Preventing Medication Errors: 60+ Tips to Implement Today

Sue Dill Calloway

RELIAS LEARNING

Speaker

- Sue Dill Calloway RN Esq. CPHRM, CCMSCP, AD, BA, BSN, MSN, JD
- President Patient Safety and Healthcare Consulting
- 5447 Fawnbrook Lane
  Dublin, Ohio 43017
- 614 791-1468
  (Call with questions, no emails)
- sdill1@columbus.rr.com
- Email questions to CMS at hospitalscg@cms.hhs.gov

Objectives

- List ways to reduce medication errors in your facility.
- Explain why medication errors are the most common type of medical errors.
- Describe TJC's medication management tracer.
- Describe CoPs on medication self-administration.

Headlines We Don't Want to See

Patient dies after medication error at a St. Charles Health hospital

Written by Heather Punke (Twitter | Google+) | December 05, 2014

A patient at St. Charles Bend (Ore.) hospital has died after being given incorrect medication in the emergency room, according to a *Bend Bulletin* report.

A 65-year-old woman who came to the ER Monday with concerns about medication doses after a recent brain surgery at Swedish Medical Center in Seattle was given a paralyzing agent, rocuronium, instead of an anti-seizure medication called fosphenytoin, according to the report. She then went into cardiac arrest and suffered brain damage before being removed from life support Wednesday.

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Now, St. Charles Health Care officials are analyzing what went wrong, walking through from when the drug order was written to when it was administered. "We've never had anything like this happen here," Michel Boileau, MD, St. Charles' chief clinical officer, told the Bend Bulletin. "Before we say exactly what happened, we're going to make sure we're accurate…We do know there was a medication error."

As a result of the error, three hospital employees are on administrative leave and receiving counseling.

Medication Errors

- **Medication errors are the most common type of medical errors**
  - CMS, in the hospital CoP manual, says drug related adverse outcomes were noted in 1.9 million inpatient stays, which is 4.7% of all stays
  - Medication errors harm at least 1.5 million people per year
- An IOM report estimated that a hospital patient is subject to one medication error per day
- IOM study found considerable variation in rates of medication errors across facilities

WHO Effort to Reduce Medication Errors

- WHO 2017 global effort to reduce medication errors by 50% over the next 5 years
- Medication errors can be caused by health worker fatigue, overcrowding, staff shortages, poor training and the wrong information being given to patients, among other reasons
- Medication errors cause at least one death every day in the US
  - This is 1.3 million patients who are effected every year
- Cost the US 42 billion dollars annually or 1% of the total health expenditure

WHO Effort to Reduce Medication Errors

www.who.int/mediacentre/news/releases/2017/medication-related-errors/en/

Many Resources on ADE PSH for Patients

http://partnershipforpatients.cms.gov/p4p_resources/tsp-adversedrugevents/tooladver

"How-to Guide: Prevent Adverse Drug Events (Medication Reconciliation) — Pediatric Supplement" (IHI)	This how-to guide specifically tailored for pediatrics describes key evidence-based care components to prevent adverse drug events (ADEs) by implementing medication reconciliation at all transitions in care (at admission, transfer, and discharge), describes how to implement these interventions, and recommends measures to gauge improvement.
"Preventing Adverse Drug Events (Medication Reconciliation): Patient and Family Fact Sheet" (IHI)	This resource for patients and families provides an overview of how to prevent adverse drug events by reconciling medications at all transitions in care (at admission, transfer, and discharge). Available in English and Spanish.
"Reducing Medication Errors" (Massachusetts Coalition for the Prevention of Medical Errors)	A Web site listing initiatives to reduce medication errors in anticoagulation medicine, ambulatory settings, acute care facilities, long-term care facilities, and consumer safety.
"MATCH Medication Reconciliation Toolkit" (IHI)	The medication reconciliation initiative at Northwestern Memorial Hospital, called MATCH, included development of a toolkit to help hospital and outpatient practice staff.
"Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs" (U.S. Department of Health & Human Services, Agency for Healthcare Research and Quality [AHRQ])	Many ADE injuries and resulting hospital costs can be reduced if hospitals make changes to their systems for preventing and detecting ADEs. Some approaches found to be successful are summarized in this Web site.
"Preventable Adverse Drug Reactions: A Focus on Drug Interactions" (U.S. Department of Health & Human Services, U.S. Food and Drug Administration [FDA])	This learning module was developed based on a needs survey sent to all third-year medicine clerkship directors and all medicine residency program directors in the United States.
"Safe Use Initiative: Collaborating to Reduce Preventable Harm from Medications" (FDA)	The mission of the Safe Use Initiative is to create and facilitate public and private collaborations within the healthcare community. The goal of the Safe Use Initiative is to reduce preventable harm by identifying specific, preventable medication risks and developing, implementing and evaluating cross-sector interventions with partners who are committed to safe medication use.

"ISMP" (Institute for Safe Medication Practices)	A comprehensive Web site with medication safety tools, reports, resources, products, alerts, and videos.
"NCC MERP" (The National Coordinating Council for Medication Error Reporting and Prevention)	Founded by the United States Pharmacopeia, the mission of NCC MERP is to maximize the safe use of medications and to increase awareness of medication errors through open communication, increased reporting, and promotion of medication error prevention strategies.
"Adverse Drug Reaction Surveillance: Practical Methods for Developing a Successful Monitoring Program" (Medscape from WebMD)	Article. Barriers to improved reporting of adverse drug events (ADEs) are evaluated and mechanisms to overcome these barriers are presented. The impact of ADR surveillance on the evaluation and modification of the medication-use system at Northeast Health to improve patient quality of care is described.
"Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention" (Journal of the American Medical Association)	Article. Assessment of the incidence and preventability of adverse drug events (ADEs) and potential ADEs, with analysis of preventable events to develop prevention strategies.
"MedWatch: The FDA Safety Information and Adverse Event Reporting Program" (FDA)	FDA gateway for clinically important safety information and for reporting serious problems with human medical products.
"Adverse Event Reporting System (AERS)" (FDA)	The Adverse Event Reporting System (AERS) is a computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. The FDA uses AERS to monitor for new adverse events and medication errors that might occur with these marketed products.

ISMP Targeted Medication Best Practices

- Hospitals should review and implement the best practices
- The 2018-2019 contains **14** best practices
- These are ones that cause fatal and harmful errors
- ISMP also encourages any hospital that has not implemented the 2016-2017 ones to do so as a priority
- Two of the these have been revised for 2018-2019 (number 4 and 7)
- Number 12-14 are new ones

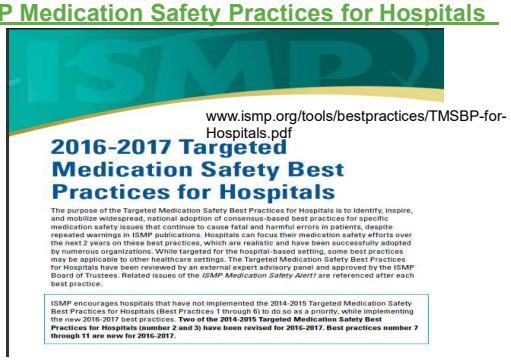
www.ismp.org/sites/default/files/attachments/2017-12/TMSBP-for-Hospitalsv2.pdf

2018-2019 Targeted Medication Safety Best Practices for Hospitals

The purpose of the Targeted Medication Safety Best Practices for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices for specific medication safety issues that continue to cause fatal and harmful errors in patients, despite repeated warnings in ISMP publications. Hospitals can focus their medication safety efforts over the next 2 years on these best practices, which are realistic and have been successfully adopted by numerous organizations. While targeted for the hospital-based setting, some best practices may be applicable to other healthcare settings. The *Targeted Medication Safety Best Practices for Hospitals* have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

ISMP encourages hospitals that have not implemented the 2016-2017 Targeted Medication Safety Best Practices for Hospitals to do so as a priority, while implementing the 2018-2019 best practices. Organizations need to focus on previous best practices 2, 3, 9 and 11 since these have the lowest implementation rate. **Two of the 2016-2017 Targeted Medication Safety Best Practices for Hospitals (number 4 and 7) have been revised for 2018-2019. Best practices number 12 through 14 are new for 2018-2019.**

ISMP Medication Safety Practices for Hospitals


www.ismp.org/tools/bestpractices/TMSBP-for-Hospitals.pdf

2016-2017 Targeted Medication Safety Best Practices for Hospitals

The purpose of the Targeted Medication Safety Best Practices for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices for specific medication safety issues that continue to cause fatal and harmful errors in patients, despite repeated warnings in ISMP publications. Hospitals can focus their medication safety efforts over the next 2 years on these best practices, which are realistic and have been successfully adopted by numerous organizations. While targeted for the hospital-based setting, some best practices may be applicable to other healthcare settings. The Targeted Medication Safety Best Practices for Hospitals have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

ISMP encourages hospitals that have not implemented the 2014-2015 Targeted Medication Safety Best Practices for Hospitals (Best Practices 1 through 6) to do so as a priority, while implementing the new 2016-2017 best practices. **Two of the 2014-2015 Targeted Medication Safety Best Practices for Hospitals (number 2 and 3) have been revised for 2016-2017. Best practices number 7 through 11 are new for 2016-2017.**

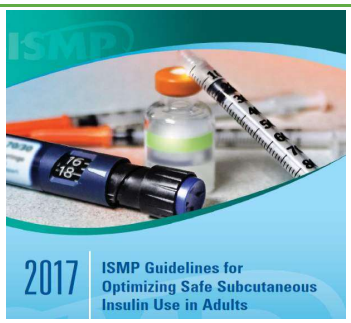
2018-2019 Targeted Best Practices

- Dispense vinCRIStine in a minibag and not a syringe
- 3 recommendations to prevent accidental daily dosing of methotrexate which is intended for weekly administration
- Weigh each patient in kg and weigh on admission and don't use lbs
- Liquid oral meds need to be dispensed by pharmacy in an oral or ENFIT syringe (ENFIT to prevent tubing misconnections) and marked oral use only
- Purchase liquid oral dosing devices in metric only and for patients being discharged provide one to measure in mL

2018-2019 Targeted Best Practices

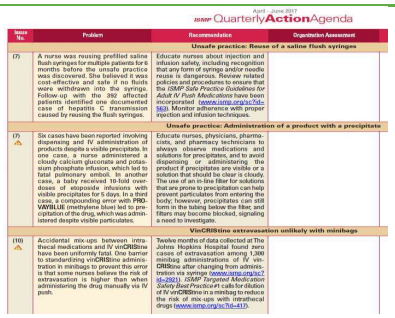
- Eliminate acetic acid from all areas of the hospital
- Separate and sequester neuromuscular blocking agents from other medications so not given to patients not receiving ventilator assistance
- Administer high alert medication through programmable pump
- Eliminate all 1,000 cc bags of sterile water labeled for irrigation or inhalation from areas outside pharmacy
- Perform an independent check to ensure proper ingredients are added when compounding sterile preparations prior to adding to the final container
- Do not use fentaNYL patches for opioid native patients or acute pain
- Eliminate Promethazine (Phenergan) from the hospital
- Use information on medication risks from outside and take action

ISMP Safe Subq Insulin Use



http://ismp.org/Tools/guidelines/Insulin-Guideline.pdf

Read the ISMP Quarterly Action Agenda



April – June 2017

ISMP QuarterlyActionAgenda

Issue No.	Problem	Recommendation	Organization Assessment
		Unsafe practice: Reuse of a saline flush syringes	
(7)	A nurse was reusing prefilled saline flush syringes for multiple patients for 6 months before the unsafe practice was discovered. She believed it was cost-effective and safe if no fluids were withdrawn into the syringe. Follow-up with the 392 affected patients identified one documented case of hepatitis C transmission caused by reusing the flush syringes.	Educate nurses about injection and infusion safety, including recognition that any form of syringe and/or needle reuse is dangerous. Review related policies and procedures to ensure that the *ISMP Safe Practice Guidelines for Adult IV Push Medications* have been incorporated (www.ismp.org/sc?id=563). Monitor adherence with proper injection and infusion techniques.	
		Unsafe practice: Administration of a product with a precipitate	
(7)	Six cases have been reported involving dispensing and IV administration of products despite a visible precipitate. In one case, a nurse administered a cloudy calcium gluconate and potassium phosphate infusion, which led to fatal pulmonary emboli. In another case, a baby received 10-fold overdoses of etoposide infusions with visible precipitates for 5 days. In a third case, a compounding error with PROVAYBLUE (methylene blue) led to precipitation of the drug, which was administered despite visible particulates.	Educate nurses, physicians, pharmacists, and pharmacy technicians to always observe medications and solutions for precipitates, and to avoid dispensing or administering the product if precipitates are visible or a solution that should be clear is cloudy. The use of an in-line filter for solutions that are prone to precipitation can help prevent particulates from entering the body; however, precipitates can still form in the tubing below the filter, and filters may become blocked, signaling a need to investigate.	
		VinCRIStine extravasation unlikely with minibags	
(10)	Accidental mix-ups between intrathecal medications and IV vinCRIStine have been uniformly fatal. One barrier to standardizing vinCRIStine administration in minibags to prevent this error is that some nurses believe the risk of extravasation is higher than when administering the drug manually via IV push.	Twelve months of data collected at The Johns Hopkins Hospital found zero cases of extravasation among 1,200 minibag administrations of IV vinCRIStine after changing from administration via syringe (www.ismp.org/sc?id=2921). *ISMP Targeted Medication Safety Best Practice* #1 calls for dilution of IV vinCRIStine in a minibag to reduce the risk of mix-ups with intrathecal drugs (www.ismp.org/sc?id=417).	

www.ismp.org/Newsletters/acutecare/ActionAgendas_PDF/ActionAgenda1703.pdf

1. Are Errors Rampant and Under-reported?

www.psnet.ahrq.gov/resource.aspx?resourceID=24450

So How Many Errors Per 1,000 Doses?

- So do you know how many errors your hospital has per 1,000 doses?
- What is the percent of admissions whose patients suffer an ADE?
- IHI has a free trigger tool to help hospitals measures these rates
- Includes how to measure the number and degree of harmful medication events
  - www.ihi.org/resources/Pages/Tools/TriggerToolforMeasuringAdverseDrugEvents.aspx

IHI Trigger Tools to Measure ADEs

2. Have a Culture of Reporting

- CMS and The Joint Commission(TJC) require reporting of all medication errors and **near misses**
- CMS and OIG issues memo on March 15, 2013 saying that 86% of hospitals are not reporting medication errors and adverse event internally to the hospital PI department
- Hospital and healthcare facilities can not fix what they do not know exists
- Hospitals are required to have non-punitive reporting systems
  - Discussed in more detail later

3. Monitor Drug Safety Alerts

- Study found that a drug safety alert program that provides up-to-date information can help to make better drug therapy decisions and can reduce medication errors
- Provided alerts on drug safety communications from the FDA and drug manufacturers
- The program used an internal scoring system to rate the severity of the drug alert and it was linked with the EHR
- If score of 80% or more the educational letter sent to clinicians with list of patients given the medication

Best Practices: An Electronic Drug Alert Program to Improve Safety in an Accountable Care Environment

Sara Griesbach, PharmD, BCPS, BCACP; Adam Lustig, MS; Luanne Malsin, PharmD, BCPS; Blake Carley, PharmD, BCPS; Kimberly D. Westrich, MA; and Robert W. Dubois, MD, PhD

ABSTRACT

BACKGROUND: The accountable care organization (ACO), one of the most promising and talked about new models of care, focuses on improving communication and care transitions by tying potential shared savings to specific clinical and financial benchmarks. An important factor in meeting these benchmarks is an ACO's ability to manage medications in an environment where medical and pharmacy care has been integrated. The program described in this article highlights the critical components of Marshfield Clinic's Drug Safety Alert Program (DSAP), which focuses on prioritizing and communicating safety issues related to medications with the goal of reducing potential adverse drug events.

PROGRAM DESCRIPTION: Once the medication safety concern is identified, it is reviewed to evaluate whether an alert warrants sending prescribers a communication that identifies individual patients or a general communication to all physicians describing the safety concern. Instead of basing its decisions regarding clinician notification about drug alerts on subjective criteria, the Marshfield Clinic's DSAP uses an internally developed scoring system. The scoring system includes criteria developed from previous drug alerts, such as level of evidence, size of population affected, severity of adverse event identified or targeted, litigation risk, available alternatives, and potential for duration of medication use. Each of the 6 criteria is assigned a weight and is scored based upon the content and severity of the alert received.

OBSERVATIONS: In its first 12 months, the program targeted 6 medication safety concerns involving the following medications: topiramate, glyburide, simvastatin, citalopram, pioglitazone, and levastatin. Baseline and follow-up prescribing data were gathered on the targeted medications. Follow-up review of prescribing data demonstrated that the DSAP provided quality up-to-date safety information that led to changes in drug therapy and to their patient population as a whole. The authors also highlight the need for additional research on health information exchanges, including the cost and resource requirements needed to successfully participate in these types of networks.

J Manag Care Spec Pharm. 2015;21(4):330-36

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What is already known about this subject

- Adverse drug events are a leading cause of morbidity and mortality in the United States and a major concern for accountable care organizations.
- Due to the vast amount of drug safety warnings issued by the FDA, it is challenging for health care providers to effectively and efficiently incorporate these warnings into clinical practice.
- Integrating health information technologies into clinical care allows for health care providers to communicate with one another and ensure continuity of care for patients.

What this study adds

- The program described in this article highlights the critical components of Marshfield Clinic's Drug Safety Alert Program, which focuses on prioritizing and communicating safety issues related to medications with the goal of reducing potential adverse drug events.
- Sending direct communications to providers regarding drug

Journal of Managed Care & Specialty Pharmacy *JMCP April 2015 Vol. 21, No. 4 www.amcp.org*

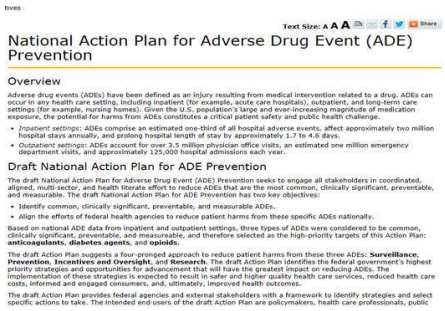
4. Read the HHS National Action Plan for ADE

- ADEs are the single largest contributor to hospital-related complications within hospitals
- ADE top priority of HHS
- One third of all hospital inpatient visits have ADE
- Affects two million hospital stays every year
- Prolongs the LOS 1.7 to 4.6 days
- Affects 3.5 million outpatients
- Affects 125,000 admission each year and results in readmissions

National Action Plan for ADE

- High priority 3 targets include **anticoagulants, diabetes agents and opioids**
  - These are also 3 categories that hospitals should be looking at
  - Mentioned by CMS in the proposed hospital improvement rule
- Focuses on opportunities for federal engagement: surveillance, prevention, incentives and oversights, and research
- 189 pages and also published in FR Sept 4, 2013
- www.hhs.gov/ash/initiatives/ade/index.htm

HHS National Action Plan for ADE



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National Action Plan for Adverse Drug Event (ADE) Prevention

Overview

Adverse drug events (ADEs) have been defined as an injury resulting from medical intervention related to a drug. ADEs can occur in any health care setting, including inpatient (for example, acute care hospitals), outpatient, and long-term care settings (for example, nursing homes). Given the U.S. population's large and ever-increasing magnitude of medication exposure, the potential for harms from ADEs constitutes a critical patient safety and public health challenge.

- *Inpatient settings*: ADEs comprise an estimated one-third of all hospital adverse events, affect approximately two million hospital stays annually, and prolong hospital length of stay by approximately 1.7 to 4.6 days.
- *Outpatient settings*: ADEs account for over 3.5 million physician office visits, an estimated one million emergency department visits, and approximately 125,000 hospital admissions each year.

Draft National Action Plan for ADE Prevention

The draft National Action Plan for Adverse Drug Event (ADE) Prevention seeks to engage all stakeholders in coordinated, aligned, multi-sector, and health literate effort to reduce ADEs that are the most common, clinically significant, preventable, and measurable. The draft National Action Plan for ADE Prevention has two key objectives:

- Identify common, clinically significant, preventable, and measurable ADEs.
- Align the efforts of federal health agencies to reduce patient harms from these specific ADEs nationally.

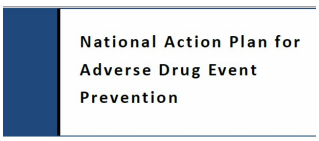
Based on national ADE data from inpatient and outpatient settings, three types of ADEs were considered to be common, clinically significant, preventable, and measurable, and therefore selected as the high-priority targets of this Action Plan: **anticoagulants, diabetes agents**, and **opioids.**

The draft Action Plan suggests a four-pronged approach to reduce patient harms from these three ADEs: **Surveillance, Prevention, Incentives and Oversight**, and **Research.** The draft Action Plan identifies the federal government's highest priority strategies and opportunities for advancement that will have the greatest impact on reducing ADEs. The implementation of these strategies is expected to result in safer and higher quality health care services, reduced health care costs, informed and engaged consumers, and, ultimately, improved health outcomes.

The draft Action Plan provides federal agencies and external stakeholders with a framework to identify strategies and select specific actions to take. The intended end-users of the draft Action Plan are policymakers, health care professionals, public

www.hhs.gov/ash/initiatives/ade/index.htm

HHS National Action Plan for ADE



www.health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf

U.S. Department of Health and Human Services
Office of Disease Prevention and Health Promotion

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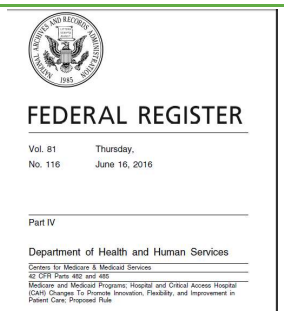
5. Establish an Antibiotic Stewardship Program

- Have an antibiotic stewardship program
- Recent study found only 2/3 of hospitals have one
  - Big focus now of CDC and will see increasing focus by CMS with proposed changes to CoP to mandate ASP
  - TJC implemented ASP in 2017 in MM.09.01.01
  - Incidence of MDROs continues to increase especially C-diff
- Antibiotic resistance is correlated with antibiotic prescribing patterns
- Can increase mortality and length of stay
  - White house releases plan against superbugs in 2015 and requests 1.2 billion to combat antibiotic resistance

CMS Proposes ASP for Hospitals



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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services
42 CFR Parts 482 and 485
Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care; Proposed Rule

www.gpo.gov/fdsys/pkg/FR-2016-06-16/pdf/2016-13925.pdf

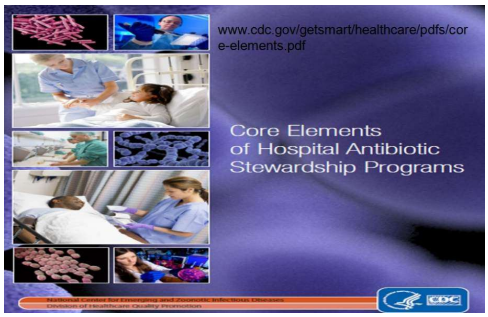
CMS Proposes ASP for Hospitals

www.federalregister.gov/documents/206/06/16/2016-13925/medicare-and-medicaid-programs-hospital-and-critical-access-hospital-cah-changes-to-promote

Antibiotic Stewardship Program

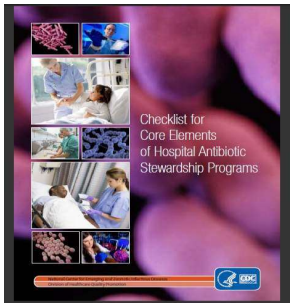
- CDC aims to cut C-diff and by 50%, hospital-acquired multidrug resistant Pseudomonas species infections by 35 %; and CRE infections by 60%
  - Concern over deaths caused by CRE in duodenum scopes used in ERCP
- President's plan wants to have a 50% reduction in inappropriate antibiotic use in outpatient setting
- Wants 20% reduction in inpatient setting
- Wants routine reporting of antibiotic use and resistance data to the CDC and follow CDC core elements

CDC Core Elements of Hospital ASP



www.cdc.gov/getsmart/healthcare/pdfs/core-elements.pdf

CDC Toolkit Hosp Core Elements



www.ahaphysicianforum.org/resources/appropriate-use/antimicrobial/content%20files%20pdf/CDC%20checklist.pdf

CDC Outpatient Core Elements

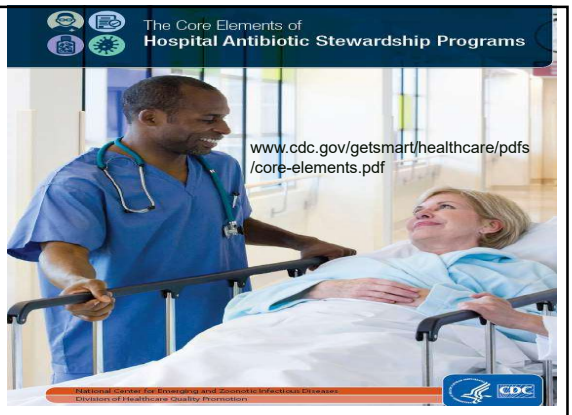
Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 65 / No. 6
November 11, 2016

http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6506.pdf

Core Elements of
Outpatient Antibiotic Stewardship

Core Elements Small and CAHs

- CDC, AHA, Office of Rural Health and Pew Charitable Trusts came out with practical strategies to implement ASP
- This is for small and critical access hospitals
- Implementation strategies include:
  - Leadership commitment and accountability
  - Pharmacist leader with drug expertise
  - Evidenced based actions
  - Tracking such as days of therapy and use the CDC Net
  - Reporting and education,



Check List of Core Elements

www.cdc.gov/getsmart/healthcare/pdfs/checklist.pdf

National Plan for Antibiotic Resistant Bacteria

NATIONAL ACTION
PLAN FOR COMBATING
ANTIBIOTIC-RESISTANT
BACTERIA

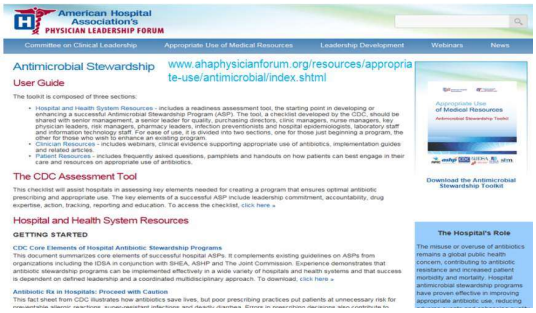
www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf

MARCH 2015

Antibiotic Stewardship Program

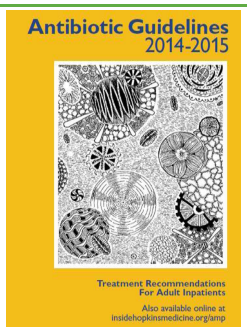
- 50% of antibiotic use is inappropriate
  - Used for treatment not caused by bacteria
  - Treatment for cultures that reflect colonization rather than infection
  - Administer broad spectrum antibiotic when narrow spectrum are equally effective
  - Prescribing longer than necessary
  - Inappropriate doses of antibacterial agents
- Source: SHEA Antimicrobial Stewardship Toolkit
  - Camins BC, King MD, Wells JB, et al. Impact of an antimicrobial utilization program on antimicrobial use at a large teaching hospital: a randomized controlled trial. *Infection control and hospital epidemiology : the official journal of the Society of Hospital Epidemiologists of America.* Oct 2009;30(10):931-938.

