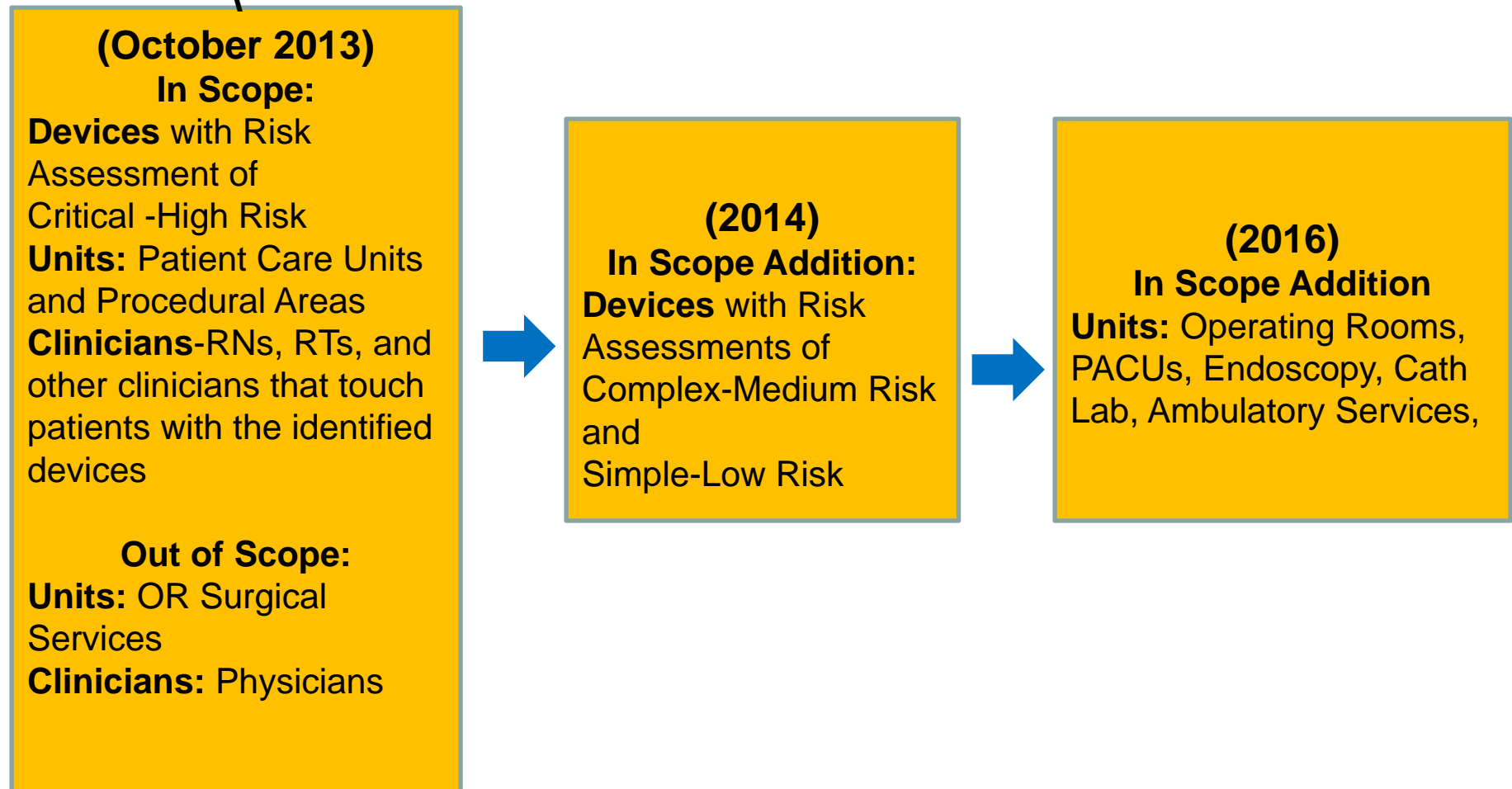
New Equipment with risk assessment of low / medium risk.
Pharmacy Department & Physicians and Physician Assits.

