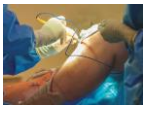
AHC Media

January 20, 2016

TJC Sentinel Event Policy, Patient Safety Systems & CMS RCA Requirements



Speaker

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- Dublin, Ohio 43017
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- sdill1@columbus.rr.com

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Objectives

- Describe The Joint Commission sentinel event policy.
- Describe the patient safety system with its goal to help improve quality of care.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

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CMS Hospital CoPs on Patient Safety Tracer and RCA Requirements

Patient Safety AE and Medical Errors

- CMS has a section on patient safety that discusses adverse events (AE) and medical errors
- This is found in the final QAPI Worksheet and in QAPI section of hospital CoP Manual Tag 286
- This part is to evaluate the hospital's leadership expectation for patient safety
- Is there staff training or communications related to expectation for patient safety to all staff?
- Is there a P&P on non-punitive approach to staff reporting medical errors which includes near misses?

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CoP Manual Also Called SOM

State Operations Manual
Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

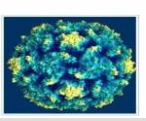
Table of Contents
(Rev. 151, 11-20-15)

Transmittals for Appendix A

Survey Protocol

Introduction
- Task 1 - Off-Site Survey Preparation
- Task 2 - Entrance Activities
- Task 3 - Information Gathering/Investigation
- Task 4 - Preliminary Decision Making and Analysis of Findings
- Task 5 - Exit Conference
- Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module
Inpatient Rehabilitation Unit Survey Module
Hospital Swing-Bed Survey Module
Regulations and Interpretive Guidelines



www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.p

Email questions **hospitalscg@cms.hhs.gov**

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CMS Manual Tag 286 Patient Safety

A-0286
(Rev. 105, Issued: 03-21-14, Effective: 03-21-14, Implementation: 03-21-14)

Patient Safety, Medical Errors & Adverse Events

§§482.21(a)(1), 482.21(a)(2), 482.21(c)(2), & 482.21(e)(3)

§482.21(a) Standard: Program Scope.

(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will … identify and reduce medical errors.

(2) The hospital must measure, analyze, and track…adverse patient events….

§482.21(c) Standard: Program Activities…

(2) Performance improvement activities must track medical errors and adverse

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Final QAPI Worksheet

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

REF: S&C: 15-12-Hospital

DATE: November 26, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Public Release of Three Hospital Surveyor Worksheets

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

Memorandum Summary

- ***Three Hospital Surveyor Worksheets Finalized:*** The Centers for Medicare & Medicaid Services (CMS) has finalized surveyor worksheets for assessing compliance with three Medicare hospital Conditions of Participation (CoPs): Quality Assessment and Performance Improvement (QAPI), Infection Control, and Discharge Planning. The worksheets are used by State and Federal surveyors on all survey activity in hospitals when assessing compliance with any of these three CoPs.
- ***Final Worksheets Made Public:*** Via this memorandum we are making the worksheets publicly available. The hospital industry is encouraged, but not required, to use the worksheets as part of their self-assessment tools to promote quality and patient safety.

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QAPI Patient Safety AE and Medical Errors

- Can staff on each unit explain hospital's expectation for their role in promoting patient safety? (286)
- Is there widespread staff training related to expectation for patient safety?
- Training related to what steps to take in situation that feels unsafe
- Is there a systematic process to identify medical errors which include near misses and AEs?
- On every unit, can the staff describe what is a medical error or near miss?

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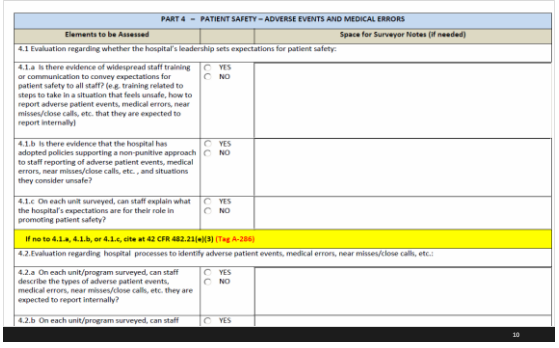
Patient Safety LD, AE and Medical Error



PART 4 – PATIENT SAFETY – ADVERSE EVENTS AND MEDICAL ERRORS		
Elements to be Assessed		**Space for Surveyor Notes (if needed)**
4.1 Evaluation regarding whether the hospital's leadership sets expectations for patient safety:		
4.1.a Is there evidence of widespread staff training or communication to convey expectations for patient safety to all staff? (e.g. training related to steps to take in a situation that feels unsafe, how to report adverse patient events, medical errors, near misses/close calls, etc. that they are expected to report internally)	○ YES ○ NO	
4.1.b Is there evidence that the hospital has adopted policies supporting a non-punitive approach to staff reporting of adverse patient events, medical errors, near misses/close calls, etc. , and situations they consider unsafe?	○ YES ○ NO	
4.1.c On each unit surveyed, can staff explain what the hospital's expectations are for their role in promoting patient safety?	○ YES ○ NO	
If no to 4.1.a, 4.1.b, or 4.1.c, cite at 42 CFR 482.21(e)(3) (Tag A-286)		
4.2.Evaluation regarding hospital processes to identify adverse patient events, medical errors, near misses/close calls, etc.:		
4.2.a On each unit/program surveyed, can staff describe the types of adverse patient events, medical errors, near misses/close calls, etc. they are expected to report internally?	○ YES ○ NO	
4.2.b On each unit/program surveyed, can staff	○ YES	

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QAPI Patient Safety AE and Medical Errors

- Can they explain how to report? (286)
  - How do they report?
    - Phone report, incident report, communicate to supervisor etc.
  - Who do they report it to?
    - Manager, risk manager, physician, pharmacist etc.
- Does the staff know what needs to be reported internally?
  - ADEs, medical errors, near misses and unsafe situations
- Does hospital employ other methods to find medical errors such as trigger tools, chart reviews, review of claims, patient grievances, interview patients etc

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QAPI Patient Safety AE and Medical Errors

- Can hospital provide evidence of medical errors and AEs identified through staff reports? (286)
- Is there a PI program with the infection preventionist (IP) to track avoidable HAI?
  - IC section requires this and starts at tag 747
- Are problems identified by the IP addressed through QAPI activities? (756 or 286)
- Does the PI program track medication errors and ADE and drug incompatibilities
  - Tag 508 requires this

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QAPI Patient Safety AE and Medical Errors

- Is there a process to report blood transfusion reaction and determine if due to medical error? (286 and 410)
  - Must be reviewed to identify if an medical error
- Did the survey team have prior knowledge of any serious AE that the hospital failed to identify? (286)
  - Were any identified by the surveyors?
- Has a RCA or QAPI review been done on all serious preventable AEs? (286)
  - Sample all serious preventable events identified in the past 12 months

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PI Causal Analysis Tracers Part 5

- The next question discuss the causal analysis tracers (RCAs) or patient safety tracers
  - Causal analysis searches for the cause and effect or causes of the particular event or adverse outcome
  - More commonly referred to as a RCA or root cause analysis
  - CMS calls it QAPI reviews
- The surveyor (not the hospital) will select **three** causal analysis done for single event or near miss during the last 12 to 24 months (286)
- Were underlying causes identified?

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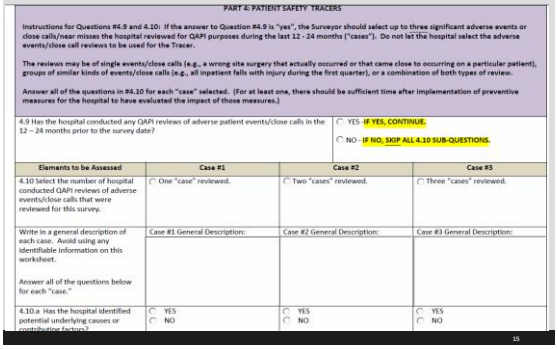
Causal Analysis Tracers



PART 4: PATIENT SAFETY TRACERS

Instructions for Questions #4.9 and 4.10: If the answer to Question #4.9 is "yes", the Surveyor should select up to three significant adverse events or close calls/near misses the hospital reviewed for QAPI purposes during the last 12 - 24 months ("cases"). Do not let the hospital select the adverse events/close call reviews to be used for the Tracer.

The reviews may be of single events/close calls (e.g., a wrong site surgery that actually occurred or that came close to occurring on a particular patient), groups of similar kinds of events/close calls (e.g., all inpatient falls with injury during the first quarter), or a combination of both types of review.

Answer all of the questions in #4.10 for each "case" selected. (For at least one, there should be sufficient time after implementation of preventive measures for the hospital to have evaluated the impact of those measures.)

4.9 Has the hospital conducted any QAPI reviews of adverse patient events/close calls in the 12 – 24 months prior to the survey date?	○ YES - IF YES, CONTINUE. ○ NO - IF NO, SKIP ALL 4.10 SUB-QUESTIONS.