AHA Toolkit on Antimicrobial Stewardship



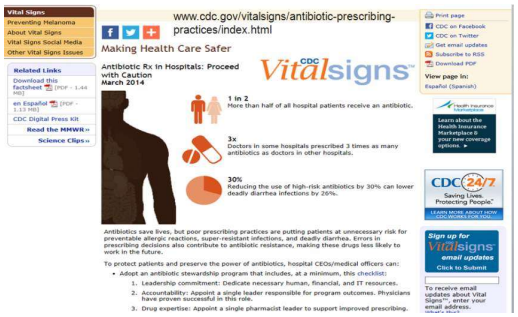
Antimicrobial Stewardship Toolkit

Follow Antibiotic Guidelines



www.hopkinsmedicine.org/amp/guidelines/Antibiotic_guidelines.pdf

CDC Toolkit on Antibiotic Prescribing



TJC Antibiotic Stewardship Program

- Standards effective January 1, 2017 and amended 2018
- Added new Medication Management standard
- MM.09.01.01 was developed after the White House Forum on Antibiotic Stewardship which occurred June 2, 2015
- TJC shows a commitment to slow the emergence of antibiotic resistance bacteria, detect resistant strains, and prevent the spread of resistant infections
  - CDC says 20-50% of all antibiotics in the US are unnecessary

6. Incorporate Use of CMS CoP IC Worksheet

- Hospitals should be familiar with and widely disseminate the information in the CMS final worksheet on infection control
  - It has a section on safe injection practices which will be discussed later
  - Proposed changes in 2018
- It also has a section on system to prevent MDRO and promote antimicrobial stewardship
- CMS will ask hospitals if they monitor antibiotic use at the unit and hospital level
- Will ask if formal procedure to review appropriateness of antibiotics

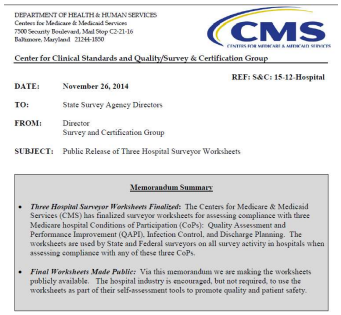
CMS CoP Infection Control Worksheet

- Are patients with targeted MDRO identified?
  - Are they placed in contact isolation?
- Does the hospital have written P&P to improve antibiotic use (antibiotic stewardship)?
- Does the hospital have a leader responsible for program outcomes of antibiotic stewardship activities? Such as a physician or pharmacist
- Is an indication for each antibiotic documented in the medical record along with duration
- Hospital has P&P to minimize risk of transmission of a targeted MDRO

Section 1.C. Systems to Prevent Transmission of MDROs and Pr Stewardship

Elements to be assessed		Su
1.C.1 The hospital has policies and procedures to minimize the risk of development and transmission of multidrug-resistant organisms (MDROs) within the hospital (applicable to all persons in the hospital).	○ Yes ○ No	
1.C.2 Systems are in place to designate patients known to be colonized or infected with a targeted MDRO and to notify receiving units and personnel prior to movement of such patients within the hospital.	○ Yes ○ No	
1.C.3 Systems are in place to designate patients known to be colonized or infected with a targeted MDRO and to notify receiving healthcare facilities and personnel prior to transfer of such patient between facilities.	○ Yes ○ No	
If no to any part of 1.C.1 through 1.C.3, cite at 42 CFR 482.42(a) (Tag A-0749)		
1.C.4 The hospital can provide a list of target MDROs. Note: Hospitals should provide a list of MDROs that are targeted for infection control because they are epidemiologically important (e.g., MRSA, VRE). Please refer to CDC's Guideline for Isolation Precautions for criteria that may be used to define epidemiology important organisms: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf	○ Yes ○ No	
1.C.5 The hospital can demonstrate the criteria used to determine epidemiologically important MDROs on their list.	○ Yes ○ No	
1.C.6 The hospital can provide justification for any epidemiologically important organisms not on their list and otherwise not targeted in their hospital.	○ Yes ○ No	

Final 3 Worksheets Infection Control



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: 15-12-Hospital

DATE: November 26, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

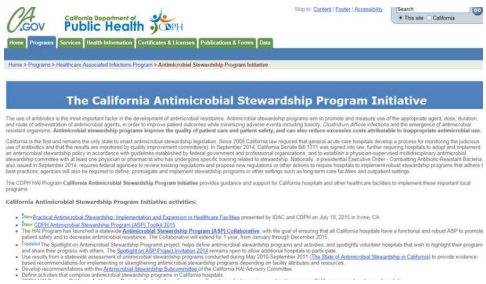
SUBJECT: Public Release of Three Hospital Surveyor Worksheets

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 as 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.

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

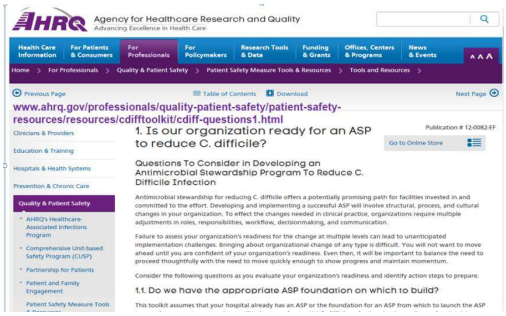
Ca First State to Enact Antimicrobial Stewardship Program



The California Antimicrobial Stewardship Program Initiative

www.cdph.ca.gov/programs/hai/Pages/AntimicrobialStewardshipProgramInitiative.aspx

AHRQ C-Diff Toolkits



Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/cdifftoolkit/cdiff-questions1.html

1. Is our organization ready for an ASP to reduce C. difficile?

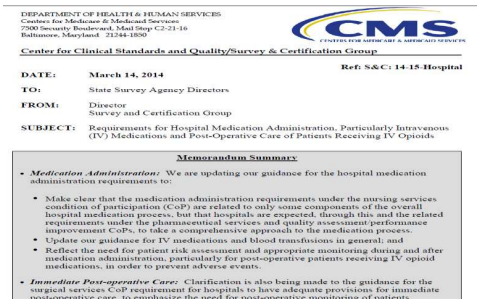
Questions To Consider in Developing an Antimicrobial Stewardship Program To Reduce C. Difficile Infection

www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/cdifftoolkit/cdiff-questions1.html

7. Follow CMS Rules on Safe Opioid Use

- CMS issues memo on **safe opioid use** and mentions the HHS plan for ADE Prevention
- Also updates the guidance on IV medications and blood transfusions effective June 6, 2014 and CAH April 7, 2015
- Discuss safety related to IV opioid medications and monitoring of patients
- Preferable to have pharmacy fix all IVs and piggyback when present in the hospital
- Need a policy to reflect requirements, must be approved by MEC, and staff must be trained

Safe Opioid Use Effective June 6, 2014



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: 14-15-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

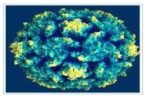
- ***Medication Administration:*** We are updating our guidance for the hospital medication administration requirements to:
  - Make clear that the medication administration requirements under the nursing services condition of participation (CoP) are related to only some components of the overall hospital 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

Final for IV Medication, Opioid

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

Table of Contents

(Rev. 116, 06-06-14)



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

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

CMS Hospital CoP on Safe Opioid Use

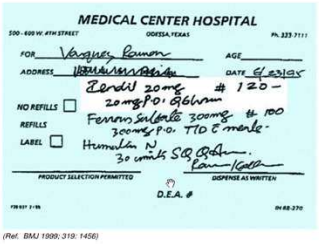
- CMS has a list of what makes a patient a high risk when receiving opioid and staff must know what these are
  - Liver or kidney failure, history of sleep apnea, obesity, smoking, drug-drug interaction and first time medication use
- Hospital must have a policy on how often an assessment must be done
- Must include what has to be in the assessment such as pulse ox, ETCO2, vital signs, sedation scale etc.
- Staff must evaluate clinical signs such as confusion, agitation, unsteady gait, itching etc.
- Patient must be informed to notify nurse if difficulty breathing or a reaction to the medication

8. Write Legibly

- It is important to write legibly since 6% of all errors
  - **Electronic prescribing** has helped reduce errors from illegible writing
- Write the type of medication on the script which can help the pharmacist such as for high blood pressure
- Don't put more than one prescription on each script
- Patient dies after pharmacist fills prescription for Plendil instead of Isordil
- Rewrite orders to be clear-Dr writes over a number and patient gets 120 mEq of KCL instead of 20

Isordil Misread as Plendil and Patient Dies

A prescription for Isordil (isosorbide mononitrate) was misread as Plendil (felodipine)



(Ref. BMJ 1999; 319: 1456)

Write Legibly

- Nephrologists orders KCl 10 meq for a patient before surgery for a right foot amputation who was a dialysis patient after the left toe was amputated
- After surgery decides to increase it
- Instead of writing a new prescription, he wrote over the existing one
- Scribbled a 2 over top of the one
- Nurses and pharmacists misread the number as 120 meq and patient dies from massive overdose
- Poor penmanship cost doctor $380,000

Dr Wrote 2 Over the Top of 1

Sloppy Script Leads to Fatal Overdose

Court orders doctor with poor penmanship to pay $379,000 in damages to patient's family.

Published: October 10, 2013

Category: Outpatient Surgery News and Trends > Surgical Malpractice

A San Antonio nephrologist who scribbled a "2" over top of a "1" after changing his mind about a dosage he'd prescribed to a post-op patient has been ordered to pay $379,000 to the family of a woman whose death the resulting misinterpretation caused.

Flavio Alvarez, MD, prescribed 10 millimoles of potassium to a dialysis patient who was having a toe on her left foot amputated, according to a story in My San Antonio. Three days later, after the patient's right foot was amputated, Dr. Alvarez decided to up the dose to 20 millimoles. But instead of writing out a new script, he simply wrote over top of the existing one.

Nurses and pharmacists misread the number as 120, and a massive overdose resulted in the patient's death.

In a jury trial, Dr. Alvarez acknowledged his negligence, but argued that trained

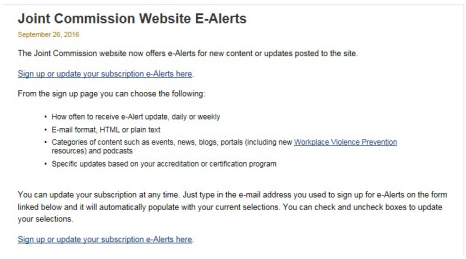
9. Writing Letters and Numbers

- FDA and ISMP note four most common mistakes and helpful in writing prescriptions
  - Between the letter "l" and the number 1
  - Between the letter "O" and the number 0
  - Between the letter "Z" and the number 2
  - Between the number "1" and "7"
- Article makes **four** recommendations
- Be sure to always leave a space between the drug name and the dose

10. Sign Up to Get TJC Sentinel Events Alerts

- Every facility should have someone who has signed up to get a copy of all sentinel events alerts
- This is true even if you are not accredited by TJC
- Put together a team to implement each one
- The TJC leadership standards require this
- Many are related to medication issues
- LD.04.04.03 state that the design of new or modified services or processes incorporates information about sentinel events
  - Sign up at www.jointcommission.org/ealerts/

Sign Up for TJC Resources



Joint Commission Website E-Alerts

September 26, 2016

The Joint Commission website now offers e-Alerts for new content or updates posted to the site.

Sign up or update your subscription e-Alerts here.

From the sign up page you can choose the following:

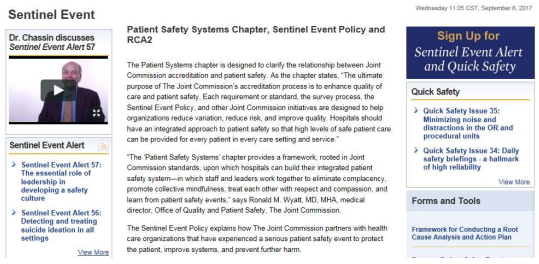
- How often to receive e-Alert update, daily or weekly
- E-mail format, HTML or plain text
- Categories of content such as events, news, blogs, portals (including new Workplace Violence Prevention resources) and podcasts
- Specific updates based on your accreditation or certification program

You can update your subscription at any time. Just type in the e-mail address you used to sign up for e-Alerts on the form linked below and it will automatically populate with your current selections. You can check and uncheck boxes to update your selections.

Sign up or update your subscription e-Alerts here.

www.jointcommission.org/ealerts/

TJC Website Has All SEAs



Sentinel Event

Wednesday 11:05 CST, September 6, 2017

Dr. Chassin discusses *Sentinel Event Alert 57*

Sentinel Event Alert

- Sentinel Event Alert 57: The essential role of leadership in developing a safety culture
- Sentinel Event Alert 56: Detecting and treating suicide ideation in all settings

View More

Patient Safety Systems Chapter, Sentinel Event Policy and RCA2

The Patient Systems chapter is designed to clarify the relationship between Joint Commission accreditation and patient safety. As the chapter states, "The ultimate purpose of The Joint Commission's accreditation process is to enhance quality of care and patient safety. Each requirement or standard, the survey process, the Sentinel Event Policy, and other Joint Commission initiatives are designed to help organizations reduce variation, reduce risk, and improve quality. Hospitals should have an integrated approach to patient safety so that high levels of safe patient care can be provided for every patient in every care setting and service."

"The 'Patient Safety Systems' chapter provides a framework, rooted in Joint Commission standards, upon which hospitals can build their integrated patient safety system—in which staff and leaders work together to eliminate complacency, promote collective mindfulness, treat each other with respect and compassion, and learn from patient safety events," says Ronald M. Wyatt, MD, MHA, medical director, Office of Quality and Patient Safety, The Joint Commission.

The Sentinel Event Policy explains how The Joint Commission partners with health care organizations that have experienced a serious patient safety event to protect the patient, improve systems, and prevent further harm.

Sign Up for *Sentinel Event Alert and Quick Safety*

Quick Safety

- Quick Safety Issue 35: Minimizing noise and distractions in the OR and procedural units
- Quick Safety Issue 34: Daily safety briefings - a hallmark of high reliability

View More

Forms and Tools

Framework for Conducting a Root Cause Analysis and Action Plan

www.jointcommission.org/sentinel_event.aspx

TJC Sentinel Event Alerts on Medications

- SEA 53 Managing Risks during transition to new tubing connectors
- SEA 49 Safe Use of Opioids
  - Note opioids is a hot topic now
- SEA 41 Preventing errors relating to commonly used anticoagulants
- SEA 39 Preventing Pediatric Medications Errors
- SEA 36 Tubing misconnections-a persistent and deadly occurrence
- SEA 35 Using medication reconciliation to prevent errors
- SEA 34 Preventing Vincristine administration errors

TJC Sentinel Event Alerts on Medications

- SEA 33 Patient controlled analgesia by proxy (PCA)
  - See also SEA 47 on Radiation Risks and Diagnostic Imaging
- SEA 23 Medication errors related to potentially dangerous abbreviations
- SEA 19 LASA Drugs
- SEA 16 Mix ups lead to medication errors
- SEA 15 Infusion pumps; preventing future errors
- SEA 11 High alert medications and patient safety
- SEA 10 Blood transfusion errors
- SEA 1 Preventing KCL errors
  - 15 of the 54 SEA are related to medications

Safe Use of Opioids TJC SEA

Sentinel Event Alert Issue 49: Safe use of opioids in hospitals

August 8, 2012

Download This File

Although hospital patients may need the strong pain relief that only opioids can provide, The Joint Commission urges hospitals to take specific steps to prevent serious complications or even deaths from opioid use.

Safe use of opioids in hospitals

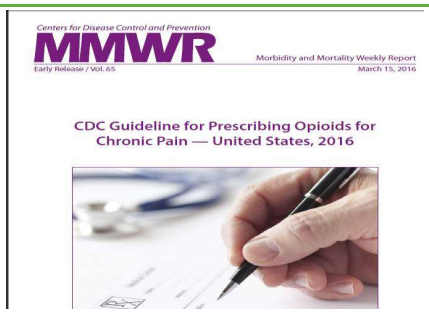
While opioid use is generally safe for most patients, opioid analgesics may be associated with adverse effects,[1,2,3] the most serious effect being respiratory depression, which is generally preceded by sedation.[4,5,6] Other common adverse effects associated with opioid therapy include dizziness, nausea, vomiting, constipation, sedation, delirium, hallucinations, falls, hypotension, and aspiration pneumonia.[4,7] Adverse events can occur with the use of any opioid; among these are fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and sufentanil. While there are numerous problems associated with opioid use, including underprescribing, overprescribing, tolerance, dependence, and drug abuse, this Alert will focus on the safe use of opioids that are prescribed and administered within the inpatient hospital setting. The Joint Commission recognizes that the emergency department presents unique challenges that should also be

Opioids Toolkit PaPSA

11. Implement a Safe Process for Opioids

- Hot issues in the news right now for many reasons
- CDC issued memo and found high rate of fatal drug overdose and drug misuse
  - 2015 data shows 91 Americans die everyday from opioid overdose
  - From 2000-2015 more than half a million people died from opioid drug overdose
- CDC issues opioid guidelines in March 2016
- Many emergency departments have new policy on prescribing but don't post in ED lobby due to EMTALA

CDC Guidelines for Rx Opioids



ww.cdc.gov/media/modules/dpk/2016/dpk-pod/rr6501e1er-ebook.pdf

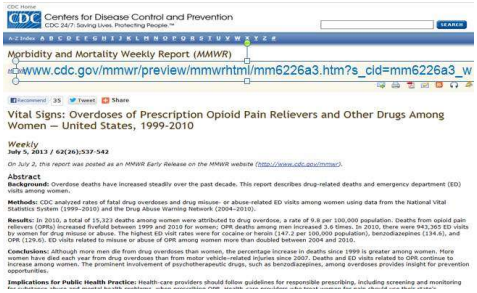
Safe Use of Opioids

- Screen patient for signs of respiratory depression
- Be aware of patients who are at high risk of over-sedation
  - Snoring, older age, no recent use of opioid use, smoker, history of sleep apnea, pre-existing pulmonary disease etc.
- Make sure staff are aware of normal doses and trained in safe use of opioids
- Assess patient's previous history of analgesic use or abuse and monitor all patients carefully
- Consider use of pulse ox and end tidal CO2

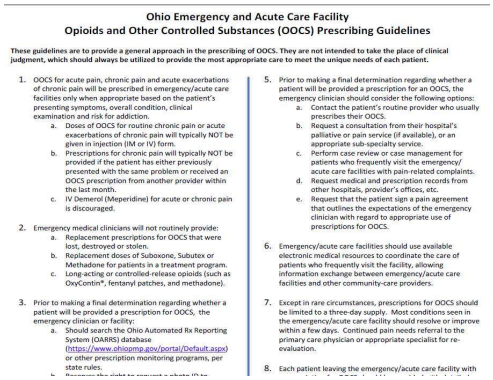
Safe Use of Opioids

- Assess all adverse events and ensure reporting to PI department and risk management
- Provide written instructions to patients who are on opioids along with family or caregiver
- Staff should be trained in CPR and should know how to recognize signs of adverse events including respiratory depression
- Have policies and procedures that allows for a second level of review by pain management specialist or pharmacist of pain management plan and ensure staff is aware

Overdose of Rx Opioid Pain Relievers



Many States are Taking This Initiative



Ohio Emergency and Acute Care Facility
Opioids and Other Controlled Substances (OOCS) Prescribing Guidelines

These guidelines are to provide a general approach in the prescribing of OOCS. They are not intended to take the place of clinical judgment, which should always be utilized to provide the most appropriate care to meet the unique needs of each patient.

1. OOCS for acute pain, chronic pain and acute exacerbations of chronic pain will be prescribed in emergency/acute care facilities only when appropriate based on the patient's presenting symptoms, overall condition, clinical examination and risk for addiction.
   a. Doses of OOCS for routine chronic pain or acute exacerbations of chronic pain will typically NOT be given in injection (IM or IV) form.
   b. Prescriptions for chronic pain will typically NOT be provided if the patient has either previously presented with the same problem or received an OOCS prescription from another provider within the last month.
   c. IV Demerol (Meperidine) for acute or chronic pain is discouraged.
2. Emergency medical clinicians will not routinely provide:
   a. Replacement prescriptions for OOCS that were lost, destroyed or stolen.
   b. Replacement doses of Suboxone, Subutex or Methadone for patients in a treatment program.
   c. Long-acting or controlled-release opioids (such as OxyContin®, fentanyl patches, and methadone).
3. Prior to making a final determination regarding whether a patient will be provided a prescription for OOCS, the emergency clinician or facility:
   a. Should search the Ohio Automated Rx Reporting System (OARRS) database (https://www.ohiopmp.gov/portal/Default.aspx) or other prescription monitoring programs, per state rules.
5. Prior to making a final determination regarding whether a patient will be provided a prescription for an OOCS, the emergency clinician should consider the following options:
   a. Contact the patient's routine provider who usually prescribes their OOCS.
   b. Request a consultation from their hospital's palliative or pain service (if available), or an appropriate sub-specialty service.
   c. Perform case review or case management for patients who frequently visit the emergency/acute care facilities with pain-related complaints.
   d. Request medical and prescription records from other hospitals, provider's offices, etc.
   e. Request that the patient sign a pain agreement that outlines the expectations of the emergency clinician with regard to appropriate use of prescriptions for OOCS.
6. Emergency/acute care facilities should use available electronic medical resources to coordinate the care of patients who frequently visit the facility, allowing information exchange between emergency/acute care facilities and other community-care providers.
7. Except in rare circumstances, prescriptions for OOCS should be limited to a three-day supply. Most conditions seen in the emergency/acute care facility should resolve or improve within a few days. Continued pain needs referral to the primary care physician or appropriate specialist for re-evaluation.
8. Each patient leaving the emergency/acute care facility with

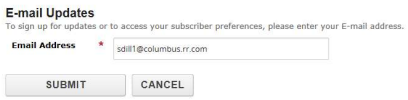
FDA Safety Labeling for Certain Opioids

- FDA has safety labeling changes for extended release and long acting opioid analgesics
- States they are indicated for pain severe enough to require daily around the clock long term treatment
- New warning to caution pregnant woman can cause neonatal withdrawal symptoms
- Changes to REMS which require companies to make education available to healthcare professionals on how to safety prescribe
  - Risk Evaluation and Mitigation Strategy (REMS)

12. Sign Up for PS Net

- Sign up to subscribe to the AHRQ PS Net (patient safety network) newsletter and Web M&M at no charge
  - Sign up at www.psnet.ahrq.gov/
- AHRQ will send you a list of the new medication related articles and other patient safety resources once a month
- Provides a short summary of the article
- Sometime can get articles and sometimes will need to have librarian pull article
- Great to use have medication team review

Sign Up for Medication Articles



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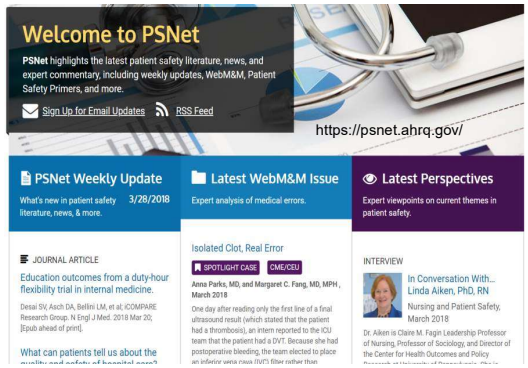
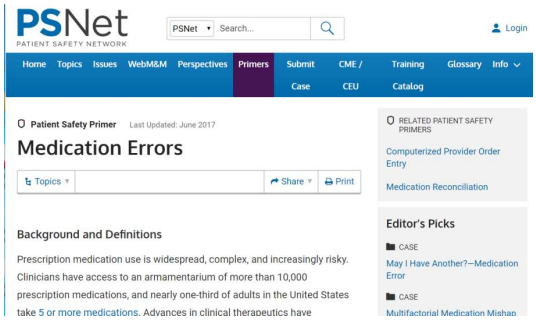
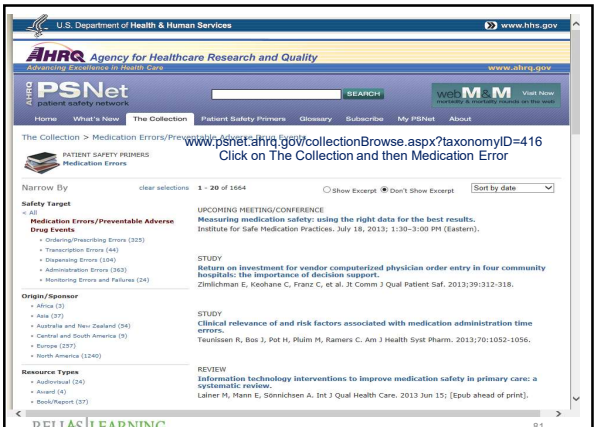


RELIAS | LEARNING 79



RELIAS | LEARNING 80



RELIAS | LEARNING 81

13. Monitor the FDA Safe Use Program

- FDA Safe Use program is designed to reduce the misuse of medications and prevent medication errors
- States can reduce 50,000 admissions
- Mentions the IOM study that estimates at least 1.5 million preventable injuries and deaths each year from overdoses, mix ups, and unintended exposure to prescription drugs
- Mentions alcohol based solutions cause 600 fires in ORs every year
- Parents reach for household spoon when it says teaspoon no matter what size it is

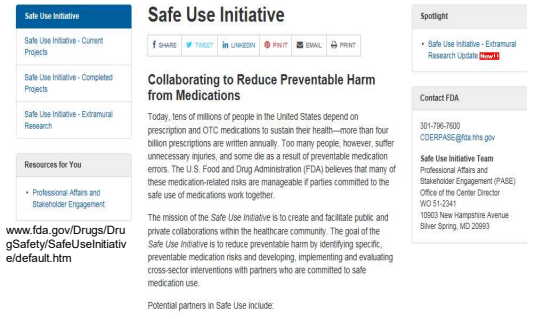
FDA Safe Use Program

- FDA says 3 billion prescriptions a year
- Many patients die or suffer injuries as result of medication errors
- Many of the risks are manageable if parties committed to safe use of medications work together
- Goal is to reduce preventable harm by identifying medication related risks
- Safe use project on acetaminophen (Tylenol) toxicity (APAP on label, tablets only 325 mg) and Fentanyl patches
- Goal to work with others to prevent medication errors
- Best practices for safe use of pediatric cough syrup

FDA Safe Use Program

- 9,000 children are accidentally exposed to prescription Opioids in 3 year period
- Worked to reduce acetaminophen toxicity and has white paper with many recommendations
  - Wording on pharmacy containers to show it has acetaminophen in it, complete spelling of name etc.
- Issued report “FDA’s Safe Use Initiative; Collaborating to Reduce Preventable Harm from Medicines”
- FDA also issues guidance entitled “Dosage Delivery Devices for OTC Liquid Drug Products,” in Federal Register on November 4, 2009
  - www.fda.gov/Drugs/DrugSafety/ucm187806.htm

FDA Safe Use Initiative



www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/default.htm

Current Projects of Safe Use Initiative

www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/ucm188762.htm

14. Pediatric Medication Errors

- Many are related to medication errors,
- Such as TJC SEA 39, issued April 11, 2008 on Preventing Pediatric Errors,
  - Also infusion pumps, LASA, medication reconciliation, VinCRISStine administration errors, mix up leads to medication error, high alert medications, KCl, etc.,
- Medication errors in children has the highest rate of harm,
- Found 11.2% rate of ADEs in children,
- Have a pediatric medication safety champion
- Always do weights in **kilograms** and not pounds

Dosing Charts for Kids Should Be in Kg

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

Pediatric Medication Errors

- 22% of the ADEs were preventable
- 17.8% could have been detected earlier
- Most common type of error was; improper dose 37.5%, omission error 19.9%, wrong drug or no order 13.7%, and prescribing error 9.4%
- Errors caused by; performance deficit 43%, knowledge deficit 29.9%, P&P not followed 20.7%, miscommunication 16.8%, and calculation error
- Will discuss use of trigger tool later
- There are several recommendation to reduce errors, oral syringes, limited number of concentrations etc.