Project Goal

Develop a process to ensure that staff education has been completed, documented and signed off on a per nurse and other appropriate caregiver basis before newly acquired critical equipment, especially, monitoring or life support equipment, is placed into service in a clinical area. All new equipment will require initial training before being put into use. Each equipment will be labeled a risk assessment category and have different levels of responsibility for training and competency assessment.

Business Case: Employees must perform at efficient and effective levels; thus, it is critical to be trained and knowledgeable about new critical equipment in their areas, to avoid risks of regulatory non-compliance and inconsistencies in patient care.

In Scope Progression



System Fail Safe Steering Committee

Interdisciplinary Membership

- Executive Sponsor
- CMO representation
- CNO Representation
- Quality
- Risk Management
- Infection Prevention
- Outpatient Services
- Operating Rooms
- Education – Nursing and other
- Clinical Specialty Representation /Hospital Representation (e.g. ER, NICU, ICU, Pedi)
- Supply Chain
- Environmental Services



Fail Safe Steering Committee

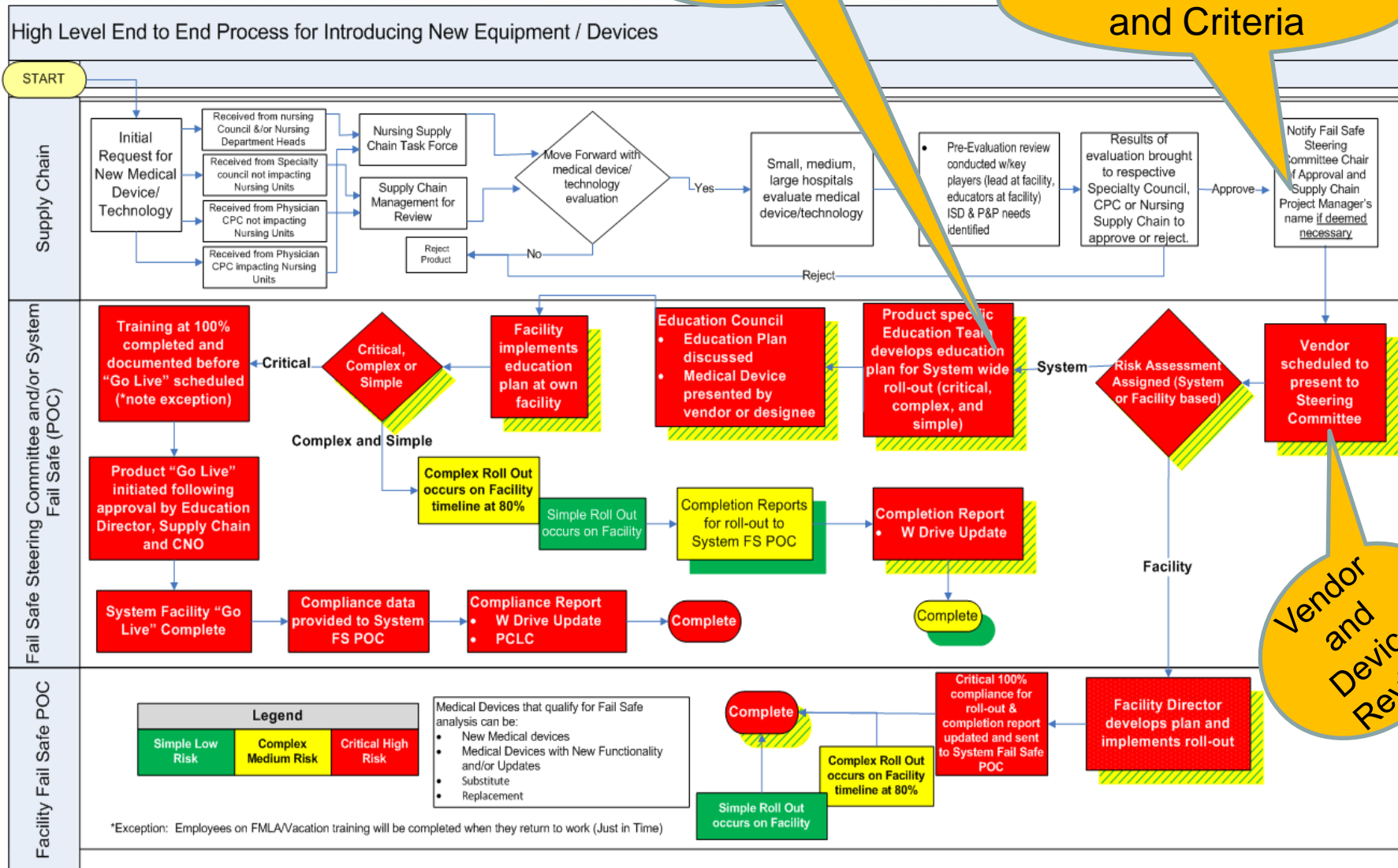
Scope and Responsibilities

- Oversee the High Level Process for education plan associated with New Medical Devices approved to come into Memorial Hermann Hospital System.
- Assign the Risk Assessment Category for each Medical Device (Critical, Complex, or Simple).
- Oversee each Medical Device Education Plan, Roll Out Status, and Completion.
- Communicate Initiative Purpose and Process Throughout the System.
- Oversee the ongoing evaluation of the Fail Safe Initiative, including Cost Benefit Analysis when appropriate.

Fail Safe High Level Process

Education Process

Intake Request and Criteria



Intake Request and Criteria for Fail Safe Analysis



Is it a Medical Device?

(<http://www.fda.gov/aboutfda/transparency/basics/ucm211822.htm>)

Is there a potential for injury or harm?

What is the complexity and/or the Change?

