Getting it Right When Things Go Wrong
Responding to Serious Safety Events

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Disclosures

I have no conflicts of interest to report
Objectives

• Gain literacy in the types of adverse events

• Develop a systematic approach to understanding incident/event classification

• Learn the key components of event reviews and action plans

• Become equipped to participate and plan adverse event reviews at your institution

• Work to “Get it right when things go wrong.”
Systematic Identification
Sentinel Events
Sentinel Event: Definition

• General
  – **Adverse** medical events requiring **immediate investigation and corrective action**.

• The Joint Commission (TJC)
  – Any patient **safety event** (not primarily related to the natural course of the patient’s illness or underlying condition) that reaches a patient and results in **death, permanent harm, or severe temporary harm**.
  – 1996: TJC issues formal Sentinel Event Policy
  – “**All sentinel events** must be reviewed by the hospital and are subject to review by TJC”
  – See also: “Comprehensive Accreditation Manual for Hospitals” Update 2, January 2015
Obstetric Sentinel Events

- Any **intrapartum maternal death** or **severe maternal morbidity**
- **Unanticipated death** of a fullterm neonate
- **Discharge** of a **neonate** to the **wrong family**
- **Abduction** of any patient receiving care
- **Wrong-site** surgery
- Unintended **retention of a foreign object** in a patient after an invasive procedure
- **Hemolytic transfusion reaction**
- **Severe neonatal hyperbilirubinemia**
- Others (suicide, abductions, crimes, etc...)


Sentinel Event:
Appropriate response (TJC)

1. A formalized **team response** that **stabilizes** the patient, **discloses** the event to the patient and family, and provides **support** for the **family** as well as **staff** involved in the event

2. **Notification** of hospital leadership

3. Immediate **investigation**

4. Completion of a comprehensive **systematic analysis** for identifying the causal and contributory factors (submit within 45 days)

5. **Corrective actions**

6. **Timeline** for implementation of corrective actions

7. Systemic **improvement**
State Reportable Events

- Lack of central and standard national reporting system system is a recognized gap in US

27 states have adverse event reporting systems

Wide variation in types of individual events reported to states

- 15 states have adopted the National Quality Forum list (“Serious Reportable Events”)
  - 29 events; covers the Sentinel Events
Systematic Classification: Serious Safety Events
OB Event Reporting Trigger List:
• 5 minute Apgar < 7
• Arterial cord blood gases < 7.0
• Shoulder dystocia
• IUFD @ > 24wks.
• Intrapartum fetal death
• Postpartum hemorrhage with transfusion, hysterectomy or embolization
• Infant birth trauma (e.g. brachial plexus injuries, fractures, other)
• Unanticipated maternal ICU admission
• Unanticipated newborn NNICU admission @ > 37 wks.
• Maternal death
• 3° lacerations
• 4° lacerations
• Uterine rupture or dehiscence
• Any safety concern, near-miss, or unanticipated adverse outcome

1. Open webpage to hospital Intranet
2. Select tab indicating “Yale-New Haven”
3. Select “Applications”
4. Select “Event Reporting:
   • RL Solutions page will load
5. Login
   • Log-in users (YNHH employees), use Novell logon and password
   • Non-log-in users, click “anonymous”
6. Click “file” button
7. Click event icon best representing type of incident (or use drop-down menu)
8. Hovering over icons will display names
9. Be brief and factual and consider how the event may be prevented in the future.
Qualities of an Effective Reporting System

• **Supportive** environment

• Protects **privacy** of patients and staff

• Reporting is done by **broad range of personnel** (nurses, doctors, midwives, residents, staff)

• **Summaries/results** are **disseminated** in timely manner (FEEDBACK)

• **Structured** mechanisms for **reviewing, classifying, and fixing**
Reporting Culture

Computerized Event Reporting

Patient Safety Committee

Patient Safety Nurse
# Event Reporting “Report”