Pediatric Medication Errors

- Use the IHI pediatric trigger tool which is discussed later 1
  - CMS, tag 508, says a hospital can not just rely on incident reports but must use another system to detect medication errors
- Ensure pediatric doses of medications are on the pediatric crash cart
- Use a current pediatric Broselow Luden tape, laminate and place on wall hook and use pediatric resources for codes like computer system, color coded charts etc.
- There are several recommendation to reduce errors, oral syringes, limited number of concentrations, use of intra-osseous infusions etc.
- www.chca.com/triggers/docs/PICU_triggertoolkit_for%20CHCAwebsite.pdf

PICU Trigger Instruction Manual:
Measuring Adverse Events in the PICU
Using a PICU Trigger Tool

Child Health Corporation of America · PPAG

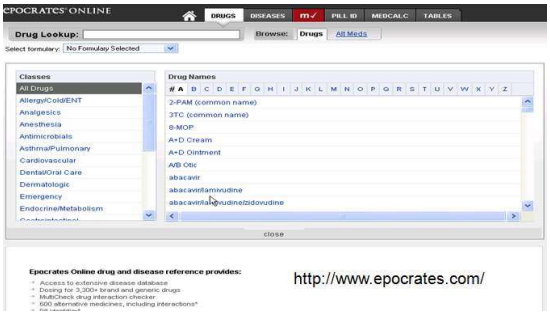
The use of "triggers," or clues, to identify adverse events (AEs) and adverse drug events (ADEs) is an effective method for measuring the overall level of harm in a health care organization. This Pediatric Intensive Care Unit (PICU) Trigger Toolkit for Measuring Adverse Events provides instructions for conducting a retrospective review of patient charts using triggers to identify AEs.

This toolkit contains:
- Background
- Definitions
- Sampling and Chart Review Methods
- List of PICU Triggers and Potential AEs
- PICU Adverse Event Guidelines/Clarifications
- Frequently Asked Questions about the trigger reviews and case examples
- Appendix A: Randomization instructions
- Appendix B: Data Collection Form Screenshots

BACKGROUND
The use of "triggers," or clues, to identify adverse events (AEs) and adverse drug events (ADEs) is an effective method for measuring the overall level of harm in a health care organization. This Trigger Toolkit for Measuring Adverse Events provides instructions for conducting a retrospective review of patient records using triggers to identify possible AEs in the Pediatric Intensive Care Unit (PICU). This tool includes a list of potential AE triggers and instructions for collecting the data you need to measure the percentage of admissions with an AE, the total number of AEs per 100 admissions, and the total number of AEs per 1000 PICU-days.

The Harvard Medical Practice Study (1991) found that 3.7% of patients experience serious adverse events related to medical management. Early findings from the Institute for Healthcare Improvement (IHI) trigger projects have found that 19% of all peri-operative patients and 55% of all ICU admissions had adverse events

Look Up Any Unfamiliar Pediatric Drug



15. Oral Syringes for Oral Medications

- Use oral syringes to administer oral medications,
- Pharmacy should use oral syringes in making oral medications also and **not** dosing spoon or medication cups
  - Confused on teaspoon, tablespoon, drams, ounces
- Educate staff about the benefits of oral syringes in preventing inadvertent IV administration of oral medications,
- Example; patient admitted with C-diff and ED doctors orders IV Flagyl and nurse gives. Attending changes to oral Flagyl and sent up in syringe.
  - Note 2018 C-diff guidelines that recommend use Vancomycin or Fidxomycin

15. Oral Syringes for Oral Medications

- Syringes is marked “oral use only not for IV” and oral syringes are different **color** so nurse does not make mistake
- Remember the ISMP 2018-2019 Best Practices
- The hospital should only purchase oral liquid doing devices that display the metric scale (milliliter)
  - Oral syringes, cups, droppers
- They only display volume with easy to read print
- Note confusing cup with drams on it and oz and a nurse made a mistake

16. Limited Number of Drug Concentrations

- This is also a current TJC MM standard,
- Want to limit the number of concentrations and dose strengths,
- So for example only IV solution of Lidocaine which has 2 grams in 500cc so if 2 mg a minute dose is standard at 30 cc/hour,
- Have dosing charts on a **laminated cards** on C-ring on the IV poles or pumps that have standardized solutions with rates to prevent errors,
- Don’t want to make an error calculating dose

17. Formulary

- Have a formulary that lists all the drugs and doses available in the hospital
- Establish and maintain a pediatric formulary
- Have policies for drug evaluations, selection, and therapeutic uses
- Review the formulary every year to see if drugs should be added or dropped
- Provide information to staff on new drugs added to the formulary and disseminate to staff
- Ensure compliance with CMS hospital CoP formulary regulations under Tag 511

CMS Hospital Regulation on Formulary

A-0511

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.25(b)(9) - A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

Interpretive Guidelines §482.25(b)(9)

The medical staff must establish a formulary system. The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs.

10 of 18 Pharmacy Standards Changed 11-20-2015

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

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

Transmittals for Appendix A

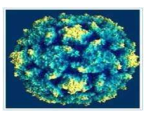
Survey Protocol

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

Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module
Inpatient Rehabilitation Unit Survey Module
Hospital Swing-Bed Survey Module

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

Email questions
hospitalscg@cms.hhs.gov



Current State Operation Manual or CoP Manual

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

Table of Contents
(Rev. 176, 12-29-17)

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Survey Protocol
Introduction
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Inpatient Rehabilitation Unit Survey Module
Hospital Swing-Bed Survey Module

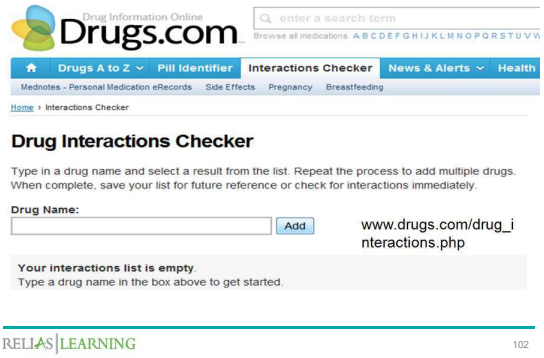
Email questions **hospitalscg@cms.hhs.gov**

www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_Appendixtoc.pdf

18. Access to Resources

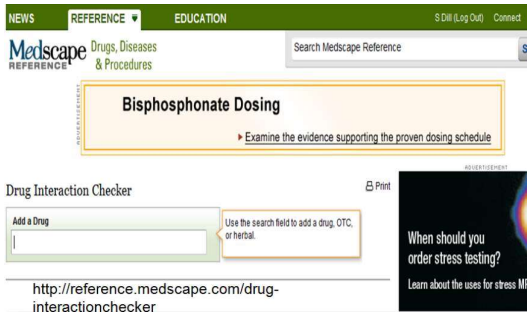
- Provide access to resources on each of the nursing units
- Including things like the formulary, PDR, Nurses Drug Book, current Broselow Luden pediatric tape (38% inaccuracy due to pediatric obesity), scanner on pediatric labels, colored coded crash carts
- Include up to date information on new drugs and pediatric specific information,
- Make sure pediatric crash carts has the pediatric doses
  - Use large signs with pediatric doses
- Many good resources on drug on the internet which can also reduce drug interactions

Drug Interactions Checker



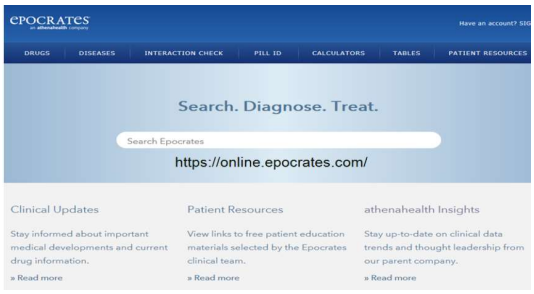
www.drugs.com/drug_interactions.php

Drug Interaction Checker



http://reference.medscape.com/drug-interactionchecker

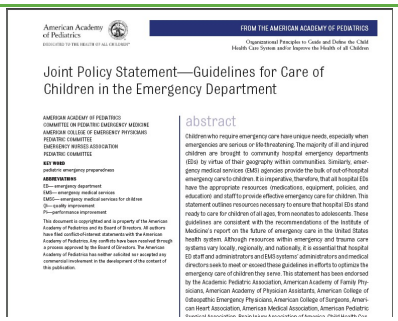
Drug Interaction & Drug Information



19. Have Care of Children in the ED Resources

- This should include pediatric research studies, pediatric growth charts, normal VS ranges for kids, emergency dose calculators, with information on minimum and maximum doses, pediatric doses and pediatric system
- Make sure medications recommended to be on the pediatric crash cart along with recommended equipment is present
  - The American Academy of Pediatrics and the American College of Emergency Physicians and others have a document on recommendations for care of children in the emergency department
  - A 2018 TJC requirement

Children Medications and Policies in the ED



American Academy of Pediatrics

FROM THE AMERICAN ACADEMY OF PEDIATRICS

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

Joint Policy Statement—Guidelines for Care of Children in the Emergency Department

AMERICAN ACADEMY OF PEDIATRICS
COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
PEDIATRIC COMMITTEE
EMERGENCY NURSES ASSOCIATION
PEDIATRIC COMMITTEE

KEY WORDS
pediatric emergency preparedness

ABBREVIATIONS
ED—emergency department
EMS—emergency medical services
EMSC—emergency medical services for children
QI—quality improvement
PI—performance improvement

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abstract

Children who require emergency care have unique needs, especially when emergencies are serious or life threatening. The majority of ill and injured children are brought to community hospital emergency departments (EDs) by virtue of their geography within communities. Similarly, emergency medical services (EMS) agencies provide the bulk of out-of-hospital emergency care to children. It is imperative, therefore, that all hospital EDs have the appropriate resources (medications, equipment, policies, and education) and staff to provide effective emergency care for children. This statement outlines resources necessary to ensure that hospital EDs stand ready to care for children of all ages, from neonates to adolescents. These guidelines are consistent with the recommendations of the Institute of Medicine's report on the future of emergency care in the United States health system. Although resources within emergency and trauma care systems vary locally, regionally, and nationally, it is essential that hospital ED staff and administrators and EMS systems' administrators and medical directors seek to meet or exceed these guidelines in efforts to optimize the emergency care of children they serve. This statement has been endorsed by the Academic Pediatric Association, American Academy of Family Physicians, American Academy of Physician Assistants, American College of Osteopathic Emergency Physicians, American College of Surgeons, American Heart Association, American Medical Association, American Pediatric

www.acep.org/Clinical---Practice-Management/Guidelines-for-Care-of-Children-in-the-Emergency-Department/

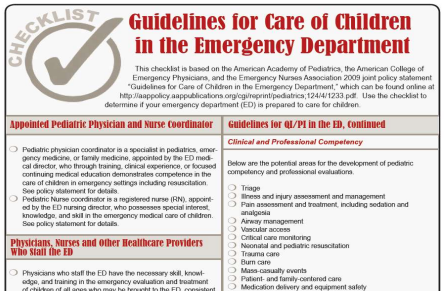
7. GUIDELINES FOR EQUIPMENT, SUPPLIES, AND MEDICATIONS FOR THE CARE OF PEDIATRIC PATIENTS IN THE ED

a. Pediatric equipment, supplies, and medications should be appropriate for children of all ages and sizes and shall be easily accessible, clearly labeled, and logically safely, and logically organized.
b. Resuscitation equipment and supplies shall be located in the ED; trays and other items may be housed in other departments (such as the newborn nursery or central supply) as long as the items are immediately accessible to the ED staff. A mobile pediatric crash cart is strongly recommended.
c. ED staff shall be appropriately educated as to the location of all items.
d. Each ED shall have a method of daily verification of proper location and function of equipment and supplies.
e. Medication chart, length-based tape, medical software, or other systems shall be readily available to ED staff to ensure proper sizing of resuscitation equipment and proper dosing of medication.
f. Table 1 and Appendix 2 outline medications, equipment, and supplies necessary for the care of children in the ED by qualified health care providers.

Table 1. Guidelines for Medications for Use in Pediatric Patients in EDs*

Resuscitation Medications	Other Drug Groups
Atropine	Activated charcoal
Adenosine	Topical, oral and parenteral analgesics

Checklist Available



CHECKLIST

Guidelines for Care of Children in the Emergency Department

This checklist is based on the American Academy of Pediatrics, the American College of Emergency Physicians, and the Emergency Nurses Association 2009 joint policy statement "Guidelines for Care of Children in the Emergency Department," which can be found online at http://aappolicy.aappublications.org/cgi/reprint/pediatrics;124/4/1233.pdf. Use the checklist to determine if your emergency department (ED) is prepared to care for children.

Appointed Pediatric Physician and Nurse Coordinator

- Pediatric physician coordinator is a specialist in pediatrics, emergency medicine, or family medicine, appointed by the ED medical director, who through training, clinical experience, or focused continuing medical education demonstrates competence in the care of children in emergency settings including resuscitation. See policy statement for details.
- Pediatric Nurse coordinator is a registered nurse (RN), appointed by the ED nursing director, who possesses special interest, knowledge, and skill in the emergency medical care of children. See policy statement for details.

Physicians, Nurses and Other Healthcare Providers Who Staff the ED

- Physicians who staff the ED have the necessary skill, knowledge, and training in the emergency evaluation and treatment

Guidelines for QI/PI in the ED, Continued

Clinical and Professional Competency

Below are the potential areas for the development of pediatric competency and professional evaluations.

- Triage
- Illness and injury assessment and management
- Pain assessment and treatment, including sedation and analgesia
- Airway management
- Vascular access
- Critical care monitoring
- Neonatal and pediatric resuscitation
- Trauma care
- Burn care
- Mass-casualty events
- Patient- and family-centered care
- Medication delivery and equipment safety

www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Children-and-Disasters/Documents/Checklist_ED_Prep.pdf

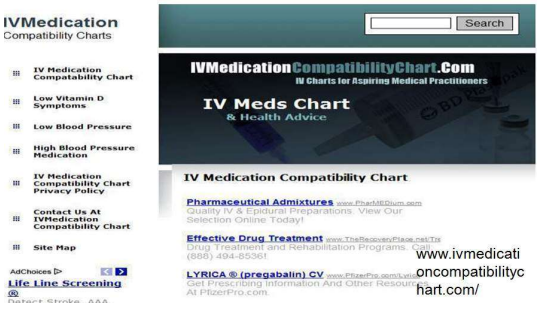
Physician Coordinator in ED for Children

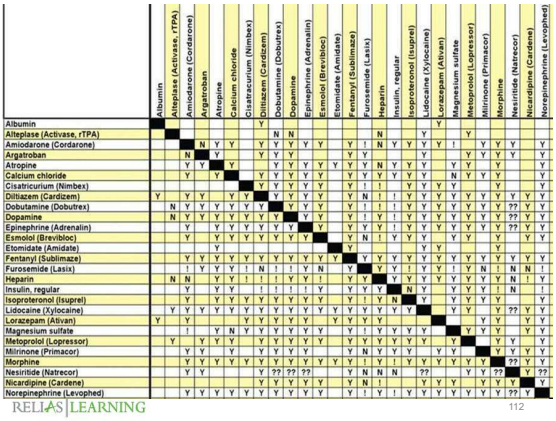
- A physician coordinator for pediatric emergency medicine is appointed by the ED medical director.
  1. The physician coordinator has the following qualifications:
     a. Meets the qualifications for credentialing by the hospital as a specialist in emergency medicine or pediatric emergency medicine. It is recognized that physicians in these specialties may not always be available in some communities; in these areas, the physician coordinator must meet the qualifications for credentialing by the hospital as a specialist in pediatrics or family medicine and demonstrate, through experience or continuing education, competence in the care of children in emergency settings, including resuscitation.
     b. Has special interest, knowledge, and skill in emergency medical care of children as demonstrated by training, clinical experience, or focused continuing medical education.
     c. Maintains competency in pediatric emergency care (see "III. GUIDELINES FOR QI/PI IN THE ED").
     d. May be a staff physician who is currently assigned other roles in the ED or may be shared through formal consultation agreements with professional resources from a hospital that is capable of providing definitive pediatric care.
  2. The physician coordinator is responsible for the following:
     a. Promoting and verifying adequate skill and knowledge of ED staff physicians and other ED health care providers (ie, physician assistants and advanced practice nurses) in the emergency care and resuscitation of infants and children.
     b. Overseeing ED pediatric QI, PI, patient safety, injury and illness prevention, and clinical care activities.

20. Have a Current Drug Incompatibility Chart

- Hospitals should have a process in place to make sure there is a current drug incompatibility chart
- This is also a CMS hospital requirement under Tag 508
- Drug incompatibilities must be reported to the attending physician
- Drug incompatibilities must be reported internally to the PI program
- Must document in the medical record
  - Drugs known to be incompatible can not be mixed together

Incompatibility Charts





	Albumin	Alteplase (Activase, rTPA)	Amiodarone (Cordarone)	Argatroban	Atropine	Calcium chloride	Cisatracurium (Nimbex)	Diltiazem (Cardizem)	Dobutamine (Dobutrex)	Dopamine	Epinephrine (Adrenalin)	Esmolol (Brevibloc)	Etomidate (Amidate)	Fentanyl (Sublimaze)	Furosemide (Lasix)	Heparin	Insulin, regular	Isoproterenol (Isuprel)	Lidocaine (Xylocaine)	Lorazepam (Ativan)	Magnesium sulfate	Metoprolol (Lopressor)	Milrinone (Primacor)	Morphine	Nesiritide (Natrecor)	Nicardipine (Cardene)	Norepinephrine (Levophed)
Albumin								Y											Y								
Alteplase (Activase, rTPA)									N	N						N			Y			Y					
Amiodarone (Cordarone)				N	N	Y	Y		Y	Y	Y	Y			Y	!	N	Y	Y	Y	!		Y	Y	Y			Y
Argatroban			N		Y				Y	Y	Y				Y	Y			Y			Y	Y	Y	Y			Y
Atropine			Y	Y		Y				Y	Y	Y	Y	Y	Y	N	Y	Y	Y		Y	Y		Y				Y
Calcium chloride			Y		Y				Y	Y	Y	Y	Y		Y	Y	Y	Y	Y		N	Y	Y	Y				Y
Cisatracurium (Nimbex)								Y	Y	Y	Y	Y	Y		Y	!	!		Y	Y	Y	Y		Y				Y
Diltiazem (Cardizem)	Y		Y	Y		Y	Y		Y	Y	Y	Y	Y		Y	N	!	!	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Dobutamine (Dobutrex)		N	Y	Y	Y	Y	Y	Y		Y	Y	Y			Y	!	!	!	Y	Y	Y	Y	Y	Y	??	Y	Y	Y
Dopamine		N	Y	Y	Y	Y	Y	Y	Y		Y	Y			Y	!	Y	!	Y	Y	Y	Y	Y	Y	??	Y	Y	Y
Epinephrine (Adrenalin)			Y		Y	Y	Y	Y	Y	Y		Y			Y	Y	Y	!	Y	Y	Y	Y	Y	Y	??	Y	Y	Y
Esmolol (Brevibloc)			Y		Y	Y	Y	Y	Y	Y	Y				Y	N	!	Y	Y	Y		Y	Y			Y	Y	Y
Etomidate (Amidate)					Y									Y					Y	Y			Y					
Fentanyl (Sublimaze)			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Furosemide (Lasix)			!	Y	Y	Y	!	N	!	!	Y	N			Y		Y	!	Y	Y	!	Y	N	!	N	N	!	
Heparin		N	N		Y	Y	!	!	!	!	Y	!			Y	Y		Y	Y	Y	Y	Y	Y	Y	N	!		!
Insulin, regular			Y		Y	Y		!	!	!	!	Y			Y	Y	Y		N	Y		Y	Y	!	N			!
Isoproterenol (Isuprel)			Y		Y	Y	Y	Y	Y	Y	Y				Y	!	Y	N		Y		Y	Y	Y				Y
Lidocaine (Xylocaine)		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y		Y	Y		Y	??	Y	Y
Lorazepam (Ativan)	Y		Y				Y	Y	Y	Y	Y		Y	Y	Y	Y							Y	Y		Y	Y	
Magnesium sulfate			!		Y	N	Y	Y	Y	Y	Y	Y		Y	!	Y	Y	Y	Y			Y	Y	Y		Y	Y	
Metoprolol (Lopressor)		Y		Y	Y	Y		Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y		Y		Y	Y		Y	Y	
Milrinone (Primacor)			Y	Y		Y		Y	Y	Y	Y			Y	N	Y	Y	Y		Y	Y			Y	Y	Y	Y	
Morphine			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	!	Y	!	Y	Y	Y	Y	Y			??	Y	Y	
Nesiritide (Natrecor)			Y	Y				Y	??	??	??				Y	N	N	N		??			Y	??		Y	??	
Nicardipine (Cardene)								Y	Y	Y	Y	Y			Y	N	!			Y	Y	Y		Y	Y		Y	
Norepinephrine (Levophed)			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y			Y	!	Y	!	Y	Y	Y	Y	Y	Y	??	Y		

21. High Alert Medications

- Limit the number of concentrations and dose strengths of high alert medications,
- Make sure you have a policy and process on high alert medications
  - TJC MM.01.01.03 and CMS Hospital CoP standard
- Make sure your staff know what it is listed as a high alert medications in your high alert policy,
- Make sure staff are educated on what they are to do such as 2 nurses will check insulin order, insulin bottle and amount in the insulin syringe, chemo is checked by pharmacist and nurse, only chemo certified nurse etc.,

High Alert How to Guide IHI

PROTECTING 5 Million lives FROM HARM

Getting Started Kit:
Prevent Harm from High-Alert Medications

How-to Guide

www.ihi.org/NR/rdonlyres/8B2475CD-56C7-4D9B-B359-801F3CC3A8D5/0/HighAlertMedicationsHowToGuide.doc

High Risk Medications

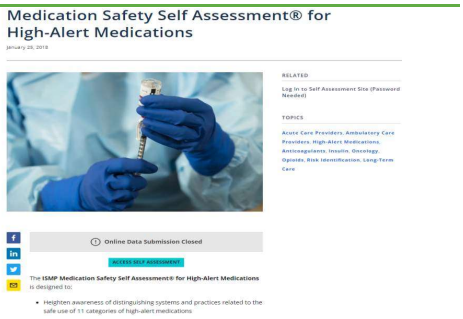
- High risk drugs are those associated with high % of errors or adverse outcomes
- List available from ISMP or USP
- Hospital needs to develop it own list of high risk or high alert drugs
  - KCl, Concentrated NaCl over 0.9 %, Chemo, insulin, paralytic agents, Fentanyl patches, neuromuscular blockers etc., and CMS says must include opioids
- Examples includes meds not FDA approved, investigational drugs, new ones, controlled substances, look-alike, ones with narrow therapeutic range

ISMP High Alert Self Assessment Tool

- Excellent 95 page tool to focus on most problematic ones
- Discusses 11 categories of high alert medications

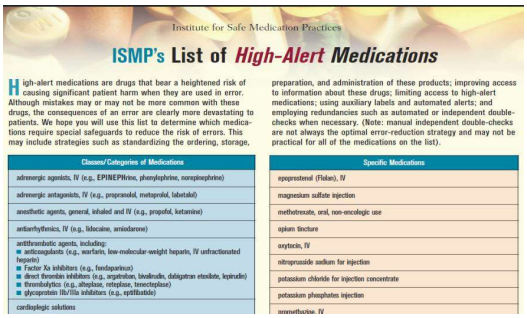
1. Neuromuscular blocking agents
2. Concentrated electrolytes
3. Magnesium sulfate injection
4. Moderate sedation of adults and children and minor sedation in children
5. Insulin both subq and IV
6. Lipid based medications
7. Methotrexate for non-oncologic use
8. Chemo both oral and parenteral
9. Anticoagulants
10. Neuraxial opioids and or locals
11. Opioids

ISMP High Alert Medication Tool



www.ismp.org/assessments/high-alert-medications

ISMP High Alert Medications



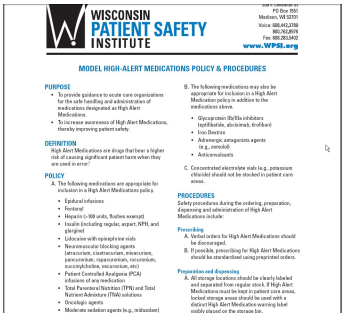
Institute for Safe Medication Practices

ISMP's List of *High-Alert* Medications

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as standardizing the ordering, storage, preparation, and administration of these products; improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; and employing redundancies such as automated or independent double-checks when necessary. (Note: manual independent double-checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list).