Elements to be Assessed	Case #1	Case #2	Case #3
4.10 Select the number of hospital conducted QAPI reviews of adverse events/close calls that were reviewed for this survey.	○ One "case" reviewed.	○ Two "cases" reviewed.	○ Three "cases" reviewed.
Write in a general description of each case. Avoid using any identifiable information on this worksheet. Answer all of the questions below for each "case."	Case #1 General Description:	Case #2 General Description:	Case #3 General Description:
4.10.a Has the hospital identified potential underlying causes or contributing factors?	○ YES ○ NO	○ YES ○ NO	○ YES ○ NO

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QAPI Patient Safety Tracers

- Was preventive actions developed based on the RCA? (286)
  - TJC had a matrix which contains elements that must be included in a reviewable sentinel event and still useful even though removed in July 2015 edition
- Did the hospital identify any other departments utilizing similar processes that are at a similar risk? (286)
  - Alarm fatigue issue in ED, CCU, ICU, and telemetry
- Were preventive actions implemented in at least one area of the hospital? (286)

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QAPI Patient Safety Tracers

- Has the hospital evaluated the impact of the preventable actions including tracking a reoccurrences or near misses? (286)
- If the goals were not met did the hospital go back to the drawing board?
  - New patient fall tool used in the ED but staff did not have a culture of safety and not implementing actions
- Has the hospital implemented the preventable actions found to be effective unless there is a documented reason for not doing so? (286)

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CMS Issues Memo on AE

- CMS issued memo on adverse events that should be reported into the hospital QAPI program
- CMS suggests hospitals use the AHRQ Common Formats to track adverse events for PI
- Several reports show that nurses and others were not reporting adverse events and not getting into the QAPI system
- In fact, the OIG said that **86%** of the time adverse events are not reported

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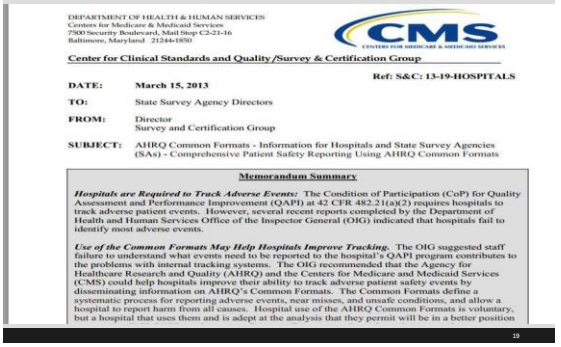
Report Adverse Events to PI



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-19-HOSPITALS

DATE: March 15, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: AHRQ Common Formats - Information for Hospitals and State Survey Agencies (SAs) - Comprehensive Patient Safety Reporting Using AHRQ Common Formats

Memorandum Summary

Hospitals are Required to Track Adverse Events: The Condition of Participation (CoP) for Quality Assessment and Performance Improvement (QAPI) at 42 CFR 482.21(a)(2) requires hospitals to track adverse patient events. However, several recent reports completed by the Department of Health and Human Services Office of the Inspector General (OIG) indicated that hospitals fail to identify most adverse events.

Use of the Common Formats May Help Hospitals Improve Tracking. The OIG suggested staff failure to understand what events need to be reported to the hospital's QAPI program contributes to the problems with internal tracking systems. The OIG recommended that the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services (CMS) could help hospitals improve their ability to track adverse patient safety events by disseminating information on AHRQ's Common Formats. The Common Formats define a systematic process for reporting adverse events, near misses, and unsafe conditions, and allow a hospital to report harm from all causes. Hospital use of the AHRQ Common Formats is voluntary, but a hospital that uses them and is adept at the analysis that they permit will be in a better position

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Adverse Event Reporting

- Hospitals are required to track AE (adverse events)
- OIG recommends using the AHRQ common formats to help with the tracking
- States could help hospitals improve the reporting process
- Encouraged all CMS hospital surveyors to develop an understanding of this tool
- So hospitals should be familiar with this tool and are encouraged to use it

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Adverse Event Reporting

- IOM (National Academy of Medicine) report discussed the need for comprehensive patient safety reporting to address the alarming high incidence of AE occurring in hospitals (Pg. 2)
- OIG report November, 2010 "AE in Hospitals: National Incidence Among Medicare Beneficiaries" encouraged internal reporting of all AE, whether preventable or not
- OIG issues report in January 2012 "Hospital Incident Reporting Systems Do Not Capture Most Patient Harm"
  - 86% of AE are never reported to the PI program
  - 44% are considered preventable

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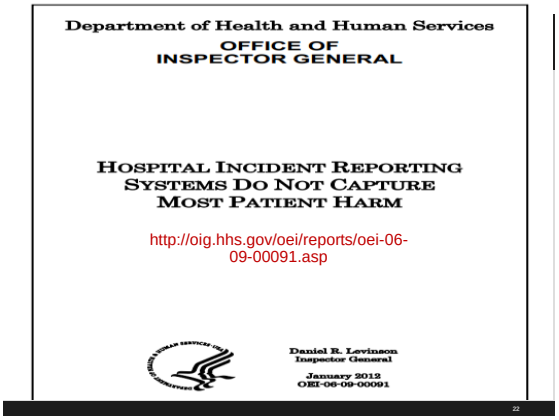

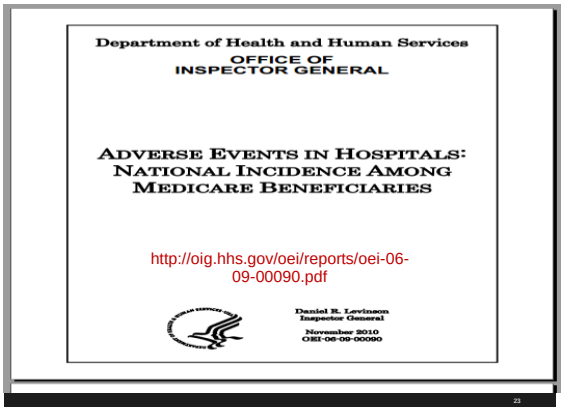

Adverse Event Reporting

- CMS PI section requires hospital to track AEs and analyze the causes and implement actions to prevent in the future
- Need to include near misses
- The internal hospital reporting system represents a foundational capability to determine if the hospital can maintain compliance with the CoPs
- The AHRQ Common Formats are evidenced based
- Common Formats allow for identification and reporting of any AE even if rare and includes NQF 29 never events such as falls and medication errors

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Events That Should be Reported

Event Category[7]	Examples of event occurrences
Event was an expected outcome or side effect	Thrush
Event caused little harm and/or harm was ameliorated	Hypoglycemia treated with orange juice (glucose)
Event was not on the hospital mandatory reporting list	Patient given wrong medication, but no harm; Reporting of Stage 2 pressure ulcers is not mandated in some states.
Event occurs frequently in hospitals	Medication given late; falls
Event symptoms became apparent after discharge	VTE diagnosed 10 days after discharge; Surgical Site infection 3 weeks after pacemaker implant.
Event occurred in a patient with a history of similar events	Falls, Stage 1 or 2 pressure ulcers
Events not caused by a perceptible error	Postoperative illeus (severe, lasting more than six days) Constipation after narcotics Adverse reaction (rash) to a medication the patient was not known to be allergic to

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9 Modules in the Common Formats

1. Blood or Blood Product
2. Device or Medical/Surgical Supply, including Health Information Technology (HIT)
3. Fall
4. Healthcare-associated Infection
5. Medication or Other Substance
6. Perinatal
7. Pressure Ulcer
8. Surgery or Anesthesia
9. Venous Thromboembolism
10. Other (allows collection of information on all other types of events)

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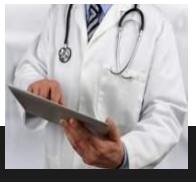
TJC Sentinel Event Policy

Sentinel Evert Alerts, Quick Safety and RCA Framework



TJC Sentinel Event Policy

- Both the TJC sentinel event (SE) policy and the patient safety system (PSS) chapter are designed to be used together
  - These taken together are intended to improve patient safety and enhance quality
- They are intended to reduce variation and risk
- The SE policy is to be used when the hospital or facility has a serious patient safety event
- It is intended to prevent future reoccurrences
  - TJC SE Hotline number is 630 792-3700 which is the Office of Quality and Patient Safety

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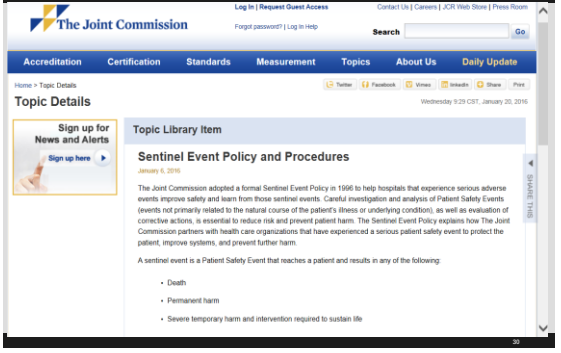
TJC Sentinel Event Policy



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Sentinel Event Policy and Procedures

Sentinel Events (SE)

www.jointcommission.org/assets/1/6/CAMH24_SE_all_CURRENT.pdf

I. Sentinel Events

The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help hospitals that experience serious adverse events improve safety and learn from those sentinel events. Careful investigation and analysis of patient safety events, as well as strong corrective actions that provide effective and sustained system improvement, is essential to reduce risk and prevent patient harm. The Sentinel Event Policy explains how The Joint Commission partners with hospitals that have experienced a serious patient safety event to protect the patient, improve systems, and prevent further harm.