- Current device (new location for use)
- New Device
- Upgrade:
 - Change in current practice
 - Change in display or functionality
 - Change in technology
- Substitute (temporary with changes)
- Replacement

- Name of Individual Requestor and Date
- Name and description of Medical Device
- Vendor Company Name
- Vendor Representative Name/Contact Information
- Supply Chain Contact/Project Manager
- Scope of Change: System or Facility
- Type of roll out: Single or Staggered - phases
- Recommended Target Clinical Area
- Recommended Target Employee Group
- Contract for Purchase finalized with internal purchase number availability
- Projected Date for roll out

Medical Device _____ Vendor _____

Discussion Topics for the Vendor Presentation

1. Medical Device Review: Purpose, Function, Technology, Type of Change, Cost
2. FDA Risk Classification
3. System implementation vs Facility Based approval for roll out
4. Evaluation Information: Number of devices evaluated, Hospital/Hospitals participating, outcome evaluation of evaluation
5. Maude reports or any negative outcome impacting safety reported
6. Training: Target population-end users
7. Training Material and Support: Training material availability including online support, competency check off tool availability, length of training required, vendor support quantified
8. Cleaning process recommendation

Critical, Complex, or Simple?

MEMORIAL
HERMANN

Risk Analysis



Risk Assessment Process



What do we need from the Risk Assessment process:

- An understanding of the potential risks inherent to medical device malfunction before using a new medical device ~ or ~ operating a device with enhanced or undated technology
- User friendly and comprehensive tool for measuring the above

The Risk Assessment tool criteria:

- Potential severity of harm to patients ***
- Probability of occurrence and frequency of harm to patients***

Resulting assessment or score:

- Determines educational rigor to be applied prior to device roll out

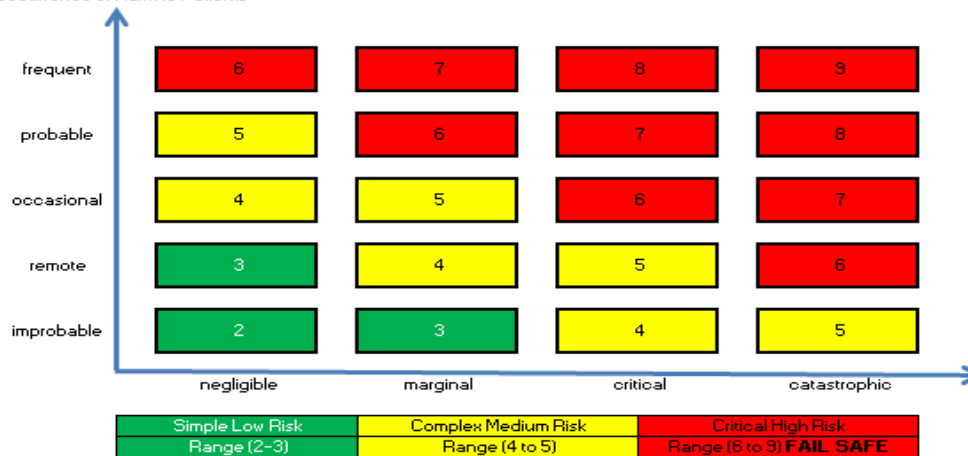
***without education and practice accountability

