AHC Media

March 15, 2016

Hot Topics in Risk Management and Patient Safety

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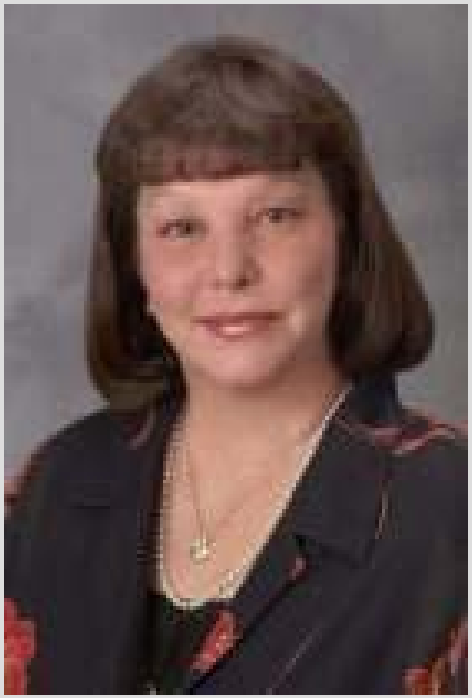
Speaker



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Objectives

- Describe the many changes to the hospital CoPs affecting patient safety.
- List the top 10 safety issues as dictated by the ERCI Institute.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

Introduction and the Faces of Patient Safety

Headlines About Patient Safety in Hospitals

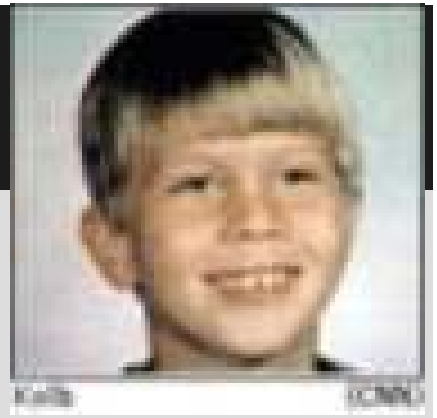
How to Survive Your Hospital Stay

Hospitals aren't always safe havens, as hazards include surgical errors, infections and falls.

The Faces We Should Remember

- Josie King died at 18 months as a result of a hospital error from severe dehydration and misused narcotics
- Condition H now allows families to call a RRT
- Sorrell King has started a foundation to improve patient safety in healthcare

The Faces of Patient Safety



- Ben Kolb, a 7 year old scheduled for elective ear surgery
- The surgeon injected with Lidocaine around the ear to numb the area
- He went in a cardiac arrest and died
- Martin Memorial Hospitals does a full investigation
- He had accidentally been given concentrated Epi which was poured into a unmarked sterile container
- Many Epi medication errors in the ED

Faces of Patient Safety

- Susan Sheridan
- She lost her son, Cal, from severe brain damage
- Failed to diagnosis and treat kernicterus or neonatal jaundice
- She co-founded Parents of Infants and Children with Kernicterus and lead patient initiative for WHO
- Her husband dies from spinal cancer after an x-ray was taken and they failed to communicate this to him timely

Evidenced Based Study on Patient Harm

- IOM estimated that there are 98,000 patients a year who die from medical errors
- Study published in the Journal of Patient Safety in 2013 estimated that there are 400,000 premature deaths associated with preventable harm to patients
- Serious harm seems to be 10-20 fold more common that lethal harm
  - Use the Global Trigger Tool
- Author said the epidemic of patient harm in hospitals must be taken more seriously to be curtained

400, 000 Preventable Deaths a Year

REVIEW ARTICLE

http://journals.lww.com/journalpatientsafety/Fulltext/2013/09000/A_New,_Evidence_based_Estimate_of_Patient_Harms.2.aspx

A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care

John T. James, PhD

Objectives: Based on 1984 data developed from reviews of medical records of patients treated in New York hospitals, the Institute of Medicine estimated that up to 98,000 Americans die each year from medical errors. The basis of this estimate is nearly 3 decades old; herein, an updated estimate is developed from modern studies published from 2008 to 2011.

Methods: A literature review identified 4 limited studies that used primarily the Global Trigger Tool to flag specific evidence in medical records, such as medication stop orders or abnormal laboratory results, which point to an adverse event that may have harmed a patient. Ultimately, a physician must concur on the findings of an adverse event and then classify the severity of patient harm.

Results: Using a weighted average of the 4 studies, a lower limit of 210,000 deaths per year was associated with preventable harm in hospitals. Given limitations in the search capability of the Global Trigger Tool and the incompleteness of medical records on which the Tool depends, the true number of premature deaths associated with preventable harm to patients was estimated at more than 400,000 per year. Serious harm seems to be 10- to 20-fold more common than lethal harm.

Conclusions: The epidemic of patient harm in hospitals must be taken more seriously if it is to be curtailed. Fully engaging patients and their advocates during hospital care, systematically seeking the patients' voice in identifying harms, transparent accountability for harm, and intentional correction of root causes of harm will be necessary to accomplish this goal.

Key Words: patient harm, preventable adverse events, transparency, patient-centered care, Global Trigger Tool, medical errors

(*J Patient Saf* 2013;9: 122–128)

the national level. The amount of new knowledge generated each year by clinical research that applies directly to patient care can easily overwhelm the individual physician trying to optimize the care of his patients.[1] Furthermore, the lack of a well-integrated and comprehensive continuing education system in the health professions is a major contributing factor to knowledge and performance deficiencies at the individual and system level.[2] Guidelines for physicians to optimize patient care are quickly out of date and can be biased by those who write the guidelines.[3–5] At the system level, hospitals struggle with staffing issues, making suitable technology available for patient care, and executing effective handoffs between shifts and also between inpatient and outpatient care.[6] Increased production demands in cost-driven institutions may increase the risk of preventable adverse events (PAEs). The United States trails behind other developed nations in implementing electronic medical records for its citizens.[7] Hence, the information a physician needs to optimize care of a patient is often unavailable.

At the national level, our country is distinguished for its patchwork of medical care subsystems that can require patients to bounce around in a complex maze of providers as they seek effective and affordable care. Because of increased production demands, providers may be expected to give care in suboptimal working conditions, with decreased staff, and a shortage of physicians, which leads to fatigue and burnout. It should be no surprise that PAEs that harm patients are frighteningly common in this highly technical, rapidly changing, and poorly integrated industry. The picture is further complicated by a lack of transparency and limited accountability for errors that harm patients.[8,9]

There are at least 3 time-based categories of PAEs recog-

HHS Report May 7, 2014

- HHS announces that data shows a reduction in hospital induced harm
- QI and patient safety initiatives prevented 15,000 deaths in hospitals, avoided 560,000 patient injuries
  - It also reduced health care spending by $4 billion
  - Shows a 8% decrease in hospital readmissions
  - Reduced HAI from 145 to 132 per 1,000 discharges
- The public and private partnerships are working to help spread best practices
  - http://innovation.cms.gov/Files/reports/patient-safety-results.pdf

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Email updates/RSS
Freedom of Information Act (FOIA)

News

FOR IMMEDIATE RELEASE
May 7, 2014

Contact: HHS Press Office
(202) 690-6343

New HHS data show quality improvements saved 15,000 lives and $4 billion in health spending

Hospital Readmissions Fall by 8 percent among Medicare beneficiaries

Today, the Department of Health and Human Services announced that new preliminary data show an overall nine percent decrease in hospital acquired conditions nationally during 2011 and 2012. National reductions in adverse drug events, falls, infections, and other forms of hospital-induced harm are estimated to have prevented nearly 15,000 deaths in hospitals, avoided 560,000 patient injuries, and approximately $4 billion in health spending over the same period.

The Affordable Care Act is also helping reduce hospital readmissions. After holding constant at 19 percent from 2007 to 2011 and decreasing to 18.5 percent in 2012, the Medicare all-cause 30-day readmission rate has further decreased to approximately 17.5 percent in 2013. This translates into an 8 percent reduction in the rate and an estimated 150,000 fewer hospital readmissions among Medicare beneficiaries between January 2012 and December 2013.

"We applaud the nationwide network of hospital systems and providers that are working together to save lives and reduce costs," said HHS Secretary Kathleen Sebelius. "We are seeing a simultaneous reduction in hospital readmissions and injuries, giving patients confidence that they are receiving the best possible care and lowering their risk of having to be readmitted to the hospital after they get the care they need."

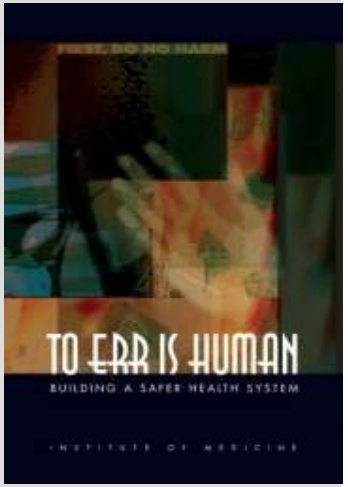
These improvements reflect policies and an unprecedented public-private collaboration made possible by the Affordable Care Act. The data demonstrates that hospitals and providers across the country are achieving reductions in hospital-induced harm experienced by patients. These major strides in patient safety are a result of strong, diverse public-private partnerships and active engagement by patients and families, including efforts from the federal Partnership for Patients initiative and Hospital Engagement Networks, Quality Improvement Organizations, the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Administration on Community Living, the Indian Health Services , and many others.

The public-private partnerships are working collaboratively – along with health care providers – to identify and spread best practices and solutions to reducing hospital acquired conditions and readmissions.

NPSF 8 Recommendation for Total Systems Safety

Expert Panel NPSF

- An15 years after the IOM report, **patient safety concerns remain a serious public health issue**
- Expert panel of the National Patient Safety Foundation in 2015 convened to assess the state of patient safety and set the stage for the next 15 years
- The report can be downloaded at no cost
- 59 page document
- Every healthcare facility should read this
- The report made 8 recommendations



http://c.ymcdn.com/sites/www.npsf.org/resource/resmgr/PDF/Free_from_Harm.pdf

Free from Harm

Accelerating Patient Safety Improvement
Fifteen Years after *To Err Is Human*

8 Recommendation for Total Systems Safety

- Make sure that the leaders establish and sustain a culture of safety
  - To improve patient safety requires an organizational culture
  - The hospital needs to prioritize safety
  - Culture changes need to be at the forefront
- Centralized and coordinated oversight of patient safety needs to be created
  - This will require coordination and oversight of safety organizations and national governing bodies

8 Recommendation for Total Systems Safety

- A common set of safety metrics need to be developed to reflect meaningful outcomes
  - We need to establish standard metrics across the care continuum and we need to identify and measure risks
- There needs to be increased funding for research in patient safety
- Safety needs to be addressed across the continuum
  - We need to evaluate care in many settings
  - Need better tools and processes to deliver care safely

8 Recommendation for Total Systems Safety

- The healthcare force needs to be supported
  - Work force safety, morale, and wellness are necessary to provide safe care
  - Staff need to be supported to reach full potential
- We need to partner with patients and families
  - Need to be actively engaged at all levels
- Technology needs to be safe and optimized to improve patient safety
  - Minimizing unintended consequences of health IT is critical

Enhanced AHRQ Network for Patient Safety

AHRQ Mergers Related to Patient Safety

- AHRQ has merged the following patient safety resources to provide one stop:
  - AHRQ Patient Safety Network (PSNet)
  - AHRQ Web M&M (morbidity and mortality rounds
- For more information go to psnet.ahrq.gov
- PSNet has weekly up dates on patient safety literature, news, tools and other resources
- Web M&M pushed monthly analysis of medical errors and recommendations for improvement
- Has patient safety primers

Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

AHRQ.gov

PSNet
PATIENT SAFETY NETWORK

PSNet | Search...

Login

Home | Topics | Issues | WebM&M Cases | Perspectives | Primers | Submit Case | CME / CEU | Training Catalog | Info

WebM&M is now on PSNet

AHRQ has merged Patient Safety Network (PSNet) and WebM&M (Morbidity and Mortality Rounds on the Web) for a more streamlined experience. Learn more.

View WebM&M content

From Current Issue 3/2/2016

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Journal Article

Does time pressure have a negative effect on

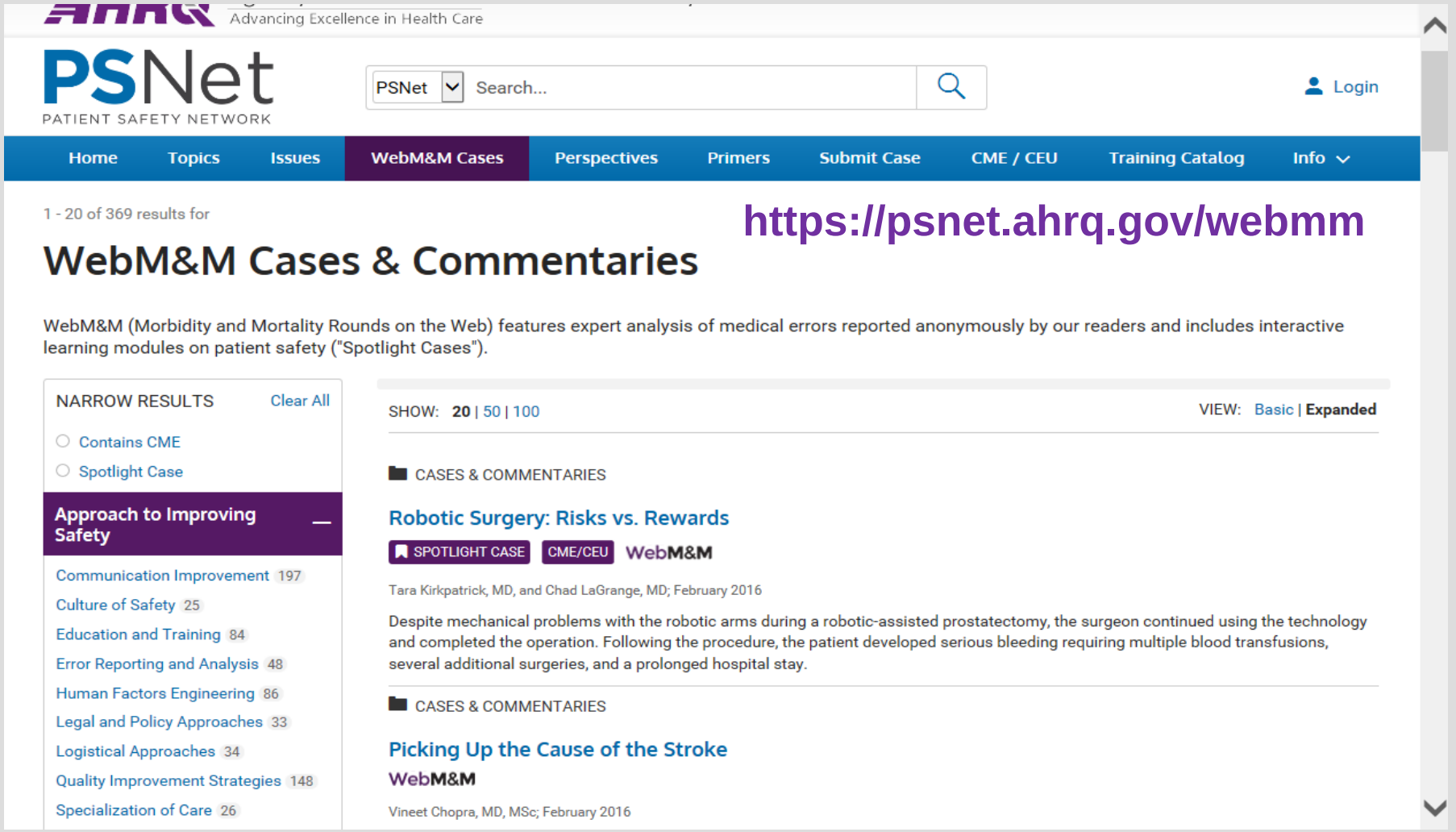
WebM&M Cases

Patient Safety Primers

- Never Events
- Safety Culture
- Medication Errors
- Root Cause Analysis
- Nursing and Patient Safety
- Computerized Provider Order Entry

View all Primers

AHRQ Patient Safety Net



Recent Patient Safety Issues in the News

What Patient Safety Have Been in the News?

- CRE or carbapenem-resistant enterobacteriaceae
  - The night mare bacteria and the cleaning of duodenoscopes for patients having an ERCP
  - CMS issues a memo on this
  - Some hospitals are now culturing the scope to reduce infections
  - ECRI Institute has a free document on this
  - Some hospitals have purchased additional one so they can sterilize them as opposed to disinfecting them
  - Surveyors hitting cleaning of all scopes in the survey process and CDC requires education on this

CRE and ERCP's in the News

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

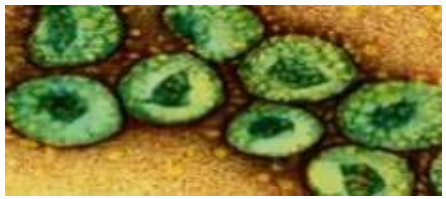
Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C-15-32 Hospitals/CAHs/ASCs

DATE: **April 3, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group



SUBJECT: Alert Related to Outbreaks of Carbapenem-Resistant *Enterobacteriaceae* (CRE) during gastrointestinal endoscopy, particularly Endoscopic Retrograde Cholangiopancreatography (ERCP)

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

Memorandum Summary

- ***Situation:*** Recent newspaper articles, medical publications, and adverse event reports associate multidrug-resistant bacterial infections caused by CRE with patients who have undergone ERCP. Duodenoscopes used to perform ERCP are difficult to clean and disinfect, even when manufacturer reprocessing instructions are followed correctly, and have been implicated in these outbreaks. The U.S. Food and Drug Administration (FDA) has issued a Safety Communication warning, with related updates, that the design of duodenoscopes may impede effective cleaning.

- ***Expectations for Reprocessing Duodenoscopes:*** Hospitals, critical access hospitals (CAHs), and ambulatory surgical centers (ASCs) are expected to meticulously follow the manufacturer's instructions for reprocessing duodenoscopes, as well as adhere to the nationally recognized Multisociety consensus guidelines developed by multiple expert organizations and issued in 2011.

HIGH PRIORITY HAZARD REPORT

ECRI Institute Recommends Culturing Duodenoscopes as a Key Step to Reducing CRE Infections

hwww.ecri.org/resource-center/Pages/Superbug.aspx

SUMMARY:

This Hazard Report updates and supersedes the information contained in Hazard Report Accession No. H0245 01, which was published on March 3, 2015. The updated information in the Problem and ECRI Institute Recommendations sections had been bolded.

This ECRI Institute Hazard Report addresses the serious risk of carbapenem-resistant Enterobacteriaceae (CRE) patient infections associated with the use of duodenoscopes. As this hazard has gained national attention, an ECRI Institute team of physicians, clinical specialists, infection control practitioners, biomedical engineers, and others have intensively researched and reviewed the best approaches to address this problem. Our current research efforts build on years of experience investigating endoscope-related infections.