Classes/Categories of Medications	Specific Medications
adrenergic agonists, IV (e.g., **EPINEPHrine**, phenylephrine, norepinephrine)	epoprostenol (Flolan), IV
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)	magnesium sulfate injection
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)	methotrexate, oral, non-oncologic use
antiarrhythmics, IV (e.g., lidocaine, amiodarone)	opium tincture
antithrombotic agents, including: ■ anticoagulants (e.g., warfarin, low-molecular-weight heparin, IV unfractionated heparin) ■ Factor Xa inhibitors (e.g., fondaparinux) ■ direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran etexilate, lepirudin) ■ thrombolytics (e.g., alteplase, reteplase, tenecteplase) ■ glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)	oxytocin, IV
cardioplegic solutions	nitroprusside sodium for injection
	potassium chloride for injection concentrate
	potassium phosphates injection
	promethazine, IV

Have a Clear Policy on High Risk Meds



WISCONSIN PATIENT SAFETY INSTITUTE

www.WPSI.org

MODEL HIGH-ALERT MEDICATIONS POLICY & PROCEDURES

PURPOSE
- To provide guidance to acute care organizations for the safe handling and administration of medications designated as High Alert Medications.
- To increase awareness of High Alert Medications, thereby improving patient safety.

DEFINITION
High Alert Medications are drugs that bear a higher risk of causing significant patient harm when they are used in error.

POLICY
A. The following medications are appropriate for inclusion in a High Alert Medications policy.
- Epidural infusions
- Fentanyl
- Heparin (>100 units, flushes exempt)
- Insulin (including regular, aspart, NPH, and glargine)
- Lidocaine with epinephrine vials
- Neuromuscular blocking agents (atracurium, cisatracurium, mivacurium, pancuronium, rapacuronium, rocuronium, succinylcholine, vecuronium, etc)
- Patient Controlled Analgesia (PCA) infusions of any medication
- Total Parenteral Nutrition (TPN) and Total Nutrient Admixture (TNA) solutions
- Oncologic agents
- Moderate sedation agents (e.g., midazolam)

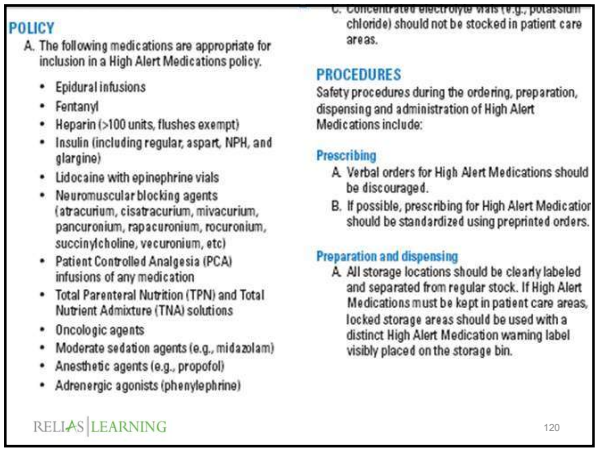
B. The following medications may also be appropriate for inclusion in a High Alert Medication policy in addition to the medications above.
- Glycoprotein IIb/IIIa inhibitors (eptifibatide, abciximab, tirofiban)
- Iron Dextran
- Adrenergic antagonists agents (e.g., esmolol)
- Anticoagulants

C. Concentrated electrolyte vials (e.g., potassium chloride) should not be stocked in patient care areas.

PROCEDURES
Safety procedures during the ordering, preparation, dispensing and administration of High Alert Medications include:

Prescribing
A. Verbal orders for High Alert Medications should be discouraged.
B. If possible, prescribing for High Alert Medications should be standardized using preprinted orders.

Preparation and dispensing
A. All storage locations should be clearly labeled and separated from regular stock. If High Alert Medications must be kept in patient care areas, locked storage areas should be used with a distinct High Alert Medication warning label visibly placed on the storage bin.



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- Total Parenteral Nutrition (TPN) and Total Nutrient Admixture (TNA) solutions
- Oncologic agents
- Moderate sedation agents (e.g., midazolam)
- Anesthetic agents (e.g., propofol)
- Adrenergic agonists (phenylephrine)

C. Concentrated electrolyte vials (e.g., potassium chloride) should not be stocked in patient care areas.

PROCEDURES

Safety procedures during the ordering, preparation, dispensing and administration of High Alert Medications include:

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22. Develop Protocols and Standing Orders

- Develop preprinted medication order forms, clinical pathways, or protocols to reflect standardized approach to care
- Include reminders and information about monitoring parameters
- Review periodically, such as **every year** to make sure still standard of care
- Make sure the medications are placed in the order sheet and signed by the doctor or LIP (CMS requirement under tag 405, 406, 450, and **457**)
- Example, protocol for heparin dose or for DVT evaluation for anticoagulants

Standing Orders

- If you have standing orders that are implemented by nursing such as starting an IV in the emergency department on a chest pain patient
- Make sure the standing order is entered in the order sheet in the medical record and signed off by the ED doctor and dated and timed
  - Make sure all orders are spelled out and not Heparin Protocol
- If orthopedic doctor pulls out 3 page preprinted orders for TKA then sign page 3 of 3 and must initial any deletions or additions (CMS Tag 457,406 & 450)

CMS Hospital CoP Tag 457 Standing Orders

A-0457

(Rev. 84, Issued: 06-07-13, Effective: 06-07-13, Implementation: 06-07-13)

§482.24(c) *(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:*

(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;

(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and

(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

Interpretive Guidelines §482.24(c)(3)

What is covered by this regulation?

There is no standard definition of a "standing order" in the hospital community at large (77 FR 29055, May 16, 2012), but the terms "pre-printed standing orders," "electronic standing orders," "order sets," and "protocols for patient orders" are various ways in which the term "standing orders" has been applied. For purposes of brevity, in our guidance we generally use the term "standing order(s)" to refer interchangeably to pre-

Standing Orders

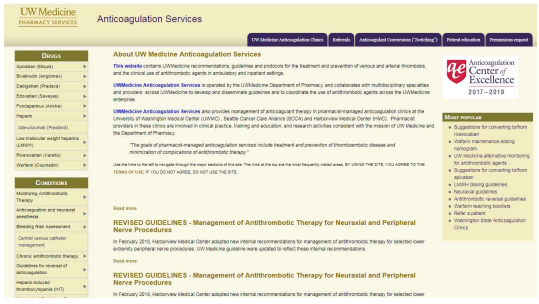
- Order must be appropriate as for **well defined scenarios**
- Must be consistent with evidenced based guidelines
- Review periodically to make sure still current
- Educate physicians and nurses and staff about standing orders in orientation and periodically
- Make sure approved by MS (MEC) along with nursing and pharmacy leadership
- Make sure consistent with state law, the person's state scope of practice and hospital P&Ps

UW Medicine

LOW MOLECULAR WEIGHT HEPARIN DOSING RECOMMENDATIONS

CLINICAL SCENARIO	LMWH DOSING RECOMMENDATIONS	
	ENOXAPARIN (preferred LMWH)	DALTEPARIN (no dose-capping)
VTE PROPHYLAXIS		
Orthopedic surgery (hip/knee replacement, hip fracture)	30mg q12h	5000 units daily
Trauma	30mg q12h	5000 units daily
Acute Spinal cord injury	30mg q12h	5000 units daily
Acute medical illness	40mg daily	5000 units daily
General surgery	40mg daily	5000 units daily
Bariatric surgery	40mg q12h	Not recommended
Morbid obesity (BMI>40)	40mg q12h	Not recommended
Severe renal impairment (Clcr < 30)	30mg daily	5000 units daily
VTE TREATMENT	Use total body weight (TBW) to calculate dosing	
Venous thrombosis *(LMWH for a minimum of 5 days)*	1mg/kg[1] SQ q12h	200 units/kg[2] daily
Cancer-associated venous thrombosis *(LMWH for a minimum of 3-6 months)*	Dalteparin preferred, or enoxaparin 1mg/kg[1] q12h x 1 month, then 1.5 mg/kg[1] daily	200 units/kg[2] daily x 1 month, then 150 units/kg[2] daily
Pregnancy	1mg/kg[1] q12h	100 units/kg[3] q12h
Low body weight (wt < 45 kg)	1mg/kg[1] q12h	200 units/kg[2] daily
Obesity (wt ≥ 99kg)	1mg/kg[1] q12h	100 units/kg[2] q12h
Moderate renal impairment	0.85mg/kg[1] q12h	200 units/kg[2] daily

Great Resource on Anticoagulants



http://depts.washington.edu/anticoag/home/

UW Medicine

Intravenous Heparin - STANDARD Protocol

Check orders to determine which algorithm to use

REGULAR Intensity (PTT Goal: 60 to 100)

PTT (seconds)	PRN RE-BOLUS	INFUSION HOLD TIME	CHANGE INFUSION DOSE (units/kg/hr)	NEXT PTT
< 40 (Notify provider for any PTT<50)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 3 units/kg/hr	6 hours
40-49 (Notify provider for any PTT<50)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 2 units/kg/hr	6 hours
50-59 (Notify provider for 2 consecutive PTTs 50-59)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 1 units/kg/hr	6 hours
60-100	None	None	NO CHANGE	6 hrs (after 2 consecutive PTTs in range, check PTT q AM)
101-110	None	None	Decrease by 1 units/kg/hr	6 hours
111-120	None	None	Decrease by 2 units/kg/hr	6 hours
121-150	None	30 minutes	Decrease by 2 units/kg/hr	6 hours
151-199	None	60 minutes	Decrease by 3 units/kg/hr	6 hours

«LOW» Intensity (PTT Goal: 60 to 80)

PTT (seconds)	PRN RE-BOLUS	INFUSION HOLD TIME	CHANGE INFUSION DOSE (units/kg/hr)	NEXT PTT
< 40 (Notify provider for any PTT<50)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 3 units/kg/hr	6 hours
40-49 (Notify provider for any PTT<50)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 2 units/kg/hr	6 hours
50-59 (Notify provider for 2 consecutive PTTs 50-59)	ONLY if ordered by provider -- see PRN orders.	None	Increase by 1 units/kg/hr	6 hours
60-80	None	None	NO CHANGE	6 hrs (after 2 consecutive PTTs in range, check PTT q AM)
81-100	None	None	Decrease by 1 units/kg/hr	6 hours
101-120	None	30 minutes	Decrease by 2 units/kg/hr	6 hours
121-150	None	60 minutes	Decrease by 2 units/kg/hr	6 hours
151-199	None	60 minutes	Decrease by 3 units/kg/hr	6 hours

Management of PTT > 200

PTT	CHECK TIMING OF SAMPLE	INSTRUCTIONS
	If < 6 hours since most recent bolus or rate change	Continue infusion at current rate, and repeat PTT at the appropriate time.

RELIAS LEARNING 127

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

Patient Safety Brief
Emergency Medicine Patient Safety Foundation
www.empsf.org

CMS Requirements on Order Sets, Protocols, Preprinted Orders, and Standing Orders

Sue Dill Calloway RN MSN JD

There are three separate tag numbers that hospitals must review in order to understand the Center for Medicare and Medicaid Services (CMS) requirements for standing orders, protocols, and order sets. Additionally, CMS included information on this topic in the changes to the hospital CoPs which was published in the Federal Register and which became effective July 16, 2012. Any hospital that accepts Medicare or Medicaid reimbursement must follow the conditions of participation (CoPs) and they must be followed for all patients seen in the hospital.

The development of protocols and standings orders is better described as a journey

RELIAS LEARNING 128

23. Bar Coding

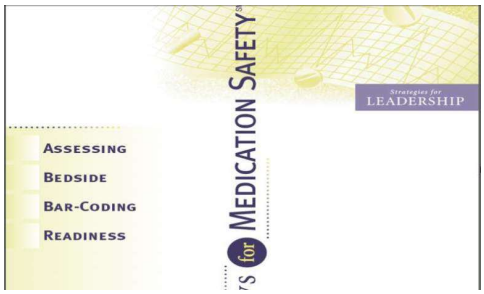
- Providers are encouraged to use bar coding, do a FMEA on this
- Providers are encourage to develop bar coding technology with pediatric capability and include IVs
- Potential errors should be considered when adapting new technology
- In other words if you get bar coding do a literature search and see errors that occurred as a result of bar coding

RELIAS LEARNING 129

Bar Coding

- Bar code eMAR increased as some hospital used it to meet the meaningful use criterion
- Studies show that bar-code technology with an electronic medical record substantially reduces transcription and administration medication errors
  - 41% reduction in non-timing administration errors
  - 51% reduction in potential drug-related ADEs
- See AHRQ study at www.ahrq.gov/news/press/pr2010/emarpr.htm

ISMP Bar Assessment Tool 54 pages



www.ismp.org/selfassessments/PathwaySection3.pdf

Bar Coding Implementation Guide

www.ismp-canada.org/barcoding/download/ResourceGuide/BarCodingResourceGuideFINAL.pdf

24. First Dose Rule Pharmacist Review

- There is the first dose rule from CMS Tag 500 and from TJC MM.05.01.01
- Medications in automated dispensing units that do not undergo appropriate pharmacist review should be limited to those need or emergency use or under the control of a LIP
  - Patient is admitted to the medical surgical unit from the ED, and before the nurse gives the first dose of the medications the pharmacist reviews the list and approves
  - Patient stuck in the ED until bed ready in 18 hours you have time to have pharmacist review first dose of regular medications

CMS Pharmacist Review A-500

- **All medication orders must be reviewed by a pharmacist before first dose is dispensed** includes review of therapeutic appropriateness of medication regime
  - Therapeutic duplication
  - Appropriateness of drug, dose, frequency, route and method of administration
  - Real or potential med-med, med-food, med-lab test, and med-disease interactions
  - Allergies or sensitivities and variation from organizational criteria for use

First Review by Pharmacist

From: CMS Hospital SCG [HospitalSCG@cms.hhs.gov]
Sent: Wednesday, June 03, 2015 3:00 PM
To: Sue Dill
Cc: Eddinger, David W. (CMS/CCSQ); CMS Hospital SCG
Subject: RE: Question on Appendix A

Ms. Dill- the answer to your question, "If the patient needs an antibiotic dose and the pharmacy is closed then a pharmacist would have to do a first review before the medication could be taken from the night cabinet by the nurses to be administered. Is that correct?" is yes.

From: Sue Dill [mailto:sdill1@columbus.rr.com]
Sent: Tuesday, June 02, 2015 3:36 PM
To: CMS Hospital SCG
Cc: Eddinger, David W. (CMS/CCSQ)
Subject: RE: Question on Appendix A

Please bear with me so I can make sure I under the answer correctly. I can understand if the patient is coding and he is given acls medications such as Epi or Atropine. If the patient needs an antibiotic dose and the pharmacy is closed then a pharmacist would have to do a first review before the medication could be taken from the night cabinet by the nurses to be administered. Is that correct? I don't think some hospitals use telepharmacy during the night when pharmacy is closed. Thanks for your patience and assistance with this question.

- CMS suggests a first review even if pharmacist is not on duty and staff are using night cabinet
- Consider use of telepharmacy

24. Educate Patient First Dose New Med

- Whenever you give a patient a medication they have never had before
- Tell them what the drug is, what is does, and important information of side effects to be aware of
- CMS tag 510 and TJC MM.06.01.01 EP 9 standard
- Advise patient and when appropriate, family, about potential clinically significant adverse reactions when giving a **new** medication (watch out for hives or red neck syndrome for Vancomycin)

This is the FIRST DOSE Of This MEDICATION

It is the responsibility of the nurse administering the 1st dose of a new medication to monitor the patient according to the clinical needs of the patient, and actual or potential medication-related problems must be addressed. Monitoring includes consideration of the patient's perceptions about adverse effects and when appropriate, perceived efficacy. Information from the patient's medical record, laboratory test results, clinical response, and the medication profile should be considered.

My patient received his/her first dose of: _____(medication)

On: _____(date) At:_____(military time)

CHECK ALL THAT APPLY:

_____ The patient tolerated the medication well. (No interventions needed)

_____ The patient exhibited or described the following side-effects: _____

_____

_____ Physician Notified. Name of Dr. _____ Date & Time _____

LIST ANY INTERVENTIONS: _____

_____

Nurse signature: _____ Date & Time _____ Place in Progress Notes

Patient Sticker

First Dose of Medication

- Hospital had the following on each line of the MAR,
- Teaching for New Med. Patient
- Evaluation of New Medication_____
- TIME_____

25. Documenting Outcome of Medication

- TJC PC.02.03.01, EP 10 addresses education of patients on safe and effective use of medication
  - Also MM.06.01.01 EP 9 and 06.01.03 EPs 3-6 on self administration of drugs
  - 2018 added pain management standards under LD.04.03.13, MS.03.01.03 and PC.01.02.07
- Hospitals must provide patient education and training on safe medication use
- Before administering a new med must tell the patient about any adverse events
- Document the response to the medications; pain medication relieved pain to 1/10, nausea medication resulted in no nausea or vomiting, etc.,

Use a Patient Education Form

Patient Education Checklist for Warfarin Therapy*

Educational Assessment		
Date of assessment_____		
Readiness/motivation to learn	___ High (Very Receptive) ___Medium (Receptive) ___ Low (Unreceptive)	
Ability to learn	___ Adequate (no cognitive impairment) ___ Low (cognitive impairment)	
Existing knowledge	___ Extensive ___ Some, but limited ___ Little or None	
How does the patient like to learn?	___ By listening ___ By reading ___ By seeing ___ By practicing	
POTENTIAL BARRIERS		
Vision	___ Adequate ___ Poor	____Needs correction (glasses or contacts)
Hearing	___ Adequate ___ Poor	____Uses hearing aids
Primary language	___ English ___Spanish ___ Other/specify:_____	
Literacy/ability to understand written material	___ Very High ___Adequate ___ Limited ___ Very low	
Willingness to follow treatment	___ High ___ Moderate ____Low ___Uncertain	
Treatment adherence history:	___ Good / Adequate ___ Poor	

26. Clarify any Unclear Order

- TDC MM.05.01.01 EP 11 and CMS CoP manual requires nurse/pharmacist to address any concerns with MD before administering or dispensing
- Have a P&P on this
- Discuss any unresolved significant concerns about the medication with the prescriber
- Make sure all your nurses and staff can articulate what to do if illegible or unclear order such as contact the ordering physician or LIP
- Document on order sheet and in nursing notes that it is clarified
  - Clarified order is Lasix 20 mg PO daily with Dr. Jones at 16:00 Sue Dill RN

27. Be Aware CMS CoP Medication Regulations

- Every hospital should be aware of the CMS hospital CoPs
- There is a separate one for CAH but most of pharmacy and medication guidelines are very similar
- April 7, 2015 CMS rewrote the entire CAH section on drugs and biologicals
  - Many rules for the storage, handling, dispensing and administration of drugs and biologicals
  - Many standards related to compounding since passage of federal law on compounding, the Drug Quality and Security Act (DQSA)
  - Also detailed section on beyond use date (BUD)

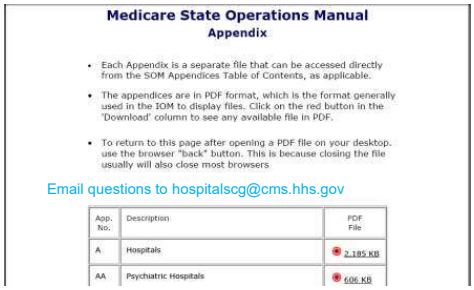
CMS CoP Medication Regulations

- Rewrote 10 of the 18 sections for hospitals as discussed previously
- Every hospital should take the hospital CoP section and do a gap analysis to determine compliance with each section
- Medication is an important topic and make sure you have enough pharmacists
- Many hospitals have put a pharmacist on their senior leadership staff because of the significance of medications on patient safety
- The number one medical error is medication errors (20% of all medical errors)
- Safe medication is also part of infection control worksheet

How to Get a Copy of the Hospital CoPs

- The hospital CoP is updated more frequently
- Anesthesia updates four times and has section on what is an anesthesia and analgesic
  - Has 528 pages and Tag 0001 to 1164
  - Pharmacy standards start at Tag A-0490 and revised 11-20-2015 and rewrites 10 of the 18 tag numbers
  - CAH April 7, 2015 and starts at tag 276 for drugs and biologicals
- There are other sections on medication issues located in other sections of the manual

Location of CMS Hospital CoP Manuals



CMS Hospital CoP Manuals
www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

CMS Medication Requirements

- List of policies required by the hospital such as high risk policy, abbreviations, have complete elements of an order, LASA, limit number of medication related devices to one or two,
- Pharmacist on call if not open 24 hours
- Flag new types of mistakes
- Weight based dosing for pediatrics
  - Remember Kg only or grams for infants
- Drug recall policy
- Policy to identify potential or actual ADE
- Timing of medication under three time frames

CMS Hospital CoP Manual

- There are other reference to medication besides the pharmacy/medication section
- Surveyor will look for outdated medication in the pharmacy
- Self administered meds Tag 412 and 413 in the nursing section also
- Surveyors to look at medications and if a risk for falls and unsteady gait (Ambien)
- Will look at the use of medications and make sure it is not a restraint

CMS CoP Manual

- Physically holding to give a medication is a restraint (Tag 160)
- Must assess medication in one hour face to face visit for patients who are V/SD (Tag 179)
- Must include medications and allergies in H&P (Tag 358)
- Surveyor to select patients and review all medication order and MARs (Tag 404)
- Drugs must be administered under the supervision of nursing and with approved MS P&Ps (Tag 405)
- Drugs must no longer just be administered within **30 minutes** of scheduled time (**3 time frames**) and nurse must remain with patient until taken (Tag 405)

CMS Hospital CoP Manual

- Must monitor medications as part of PI process including errors and ADE (Tag 405)
- Any questions on medications is resolved prior to administration (Tag 406)
- Need all elements of a complete drug order (Tag 406 and similar to questions asked on TJC Medication Management tracer)
- Verbal orders used infrequently and pose a risk of medication errors (Tag 407)

CMS Manual Other Sections

- Staff must be competent on blood and IV medications, (Tag 409,)
- Medical record must contain response to medications (Tag 449 and 464)
- Medical record must contain all medications given including any unfavorable reactions to drugs (Tag 467)
- Diets must meet needs of patients including patients taking certain medications (Tag 628)
- Adequate lighting in medication preparation areas (Tag 726)

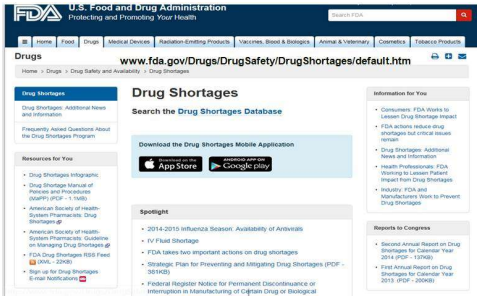
CMS Manual Other Sections

- Patients must be counseled in timing and dosage of medications and effects for post hospital care (Tag 822)
- Need policy on storage, access, control, and administration of medications and medications errors (Tag 1160)
- Need policy on medication errors, adverse events, and drug incompatibilities
  - Must be based on national standard
  - Must notify physician and document in the medical record
  - Must include in PI process

28. Drug Recall and Shortages Policy

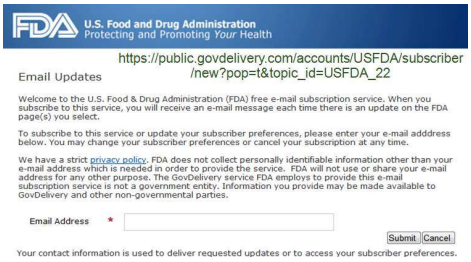
- This is a TJC and CMS requirement
- Subscribe to the FDA's email to receive notification of when drugs are recalled or shortages occur
- Have a person responsible for this area
- Communicate this to staff and physicians
- Have a plan for how you are going to handle the issue such as when Vioxx and Darvocet were pulled
  - Recently, important issue and patient deaths from shortage
- FDA list of shortages at www.fda.gov/cder/drug/shortages/default.htm

FDA Drug Shortages Website



www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

Sign Up for Information on Drug Shortages



Shortages

- American Society of Health-System Pharmacist also have a website on shortages,
  - http://www.ashp.org/shortages
- They also have a tool for managing shortages
- Sharp increase in numbers lately,
- Both issues can lead to medication errors,
- When did you know Heparin was recalled when found to be contaminated and what did you do?
- What did you do when Darvon and Darvocet recalled?
- Federal law passed related to drug shortages

ASHP Managing Drug Shortages

- Ask your legislators to support drug shortages provisions in PDUFA

Managing Drug Shortages www.ashp.org/shortages

- New Guidance from A.S.P.E.N. on Managing Shortage of Adult Multivitamin Injection (05/22/2012)
- ASHP Agrees with FDA's Revised Definitions Related to Drug Shortage Reporting Requirements (PDF)
- ASHP Letter To Congressman Carney Supporting HR 3839 (Drug Shortage Prevention Act of 2012) (PDF)
- ASHP's Comments to the FDA Following Drug Shortage Public Workshop (PDF)
- Information on Drug Shortages for Patients and Consumers
- A.S.P.E.N.'s Recommendations for Managing Parenteral Nutrition Cysteine Product Shortage
- Read FDLI's published article, "Can the United States Ensure an Adequate Supply of Critical Medications?" by ASHP staff members Joe Hill and Cindy Reilly (PDF)
- ASHP Guidance for Purchasing Drug Products in Short Supply (PDF)
- Action Alert! Access ASHP's Advocacy Center to Contact your Senators About the Impact of Drug Shortages
- ASHP, Co-conveners Release Recommendations from Drug Shortages Summit (PDF) (May take a moment to open the file.)
- Sample Drug Shortages Policy *by University Healthcare Hospitals and Clinics* (PDF)
- ASHP Guidelines on Managing Drug Product Shortages (PDF)
- Understanding and Managing Drug Product Shortages (PDF)

ASHP REPORT

www.ashp.org/DocLibrary/Policy/DrugShortages/ASHP_shortage_guide09.pdf

ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems

DEVELOPED BY AN ASHP EXPERT PANEL ON DRUG PRODUCT SHORTAGES: ERIN R. FOX, ANNETTE BIRT, KEN B. JAMES, HEATHER KOKKO, SANDRA SALVERSON, AND DONNA L. SOFLIN

Am J Health-Syst Pharm. 2009; 66:1399-406

Purpose

Drug product shortages can adversely affect drug therapy, compromise or delay medical procedures, and result in medication errors.[1,2] Health care professionals are increasingly concerned about the clinical effect that shortages have on patients and the tremendous resources required to address shortages.[1-5] Adverse patient outcomes related to drug product shortages[1,2,6-9] have prompted aggressive management strategies by health care providers

Commission,[10] the government,[11,12] and the media.[13,14] Drug product shortages adversely affect health-system finances by increasing the cost of delivering patient care, largely through higher drug acquisition and personnel costs.[5] In addition, shortages create a high level of frustration for everyone involved, including purchasing agents, pharmacists, nurses, physicians, and patients.[7]

Managing drug product shortages is particularly complex for practitioners in hospitals and health sys-

because these facilities routinely treat patients with acute or emergent conditions, use a significant number of medically necessary or single-source products, and use high-cost new drug technologies. These health care providers are challenged during drug product shortages to ensure the provision of seamless, safe, and therapeutically equivalent drug therapy, preferably at comparable costs. The pharmacy department must take a leadership role in efforts to develop and implement appropriate

Drug Shortages www.empsf.org

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

Drug Shortages – The Challenge of Hospital Pharmacies

WRITTEN BY: Darryl S. Rich, Pharm.D., M.B.A., FASHP

Medication Safety Specialist, Institute for Safe Medication Practices, Horsham PA.