Medical Device-Technology Assessment Tool



Fail Safe Medical Device-Technology Risk Assessment Tool

Probability of Occurrence of Harm to Patients



Date:
Medical Device/Technology:

Name of Reviewer

Severity of Harm to Patients without
Education and Fracture Accountability

| Severity | Criteria | Rank |
|--------------|--|------|
| Catastrophic | Death or life threatening | 4 |
| Critical | major injury / adverse health outcome | 3 |
| Marginal | moderate injury / adverse health outcome | 2 |
| Negligible | possible minor injury / adverse health outcome | 1 |

Probability of Occurrence of Harm to Patients

| Occurrence | Criteria | Rank |
|------------|---|------|
| Frequent | Expected to occur frequently, almost on every occasion | 5 |
| Probably | Expected to occur in most circumstances, will occur several times | 4 |
| Occasional | Likely to occur sometimes | 3 |
| Remote | Unlikely, but possible | 2 |
| Improbable | So unlikely, it can be assumed occurrence may not be experienced | 1 |

FDA Class Definitions

- Class I - low risk and are therefore subject to the least regulatory controls
- Class II - higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness
- Class III - the highest risk devices are are therefore subject to the highest level of regulatory control, and must typically be approved by FDA before marketed

© Wipro Technologies
Innovative Solutions. Quality Leadership

Determine Ranks

Severity
What is the harm to patients or employees if a device is misused, employee has no training on it, or device breaks down? Rank

Occurrence
How likely will a patient or employee be harmed if something went wrong with the particular device? Rank

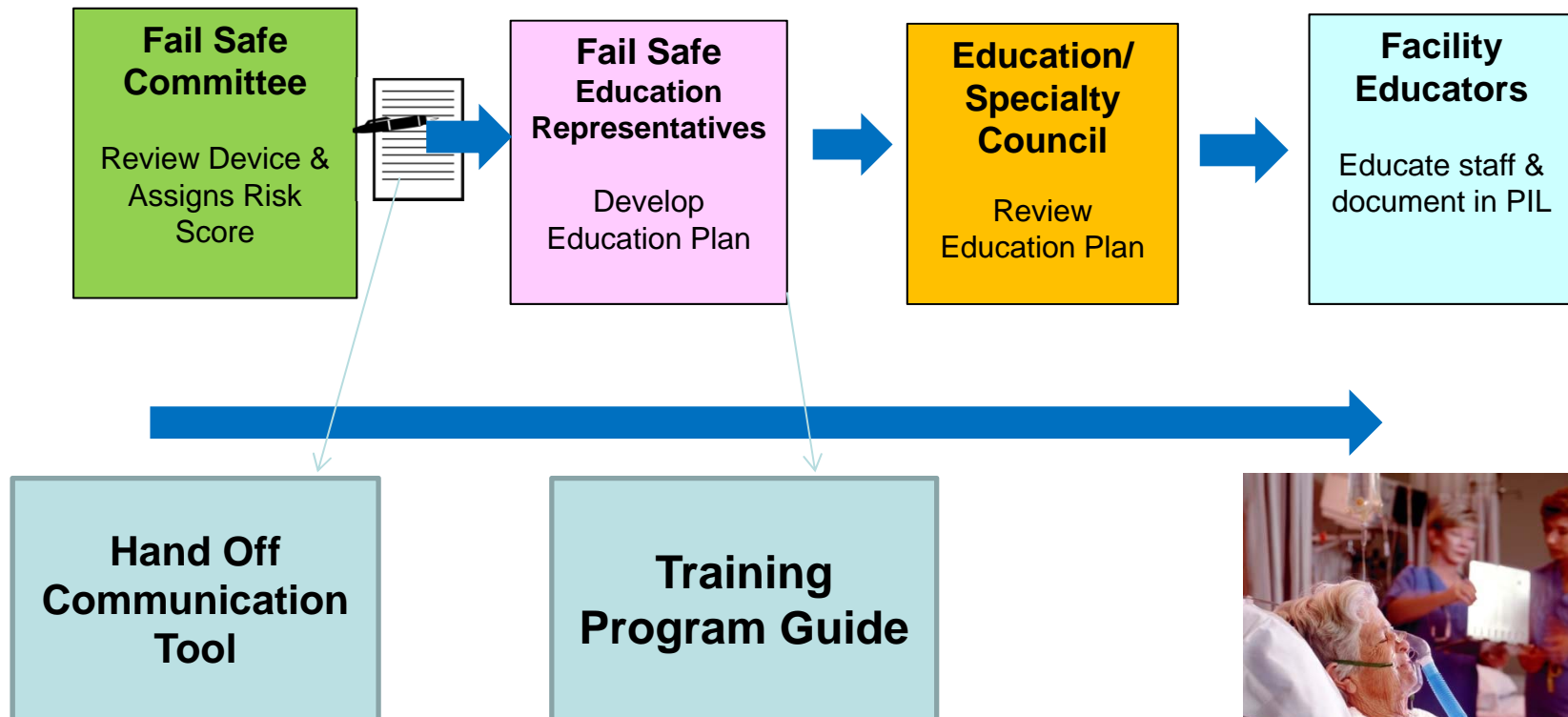
Total (add together)