## General Event Type: Equipment/Medical Device

<table>
<thead>
<tr>
<th>FileNr</th>
<th>Unit Event</th>
<th>Event Date (mm/dd/yyyy)</th>
<th>Type Of Person Affected</th>
<th>Specific Event Type</th>
<th>Brief/Factual Description</th>
<th>HP/SEC Levels of Harm</th>
<th>Resolution Comment</th>
<th>Person Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>INC_111484</td>
<td>WP 10 MSC</td>
<td>04-13-2016</td>
<td>Person Not Applicable</td>
<td>Device Failure</td>
<td>The Pyxis machine at POD 3 on WP 10 MSCU crashed twice and would not accept RN finger print. Pharmacy called to assist. Presented quickly and was able to get into the Pyxis but stated that it was functioning at an extremely slow rate. Machine was down for a total of 30 minutes causing a delay in patient medication administration.</td>
<td>Not a Safety Event</td>
<td>Fixed quickly when Pharmacy notified</td>
<td>N. Ciccione</td>
</tr>
</tbody>
</table>

## General Event Type: Fall

<table>
<thead>
<tr>
<th>FileNr</th>
<th>Unit Event</th>
<th>Event Date (mm/dd/yyyy)</th>
<th>Type Of Person Affected</th>
<th>Specific Event Type</th>
<th>Brief/Factual Description</th>
<th>HP/SEC Levels of Harm</th>
<th>Resolution Comment</th>
<th>Person Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>INC_111787</td>
<td>MFM Langwharf</td>
<td>04-15-2016</td>
<td>Out-Patient</td>
<td>Ambulating Without Assistance</td>
<td>It was coming out of bathroom in NST area and tripped on the floor base at the door. Went to the floor it knee. No subsequent swelling redness or bruising. Stayed in NST room for 30 minutes with no complaints and said she felt fine.</td>
<td>Not a Safety Event</td>
<td>Reviewed. No deviation in GAPPS</td>
<td>N. Busch</td>
</tr>
</tbody>
</table>

## General Event Type: Lab/Specimen

<table>
<thead>
<tr>
<th>FileNr</th>
<th>Unit Event</th>
<th>Event Date (mm/dd/yyyy)</th>
<th>Type Of Person Affected</th>
<th>Specific Event Type</th>
<th>Brief/Factual Description</th>
<th>HP/SEC Levels of Harm</th>
<th>Resolution Comment</th>
<th>Person Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>INC_111137</td>
<td>Women's Center</td>
<td>04-13-2016</td>
<td>Out-Patient</td>
<td>Collection Issue: Other</td>
<td>Patient collected a urine specimen which was not labeled with her ID label.</td>
<td>PSE 2 - Minimal Temporary Harm</td>
<td>Discussed at unit huddle. Employee counseled</td>
<td>N. Busch</td>
</tr>
<tr>
<td>INC_111136</td>
<td>Women's Center</td>
<td>04-13-2016</td>
<td>Out-Patient</td>
<td>Collection Issue: Other</td>
<td>Patient left a urine specimen which was left unlabed and the specimen was unable to be sent.</td>
<td>PSE 2 - Minimal Temporary Harm</td>
<td>Discussed at unit huddle. Employee counseled</td>
<td>N. Busch</td>
</tr>
</tbody>
</table>

## General Event Type: Maternal/Childbirth

<table>
<thead>
<tr>
<th>FileNr</th>
<th>Unit Event</th>
<th>Event Date (mm/dd/yyyy)</th>
<th>Type Of Person Affected</th>
<th>Specific Event Type</th>
<th>Brief/Factual Description</th>
<th>HP/SEC Levels of Harm</th>
<th>Resolution Comment</th>
<th>Person Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>INC_111472</td>
<td>MFM Langwharf</td>
<td>04-10-2016</td>
<td>Out-Patient</td>
<td>Other (please specify)</td>
<td>Meas not in H&amp;P AND snapshot not clear about dose of lovenox. Phone call to patient confirmed dose.</td>
<td>&lt;/&gt;</td>
<td></td>
<td>K. Campbell</td>
</tr>
<tr>
<td>INC_110191</td>
<td>WP 4 L&amp;D</td>
<td>04-10-2016</td>
<td>In-Patient</td>
<td>Cord Prolapse</td>
<td>In-patient on MSCU, ruptured membranes at 28 4 weeks. Cord prolapse resulted. Emergent transfer and cesarean birth under general anesthesia. Patient needed to be intubated with</td>
<td>&lt;/&gt;</td>
<td></td>
<td>C. Raab</td>
</tr>
</tbody>
</table>
Safety Event Classification (HPI)

A deviation from generally accepted performance standards (GAPS) that...