We believe that this hazard requires immediate action and executive level attention. Our recommendations will likely require additional costs and changes in workflow and processes. Further, no single solution will work for all healthcare organizations and no solutions currently exist to completely eliminate this risk. However, through rigorous management, the infection risks can be minimized. The most effective course of action that healthcare facilities should take will depend on their existing processes, technology, procedure volumes, and financial resources. Also, we believe that despite the risk of infection, Endoscopic Retrograde Cholangiopancreatography (ERCP) endoscopy procedures are

Publication Date:

May 13, 2015

Accession # H0245 02

UMDNS Terms:

Free Toolkits on Endoscope Cleaning

CDC Advisory on Cleaning & Disinfecting

- Issues advisory on immediate need for healthcare facilities to review procedures for cleaning, disinfecting, and sterilizing reusable medical devices and updates October 2, 2015
- All staff must be trained who reprocess equipment or clean scopes and at least annually and in orientation
- Must demonstrate competency with a trained observer and document and follow P&P
- If hires contractor must verify they have the appropriate training and keep copies of mfg instructions and use of chemical disinfectants

CDC Advisory on Cleaning & Disinfecting

September 11, 2015, 12:15 EDT (12:15 PM EDT)

CDCHAN-00382

Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

http://stacks.cdc.gov/view/cdc/34153

and minor update October 15, 2015

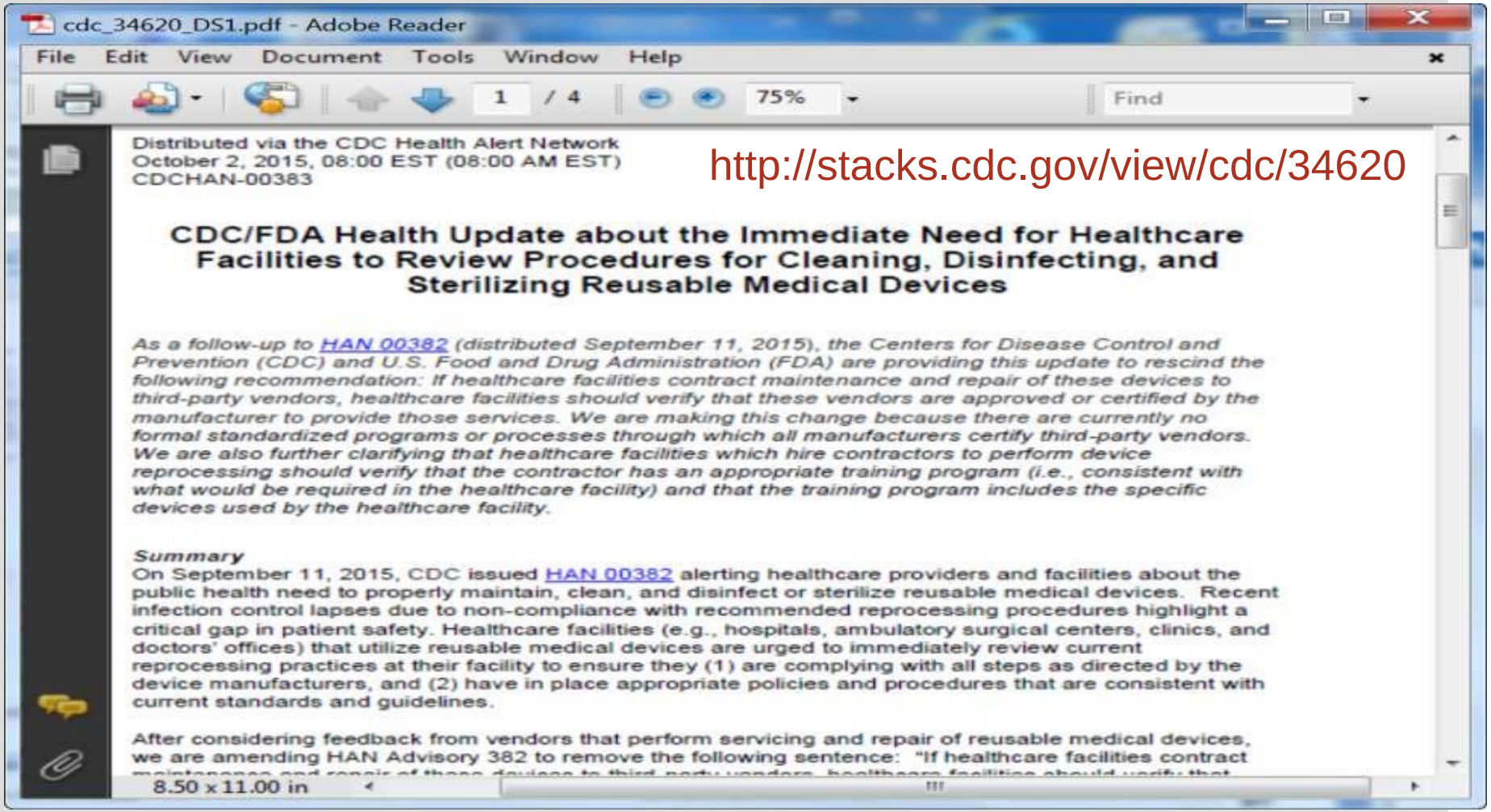
Summary

The Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices. Recent infection control lapses due to non-compliance with recommended reprocessing procedures highlight a critical gap in patient safety. Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they (1) are complying with all steps as directed by the device manufacturers, and (2) have in place appropriate policies and procedures that are consistent with current standards and guidelines.

Background

Recent media reports describe instances of patients being notified that they may be at increased risk for infection due to lapses in basic cleaning, disinfection, and sterilization of medical devices. These

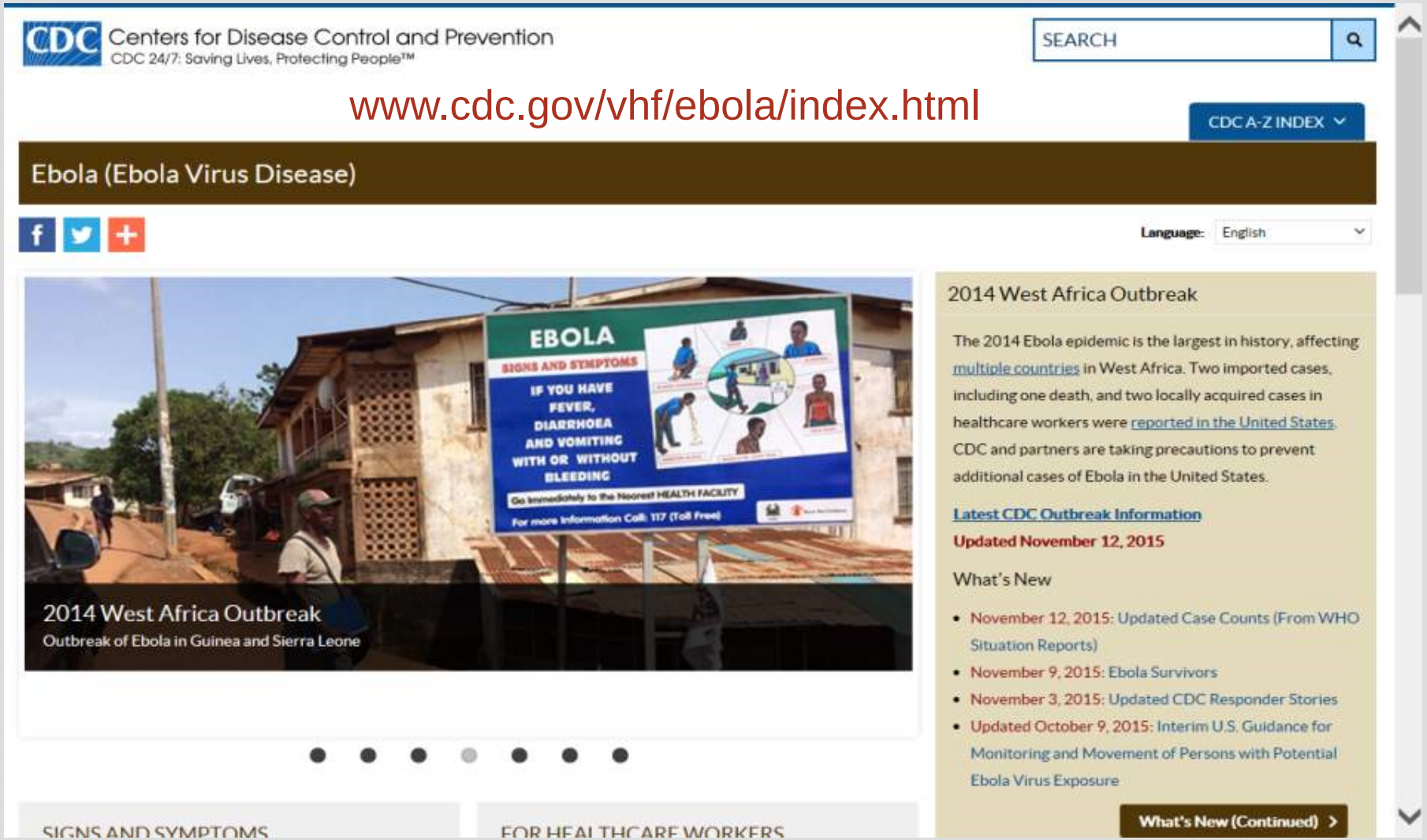
CDC Advisory on Cleaning & Disinfecting



Ebola and Use of PPE

- Ebola and training staff on how to properly use personal protective equipment
  - 2 nurses in Texas get Ebola from patients
  - Many great websites with information including the CDC
    - Ebola and the Law,
    - Protocols for the states
    - PPE for Ebola Preparedness
    - Preparedness checklist
    - Monitoring people exposed
    - Ebola survivors
    - Signs and symptoms
    - Guidance for Healthcare workers
  - To help hospitals to be prepared to care for Ebola patients
  - CMS issues 3 survey memos on Ebola and also has it relates to the federal EMTALA law

CDC Ebola Resource Page



CMS Issues 3rd Ebola Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES
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7500 Security Boulevard, Mail Stop C2-21-16
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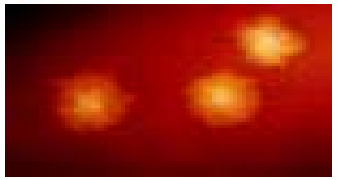
CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-24-Hospitals



DATE: **February 13, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Emergency Medical Treatment and Labor Act (EMTALA) and Ebola Virus Disease (EVD) – Questions and Answers (Q+A)

Memorandum Summary

***EMTALA & Ebola Requirements*:**

- On November 21, 2014 the Centers for Medicare & Medicaid Services (CMS) Survey & Certification Group released SC 15-10-Hospitals concerning EMTALA Requirements and Implications Related to the EVD.
- The CMS has received follow-up questions regarding EMTALA and Ebola and has produced a Q+A document in response.

The CMS released S&C 15-10 on November 21, 2014 to provide guidance to hospitals and critical access hospitals (CAHs) regarding meeting EMTALA requirements in the case of individuals potentially exposed to Ebola. The memo is available via the following link:

Patient Safety in the News

- Robotic Surgery
  - Recently articles about the safety of robotic surgery
  - Is there lack of evidence of clinical effectiveness?
  - Articles published that talk about the inadequate training of some surgeons
  - There is always an initial learning curve and complications rose during this period
  - Carries promise of advancing technology

Robotic Surgery in the News NY Times

The New York Times LOG IN

New Concerns on Robotic Surgeries

By RONI CARYN RABIN SEPTEMBER 9, 2013 5:15 PM 110 Comments

A technologist with the da Vinci surgical system, which haa been criticized in a series of reports. Mike Spencer/Wilmington Star-News, via Associated Press

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In early March 2009, Erin Izumi, a woman in her 30s from Tacoma, Wash., underwent robotically assisted surgery to treat endometriosis. The operation at St. Joseph Medical Center dragged on for nearly 11 hours.

Ten days later, Ms. Izumi was rushed to an emergency room, where doctors discovered that her colon and rectum had been torn during the operation. She was hospitalized for five weeks, undergoing a

WHO Patient Safety in Robotic Surgery

TJC Has Free Document on Robotic Surgery

Issue Three **June 2014**

Potential risks of robotic surgery

www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Three_June_2014.pdf **and good resouces**

Issue:

Robotic surgery (also called minimally invasive surgery, laparoscopic surgery or a closed procedure) is becoming more prevalent, especially for gynecologic or urologic procedures, and The Joint Commission is receiving increasing numbers of reports to our Sentinel Event database associated with robotic procedures. Of 34 reports that affected 36 patients, 27 are related to unintended retained foreign objects (URFOs), and seven are related to operative or postoperative complications. The complications are usually due to hemorrhage caused by laceration. Other reported complications include injury to surrounding tissue, and serious injury (including blindness) related to prolonged surgery. These complications are consistent with the risks of this new technology as reported in current literature. Of the seven operative/postoperative complication reports, two resulted in death. The two deaths were related to excessive blood loss (one report was also related to delay in treatment), which is consistent with current literature for most serious events involving robotic surgery.

Risks of robotic surgery can be categorized into those directly related to the use of the robotic system and the general risks of the operative procedure. According to a recent consensus statement, robotic telesurgery, in which the surgeon may be located at some distance from the patient, poses unique risks. For example, precise control of the robot depends on the quality of the data connection between the surgeon's console and the operating room robot. Issues pertaining to the quality and maintenance of such data connections may be beyond the control of the surgical team, but still represent a risk management challenge of which the organization must be mindful. All mechanical and electronic devices are subject to failure; surgical robots are no exception. Current systems are designed with features intended to minimize the potential for harm to the patient. Such features include system redundancy, fault tolerance, just-in-time maintenance, and system alerting.

Top Ten Patient Safety Issues

ERCI Top 10 Patient Safety Issues

- ECRI Institute publishes list of top ten patient safety issues
- ECRI is a PSO and the list is the result of patient safety event reports, research requests, and root-cause analyses (RCA) submitted to ECRI
- Also from knowledge gained through investigating incidents, observing and assessing hospital practices, and reviewing health-technology-related problem reports
- Mislabeled lab specimens and patient falls while toileting still remains a concern

ERCI Top 10 Patient Safety Issues

ERCI Top 10 Patient Safety Issues

1. Alarm hazards: inadequate alarm configuration policies and practices
   - Do you have a monitor watcher?
   - How do you make sure if a monitor goes off that someone goes in to assess the patient
   - Remember the issue of alarm fatigue where there are so many things that beep that staff may not hear the alarm
   - It is a Joint Commission (TJC) NPSG (National Patient Safety Goal) and as of 2016 must have P&P to manage alarms identified by the hospital
   - Discussed in detail later

ERCI Top 10 Patient Safety Issues

2. Data integrity: incorrect or missing data in EHRs and other health IT systems
   - Create an EHR that includes all of the required documentation elements
   - Technology can create safety risks if not designed appropriately or implemented correctly
   - Missed data so no allergy recorded and patient gets medication she is allergic to
   - Initially missed diagnosis of EBOLA in Texas ED was reported to be due to ED physician not being able to see ED triage nurses notes but later recanted
   - Outdated information being copied and pasted into chart

ERCI Top 10 Patient Safety Issues

3. Managing patient violence

- Major issue in the ED and with the Emergency Nurses Association (ENA) and American College of Emergency Physicians (ACEP) and focus of OSHA now
- Accounts for 900 deaths and 1.7 million non-fatal assaults every year
- ENA has many excellent workplace violence resources along with a study of the problem and a violence position statement at www.ena.org/government/State/Pages/WVResources.aspx
- ENA has workplace violence toolkit at www.ena.org/practice-research/Practice/ViolenceToolKit/Documents/toolkitpg1.htm
- Staff need proper training to recognize : CPI, MOAB, etc.
- TJC requires de-escalation training. See PC.01.01.01 EP 4 and 24

ACEP Violence in the ED Policy

Protection from Physical Violence in the Emergency Department Environment

www.acep.org/Clinical---Practice-Management/Protection-from-Physical-Violence-in-the-Emergency-Department-Environment/

Revised and approved by the ACEP Board of Directors June 2011 and April 2008
Reaffirmed by the ACEP Board of Directors October 2001 and October 1997
Originally approved by the ACEP Board of Directors January 1993

The American College of Emergency Physicians (ACEP) believes that optimal patient care can be achieved only when patients, health care workers, and all other persons in the emergency department (ED) are protected against violent acts occurring within the department. As such, ACEP advocates for increased awareness of violence against health care workers in the ED and for increased safety measures in all EDs. Further, ACEP encourages all states to enact legislation that provides a maximum category of offense and criminal penalty against individuals who commit violence against health care workers in the ED.

To ensure the security of the ED environment, the hospital has the following responsibilities:

- Provide a best-practices security system including adequate security personnel, sufficient training of personnel, physical barriers, surveillance equipment, and other security components.
- Coordinate the hospital security system with local law enforcement agencies.
- Develop written emergency department protocols for violent situations occurring in the ED to ensure the safety of patients and health care workers alike.
- Educate staff on preventing, recognizing, and dealing with potentially violent situations.
- Conduct ongoing assessments of the ED security system performance.
- Maximum criminal prosecution will be pursued against those individuals who commit violent acts against health care workers, when deemed appropriate, based on the circumstances of the incident.

Additionally, ACEP recognizes that the EMS system is an integral component of emergency care and supports and encourages efforts to protect EMS personnel against physical violence in the prehospital

ERCI Top 10 Patient Safety Issues

4. Mix-up of IV lines leading to misadministration of drugs and solutions
   - CMS now requires nurses to trace back or evaluate all IVs and tubes when getting out of report and to verify everything is current and consider labeling each infusion line
   - CMS requires the nurse to verify that the infusion rate is correct also and hospital should have a P&P
   - CMS has issued a tubing misconnection memo
   - TJC has issued a sentinel event alert
     - Case reported to ECRI was patient sent from the ED to the CCU and when arrived Heparin bag was empty because ED nurse mixed up the two IVs

Luer Misconnections Memo

- CMS issues memo on luer misconnections
- This has been a patient safety issues for many years
- Staff can connect two things together that do not belong together because the ends match
  - For example, a patient had the blood pressure cuff connected to the IV and died of an air embolism
  - New connectors being developed
- Luer connections easily link many medical components, accessories and delivery devices

Luer Misconnections Memo

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

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-14-ALL

DATE: March 8, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Luer Misconnection Adverse Events

Memorandum Summary

- **Luer Misconnections continue to result in adverse events and deaths** – Luer connectors easily link many medical components, accessories, and delivery systems. Clinicians, in any type of provider or supplier setting, can mistakenly connect the wrong devices and deliver substances through the wrong route. Despite numerous alerts and warnings, a patient's blood pressure tubing was recently misconnected to an intravenous (IV) line in an ambulatory surgery center (ASC) resulting in a patient death.
- **Adverse Event Complaint Investigation:** During a complaint investigation for an adverse event involving delivery of an incorrect substance or utilization of an incorrect delivery route, surveyors must be alert to whether the event involved misconnection of a Luer device. If so, surveyors must determine whether the facility has taken actions to ensure systems are in place to prevent recurrence of this type of adverse event.
- **Facility Reporting to Food & Drug Administration (FDA):** Surveyors should encourage health care facilities to report problems with Luer misconnections to the FDA, even if no adverse event occurred.

PA Patient Safety Authority Article

Table. Tubing Misconnections Reported to the Pennsylvania Patient Safety Authority, January 2008 to September 2009

MISCONNECTION	NUMBER OF REPORTS
Secondary intravenous (IV) infusion connected to lower "Y" port of primary IV tubing set	8
Hemodialysis arterial and venous tubing lines reversed	5
G-tube and J-tube lines reversed	3
Incorrect tubing connection (no further explanation provided in reports)	3
Epidural and patient-controlled analgesia (PCA) tubing sets reversed	2
Nonhemodialysis arterial and venous tubing lines reversed	2
Cell saver tubing connected to cell saver reservoir	1
Feeding tube set connected to Broviac®	1
Feeding tube set connected to peripherally inserted central catheter (PICC) line	1
Feeding tube set connected to suction port	1
Imaging contrast tubing set connected to tracheostomy cuff	1
IV tubing set connected to dialysis catheter	1
IV tubing set connected to PICC line	1
IV tubing set connected to tracheostomy cuff	1
Knee irrigation connected to peripheral IV tubing	1
Miscommunication (arterial line noted in medical record as peripheral IV)	1
Oral medication delivered through peripheral IV line	1
Suction line connected to water seal	1
Suction and feeding tubing sets reversed	1
Total	**36**

http://patientsafetyauthority.org/Pages/default.aspx

ADDRESS:
Patient Safety Authority
333 Market Street
Lobby Level
Harrisburg, PA 17120

Phone: 717-346-0469
Fax: 717-346-1090

Patient Safety Tools

The Pennsylvania Patient Safety Authority publishes additional information related to some *Pennsylvania Patient Safety Advisory* articles. This information may include research posters, toolkits, brochures, and other educational materials.

Featured

The Authority provides to Pennsylvania patient safety officers and infection prevention designees an array of educational webinars addressing important patient safety topics. Subsequently, recordings of these webinars are made available on the Authority's website. View a collection of the Authority's recent webinars to learn more.

- Airway Fires during Surgery
- Anticoagulation Management Service
- Applying the Universal Protocol to Radiology
- ASF Infection Prevention Practices
- ASF Patient Screening and Assessment
- Aspiration Screening
- Behavioral Health Patient Safety
- Blood Specimen Labeling
- Blood Transfusion Process
- Bone Cement Implantation Syndrome
- Care at Discharge
- CAUTI Prevention Practices
- CLABSI Risk Reduction
- Clostridium Difficile Strategies
- Color-Coded Wristbands
- Contrast-Induced Nephropathy
- Delirium
- Diagnostic Error
- Diagnostic Radiation and Pregnancy
- Difficult Intubation
- Hospital Bed Safety
- HYDROmorphone Risk Reduction
- Influenza (Flu)
- Insulin Therapy
- Managing Clinical Emergencies
- Newborn Injuries
- Norovirus
- Nursing Home Infection Prevention Practices
- Obesity
- Obstructive Sleep Apnea
- Opioids
- Patient Flow in the Emergency Department
- Patient Safety Practices
- Pneumatic Tourniquets
- Pneumonia
- Preventing Retention of Surgical Items
- Preventing Wrong-Site Surgery
- Safety in the MR Environment
- Skin Tears
- Surgical Site Infections

TJC Sentinel Event Alert #36

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Topic Library Item

Sentinel Event Alert, Issue 36: Tubing misconnections—a persistent and potentially deadly occurrence

April 3, 2008

Download This File

Tubing and catheter misconnection errors are an important and under-reported problem in health care organizations. In addition, these errors are often caught and corrected before any injury to the patient occurs. Given the reality of and potential for life threatening consequences, increased awareness and analysis of these errors—including averted errors—can lead to dramatic improvement in patient safety.

Managing Risk During the Transition

A complimentary publication of The Joint Commission
Issue 53, August 20, 2014

Managing risk during transition to new ISO tubing connector standards

Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Event Alert* identifies specific types of sentinel and adverse events and high risk conditions, describes their common underlying causes, and recommends steps to reduce risk and prevent future occurrences.