Definition of Sentinel Event

A sentinel event is a 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 any of the following:

- Death
- Permanent harm
- Severe temporary harm'

An event is also considered sentinel if it is one of the following:

- Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital's emergency department (ED)
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, and services

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Sentinel Event Policy and Procedures

- TJC has had a SE policy since 1996
  - It has been amended many times since including changes July 1, 2015 and January 6, 2016
  - Implementing the policy can help hospitals improve safety by getting the root cause of the problem and fixing it by taking correction actions so it doesn't happen again
- A **sentinel event** is a Patient Safety Event that reaches the patient and can result in death, permanent harm, or severe temporary harm and intervention required to sustain life
  - Not primarily related to the natural course of the illness
  - SE is a subcategory of adverse events (AEs)

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What Does Severe Temporary Harm Mean?

- Severe Temporary Harm means:
  - Potentially life threatening harm
  - Lasts for a limited time with no permanent residual
  - Patient was transferred to a higher level of care such as transfer to the ICU
  - Could include additional major surgery
- **Adapted from:** Throop C, Stockmeier C. ***The HPI*** *SEC & SSER Patient Safety Measurement System for Healthcare. 2011 May. Accessed Aug 12, 2014.* http://hpiresults.com/publications/

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Sentinel Event Policy and Procedures

- They are called “sentinel” because the hospital or facility needs to do an immediate investigation into the matter and response
- TJC has a patient safety expert in the SE unit of the Office of Quality and Patient Safety that can be contacted for assistance
- TJC has sentinel event policy and procedure that differ according to the type of facility
- Hospital SE P&P is 20 pages long and amended in 2015 and 2016
  - Sentinel event differs by accreditation program

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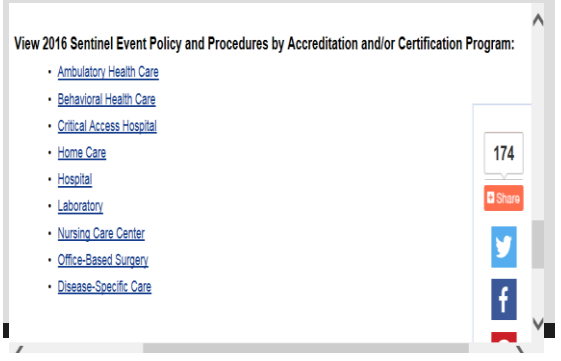
TJC SE Policy by Accreditation Program



Goals of the Sentinel Event Policy

- Improve patient care and prevent harm
- Understand the factors that caused the event
  - Changing the culture and system so it doesn’t happen again
  - What factors contributed to it such as active failures and latent conditions
- Increase knowledge about patient safety event, what caused them and how to prevent
- Maintain confidence of staff, clinicians and the public that patient safety is a priority of the hospital

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What is a Latent or Active Failure?

- The Reason's Model of Safety classified errors as either **active failures** or **latent conditions**
- Numerous studies show the impact of human error on patient safety
- Famous Harvard Medical Practice Study found that 69% of injuries were caused by human error
- **Active failures** are those errors made by those who provide direct care to the patient such as nurses and physicians

Active Failure or the Sharp End

- Active errors occur at the point of contact between a human and some aspect of a larger system (human-machine interface)
  - Like ignoring warning light or pushing an incorrect button
- Active failures are difficult to predict and are sometimes referred to as the "sharp end"
- Errors that happen at the sharp end are noticed first because they are committed by the person closest to the patient
- Nurse giving wrong dose of heparin to 6 babies or programming the IV pump incorrectly

Latent Failure or the Blunt End

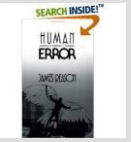
- Latent failure are those conditions which are present in the healthcare system and are less apparent
- The facility, equipment, and processes that **contribute** with the active failures to produce error or allowed them to happen
- Latent failures arise because of lack of standardization of equipment and processes
- Poor visibility, high noise levels and excessive movement of patients

Latent Errors

- **Latent errors** are also referred to as the "**blunt end**"
  - It is all the many layers of the health care system that affect the person holding the scalpel
- These are the less apparent failures of the organizational design that contribute to the error and allowed it to happen
- Pharmacy tech put wrong heparin in machine, pharmacist failed to catch it, look alike of labels, no bar coding technology etc.

Latent Errors

- Latent Errors could be caused by:
- Lack of computer warnings
- Ambiguous drug references
- Unclear policies and procedures
- Incomplete patient information such as missing allergy information or diagnosis,
- Latent errors called contributing errors or blunt end errors



Latent Failures or Blunt End

- Latent failures can be identified, unless active failures
- Can be remedied with safety barriers before they contribute to an adverse event
- In systems approach, error reduction is obtained by building barriers and safeguards into equipment and technology and processes

The Following are Sentinel Events

- If it is a sentinel event, then the hospital should do a through and credible RCA (RCA2 or systematic analysis)
- Based on available information TJC will determine if meets the definition of SE and includes
  - Inpatient suicide or suicide within 72 hours of discharge
  - Unanticipated death of a full-term infant
  - Discharge of an infant to the wrong family
  - Elopement that results in death or harm
  - Unintended retention of foreign object after procedure

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The Following are Sentinel Events

- Abduction of any patient
- Rape, assault, or homicide of patient, staff, visitor or vendor
- Wrong site, wrong patient or wrong procedure
- Severe neonatal hyperbilirubinemia
- Prolonged fluoroscopy of dose over 1,500 rads to a single field or radiotherapy to wrong body region
- Fire, flame, or unanticipated smoke
- Intrapartum maternal death or sever morbidity

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Sentinel Event Policy and Procedures

- The bottom line is if it is a sentinel event then the hospital needs to review it
- Appropriate response to a SE may include:
  - A team response to stabilize and take care of the patient
  - Notifying hospital leadership
  - Doing an immediate investigation and RCA (RCA2 or systematic analysis)
  - Implementing corrective actions so it wouldn't happen again

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Sentinel Event Policy and Procedures

- Sentinel events are one category of patient safety events
- A **patient safety event** is defined as a event, incident, or condition that could have or did result in patient harm
  - Could be from equipment failure (the ventilator), human error, or system breakdown
- Patient safety events include adverse events (AE), close calls (near misses or good catch), no-harm events, and hazardous or unsafe conditions
  - Falls, infant abductions, wrong site surgery, restraint injuries

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Sentinel Event Policy and Procedures

- TJC references LDS.04.04.05, EP 3, which addresses the hospital's patient safety program
- It discusses that the scope of the safety program and that it needs to include a full range of safety issues
- This includes from potential or near misses to hazardous conditions and sentinel events
- Program might include prevention of falls, medication errors, communication errors, health care associated infections, prevention of wrong site surgery, culture of safety, safe injection practices etc.

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LD.04.04.05 Patient Safety Program

- Standard: The hospital must have an integrated patient safety program within its PI activities
- The hospital leaders are responsible for implementing a hospitalwide patient safety program
- One or more people (like the patient safety officer) or a group must manage the safety program
- All departments and programs must participate in patient safety
  - Everyone has a role in patient safety

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LD.04.04.05 Patient Safety Program

- The leaders create procedures for responding to system or process failures
  - The process to identify and manage SEs need to be specified
  - Are appropriate individuals aware of the SE when it occurs?
  - Is the event investigated?
    - RCA , QAPI review or FMEA
  - Incident reporting form completed or reported into the QAPI system?

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Patient Safety Program Jan 2016

- The leaders encourage blame free reporting and understand the system analysis theory or the results of a proactive risk assessment (FMEA)
  - Most errors are made by long term employees with unblemished records
  - It is the failure of the system that allows the error to occur
  - It is not a blame and train mentality
  - Need to fix the system so it doesn't happen again
  - Need non-punitive environment to encourage reporting
  - Many hospitals balance this with Just Culture

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Patient Safety Program

- Blame free reporting
  - TJC added blame free (non-punitive environment) which is intended to get staff to report
  - You can't fix what you do not know is wrong
  - Does not conflict with holding individuals accountable for blameworthy errors
  - Many hospitals use the just culture theory
- The leaders define "patient safety event" and communicate this definition throughout the hospital

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LD.04.04.05 Patient Safety Program

- Must include the list of reviewable SEs
  - Should include near misses if could cause a serious adverse outcome
- Remember TJC does define this as previously discussed:
  - A **patient safety event** is defined as a event, incident, or condition that could have or did result in patient harm
  - Could be from equipment failure (the ventilator), human error, or system breakdown
  - Patient safety events include adverse events (AE), close calls (near misses or good catch), no-harm events, and hazardous or unsafe conditions

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LD.04.04.05 Patient Safety Program

- The hospital conducts a thorough and credible systematic analysis (like a RCA) when a SE occurs
  - The TJC SE policy describes in detail what is meant by both thorough and credible
- The leaders make support systems available for staff who have been involved in an AE or SE
  - This is known as the second victim
  - Staff who create an error are often devastated
  - Again most errors made by physicians and staff with unblemished records

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LD.04.04.05 Patient Safety Program

- Select one high-risk process and conduct a proactive risk assessment every 18 months
  - Example: hospital performs a FMEA to prevent blood transfusion reactions, patient identification, falls, medication errors, preventing surgical site infections etc.
- Hospital using information about system and process failure and the results of the proactive risk assessment to improve patient safety
  - Want to proactively assess risks to patients
  - And not just wait until a patient is injured to act
  - Many tools to help hospitals identify risk before it occurs such as simulation, SBAR, FMEA, model for improvement, or daily safety briefings