**Serious Safety Event**
- Reaches the patient
- Results in moderate to severe harm or death

**Precursor Safety Event**
- Reaches the patient
- Results in minimal harm or no detectable harm

**Near Miss Safety Event**
- Does not reach the patient
- Error is caught by a detection barrier or by chance

From: Healthcare Performance Improvement
Algorithm for Classifying Safety Events

- Was there a deviation from generally accepted performance standards (GAPS)?
  - No ➞ Not a Safety Event
  - Yes ➞ Did the deviation reach the patient?
    - No ➞ Near Miss Safety Event
    - Yes ➞ Did the deviation cause moderate to severe harm or death?
      - No ➞ Precursor Safety Event
      - Yes ➞ Serious Safety Event
Safety Event Classifications

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

From: Healthcare Performance Improvement
Event Reports by Classification (FY ‘15)

- Serious Safety Event (SSE): 3
- Precursor Safety Event (PSE): 435
- Near Miss Events (NME): 119
- Not a Safety Event: 459
- Total: 1016
# 2014-2016 OB/GYN Serious Safety Events

<table>
<thead>
<tr>
<th>Serious Safety Event</th>
<th>Date</th>
<th>Campus</th>
</tr>
</thead>
<tbody>
<tr>
<td>XXXX with ICU admission</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td>Perinatal Death</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td>Misplaced XXX biopsy</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td>Retained foreign body</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td>Newborn unexpectedly admitted to NNICU</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td>Newborn unexpectedly admitted to NNICU</td>
<td>XXX</td>
<td>XXX</td>
</tr>
</tbody>
</table>

Days since last safety event: 110

Intervals between SSE:
- Mean 133 days 2016 (last report: 100d)
- Median 120 days 2016 (last report: 111d)

(details censored to respect confidentiality)
Yale-New Haven Hospital
"Days Since Last Serious Safety Event"

Mean and Median comparison for FY'14, FY'15, and FY'16.
SSE: Rolling 12 Month Total
Serious Safety Event Rate

Apparent Increase due to healthier reporting culture

Significant performance improvement as a result of prevention activities

Actual increase due to complacency or reverting to old habits

Long term improvement through sustained prevention

Source: Healthcare Performance Improvement, LLC
Systematic Review: Root Cause Analysis
Root Cause Analysis: What is it?

• RCA^2 : Root cause analysis and ACTIONS

• Goals:
  – identify the systems factors that led to the error
  – suggest solutions that can prevent similar errors from causing harm in the future

• Should also include investigations of human error
Root Cause Analysis: How do they fail?

• Reasons for Failure:
  ★ lack of standardized approach
  ★ failure to identify ‘systems-level’ causes
  ★ superficial solutions/countermeasures
  ★ poor implementation of solutions
  ★ lack of follow-up and accountability

• Root Cause Analysis and ACTION
  – Standardize process, systems based approach
  – Goal is real action & improvement
  – Sustainable results
RCA: When and Who

• TIMING
  – Investigation should begin within 72h
    • completed in 30-45 days
  – Scheduled meetings (many more than 1)
    • with work between meetings

• TEAM
  – Led by an expert in RCA and subject area
    • experienced and skilled; with leadership skills
    • can be a pair
  – 4-6 members
    • limit conflicts of interest
    • interdisciplinary; consider a ‘content expert’
  – consider patient or family member
Interviewing

• Requires preparation
• Requires skilled interviewer
• Active listening
• Tell the story, but stick to the facts
Causation/Causal Statements

• Determination
  – **Systems** based approach
  – Human error must have a preceding cause
  – Failure to follow procedure by itself is not a root cause (why?)
  – Failure to act is not a cause without a pre-existing requirement to act
  – Negative descriptors are not actionable

• “**WHO** did **WHAT**, because **HOW** and **WHY**?”
  – Individual failure modes: HOW the individual experienced the error
  – System failure modes: WHY the individual experienced the error
WHOW did WHAT because HOW and WHY?