Revised January 2013

Is there any emergency room that has not experienced the unavailability of a critical medication recently? The answer is apparently no. According to a July 2011 American Hospital Association survey, 99.4% percent of 820 hospitals surveyed had experienced at least one drug shortage in the past six months and nearly half experienced 21 or more shortages in this period[1]. If the past trend holds true, the problem is getting worse. Manufacturers voluntarily reported 56

GAO Drug Shortages - Number Still High

GAO

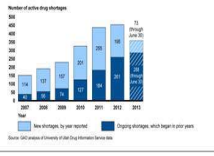
United States Government Accountability Office

Report to Congressional Addressees

February 2014

DRUG SHORTAGES

Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability



GAO-14-194

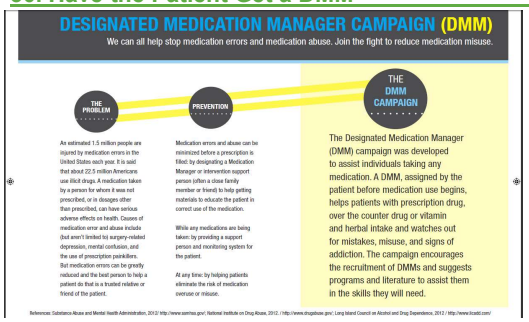
29. External Alerts and Recommendations

- CMS Tag 490 and TJC LD.04.04.05 requires facilities to incorporate external alerts and recommendation from national associations and government for review and policy revision
- Examples include the Joint Commission, TJC Sentinel Event Alerts, ISMP, FDA, CDC, IHI, AHRQ, Med Watch, NCCMER, etc.,
- Have a medication management team and each person is assigned one to monitor every month and report back to the committee,
- Have a medication champion on every unit

30. Have the Patient Get a DMM

- As patients age, the number of prescriptions taken can increase
- Patients with cognitive issues increase such as patients with dementia or Alzheimer's
- Having a close friend or family member who can act as the designated medication manager
- Can help by using smart boxes, medication documentation sheets, or pre-filled medication boxes
- Study shows reduces medication errors

30. Have the Patient Get a DMM



http://pulseofny.org/resources/PULSE_DMM_02.22nologo.pdf

31. Hospital Discharges & Med List

- Patients will get a **complete** list of the medications they are to take at home
  - TJC calls medication reconciliation and standard is found at NPSG.06.06.01
  - CMS requires in proposed Hospital Improvement Act June 16, 2016 and in the CMS worksheet
- Make sure they understand medication reconciliation or medication list
  - Issue of low health literacy
- List the medication, reason for taking, and show times and any special information

Medication Reconciliation

- Studies show 17% of patients discharge return within 30 days and many medication related
- Hospital inpatients discharged with complex and high risk medications regimens should receive discharge medication counseling managed by a pharmacist
  - Studies show patients are readmitted because of medication related issues
  - Pharmacist that review high risk medications or do a home visit have lower readmission rates

Reconciling Medication Information

Hospital Accreditation Program

NPSG.03.06.01

Maintain and communicate accurate patient medication information.

Elements of Performance for NPSG.03.06.01

1. Obtain information on the medications the patient is currently taking when he or she is admitted to the hospital or is seen in an outpatient setting. This information is documented in a list or other format that is useful to those who manage medications.
   Note 1: Current medications include those taken at scheduled times and those taken on an as-needed basis. See the Glossary for a definition of medications.
   Note 2: It is often difficult to obtain complete information on current medications from a patient. A good faith effort to obtain this information from the patient and/or other sources will be considered as meeting the intent of the EP.
2. Define the types of medication information to be collected in non–24-hour settings and different patient circumstances.
   Note 1: Examples of non–24-hour settings include the emergency department, primary care, outpatient radiology, ambulatory surgery, and diagnostic settings.
   Note 2: Examples of medication information that may be collected include name, dose, route, frequency, and purpose.
3. Compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies.
   Note: Discrepancies include omissions, duplications, contraindications, unclear information, and changes. A qualified individual, identified by the hospital, does the comparison. (See also HR.01.06.01, EP 1)
4. Provide the patient (or family as needed) with written information on the medications the patient should be taking when he or she is discharged from the hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose).
   Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications. For more information about communications to other providers of care when the patient is discharged or transferred, refer to Standard PC.04.02.01.
5. Explain the importance of managing medication information to the patient when he or she is discharged from the hospital or at the end of an outpatient encounter.
   Note: Examples include instructing the patient to give a list to his or her primary care physician; to update the information when medications are discontinued, doses are changed, or new medications (including over-the-counter products) are added; and to carry medication information at all times in the event of emergency situations. (For information on patient education on medications, refer to Standards MM.06.01.03, PC.02.03.01, and PC.04.01.05.)

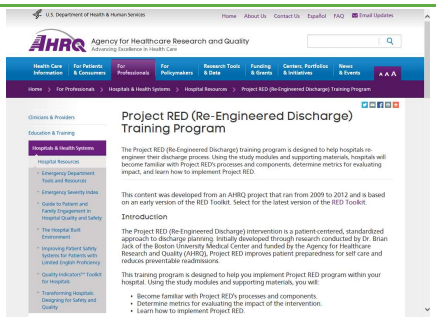
Medication List - From RED

What medicines do I need to take?

Each day, follow this schedule:

Morning Medicines			
Medicine name (generic and name brand) and amount	Why am I taking this medicine?	How much do I take?	How do I take this medicine?

Updated RED Resources



http://www.ahrq.gov/professionals/systems/hospital/red/index.html

32. Medication Information & Health Literacy

- Want to make sure patients understand their discharge and medication information
  - 52% of patients could not understand their medication instruction sheets
  - 20% of patients read at a sixth grade level but instruction sheets often written at 11th grade level
- Have patients **repeat back** or **teach back** information regarding medications
- Have pharmacist visit or call patients after discharge with high risk medications
- AHRQ has toolkit on advancing pharmacy health literacy practices through QI with 17 guides

AHRQ Health Literacy Practices Through QI

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

33. Standard Design Medication Room

- Medication administration is one of the most dangerous tasks in the hospital
- One study found the use of a standard design medication room promoted medication safety
- Used guidelines for planning and designing the medication room based on safety and human engineering principles
- So if building new hospital consider this resource
  - Discusses noise, air quality, lighting, work interruptions, equipment and facility design
  - Rozenbaum H, Gordon L, Brezis M, Porat N. Int J Qual Health Care. 2013;25:188-196.

International Journal for Quality in Health Care Advance Access published January 18, 2013

International Journal for Quality in Health Care 2013; pp. 1–9 10.1093/intqhc/mzt005

The use of a standard design medication room to promote medication safety: organizational implications

H. ROZENBAUM, L. GORDON, M. BREZIS AND N. PORAT

Hadassah Hebrew University Medical Center, Ein-Kerem, PO Box 12000, 91120 Jerusalem, Israel

Address reprint requests to: Porat. Tel: +972-2-677-6401; Fax: +972-2-677-8256; E-mail: nuritp@hadassah.org.il

Accepted for publication 2 December 2012 www.hadassah.org.il/media/2756369/The_use_of_a_standard_design_medication_room_to_promote_medication_safety.pdf

Abstract

Quality problem. Medication administration is one of the most potentially dangerous tasks in hospitals. In recent years, the medical establishment has gained insight into the importance of environmental and ergonomic factors on patient safety. Limited data are available on how a standard designed medication room (MR) supports safety medication administration.

Initial assessment. Proactive observations were conducted at a tertiary care facility, the Hadassah University Medical Center, Jerusalem, Israel, to determine if safety principles were being implemented in the medication preparation and storage environment. These observations revealed that no designated MRs existed in the hospitals wards and safety systemic weaknesses in medication preparation.

Choice of solution. Guidelines for planning and designing MRs, based on safety and human engineering principles, were established to promote safer medication administration in hospital wards.

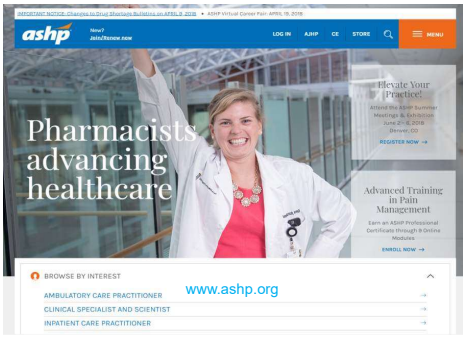
Standard Design Medication Room

- Sole use of medication room for drug preparation and storage with special storage of color coded high risk meds
- Entrance doors are electronically controlled and semitransparent sliding door
- Architectural design included optimal lighting, air quality, optimal height work surfaces and access to modular storage
- Bulletin board, bookshelf for medication information and clock
- Standard drug refrigerator with transparent door and dedicated cells for arranging drugs

34. ASHP Common Causes of Medication Errors

- Get a copy of the ASHP 9 page document on Guidelines on Preventing Medication Errors in Hospitals and 2018 67 pages update
- States many medication errors are undetected
- Discusses culture of safety and blaming workers will hot help and need to support the second victim
- List common cause of medication errors
  - Ambiguous strength designation on labels
  - Look-alike or sound alike drugs (LASA) and list strategies for same
  - Illegible handwriting, inappropriate abbreviations
  - Excessive workloads, medication unavailable
  - Inaccurate dosage calculations

ASHP Website



www.ashp.org

ASHP Guidelines on Preventing Medication Errors in Hospitals

www.ashp.org

The goal of drug therapy is the achievement of defined therapeutic outcomes that improve a patient's quality of life while minimizing patient risk.[1] There are inherent risks, both known and unknown, associated with the therapeutic use of drugs (prescription and nonprescription) and drug administration devices. The incidents or hazards that result from such risk have been defined as drug misadventuring, which includes both adverse drug reactions (ADRs) and medication errors.[2] This document addresses medication errors—episodes in drug misadventuring that should be preventable through effective systems controls involving pharmacists, physicians and other prescribers, nurses, risk management personnel, legal counsel, administrators, patients, and others in the organizational setting, as well as regulatory agencies and the pharmaceutical industry.

This document suggests medication error prevention approaches that should be considered in the development of organizational systems and discusses methods of managing medication errors once they have occurred. These guidelines are primarily intended to apply to the inpatient hospital setting because of the special collaborative processes established in the setting [e.g., formulary system, pharmacy and therapeutics (P&T) committee, and opportunity for

injectable products, radiopharmaceuticals, radiopaque contrast media, anesthetic gases, blood-fraction drugs, dialysis fluids, respiratory therapy agents, investigational drugs, drug samples, drugs brought into the hospital setting by patients, and other chemical or biological substances administered to patients to evoke a pharmacological response.[6]

Through a systems-oriented approach, the pharmacist should lead collaborative, multidisciplinary efforts to prevent, detect, and resolve drug-related problems that can result in patient harm.[1] An understanding of the risk factors associated with medication errors should enable improved monitoring of patients and medications associated with increased risk for serious errors and should enable the development of organizational systems designed to minimize risk.[7] The pharmacist should participate in appropriate organizational committees and work with physicians, nurses, administrators, and others to examine and improve systems to ensure that medication processes are safe.

Types of Medication Errors

Medication errors include prescribing errors, dispensing errors, medication administration errors, and patient compliance

ASHP Guidelines on Preventing Medication Errors in Hospitals

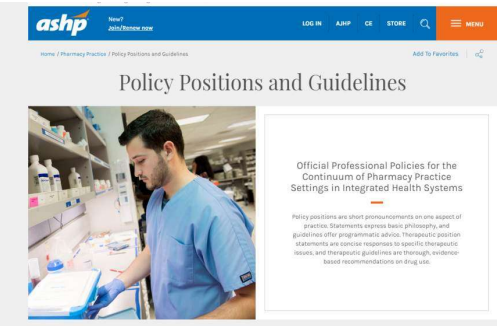
Purpose www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-medication-errors-hospitals.ashx

The goal of medication therapy is the achievement of defined therapeutic outcomes that improve a patient's quality of life while minimizing patient risk.[1] There are inherent risks, both known and unknown, associated with the use of medications (prescription and nonprescription). This document addresses medication errors: "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use."[2]

The landmark Institute of Medicine (IOM) report *To Err is Human: Building a Safer*

Guidelines on Preventing Medication Errors

- Prepress version will replace preliminary version when final
- Error reporting and review system is essential including reporting of close calls
- Need to analyze errors such as RCA, FMEA, or other tools
- Need a multi-disciplinary medication safety team
- Discusses medication safety officer and may sure a leader in the organization
  - ISMP has medication safety officer group
- Recommends self assessment and proactive risk assessments
- Follow position statements and best practices
  - Also a CMS requirement
  - ASHP has website on same



www.ashp.org/Pharmacy-Practice/Policy-Positions-and-Guidelines

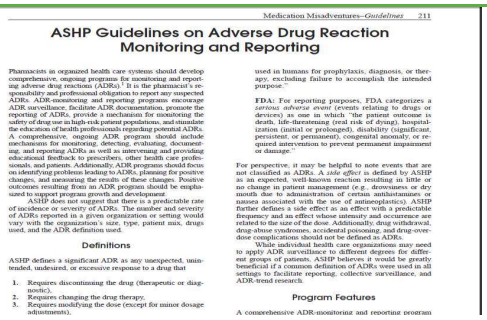
Guidelines on Preventing Medication Errors

- Has high alert medication checklist
- Use smart pumps
- Use electronic prescribing system with clinical decision support
- Evidenced based order sets
- Use commercially prepared products instead of compounding
- Improve readability of labels
- Perform double checks on dosing and concentrations when appropriate but note section on misuse
- Avoid abbreviations
- Know which one are managed via a REMS or risk evaluation and mitigation strategy –FDA mandated program to manage a med with known or serious risks

Guidelines on Preventing Medication Errors

- This could be a medication guide, patient package insert, communication plan, elements to assure safe use (ETASU), or an implementation system
- Discusses selection and procurement of the drug including purchasing of standard concentrations
- Need well designed formulary system to guide clinicians to prescribe safest and most effective agent
  - There are examples in the ASHP Medication Use Safety Resource Center
- Monitor National Alert Network (NAN) for urgent information needing attention and advisories about serious errors of the National Coordinating Council (27 organizations)
- Discusses minimum standards for hospital pharmacies

Also ASHP Guidelines on ADRs



Medication Misadventures–*Guidelines* 211

ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting

Pharmacists in organized health care systems should develop comprehensive, ongoing programs for monitoring and reporting adverse drug reactions (ADRs).[1] It is the pharmacist's responsibility and professional obligation to report any suspected ADRs. ADR-monitoring and reporting programs encourage ADR surveillance, facilitate ADR documentation, promote the reporting of ADRs, provide a mechanism for monitoring the safety of drug use in high-risk patient populations, and stimulate the education of health professionals regarding potential ADRs. A comprehensive, ongoing ADR program should include mechanisms for monitoring, detecting, evaluating, documenting, and reporting ADRs as well as intervening and providing educational feedback to prescribers, other health care professionals, and patients. Additionally, ADR programs should focus on identifying problems leading to ADRs, planning for positive changes, and measuring the results of these changes. Positive outcomes resulting from an ADR program should be emphasized to support program growth and development.

ASHP does not suggest that there is a predictable rate of incidence or severity of ADRs. The number and severity of ADRs reported in a given organization or setting would vary with the organization's size, type, patient mix, drugs used, and the ADR definition used.

Definitions

ASHP defines a significant ADR as any unexpected, unintended, undesired, or excessive response to a drug that

1. Requires discontinuing the drug (therapeutic or diagnostic),
2. Requires changing the drug therapy,
3. Requires modifying the dose (except for minor dosage adjustments),

used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose.[2]

FDA: For reporting purposes, FDA categorizes a *serious adverse event* (events relating to drugs or devices) as one in which "the patient outcome is death, life-threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent, or permanent), congenital anomaly, or required intervention to prevent permanent impairment or damage."[3]

For perspective, it may be helpful to note events that are not classified as ADRs. A *side effect* is defined by ASHP as an expected, well-known reaction resulting in little or no change in patient management (e.g., drowsiness or dry mouth due to administration of certain antihistamines or nausea associated with the use of antineoplastics). ASHP further defines a side effect as an effect with a predictable frequency and an effect whose intensity and occurrence are related to the size of the dose. Additionally, drug withdrawal, drug-abuse syndromes, accidental poisoning, and drug-overdose complications should not be defined as ADRs.

While individual health care organizations may need to apply ADR surveillance to different degrees for different groups of patients, ASHP believes it would be greatly beneficial if a common definition of ADRs were used in all settings to facilitate reporting, collective surveillance, and ADR-trend research.

Program Features

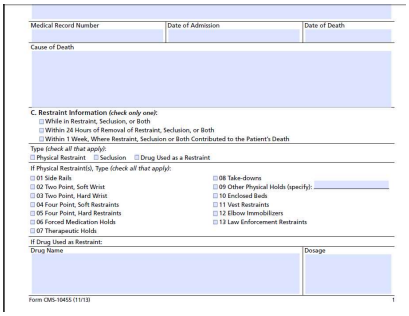
A comprehensive ADR-monitoring and reporting program

www.ashp.org/qii/

35. Know What is a Drug Used as a Restraint

- CMS in the hospital CoP has 50 pages of interpretive guidelines on Restraint and Seclusion
- They contain a definition of when a drug is used as a restraint
- Hospital should include this in their P&P and staff should be aware
- Okay to use Ativan if patient is going into DTs but not prn Haldol for agitation

CMS Restraint Reporting Form



Medical Record Number	Date of Admission	Date of Death

Cause of Death

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

Form CMS-10455 (11/13) 1

Restraint Definition

- A DRUG or medication is a restraint when it is used as a restriction to manage the patient's behavior,
- Or if it restrict the patient's freedom of movement, and is not a standard treatment or standard dosage for the patient's condition
  - Tag Number 160
- Note use of PRN drug is only prohibited if medication meets definition of drug,
  - So careful about twice the normal dose or off label use

Standard Treatment

Standard treatment would include all the following (and therefore not be a restraint):

- Medication is within pharmacy parameters set by FDA and manufacturer for use
- Use follows national practice standards
- Used to treat a specific condition based on patient's symptoms
- Standard treatment would enable patient to be effective or appropriate functioning

36. Be Aware of TJC MM Chapter

- Every hospital should be aware of the TJC medication management chapter
  - Even if not TJC accredited since SOC and evidenced based recommendations
- Be sure to document compliance with each section as in the PPR
- Medication errors are the most common type of medical error
- Medication management is important to both TJC and CMS

TJC MM Chapter Standards

- I. Planning
  - Medication Planning (MM.01.01.01, MM.01.01.03)
  - Look-alike/Sound-alike Medications (MM.01.02.01)
    - Called LASA drugs
- II. Selection and Procurement (MM.02.01.01)
- III. Storage (MM.03.01.01, MM.03.01.03,) MM.03.01.05 was **deleted** July 1, 2016

TJC MM Chapter Standards

- V. Preparing and Dispensing (MM.05.01.01, MM.05.01.07, MM.05.01.09, MM.05.01.11, MM.05.01.13, MM.05.01.17, MM.05.01.19)
  - MM.05.01.15 is not applicable to hospitals
- VI. Administration (MM.06.01.01, MM.06.01.03, MM.06.01.05)
- VII. Monitoring (MM.07.01.03)
  - MM.07.01.01 is not applicable to hospitals
- VIII. Evaluation (MM.08.01.01) EP4 deleted July 1, 2016 and 09.01.01 Antibiotic Stewardship Program

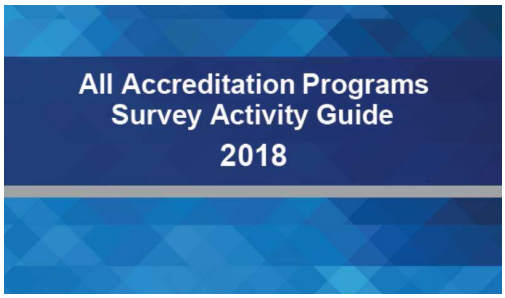
37. Practice Medication Management Tracer

- TJC is doing a medication management tracer during the unannounced survey process
- Remember MM is important to TJC
- MM is one of the 14 **priority focus areas**
- Four of top problematic standards are in the area of medication management
- Will look at medication labels and medication process during tracers
- Tracer includes patient on high risk medications

Medication Management Tracer

- When was last time unit was informed of a drug recall and look at process for drug recall
- Identify a patient receiving a high risk medication and the process, watch prepare chemo
- Explore LASA drugs and drug security
- How meds are prepared
- Process for clarifying unclear med orders
- Process for reviewing prescriptions for many things; dose, frequency, interactions with food, allergies, lab values

TJC Medication Management Tracer



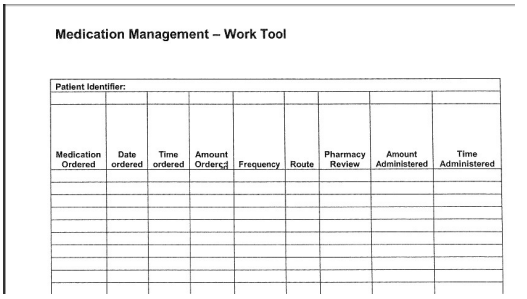
Medication Management Tracer

- Make sure crash carts are locked or under constant supervision even with red locks or document hazard vulnerability analysis (HVA) evaluation done if not
- Appropriate labeling of meds
- List of meds for dispensing must be available
- Safe storage of meds especially controlled substances
- What is process for patients who bring own meds from home and how do you secure these drugs
- Access to meds when pharmacy is closed and nigh cabinet
  - Data collection on meds accessed after hours

Medication Management Tracer

- Education of patient and staff including patient role in medication management
- Education of staff and patient about medication safety
- Process for reporting errors or near misses, system breakdowns or overrides
- Will look at medication reconciliation process during handoffs
- Monitor overrides for automatic dispensing cabinets
- PI initiatives on medications & data collection

Medication Management Work Tool



Medication Management – Work Tool

Patient Identifier:

Medication Ordered	Date ordered	Time ordered	Amount Ordered	Frequency	Route	Pharmacy Review	Amount Administered	Time Administered

38. Include Near Miss Reporting

- Both CMS and TJC require **near misses** (good catches) to be included in the definition of medication error
- This means they must be reported to the QAPI program
- Many nurses and other staff are not aware of this
- Provide education on this
- Communicate how reporting should be done; report to supervisor, complete incident report or adverse medication report, or leave on phone line, contact risk management etc.

CMS Memo on Reporting

- CMS issues Memo March 15, 2013 on AHRQ Common Formats
  - Hospitals are required to track adverse events for PI
- OIG said **86%** of time nurses and others are not reporting near misses and AEs into hospital PI system
- CMS reminds hospitals this is required
- Recommend use of the AHRQ Common Format too

Report Adverse Events to PI

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-19-HOSPITALS

DATE: March 15, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

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

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

39. Medication Management Champions

- Have a medication management champion on each unit
- They can be members of the medication management team or patient safety team
- They can do a project on medication related issues once every 3 months to all the staff on their unit
- Nationwide Children's Hospital has one on each unit and they have flip chart and have each staff sign sheet and do one project quarterly

THE MEDICINES CHAMPIONS ROLE

Aim and objectives www.southernhealth.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=43371

The aim of the Medicines Champions (MC) is to promote best practice in medicines management across their area. This is achieved by supporting the work of the ward or team manager, area modern matrons, the Medicines Managememt Team (MMT) and Medicines Management Committee in ensuring the safe, appropriate, cost-effective and legal use of medicines by:

- Promoting adherence to medicines-related policies and procedures within the team
- Being the eyes and ears of the Team to help inform policy or training needs
- Encourage medicine-related incident reporting to system/process improvement.
- In liasison with the ward or team manager ensure safe, appropriate and secure storage/carriage/use of medicines within the team.
- Diseminating pertinent medicines information from the medicines committees and medicines management team (e.g. from breaking news or audit results).

1. Each team, in conjunction with the ward or team manager will nominate a lead staff nurse as the MC. Ideally this will be a senior band 6 staff nurse or experienced band 5 nurse. The ability to influence others and improve practice is essential for this role.

40. Do RCA for Medication Sentinel events

- Do a through and credible root cause analysis
- TJC requires a **RCA** (systematic analysis) if one of the reviewable SE occurs, within **45 days**
- Have a user friendly tool and teach all managers and assistants and other staff how to do RCA
  - States what areas must be covered in RCA such as physical assessment process, patient identification process, continuum of care, staff levels, orientation and training, communication among staff members, medication management etc.,
- CMS calls causal analysis in new PI worksheets and will ask to see **three** RCAs so be prepared
  - Matrix removed but still helpful

ROOT CAUSE ANALYSIS
INCIDENT INVESTIGATION TOOL

ATTACHMENT I

DETERMINATION OF SEVERITY

Date Identified: _____

What type of incident is this? (See below for definitions)

☐ Error ☐ Near Miss / Hazardous Condition ☐ Sentinel Event

Explain: _____

Identified How: _____

Brief Description (No names or other individual identifiers): _____

Team Leader: _____ Date RCA Completed: _____

Definitions:

Error:
An unforeseen act, either or omission or commission, or an act that does not achieve it's intended outcome.

Sentinel Event:
An unexpected occurrence involving death or serious physical or psychological injury or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase or risk thereof includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

Near Miss:
Used to describe any process variation that did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome. Such a near miss falls within the scope of the definition of sentinel event, but outside the scope of those sentinel events that are subject to review by the Joint Commission under its sentinel event policy. Refer to the Sentinel Event Policy for JCAHO reviewable events.

Hazardous Condition:

Removed But Still Useful

Root Cause Analysis Matrix
Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events – October 2005

Note: Updates are highlighted in RED
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.

	Suicide (24-7 care)	Med. 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	Unanticipated death following discharge	Fall - related
Behavioral assessment process (1)	X					X	X	X					
Physical assessment process (2)	X	X	X	X	X	X	X				X		X
Patient identification process		X		X					X				
Patient 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 & training of staff	X	X	X	X	X	X	X	X	X	X	X	X	X
Competency assessment/ credentialing	X	X	X	X	X	X	X	X	X	X	X	X	X
Supervision of staff (3)	X	X	X		X	X			X			X	
Communication with patient/ family	X	X		X	X	X	X			X			X
Communication among staff members	X	X	X	X	X	X	X	X	X	X	X	X	X
Availability of information	X	X	X	X	X	X			X		X		X
Adequacy of technological support		X	X										
Equipment maintenance/ management		X	X		X	X					X		X
Physical environment (4)	X	X	X	X		X	X	X	X	X			X
Security systems and processes	X						X	X		X			
Medication Management (5)		X	X		X				X		X		X

(1) Includes the process for assessing patient's risk to self (and to others, in cases of assault, rape, or homicide where a patient is the assailant).
(2) Includes search for contraband.
(3) Includes supervision of physicians-in-training.
(4) Includes furnishings; hardware (e.g., bars, hooks, rods); lighting; distractions.