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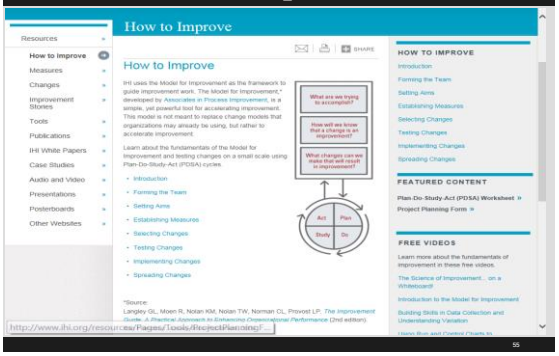
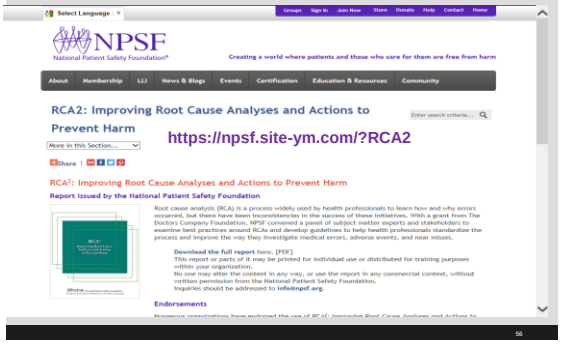
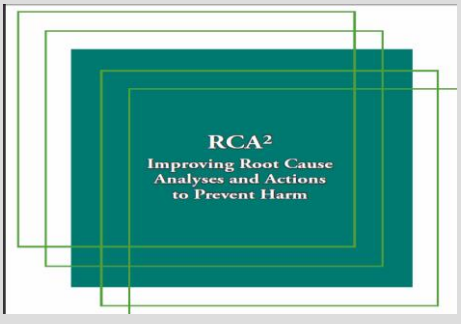
IHI Model for Improvement



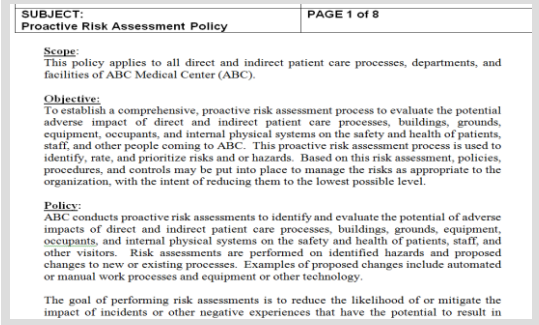
NPSF RCA2



RCA2 NPSF 51 Pages Jan 1 2016



Proactive Risk Assessment Policy



SUBJECT: Proactive Risk Assessment Policy	PAGE 1 of 8

Scope:
This policy applies to all direct and indirect patient care processes, departments, and facilities of ABC Medical Center (ABC).

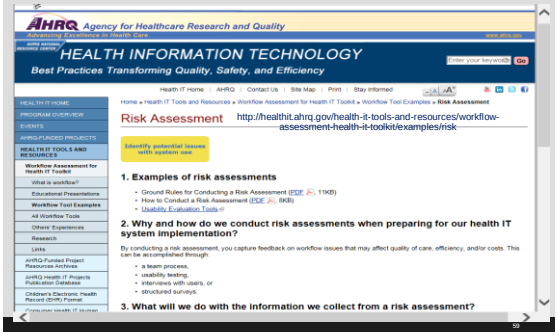
Objective:
To establish a comprehensive, proactive risk assessment process to evaluate the potential adverse impact of direct and indirect patient care processes, buildings, grounds, equipment, occupants, and internal physical systems on the safety and health of patients, staff, and other people coming to ABC. This proactive risk assessment process is used to identify, rate, and prioritize risks and or hazards. Based on this risk assessment, policies, procedures, and controls may be put into place to manage the risks as appropriate to the organization, with the intent of reducing them to the lowest possible level.

Policy:
ABC conducts proactive risk assessments to identify and evaluate the potential of adverse impacts of direct and indirect patient care processes, buildings, grounds, equipment, occupants, and internal physical systems on the safety and health of patients, staff, and other visitors. Risk assessments are performed on identified hazards and proposed changes to new or existing processes. Examples of proposed changes include automated or manual work processes and equipment or other technology.

The goal of performing risk assessments is to reduce the likelihood of or mitigate the impact of incidents or other negative experiences that have the potential to result in

58

AHRQ How to do a Risk Assessment



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LD.04.04.05 Patient Safety Program

- Leaders disseminate lessons learned
- Board is provided a written report once a year that include systems or process failures, number of sentinel events, and actions taken
  - Include number of distinct PI projects (DS)
  - Results of staffing analysis to determine if adequate
- The leaders encourage external reporting of significant adverse events
  - Including voluntary reporting such as FDA MedWatch

60

Other TJC Standards

- MS.05.01.01, EP 10, requires SE data and patient safety data be used to improve quality and safety
- RI.01.02.01, EP 21, requires disclosure of unanticipated outcomes related to SEs
- RI.01.02.01, EP 22 requires the LIP who is responsible for the patient's care to inform them if patient is not aware
  - Telling the patient- consider having trained disclosure coaches-ASHRM has four great resources

61

System Analysis Approach

- The systems analysis approach recognized that most errors occur because the system is defective
  - Example: A nurse is interrupted 19 times when trying to pass medications
- When SE occurs, need to identify the factors that caused the problem
  - Factors known to contribute to errors include distractions, workload increase, inexperienced or insufficient staff, shift change, inadequate patient information, poor lighting etc.
- A RCA focuses on systems and processes
- A hospital can use other tools as appropriate

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System Analysis Approach

- TJC has a Patient Safety Specialist to assist or contact the SE unit at 630 792-3700
- Case In Point: A hospital has three different types of IV pumps. A nurse comes to work one day to find a new pump on which she has received no education. The pump is not properly programmed and the patient gets too much Lidocaine and codes.
- Is this a bad nurse or a bad system?
- CMS does not allow more than 1 or 2 different types of IV pumps, why was a nurse not educated on new equipment, etc.

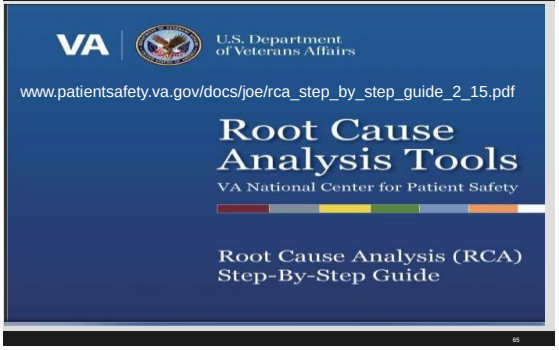
63

Action Plan

- Action plan identifies strategies or corrective actions that the facility needs to do to reduce risk of similar events reoccurring
  - Eliminate or **control system hazards** or vulnerabilities
- Plan should address responsibility for implementing, and time lines for completion
- Should include strategies to measure how effective it is working and how to maintain the change
  - Example of medication error: chemo order double checked, only use chemo certified nurses, pharmacist on oncology unit, CPOE with weight and dose mandatory, in-services, etc.

64

VA RCA Step by Step 7 Pages



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Reporting a SE

- Hospital must do a thorough and credible RCA within 45 days if a SE occurs
- Reporting to TJC is **not** required
  - Some hospital choose the legal option because of concerns that their state peer review protection will be lost
- TJC encourages reporting and discusses benefits of reporting
  - TJC can provide support and assistance
  - Reporting raises the level of transparency
  - Message to the public that hospital is doing everything to prevent it from reoccurring

66

Four Options

1. Take to TJC and take back with you (3%)
2. Meeting at hospital to review systematic analysis and action plan
3. On-site review but patient safety specialist will ask questions about process but will not review the actually RCA and action plan

- The above three can be done by web-based video conference
- There is a fee charged
- In 2014 20% RCA were shared via video conference

67

Four Options

4. On site visit and will ask questions about the process used
   - Will look at the relevant P&P
   - Specially trained surveyor
   - It is a standards based survey
   - Will ask sufficient questions to infer to determine that the hospital
   - Also referred to as the legal option

- Initial on-site review not done unless potential immediate threat to health or safety

68

Reporting a SE

- 77% of hospitals self report
- If hospital wants to self report, needs to complete a form which is accessible through its Joint Commission Connect extranet site
- Click on “Continuous Compliance Tools” and a drop down list will appear
- Select “Self Report Sentinel Event”
  - If TJC becomes aware of the SE that is not self-reported will contact the CEO or designee and will do a preliminary assessment and can ask for summary of processes

69

Required Response to a SE

- What are the SE expectations by TJC?
- Hospital must identify and respond to all SEs
- The hospital must review all SEs whether or not they are reported
- If TJC becomes aware of the reviewable SEs then hospital is expected to:
- Do a thorough and credible systematic analysis (RCA) and action plan
- It must be done within 45 business days of the event or of becoming aware of the SE

70

Systematic Analysis and Action Plan

- If reporting the SE then the hospital must include the systemic analysis (like a RCA) and action plan
- It needs to include the risk reduction strategies
  - A patient falls resulting in a severe cerebral bleed. The hospital implements a new falls program, staff are trained, a fall tool that is evidenced based is selected, hourly rounding, toileting, no pass zone, hospital hires a part time falls CNS to monitor program, audits on fall requirements are implemented, a falls team is put together, leadership supports falls program etc.
- It must include how effective these were
  - The hospital's fall rate went from 7.4 to 2.4 in six months with a reduction in falls with injuries and increased mobility