Accredited organizations should consider information in a *Sentinel Event Alert* when designing or redesigning processes and consider implementing relevant suggestions contained in the alert or reasonable alternatives.

Tubing misconnections continue to cause severe patient injury and death, since tubes with different functions can easily be connected using luer connectors, or connections can be "rigged" (constructed) using adapters, tubing or catheters. This is why new ISO (International Organization for Standardization) tubing connector standards are being developed for manufacturers. Through an international consensus process, the standards are being developed, tested and approved to assure reliable designs and processes. The phased implementation of redesigned tubing connectors that are the result of these new ISO connector standards begins now. The Joint Commission urges health care organizations to be vigilant and begin planning for the upcoming period of transition, which will introduce changes and new risks into the health care environment. Under the new ISO connector standards, small-bore (less than 8.5 mm inner diameter) connectors will be engineered to make it nearly impossible to connect one delivery system to another delivery system that serves a completely different function[1,2,3,4,5] – for example, accidentally connecting a feeding administration set to a tracheostomy tube, or an intravenous (IV) tube to an epidural site.

The first new ISO connector standard (ANSI/AAMI/ISO 80369-1) has been adopted and others are expected to be introduced and adopted through 2014 and 2015. Health care organizations should begin preparing for changes in

ERCI Top 10 Patient Safety Issues

5. Care coordination events related to medication reconciliation
   - Get a list of all medications from every patient along with dose and frequency
   - If patient is admitted then full reconciliation can occur
   - Keep current and give list discharged
   - Discussed later under the section on medication reconciliation which is TJC NPSG.03.06.01
   - CMS now requires medication reconciliation

ERCI Top 10 Patient Safety Issues

6. Failure to conduct independent double checks independently

- CMS requires hospitals to have two practitioners check to make sure the blood is correct and one must be RN who is administering it but CMS confirms can have one person with bar coding since approved by AABB
- CMS requires hospitals to have a list of high alert medication
- Hospital P&P must specify when independent double checks should occur
- So two nurses verify Heparin bolus amount and drip or the subq insulin is correct

ERCI Top 10 Patient Safety Issues

7. Opioid-related events

- Use and prescribing of opioids has significantly increases
- So has the number of adverse events and overdoses with the number of overdoses doubling from 2004 to 420,000 in 2011
- Commonly involved is Dilaudid (HydroMORPHONE), oxycodone, PCA opioid, and fentanyl patches
- CMS implemented detailed process for hospitals on June 6, 2015 and April 7, 2015 for CAH
- Must have P&P, must train staff, P&P must be approved by MEC, must include how to monitor patients (VS, Pulse Ox, $ETCO_2$ etc) and how often

Medication and Safe Opioid Use

- CMS issues 32 page memo on medication administration and safe opioid use March 14, 2014 and effective June 6, 2014 and April 7, 2015 for CAH
  - Risk and patient safety need to review this besides nursing, pharmacy, MEC, and nurse educator
- Concerned about the number of patients with adverse events when taking opioids
- Must have a P&P
- Must train staff and include information that must be in the assessment
- Must document process
  - **Questions to hospitalscg@cms.hhs.gov**

CMS Memo Med & Safe Opioid Use

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

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-15-Hospital

DATE: **March 14, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-Operative Care of Patients Receiving IV Opioids

Memorandum Summary

- ***Medication Administration:*** We are updating our guidance for the hospital medication administration requirements to:
  - Make clear that the medication administration requirements under the nursing services condition of participation (CoP) are related to only some components of the overall hospital medication process, but that hospitals are expected, through this and the related requirements under the pharmaceutical services and quality assessment/performance improvement CoPs, to take a comprehensive approach to the medication process.
  - Update our guidance for IV medications and blood transfusions in general; and
  - Reflect the need for patient risk assessment and appropriate monitoring during and after medication administration, particularly for post-operative patients receiving IV opioid medications, in order to prevent adverse events.
- ***Immediate Post-operative Care:*** Clarification is also being made to the guidance for the surgical services CoP requirement for hospitals to have adequate provisions for immediate post-operative care, to emphasize the need for post-operative monitoring of patients

ERCI Top 10 Patient Safety Issues

8. Inadequate reprocessing of endoscopes and surgical instruments

- Instruments are wiped down after use, soaked in an enzymatic solution and sent to central supply for processing

9. Inadequate patient handoffs related to patient transport

- Have good report process and consider bedside report and when transferring patient to their bed and discussed in detail later (safe handoffs)

10. Medication errors related to pounds and kilograms

- initiative of many organizations like ENA and ISMP and always weigh in kg and not pounds and grams for babies

Hall Pass or Ticket to Ride

Ticket to Ride

PATIENT HAND OFF

Date: Room #:
Time:

S Situation
Type Test ☐ X-ray ☐ CT ☐ US ☐ Cardiology ☐ MRI
Mode of Transportation ☐ Cart ☐ Wheelchair ☐ Ambulatory
Multiple Tests Ordered ☐ Yes ☐ No

B Background
Allergies ☐ Yes (See band) ☐ No
DNR ☐ Yes ☐ No
Precautions ☐ Fall ☐ Suicide ☐ Seizure
Isolation ☐ Contact ☐ Airborne ☐ Droplet
Impairment ☐ Speech ☐ Vision ☐ Hearing ☐ None

A Assessment
Mental Status ☐ Oriented ☐ Disoriented
Mobility ☐ Self ☐ Assist Staff 1 ☐ Assist Staff 2
☐ Total
Equipment ☐ O2 ____ liters ☐ Intubated
☐ IV started
Restraints ☐ Yes ☐ No ☐ Labs drawn
NPO ☐ Yes ☐ No
Catheter inserted ☐ Yes ☐ No Cath & Fill ☐ Yes ☐No
Department notified patient ready ☐ Yes ☐ No

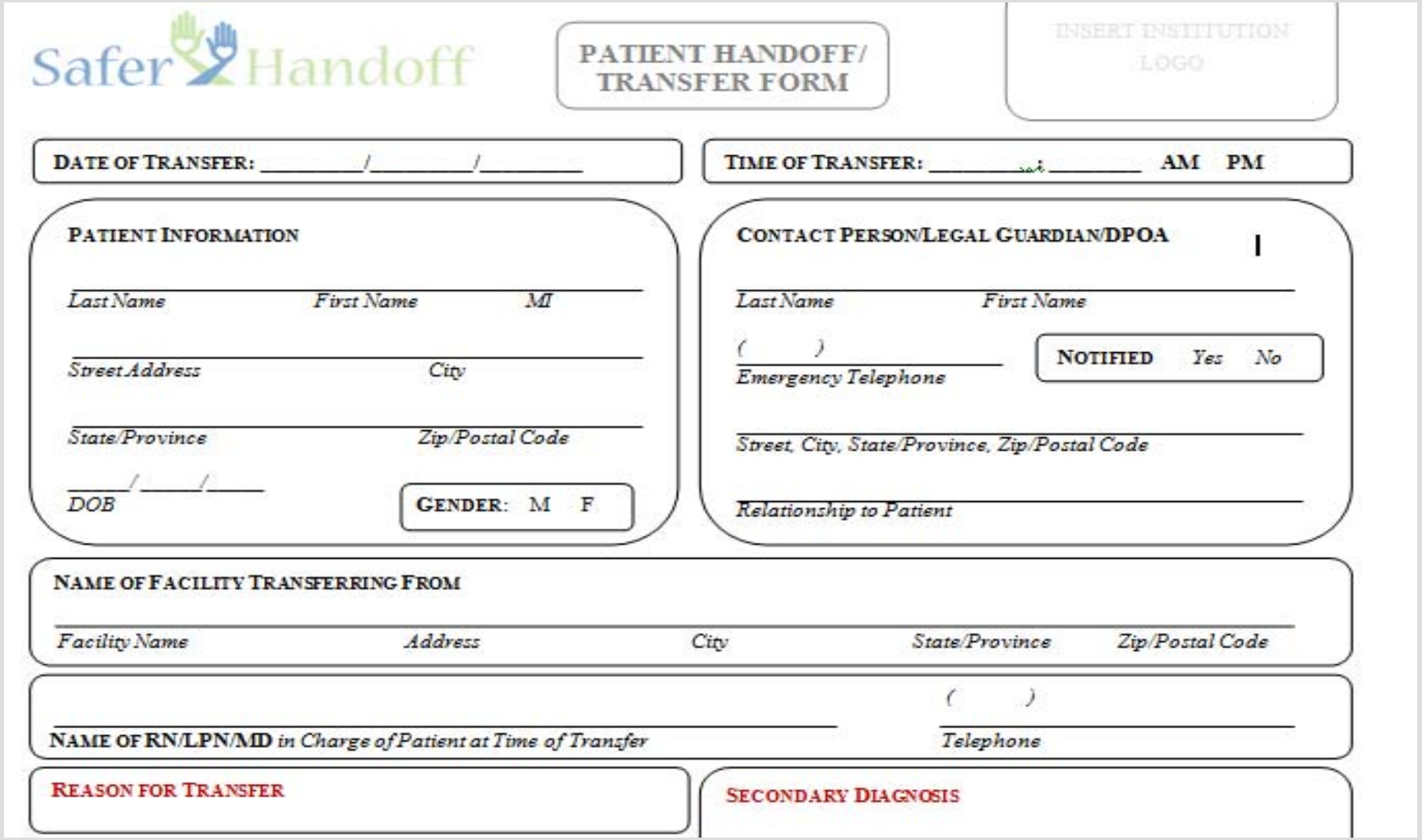
R Recommendation
Assistive device/Help needed for transfer:

Other comments:

RN Name:
Contact Number

Return Trip:

ENA Safer Handoff Tool



Safer Handoff

PATIENT HANDOFF/ TRANSFER FORM

INSERT INSTITUTION LOGO

DATE OF TRANSFER: _____/_____/_____

TIME OF TRANSFER: _____:_____ AM PM

PATIENT INFORMATION

Last Name First Name MI

Street Address City

State/Province Zip/Postal Code

_____/_____/_____
DOB

GENDER: M F

CONTACT PERSON/LEGAL GUARDIAN/DPOA

Last Name First Name

( )
Emergency Telephone

NOTIFIED Yes No

Street, City, State/Province, Zip/Postal Code

Relationship to Patient

NAME OF FACILITY TRANSFERRING FROM

Facility Name Address City State/Province Zip/Postal Code

NAME OF RN/LPN/MD *in Charge of Patient at Time of Transfer*

( )
Telephone

REASON FOR TRANSFER

SECONDARY DIAGNOSIS

ACUTE CHANGES FROM BASELINE ASSOCIATED WITH TRANSFER

VITAL SIGNS AT TRANSFER – TIME TAKEN: _____ : _____ AM PM

BP: /	TEMP:	PULSE:	RESP:	SAO_2 : ☐ O_2 Therapy

IMMUNIZATION STATUS ☐ *Attached*

T.S.T. (PPD)	Date:	Results:			
Influenza	Date: _____	☐ UNK	Hepatitis A:	Date: _____	☐ UNK
Pneumococcal	Date: _____	☐ UNK	Hepatitis B:	Date: _____	☐ UNK
Meningococcal	Date: _____	☐ UNK	Measles, Mumps, Rubella	Date: _____	☐ UNK
D.T.P.	Date: _____	☐ UNK	Varicella	Date: _____	☐ UNK
Tetanus	Date: _____	☐ UNK	Inactivated Poliovirus	Date: _____	☐ UNK

TB Test	Date	Type	Result	***Biochem***	Date	Result
Chest X-Ray	Date	Result		***Urinalysis***	Date	Result
C.B.C.	Date	Result		***Fasting Glucose***	Date	Result

ALLERGIES ☐ None ☐ UNK

Allergic To:	Reaction:	☐ UNK
Allergic To:	Reaction:	☐ UNK
Allergic To:	Reaction:	☐ UNK

ISOLATION/PRECAUTION

☐ None
☐ Contact
☐ Droplet
☐ Airborne

☐ MRSA	Date:	Site:
☐ VRE	Date:	Site:
☐ ESBL	Date:	Site:
☐ Other	Date:	
☐ C-Diff.	Date:	

SKIN/ WOUND CARE ☐ Intact ☐ Not Intact

Describe Decubitus/ Wound (Size, Site, Drainage):

Safer Sign Out Protocol ACEP EMPSF

FEATURED PROJECT

Safer Sign Out Protocol

The "Safer Sign Out" protocol provides simple but critical structure to the process of handing off ED patients during a shift change in the community hospital setting. See the process, download helpful documents, forms and tools.

www.acep.org/qipssection/

Safer Sign Out Form *(v20)*

☐ *Check if No Patients Signed Out* Off-Going Clinician*: _____ Receiving Clinician: _____ Date Shift Started_____

Patient Name/Age	Problem List & Key Issues	Pending Items	Disposition	*Receiving Clinician's Notes*
Room	**Diagnosis/CC:** **Key Issues:** ***Potential Safety Issues or Precautions?***		Home_____ Admit_____ Transfer_____ NH_____ TBD_____	☐ *Rounded on Patient* ☐ *Communicated with Nurse*_____
Room	**Diagnosis/CC:** **Key Issues:** ***Potential Safety Issues or Precautions?***		Home_____ Admit_____ Transfer_____ NH_____ TBD_____	☐ *Rounded on Patient* ☐ *Communicated with Nurse*_____
Room	**Diagnosis/CC:** **Key Issues:** ***Potential Safety Issues or Precautions?***		Home_____ Admit_____ Transfer_____ NH_____ TBD_____	☐ *Rounded on Patient* ☐ *Communicated with Nurse*_____
Room	**Diagnosis/CC:** **Key Issues:** ***Potential Safety Issues or Precautions?***		Home_____ Admit_____ Transfer_____ NH_____ TBD_____	☐ *Rounded on Patient* ☐ *Communicated with Nurse*_____

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

*This form is a Quality Assurance Tool and is **NOT** part of the medical record*

Use Kg and Not Pounds for Children

Acetaminophen Dosing Chart

Acetaminophen (Tylenol) Dose every 4 to 6 hours *Maximum 5 doses in 24 hours*		Infants' Concentrated Drops 80 mg/ 0.8 mL	Children's Suspension Liquid 160 mg/ 5 mL	Children's Soft Chews Chewable 80 mg each	Junior Strength Chewable 160 mg each	Adult Regular Strength 325 mg each
		Dropperful (Use only the dropper provided)	Teaspoon (tsp)	Tablet	Tablet	Tablet
Weight	Age					
6-11 lbs	0-3 mos	½ = 0.4 mL				
12-17 lbs	4-11 mos	1 = 0.8 mL	½ tsp			
18-23 lbs	12-23 mos	1 ½ = 0.8+ 0.4mL	¾ tsp			
24-35 lbs	2-3 yrs	2 = 0.8 + 0.8 mL	1 tsp	2	1	
36-47 lbs	4-5 yrs		1 ½ tsp	3	1 ½	
48-59 lbs	6-8 yrs		2 tsp	4	2	
60-71 lbs	9-10 yrs		2 ½ tsp	5	2 ½	1
72-95 lbs	11 yrs		3 tsp	6	3	1 ½
96 lbs +	12 yrs +		4 tsp	8	4	2

Ibuprofen Dosing Chart

Ibuprofen (Motrin, Advil) Dose every 6 to 8 hours *Maximum 4 doses in 24 hours*		Infants' Concentrated Drops 50 mg/ 1.25 mL	Children's Suspension Liquid 100 mg/ 5 mL	Children's Chews Chewable 50 mg each	Junior Strength 100 mg each	Adult Regular Strength 200 mg each
		Dropperful (Use only the dropper provided)	Teaspoon (tsp)	Tablet	Tablet	Tablet
Under 6 mos		*Consult Your Child's Provider*				
Weight	Age					
12-17 lbs	6-11 mos	1=1.25 mL				
18-23 lbs	12-23 mos	1 ½ =1.875 mL				
24-35 lbs	2-3 yrs		1 tsp	2		
36-47 lbs	4-5 yrs		1 ½ tsp	3		
48-59 lbs	6-8 yrs		2 tsp	4	2	
60-71 lbs	9-10 yrs		2 ½ tsp	5	2 ½	
72-95 lbs	11 yrs		3 tsp	6	3	
96 lbs +	12 yrs +		4 tsp	8	4	2

Acetaminophen& Ibuprofen Dosing Charts

Fever Medication: Dosage Charts

Acetaminophen Dosage Chart

Dosages may be repeated every four hours, but should not be given more than five times in twenty- four hours. (Note:Milliliter is abbreviated as mL; 5 mL equals 1 teaspoon [tsp]. Don?t use household teaspoons, which can vary in size.) Be sure to read the label to make sure you are using the right product.

Age*	Weight†	Infant Drops 80 mg/0.8 mL	Children's Elixir 160 mg/5 mL	Chewable Tablets 80 mg tabs
0-5 mos.	6-11 lbs. (2.7-5 kg)	0.4 mL	-	-
6-11 mos.	12-17 lbs. (5.5-7.7 kg)	0.8 mL	½ tsp	1 tab
1-2 yrs.	18-23 lbs. (8.2-10.5 kg)	1.2 mL	¾ tsp	1½ tabs
2-3 yrs.	24-35 lbs. (10.9-15.9 kg)	1.6 mL	1 tsp	2 tabs
4-5 yrs.	36-47 lbs. (16.3?21.4 kg)	2.4 mL	1½ tsps	3 tabs

*: Note: Age is provided as a convenience only. Dosing for fever should be based on current weight.

†: Weight given is representative of the age range.

www.healthychildren.org/Documents/tables/Fever-Med-Dosage.

Ibuprofen Dosage Chart

Dosages may be repeated every six to eight hours, but should not be given more than four times in twenty- four hours. (Note: Milliliter is abbreviated as mL; 5 mL equals 1 teaspoon [tsp]. Don?t use household teaspoons, which can vary in size.) Be sure to read the label to make sure you are using the right product.

Age*	Weight†	Infant Drops 50 mg/1.25 mL	Children's Elixir 100 mg/5 mL	Chewable Tablets 50 mg tabs
6-11 mos.	12-17 lbs. (5.5-7.7 kg)	1.25 mL	2.5 mL	-
	18-23 lbs.			