RELIAS LEARNING 205

TJC Framework for Conducting RCA

RELIAS LEARNING 206

Sentinel Event Policy and Procedures

Sentinel Events (SE)

www.jointcommission.org/assets/1/6/CAMH_24_SE_all_CURRENT.pdf

I. Sentinel Events

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

Definition of Sentinel Event

A sentinel event is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following:

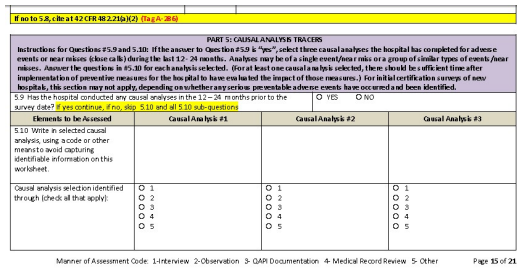
- Death
- Permanent harm
- Severe temporary harm

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

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

RELIAS LEARNING 207

CMS QAPI Causal Analysis Tracers



If no to 5.8, cite at 42 CFR 482.21(a)(2) (Tag A-286)

PART 5: CAUSAL ANALYSIS TRACERS

Instructions for Questions #5.9 and 5.10: If the answer to Question #5.9 is "yes", select three causal analyses the hospital has completed for adverse events or near misses (close calls) during the last 12- 24 months. Analyses may be of a single event/near miss or a group of similar types of events/near misses. Answer the questions in #5.10 for each analysis selected. (For at least one causal analysis selected, there should be sufficient time after implementation of preventive measures for the hospital to have evaluated the impact of those measures.) For initial certification surveys of new hospitals, this section may not apply, depending on whether any serious preventable adverse events have occurred and been identified.

5.9 Has the hospital conducted any causal analyses in the 12 – 24 months prior to the survey date? If yes continue, if no, skip 5.10 and all 5.10 sub-questions	O YES	O NO

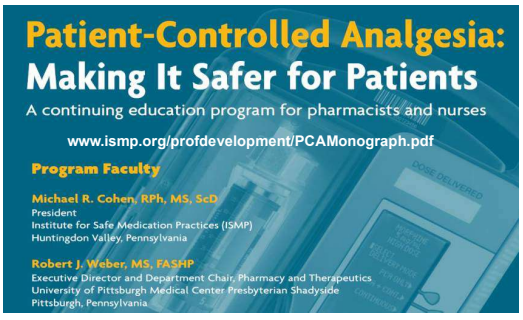
Elements to be Assessed	Causal Analysis #1	Causal Analysis #2	Causal Analysis #3
5.10 Write in selected causal analysis, using a code or other means to avoid capturing identifiable information on this worksheet.			
Causal analysis selection identified through (check all that apply):	O 1 O 2 O 3 O 4 O 5	O 1 O 2 O 3 O 4 O 5	O 1 O 2 O 3 O 4 O 5

Manner of Assessment Code: 1-Interview 2-Observation 3- QAPI Documentation 4- Medical Record Review 5- Other Page 15 of 21

41. Have PCA by Proxy Information

- Have a PCA by proxy policy
- Have an education flier for all patients on PCA
- Document information given verbally and flier given
- Educate nursing staff on dangers of administering dose outside of protocol
- Have sign on every PCA machine that only the patient should press the button which is why it is called Patient control analgesia
  - Remind family members and visitors **not** to push the button
  - TJC has SEA 33 issued December 20, 2004, and even though retired still useful-refers to ISMP patient controlled analgesia

ISMP PCA



APSF Recommends ETCO2 on PCA Patients

APSF NEWSLETTER Fall 2011 PAGE 26

Leaders and Experts Share Perspectives

From "Monitoring," Page 21

saturation. He also predicted that the increased emphasis on postoperative pain management by centers that go/ern reimbursement will undoubtedly result in a higher incidence of opioid-induced respiratory depression.

There was not uniform agreement initially regarding selective versus universal monitoring, or risk stratification, for patients receiving postoperative opioids. Several speakers discussed coexisting conditions and diseases associated with postoperative drug-induced respiratory depression including obesity, sleep apnea syndromes, advanced age, organ system dysfunction, concurrent CNS depressant use, and preoperative chronic opioid tolerance. Many of these risk factors (especially obesity) have been increasing in the general population. Yet, some of these conditions that predispose to opioid-induced respiratory depression may be undiagnosed in the surgical patient. In particular, Dr. Frances E. Chung, professor of Anesthesiology at the University of Toronto presented data showing that over three-quarters of men and women with moderate to severe sleep apnea are undiagnosed, with a 7-22% prevalence.[1] Therefore, risk stratification for increased postoperative electronic monitoring would potentially miss a large population of patients that is at increased risk for opioid-induced respiratory depression.

Ray R. Maddox, PharmD, from St. Joseph's/Candler Health System in Savannah, GA, shared his experience during the general audience discussion session. His hospital instituted capnography with or without pulse oximetry monitoring over 5 years ago for all patients receiving parenteral or neuraxial opioids postoperatively after some high-severity adverse events involving opioids. They found early in their beta testing that it was not possible to reliably predict opioid responsiveness based on risk stratification and elected to monitor all patients receiving postoperative opioids. To date, they have not had any respiratory arrests related to the administration of postoperative opioids since they instituted the increased monitoring.[2]

Further data from Dr. Chung demonstrated that monitoring patients postoperatively for respiratory depression may entail more than one or two nights after surgery. Her data showed that the apnea-hypopnea index (AHI) in sleep apnea patients is highest on the third night after surgery and remains above the preoperative baseline out to the seventh postoperative night.[3] Further research is needed to determine if the type and duration of surgery and anesthesia impact these findings. It remains unclear how to best monitor severe sleep apnea patients after procedures that would be considered outpatient surgery.

Dr. Scott F. Gallagher, associate professor of Surgery from the University of Florida in Tampa, FL, provided data showing that bariatric sleep apnea patients will have severe prolonged hypoxemia even with their continuous positive airway pressure (CPAP) in place.[4] Consequently, monitoring of oxygenation and ventilation is still needed in these patients postoperatively, even when they are using CPAP.

Dr. J. Paul Carey, clinical professor of Anesthesiology at the University of California in Los Angeles David Geffen School of Medicine, and staff anesthesiologist at Hoag Memorial Hospital Presbyterian in Newport Beach, CA, and Dr. Larry A. Lynn, a pulmonary intensivist and the executive director of the Sleep and Breathing Research Institute in Columbus, OH, presented unique data describing 3 different patterns of unexpected hospital deaths. These patterns included progressive metabolic acidosis (e.g., sepsis), opioid-induced carbon dioxide narcosis, and drug-induced arousal failure with sleep apnea (see article on page 32). They showed different trends in pulse oximetry values, minute ventilation, respiratory rate, and arterial carbon dioxide levels associated with each of these 3 patterns of death.[5] They noted that health care providers are not well educated about these patterns and may miss early warning signs. Further, they believe that monitors with threshold alarms (i.e., alarm upon reaching a specific value) are not useful because of their inability to distinguish meaningful from nuisance alarms, depending on the death mechanism. They also dis-

Table 1. Comparison of Available Monitoring Modalities for Detection of Opioid-Induced Respiratory Depression in the Postoperative Period

Monitoring Modality	Sensitivity *	Specificity	Reliability	Response Time

www.apsf.org/newsletters/html/2011/fall/pdf/fall_2011.pdf

41. Have PCA by Proxy Information

- Carefully monitor patients and ensure pulse ox and or ETCO2 monitors
  - Inadequate patient assessment and monitoring is a source of error
- ISMP documents several errors involving PCA including death of a healthy teenage girl who died because her mother continuously pushed the button
- Need appropriate patient selection so not ideal for infants, young children, or confused patients
- Opioids cause more than 60% of serious AEs in the US

42. Avoid Tubing Misconnections

- Tubing and catheter misconnection errors are under-reported
- Many are caught before injury to the patient
- If a surveyor goes with a nurse to observe an assessment the nurse needs to follow from the tube to the patient and assess IV solution and rate is correct
- CMS issues a memo on Luer misconnections
  - Staff can connect two things together that do not belong together because the ends match

Avoid Tubing Misconnections

- CMS issues a memo on Luer misconnections
  - For example, a patient had the blood pressure cuff connected to the IV and died of an air embolism
  - Luer connections easily link many medical components, accessories and delivery devices
- Many other organization, like the Pa Patient Safety Authority, FDA, and ISMP, has published article on tubing misconnections
- TJC issues SEA 54 to help hospitals manage the risk during the transition to new tubing connections to prevent this

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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**

ISMP Tubing Misconnections

ISMP MedicationSafetyAlert!

PREVENTING CATHETER/TUBING MISCONNECTIONS: MUCH NEEDED HELP IS ON THE WAY

From the July 15, 2010 issue

Catheter/tubing misconnections remain a serious problem in healthcare. Just a few weeks ago we learned of another fatal event. Over Memorial Day weekend, a 19-month-old child, who was receiving treatment for a chronic gastrointestin disorder, died at a pediatric care center. A suspension of **QUESTRAN** (cholestyramine) was accidentally given via a central line intravenous catheter instead of through an enteral feeding tube.

In May 2010, another report was published about barium sulfate being administered via the superior vena cava during upper gastrointestinal study (Soghoian S, Hoffman RS, Nelson L. Unintentional IV injection of barium sulfate in a child. *J Med Toxicol Pharm*. 2010;67:734-36). The patient, a 17-month-old child, had a central venous catheter (CVC) in place f antibiotic therapy. As the procedure began, approximately 3 mL of barium sulfate was injected into the CVC, which was mistaken as the child's gastrostomy tube. Fortunately, no respiratory distress developed and the child was discharged days later.

Luer connector systems, common to many healthcare catheters, tubes, administration sets, extension sets, and syringe have been at the heart of many catheter/tubing misconnections. At the center of one of the most commonly reported problems is the fact that some manufactured enteral catheters still have ports that only accept parenteral administratio sets and syringes. So, even if a liquid medication is prepared in an oral syringe, the medication must be transferred to parenteral syringe for administration via this type of enteral catheter port, risking the accidental administration of the drug via a parenteral line.

Below are examples of the type of reports we have received associated with catheter/tubing misconnections, all of whi we've described in this newsletter since publication began in 1996:

- IV infusions connected to epidural lines, and epidural solutions connected to IV lines
- Syringe containing IV medication given via an intrathecal catheter
- IV tubing connected to inflation balloon port of endotracheal tube or tracheostomy tube
- Sequential compression device tubing or pneumatic blood pressure cuff tubing attached to port of IV administrati set
- Oxygen tubing connected to port of IV administration set
- Breast milk intravenously infused into neonates
- Bladder irrigation solutions given IV, or TPN solutions administered via foley catheter port
- IV administration set spiked into enteral nutrition container, resulting in enteral nutrition administered IV.

www.ismp.org

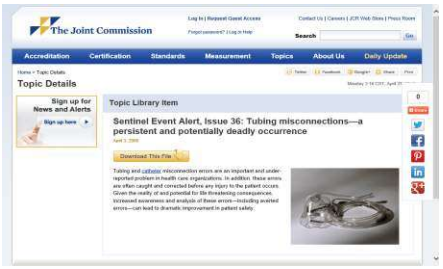
New Standards Prevent Tubing Misconnections

- New and unique international standards being developed for connectors for gas and liquid delivery systems
- To make it impossible to connect unrelated systems
- Includes new connectors for enteral, respiratory, limb cuff inflation neuraxial, and intravascular systems
- Phase in period for product development, market release and implementation guided by the FDA and national organizations and state legislatures
  - FAQ on small bore connector initiative

Luer Misconnections Memo

- CMS issues memo March 8, 2013 on this very same topic as do many professional organizations
- States 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
- Luer connections easily link many medical components, accessories and delivery devices

TJC Sentinel Event Alert #36



http://www.jointcommission.org/sentinel_event_alert_issue_36_tubing_misconnections—a_persistent_and_potentially_deadly_occurrence/

Tubing Misconnections Recommendations

- Do not buy non-IV equipment with connections that mate with female Luer IV connector,
- Have a policy on this
- Discuss issue during orientation and periodically,
- Never use standard luer syringe for oral medications or enteric feeding
- Always trace tube or catheter from patient to point of origin before connecting new device of infusion,
- Recheck connections as part of hand off and returns from x-ray or other departments
- Label high risk catheters such as epidurals, arterial, intrathecal

43. Prevent Vincristine Errors

- Errors are related to inadvertent administration of vin**CRIST**ine intrathecally (into subarachnoid space)
  - TJC Sentinel Event Alert 34 and important even though retired in August 2016
  - Can only be given IV
  - Use tall man lettering
  - Dilute in a volume like **minibag and not a syringe**
  - If administered in syringe mark it “FATAL IF GIVEN INTRATHECALLY-IV USE ONLY”
  - Time out before you give it-high risk med
  - Have another staff person double check

Preventing VinCRISTine Errors

- WHO also has recommendations
- Warning label should read “FOR INTRAVENOUS USE ONLY-FATAL IF GIVEN BY OTHER ROUTES”
- Do not use syringes to give this drug
- ISMP did survey to see what hospitals were doing
- Survey results at www.ismp.org/survey/vincristineReports.asp

ISMP Survey on Administration of IV Vincristine
(All Respondants)

Total: 418

1. Please tell us whether these error-reduction strategies are employed when dispensing and/or administering IV vincristine.

Error-Reduction Strategies	Yes	No	Sometimes
a. Are doses of IV vincristine diluted and dispensed/administered in a minibag?	23%	71%	5%
b. Are doses of IV vincristine diluted and dispensed/ administered in a syringe?	52%	43%	5%
c. Are intrathecal medications packaged in a distinctive container not used for any other purpose to prevent confusion with IV medications, including vincristine?	55%	41%	4%
d. Do doses of IV vincristine include warning labels stating: "Fatal if given intrathecally. For IV use only." (or similar labeling)?	54%	7%	1%
e. Are vincristine injections placed in an overwrap with a second warning label affixed?	77%	20%	3%
f. Does a pharmacist independently double-check IV vincristine doses, even if another pharmacist initially prepared the dose?	76%	17%	7%
g. Is IV vincristine delivered from the pharmacy to a location where intrathecal drugs are prohibited?	24%	71%	5%
h. If a patient is receiving IV vincristine and an intrathecal medication, does the organization have a process to verify that the intrathecal injection has been completed before dispensing IV vincristine (or vice versa)?	43%	54%	3%
i. Do two health professionals independently check IV vincristine doses before administration?	94%	4%	2%
j. Are doses of IV vincristine prohibited from being administered in the same location where intrathecal medications are given?	39%	58%	4%
k. Is IV vincristine banned from rooms where lumbar punctures are performed?	40%	58%	2%
l. Are those who prescribe, prepare, dispense, and administer chemotherapy educated about published case reports of fatal intrathecal administration of IV vincristine?	90%	3%	7%

2. Please answer the following questions by placing checkmarks in the appropriate column. Use **column A** if referring to your experiences with administering **undiluted** IV vincristine from a syringe. Use **column B** if referring to your experiences with administering **diluted** IV vincristine via a bag or syringe. Do not use column B if you have no experience with administering diluted IV vincristine.

Questions	Column A: *Undiluted*		Column B: *Diluted*		
a. What is the typical volume of solution administered for each dose of IV vincristine in your facility?			25 mL 18%	50 mL 44%	Other 38%
b. During administration of IV vincristine, does a trained licensed practitioner remain at the bedside to continually monitor the patient and assess IV patency and signs of extravasation?	Yes 96%	No 4%	Yes 80%	No 20%	
c. Are you aware of any extravasations that have occurred within the past 2 years related to administration of **undiluted** IV vincristine?	Yes 5%	No 95%	Mild: 11 Moderate: 7		

ISMP Best Practice for Hospitals

BEST PRACTICE 1:
Dispense vinCRISTine (and other vinca alkaloids) in a minibag of a compatible solution and not in a syringe.

Rationale:
The goal of this best practice is to ensure that vinca alkaloids are administered by the intravenous route only. Vinca alkaloids (vinBLAStine, vinorelbine, vinCRIStine, and vinCRIStine liposomal) can cause fatal neurological effects if given via the intrathecal route instead of intravenously. VinCRIStine is particularly problematic, and the most frequently reported, because it is often ordered in conjunction with medications that are administered intrathecally (e.g., methotrexate, cytarabine, and/or hydrocortisone). When vinca alkaloids are injected intrathecally, destruction of the central nervous system occurs, radiating out from the injection site. The few survivors of this medication error have experienced devastating neurological damage. Despite repeated warnings by various national and international safety agencies, deaths from this type of error still occur. The product labeling also carries a special warning ("For Intravenous Use Only—Fatal If Given by Other Routes"). An effective prevention strategy that reduces the risk of inadvertently administering vinca alkaloids via the intrathecal route is to dilute the drug in a minibag that contains a volume that is too large for intrathecal administration (e.g., 25 mL for pediatric patients and 50 mL for adults). Many organizations have successfully switched to preparing vinca alkaloids in minibags, including pediatric hospitals,

BEST PRACTICE 2:

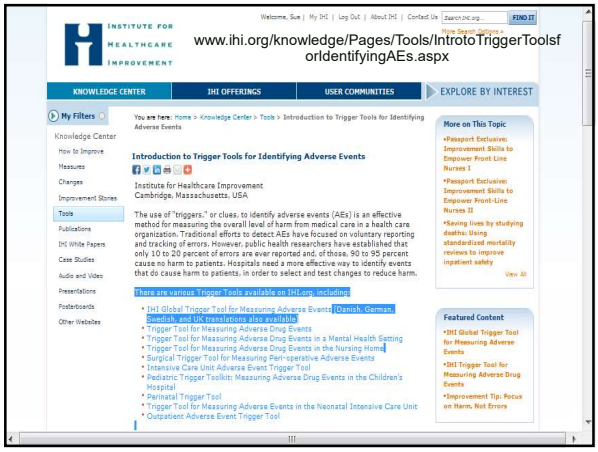
a) **Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.**
For manual systems, require verification of an appropriate oncologic indication before dispensing oral methotrexate for daily administration.

b) **Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.**
Ensure that written drug information leaflets are given to patients that contain clear instructions about the weekly dosing schedule. Explain to the patient that taking extra doses is dangerous. Have the patient repeat back the instructions to ensure that the patient understands the weekly dosing schedule and that the medication is not to be used "as needed" for symptom control. Provide the patient with a copy of the free ISMP high-alert medication consumer leaflet on oral methotrexate (found at www.ismp.org/AHRQ/default.asp).

Rationale:
The goal of this best practice is to prevent errors involving inadvertent daily dosing of oral methotrexate both in the inpatient setting and after discharge. Since early 1996 and as recently as 2013, fatal errors have been reported to ISMP about the accidental daily dosing of oral methotrexate that was intended for weekly administration. Methotrexate is a folate antimetabolite used to treat

44. Use a Trigger Tool

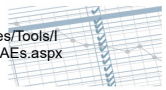
- In hospital CoPs there is a list of indicator drugs or IHI has trigger tools
  - Use to find errors since incident reports are filled out only in small % of cases
  - Mayo Study found to be effective in improving patient safety
  - IHI global trigger tool at www.ihi.org, 46 pages, also separate one for perinatal
  - Had separate sections like medication trigger
- C-diff positive assay if history of antibiotic use
- PTT greater than 100 seconds if on Heparin-if evidence of bleeding
- INR greater than 6 if evidence of bleeding



www.ihi.org/resources/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx and see implementation tool

INSTITUTE FOR HEALTHCARE IMPROVEMENT

http://www.ihi.org/resources/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx



Innovation Series 2009

IHI Global Trigger Tool
for Measuring Adverse Events

Second Edition

Trigger Tools

- Review 20 charts per month
- No longer than 20 minutes
- Look for opportunities for improvement
- Separate trigger tool for **measuring medication** related harm
- See trigger tool to identify errors in pediatric hospitals
- www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/IntrotoTriggerToolsforIdentifyingAEs.htm

Trigger Drugs

- Benadryl, Vitamin K, Romazicon,
- Droperidol, Zofran, Phenergan, Vistaril, Reglan,
- Narcan,platelet count less 50,000,
- Digibind, Glucose less than 50,
- PTT over 100 seconds, INR over 6,
- Rash, abrupt cessation of medications,
- Transfer to higher care,
- Over sedation and fall or lethargy,

INSTITUTE FOR HEALTHCARE IMPROVEMENT

www.ihi.org/resources/Pages/Tools/TriggerToolMeasuringADEsinMentalHealthSetting.aspx

Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting

Institute for Healthcare Improvement

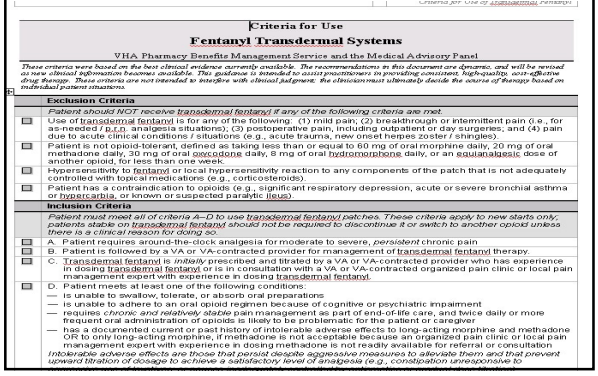
45. Look at Fentanyl Patches

- VA received hundreds of adverse events regarding fentanyl patches
- Ensure old ones are removed when new one applied
- Patients should not take long hot showers, use heating pad or electric blanket over patch
- Provide discharge instructions on how to dispose of properly (fold sticky side together and flush) and keep out of the reach of children
- Label the patch with date applied
- Used only on chronic pain patients and must be **opioid tolerate**
- Do not drink alcohol with patch on
- Will not receive steady state for 12-18 hours and will not peak until 24-72 hours

Fentanyl Patches

- Many good articles about safety in using fentanyl patches
  - Nurses should have special training on the use and indication of fentanyl patches
  - Some hospitals have a special process that physicians must do to order this on new patients such as the VA hospital had 100s of ADE so physician must consult with the pharmacist first before ordering
  - Should not be used for acute or post-operative pain
  - Mark with F to make it more visible, make sure correct dose, need indication for use of drug
  - Patient must not be opioid naïve, standardize placement and rotation so staff know where to look, need clear P&P, be careful about overrides
  - Do not cover with heating pad, electric blankets which can increase absorption, know how to properly dispose of patches
  - For new patients the dose of the patch cannot be increased until steady state in reached at 3 days

www.pbm.va.gov/Clinical%20Guidance/Criteria%20For%20Use/Fentanyl%20Transdermal%20Patch,%20Criteria%20for%20Use.doc



Criteria for Use

Fentanyl Transdermal Systems

VHA Pharmacy Benefits Management Service and the Medical Advisory Panel

These criteria were based on the best clinical evidence currently available. The recommendations in this document are dynamic, and will be revised as new clinical information becomes available. This guidance is intended to assist practitioners in providing consistent, high-quality, cost-effective drug therapy. These criteria are not intended to interfere with clinical judgment; the clinician must ultimately decide the course of therapy based on individual patient situations.

Exclusion Criteria

Patient should NOT receive transdermal fentanyl if any of the following criteria are met:

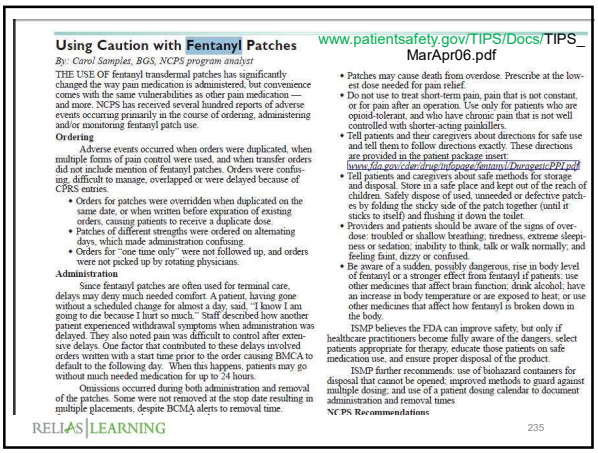
- ☐ Use of transdermal fentanyl is for any of the following: (1) mild pain; (2) breakthrough or intermittent pain (i.e., for as-needed / p.r.n. analgesia situations); (3) postoperative pain, including outpatient or day surgeries; and (4) pain due to acute clinical conditions / situations (e.g., acute trauma, new onset herpes zoster / shingles).
- ☐ Patient is not opioid-tolerant, defined as taking less than or equal to 60 mg of oral morphine daily, 20 mg of oral methadone daily, 30 mg of oral oxycodone daily, 8 mg of oral hydromorphone daily, or an equianalgesic dose of another opioid, for less than one week.
- ☐ Hypersensitivity to fentanyl or local hypersensitivity reaction to any components of the patch that is not adequately controlled with topical medications (e.g., corticosteroids).
- ☐ Patient has a contraindication to opioids (e.g., significant respiratory depression, acute or severe bronchial asthma or hypercarbia, or known or suspected paralytic ileus).

Inclusion Criteria

Patient must meet all of criteria A–D to use transdermal fentanyl patches. These criteria apply to new starts only; patients stable on transdermal fentanyl should not be required to discontinue it or switch to another opioid unless there is a clinical reason for doing so.

- ☐ A. Patient requires around-the-clock analgesia for moderate to severe, *persistent* chronic pain
- ☐ B. Patient is followed by a VA or VA-contracted provider for management of transdermal fentanyl therapy.
- ☐ C. Transdermal fentanyl is *initially* prescribed and titrated by a VA or VA-contracted provider who has experience in dosing transdermal fentanyl or is in consultation with a VA or VA-contracted organized pain clinic or local pain management expert with experience in dosing transdermal fentanyl.
- ☐ D. Patient meets at least one of the following conditions:
  - — is unable to swallow, tolerate, or absorb oral preparations
  - — is unable to adhere to an oral opioid regimen because of cognitive or psychiatric impairment
  - — requires *chronic and relatively stable* pain management as part of end-of-life care, and twice daily or more frequent oral administration of opioids is likely to be problematic for the patient or caregiver
  - — has a documented current or past history of intolerable adverse effects to long-acting morphine and methadone OR to only long-acting morphine, if methadone is not acceptable because an organized pain clinic or local pain management expert with experience in dosing methadone is not readily available for referral or consultation

Intolerable adverse effects are those that persist despite aggressive measures to alleviate them and that prevent upward titration of dosage to achieve a satisfactory level of analgesia (e.g., constipation unresponsive to



Using Caution with Fentanyl Patches

By: Carol Samples, BGS, NCPS program analyst

THE USE OF fentanyl transdermal patches has significantly changed the way pain medication is administered, but convenience comes with the same vulnerabilities as other pain medication — and more. NCPS has received several hundred reports of adverse events occurring primarily in the course of ordering, administering and/or monitoring fentanyl patch use.