FDA Rating for the Equipment Class: I II III

100% education required prior to roll out? Yes No

Fail Safe Education

Fail Safe Assessment & Education Process



Hand Off Communication Tool and Guide



Medical Device:

Fail Safe Meeting Date:

Owner:

Date of Request:

- Description of the Medical Device
- Reason for analysis by Fail Safe Steering Committee
- Type of Change
- FDA Rating
- MAUDE Report/s
- Vendor/Contact Information
- Supply Chain Product Manager
- Device Evaluation: Dates/Location /Specialties
- Approvals: Councils/Other
- **Risk Assessment Rating/Competency Accountability Requirement**
- Scope of Change and Facilities with Roll Out
- Target Population: Clinical Areas and Employee groups
- Product Availability and Cost
- Key Dates: Projected Time for Roll Out

Training Program Guide for (Medical Device)

Education required, not quantified prior to rollout

80%

100%

| Training Program (Minimum Requirements) | Equipment Risk Assessment | | |
|---|---------------------------|---------------------|--------------------|
| | Simple Low Risk | Complex Medium Risk | Critical High Risk |
| Content Deliverable | ✓ | ✓ | ✓ |
| PIL module | | | |
| Vendor module | | | |
| written documents | | | |
| Other (Specify) | | | |
| Validation of Skill Knowledge | | ✓ | ✓ |
| written / online quiz | | | |
| oral quiz | | | |
| Return Demonstration (verbal or action) | | | |
| Other (Specify) | | | |
| Hands on Facilitated / Precepted "skills" Return Demonstration | | | ✓ |
| Classroom | | | |
| Bedside | | | |
| Simulation Lab | | | |
| Other (Specify) | | | |
| Identified and Trained Super Users | | | ✓ |
| Unit specific individuals (on every shift) | | | |
| Operational Administrators (OAs) | | | |
| Other (Specify) | | | |
| Support and Resources during Facility "Go Live" | ✓ | ✓ | ✓ |
| Onsite Vendor Representative | | | |
| System Supply Chain Project Manager | | | |
| System Bio Med Project Manager | | | |
| Facility Educator | | | |
| Facility Director and Managers | | | |
| Facility Materials Management | | | |
| Facility Bio Med | | | |

✓ Represents a "Must Have" in Training Design

Training Program Guide for Ventilator (Example)