• The anesthesiologist failed to abandon attempts at intubation because he did not know how much time had passed and there is no system to provide a person to identify time landmarks during airway emergencies.

• The nurse was not able to get the attention of the anesthesiologist to suggest performing tracheotomy because she was not empowered to speak up and there is a lack of culture to support crew resource management tools for expressing concerns.
“Taxonomy of Failure Modes”

From: Healthcare Performance Improvement
RCA and Human Error

- RCA focuses on **systems errors**
- Human error should not be ignored
  - Systems errors can beget human errors
  - Look for systems that can prevent human error in the future

- Cases with **human error**
  - Other venues for review:
    - Medical staff credentialing
    - Peer review committee
  - Accountability and responsibility
    - Just culture
“Right” Leadership

• Inadequate leadership contributing factor in 50% of sentinel events
  – Available, affable, able

• Post-event response (“Just Culture”)
  – Culture of blame → Culture of safety
  – Rehabilitation/Restoration (vs. retribution)
  – Intolerance for recklessness or misconduct
Peer Review: Just Culture

Individual Behavior

Human Error
(inadvertent action, lapse, slip, mistake)

Coach/Learn

Risky
(behavioral choice that increases risk; risk unrecognized or believed to be justified)

Corrective Action

Reckless
(conscious disregard of substantial and unjustifiable risk)
Common Cause Analysis

Root Cause Analysis
- Single case
- Event directed
- Process, protocol, technology focus
- Investigates cause-and-effect directly
- *Unit change*

Common Cause Analysis
- Many cases
- Time or trend directed
- People, leadership, environmental focus
- Infers cause-and-effect relationships using analysis
- *Institutional change*

“Collective examination of past events for common causes, not common outcomes.”
Systematic Improvement
Corrective Action Plans
Corrective Action Plans

• Aims
  – Mitigate recurrence
    • Prevent, reduce (probability or severity)
  – Ensure each cause/error has one or more actions

• Anatomy
  – Systematic
  – Accountability built in
## RCA & Action Plans

### Root Cause Analysis Summary

<table>
<thead>
<tr>
<th>Patient Initials</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient MRN/DOB/Age</td>
<td></td>
</tr>
<tr>
<td>Admission Date and Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Event Date / RL Number</td>
<td></td>
</tr>
<tr>
<td>Event Location</td>
<td></td>
</tr>
<tr>
<td>Date RCA Initiated</td>
<td></td>
</tr>
<tr>
<td>Event Type</td>
<td></td>
</tr>
<tr>
<td>Safety Event Classification</td>
<td>☒ Serious Safety Event ☐ Precursor Safety Event ☐ Near Miss Event ☐ DPH Not Safety Event</td>
</tr>
<tr>
<td>Persons Involved in Event</td>
<td>XXX</td>
</tr>
<tr>
<td>Persons Involved in RCA</td>
<td>RCA Cause Analysis Facilitator:</td>
</tr>
<tr>
<td></td>
<td>RCA Analyst (ASRA staff or other):</td>
</tr>
<tr>
<td></td>
<td>Executive Sponsor:</td>
</tr>
<tr>
<td></td>
<td>Dept Representative(s):</td>
</tr>
<tr>
<td></td>
<td>Subject Matter Expert:</td>
</tr>
</tbody>
</table>

### Brief Summary of the Facts

(Guidelines: Limit summary to ½ page; 12 point font; Use SBAR format)

### Situation:

### Background:

### Assessment:

### Recommendation:

### Analysis Summary

Inappropriate Act Statements:

1. XXX
   (The individual failure was: Skills Based ☐ Rules Based ☒ Knowledge Based ☐)

2. XXX.
   (The individual failure was: Skills Based ☐ Rules Based ☐ Knowledge Based ☒)
# RCA & Action Plans

## Root Cause Analysis Summary

- **Root Cause:** (Describe)
- **High Reliability Environment**

<table>
<thead>
<tr>
<th>Were the following considered and addressed?</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Disclosure and apology: Yes ☑ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Second victim: Yes ☑ No ☐</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Staffing Reviewed at the time of the event and staffing levels were found to be contributory to the event.</th>
<th>Yes ☑ No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competency of Staff reviewed and it was found that competency was contributory to the event.</td>
<td>Yes ☑ No ☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Look back: Has this type of SSE occurred in the past?</th>
<th>Yes ☑ No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was prior action plan reviewed?</td>
<td>Yes ☑ No ☐</td>
</tr>
</tbody>
</table>

## Corrective Action Plan

<table>
<thead>
<tr>
<th>Action Number</th>
<th>Action</th>
<th>Name of Responsible Person</th>
<th>Start Date</th>
<th>Complete Date</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Specific** – target a specific area for improvement.
- **Measurable** – quantify or at least suggest an indicator of progress.
- **Assignable** – specify who will do it.
- **Realistic** – specify what results can realistically be achieved, given available resources.
- **Time-related** – specify when the result(s) can be achieved.
Action Plans: Strength of Plans

Weaker

• Warnings and labels (watch out!)

• Training and Education (here is how you do it)

• Supervision (don’t do that)

• Procedure changes (instructions for doing it)

• Force functions (I won’t let you do that)

• Eliminate any way to do it any different (there is one way to do it)

Stronger
Accountability

• Designate people in charge
• Dates of completion

• Measure
  – process
  – outcomes
  – audit

• Report to leadership and/or boards
Systematic Transparency
Error Disclosure
Transparency
Patient Disclosure Program

• Disclosure
  – Complete and honest communication with patients after an unexpected medical event
  – Patients want to know:
    • An explicit statement that an error occurred
    • What the error was
    • Why the error happened
    • How recurrences will be prevented
    • An apology

• Barriers
  – Unease, Fear of litigation, Culture of blame

• CLEAR program: Communication Leads to EARly Resolution
Patient Disclosure Program

- **Components (“Protocol”)**
  - **CLEAR** program: *Communication Leads to Early Resolution*
  - **Endorsement** of liability carriers ($ credits?)
  - **Trigger** events; “just in time”
  - **Response team**
    - nurse manager
    - obstetrician leader
    - risk management
    - disclosure coach
    - patient relations
    - social work, pastoral care
  - **Training** (Simulations)
    - scenarios
    - unknown, unpreventable
    - known/inappropriate causes

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**SPIKES – A Framework**

| S – “Set up” | • Brief. Prepare yourself and the team. Assess emotional readiness. Determine what is known and not known. • Ensure privacy, involve significant others, sit down, connect, manage time constraints. |
| P – “Perceptions” | • Assess Patient’s perceptions |
| I – “Invitation” | • Obtain the Patient’s invitation |
| S – “Strategy” | • Include steps you will take to avoid this in future. Invite questions. Make follow up plan together. Document. |
Systematic Emotional Support
Critical Incident Debriefing
Debriefing

Goal 1

1. **Exploratory fact-finding**
   - Assist future event review, root cause analysis

Goal 2

1. **Processing and sharing** feelings/emotions;
   - Educate about stress reactions and how to cope;
   - Normalize these stress reactions;
   - Provide information about and opportunities for further intervention if needed.

Modified from Gray, et al. 2006
Goal 1: Reduce Recurrence

Debriefing (Fact Finding)

- Root Cause Analysis
- Corrective Action Plan
- Failure Modes and Effects Analysis
Critical Event Debriefing

• Critical incident stress management (CISM)
  – **Diffusing** (immediately)
    • informal, to address immediate needs
    • normalize feelings
    • extend lines of assistance
  – **Debriefing** (within 72 hours)
    • more official gathering; formal model
  – **Follow-up** (one week later)
    • check-in (often 1:1)

• **Separate** from root cause or event analysis

**Diffuse**  **Debrief**  **Follow-up**
Thank You

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