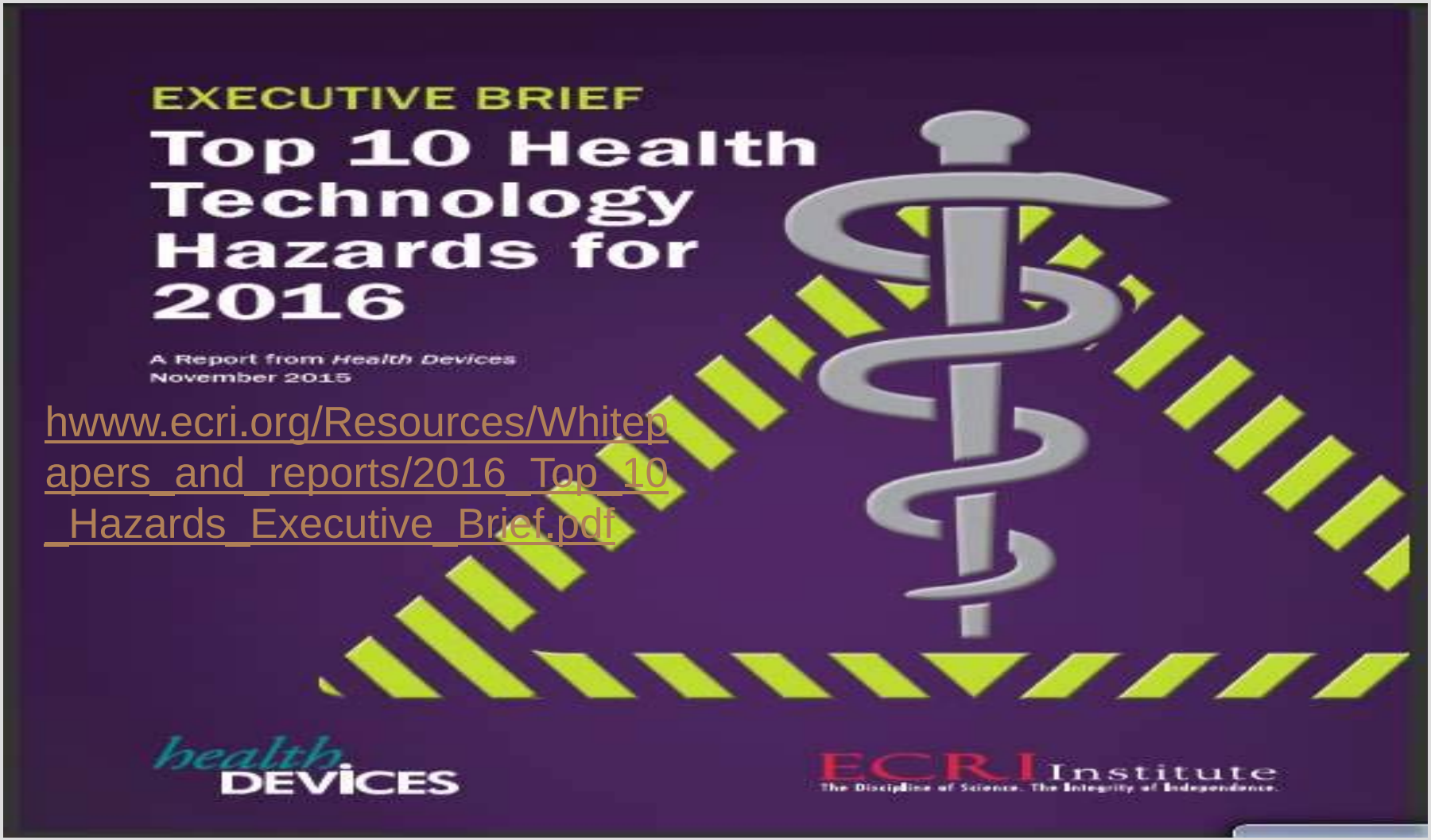
CDC Dosing Charts HIV Meds

Peds Dosing Guide 22" x 10" 112706 11/27/06 11:30 AM Page 1

www.cdc.gov/globalaids/docs/program-areas/pmtct/peds-dosing-guide.pdf

Weight range (kg)	Abacavir (Ziagen®, ABC)		Didanosine (Videx®, DDI)			Lamivudine (Epivir®, 3TC)		Stavudine (Zerit®, d4T)		Zidovudine (Retrovir®, ZDV, AZT)		
	8 mg/kg/dose TWICE daily		90-120 mg/m^2/dose TWICE daily	120 mg/m^2/dose TWICE daily	180-240 mg/m^2/dose ONCE daily	4 mg/kg/dose TWICE daily		1 mg/kg/dose TWICE daily		180-240 mg/m^2/dose TWICE daily		
	20 mg/ml solution	300 mg tablets	10 mg/ml suspension	25, 50, 100 mg chewable tablets	125, 200, 250, 400 mg EC capsules	10 mg/ml solution	150 mg tablets	1 mg/ml solution	15, 20, 30 mg capsules	10 mg/ml syrup	100 mg capsules	300 m tablet
5 - 5.9	2 ml		4 ml	25 mg + 25 mg tabs		3 ml		6 ml		6 ml		
6 - 6.9	3 ml		5 ml	25 mg + 25 mg tabs		3 ml		7 ml	10 mg (as 0.5 x 20 mg)	7 ml		
7 - 7.9	4 ml		6 ml	25 mg + 25 mg tabs		4 ml		8 ml	10 mg (as 0.5 x 20 mg)	8 ml		
8 - 8.9	4 ml		6 ml	25 mg + 25 mg tabs		4 ml		9 ml	10 mg (as 0.5 x 20 mg)	9 ml	1 cap	
									10 mg			

ECRI 2016 Health Technology Hazards



THE LIST FOR 2016

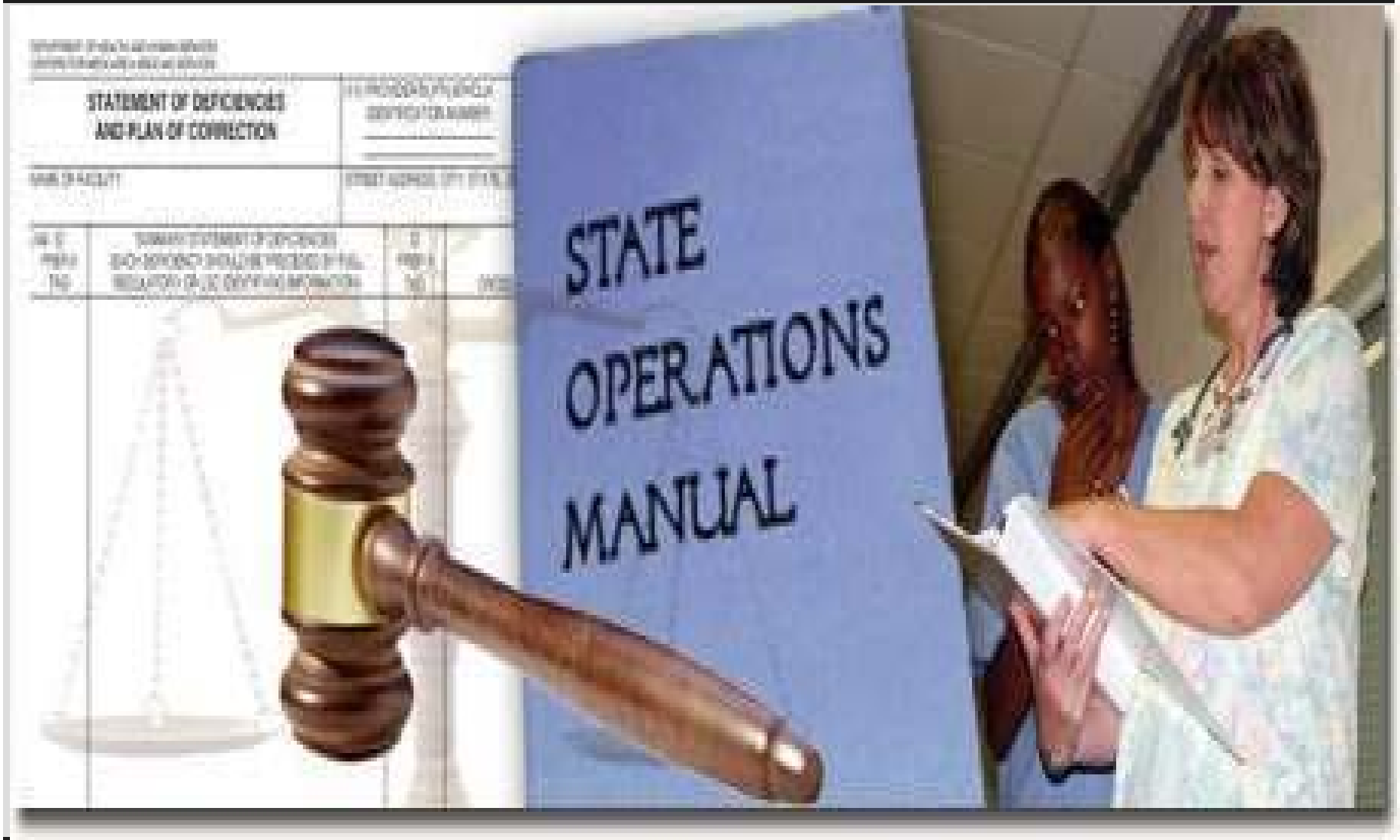
1. Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens
2. Missed Alarms Can Have Fatal Consequences
3. Failure to Effectively Monitor Postoperative Patients for Opioid-Induced Respiratory Depression Can Lead to Brain Injury or Death
4. Inadequate Surveillance of Monitored Patients in a Telemetry Setting May Put Patients at Risk
5. Insufficient Training of Clinicians on Operating Room Technologies Puts Patients at Increased Risk of Harm
6. Errors Arise When HIT Configurations and Facility Workflow Do Not Support Each Other
7. Unsafe Injection Practices Expose Patients to Infectious Agents
8. Gamma Camera Mechanical Failures Can Lead to Serious Injury or Death
9. Failure to Appropriately Operate Intensive Care Ventilators Can Result in Preventable Ventilator-Induced Lung Injuries
10. Misuse of USB Ports Can Cause Medical Devices to Malfunction

CMS Hospital CoPs on Risk Management and Patient Safety

CMS CoPs Risk Managers & Patient Safety

- There are many recent changes and important regulations that impact risk managers and patient safety officers that are found in the CMS hospital Conditions of Participations (CoPs)
  - Many revised ones include: Visitation, Reporting to PI, Restraint and Seclusion, Telemedicine, Blood Transfusion and IV Medication, Anesthesia, Standing Orders, Self Administered Medications, Luer Misconnections, Safe Medication Practices, Pharmacy, Rehab and Respiratory Therapy Orders and medication administration rule and safe opioid use

You Don’t Want One of These



The Conditions of Participation (CoPs)

- Regulations first published in 1986
  - Manual updated more frequently now
- First regulations are published in the **Federal Register** then CMS publishes the **Interpretive Guidelines** and some have **survey procedures** [2]
  - Hospitals should check this website once a month for changes

[1]www.gpoaccess.gov/fr/index.html [2]www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp

The Conditions of Participation (CoPs)

- The manual is known as the conditions of participation or the CoPs for short
- The CoP sections are called tag numbers
- They go from Tag 0001 to 1164
- All the sections contain a tag number so it is easy to go back and look up that section if you want to read more about it
- Many changes recently including rewriting radiology and nuclear medicine, discharge planning, pharmacy and nursing

Location of CMS Hospital CoP Manuals

Medicare State Operations Manual

Appendix

Email questions to CMS at hospitalscg@cms.hhs.gov

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the red button in the 'Download' column to see any available file in PDF.
- To return to this page after opening a PDF file on your desktop, use the browser "back" button. This is because closing the file usually will also close most browsers

CMS Hospital CoP Manuals new address

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

App. No.	Description	PDF File
A	Hospitals	2,185 KB
AA	Psychiatric Hospitals	606 KB

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)

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

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

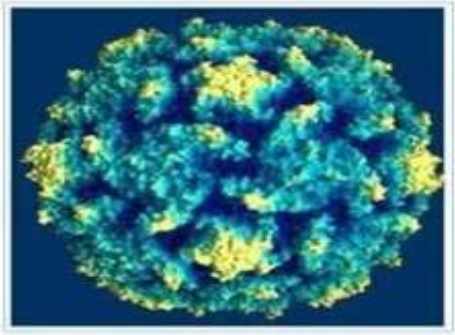
Rehabilitation Hospital Survey Module

Inpatient Rehabilitation Unit Survey Module

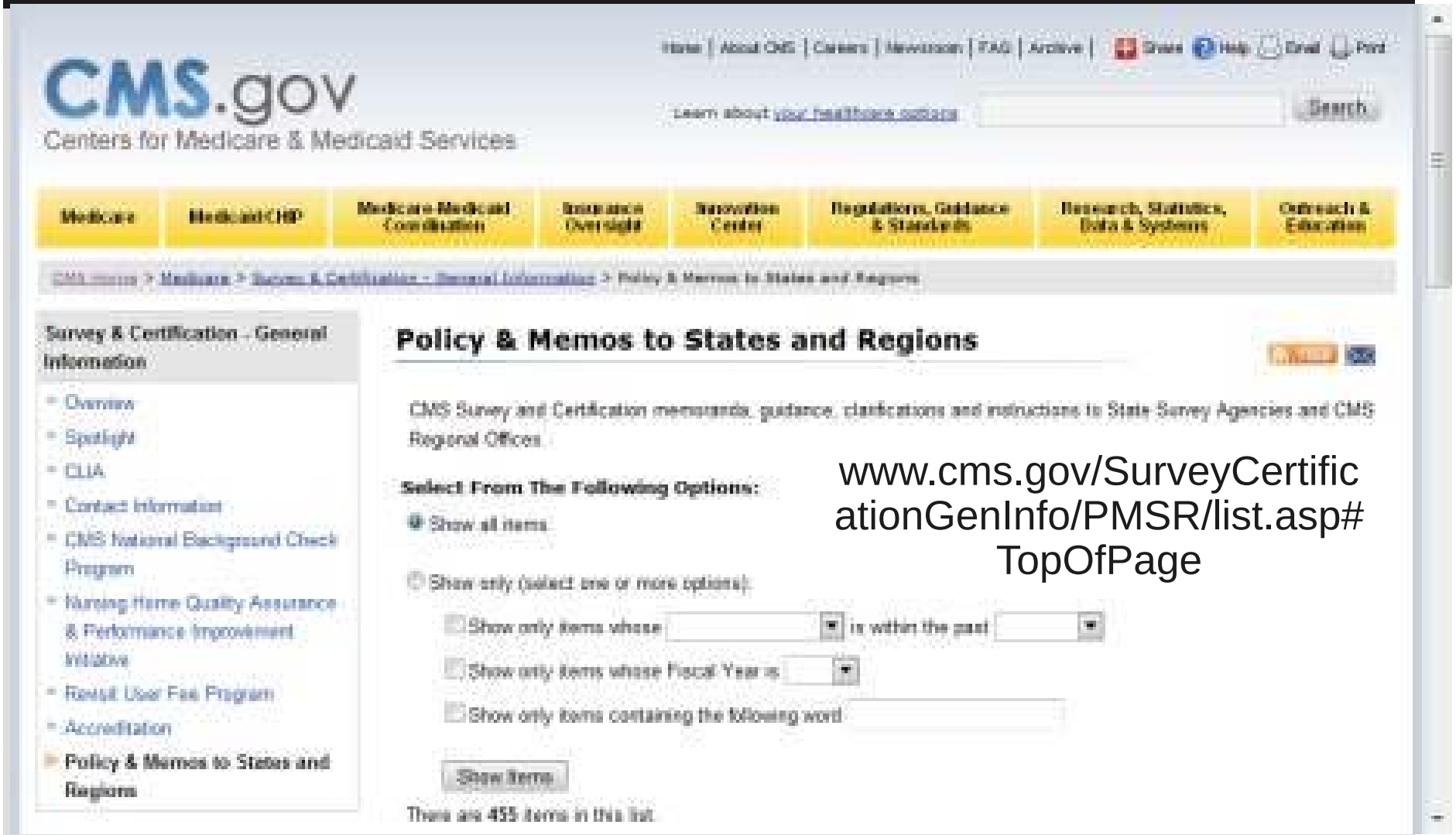
Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelines

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



CMS Survey and Certification Website



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

CMS Policy & Memo to States

Policy & Memos to States and Regions

CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices.

Show entries: 10

Filter On:

Title	Memo #	Posting Date	Fiscal Year
Critical Access Hospital (CAH) Recertification Checklist for Evaluation of Compliance with the Location and Distance Requirements	16-08-CAH	2016-02-12	2016
FY 2015 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program	16-07-AO	2016-01-29	2016
Medicare Learning Network (MLN) Infection Control Courses	16-06-ALL	2016-01-22	2016
Infection Control Pilot Project	16-05-ALL	2015-12-23	2016
Focused Dementia Care Survey Tools	16-04-NH	2015-11-27	2016
Release of Fiscal Year (FY) 2016 End Stage Renal Disease (ESRD) Core Survey Data Worksheet	16-03-ESRD	2015-11-20	2016
Advanced Notification: Revisions to State Operations Manual (SOM), Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services	16-02-CLIA	2015-11-06	2016
Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance Related to Compounding of Medications	16-01-Hospital	2015-10-30	2016

CMS IC Breaches Memo

- CMS publishes 4 page memo on infection control breaches and when they warrant referral to the public health authorities
- This includes a finding by the state agency (SA), like the Department of Health, or an accreditation organization
  - TJC, DNV Healthcare, CIHQ, or AOA HFAP
- CMS has a list and any breaches should be referred
- Referral is to the state authority such as the state epidemiologist or State HAI Prevention Coordinator

Infection Control Breaches

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: 14-36-All

DATE: **May 30, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Infection Control Breaches Which Warrant Referral to Public Health Authorities

Memorandum Summary

- ***Infection Control Breaches Warranting Referral to Public Health Authorities:*** If State Survey Agencies (SAs) or Accrediting Organizations (AOs) identify any of the breaches of generally accepted infection control standards listed in this memorandum, they should refer them to appropriate State authorities for public health assessment and management.

- ***Identification of Public Health Contact:*** SAs should consult with their State's Healthcare Associated Infections (HAI) Prevention Coordinator or State Epidemiologist on the preferred referral process. Since AOs operate in multiple States, they do not have to confer with State public health officials to set up referral processes, but are expected to refer identified breaches to the appropriate State public health contact identified at: http://www.cdc.gov/HAI/state-based/index.html

CMS Memo Infection Control Breaches

- Using the same needle for more than one individual
- Using the same (pre-filled/manufactured/insulin or any other) syringe, pen or injection device for more than one individual
- Re-using a needle or syringe which has already been used to administer medication to an individual to subsequently enter a medication container (e.g., vial, bag), and then using contents from that medication container for another individual
- Using the same lancing/fingerstick device for more than one individual, even if the lancet is changed

Medication and Safe Opioid Use

- CMS issues 32 page memo on medication administration and safe opioid use
  - Went into effect June 6, 2014
- Risk and patient safety need to review this
- Concerned about the number of patients with adverse events when taking opioids
- Must have a P&P
- Must train staff and include information that must be in the assessment
- Must document process

Medication and Safe Opioid Use

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Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-15-Hospital

DATE: **March 14, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-Operative Care of Patients Receiving IV Opioids

Memorandum Summary

- ***Medication Administration:*** We are updating our guidance for the hospital medication administration requirements to:
  - Make clear that the medication administration requirements under the nursing services condition of participation (CoP) are related to only some components of the overall hospital medication process, but that hospitals are expected, through this and the related requirements under the pharmaceutical services and quality assessment/performance improvement CoPs, to take a comprehensive approach to the medication process.
  - Update our guidance for IV medications and blood transfusions in general; and
  - Reflect the need for patient risk assessment and appropriate monitoring during and after medication administration, particularly for post-operative patients receiving IV opioid medications, in order to prevent adverse events.
- ***Immediate Post-operative Care:*** Clarification is also being made to the guidance for the surgical services CoP requirement for hospitals to have adequate provisions for immediate post-operative care, to emphasize the need for post-operative monitoring of patients

Blood and IV Medication Training

- Must still follow **state law requirements**
  - In some states an LPN can not hang blood
  - Or the LPN can not push certain IV medications in some states
  - Must show they are competent
- Must still have approved **Medical Staff Policies** and Procedures in place
- Staff must follow these which have most of the things that were previously required

Staff Must be Competent 409

- However, there must be evidence that staff is competent in:
- Maintaining fluid and electrolyte balance
- Venipuncture technique
- Blood transfusions: blood components, process to verify right blood for the right patient, transfusion reactions and how to report transfusion reactions, how to monitor the patient with blood including frequency, and hospital P&P and nationally recognized standards of practice

Blood Transfusions and IVs 409

- Discusses peripheral lines, PICC lines, arterial lines, central lines, and arterial lines
- Hospital P&P must discuss what medications can given in each type of access
- Trace lines and tubes prior to administration
- Verify proper programming of infusion devices such as flow rate, concentration, and dose rate
- Must have P&P to address appropriate IV medication monitoring requirements
  - Must include frequency of monitoring and risk factors

Blood Transfusions and IVs 409

- Hospital P&P is expected to address:
  - Monitoring for fluid and electrolyte balance
  - Monitoring patients for high alert medications including opioids
  - Expected to address monitoring for over-sedation and respiratory depression for safe opioid use
    - Can erroneous assume patient is asleep when they are having progressive symptoms of respiratory compromise
    - Factors that put patients at high risk include snoring, history of sleep apnea, first time use of IV opioids, increased opioid dose, longer length of time receiving general anesthesia, pulmonary or cardiac disease or thoracic or surgical incisions

CMS Hospital Worksheets History

- October 14, 2011 CMS issues a 137 page memo in the survey and certification section and it was pilot tested in hospitals in 11 states
- Memo discusses surveyor worksheets for hospitals by CMS during a hospital survey
- Addresses discharge planning, infection control, and QAPI (performance improvement)
  - May 18, 2012 CMS published a second revised edition and pilot tested each of the 3 in every state over summer 2012
  - November 9, 2012 CMS issued the third revised worksheet
  - Final ones issued November 26, 2014

Final 3 Worksheets

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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.

CMS Hospital Worksheets

- Contains a section on Patient Safety, LD, adverse events (AE) and Medical Error
- The regulations are the basis for any deficiencies that may be cited and not the worksheet per se
  - The worksheets are designed to assist the surveyors and the hospital staff to identify when they are in compliance
  - Will not affect critical access hospitals (CAHs) but CAH would want to look over the one on PI and especially infection control
- Questions or concerns should be addressed to PFP.SCG@cms.hhs.gov

Patient Safety LD, AE and Medical Error

PART 5 – PATIENT SAFETY – ADVERSE EVENTS AND MEDICAL ERRORS		
Elements to be Assessed		**Manner of Assessment Code (Enter all that apply) & Surveyor Notes**
5.1 In this multipart question evaluate if the hospital's leadership sets expectations for patient safety? Specifically:		
5.1.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 medical errors (including near misses/close calls) adverse events, etc.)	O YES O NO	O 1 O 2 O 3 O 4 O 5
5.1.b Is there evidence that the hospital has adopted policies supporting a non-punitive approach to staff reporting of medical errors (including near misses/close calls), adverse events, and situations they consider unsafe?	O YES O NO	O 1 O 2 O 3 O 4 O 5
5.1.c On each unit surveyed, can staff explain what the hospital's expectations are for their role in promoting patient safety?	O YES O NO	O 1 O 2 O 3 O 4 O 5

PI Patient Safety AE and Medical Errors

- Can staff on each unit explain hospital's expectation for their role in promoting patient safety?
- 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?
- Can they explain how to report?
- Does hospital employ other methods to find medical errors such as trigger tools, chart reviews, review of claims, patient grievances, interview patients etc.