Ordering

Adverse events occurred when orders were duplicated, when multiple forms of pain control were used, and when transfer orders did not include mention of fentanyl patches. Orders were confusing, difficult to manage, overlapped or were delayed because of CPRS entries.

- Orders for patches were overridden when duplicated on the same date, or when written before expiration of existing orders, causing patients to receive a duplicate dose.
- Patches of different strengths were ordered on alternating days, which made administration confusing.
- Orders for "one time only" were not followed up, and orders were not picked up by rotating physicians.

Administration

Since fentanyl patches are often used for terminal care, delays may deny much needed comfort. A patient, having gone without a scheduled change for almost a day, said, "I know I am going to die because I hurt so much." Staff described how another patient experienced withdrawal symptoms when administration was delayed. They also noted pain was difficult to control after extensive delays. One factor that contributed to these delays involved orders written with a start time prior to the order causing BMCA to default to the following day. When this happens, patients may go without much needed medication for up to 24 hours.

Omissions occurred during both administration and removal of the patches. Some were not removed at the stop date resulting in multiple placements, despite BCMA alerts to removal time.

www.patientsafety.gov/TIPS/Docs/TIPS_MarApr06.pdf

- Patches may cause death from overdose. Prescribe at the lowest dose needed for pain relief.
- Do not use to treat short-term pain, pain that is not constant, or for pain after an operation. Use only for patients who are opioid-tolerant, and who have chronic pain that is not well controlled with shorter-acting painkillers.
- Tell patients and their caregivers about directions for safe use and tell them to follow directions exactly. These directions are provided in the patient package insert: www.fda.gov/cder/drug/infopage/fentanyl/DuragesicPPI.pdf
- Tell patients and caregivers about safe methods for storage and disposal. Store in a safe place and kept out of the reach of children. Safely dispose of used, unneeded or defective patches by folding the sticky side of the patch together (until it sticks to itself) and flushing it down the toilet.
- Providers and patients should be aware of the signs of overdose: troubled or shallow breathing; tiredness, extreme sleepiness or sedation; inability to think, talk or walk normally; and feeling faint, dizzy or confused.
- Be aware of a sudden, possibly dangerous, rise in body level of fentanyl or a stronger effect from fentanyl if patients: use other medicines that affect brain function; drink alcohol; have an increase in body temperature or are exposed to heat; or use other medicines that affect how fentanyl is broken down in the body.

ISMP believes the FDA can improve safety, but only if healthcare practitioners become fully aware of the dangers, select patients appropriate for therapy, educate those patients on safe medication use, and ensure proper disposal of the product.

ISMP further recommends: use of biohazard containers for disposal that cannot be opened; improved methods to guard against multiple dosing; and use of a patient dosing calendar to document administration and removal times

NCPS Recommendations

RELIAS | LEARNING 235

U.S. Department of Health & Human Services — www.hhs.gov

FDA U.S. Food and Drug Administration — A-Z Index — Search

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Second Safety Warning on Fentanyl Skin Patch

Search Consumer Updates

FDA issued its second safety warning on Dec. 21, 2007, about the fentanyl transdermal system an adhesive patch that delivers a potent pain medicine through the skin. In July 2005, FDA issued a similar warning to the public and to health care providers emphasizing that the directions on the product label and on the patient package insert should be followed exactly in order to avoid overdose.

FDA has continued to receive reports of deaths and life-threatening side effects after doctors have inappropriately prescribed the patch or after people incorrectly used it.

The agency is also asking manufacturers of all fentanyl patches to update their product information and to develop a medication guide for patients. The patch is marketed as Duragesic by Johnson and Johnson, and generic versions are sold by other manufacturers.

The fentanyl skin patch contains the opioid fentanyl, a potent narcotic. The patch was approv by FDA in 1990 for use in people with persistent, moderate-to-severe pain who have become opioid-tolerant—meaning that they have been using another strong opioid narcotic pain medicir around-the-clock for a week or longer. The skin patch is most commonly prescribed for people with cancer.

Recent reports to FDA describe deaths and life-threatening side effects after health care professionals inappropriately prescribed the patch or after people used the patch incorrectly.

Advice for Consumers

Fentanyl patches are only for people who are opioid-tolerant and have chronic pain that is n well controlled with other pain medicines. The patches are not to be used to treat sudden, occasional, or mild pain, or pain after surgery.

www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/default.htm

RELIAS | LEARNING 236

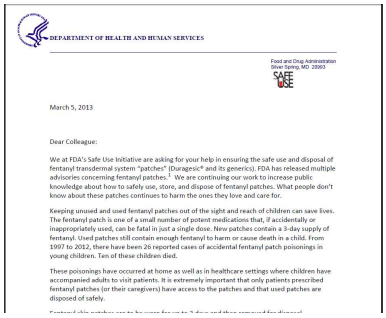
Fentanyl Patches

- New patches only contain a 3 day supply
- Used patches still contain enough Fentanyl to harm children
- Need to instruct FDA mentions 26 children died from accidental poisoning by putting on a patch from 1997 to 2012
- Parents to dispose of in a safe manner that children cannot get access
  - Stick sides together and flush down the toilet
- See FDA website on disposal of unused medication

RELIAS | LEARNING 237

Disposal of Unused Medications

FDA Initiative on Fentanyl Patches


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

SAFE USE

March 5, 2013

Dear Colleague:

We at FDA's Safe Use Initiative are asking for your help in ensuring the safe use and disposal of fentanyl transdermal system "patches" (Duragesic® and its generics). FDA has released multiple advisories concerning fentanyl patches.[1] We are continuing our work to increase public knowledge about how to safely use, store, and dispose of fentanyl patches. What people don't know about these patches continues to harm the ones they love and care for.

Keeping unused and used fentanyl patches out of the sight and reach of children can save lives. The fentanyl patch is one of a small number of potent medications that, if accidentally or inappropriately used, can be fatal in just a single dose. New patches contain a 3-day supply of fentanyl. Used patches still contain enough fentanyl to harm or cause death in a child. From 1997 to 2012, there have been 26 reported cases of accidental fentanyl patch poisonings in young children. Ten of these children died.

These poisonings have occurred at home as well as in healthcare settings where children have accompanied adults to visit patients. It is extremely important that only patients prescribed fentanyl patches (or their caregivers) have access to the patches and that used patches are disposed of safely.

46. Neuromuscular Blocking Agents

- Consider use of neuromuscular blockers a high risk drug
  - Many injury and deaths from NMBAs-651 from 2000-2005 MedMarRx
- To relax skeletal muscles during OR while under general anesthesia or when intubating
- If given by mistake, will paralyze muscle and patient can die so should be marked with red label- warning paralyzing agent
- Provide training to all nursing staff
  - Atracurium, Vecuronium, Cisatracurium, Pancuronium, Norcuron, are examples

Neuromuscular Blocking Agents

- Store separately from other medications
- Do not dispense on unit dose medication carts or in automated dispensing units
- Establish P&P to ensure medication is labeled properly and guidelines are followed
- Educate staff who administer this or work in units where drug is given
- Do FMEA before added to formulary or RCA if error occurs
- Use bar coding to improve accuracy of med delivered
- Prompt retrieval of drug when used
- FDA, ISMP , and USP have recommendations to prevent injury and death

47. Heparin and Insulin Mix Up

- Staff should be suspicious if patient's blood sugar keeps dropping with use of IV
- Many cases of mix up with heparin and insulin
- Past reports-insulin added to TPN bags instead of Heparin
- ISMP notes same which can deadly with infants
- Another error when pharmacist enter order for heparin 500 units as regular insulin 500 units

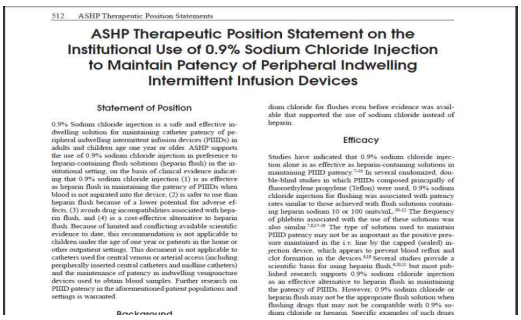
Heparin and Insulin Mix Up

- Nurse transcribed order for 10 units of regular insulin instead of heparin 0.5 ml (5,000 units)
- Recommend do not keep next to each other
- Do double checks of both
- Patient develops unexplained hypoglycemia consider possibility an error has occurred and change IV bag
  - www.state.nj.us/health/ps/documents/ps_alert_april07.pdf\

48. Use Saline instead of Heparin Flushes

- American Society of Health-System Pharmacist published a position statement on this
- Use 0.9% saline flushes to maintain patency of peripheral indwelling intermittent infusion devices and not heparin 100 units
- Less complications and safer
- Avoids drug incompatibilities
- Not for pregnant patients, those less than 12 or those with central venous or a-lines
- http://www.ashp.org/bestpractices/tps/TPS_NaCl.pdf

Use Saline to Flush not Heparin 100 units



512 ASHP Therapeutic Position Statements

ASHP Therapeutic Position Statement on the Institutional Use of 0.9% Sodium Chloride Injection to Maintain Patency of Peripheral Indwelling Intermittent Infusion Devices

Statement of Position

0.9% Sodium chloride injection is a safe and effective indwelling solution for maintaining catheter patency of peripheral indwelling intermittent infusion devices (PIIDs) in adults and children age one year or older. ASHP supports the use of 0.9% sodium chloride injection in preference to heparin-containing flush solutions (heparin flush) in the institutional setting, on the basis of clinical evidence indicating that 0.9% sodium chloride injection (1) is as effective as heparin flush in maintaining the patency of PIIDs when blood is not aspirated into the device, (2) is safer to use than heparin flush because of a lower potential for adverse effects, (3) avoids drug incompatibilities associated with heparin flush, and (4) is a cost-effective alternative to heparin flush. Because of limited and conflicting available scientific evidence to date, this recommendation is not applicable to children under the age of one year or patients in the home or other outpatient settings. This document is not applicable to catheters used for central venous or arterial access (including peripherally inserted central catheters and midline catheters) and the maintenance of patency in indwelling venipuncture devices used to obtain blood samples. Further research on PIIDpatency in the aforementioned patient populations and settings is warranted.

Background

dium chloride for flushes even before evidence was available that supported the use of sodium chloride instead of heparin.

Efficacy

Studies have indicated that 0.9% sodium chloride injection alone is as effective as heparin-containing solutions in maintaining PIID patency.[7-10] In several randomized, double-blind studies in which PIIDs composed principally of fluoroethylene propylene (Teflon) were used, 0.9% sodium chloride injection for flushing was associated with patency rates similar to those achieved with flush solutions containing heparin sodium 10 or 100 units/mL.[9-11] The frequency of phlebitis associated with the use of these solutions was also similar.[7,8,11-13] The type of solution used to maintain PIID patency may not be as important as the positive pressure maintained in the i.v. line by the capped (sealed) injection device, which appears to prevent blood reflux and clot formation in the devices.[8,12] Several studies provide a scientific basis for using heparin flush,[8,10,11] but most published research supports 0.9% sodium chloride injection as an effective alternative to heparin flush in maintaining the patency of PIIDs. However, 0.9% sodium chloride or heparin flush may not be the appropriate flush solution when flushing drugs that may not be compatible with 0.9% sodium chloride or heparin. Specific examples of such drugs

www.ashp.org/DocLibrary/BestPractices/TPS_NaCl.aspx

49. Saline Flushes Single Use Only

- Saline flushes should be unit dose
  - CDC requirement and one of ten safe injection practices in the CDC isolation guidelines
  - If manufacturer makes it in a single dose then need to buy it in a single dose or have pharmacy prepare
  - FDA does not classify saline flush as a medication
  - CMS says saline flushes can not be left at bedside (CMS security of medications) if can not be tampered with

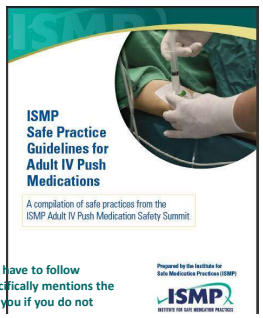
Saline Flushes Single Use Only

- Must be secure such as in locked cabinet or in area under constant supervision or in tamper resistant packaging
- Also recommendation of Infusion Nurses Society who has standards on IVs called Infusion Nursing Standards of Practice at www.ins1.org,
- Multi dose vials were found to be contaminated even with cleaning top with alcohol
- Every hospital should have this standards and include in your infusion policies and procedures
- All staff should be trained on safe injection practices

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



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

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

50. Follow Safe Injection Practices

- One issue is safe injection especially with CMS infection control worksheet
  - Be sure to use new needle and syringe each time
  - Be sure to use single dose vials for one patient only
  - Multi-dose vials for one patient if not available and do not take into the patient's room
  - If not mark and do not use after 28 days
  - Clean glucometers after each use and single use lancets
  - CMS issued 2 memos on this and in IC worksheet

Safe Injection Practices

- Have a safe injection policy
- Make sure mask is worn if LP done or if CRNA or anesthesiologist puts in a spinal or epidural for pain relief in OB patient
- Know the CDC 10 recommendations
- Include in orientation and periodically
  - Toolkit at ASC Collaboration at http://ascquality.org/advancing_asc_quality.cfm
  - CDC information at http://www.cdc.gov/ncidod/dhqp/injectionSafetyPractices.html

Follow Recommendation on Medications in the OR

The Official Journal of the Anesthesia Patient Safety Foundation

apsf NEWSLETTER Spring 2010

www.apsf.org/newsletters/html/2010/spring/01_conference.htm

In this issue:

APSF Hosts Medication Safety Conference

APSF Funds New Registry

Web Application to Track Patient Safety During Sedation

Dear SIRS—Why Do New Defaults Turn Off CO_2 and Apnea Alarms?

Q&A—Exposure to Ultraviolet Radiation in the Operating Room

Hospital Coalition Group Endorses APSF Recommendations for PCA Monitoring

Letters to the Editor:

Accidental Intrathecal Injection of Tranexamic Acid

APSF Hosts Medication Safety Conference

Consensus Group Defines Challenges and Opportunities for Improved Practice

by John H. Eichhorn, MD

Overview

On January 26, 2010, the Anesthesia Patient Safety Foundation (APSF) convened a consensus conference of 100 stakeholders from many different backgrounds to develop new strategies for "predictable prompt improvement" of medication safety in the operating room. The proposed new paradigm to reduce medication errors causing harm to patients in the operating room is based on Standardization, Technology, Pharmacy/Prefilled/Premixed, and Culture (STPC). This new paradigm goes far beyond the important but traditional emphasis on medication label format and the admonition to "always read the label." Small group sessions on each of the 4 elements of the new paradigm (STPC) debated and formulated specific recommendations that were organized and prioritized by all the attendees.

The resulting consensus recommendations include:

Standardization

- High alert drugs (such as phenylephrine and epinephrine) should be available in

ASC Toolkits Safe Injections

ASC Quality Collaboration

http://ascquality.org/advancing_asc_quality.cfm

ASC Quality Collaboration | Quality Measures and Guide | Quality Report | Advancing ASC Quality: ASC TIPs

Hand Hygiene Toolkit
Safe Injection Practices Toolkit
Point of Care Devices Toolkit
Environmental Infection Prevention Toolkit
Single-Use Device Reprocessing Toolkit
Endoscope Reprocessing Toolkit
Sterilization and High-Level Disinfection Toolkit

Advancing ASC Quality

To support the ASC industry's focus on high quality care, the ASC Quality Collaboration is assembling **ASC Tools for Infection Prevention**, or **ASC TIPs.** Our goal is to make infection prevention resources readily accessible to ASCs by bringing them together in one location.

The following **ASC TIPs** are now available:

- Hand Hygiene Toolkit
- Safe Injection Practices Toolkit
- Point of Care Devices Toolkit
- Environmental Infection Prevention Toolkit
- Single-Use Device Reprocessing Toolkit
- Endoscope Reprocessing Toolkit
- Sterilization and High-Level Disinfection Toolkit

Each toolkit is available in two versions, **BASIC** and **EXPANDED**:

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.

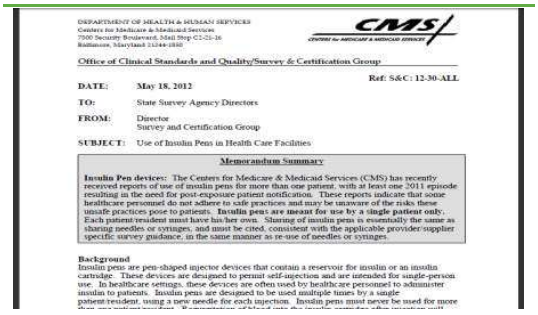
Procedure
The following procedures apply to the use of needles, cannulas that replace needles, and intravenous delivery systems.

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.

51. Follow CMS Memo on Insulin Pens

- CMS issues memo on insulin pens
- 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



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C1-21-16
Baltimore, Maryland 21244-1850

CMS

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

Memorandum Summary

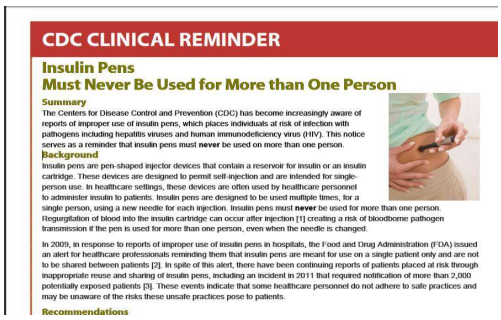
Insulin Pen devices: The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in the need for post-exposure patient notification. These reports indicate that some healthcare personnel do 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

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

CDC Reminder on Insulin Pens

CDC Has Flier for Hospitals on Insulin Pens



CDC CLINICAL REMINDER

Insulin Pens
Must Never Be Used for More than One Person

Summary

The Centers for Disease Control and Prevention (CDC) has become increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV). This notice serves as a reminder that insulin pens must **never** be used on more than one person.

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, for a single person, using a new needle for each injection. Insulin pens must **never** be used for more than one person. Regurgitation of blood into the insulin cartridge can occur after injection [1] creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed.

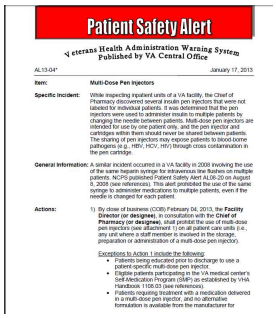
In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration (FDA) issued an alert for healthcare professionals reminding them that insulin pens are meant for use on a single patient only and are not to be shared between patients [2]. In spite of this alert, there have been continuing reports of patients placed at risk through inappropriate reuse and sharing of insulin pens, including an incident in 2011 that required notification of more than 2,000 potentially exposed patients [3]. These events indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients.

Recommendations

VA Alert on Insulin Pens

- Pharmacist found several insulin pens not labeled for individual use
- Found used multi-dose pen injectors used on multiple patients instead of one patient use
- New requirement that can only be stored in pharmacy and never ward stocked
- Instituted new education for staff on use
- Part of annual competency of staff
- Instituted new policy of safe use of pen injectors

VA Issues Alert



Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL13-04* January 17, 2013

Item: **Multi-Dose Pen Injectors**

Specific Incident: While inspecting inpatient units of a VA facility, the Chief of Pharmacy discovered several insulin pen injectors that were not labeled for individual patients. It was determined that the pen injectors were used to administer insulin to multiple patients by changing the needle between patients. Multi-dose pen injectors are intended for use by one patient only, and the pen injector and cartridges within them should never be shared between patients. The sharing of pen injectors may expose patients to blood-borne pathogens (e.g., HBV, HCV, HIV) through cross contamination in the pen cartridge.

General Information: A similar incident occurred in a VA facility in 2009 involving the use of the same heparin syringe for intravenous line flushes on multiple patients. NCPS published Patient Safety Alert AL08-20 on August 8, 2008 (see references). This alert prohibited the use of the same syringe to administer medications to multiple patients, even if the needle is changed for each patient.

Actions:

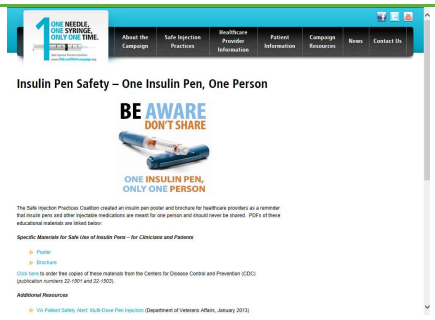
1) By close of business (COB) February 04, 2013, the **Facility Director (or designee)**, in consultation with the **Chief of Pharmacy (or designee)**, shall prohibit the use of multi-dose pen injectors (see attachment 1) on all patient care units (i.e., any unit where a staff member is involved in the storage, preparation or administration of a multi-dose pen injector).

Exceptions to Action 1 include the following:

- Patients being educated prior to discharge to use a patient-specific multi-dose pen injector.
- Eligible patients participating in the VA medical center's Self-Medication Program (SMP) as established by VHA Handbook 1108.03 (see references).
- Patients requiring treatment with a medication delivered in a multi-dose pen injector, and no alternative formulation is available from the manufacturer for

RELIAS | LEARNING 262

Insulin Pen Posters and Brochures Available



www.oneandonlycampaign.org/content/insulin-pen-safety

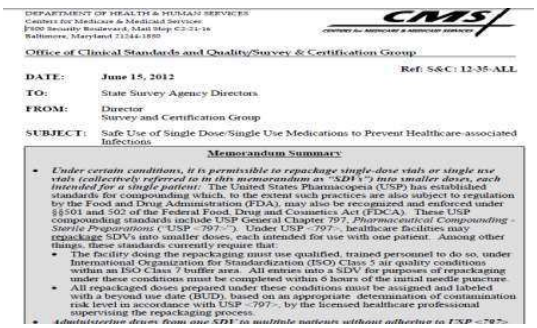
RELIAS | LEARNING 263

RELIAS | LEARNING 264

52. Follow CMS Memo on Safe Injection Practices

- June 15, 2012 CMS issues a 7 page memo on safe injection practices
  - Discusses the safe use of single dose medication to prevent healthcare associated infections (HAI)
  - If they make in a single dose vial then hospital must buy it
- If not then try and use the multi-dose vial on only one patient
- Do not take vial into patient room
  - If taken into OR must have P&P and treat as SDV and dispose of at the end of the case

CMS Safe Injection Practices



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

CMS

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 "SDVs") 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 doses from one SDV to multiple patients without adherence to USP <797>*

CMS Memo on Safe Injection Practices

- Mark it expires in 28 days unless sooner by manufacturer
- 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 Memo on Safe Injection Practices

- CMS will cite hospital under the hospital CoP infection control standards since must provide sanitary environment
- 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

Safe Injection Practices

- The vials must have a beyond use date (BUD) and storage conditions on the label
- 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
- CMS issues a second memo

CMS Memo May 30, 2014

- 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 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 (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
- CMS also issued EBOLA and CRE memos

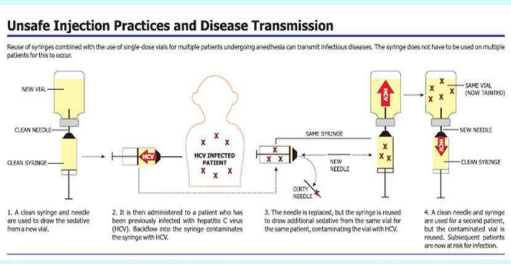
Safe Injection Practices www.empsf.org

EMPSF
EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

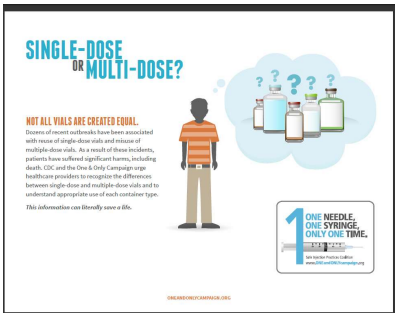
Safe Injection Practices Patient Safety Brief
Emergency Medicine Patient Safety Foundation

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

July 2012



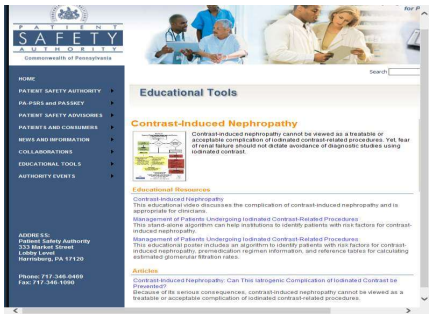
Not All Vials Are Created Equal



53. Prevent Contrast Induced Nephropathy (CIN)

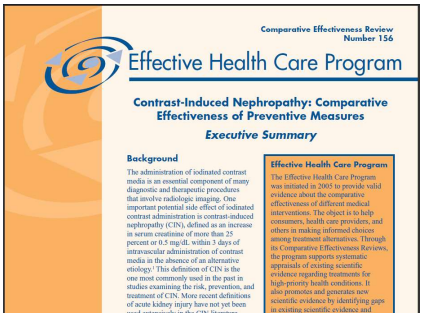
- Kidney failure can occur from iodine dye used for x-rays (70 reports)
- Make sure BUN/creatinine done and communicate level to radiology
- Especially with patients with known history of serious renal failure or impairment
- Hospitals should amend informed consent to include this
- Consider doing a FMEA on this and they have a toolkit on this
  - **http://www.psa.state.pa.us/psa/lib/psa/advisories/vol1no4_supplementary_march_2007/v4_s1_suppl_advisory_mar_30_2007.pdf.** See also ACR MRI Safety guideline of American College of Radiology and their IV Contrast Guideline,

Contrast Induced Nephropathy Toolkit



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

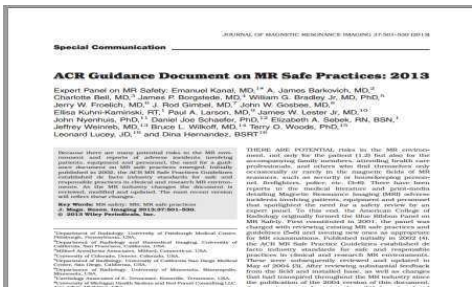
2016 AHRQ Contrast Induced Nephropathy



54. Prevent Gadolinium Based Contrast

- These can cause nephrogenic systemic fibrosis
- Be aware of BUN creatinine when ordering Magnetic resonance angiography (MRA) that requires IV contrast
- Uses MRI to take pictures of blood vessels
- Dose for MRA may be 3x higher than dose for MRI
- If patient being dialyzed do immediately after test
- Patients with severe renal impairment at risk for NSF
- Risk is 4% in this population- consider including in informed consent
- New box warning now and TJC and CMS standards for 2015
- See ACR MRI Safety Guideline issued 2013,

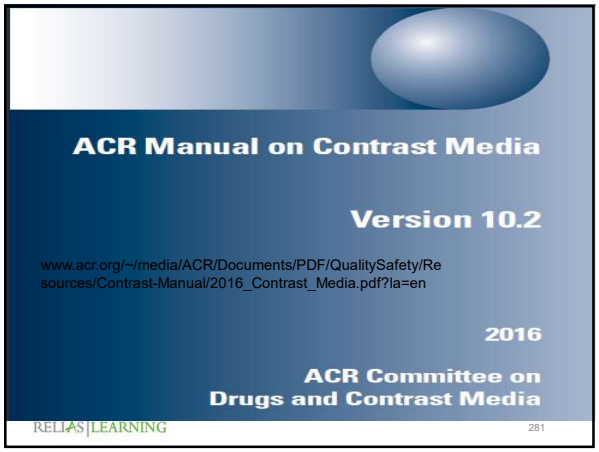
ACR MR Safe Practices



Special Communication

ACR Guidance Document on MR Safe Practices: 2013

http://www.acr.org/Quality-Safety/Standards-Guidelines



55. Prevent Betadine Burns in the OR

- Pa Safety Authority received dozens of reports of betadine (providine iodine) burns in the OR
- Skin irritation and severe skin reaction may occur when wet, evaporated solution comes in prolonged contact with skin
- Place absorbent pads under patient to absorb excess betadine
- Do not saturate applicators so excess solution does not run off area being prepped
- Remove absorbent pads prior to draping patient

56. Manage Insulin

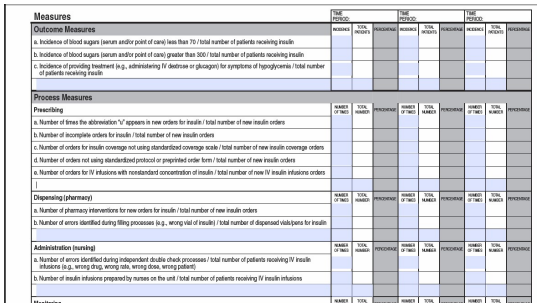
- Make sure staff are well trained on how to manage patients receiving insulin
- Ensure there are appropriate P&P on insulin management
- Have evidenced based guidelines on insulin
- 16% of all errors reported to PPSA involved the use of insulin
- Make sure staff don't confuse an insulin syringe from a tuberculin syringe
- PPSA has an excellent toolkit

TB and Insulin Syringes

Figure 1. Tuberculin and Insulin Syringes from One Manufacturer. The TB syringe appears at the top of the photo, the insulin syringe at the bottom. The vertical orange stripes on both products contribute to the confusion.