71

Systematic Analysis and Action Plan

- Recommendation to consider when developing causative factors:
- Clearly show cause and effect
- Use specific descriptors for what occurred and not negative or vague words
- Human errors must have a preceding cause
- Violations of procedures are not root causes
- Failure to act is only causal when there is preexisting duty to act

72

Through RCA (Systemic Analyses)

- Ask "why" to identify causal factors
- Focus on systems and processes and not on individual performance
- Look to see if due to human factors
- Identify risk points that contributed to the event
- Inquire into all areas appropriate to the specific type of event
  - Inquire into areas contained in the Matrix even though removed from policy in July of 2015
- Determine what to do to decrease likelihood if would occur again

73

Credible Systematic Analysis Includes

- Participation by senior leader and those most closely involved in the process and system under review
- Each action recommended should be approved or disapproved by the CEO or senior leader
- If action is disapproved then the reason should be shared with the team
- Include patients, family, or patient representative when appropriate to ensure clear understanding of what happened

74

Credible Systematic Analysis

- Be internally consistent and not leave obvious questions unanswered
- Explain findings marked N/A or no problem
- Include all relevant literature
- Eg. Ben Kolb case in Florida at Marten Memorial who died from a medication error after having an injection around the ear of concentrated Adrenaline instead of 1% Lidocaine with Epi

75

RCA Pick Your Tool

- Flow charts or flow diagrams
- Pareto charts
- Ishikawa diagrams (fishbone)
- Control charts
- Scatter plots
- Histograms
- Check sheets
- Contingency diagram

RCA Pick Your Tool

- Barrier analysis
- Change analysis
- Fault tree analysis
- Failure mode, effect, and critically analysis (FMEA)
- Reliability analysis
- Systemic approach to repetitive failure
- Process decision program chart (PDPC)

Acceptable Action Plan

- Identify changes to reduce risk or develop rational for not doing changes
- Recommended to identify actions that will prevent it from happening again
- Recommended to use a tool that will assist in identifying actions for improvement
- Teams should identify at least one strong action

78

Acceptable Action Plan

- Identify person responsible when improvements actions will be implemented
- Who will responsible to implement the plan
- How will the effectiveness of the actions be evaluated
- How will the actions be continued?

79

Follow -Up

- Be sure to be specific with time lines and who will be responsible for monitoring and follow-up
- After the systematic analysis and action plan are acceptable an acceptable follow up activity will be scheduled
- Will require a written follow-up report
  - There will be mutually agreed upon documentation to show the improvements are continued
  - Must show that risk is reduced
  - May include 1 or more SE Measures of Success (SE MOS)

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SE Database

- A goal of the SE policy is to increase knowledge about patient safety events, their causes, and how they can be prevented
- Lists the top problems and how often they have occurred
- Data used to draft SE Alerts
- Data used to develop and maintain NPSGs
- TJC periodically updates data
- A rich source of information for hospitals

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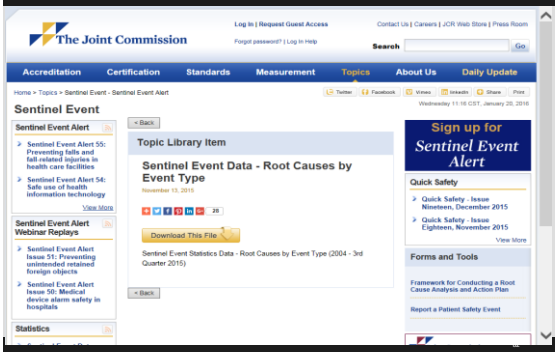
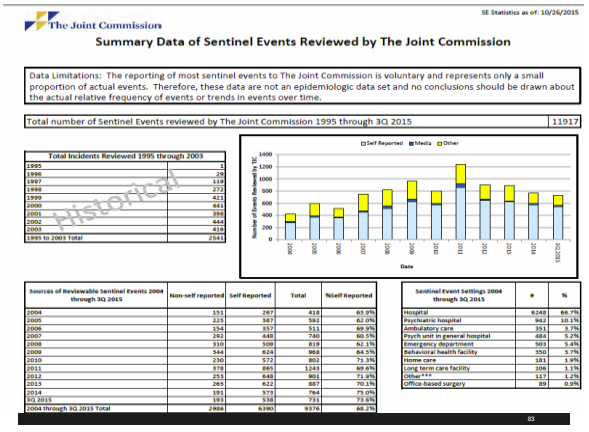
Sentinel Event Data is Periodically Updated





SE Database

- Includes number of SE reviewed since 1995
- However, data represents only a small proportion of actual events
  - Lists SE per hospital such as around 66.5%
- Lists the type of SE such as anesthesia related, delay in treatment, elopement, dialysis related, falls, infant abductions, infection related, medication error, post-operative complication, radiation overdose, suicide, perinatal injury, equipment related, fire, restraint related, etc.
  - Includes SE data, RCA by event type

84

Commonly Identified RCA Categories

- TJC has a detailed list of commonly identified root cause categories and assess when doing a RCA
- For example:
- **Assessment;** adequacy, timing, scope of assessment, care decisions, etc.
- **Care planning**: planning or collaboration
- **Communication:** oral, written, electronic, among staff, patients, administration or family
- **Human Factor:** staff levels, orientation, in-service education, competency, supervision, etc.

85

Charts to Show Root Causes

Root Cause Information for Wrong-patient, Wrong-site, Wrong-procedure Events Reviewed by The Joint Commission

(Regardless of the magnitude of the procedure)

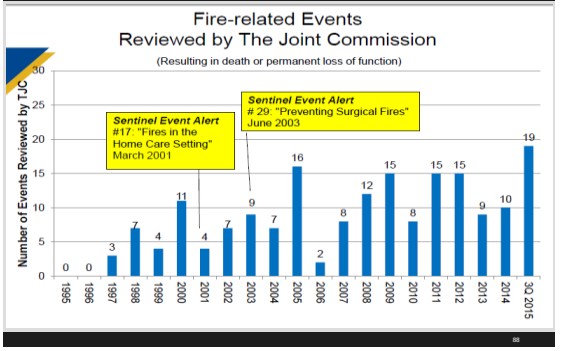
2004 through 3Q 2015 (N=1196) *The majority of events have multiple root causes*	
Leadership	1635
Human Factors	1313
Communication	1298
Assessment	504
Information Management	489
Operative Care	394
Physical Environment	124
Patient Rights	72
Anesthesia Care	64
Continuum of Care	44

Commonly Identified RCA Categories

- Has charts to show what were the most common root cause for many of the SE such as falls, medication errors, wrong site surgery, ventilator related, retained surgical items, etc.
  - Common ones are human factors, leadership, assessment, communication, PI, physical environment, information management, continuum of care, care planning
- Also has charts to show the number of SE by year including falls, medication errors, abduction, anesthesia related, delay in treatment, elopement, fire related, hyperbilirubinemia, infection related, drug overdose, maternal events, etc.

87

Charts with Number of Events per Year



88

Most Common SEs

- Retained foreign body (most common)
- Fall
- Suicide
- Delay in treatment
- Wrong site surgery
- Post-operative complications
- Criminal event
- Perinatal event and medication error

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Sentinel Events

- If TJC receives an inquiry the hospital's current accreditation status will be reported without referencing the SE
- If the inquirer references the SE then TJC will acknowledge they are aware of and are working with the hospital through the SE review process
- If TJC feels the systematic analysis and action plan is adequate will notify the hospital
  - RCA is the most common systematic analysis
  - Will assign agreed upon measure to make sure improvement is sustained such as SE MOS

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Sentinel Events

- Board of Commissioners are responsible for oversight and approval of the SE policy
- TJC periodically audits the RCAs and follow-up activities
- Data is provided to the Board and the Accreditation Committee
- During the survey process, surveyors are instructed not to search for or investigate SE
- Surveyors are not to inquire if a SE has been reported to TJC

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Discovery of a Sentinel Event

- If a surveyor discovers a potentially serious patient safety event during a survey, the surveyor should
  - Notify the CEO
  - Report the issue to TJC for further review and follow-up
  - Surveyor is not to determine if SE and is not authorized to investigate
  - Rather, staff in the SE Unit or Office of Quality and Patient Safety will follow
  - They will determine if submission of RCA is needed

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Minimum Scope of RCA for Specific SEs

- TJC use to have in the SE policy a section on the minimum scope of RCA analysis for specific types of sentinel events
- This is **not** in the 2016 TJC SE policy
- However, many hospitals may still find the matrix helpful when performing a RCA on these types of sentinel events
  - For example if patient dies from a fall it lists the areas that should be evaluated such as was a proper assessment done, were there adequate staffing levels, was staff oriented to the falls program, etc.

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Table 3. Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events

Detailed inquiry into these areas is expected when conducting a root cause analysis for the specified type of sentinel event. Inquiry into areas not checked (or listed) should be conducted as appropriate to the specific event under review.