PI Patient Safety AE and Medical Errors

- Can hospital provide evidence of medical errors and AEs identified through staff reports?
- 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 PI?
- Does the PI program track medication errors and ADE and drug incompatibilities
  - Tag 508 in the Pharmacy section requires this

PI Patient Safety AE and Medical Errors

- Is there a process to report blood transfusion reaction and determine if due to medical error?
- Did the survey team have prior knowledge of any serious AE that the hospital failed to identify?
  - Were any identified by the surveyors?
- Has a RCA been done on all serious preventable AEs?

PI Causal Analysis Tracers Part 5

- The next question discuss the **causal analysis 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 (RCA2 or systematic analysis)
- The surveyor will select three causal analysis done for single event or near miss
- Were underlying causes identified?

NPSF RCA2 (RCA Squared)

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RCA2: Improving Root Cause Analyses and Actions to Prevent Harm

Enter search criteria...

https://npsf.site-ym.com/?RCA2

More in this Section...

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RCA²: Improving Root Cause Analyses and Actions to Prevent Harm

Report issued by the National Patient Safety Foundation

Root cause analysis (RCA) is a process widely used by health professionals to learn how and why errors occurred, but there have been inconsistencies in the success of these initiatives. With a grant from The Doctors Company Foundation, NPSF convened a panel of subject matter experts and stakeholders to examine best practices around RCAs and develop guidelines to help health professionals standardize the process and improve the way they investigate medical errors, adverse events, and near misses.

Download the full report here. [PDF]
This report or parts of it may be printed for individual use or distributed for training purposes within your organization.
No one may alter the content in any way, or use the report in any commercial context, without written permission from the National Patient Safety Foundation.
Inquiries should be addressed to **info@npsf.org**.

Endorsements

Numerous organizations have endorsed the use of *RCA²: Improving Root Cause Analyses and Actions to*

PI Causal Analysis Tracers

- Was preventive actions developed based on the RCA?
- TJC has a **matrix** which contains elements that must be included in a reviewable sentinel event
  - Removed in July 2015 changes but still useful
- Has the hospital evaluated the impact of the preventable actions including tracking a reoccurrences or near misses?
- Has the hospital implemented the preventable actions found to be effective unless there is a documented reason for not doing so?

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

Hospital CoPs for QAPI

- CMS issued new hospital COPs memo for QA and Performance Improvement (QAPI)
- CMS issues Memo March 15, 2013 on AHRQ Common Formats
  - Hospitals are required to track adverse events for PI
- Said that 86% of the time nurses and other staff are not completing an incident report or reporting adverse events, medical errors, and medication errors into the hospital's internal PI system
- This is a CMS requirement

Report Adverse Events to PI

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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

Adverse Event Reporting

- IOM 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

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

HOSPITAL INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM

http://oig.hhs.gov/oei/reports/oei-06-09-00091.asp

Daniel R. Levinson
Inspector General

January 2012
OEI-06-09-00091

CMS Memo on Insulin Pens

- CMS issues memo on insulin pens on May 18, 2012
- Insulin pens are intended to be used on one patient only
- CMS notes that some healthcare providers are not aware of this
- Insulin pens were used on more than one patient which is like sharing needles
- Every patient must have their own insulin pen
- Insulin pens must be marked with the patient's name

Insulin Pens

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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-30-ALL

DATE: May 18, 2012

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Use of Insulin Pens in Health Care Facilities

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

Memorandum Summary

Insulin Pen devices: The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in the need for post-exposure patient notification. These reports indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients. **Insulin pens are meant for use by a single patient only.** Each patient/resident must have his/her own. Sharing of insulin pens is essentially the same as sharing needles or syringes, and must be cited, consistent with the applicable provider/supplier specific survey guidance, in the same manner as re-use of needles or syringes.

Background
Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times by a single patient/resident, using a new needle for each injection. Insulin pens must never be used for more

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

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.

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

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

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

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.

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

Safe Injection Practices

A Patient Safety Issue

CMS Memo on Safe Injection Practices

- CMS issues a 7 page memo on safe injection practices and adds section in nursing in 2016
- Discusses the safe use of single dose medication to prevent healthcare associated infections (HAI)
- Notes new exception which is important especially in medications shortages
- General rule is that single dose vial (SDV)can only be used on one patient
- Will allow SDV to be used on multiple patients if prepared by pharmacist under laminar hood following USP 797 guidelines

Safe Injection Practices

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Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-35-ALL

DATE: June 15, 2012

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections

Memorandum Summary

- ***Under certain conditions, it is permissible to repackage single-dose vials or single use vials (collectively referred to in this memorandum as "SDV's") into smaller doses, each intended for a single patient.*** The United States Pharmacopeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, *Pharmaceutical Compounding – Sterile Preparations* ("USP <797>"). Under USP <797>, healthcare facilities may repackage SDVs into smaller doses, each intended for use with one patient. Among other things, these standards currently require that:
  - The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repackaging under these conditions must be completed within 6 hours of the initial needle puncture.
  - All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process.
- ***Administering drugs from one SDV to multiple patients without adhering to USP <797>***

CMS Memo on Safe Injection Practices

- All entries into a SDV for purposes of repackaging must be completed with 6 hours of the initial puncture in pharmacy following USP guidelines
- Only exception of when SDV can be used on multiple patients
- Otherwise using a single dose vial on multiple patients is a violation of CDC standards
- CMS will cite hospital under the hospital CoP infection control standards since must provide sanitary environment
  - Also includes ASCs, hospice, LTC, home health, CAH, dialysis, etc.

CMS Memo on Safe Injection Practices

- Bottom line is you can not use a single dose vial on multiple patients
  - CMS requires hospitals to follow nationally recognized standards of care like the CDC guidelines
- SDV typically lack an antimicrobial preservative
- Once the vial is entered the contents can support the growth of microorganisms
- The vials must have a beyond use date (BUD) and storage conditions on the label
  - Such as vial expires in December 2017 and if opened and draw it up into a syringeyou must use it within one hour

CMS Memo on Safe Injection Practices

- Make sure pharmacist has a copy of this memo
- If medication is repackaged under an arrangement with an off site vendor or compounding facility ask for evidence they have adhered to 797 standards
- ASHP Foundation has a tool for assessing contractors who provide sterile products
- Go to www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx
- Click on starting using sterile products outsourcing tool now

CMS Memo on Safe Injection Practices

- So if make it in a single dose vial then you need to buy it in a single dose vial
  - If they only make it in a multi-dose vial then try and use it as a single dose vial
  - If not then try and use it only on one patient
- Do not take multi-dose vial into patient room or into OR
  - Unless in OR you treat it as a single dose vial and discard
  - Mark multi-dose vial expires in 28 days unless sooner by manufacturer
- Clean off lid even if new vial for 10-15 seconds and let dry

Safe Injection Practices

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

Safe Injection Practices Patient Safety Brief
Emergency Medicine Patient Safety Foundation

By: Sue Dill Calloway RN MSN JD CPHRM
Ruth Carrico PhD RN FSHEA CIC

July 2012

Injection Safety

- Hospitals should consider having an injection safety policy and procedure in place
- Hospitals should consider having education for nurses, physicians, and other staff on safe injection practices
  - Safe injection practices should include the ten CDC guidelines
- CMS using infection control worksheet for ASC and hospitals should be aware of this document
- Don’t leave needle in stopper and IV must be used within 1 hour of puncture

Injection Safety

- Recent issue where syringes were reused resulting in contamination to many patients in Nevada
- Never reuse a needle or syringe
- Use single doses vials when possible and single dose for one patient only
- Multidose vials for single patient
- If have to use multidose vial then mark it with expiration date in 28 days
  - CDC has list of 10 recommendation for injection safety at http://www.cdc.gov/injectionsafety/

Not All Vials Are Created Equal

SINGLE-DOSE OR MULTI-DOSE?

NOT ALL VIALS ARE CREATED EQUAL.

Dozens of recent outbreaks have been associated with reuse of single-dose vials and misuse of multiple-dose vials. As a result of these incidents, patients have suffered significant harms, including death. CDC and the One & Only Campaign urge healthcare providers to recognize the differences between single-dose and multiple-dose vials and to understand appropriate use of each container type.

This information can literally save a life.

ONEANDONLYCAMPAIGN.ORG

CDC Home

Centers for Disease Control and Prevention

CDC 24/7: Saving lives, protecting people, reducing health costs

SEARCH

A-Z Index A B C D E F G H I J K L M N O P Q R S T U V W X Y Z #

Injection Safety

http://www.cdc.gov/injectionsafety

Injected medicines are commonly used in healthcare settings for the prevention, diagnosis, and treatment of various illnesses. Unsafe injection practices put patients and healthcare providers at risk of infectious and non-infectious adverse events and have been associated with a wide variety of procedures and settings. This harm is preventable. Safe injection practices are part of Standard Precautions and are aimed at maintaining basic levels of patient safety and provider protections. As defined by the World Health Organization, a safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community. Visit the page on CDC's role in safe injection practices.

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Guidelines, Recommendations...

Assisted Monitoring of Blood Glucose
CDC Clinical Reminder, FAQs...

One & Only Campaign

About the campaign »

Contact Us:

Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333

800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348
24 Hours/Every Day

cdcinfo@cdc.gov

ISMP IV Push Medications Guidelines

- ISMP has published a 26 page document called “ISMP Safe Practice Guidelines for Adult IV Push Medications
- The document is organized into factors that increase the risk of IV push medications in adults,
  - Current practices with IV injectible medications
  - Developing consensus guidelines for adult IV push medication and
  - Safe practice guidelines
  - About 90% of all hospitalized patients have some form of infusion therapy

IV Push Medicine Guidelines

ISMP Safe Practice Guidelines for Adult IV Push Medications

A compilation of safe practices from the ISMP Adult IV Push Medication Safety Summit

Remember; CMS says you have to follow standards of care and specifically mentions the ISMP so surveyor can site you if you do not follow this.

Prepared by the Institute for Safe Medication Practices (ISMP)

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

IV Push Medications Guidelines

- Provide IV push medications in a ready to administer form
- Use only commercially available or pharmacy prepared prefilled syringes of IV solutions to flush and lock vascular access devices
- If available in a single dose vial then need to buy in single dose vial
- Aseptic technique should be used when preparing and administering IV medication
  - This includes hand hygiene before and after administration

IV Push Medications Guidelines

- The diaphragm on the vial should be disinfected even if newly opened
  - The top should be cleaned using friction and a sterile 70% isopropyl alcohol, ethyl alcohol, iodophor, or other approved antiseptic swab for at least ten seconds to it dr
- Medication from a glass vial should be with a filter needle unless the specific drug precludes this
- Medication should only be diluted when recommended by the manufacturer or in accordance with evidence based practice or approved hospital policies

IV Push Medications Guidelines

- If IV push medication needs to be diluted or reconstituted these should be performed in a clean, uncluttered, and separate location
- Medication should not be withdrawn from a commercially available, cartridge type syringe into another syringe for administration
- It is also important that medication not be drawn up into the commercially prepared and prefilled 0.9% saline flushes
  - This are to flush an IV line and are not approved to use to dilute medication

3.6 Do NOT dilute or reconstitute IV push medications by drawing up the contents into a commercially-available, prefilled flush syringe of 0.9% sodium chloride.

Discussion: Commercially available prefilled syringes of saline and heparin are regulated by the US Food and Drug Administration as *devices*, not as medications. These devices have been approved for the flushing of vascular access devices, but have NOT been approved for the reconstitution, dilution, and/or subsequent administration of IV push medications. Such use would be considered "off label" and not how manufacturers intended these products to be used, nor have prefilled flush syringes been tested for product safety when used in this manner.

Warnings intended to limit the use of prefilled syringes for medication preparation and administration appear on some syringe barrels, clearly stating "IV flush only." Some manufacturers have also limited or removed the gradation markings on the prefilled flush syringes in order to prevent measurement of a secondary medication in the flush syringe. When prefilled syringes are used in an off-label manner, the practitioner and employer bear the legal liability for any adverse events occurring from this practice.[31]

The mislabeling that occurs when medications are added to a prefilled syringe and a secondary label is not applied creates significant risk for errors. In many cases, the manufacturer's label is permanently affixed to the syringe barrel and contains product codes and a barcode as well as specific information about the fluid and its volume. When another medication is added to this syringe, there is no adequate method to amend the manufacturer's label, without covering the current information.[31] Thus, the syringe frequently remains labeled as 0.9% sodium chloride, when it also contains the diluted or reconstituted medication.

Although this unsafe practice is widespread, and many who use it mistakenly believe the risk of an error is insignificant—a belief clearly reinforced during public comment regarding this guidance statement—summit participants arrived at a consensus that the practice must be eliminated.

3.7 When necessary to prepare more than one medication in a single syringe for IV push administration

IV Push Medications Guidelines

- Combination of more than one medication is a single syringe is seldom necessary and could result in unwanted changes in the medication
- Never use IV solution or mini bags as a common source to flush an IV as to dilute for more than one patient
- Label syringes of IVP medication unless prepared and immediately given with no break
- Administer IV push medication at rate recommended by manufacturer or supported by evidenced based practices and often given too fast

CDC 10 Recommendations

- The CDC has a page on Injection Safety that contains the excerpts from the Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
  - IV and tubing used on one patient
  - Do not keep multidose vials in patient treatment area
  - One needle, one syringes every time
  - Single dose vial used on one patient only
  - Wear a mask when doing LP or putting in epidural/spinal
- Summarizes their 10 recommendations
  - www.cdc.gov/ncidod/dhqp/injectionSafetyPractices.html

Injection Safety

Safe Injection Practices to Prevent Transmission of Infections to Patients

Excerpted from Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007.

III.A.1.b. Safe Injection Practices

The investigation of four large outbreaks of HBV and HCV among patients in ambulatory care facilities in the United States identified a need to define and reinforce safe injection practices. The four outbreaks occurred in a private medical practice, a pain clinic, an endoscopy clinic, and a hematology/oncology clinic. The primary breaches in infection control practice that contributed to these outbreaks were 1) reinsertion of used needles into a multiple-dose vial or solution container (e.g., saline bag) and 2) use of a single needle/syringe to administer intravenous medication to multiple patients. In one of these outbreaks, preparation of medications in the same workspace where used needle/syringes were dismantled also may have been a contributing factor. These and other outbreaks of viral hepatitis could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications. These include the use of a sterile, single-use, disposable needle and syringe for each injection given and prevention of contamination of injection equipment and medication.

Whenever possible, use of single-dose vials is preferred over multiple-dose vials, especially when

Infection Control Topics

- Infection Control Home
- Healthcare-Associated Infections
- **Protecting Patients**
- Protecting Healthcare Workers
- Infection Control Guidelines
- Infection Control A-Z
- About DHQP

www.cdc.gov/ncidod/dhqp/injectionSafetyPractices.html

Safe Injection Practices Toolkit

So What's In Your Policy?

Injection Practices Policy and Procedure

Purpose
Safe injection practices help prevent the transmission of bloodborne infections from patient to patient.

Policy
All members of the healthcare team will comply with current Centers for Disease Control and Prevention (CDC) recommendations for safe injection practices.

Procedure
The following procedures apply to the use of needles, cannulas that replace needles, and intravenous delivery systems.

1. Needles, cannulae and syringes are sterile, single-use items. They should never be reused for another patient nor to access a medication or solution that might be used for a subsequent patient.

2. Use aseptic technique to avoid contamination of sterile injection equipment.

3. Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed.

Other CMS Section Involving RM and Patient Safety

Pharmaceutical Services Tag A-508

- Standard: Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician
  - If appropriate also to the PI program and must ensure incident report is made out
- Hospitals are required to make sure the attending doctor is immediately aware of:
  - Medication errors or drug errors, adverse drug reactions (ADRs), and drug incompatibilities
    - Must have acceptable definition for each
- Must document physician notified in chart

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: 16-01-Hospital

DATE: **October 30, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance Related to Compounding of Medications

Memorandum Summary

Hospital Appendix A Updated: The Centers for Medicare & Medicaid Services (CMS) has updated the State Operations Manual (SOM) Appendix A with respect to both the hospital survey process and the interpretive guidelines for the pharmaceutical services Condition of Participation (CoP). The update includes the following features:

- ***Pharmaceutical Services:*** Revisions were made to portions of the pharmaceutical services CoP to bring them into alignment with current accepted standards of practice. To improve clarity, the revised guidance addresses: accepted professional pharmacy principles, including United States Pharmacopeia (USP) standards; compounding of medications, particularly compounded sterile preparations (CSPs); determining

8.50 x 11.00 in

CMS Rewrites 10 of 18 Pharmacy Tags

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

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

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

Transmittals for Appendix A

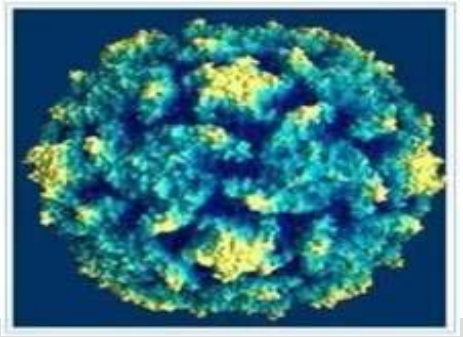
Survey Protocol

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

Email questions
hospitalscg@cms.hhs.gov



Drug Incompatibilities

- Any unexpected reaction that occurs between the IV medications must also be reported
- CMS said hospitals can minimize risk by having resources available such as
  - Drug incompatibility (DI) chart
  - Online incompatibility references
- Incompatibility information must be readily available to staff
  - Must be kept up-to-date as information is frequently updated by manufacturer

Hospital Policies and Procedures (P&P) 508

- Hospital must establish P&P for the reporting of medication errors, ADRs, and incompatibilities
- Hospital must make sure staff are aware of the reporting requirements
  - Hospital should add this information to orientation for new employees
  - Hospital should consider periodic CNE
- Immediate reporting must be required in the P&P with timeframes for reporting that are based on the clinical effects of harm on the patient

Verbal Orders

- Common problematic standard with CMS and TJC
- Should not be a common practice
- Physician is not allowed to give if standing in nursing station absent an emergency
- May take if needed and physician not in the department
- Nurse needs to write it down and **read** it back
- Nurse needs to sign name, date and **time**
- Physician must sign name, date and **time** also

Verbal Orders

- Physician must sign off the VO (including date time, and sign their name) **ASAP**
  - Most states say 24 or 48 hours and must follow stricter state law
  - If state does not say then CMS use to say 48 hours but now within your hospital P&P and many are now changing to 30 days but sign as asap
- CMS will allow PA or NP to sign off VO for the physician if state and hospital allows and within their scope of practice (except CAH)
- Any physician on the case can sign off the VO for any other doctor on the case

Verbal Orders

- Have a P&P on who can accept VO in your facility
  - Must be qualified staff
  - Policy may allow pharmacist for pharmacy orders, dietician for dietary orders, nurses, etc.
- Include in P&P when will not take VO
  - Such as many hospitals do not take a VO for chemotherapy
  - CMS 407-408 and 454 and 457, changes 6-7-2013
  - TJC RC.02.03.07. PC.02.02.07 and PC.01.01.01

Post Anesthesia Assessment

- CMS defines four things in their anesthesia bucket
- This includes General, epidural and spinal (regional), MAC, and deep sedation
  - Must be done by one of five groups qualified to give anesthesia
  - Must have pre and post-anesthesia assessment done within 48 hours
  - CMS is very specific about what must be included
  - Hospitals should have a form to capture the required elements

Post Anesthesia Evaluation 1005

- Has to be done within 48 hours on inpatients and outpatients by anesthesia person except in CAH hospitals
  - CRNA, AA, anesthesiologist, or qualified doctor, dentist, podiatrist, or oral surgeon
  - Can not delegate to NP, RN, or PA
- 48 hours starts at time patient moved into PACU or designated recovery area (SICU etc.)
- 48 hour is an outside parameter
- If patient goes home before seen by anesthesia provider can call and complete

Post-Anesthesia Assessment to Include 1005

- Respiratory function with respiratory rate, airway patency and oxygen saturation
- CV function including pulse rate and BP
- Mental status, temperature
- Pain
- Nausea and vomiting
- Post-operative hydration
  - Consider having a form to capture these requirements

Interpreters and Health Literacy

- To prevent medical errors and improve patient safety
- Make sure interpreters are provided when indicated and document
  - 55 million American English in not primary language
- Remember the issue low health literacy so ensure discharge instruction, consent forms, medication sheets and other documents provided to the patient are written in a manner the patient can understand
  - 90 million Americans with low health literacy
  - Use teach back to ensure patient understanding

Patient Safety Issues and Restraint and Seclusion

Restraints

- Many changes were made to both TJC and CMS Restraint and Seclusion standards
- CMS Hospital CoPs has 50 pages of restraint standards from Tag 0154-0214
- TJC has 10 standards in PC chapter (deemed status)
- Need to rewrite policies and procedures, order sheet and documentation sheet to be compliant
- Need to train all staff in accordance with requirements
- Physicians must be trained on R&S P&P