Fail Safe - Training Program Design Guide

Medical Device/Technology: Name

Ventilator-Critical

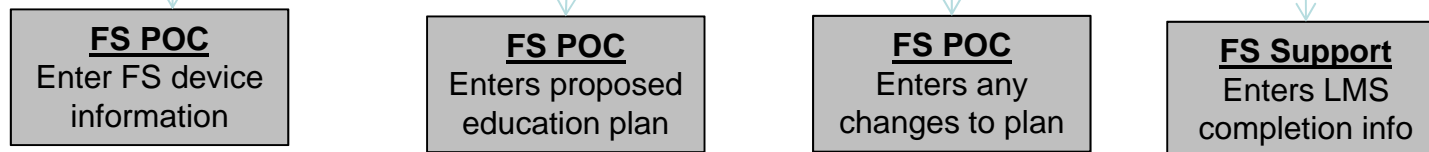
| | Equipment Risk Assessment | | |
|---|---------------------------|------------------------|-----------------------|
| | Simple Low Risk | Complex Medium Risk | Critical High Risk |
| Training Program (Minimum Requirements) | | | |
| Content Deliverable- *Including Practice Accountability | ✓ | ✓ | ✓ |
| PIL module | | | ☒ |
| Vendor module | | | ☒ |
| Written documents | | | ☒ |
| Other (Specify) | | | |
| Validation of Skill Knowledge | | ✓ | ✓ |
| Written / online quiz | | | ☒ |
| Oral quiz | | | |
| Return Demonstration (verbal or action) | | | ☒ |
| Other (Specify) | | | |
| Hands on Facilitated / Precepted "skills" Return Demonstration | | | ✓ |
| Classroom | | | ☒ |
| Bedside | | | ☒ |
| Simulation Lab | | | |
| Other (Specify) | | | |
| Identified and Trained Super Users | | | ✓ |
| Unit specific individuals (on every shift) | | | Respiratory T |
| Operational Administrators (OAs) | | | ☒ |
| Other (Specify) | | | |
| Support and Resources during Facility "Go Live" | ✓ | ✓ | ✓ |
| Onsite Vendor Representative | | | ☒ |
| System Supply Chain Project Manager | | | ☒ |
| System Bio Med Project Manager | | | ☒ |
| Facility Educator | | | ☒ |
| Facility Director and Managers | | | ☒ |
| Facility Materials Management | | | ☒ |
| Facility Bio Med | | | |

✓ Represents a "Must Have" in Training Design

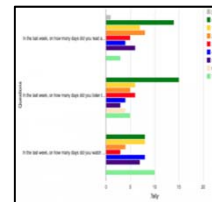
Fail Safe Compliance with Database Management

Hand off
Communication
Tool and Guide

Database Management Process



Process Stakeholders
 FS POC-Point of Contact
 FS Support - Administrative
 FS Director - Clinical Director



Fail Safe Education
Compliance Report

FS Director
 Send report monthly to
 stakeholders
 Education/Specialty Council
 Fail Safe Steering Committee
 CNO Council
 Enterprise Risk Committee

Fail Safe Database Resource



| | | Cost Centers | | | | | | | | | |
|---|------|--------------|--------|----------|----------|----------|----------|----------|----------|----------|----------|
| | | 029-5500 | | 029-5550 | | 029-5551 | | Total | | | |
| Fail Safe Database Resource | | Job Codes | | Required | Complete | Required | Complete | Required | Complete | Required | Complete |
| Calculate completion percentage & education cost | | RNI | PC0901 | | | | | | | | |
| # of employees requiring education by cost center | 0 | RN II | PC1001 | | | | | | | | |
| # of employees completed education by cost center | 0 | RN III | PC1101 | | | | | | | | |
| % Completion | 0% | RN IV | PC1207 | | | | | | | | |
| Cost of Education * | \$ - | Total | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| * # of employee X \$40/hr X ed time | | % Complete | | | 0% | | 0% | | 0% | | 0% |

Objective

- Using LMS reports, input compliance data into database



Education Compliance Report



Fail Safe Devices FY 2018.xls [Compatibility Mode] - Microsoft Excel

| Device (Example) | Fail Safe Committee | Facility/Specialty Team | Education/Specialty Council | Risk Assessment | Education % Required | Scope of Change | Clinical Area | # of Staff Educated | Completion % | Estimated Education Cost |
|--------------------------|---------------------|-------------------------|-----------------------------|-----------------|----------------------|-----------------|----------------|---------------------|--------------|--------------------------|
| EKG leads | 8/1/2017 | 8/15/2017 | 9/6/2017 | Simple 2 | | System-wide | Respiratory Tx | 216 | 95% | \$ 6,566.40 |
| Midline Catheter | 8/1/2017 | 8/21/2017 | 9/6/2017 | Critical 7 | 100% | System-wide | Nursing - All | 1023 | 78% | \$ 25,534.08 |
| Chest Compression Devise | 10/3/2017 | 11/5/2017 | | Complex 4 | 80% | TMC | Nursing - All | 1023 | | |
| ABC Rapid Infuser | 10/3/2017 | 11/5/2017 | | Critical 7 | 100% | TMC | ICU | 325 | | |
| XYZ Code | 10/3/2017 | 11/5/2017 | | Critical 7 | 100% | System-wide | Nursing - All | 1023 | | |