	TYPES OF SENTINEL EVENTS												
Areas of Potential Root Causes	Suicide (24-Hour Care)	Medication Error	Procedural Complication	Wrong-Site Surgery	Treatment Delay	Restraint Death	Elopement Death	Assault/Rape/Homicide	Transfusion Death	Patient Abduction	Unanticipated Death of Full-Term Infant	Unintended Retention of Foreign Body	Fall Related
Behavioral assessment process[‡‡]	X					X	X	X					
Physical assessment process[§§]	X	X	X	X	X	X	X				X		X
Individual identification process		X		X					X				
Individual observation procedures	X				X	X	X	X	X		X		X
Care planning process	X		X			X	X				X		X
Continuum of care	X	X			X	X							X
Staffing levels	X	X	X	X	X	X	X	X	X	X		X	X
Orientation and training of staff	X	X	X	X	X	X	X	X	X	X	X	X	X

continued on next page

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SE POLICY 2015 actual one.pdf - Adobe Reader

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Table 3. *(continued)*

	TYPES OF SENTINEL EVENTS												
Areas of Potential Root Causes	Suicide (24-Hour Care)	Medication Error	Procedural Complication	Wrong-Site Surgery	Treatment Delay	Restraint Death	Elopement Death	Assault/Rape/Homicide	Transfusion Reaction	Patient Abduction	Unanticipated Death of Full-Term Infant	Unintended Retention of Foreign Body	Fall Related
Competency assessment/credentialing	X	X	X	X	X	X	X	X	X	X	X	X	X
Supervision of staff[§§]	X	X	X		X	X			X			X	
Communication with individual/family	X	X		X	X	X	X			X			X
Communication among staff members	X	X	X	X	X	X	X	X	X	X	X	X	X
Availability of information	X	X	X	X	X	X			X		X		X
Adequacy of technological support		X	X										
Equipment maintenance/management		X	X		X	X					X		X
Physical environment[‡‡]	X	X	X	X		X	X	X	X	X			X
Security systems and processes	X					X	X	X		X			
Medication management[¶¶]		X	X		X				X		X		X

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95

TJC Framework for Conducting a RCA

- TJC has a framework for conducting a RCA that hospitals can use if they have a sentinel event
- It is an 11 page document and free off the TJC website
- The RCA and action plan tool has 24 analysis questions
- Not all questions may be applicable to the case under review so answer the ones that are relevant
- Continue to ask “why” and drill down further
  - Why did it contribute to the event occuring

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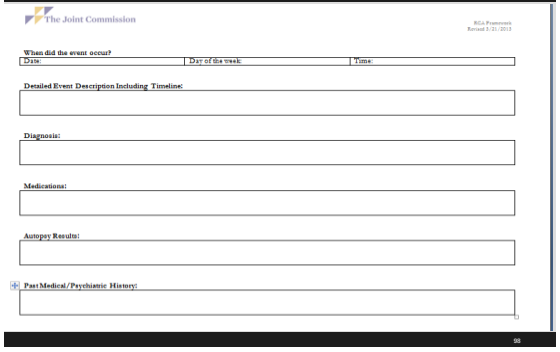
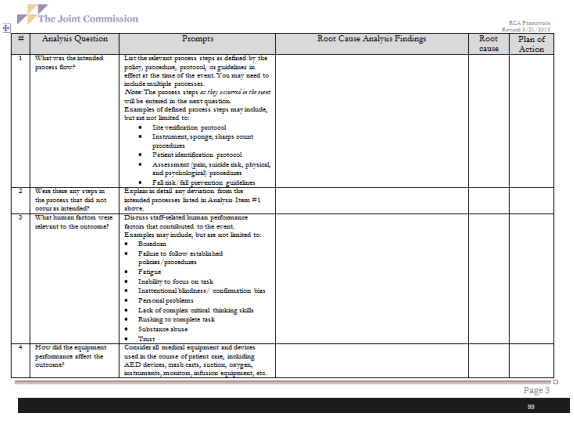
TJC Framework for Conducting a RCA

TJC 11 Page RCA Framework





TJC Framework for Conducting a RCA

- The plan of action is what the hospital is going to fix the problem
- Answer "yes" on the plan of action section for any action that can be considered a risk reduction strategy
  - For example; a patient dies in a fall and hospital implements many actions such as rewrites policy that is shown to implement correct interventions to prevent falls, implements toileting in high risk patients, conducts hourly rounding during the day and evening, trains staff, audits charts, hires a part time CNS to monitor program, puts together a falls team, etc.

100

TJC Framework for Conducting a RCA

- The form asks basis questions such as date of event, diagnosis, medications, autopsy reports, past medical and psychiatric history and a detailed description of the event
- Analysis questions include:
  - What was the intended flow process?
  - Were there any steps in the process did not occur as intended?
  - What human factors were relevant to the outcome?
  - Were there any equipment failures that effected the outcome?

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TJC Framework for Conducting a RCA

- Analysis questions include (continued):
  - Any controllable environmental factors such as didn't hear the over head pager when the code was called, any risks involving visitors such as visitors step out when epidural put in to prevent contamination, space issue such as in pharmacy error made since cramped corners in reviewing the pharmacy tech prepared solutions, poor lighting leading to a medication error
  - Where there any other factors that affected the outcome?
  - Are there other areas in the hospital where this could happen?
    - Patient dies when no one picks up the cardiac monitor is alarming

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TJC Framework for Conducting a RCA

- Analysis questions include (continued):
  - Was the staff properly qualified and competent?
    - Can orientation and inservice education be revised to reduce the risk this will happen again?
  - Was staffing an issue?
  - Was all the necessary information available when needed and was it adequate?
  - Were there any communication issues or barriers that contributed to the problem?
  - Does the hospital's culture support risk reduction?
  - Can technology be used to prevent this from reoccuring?

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TJC Sentinel Event Alerts

- Sign up to get copies at no cost for when SE alerts (SEAs) are issued
- Consider having a TJC Sentinel Event Committee that can meet after new ones are issued
- Hospital can add ad hoc members to join the committee based on the topic of the SEA
  - Example; SEA 54 on safe use of health information technology so probably want IS director involvement
- SE Committee can take the SE Alert and figure out how to implement in policies and what training needs to be to put the SEA into process and practice

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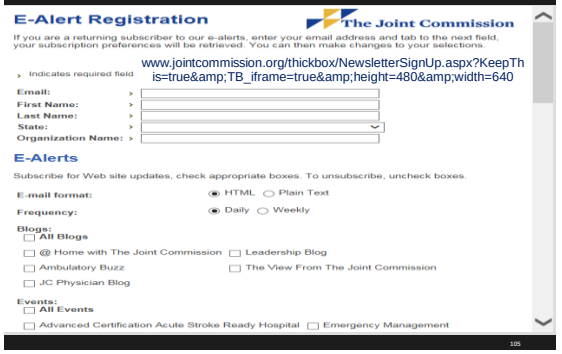
Sign Up to Get Free Sentinel Event Alerts



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TJC List of Sentinel Event Alerts

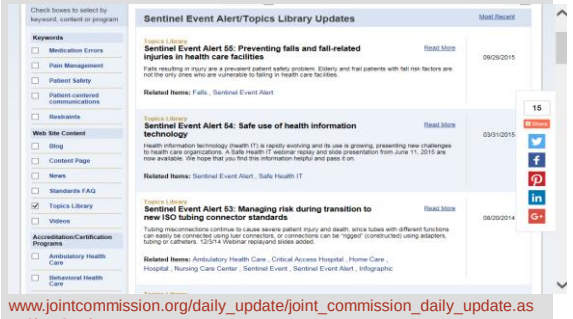
- TJC has a list of the sentinel event alerts which includes the following:
  - 55 Falls and Fall Related Injuries
  - 54 Safe Use of Health Information Technology
  - 53 Managing Risk with the Transition to the New ISO Tubing Connectors
  - 52 Safe Injection Practices Related to preventing infections from the Misuse of Vials
  - 51 Preventing Retained Surgical Items or FB
  - 50 Medical Device Alarm Safety in Hospitals
  - 49 Safe Opioid Use

106

www.jointcommission.org/daily_update/joint_commission_daily_update.aspx?k=721&b=&t=4

107

TJC List of Sentinel Event Alerts



www.jointcommission.org/daily_update/joint_commission_daily_update.aspx?k=721&b=&t=4

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TJC Quick Safety

- TJC has Quick Safety which is a monthly newsletter that addresses an issue of safety
- Just mark the "Quick Safety" box to receive it via email
  - 19 Alleviating ED Boarders of Psychiatric Patients
- Issue 14 addresses Obstructive Sleep Apnea (OSA)
  - Includes risk factors
  - Every patient who has surgery should be evaluated for OSA
  - Provides safety actions to consider

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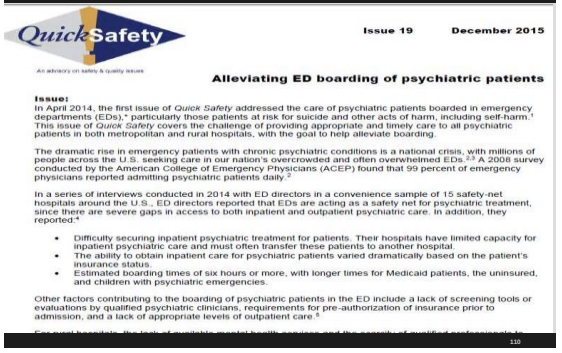
ED Boarding of Psychiatric Patients



QuickSafety

An advisory on safety & quality issues

Issue 19 December 2015

Alleviating ED boarding of psychiatric patients

Issue:

In April 2014, the first issue of *Quick Safety* addressed the care of psychiatric patients boarded in emergency departments (EDs),* particularly those patients at risk for suicide and other acts of harm, including self-harm.[1] This issue of *Quick Safety* covers the challenge of providing appropriate and timely care to all psychiatric patients in both metropolitan and rural hospitals, with the goal to help alleviate boarding.