EMPSF Free Patient Safety Briefs

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

Restraint and Seclusion Patient Safety Briefing
Emergency Medicine Patient Safety Foundation

Written by: Sue Dill Calloway RN MSN JD CPHRM
Michael Gerardi, MD, FAAP, FACEP
John (Jack) Kelly DO, FACEP, FAAEM

March 2012
Revised July 16, 2012

Introduction

Restraint and seclusion is a very important patient safety issue. Appropriately applied restraints can protect patients from harming themselves or others. Paradoxically, improperly applied restraints can result in patient injury and death. It is also an important regulatory issue for accreditation organizations such as the Joint Commission. Likewise, any hospital accredited by DNV Healthcare or by the American Osteopathic

Restraint Worksheet

- Revised CMS restraint worksheet is available off the internet at
- R&S reports are to the regional office not the state agency
- List of regional offices (to put in your P&P) at www.cms.hhs.gov/RegionalOffices/01_overview.asp
- Must still notify regional office by phone the next business day and document this in medical record
- Patient dies in restraint, within 24 hours of being in a restraint or 7 day rule if death caused by R&S
  - Except if patient dies in **wrist restraints** as long as the restraint does not cause the death

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-1210

REPORT OF A HOSPITAL DEATH ASSOCIATED WITH RESTRAINT OR SECLUSION

A. Hospital Information:

Hospital Name		CCN
Address		
City	State	Zip Code
Person Filing the Report		Filer's Phone Number

B. Patient Information:

Name		Date of Birth
Primary Diagnosis(es)		
Medical Record Number	Date of Admission	Date of Death
Cause of Death		

www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10455.pdf

C. Restraint Information *(check only one)*:

- ☐ While in Restraint, Seclusion, or Both
- ☐ Within 24 Hours of Removal of Restraint, Seclusion, or Both
- ☐ Within 1 Week, Where Restraint, Seclusion or Both Contributed to the Patient's Death

Type *(check all that apply)*:

☐ Physical Restraint ☐ Seclusion ☐ Drug Used as a Restraint

If Physical Restraint(s), Type *(check all that apply)*:

- ☐ 01 Side Rails
- ☐ 02 Two Point, Soft Wrist
- ☐ 03 Two Point, Hard Wrist
- ☐ 04 Four Point, Soft Restraints
- ☐ 05 Four Point, Hard Restraints
- ☐ 06 Forced Medication Holds
- ☐ 07 Therapeutic Holds
- ☐ 08 Take-downs
- ☐ 09 Other Physical Holds (specify): _____
- ☐ 10 Enclosed Beds
- ☐ 11 Vest Restraints
- ☐ 12 Elbow Immobilizers
- ☐ 13 Law Enforcement Restraints

If Drug Used as Restraint:

Drug Name	Dosage

Restraint Death Soft Wrist Restraint

- An exception is if the patient dies and only used two soft wrist restraints
  - Instead the hospital could just keep an **internal log**
  - The log would include the patient's name, date of birth, date of death, attending physician, primary diagnosis, and medical record number
  - Name of practitioner responsible for patient could be used in lieu of attending if under care on non-physician practitioner
  - CMS could request to review the log at anytime
  - Published in FR May 16, 2012 and effective June 7, 2013

Restraint and Seclusion

- Patient has a right to be free from unnecessary R&S
- Leadership has responsibility to create culture that supports right to be free from R&S
- Should not considered as part of routine part of fall prevention
- If use protocol you still need an order
- Know the CMS definition of restraint and seclusion
- Know if drug used as a restraint

Restraint and Seclusion

- R&S number one problematic standard!
- CMS calls it violent and or self destructive as opposed to TJC who calls it behavioral health
- CMS calls it non violent/non self destructive and TJC calls it non behavioral health patient
- Know what restraints do not include such as forensic restraints, orthopedically prescribed devices, holding for medical test, surgical dressings, or postural supports
- Mitt is a restraint if boxing glove style

Restraint and Seclusion

- Know what it does include such as freedom splints, and all 4 side rails if patient can not lower them
- Try or consider and document less restrictive interventions and alternatives
- Document the assessment
- Need order from physician or LIP
- If LIP gives order notify doctor ASAP
- Amend plan of care
- Consider debriefing although not required by CMS on V/SD patients

Restraint and Seclusion

- End at the earliest time
- Do PI
- Use as directed
- If V/SD need one hour face to face
- Time limited orders for V/SD patients
- Need P&P on R&S
- Educate staff and document this
- Follow any stricter state law, and
- Report restraint deaths as required

Alarm Fatigue

Alarm Fatigue

- Recent risk management and patient safety issue
- Brought to light by several articles in the press including Boston Globe article
- Hospital staff fails to hear a cardiac monitor and patient was found flat lined for more than two hours
- With increased use of alarms they are either ignored or just not heard
- Staff have sometimes forgotten to turn them back on
- Staff can tune out the alarm noise
  - Cardiac monitors, infusion pumps, ventilators, etc.

Patient Alarms Often Unheard or Unheeded

SPECIAL REPORT

The Boston Globe

Patient alarms often unheard, unheeded

The incessant din of beeping monitors can numb or distract hospital staff; the consequences can be deadly

Alarm Fatigue

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

Addressing Alarm Problems in the Emergency Department

By Kathryn M Pelczarski
Director, Applied Solutions Group, ECRI Institute
September 2012

Stand for a few moments in the middle of your emergency department (ED) to just listen and observe. How many alarms do you hear? Can you distinguish where each alarm is coming from and whether it's a physiologic monitor or ventilator or infusion pump alarm? Does each alarm connote the level of urgency needed for the nurse to respond promptly and appropriately? Do you observe the nurses scurrying to respond? Or do the alarms continue to perpetuate while no one responds?

Device alarms should provide an effective safety net to alert caregivers to critical changes in patient conditions or safety-related problems with devices. Does this statement hold true in your organization? Do device alarms provide an effective safety net in your ED?

Unfortunately, as many experts agree, there are serious problems with both the design and use of clinical

Alarm Fatigue

- ECRI Institute issues a report and finds 216 deaths from 2005 to mid 2010 in which problems with monitor alarms occurred
- ECRI published top hazards for 2011to 2016 and alarm hazards makes the top ten list
- Staff overwhelmed by sheer number of alarms (alarm overload)
- Staff improperly modified the alarm settings
- Staff become desensitized to alarms leading to slow response time
  - CMS cited hospital under staffing when staff did not respond timely and some hospital gets monitor watchers

TJC 2016 NPSG

- Identify most important alarm signals to manage
- What is risk to patient if not attended to
- If the alarm signal needed or does it contribute to alarm noise and alarm fatigue?
- Look at best practices and guidelines
- January 1, 2016 establish P&P that address the issues identified by TJC and
- Must educate staff and LIPs on the purpose and proper operation of alarm systems that they are responsible

Alarm Fatigue

- Alarm settings not restored to their normal levels
- Alarms not properly relayed to ancillary notification systems
  - Paging systems, wireless phones, etc.
- ECRI makes recommendations
  - Establish protocols for alarm system settings
  - Ensure adequate staffing
  - Establish alarm response protocols and ensure each alarm will be recognized
  - Assign one person responsible for addressing the alarm

TJC Sentinel Event Alert 50 Alarm Safety

The Joint Commission
Sentinel Event Alert

A complimentary publication of The Joint Commission

Issue 50, April 8, 2013

Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Event Alert* identifies specific types of sentinel events, describes their common underlying causes, and suggests steps to prevent occurrences in the future.

Accredited organizations should consider information in an Alert when designing or redesigning relevant processes and consider implementing relevant suggestions contained in the Alert or reasonable alternatives.

Please route this issue to appropriate staff within your organization. *Sentinel Event Alert* may only be reproduced in its entirety and credited to The Joint Commission. To receive by email, or to view past issues, visit www.jointcommission.org.

Medical device alarm safety in hospitals

Many medical devices have alarm systems; among them are bedside physiologic monitors that include ECGs (electrocardiogram) machines, pulse oximetry devices, and monitors of blood pressure and other parameters; bedside telemetry; central station monitors; infusion pumps; and ventilators. These alarm-equipped devices are essential to providing safe care to patients in many health care settings: clinicians depend on these devices for information they need to deliver appropriate care and to guide treatment decisions. However, these devices present a multitude of challenges and opportunities for health care organizations when their alarms create similar sounds, when their default settings are not changed, and when there is a failure to respond to their alarm signals.

The number of alarm signals per patient per day can reach several hundred depending on the unit within the hospital, translating to thousands of alarm signals on every unit and tens of thousands of alarm signals throughout the hospital every day. It is estimated that between 85 and 99 percent of alarm signals do not require clinical intervention, such as when alarm conditions are set too tight; default settings are not adjusted for the individual patient or for the patient population; ECG electrodes have dried out; or sensors are malpositioned.[1] As a result, clinicians become desensitized or immune to the sounds, and are overwhelmed by information – in short, they suffer from "alarm fatigue." In response to this constant barrage of noise, clinicians may turn down the volume of the alarm, turn it off, or adjust the alarm settings outside the limits that are safe and appropriate for the patient – all of which can have serious, often fatal, consequences.[2] One such example occurred in the summer of 2010. According to a Boston Globe article, a 60-year-old man died in the intensive care unit of a hospital – not from the injury he suffered to his head from a fallen tree branch – but from a system failure that resulted in delayed response to an alarm signal that indicated significant changes in his condition.[3] These changes – that set off alarms – included rapidly increasing heart rate and falling blood oxygen levels. Staff responded only after one hour, when a critical alarm condition signaled that the patient had stopped breathing –

Excellent Resource Extension Healthcare

AAMI
Advancing Safety in Medical Technology
We take care of alarms
so you can take care of patients.
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Infusion Systems
Interoperability
Reprocessing
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Related Links
Clinical Alarms
www.aami.org/htsi/alarms
Medical device alarms provide essential warnings to alert caregivers of changes in a patient's condition. When alarms work well, the environment of care is enhanced. When alarms don't work well, they pull caregivers away from other duties and other patients — or worse, train caregivers to ignore the alarm sounds altogether. Alarms that are ignored can and have resulted in patient deaths.
Experts agree that resolving problems with medical device alarms requires an interdisciplinary effort and buy-in from a wide array of players at the highest levels.
What's New
National Coalition for Alarm Management
The Coalition is a group of thought-leaders in the alarm management field who are driving improvement in alarm management nationwide, and seeking standardization where possible. Members come from all aspects of alarm management—the clinical community, industry, device regulators, hospital accreditors, and professional societies. Learn more.
Pioneering Spirit Award
The American Association of Critical-Care Nurses' (AACN) bestowed the GE Healthcare-AACN Pioneering Spirit Award upon HTSI for its efforts to advance high acuity and critical care nursing regionally and nationally. Read more about this award.
VHA Patient Safety Assessment Tool (PSAT)
The PSAT application is only available to VHA staff that have been granted permission by NCPS. However, non-

Clinical Alarms Best Practices Library AAMI

Foundation Library: Clinical Alarms

AAMI Resources

www.aami.org/thefoundation/content.aspx?ItemNumber=1730&navItemNumber=674

- Alarm Parameter Inventory
- Alarm Summit Publication, 2011
- Alarm System Vocabulary according to industry accepted standards; IEC 60601-1:2006+A1:2012.
- Cvach, Maria, MS, RN, Monitor Alarm Fatigue: An Integrative Review. *Biomedical Instrumentation & Technology* July/August 2012, 268-277.
- Taming the Alarm Problem, Lane Desborough, Medtronic Diabetes

Alarms Best Practices Literature Review

Documents in this library were reviewed and recommended by the Alarm Best Practices workgroup to identify areas for potential research and to share best practice strategies to reduce alarm fatigue, increase patient safety and encourage the delivery of high quality healthcare.

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Choosing Wisely and Image Wisely

Choosing Wisely

- Be familiar with the website Choosing Wisely
- Helps patients choose by selecting care that is evidenced based
- Has a list of things that providers and patients should question
- Many prestigious organizations are partners
- Have a list of things that should be questioned and helps educate patients on making wise decisions
- Basically important from both a risk management, compliance and patient safety perspective

Choosing Wisely Website

Choosing Wisely

- List first published in Archives of Internal Medicine
- ACEP has a list of tests and procedures that are not effective and two are related to medications
- Avoid antibiotics and wound cultures in patients with uncomplicated skin abscesses after successful I&D with adequate follow up
  - Abscesses become walled off and form pus under the skin and antibiotics offer no benefit after I&D done
- Avoid IV fluids before doing a trial of oral rehydration in cases of mild to moderate dehydration in children

Lists

United States health care provider organizations representing more than one million providers developed lists of *Things Physicians and Providers Should Question* in recognition of the importance of conversations to improve care and eliminate unnecessary tests and procedures.

Download a pdf of all specialty society lists

These lists represent specific, evidence-based recommendations providers and patients should discuss together in order to make wise decisions about the most appropriate care based on their individual situation. Each list provides information on when tests and procedures may be appropriate, as well as the methodology used in its creation.

Choosing Wisely recommendations should not be used to establish coverage decisions or exclusions. Rather, they are meant to spur conversation about what is appropriate and necessary treatment. As each patient situation is unique, providers and patients should use the recommendations as guidelines to determine an appropriate treatment plan together.

In collaboration with the partner organizations, Consumer Reports has created resources for consumers and providers to engage in these important conversations about the overuse of medical tests and procedures that provide little benefit and in some cases harm.

Specialty Society Lists of Five Things Physicians and Patients Should Question (for physicians):

- AMDA – Dedicated to Long Term Care Medicine
- American Academy of Allergy, Asthma & Immunology
- American Academy of Dermatology
- American Academy of Family Physicians
- American Academy of Hospice and Palliative Medicine
- American Academy of Neurology
- American Academy of Ophthalmology
- American Academy of Orthopaedic Surgeons
- American Academy of Otolaryngology — Head and Neck Surgery Foundation
- American Academy of Pediatrics
- American Association for Pediatric Ophthalmology and Strabismus
- American Association for the Study of Liver Diseases

http://www.choosingwisely.org/doctor-patient-lists/antibiotics-for-pink-eye/

Patient-Friendly Resources from Specialty Societies and Consumer Reports:

- Allergy tests: When you need them and when you don't
- Antibiotics for ear infections in children: when you need them...
- Antibiotics for pink eye...
- Antibiotics for urinary tract infections in older people
- Antibiotics for your skin: When you need them...
- Antibiotics: When children need them for respiratory illness
- Bone-density tests: When you need them...
- Cancer care at the end of life: When to choose supportive care
- Chest X-rays before surgery: When you need them...
- Choosing pain relievers with kidney disease/heart problems
- Chronic kidney disease: Making hard choices
- Colonoscopy: When you need it...

Image Wisely

- American College of Radiology (ACR) and Radiological Society of North American (RSNA) joined forces to address concerns about the increased exposure of patients to ionizing radiation
- Objective is to lower the amount of radiation used in medically necessary imaging studies and to eliminate unnecessary procedures
- CMS rewrites all the hospital radiology and nuclear medicine CoPs on because of the safety issues
- TJC implements Diagnostic Imaging Services standards with same goal both in July 2015

Image Wisely Radiation Safety

Radiation Safety & Image Gently

- Image gently campaign was launched to raise awareness about measures to reduce radiation dose during pediatric medical imaging exams
  - Parent may give nurse a card to fill out with information on exam performed
  - Has many free resources available off the website including pediatric CT protocol
- Image wisely is an awareness program of the American College of Radiology and others to address concerns about patient exposure to ionizing radiation from medical imaging

Image Gently Radiation Safety in Pediatrics

www.pedrad.org/associations/5364/ig/

Child Sized Protocols

American Registry of Radiologic Technologists Supports Image Gently Campaign...

Adjust Your Action Plans to Ensure 'Child-Size' Protocols

The goal of the Alliance for Radiation Safety in Pediatric Imaging, sponsors of the "Image Gently" campaign, is to raise awareness of the opportunities to lower radiation dose in the imaging of children. Visit their website at www.imagegently.org for simple educational resources to inform radiology practices on what can be done now to improve radiation protection for children. In the meantime, the Image Gently alliance calls for technologists to get on board by following these five recommendations.

1 Increase awareness for the need to decrease radiation dose to children during CT scanning. Encourage your fellow professionals to get involved in the effort.

2 Be committed to make a change in your daily practice by working as a team with your radiologist, medical physicist, referring doctors, and parents to decrease the radiation dose. You can even sign a pledge found on the Image Gently website at www.imagegently.org.

3 Know the practice standards ("The Practice Standards for Medical Imaging and Radiation Therapy" from ASRT). Standards 1 and 2 on assessment and analysis are your guide to ensuring an appropriate action plan is established for completing a CT exam.

4 Work with your medical physicist, radiologist, and department manager to review your adult CT protocols; then use the simple CT protocols on the Image Gently website to down-size for kids. More is *not* better; adult-size KV and mAs are not necessary for small bodies.

5 Be involved with your patients. Be the patient's advocate. Ask the questions required to ensure that you child-size the scan and that you scan only the area required to obtain the necessary information.

Your patients and their families will thank you.

For more information on "Image Gently," visit www.imagegently.org

CMS Radiology Standards

- Patient exposure to ionizing radiation has doubled in 20 years
  - Due to diagnostic imaging, CT, fluoroscopy, and nuclear medicine (NM) studies which can cause cancer
  - Amount of ionizing radiation from CT scan is significantly greater and patient may receive several over their lifetime
  - 80 million studies done every year
- FDA has taken initiative to reduce unnecessary radiation exposure
  - Want to make sure it **justified** to use it and dose optimization so **lowest dose** is used (as low as reasonably achievable)

CMS Radiation Safety

- Person exposed to x-ray can develop cancer later in life and risk from CT scan is 1:1000
- Risk is small but depends on the amount of radiation, age exposed, and sex of patient
  - Women are at higher lifetime risk for developing radiation associated cancer
  - Risk is greater for x-rays at a younger age
  - Larger the dose and more x-rays increase risk of getting cancer
- Need proper safety precautions maintained against radiology hazards (Tag 535)

Hair Loss In Radiation Overdoses

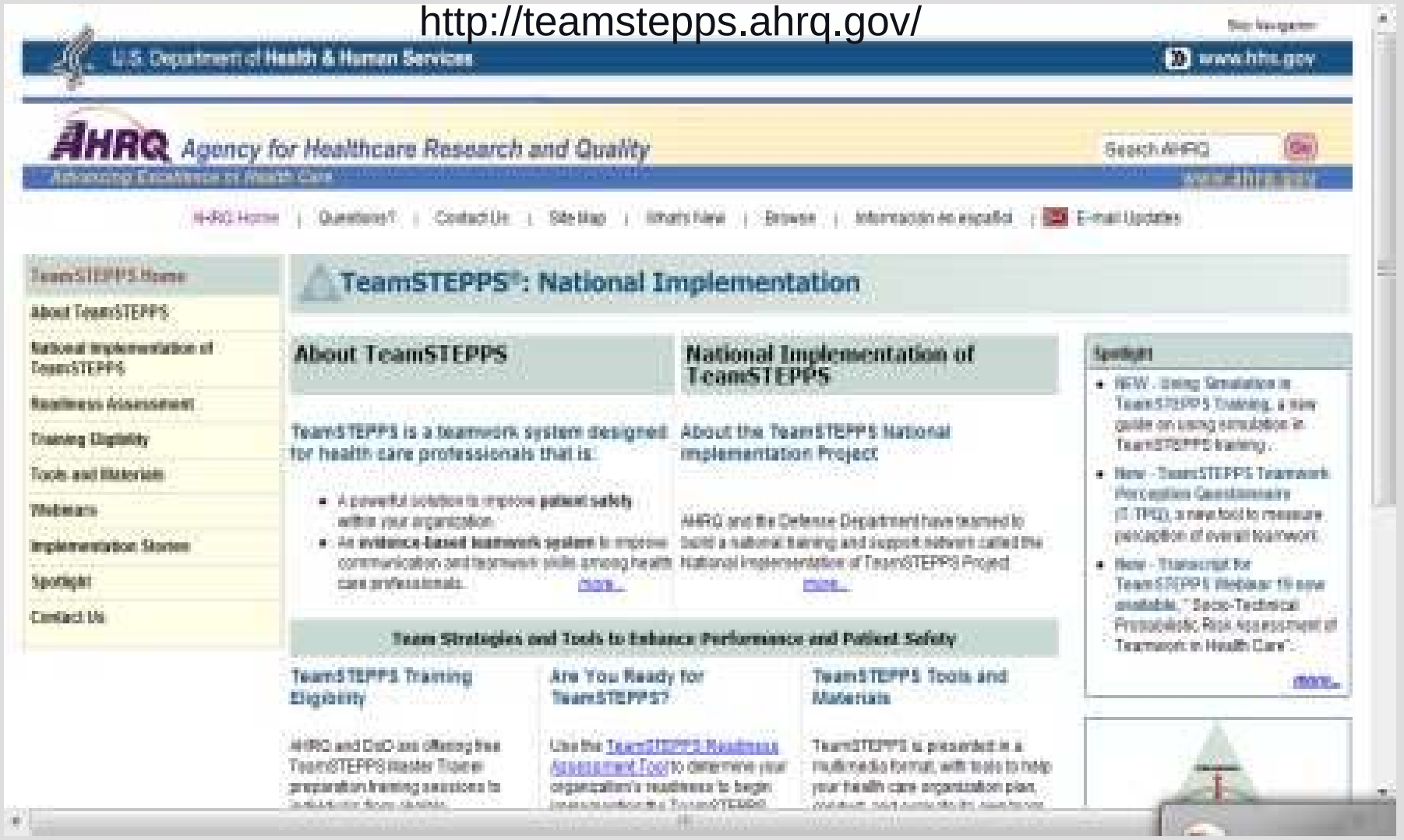
Team Work, Communication & Patient Safety Tools

Teamwork and Patient Safety Culture

- There are many studies that show the importance of team work on patient safety culture
- Teamwork training provides safer healthcare
- Teamwork is a powerful solution to improve patient safety
- Evidenced based teamwork system will improve both teamwork and communication among ED staff
- Common ones include crew resource management (CRM) or AHRQ TeamSTEPPS
  - AHRQ has many excellent free resources on teamwork and other patient safety tools

AHRQ Teamwork Resources

http://teamstepps.ahrq.gov/



Communication

- Communication break downs are the leading system failure that contributes to error
- TJC sentinel event data support this which is why it became a NPSG
  - Left with notifying physicians of panic values and document
  - Most common root cause of sentinel events is communication and accounts for 70% of all errors
- A communication model (like SBAR or standard report sheet form, ticket to ride, hall pass, or report template) could help
  - Improving communication in the emergency department. Redfern E, Brown R, Vincent CA. Emerg Med J. 2009;26:658-661.