Report Objectives

- Distribute to identified stakeholders
- Obtain feedback
- Revise process as needed

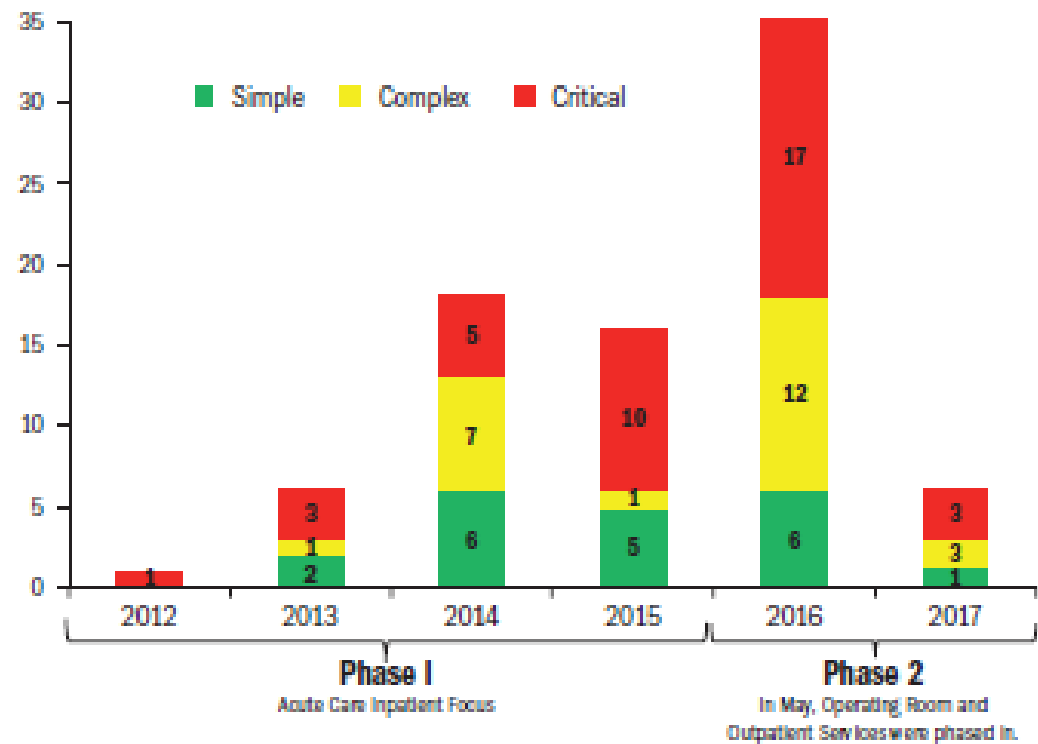
49

3:48 PM 11/28/2017

Medical Device Assessments MEMORIAL HERMANN

Fall Safe Committee Count of Medical Device Assessments by Year and Risk Category

- Phase 1 - 47% (39) assessed as Critical
- Phase 2 - 39% (7) OR Medical Devices assessed as critical (since May 2016)



Why we assess the risk....

RMs share lessons learned from adverse events involving medical device use in the acute care setting to include:

- ✓ Gaps identified in the existing safety culture
- ✓ ID ways to engage third party partners in adopting and supporting a safety culture
- ✓ Re-engagement of RM and hospital leadership oversight of equipment management to mitigate future risks to our patients and to the organization

Our goal is, with 100% compliance, the frequency of all medical device safety events will decrease!