The dramatic rise in emergency patients with chronic psychiatric conditions is a national crisis, with millions of people across the U.S. seeking care in our nation's overcrowded and often overwhelmed EDs.[2,3] A 2008 survey conducted by the American College of Emergency Physicians (ACEP) found that 99 percent of emergency physicians reported admitting psychiatric patients daily.[3]

In a series of interviews conducted in 2014 with ED directors in a convenience sample of 15 safety-net hospitals around the U.S., ED directors reported that EDs are acting as a safety net for psychiatric treatment, since there are severe gaps in access to both inpatient and outpatient psychiatric care. In addition, they reported:[4]

- Difficulty securing inpatient psychiatric treatment for patients. Their hospitals have limited capacity for inpatient psychiatric care and must often transfer these patients to another hospital.
- The ability to obtain inpatient care for psychiatric patients varied dramatically based on the patient's insurance status.
- Estimated boarding times of six hours or more, with longer times for Medicaid patients, the uninsured, and children with psychiatric emergencies.

Other factors contributing to the boarding of psychiatric patients in the ED include a lack of screening tools or evaluations by qualified psychiatric clinicians, requirements for pre-authorization of insurance prior to admission, and a lack of appropriate levels of outpatient care.[5]

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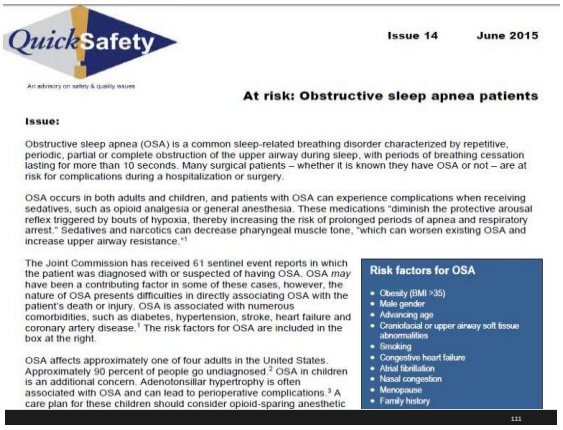

QuickSafety

An advisory on safety & quality issues

Issue 14 June 2015

At risk: Obstructive sleep apnea patients

Issue:

Obstructive sleep apnea (OSA) is a common sleep-related breathing disorder characterized by repetitive, periodic, partial or complete obstruction of the upper airway during sleep, with periods of breathing cessation lasting for more than 10 seconds. Many surgical patients – whether it is known they have OSA or not – are at risk for complications during a hospitalization or surgery.

OSA occurs in both adults and children, and patients with OSA can experience complications when receiving sedatives, such as opioid analgesia or general anesthesia. These medications "diminish the protective arousal reflex triggered by bouts of hypoxia, thereby increasing the risk of prolonged periods of apnea and respiratory arrest." Sedatives and narcotics can decrease pharyngeal muscle tone, "which can worsen existing OSA and increase upper airway resistance."[1]

The Joint Commission has received 61 sentinel event reports in which the patient was diagnosed with or suspected of having OSA. OSA *may* have been a contributing factor in some of these cases, however, the nature of OSA presents difficulties in directly associating OSA with the patient's death or injury. OSA is associated with numerous comorbidities, such as diabetes, hypertension, stroke, heart failure and coronary artery disease.[1] The risk factors for OSA are included in the box at the right.

Risk factors for OSA

- Obesity (BMI >35)
- Male gender
- Advancing age
- Craniofacial or upper airway soft tissue abnormalities
- Smoking
- Congestive heart failure
- Atrial fibrillation
- Nasal congestion
- Menopause
- Family history

OSA affects approximately one of four adults in the United States. Approximately 90 percent of people go undiagnosed.[2] OSA in children is an additional concern. Adenotonsillar hypertrophy is often associated with OSA and can lead to perioperative complications.[3] A care plan for these children should consider opioid-sparing anesthetic

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TJC Quick Safety

- Other Quick Safety Topics Include:
- Transcription Related to Voice Recognition Systems and Patient Risk for Injury
- CRE Superbug Reveals Challenges with High Level Disinfection
- Preventing Copy and Paste errors in EHR
- Preventing Delays in Treatment
- Power Morcellation for Gynecologic Surgery
- Preparing for Active Shooter

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TJC Quick Safety

- Other Quick Safety Topics Include:
- Potential Risks of Robotic Surgery
- Improperly Sterilized or High-Level Disinfected Equipment
- Care of Psychiatric Patients Boarded in the ED
- Preparing for EBOLA
- Reviewing Maternity Morbidity
- Preventing Violence and Criminal Events

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TJC Patient Safety Systems Chapter

TJC PS System Chapter

- TJC Patient Safety System (PS) chapter is 54 pages long
- New chapter effective January 1, 2015 and amended July 1, 2015 and January 1, 2016
  - Does not contain any new standards
- You can find this chapter by using the website on the next page, or in the hard copy of the manual immediately after the section on "How to Use This Manual"
- In E-dition it is located in the Accreditation Process Info section which is after the HM chapter

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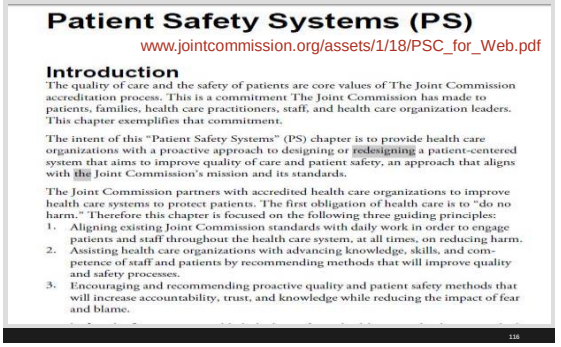
TJC PS System Chapter 2016



Patient Safety Systems (PS)

www.jointcommission.org/assets/1/18/PSC_for_Web.pdf

Introduction

The quality of care and the safety of patients are core values of The Joint Commission accreditation process. This is a commitment The Joint Commission has made to patients, families, health care practitioners, staff, and health care organization leaders. This chapter exemplifies that commitment.

The intent of this "Patient Safety Systems" (PS) chapter is to provide health care organizations with a proactive approach to designing or redesigning a patient-centered system that aims to improve quality of care and patient safety, an approach that aligns with the Joint Commission's mission and its standards.

The Joint Commission partners with accredited health care organizations to improve health care systems to protect patients. The first obligation of health care is to "do no harm." Therefore this chapter is focused on the following three guiding principles:

1. Aligning existing Joint Commission standards with daily work in order to engage patients and staff throughout the health care system, at all times, on reducing harm.
2. Assisting health care organizations with advancing knowledge, skills, and competence of staff and patients by recommending methods that will improve quality and safety processes.
3. Encouraging and recommending proactive quality and patient safety methods that will increase accountability, trust, and knowledge while reducing the impact of fear and blame.

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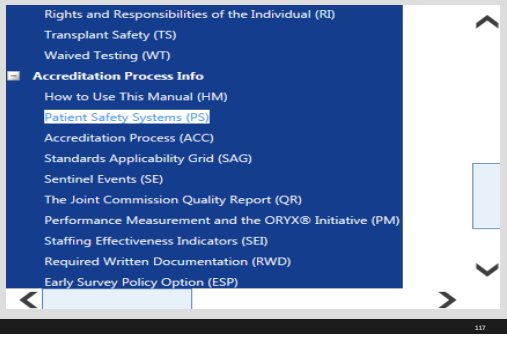
Where to Find in E-dition



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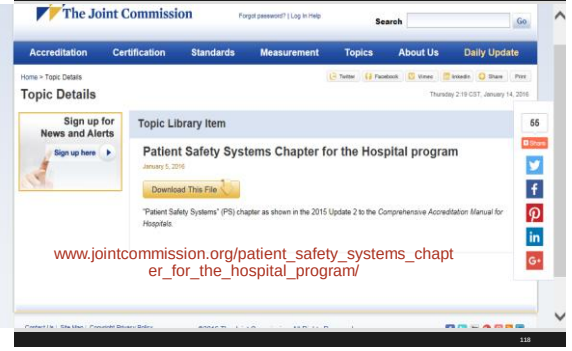
TJC Website for PS System Chapter



www.jointcommission.org/patient_safety_systems_chapter_for_the_hospital_program/

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TJC Patient Safety System Chapter

- Chapter describes how patient safety can be improved by using the existing standards
- Hospitals should have an integrated approach to patient safety so that everyone is working together
- Discussed LD.04.04.05 that requires the hospital to have an integrated patient safety program
  - This was previously discussed in detail
- Strategies discussed can help hospitals evaluate and enhance their system to prevent patient safety events

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TJC Patient Safety System Chapter

- Having a strong safety culture is imperative to have a successful patient safety system
- The intent of this chapter is to provide hospitals with a proactive approach to designing a patient centered system to improve quality and safety
  - The importance of being proactive instead of just reacting when something has occurred has been discussed previously
- Patient safety system includes standardized ways for team to communicate
- AHRQ has a tool to measure safety culture