Communication Bedside Shift Report

- Important in giving report for ED nurses and physicians going off duty
  - TJC standard on handoff
  - NPSG.02.03.02
  - Bedside shift report improves patient safety and nurse accountability
  - Bedside shift report improves patient safety and nurse accountability. Baker SJ. J Emerg Nurs. 2010;36:355-358
  - Watch chasing zero by Dennis Quade at http://safetyleaders.org/Quaid/
- Good communication is also important for preventing lawsuits

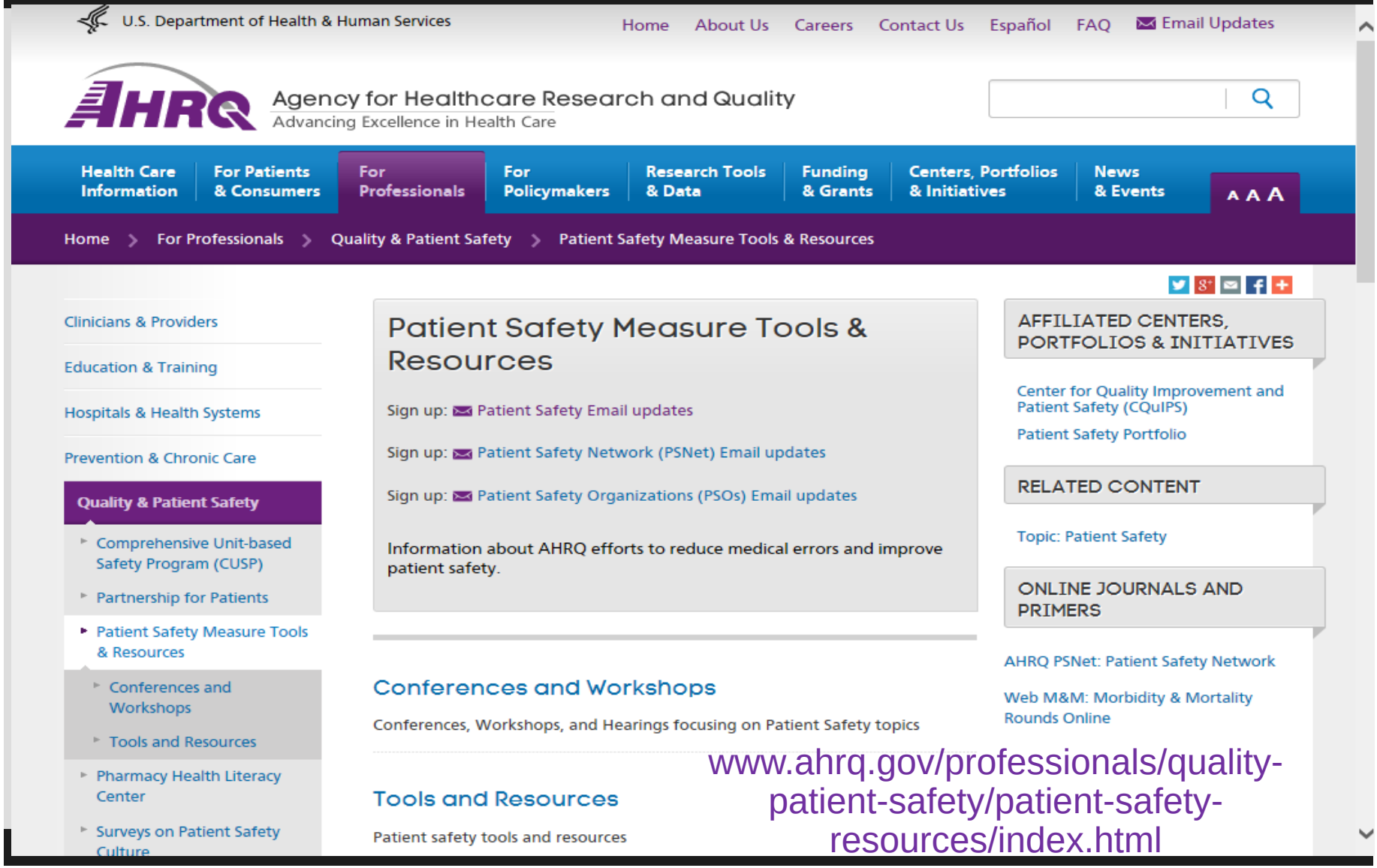
Watch This Video Bedside Nurse Report

Heparin Mix Up Almost Killed Their Twins

AHRQ Medical Errors and Patient Safety

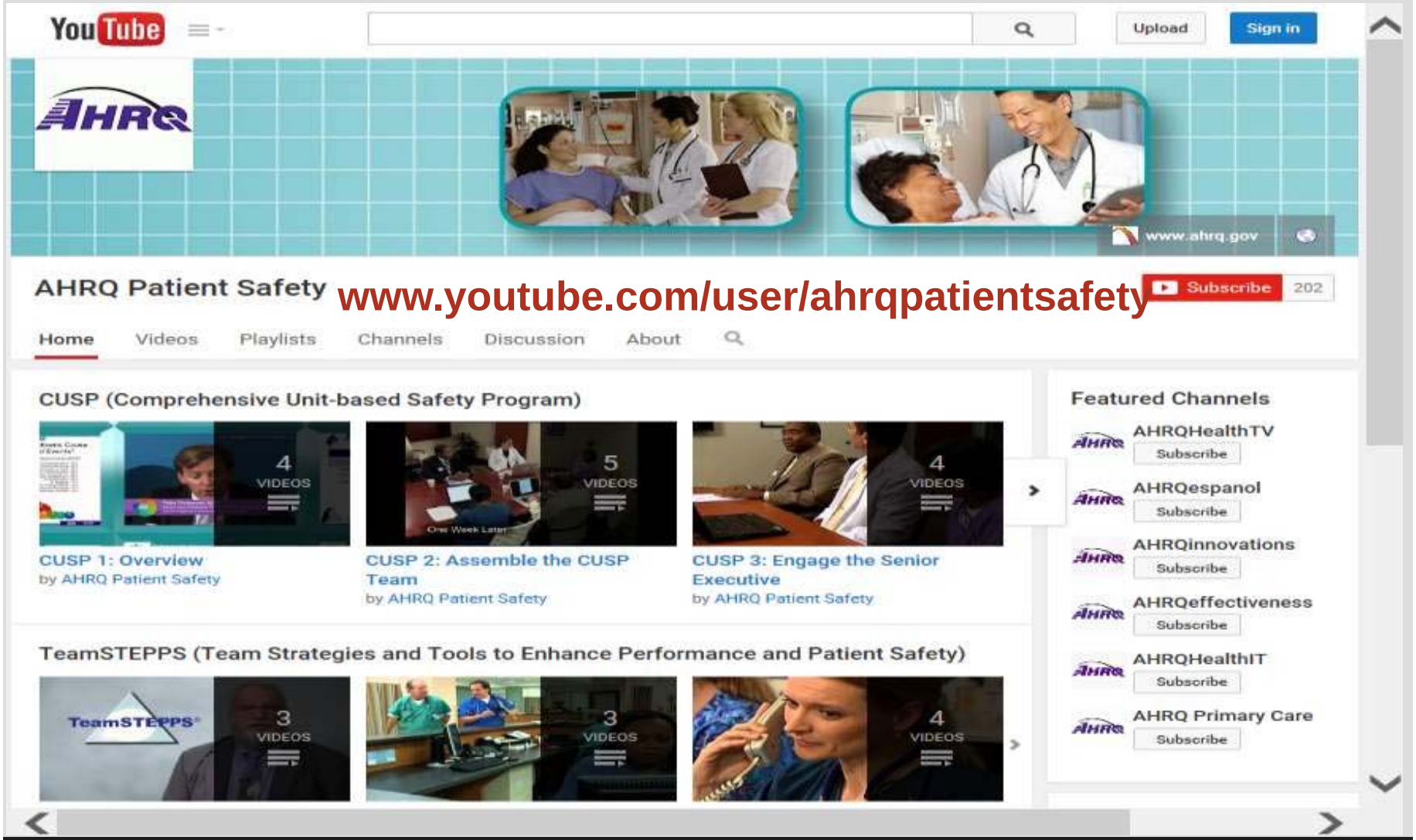
- Can sign up to get emails on medical errors and patient safety
  - Journals and primers on patient safety
  - Resources such as patient education material on patient safety
  - Many patient safety tools
- Be sure to sign up to get the PSNet or patient safety network send to your email
  - Will send list of published research on quality and safety
  - You can do a search and locate articles of interest

AHRQ Patient Safety Tools



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

AHRQ Patient Safety Videos



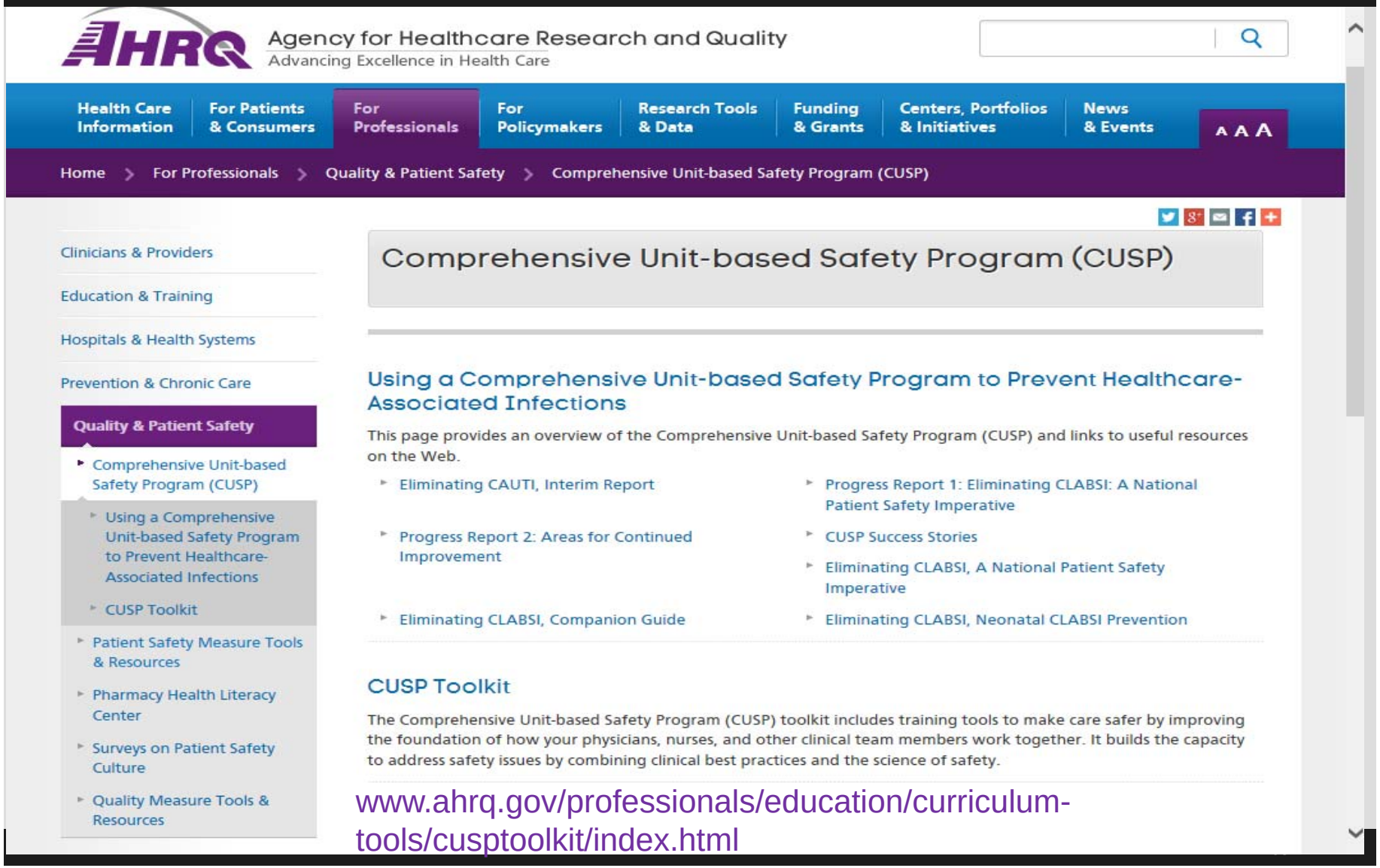
AHRQ Patient Safety Tools

- ESI triage tool for emergency care
- Crowding and boarding, ED Simulation Peds
- Medication reconciliation and handoffs
- Hospital survey on patient safety culture
- CUSP toolkit, Falls toolkit
- Evidence for Patient Safety Practices
- Mistake proofing the design of healthcare processes
- Patient safety indicators

CUSP Toolkit

- AHRQ has a free toolkit on the comprehensive unit-based safety program
  - November 2015 one on CaUTI
- Includes training tool to make care safer by improving the foundation of how physicians, nurses, and staff work together
- It addresses safety issues by combining best practices
- The toolkit has modules which include teamwork and communication, patient and family engagement, and more!

CUSP Toolkit



www.ahrq.gov/professionals/education/curriculum-tools/cusptoolkit/index.html

Clinicians & Providers

Education & Training

- Continuing Education
- Curriculum Tools
  - Diabetes Planned Visit Notebook
  - Advancing Pharmacy Health Literacy Practices Through Quality Improvement
  - TeamSTEPPS
  - Staying Healthy Through Education and Prevention (STEP)
  - Chronic Care Model
  - CLABSI Tools
  - CUSP Toolkit

Hospitals & Health Systems

CUSP Toolkit

The Comprehensive Unit-based Safety Program (CUSP) toolkit includes training tools to make care safer by improving the foundation of how your physicians, nurses, and other clinical team members work together. It builds the capacity to address safety issues by combining clinical best practices and the science of safety.

Introduction to CUSP

Three videos describe the CUSP toolkit's success in reducing infections in hospital settings.

How to Use the CUSP Toolkit

The CUSP Toolkit is composed of instructional modules that a unit leader (facilitator) can use to teach his or her unit team members about CUSP

ABOUT CUSP

Introductory videos on CUSP tool

- What is CUSP?
- A Doctor's Perspective
- A Nurse's Perspective

CUSP RESOURCES

Using a CUSP to Prevent HAI's

Tools for Reducing Central Line-Associated Blood Stream Infectio

Webinars: learn more about how CUSP works.

Non-Punitive Environment, Dilaudid Safety Issues, Trigger Tools and Fatigue

Patient Safety & Non-Punitive

- Having a **non-punitive environment** would encourage reporting of errors and near misses
- Both the Joint Commission (TJC) and the Centers for Medicare and Medicaid Services (CMS) require a non-punitive environment
- However, many healthcare facilities have balanced this with the **Just Culture theory**
- A person who is reckless or does something intentional to harm a patient should be terminated from employment

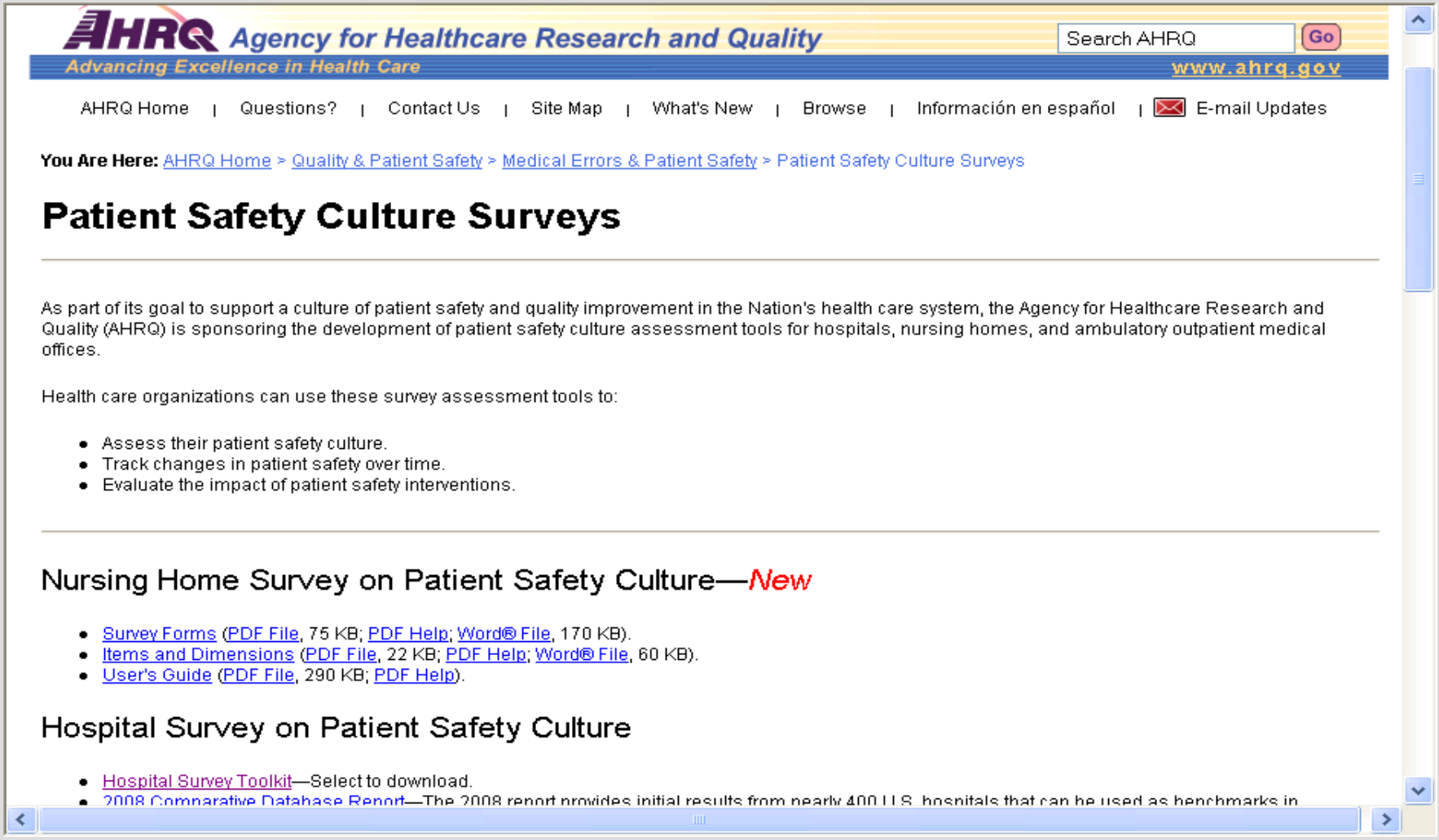
Reporting Medical Errors and Near Misses

- Staff need to feel comfortable in reporting medical errors and near misses
- Reporting system should facilitate the sharing of patient safety information
  - In fact, this is a TJC requirement
  - We need a learning environment so we can learn from our mistakes
  - Need to use a system analysis approach and fix the system to prevent medical errors in the future
- The entire hospital needs to be focused on patient safety if a culture of safety is to be established

Patient Safety Culture of Safety Tool

- CMS discussed non-punitive environment and having a culture of safety
- One way to gauze where your facility is at is to do a safety culture survey
  - NQF recommends you do the culture survey also
- Need to evaluate results carefully and put into place plan and monitor results
  - Hospitals can go to their AHRQ Culture Survey website for additional resources at www.ahrq.gov/qual/hospculture/
  - The survey tool allows hospitals and other healthcare organizations to track changes over time

Patient Safety Culture Survey



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You Are Here: AHRQ Home > Quality & Patient Safety > Medical Errors & Patient Safety > Patient Safety Culture Surveys

Patient Safety Culture Surveys

As part of its goal to support a culture of patient safety and quality improvement in the Nation's health care system, the Agency for Healthcare Research and Quality (AHRQ) is sponsoring the development of patient safety culture assessment tools for hospitals, nursing homes, and ambulatory outpatient medical offices.