Serious Safety Events

MEMORIAL
HERMANN



2014

MEMORIAL
HERMANN

High Reliability Certified Zero Award

To: Memorial Hermann Northwest Hospital

Zero Serious Safety Events 1 & 2 for 12 months

January 2013 to December 2013




Dan Wolterman
President & Chief Executive Officer


M. Michael Shabot, M.D.
System Chief Medical Officer




Will Williams
Chair, Health System Board

2015

MEMORIAL
HERMANN

18

h Reliability
ed Zero Harm
To: Memorial Hermann
Zero Serious Safety Events for 24 Months
from June 2013 to May 2015



[Signature]
man
President and Executive Officer

[Signature]
M. Mich
System Chief

[Signature]
Will Williams
Chair, Health System Board





**September 6, 2015
MH Greater Heights Hospital
1000 Days Since Last SSE1-2**

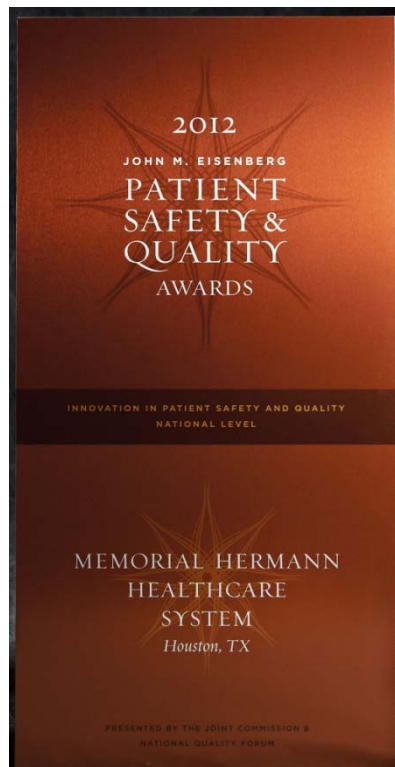
John M. Eisenberg Patient Safety and Quality Award

MEMORIAL
HERMANN

March 8, 2013 | Washington, DC



NATIONAL
QUALITY FORUM



MH Sugar Land Hospital *Malcolm Baldrige Award*

MEMORIAL
HERMANN



High Reliability Organizations



Commercial Aviation



Nuclear Aircraft Carriers

Air Traffic Control



OPERATION BREAKTHROUGH
PATIENT SAFETY

High Reliability Organizations

MEMORIAL
HERMANN



Memorial Hermann Health System



Nuclear Aircraft Carriers



Commercial Aviation

Air Traffic Control



OPERATION BREAKTHROUGH
PATIENT SAFETY

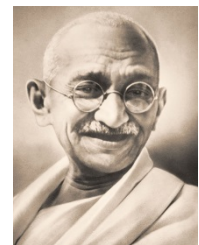
BEST OF THE BEST 59

Thank you!

MEMORIAL
HERMANN

***“You must be the change
you want to see in the world”***

Mahatma Gandhi (1869-1948)



Future/Ongoing Initiatives

December 15, 2017 12 noon to 1 pm EST

**“UCSF’s Experience With Sending Alarms to
Phones in the Intensive Care Nursery”**

***Please join us to learn the strategy UCSF used
to determine how and when and which alarms
to send to the nurses phones in the NICU...and
all the lessons learned!***

**Presenter: Kevin Spolini, MSN, RN
Clinical Informatics Mission Bay Hospitals
UCSF Benioff Children's Hospital
San Francisco, CA**

January 15, 2018 12:00 PM to 1 PM EST

**“Clinical Alarm Management Strategies –
Meaningful Alerts; Reducing Non-actionable
Alarms”**

*Please join us to learn the technique of
creating alarm default settings specific to
certain patient profiles to reduce alarm fatigue!*

Presenter: Sharon H. Allan, DNP, RN, ACNS-BC
Central Nursing - Clinical Standards
The Johns Hopkins Hospital

Thank You to Our Industry Partners!

DIAMOND



Platinum



Gold



bringing technology to life

Questions?



- Post a question on [AAMI Foundation's LinkedIn](#)
- Type your question in the “Question” box on your webinar dashboard
- Or you can email your question to: mflack@aami.org.

Consider Making a Donation to the AAMI Foundation Today!

Making Healthcare Technology Safer, Together

**Look for the “Donate” button on our
homepage!**

Thank you for your support!

www.aami.org/thefoundation

AAMI FOUNDATION