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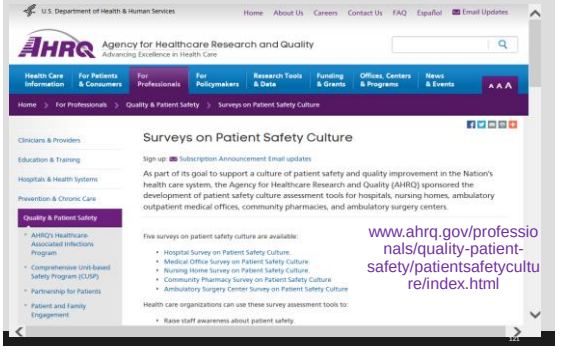
Hospital Survey on Patient Safety Culture



www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/index.html

TJC Patient Safety System Chapter

- Includes some key terms for hospitals to understand
  - **Patient safety event:** An event, incident, or condition that could have resulted or did result in harm to a patient.
  - **Adverse event:** A patient safety event that resulted in harm to a patient.
  - **Sentinel event**: A subcategory of Adverse Events, a Sentinel Event is a patient safety event (not primarily related to the natural course of the patient's illness or Death, Permanent harm or Severe temporary harm

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TJC Patient Safety System Chapter

- Includes some key terms for hospitals to understand:
  - **No-harm event**: A patient safety event that reaches the patient but does not cause harm.
  - **Close call** (or "near miss" or "good catch"): A patient safety event that did not reach the patient.
  - **Hazardous** (or "unsafe") **condition**(s): A circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event.

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Become a Learning Organization

- We need to learn from our mistakes
- A learning organization is defined as one in which people learn continuously, thereby enhancing their capabilities to create and innovate.
- Learning organizations uphold five principles: team learning, shared visions and goals, a shared mental model (similar ways of thinking), individual commitment to lifelong learning, and systems thinking
- Need non-punitive approach to reporting because we can't fix what we don't know is broke

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Role of Leaders in Patient Safety

- This discusses how leaders can provide the foundation for an effective patient safety system
- Can do this by promoting learning, motivating staff to have a fair and just culture, model professional behavior, remove intimidating behavior, and provide resources and training
- Many of the standards on hospital patient safety appear in the leadership chapter
  - Especially LD.04.04.04 on the hospital safety program
- Most initiatives require people to change their behavior (75 to 80%)

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Safety Culture

- Strong safety culture is needed for successful patient safety system
- Safety culture is discussed in LD.03.01.01
- A safety culture is the individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the hospital's commitment to quality and safety
- Have collective mindfulness where staff realize the system can fail and are focused on finding near misses or hazardous conditions before the patient is harmed

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Safety Culture

- A culture of safety is one in which staff feel comfortable disclosing
- Staff do not cover them up but report errors so we can learn from them
- In a safety culture, staff trust their that their coworkers and leaders will support them
- Hospital should promote a code of conduct and eliminate any intimidating and disrespectful behavior
  - No shaming others, profane language, no refusal to comply with acceptable standards of practice etc.

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Fair and Just Culture

- LD.04.04.05 mentions a blameless or non-punitive environment which hospitals need to adopt
- The balance to this is the just culture theory process
  - It takes into account that individuals are human and can make a mistake so don't just fire if a mistake is made
- However, there needs to be accountability and an individual who ignores all the safety rules and policies should be held accountable
- Mentions the UK National Patient Safety Agency's Decision Tree

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UK National Patient Safety Agency

http://www.npsa.nhs.uk

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Fair and Just Culture

- Ask if actions were intentional (deliberate harm test)
- Is there evidence of poor health or substance abuse?
- Did the person depart from agreed protocols and safe practices?
- Would another person in the same position have acted in the same way?
- David Marx is another one who talks about just culture and is a well known expert on this

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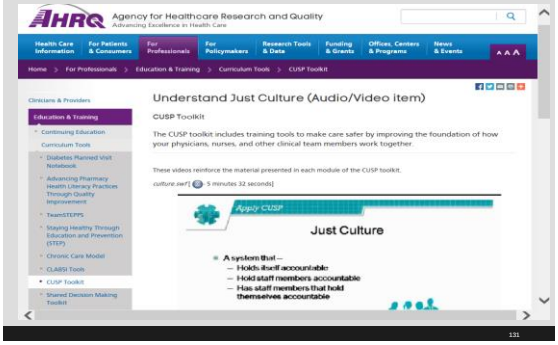
AHRQ Just Culture Resources



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Data Use and Reporting

- Discusses the importance of data collection, data analysis, and reporting
- Need a transparent and non-punitive approach to reporting so we can learn from the AEs, close calls and hazardous conditions
- Need to find out about if we want to institute change
- PI.01.01.01 requires the hospital to collect data to monitor how they are doing
- LD.03.02.01 says we use this data to make decisions and understand variations in performance

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Data Use and Reporting

- Mentions a number of standards that require data collection and analysis
  - Identify risks for getting and transmitting infections, evaluation medication management process, report restraint deaths, etc.
- We need data to determine if we have a problem or not
- Can use run charts, statistical processes charts, or capability charts to determine how the hospital is doing

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Proactive Approach to Preventing Harm

- A proactive approach prevents harm before it occurs
- Hospital can correct problems that could lead to error and patient harm
- Can use proactive risk assessment to determine where the system could fail
- Should look at high-risk and high-volume areas
- Risk assessment tools should be used from credible sources include the sentinel event alerts and nationally recognized assessment tools

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Proactive Approach to Preventing Harm

- FMEA is one tool
- The National Patient Safety Foundation has a 51 page book on RCA (RCA2)
- ISMP has a safe medication safety risk assessment
- Contingency diagram uses brainstorming to generate a list of problems that could arise from a variation
- Process decision program chart provide way of finding errors with a plan while it is being created

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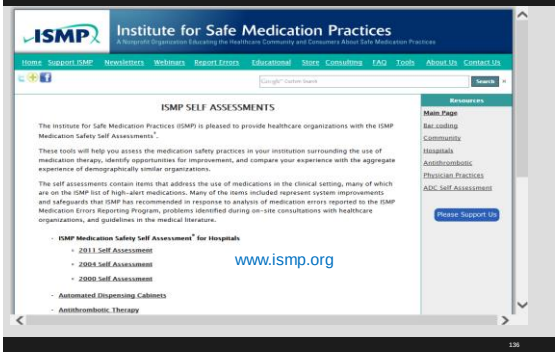
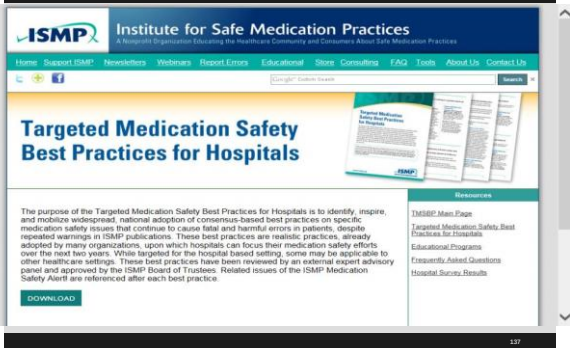
ISMP Medication Risk Assessment

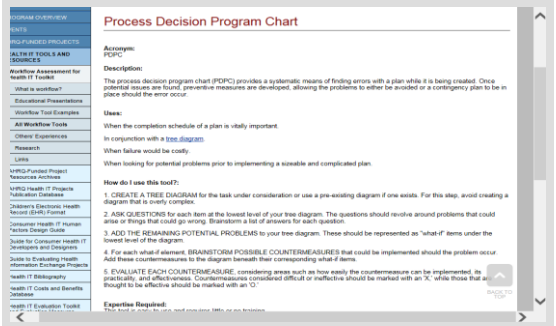


Also Has Targeted Best Practices



NPSF RCA 51 Page Tool

AHRQ Process Decision Program Chart



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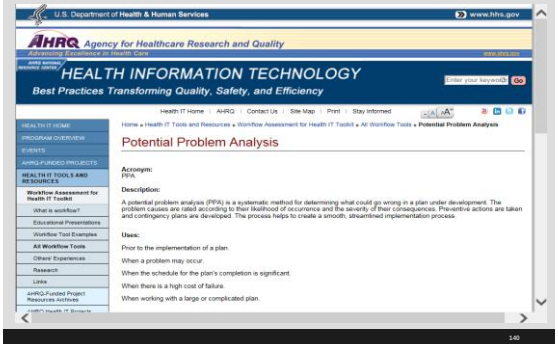
AHRQ Potential Problem Analysis



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Encourage Patient Activation

- Patients and families need to be more actively engaged in decisions about their care
- Activated or engaged patients are less likely to experience an adverse event or to have an unnecessary hospital readmission
- Consider adopting some principles:
  - Patients and families are partners at every level
  - Patient safety guides all decision making
  - Disclose unanticipated outcomes

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TJC is Your Patient Safety Partner

- TJC has many resources to help create high reliable patient safety systems
  - SE Unit
  - SE Hotline at 630 792-3700
    - Can tell you if patient safety event is a reviewable SE
    - Can discuss any aspect of the SE policy
  - Standards Interpretation Group or SIG
  - TJC Center for Transforming Healthcare

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TJC is Your Patient Safety Partner

- SE Alerts,
- NPSGs,
- Quick Safety Quick
- JC Resources,
- Speak Up Program
- Standards Booster Paks and Lending Library
- Appendix has a list of key patient safety requirements
- Reference list is also provided

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The End. Questions???

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