Health care organizations can use these survey assessment tools to:

- Assess their patient safety culture.
- Track changes in patient safety over time.
- Evaluate the impact of patient safety interventions.

Nursing Home Survey on Patient Safety Culture—*New*

- Survey Forms (PDF File, 75 KB; PDF Help; Word® File, 170 KB).
- Items and Dimensions (PDF File, 22 KB; PDF Help; Word® File, 60 KB).
- User's Guide (PDF File, 290 KB; PDF Help).

Hospital Survey on Patient Safety Culture

- Hospital Survey Toolkit—Select to download.
- 2008 Comparative Database Report—The 2008 report provides initial results from nearly 400 U.S. hospitals that can be used as benchmarks in

Developing a Culture of Safety

- Institute blame free reporting
- Open discussion of human conditions
- Story telling especially about incidences within the organization
- Confidential and anonymous reporting process
- Communication and team work
- Executive walk arounds

Dilaudid (HYDROmorphine)

- Even though this drug is used frequently, it is one of the top 10 medications to harm patients
- Always include both names and use tall man lettering
- Staff get it confused with Morphine
- It is a 7:1 to help people remember and use laminated dosing charts
- Make sure include information on this in orientation for new staff and periodically
- Do not stock in 4 mg vials only 2 mg or 1 mg

Dilaudid (HYDROmorphine)

- Limit the starting doses of HYDROmorphone to 0.5 mg
  - Especially for opioid naïve patients and those with other risk factors such as obesity, asthma, obstructive sleep apnea or those receiving other medications that can potentiate the effects
- Employ technology to alert practitioners
  - Barcode medication verification, hard stops in smart infusion pump libraries for catastrophic doses
- Perform independent double checks when HYDROmorphone is removed from stock
  - Especially if a pharmacist has not reviewed the order prior to drug administration

EMPSF Patient Safety Brief

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

Dilaudid Patient Safety Brief
Emergency Medicine Patient Safety Foundation

Hydromorphone – have you ensured its safe use?

By: Jeannie Taylor
July 2012

Hydromorphone, or Dilaudid, is a semi-synthetic narcotic used to control moderate to severe pain. Its use has increased at least in part to due to Demerol falling out of favor in many emergency departments. Hydromorphone is also a popular drug of abuse, with effects and a potential for addiction similar to morphine.

If your facility or emergency department physician group has not reviewed its practices related to ordering, monitoring and protocols for hydromorphone including the administration of reversal agents, now is the time. An evaluation of cases in Ontario from 1985 to 2003 identified 251 cases where hydromorphone was implicated in a fatality.[1] The Pennsylvania Patient Safety Authority (PA-PSRS) investigated 1,694 reports of medication errors related to hydromorphone between January 2008 and October 2009 (Table 1). Dosing errors were the most common error, and administering the wrong drug, typically a mix-up with morphine, was second:

Table 1. Predominant Medication Error Event Types Associated with the Use of HYDROmorphone (n = 1,135, 67%), January 2008 to October 2009

EVENT TYPE	NUMBER	% OF TOTAL REPORTS (N = 1,694)
Wrong dose/overdosage	287	16.9%
Wrong drug	185	10.9
Monitoring error/ documented allergy	137	8.1

PPSA Has Dilaudid Toolkit

http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/hydromorphone/Pages/home.aspx

Use a Trigger Tool

- There are nine trigger tools that could be used in the hospitals
- CMS and TJC say you can't just rely on incident reports
  - CMS Tag 508 and CMS calls them indicator drugs
- Need another source to discover errors like medication errors
- In the hospital CoPs, there is a list of indicator drugs or IHI had trigger tools
  - August 11, 2010 Mayo Clinic publishes research that the trigger tool is promising approach to measuring patient safety

Measuring Hospital Adverse Events: Assessing Inter-rater Reliability and Trigger Performance of the Global Trigger Tool

James M. Naessens; Thomas J. O'Byrne; Matthew G. Johnson; Monica B. Vansuch; Corey M. McGlone; Jeanne M. Huddleston

Posted: 08/11/2010; International Journal for Quality in Health Care. 2010;22(4):266-274. © 2010 Oxford University Press

Abstract and Introduction

Abstract

Objective. To determine the inter-rater reliability of the Institute for Healthcare Improvement's Global Trigger Tool (GTT) in a practice setting, and explore the value of individual triggers.
Design. Prospective assessment of application of the GTT to monthly random samples of hospitalized patients at four hospitals across three regions in the USA.
Setting. Mayo Clinic campuses are in Minnesota, Arizona and Florida.
Participants. A total of 1138 non-pediatric inpatients from all units across the hospital.
Intervention. GTT was applied to randomly selected medical records with independent assessments of two registered nurses with a physician review for confirmation.
Main Outcome Measure. The Cohen Kappa coefficient was used as a measure of inter-rater agreement. The positive predictive value was assessed for individual triggers.
Results. Good levels of reliability were obtained between independent nurse reviewers at the case-level for both the occurrence of any trigger and the identification of an adverse event. Nurse reviewer agreement for individual triggers was much more varied. Higher agreement appears to occur among triggers that are objective and consistently recorded in selected portions of the medical record. Individual triggers also varied on their yield to detect adverse events. Cases with adverse events had significantly more triggers identified (mean 4.7) than cases with no adverse events (mean 1.8).
Conclusions. The trigger methodology appears to be a promising approach to the measurement of patient

Trigger Tool Finds More Adverse Events

- One study found that an adverse event occurred in about one out of three admissions
- This is 10 times the number of previous estimates
- Found that trigger tool confirmed ten times more serious adverse events in hospitals
  - This compared to using the AHRQ 28 patient safety indicators
- Trigger tool has a much broader definition of adverse event
  - Global Trigger Tool Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Thought, Classen, David, Roger, Resar etc. Health Affairs, Vol 30, No.5, May 2011

Health Affairs Global Trigger Tool

AT THE INTERSECTION OF HEALTH, HEALTH CARE, AND POLICY

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'Global Trigger Tool' Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured

Expand

David C. Classen[1,*], Roger Resar[2], Frances Griffin[3], Frank Federico[4], Terri Frankel[5], Nancy Kimmel[6], John C. Whittington[7], Allan Frankel[8], Andrew Seger[9] and Brent C. James[10]

Author Affiliations

*Corresponding author

http://content.healthaffairs.org/content/30/4/581.abstract

Abstract

Identification and measurement of adverse medical events is central to patient safety, forming a foundation for accountability, prioritizing problems to work on, generating ideas for safer care, and testing which interventions work. We compared three methods to detect adverse events in hospitalized patients, using the same patient sample set

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This Article

doi: 10.1377/hlthaff.2011.0190
Health Aff April 2011 vol. 30 no. 4 581–589

» Abstract
Full Text
PDF
A correction has been published
Appendix
Erratum

Classifications

Errors & Adverse Events

Services

Email this article to a colleague
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Trigger Tool

- Use to find errors since incident reports are filled out only in small % of cases
- IHI has 44 page global trigger tool at www.ihi.org
- Has separate sections like medication trigger
- PTT greater than 100 seconds if on Heparin-if evidence of bleeding, or INR greater than 6 if evidence of bleeding
- C-diff positive assay if history of antibiotic use
- Review 20 charts per month and no longer than 20 minutes

Trigger Tools for Patient Safety

- Look for opportunities for improvement
- Separate trigger tool for measuring medication related harm at http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Literature/DevelopmentPediatricFocusedTriggerTool.htm
- See trigger tool to identify errors in pediatric hospitals at www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Literature/DevelopmentPediatricFocusedTriggerTool.htm
- Outpatient trigger tool; look at reason for the visit and AE related to ED care

Programs
Topics
Improvement
Leading System Improvement
Chronic Conditions
Critical Care
Developing Countries
End Stage Renal Disease
Flow
Healthcare-Associated Infections
Health Professions Education
HIV/AIDS
Medical-Surgical Care
Office Practices
Palliative Care
Patient-Centered Care
Patient Safety
Safety: General
Measures
Changes
Improvement Stories
Tools
Resources
Literature

Introduction to Trigger Tools for Identifying Adverse Events

The use of "triggers," or clues, to identify adverse events (AEs) is an effective method for measuring the overall level of harm from medical care in a health care organization. Traditional efforts to detect AEs have focused on voluntary reporting and tracking of errors. However, public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients. Hospitals need a more effective way to identify events that do cause harm to patients, in order to select and test changes to reduce harm.

There are various Trigger Tools available on IHI.org, including:

- IHI Global Trigger Tool for Measuring Adverse Events [Danish, German, Swedish, and UK translations also available]
- Trigger Tool for Measuring Adverse Drug Events
- Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting
- Trigger Tool for Measuring Adverse Drug Events in the Nursing Home
- Surgical Trigger Tool for Measuring Peri-operative Adverse Events
- Intensive Care Unit Adverse Event Trigger Tool
- Pediatric Trigger Toolkit: Measuring Adverse Drug Events in the Children's Hospital
- Paediatric Trigger Tool for Measuring Adverse Events (UK version)
- Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit
- Outpatient Adverse Event Trigger Tool

Related Information
- Measures
- Changes
- Tools
- Improvement Tip: Focus on Harm, Not Errors

Join the Discussion

Free Trigger Tools Listserv

Join a free listserv with other users of IHI Trigger Tools.

1. Send a completely blank email (no subject, signature, or text in message body) to: subscribe-triggertools@ls.ihi.org.

2. You will receive a confirmation message.

3. Post messages to the listserv by sending emails to triggertools@ls.ihi.org.

Fatigue

- Nurses working nights and rotating shifts rarely obtain optimal amounts of sleep
- Insufficient sleep has variety of adverse effects
  - More medical errors
  - Associated with cognitive problems, mood alterations, reduced job performance, increased safety risks and physiological changes
- Reviewed several hundred studies and none showed any positive effects from insufficient sleep
- Growing body of evidence linked to metabolism and can contribute to obesity

Nursing Linked to Safety & Fatigue

- Limits the number of hours worked to prevent fatigue
- No mandatory overtime and don't let a nurse do a double and then double back
- Never work clinically over **12 hours** or **60 hours** in one week (or will have 3 times the error)
- Also showed medication error rate linked to staffing
- Redesigning the work force
  - See Keeping Patients Safe: Transforming the Work Environment of Nurses 2004 by IOM
  - www.nap.edu/openbook/0309090679/html/23/html

TJC Issues SEA 48

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Topic Library Item

Sentinel Event Alert Issue 48: Health care worker fatigue and patient safety

December 14, 2011

Download This File

www.jointcommission.org/sentinel_event.aspx

The link between health care worker fatigue and adverse events is well documented, with a substantial number of studies indicating that the practice of extended work hours contributes to high levels of worker fatigue and reduced productivity. These studies and others show that fatigue increases the risk of adverse events, compromises patient safety, and increases risk to personal safety and well-being. While it is acknowledged that many factors contribute to fatigue, including but not limited to insufficient staffing and excessive workloads, the purpose of

Patient Falls and Preventing OR Fires

Falls Program

- Have a definition of falls and make sure staff knows the definition
  - Measure the fall rate and the severity of the fall
- Provide in-service education to all nurses yearly and in orientation
- Provide patient education on falls such as call before you fall
- Consider toileting, sitters, and hourly rounds for high risk patients
- Audit charts for compliance with fall program
- Consider computerized system for falls

Call Before You Fall Posters

Falls

- Do an assessment for the fall risk on every patient
- The intervention and plan of care is based on the fall risk and communicate risk in handoffs
- Have a comprehensive policy
- Have an active and educated falls committee
- Have a special incident report for fall
- Have a post fall assessment form so staff know what to do and how often assessment will be
- Special precautions for patients on blood thinner

dicates you are taking anticoagulant or anti-platelet medicine.
2. Carry a list of your current medication (prescribed and over-the-counter) on your person when you are out of the house. You could keep a copy of this list in your wallet or purse. Make sure this list is the same as the one you keep in your home for emergency personnel.
3. On your medication list, include the name and phone number of your healthcare provider, in case a stranger or emergency paramedic needs to call them.
4. If you require a mobility aid (such as a cane or walker) for safe transfers and/or walking, be sure to use your mobility aids as prescribed. These devices are prescribed to help you walk safely.
5. Treat all falls as serious. Call your healthcare provider and report your fall, even if you think that you were not hurt.
6. If you are on an anticoagulant, call your health care provider before taking any drug for pain to check on possible increased effect on bleeding.

For Family Members of a Person Taking Blood Thinners who has Fallen:
1. Check for injury and bleeding. DO NOT get the person up until you are certain there is no serious injury or bleeding.

- Are they breathing? If not, call 911 and start CPR.
- Are they bleeding? If yes, put pressure on the site of the bleeding, call 911 and inform them that the person takes an anticoagulant or anti-platelet medicine.
- Did they lose consciousness? Are they more confused? If yes, call 911. If the person is confused, talk to the them and orient them to the situation.
- Where do they hurt? Ask the person if they have pain anywhere. Look for any obvious fractures. Do NOT get the person up. Call 911 for help.

2. Do NOT attempt to lift the person by yourself. Trying to lift a person can injure both of you.

3. Reassure the person. They may be confused, frightened, and embarrassed. If possible, provide a calm environment, cover them with a blanket, and stay until help arrives.

4. Ask for details about the fall, and get as much information as possible from any witnesses.

5. Ask the person how long they have been taking blood thinners, what kind, and the last time they took their medication.

6. As soon as possible notify the person's healthcare provider about the fall. A fall can be a symptom of serious problems. Most falls can be prevented.

For more information contact:
VISN 8 Patient Safety Center
11605 N. Nebraska Ave.
Tampa, Fl. 33612-5738
813-558-3900

Blood Thinners:

Risk Factors Associated with Falling and What to Do When You Fall

VISN 8 Patient Safety Center of Inquiry, Tampa, FL

A NATIONAL VA FALLS COLLABORATIVE PROJECT

AHRQ Toolkit

- AHRQ toolkit is an excellent resource available at no cost
- It is called “Preventing Falls in Hospitals; A Toolkit for Improving Quality of Care”
- It is a roadmap for preventing of falls in hospitals
- It has many excellent evidence based tools
- States a number of practices have been shown to reduce the occurrence of falls but these practices are not systematically used in all hospitals
  - www.ahrq.gov/legacy/research/ltc/fallpxtoolkit/index.htm

AHRQ Preventing Falls in Hospitals

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You Are Here: AHRQ Home > Research Findings > Long-Term Care > Preventing Falls in Hospitals: A Toolkit for Improving Quality of Care

Preventing Falls in Hospitals
A Toolkit for Improving Quality of Care

Each year, somewhere between 700,000 and 1,000,000 people in the United States fall in the hospital. A fall may result in fractures, lacerations, or internal bleeding, leading to increased health care utilization. Research shows that close to one-third of falls can be prevented. Fall prevention involves managing a patient's underlying fall risk factors and optimizing the hospital's physical design and environment. This toolkit focuses on overcoming the challenges associated with developing, implementing, and sustaining a fall prevention program.

Select for print version (PDF File, 3.3 MB) (Plugin Software Help).

Select to download individual sections from the falls prevention toolkit roadmap.

Prepared for:

Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Prepared by:

RAND Corporation
Boston University School of Public Health
ECRI Institute

Contract No. HHSA290201000017I TO #1

Contents

Roadmap
Acknowledgments
Overview
- The Problem of Falls
- The Challenges of Fall Prevention
- Toolkit Designed for Multiple Audiences
- Implementation Guide Organized To Direct Hospitals Through the Change Process
- Sections of the Guide
- Adaptation of the Guide to Your Organization
- Improvement as Puzzle Pieces

Icons

www.ahrq.gov/legacy/research/ltc/fallpxtoolkit/index.html

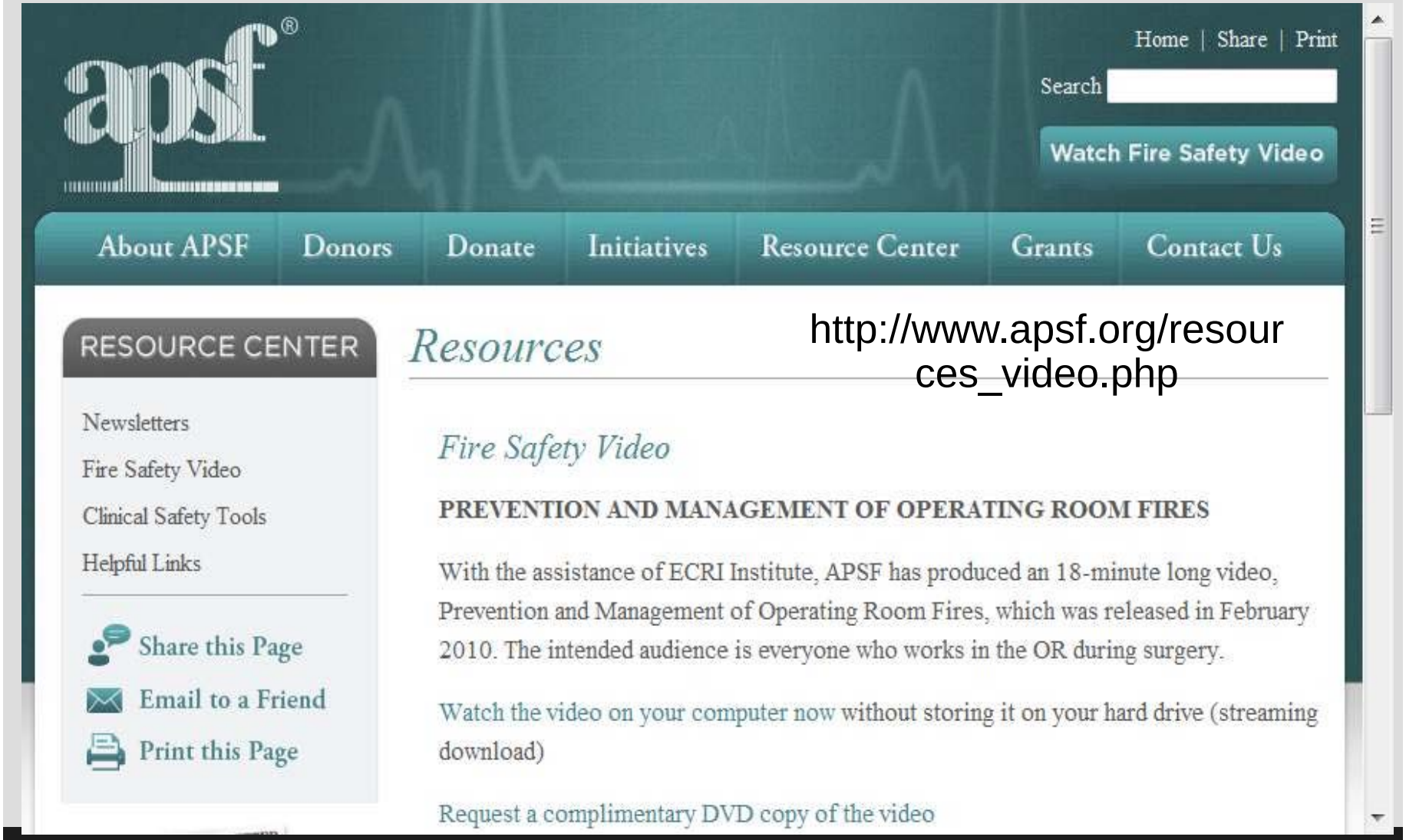
Preventing and Managing an OR Fire

- There are updated clinical guidelines to preventing an OR fire
  - Made by ECRI, ASA, FDA, and the Anesthesia Patient Safety Foundation
- Recommendations include two important things
  - Eliminate the traditional practice of open delivery of 100% oxygen during sedation
  - Securing the airway is recommended if the patient requires an increased oxygen concentration
- The surgery team should talk about the risk of a surgical fire before each surgery and document the risk

Preventing and Managing an OR Fire

- Don’t ever assume this will not happen to you
- Make sure all appropriate staff are trained in preventing and managing an OR fire
- Have mock drills in which everyone in the OR participates
- Make it mandatory to watch the APSF video
- Make sure staff are aware of all P&P
- Make sure P&P reflect recent guidelines
- Staff should make sure surgical prep is dry before draping

Fire Safety Video



Preventing and Managing An OR Fire

- Every hospital should have a copy of the ASA or the American Society of Anesthesiologists 16 page practice advisory on the prevention and management of operating room fires
- These are evidenced based and should be incorporated into the P&P and education of staff
- Should be aware TJC and CMS CoP has standards
- Use the AORN toolkit to make sure all OR staff are competent and staff are evaluated
  - Include risk of fire in time out and all staff know their job in case a fire breaks out

Only You Can Prevent a Surgical Fire

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Thanks for attending! Questions??

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