Insulin Toolkit Patient Safety Authority

PPSA Insulin Measures Worksheet



Measures	TIME PERIOD:			TIME PERIOD:			TIME PERIOD:		
Outcome Measures	INCIDENCE	TOTAL PATIENTS	PERCENTAGE	INCIDENCE	TOTAL PATIENTS	PERCENTAGE	INCIDENCE	TOTAL PATIENTS	PERCENTAGE
a. Incidence of blood sugars (serum and/or point of care) less than 70 / total number of patients receiving insulin									
b. Incidence of blood sugars (serum and/or point of care) greater than 300 / total number of patients receiving insulin									
c. Incidence of providing treatment (e.g., administering IV dextrose or glucagon) for symptoms of hypoglycemia / total number of patients receiving insulin									
Process Measures									
Prescribing	NUMBER OF TIMES	TOTAL NUMBER	PERCENTAGE	NUMBER OF TIMES	TOTAL NUMBER	PERCENTAGE	NUMBER OF TIMES	TOTAL NUMBER	PERCENTAGE
a. Number of times the abbreviation "u" appears in new orders for insulin / total number of new insulin orders									
b. Number of incomplete orders for insulin / total number of new insulin orders									
c. Number of orders for insulin coverage not using standardized coverage scale / total number of new insulin coverage orders									
d. Number of orders not using standardized protocol or preprinted order form / total number of new insulin orders									
e. Number of orders for IV infusions with nonstandard concentration of insulin / total number of new IV insulin infusions orders									
Dispensing (pharmacy)	NUMBER OF TIMES	TOTAL NUMBER	PERCENTAGE	NUMBER OF TIMES	TOTAL NUMBER	PERCENTAGE	NUMBER OF TIMES	TOTAL NUMBER	PERCENTAGE
a. Number of pharmacy interventions for new orders for insulin / total number of new insulin orders									
b. Number of errors identified during filling processes (e.g., wrong vial of insulin) / total number of dispensed vials/pens for insulin									
Administration (nursing)	NUMBER OF TIMES	TOTAL NUMBER	PERCENTAGE	NUMBER OF TIMES	TOTAL NUMBER	PERCENTAGE	NUMBER OF TIMES	TOTAL NUMBER	PERCENTAGE
a. Number of errors identified during independent double check processes / total number of patients receiving IV insulin infusions (e.g., wrong drug, wrong rate, wrong dose, wrong patient)									
b. Number of insulin infusions prepared by nurses on the unit / total number of patients receiving IV insulin infusions									
	NUMBER	TOTAL		NUMBER	TOTAL		NUMBER	TOTAL	

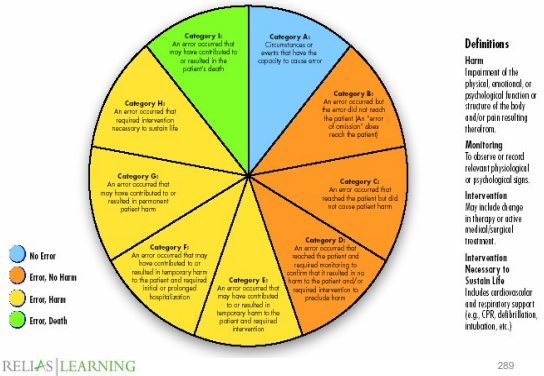
56. Have a Definition of Medication Error

- A **medication error** is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medicine is in the control of the health care professional or patient. (MedMARx)
  - Better to define as medication error
- Make sure reflected in your P&P
- Make sure staff know what the definition is and how to measure them by category
- **CMS** requires hospitals to have national definition of medication error, ADE, and drug incompatibility

Definition of Medication Error

- …Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."
- National Coordination Council for Medication Error Reporting and Prevention
- Used by USP, FDA, and CMS

NCC MERP Index for Categorizing Medication Errors



RELIAS LEARNING 289

NCC MERP Error Outcome Category

A	Circumstances or events that have the capacity to lead to error.
B	An error occurred but did not reach the patient.
C	An error occurred but did not cause patient harm.
D	Error reached the patient and required monitoring to confirm there was no harm to the patient,
E	Error may have contributed or resulted in temporary harm to the patient-requires intervention.
F	Same as E and required initial/prolonged hospital.
G	Error and contributes or resulted in permanent harm.
H	Error and intervention necessary to sustain life,
I	Error contributes to or resulted in patient's death.

RELIAS LEARNING 290

57. Be Aware of Off Label Use

- Be aware of off label use and when it is appropriate
- Have a P&P on off label use
- Highest rate in peds with 20-60%
- Second largest is oncology (Poole, 2004, KGS, 2005) with 60% off label use
- Very common and in fact one in every 5 prescriptions is off-label (WebMD)
- When is off label use acceptable?
- If medically acceptable as supported by one of the following

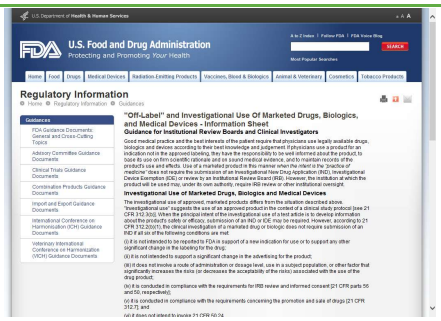
RELIAS LEARNING 291

Off Label Use

1. American Hospital Formulary Services Drug Information,
2. AMA Drug Evaluations,
3. USP (United States Pharmacopeia) Drug Information, or
4. Scientific studies published in peer review magazines.

- Source; IOM Report, July 20, 2006
- FDA has information and guidance on off label use of drugs

FDA Off-Label Guidance



www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm

Preventing Medication Errors

- Preventing Medication Errors: Quality Chasm Series,
- 4 our of 5 adults will use prescription medication any given week,
- 1/3 of adults will take 5 or more different types of medications,
- One medication error per day in hospital patients, IOM Report issued July 20, 2006
- CMS requires hospitals to bench mark and be aware of studies on the number of errors

58. Properly Store Medications

- TJC MM and CMS requires that medications be stored properly and safely
- This was one of the most problematic standard for hospitals in the past
- Follow instructions such as stay out of light or refrigerate
- Make sure you log refrigerator temperatures daily
- Medication must be secure
- Housekeeping and maintenance can not have access to pharmacy or med rooms if unsecured medications

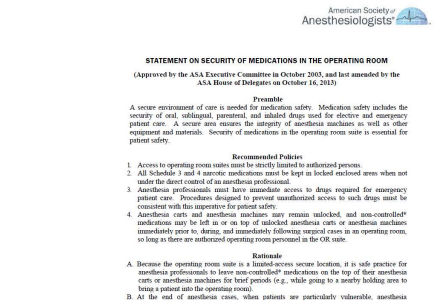
Properly Store Medications

- Make sure c-section carts are locked
- Do not leave medication on the ledge of the dumb waiter or tube system if in a hallway
- Drugs and biologicals must be kept in a secure and locked area
- Also strictly enforced by CMS under tag 502
- May sure narcotics are locked up
- Setting up for patients on OR is considered secure such as the anesthesia carts but after case or when OR is closed need to lock cart

Properly Store Medications

- In the OR must lock up narcotic and schedule 2-5 drugs but if others in room do not have to lock up other drugs
  - Anesthesia carts must be locked evenings and weekends when no cases are going on
  - Some hospitals implement more stringent standards where all anesthesia drugs have to be locked because of several cases where drugs stolen and replaced dirty syringes which infected patients like Kristen Parker case
  - APSF has excellent recommendations and ASA has guidelines
- ADC are considered secure

Medications in the OR ASA Position



American Society of Anesthesiologists

STATEMENT ON SECURITY OF MEDICATIONS IN THE OPERATING ROOM

(Approved by the ASA Executive Committee in October 2003, and last amended by the ASA House of Delegates on October 16, 2013)

Preamble

A secure environment of care is needed for medication safety. Medication safety includes the security of oral, sublingual, parenteral, and inhaled drugs used for elective and emergency patient care. A secure area ensures the integrity of anesthesia machines as well as other equipment and materials. Security of medications in the operating room suite is essential for patient safety.

Recommended Policies

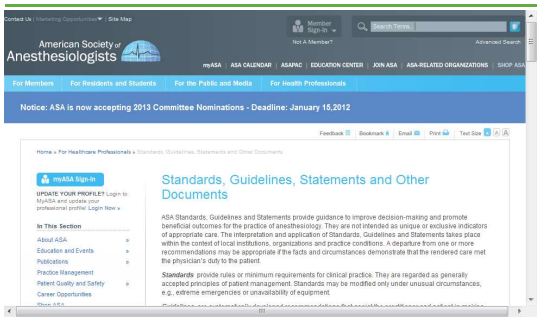
1. Access to operating room suites must be strictly limited to authorized persons.
2. All Schedule 3 and 4 narcotic medications must be kept in locked enclosed areas when not under the direct control of an anesthesia professional.
3. Anesthesia professionals must have immediate access to drugs required for emergency patient care. Procedures designed to prevent unauthorized access to such drugs must be consistent with this imperative for patient safety.
4. Anesthesia carts and anesthesia machines may remain unlocked, and non-controlled* medications may be left in or on top of unlocked anesthesia carts or anesthesia machines immediately prior to, during, and immediately following surgical cases in an operating room, so long as there are authorized operating room personnel in the OR suite.

Rationale

A. Because the operating room suite is a limited-access secure location, it is safe practice for anesthesia professionals to leave non-controlled* medications on the top of their anesthesia carts or anesthesia machines for brief periods (e.g., while going to a nearby holding area to bring a patient into the operating room).
B. At the end of anesthesia cases, when patients are particularly vulnerable, anesthesia

www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

ASA Guidelines and Statements



http://asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx

www.apsf.org/newsletters/html/2010/spring/01_conference.htm

Recommendation on Medications in the OR

The Official Journal of the Anesthesia Patient Safety Foundation

apsf NEWSLETTER Spring 2010

In this issue:

APSF Hosts Medication Safety Conference

APSF Funds New Registry

Web Application to Track Patient Safety During Sedation

Dear SIRS—Why Do New Defaults Turn Off CO_2 and Apnea Alarms?

Q&A—Exposure to Ultraviolet Radiation in the Operating Room

Hospital Coalition Group Endorses APSF Recommendations for PCA Monitoring

Letters to the Editor:

Accidental Intrathecal Injection of Tranexamic Acid

APSF Hosts Medication Safety Conference

Consensus Group Defines Challenges and Opportunities for Improved Practice

by John H. Eichhorn, MD

Overview

On January 26, 2010, the Anesthesia Patient Safety Foundation (APSF) convened a consensus conference of 100 stakeholders from many different backgrounds to develop new strategies for "predictable prompt improvement" of medication safety in the operating room. The proposed new paradigm to reduce medication errors causing harm to patients in the operating room is based on Standardization, Technology, Pharmacy/Prefilled/Premixed, and Culture (STPC). This new paradigm goes far beyond the important but traditional emphasis on medication label format and the admonition to "always read the label." Small group sessions on each of the 4 elements of the new paradigm (STPC) debated and formulated specific recommendations that were organized and prioritized by all the attendees.

The resulting consensus recommendations include:

Standardization

- High alert drugs (such as phenylephrine and epinephrine) should be available in

59. Abbreviation Use

- CMS requires you to have a list of do not use abbreviation
- TJC has 9 mandatory do not use ones under IM standards
- NQF lists this as one of the 34 patient safety practices for Better Healthcare that every hospital should follow
  - Consider giving all physicians and posting on all units the ISMP 2 page list of dangerous abbreviations
  - You must enforce this; consider process where all LIP and physicians hand chart to staffer before leaving nursing unit and they check it quickly for do not use abbreviation, illegible entries and for verbal orders

TJC's Do Not Use Abbreviation List

Facts about the Official "Do Not Use" List

In 2001, The Joint Commission issued a *Sentinel Event Alert* on the subject of medical abbreviations, and just one year later, its Board of Commissioners approved a National Patient Safety Goal requiring accredited organizations to develop and implement a list of abbreviations not to use. In 2004, The Joint Commission created its "do not use" list of abbreviations (see below) as part of the requirements for meeting that goal. In 2010, NPSG.02.02.01 was integrated into the Information Management standards as elements of performance 2 and 3 under IM.02.02.01.

Currently, this requirement does not apply to preprogrammed health information technology systems (for example, electronic medical records or CPOE systems), but this application remains under consideration for the future. Organizations contemplating introduction or upgrade of such systems should strive to eliminate the use of dangerous abbreviations, acronyms, symbols, and dose designations from the software.

Official "Do Not Use" List[1]

Do Not Use	*Potential Problem*	Use Instead
U, u (unit)	Mistaken for "0" (zero), the number "4" (four) or "cc"	Write "unit"
IU (International Unit)	Mistaken for IV (intravenous) or the number 10 (ten)	Write "International Unit"
Q.D., QD, q.d., qd (daily)	Mistaken for each other	Write "daily"
Q.O.D., QOD, q.o.d, qod (every other day)	Period after the Q mistaken for "I" and the "O" mistaken for "I	Write "every other day"
Trailing zero (X.0 mg)* Lack of leading zero (.X mg)	Decimal point is missed	Write X mg Write 0.X mg
MS	Can mean morphine sulfate or magnesium sulfate	Write "morphine sulfate" Write "magnesium sulfate"
MSO_4 and $MgSO_4$	Confused for one another	

Set	Item	Abbreviation	Potential Problem	Preferred Term
1.	1.	U (for unit)	Mistaken as zero, four or cc	Write "unit"
2.	2.	IU (for International unit)	Mistaken as IV (intravenous) or 10 (ten)	Write "International unit"
3.	3. 4.	Q.D., Q.O.D. (Latin abbreviation for once daily and every other day)	Mistaken for each other. The period after the Q can be mistaken for an "I" and the "O" can be mistaken for "I".	Write "daily" and "every other day

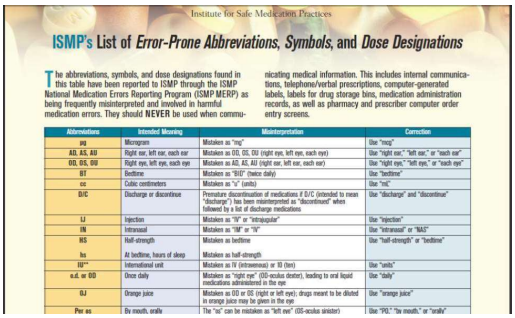
Do Not Use Abbreviations

4.	5. 6.	Trailing Zero (X.0 mg) [Note: Prohibited only for medication-related notations]; Lack of Leading Zero (.X mg)	Decimal point is missed	Never write a zero by itself after a decimal point (X mg), and always use a zero before a decimal point (0.X mg).
5.	7. 8. 9.	MS MSO_4 $MgSO_4$	Confused for one another. Can mean morphine sulfate or magnesium sulfate.	Write "morphine sulfate" or "magnesium sulfate"

Dangerous Abbreviations

- Institute for Safe Medication Practices (ISMP) has published a list of dangerous abbreviations relating to medication use,
- Post copies in nursing station and give copy to all physicians,
- Go to www.ismp.org or www.ismp.org/PDF/ErrorProne.pdf,
- Trailing zero is prohibited only for medication related notations-okay for lab such as K+ is 4.0 or ET tube is 7.0

Do Not Use Abbreviations ISMP



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ISMP's List of *Error-Prone Abbreviations, Symbols,* and *Dose Designations*

The abbreviations, symbols, and dose designations found in this table have been reported to ISMP through the ISMP National Medication Errors Reporting Program (ISMP MERP) as being frequently misinterpreted and involved in harmful medication errors. They should **NEVER** be used when communicating medical information. This includes internal communications, telephone/verbal prescriptions, computer-generated labels, labels for drug storage bins, medication administration records, as well as pharmacy and prescriber computer order entry screens.

Abbreviations	Intended Meaning	Misinterpretation	Correction
ug	Microgram	Mistaken as "mg"	Use "mcg"
AD, AS, AU	Right ear, left ear, each ear	Mistaken as OD, OS, OU (right eye, left eye, each eye)	Use "right ear," "left ear," or "each ear"
OD, OS, OU	Right eye, left eye, each eye	Mistaken as AD, AS, AU (right ear, left ear, each ear)	Use "right eye," "left eye," or "each eye"
BT	Bedtime	Mistaken as "BID" (twice daily)	Use "bedtime"
cc	Cubic centimeters	Mistaken as "u" (units)	Use "mL"
D/C	Discharge or discontinue	Premature discontinuation of medications if D/C (intended to mean "discharge") has been misinterpreted as "discontinued" when followed by a list of discharge medications	Use "discharge" and "discontinue"
IJ	Injection	Mistaken as "IV" or "intrajugular"	Use "injection"
IN	Intranasal	Mistaken as "IM" or "IV"	Use "intranasal" or "NAS"
HS hs	Half-strength At bedtime, hours of sleep	Mistaken as bedtime Mistaken as half-strength	Use "half-strength" or "bedtime"
IU**	International unit	Mistaken as IV (intravenous) or 10 (ten)	Use "units"
o.d. or OD	Once daily	Mistaken as "right eye" (OD-oculus dexter), leading to oral liquid medications administered in the eye	Use "daily"
OJ	Orange juice	Mistaken as OD or OS (right or left eye); drugs meant to be diluted in orange juice may be given in the eye	Use "orange juice"
Per os	By mouth, orally	The "os" can be mistaken as "left eye" (OS-oculus sinister)	Use "PO," "by mouth," or "orally"

60. Monitor Program for Medication Errors

- Both TJC and CMS require the hospital to monitor for medication errors
  - Electronic systems may only capture about half of errors
- ASHP guidelines on preventing medication errors in hospitals recommend monitoring for the following and consider the following risk factors;

1. Work shift (higher error rates typically occur during the day shift)
2. Inexperienced and inadequately trained staff
   - www.ashp.org/DocLibrary/BestPractices/MedMisGdlHosp.aspx

Monitor Program for Medication Errors

3. Medical service (e.g., special needs for certain patient populations, including geriatrics, pediatrics, and oncology)
4. Increased number or quantity of medications per patient
5. Environmental factors (lighting, noise, and frequent interruptions)
6. Staff workload and fatigue
7. Poor communication among health-care providers.

Monitor Program for Medication Errors

8. Dosage form (e.g., injectible drugs are associated with more serious errors)
9. Type of distribution system (unit dose distribution is preferred; floor stock should be minimized)
10. Improper drug storage
11. Extent of measurements or calculations required
12. Confusing drug product nomenclature, packaging, or labeling

Monitor Program for Medication Errors

13. Drug category (e.g., antimicrobials)
14. Poor handwriting
15. Verbal (orally communicated) orders
16. Lack of effective policies and procedures
17. Poorly functioning oversight committees

- CMS requires hospital to know to benchmark so they know if staff have a culture of safety and are reported errors and ADEs

The End! Questions???

- Sue Dill Calloway RN Esq. CPHRM, CCMSCP, AD, BA, BSN, MSN, JD
- President Patient Safety and Healthcare Consulting
- 5447 Fawnbrook Lane
  Dublin, Ohio 43017
- 614 791-1468
  (Call with questions, no emails)
- sdill1@columbus.rr.com
- Email questions to CMS at hospitalscg@cms.hhs.gov

THANK YOU

RELIAS LEARNING

Additional Resources

RELIAS LEARNING

61. “Epi” demic with Ephinephrine

- PSA received numerous reports of accidental administration of concentrated epinephrine, a high alert drug
  - Errors from expressing as a **ratio strength** instead of a metric per volume concentration-gave 1:1000 (1mg) instead of more dilute form 1:10,000 (0.1mg), which is why ratios being eliminated
- Also confusion between epinephrine and ephedrine (look alike names)
- Have a P&P, Communicate issues to staff especially ED and ICU and CCU staff

- Wheeler DW, Carter JJ, Murray LJ, et al. The effect of drug concentration expression on epinephrine dosing errors: a randomized trial. Ann Intern Med 2008; 148:11-14

PATIENT SAFETY/CONCEPTS

Confusion About Epinephrine Dosing Leading to Iatrogenic Overdose: A Life-Threatening Problem With a Potential Solution

Manreet Kanwar, MD
Charlene B. Irvin, MD
John J. Frank, MD
Kathryn Weber, PharmD
Howard Rosman, MD

From the Division of Cardiology, Department of Medicine (Kanwar, Frank, Rosman), Department of Emergency Medicine (Irvin), and Department of Pharmacy (Weber), St. John Hospital and Medical Center, Detroit, MI.

Epinephrine is indicated for various medical emergencies, including cardiac arrest and anaphylaxis, but the dose and route of administration are different for each indication. For anaphylaxis, it is given intramuscularly at a low dose, whereas for cardiac arrest a higher dose is required intravenously. We encountered a patient with suspected anaphylaxis who developed transient severe systolic dysfunction because of inappropriately received cardiac arrest dose, ie, larger dose given as an intravenous push. Three additional patients who experienced potentially lethal cardiac complications after receiving inappropriately higher doses intravenously were also identified. These iatrogenic errors resulted from underlying confusion by physicians about proper dosing of epinephrine for anaphylaxis. The risk of error was amplified by the need for rapid decisionmaking in critically ill anaphylactic patients. An e-mail survey of local hospitals in southeast Michigan revealed that 6 of 7 hospitals did not stock prefilled intramuscular dose syringes for emergency use in anaphylaxis. At our institution, we have introduced prefilled and appropriately labeled intramuscularly dosed epinephrine syringes in crash carts, which are easily distinguished from intravenously dosed epinephrine syringes. In this Concepts article, we describe the clinical problem of inadvertent epinephrine overdose and propose a potential solution. Epinephrine must be clearly packaged and labeled to avoid inappropriate usage and unnecessary, potentially lethal complications in patients with anaphylaxis. [Ann Emerg Med. 2010;55:341-344.]

Even Article Had Incorrect Information

Figure. Clearly labeled prefilled syringes containing (upper box) ~~0.3 mg of 1:10,000 concentration IM dose~~ in an autoinjector labeled "for anaphylaxis use only." Lower box contains 1 mg of 1:10,000 concentration IV dose labeled "for cardiac arrest use only."

Relabeled Epi

- Epi relabeled to decrease confusion over the dose
- Will now be displayed in mass concentration format as used in most other medication
- Epinephrine 1:10,000, used for cardiac arrest, will now be labeled 0.1mg/ml
- Epinephrine 1:1000, used in anaphylaxis, will now be labeled 1.0 mg/ml
- New labeling will also appear for isoproterenol where 1:5000 will now be shown as 0.2 mg/ml and neostigmine where 1:1000 will now be 1 mg/ml

62. Carefully Using Diprivan (Propofol)

- Recently patient safety debate on who is administering to non intubated patients,
- Patients can go into deep sedation and may need to be rescued
  - Is considered deep sedation by manufacturer
- Works faster and patient wakes up earlier,
- Fewer side effects like N&V,
- But patient can drop blood pressure and go into respiratory arrest,
  - No reversal agent for drug,
  - Must have IV access, pulse ox, cardiac monitor and monitor vital signs at least every five minutes, $ETCO_2$, etc.

Diprivan (Propofol)

- Pa Patient Safety Authority reported over 100 reports of complications and problems with this drug at http://www.psa.state.pa.us/psa/lib/psa/advisories/mar_2006_advisory_v3_n1.pdf
- Four deaths and 16% sentinel events,
- CMS CoP says need position statement to allow and make sure staff is trained and or credentialed (Tag 1000-1005)
- Conflict between national position statements,
- 13 states do not allow RN to give unless CRNA,
- Warning section of the drug's package insert states that this drug used for sedation or anesthesia should be administered only by persons trained in the **administration of general anesthesia and not involved in** the conduct of the surgical or diagnostic procedure.

63. Use Verbal Orders Infrequently

- Use verbal orders for medication infrequently
- Not allowed if doctor standing in the nursing station unless code or emergency situation
  - CMS Hospital CoP and TJC requirement RC.02.03.07,
- Have a P&P on this
- Make sure verbal orders signed off **asap,** dated and timed within your state limit
  - If no state law then sign off according to your policy and be sure to date and time order
- Any doctor can sign off VO for any doctor on the case

Verbal Orders

- NP or PA can sign off if you have in your P&P and within their scope of practice
- Can fax orders to get signed off
- Be sure to write down the verbal order and repeat it back to make sure you have it right
- State in policy who can receive them such as pharmacist for drugs or dietician for diet orders
- Specify when they are not accepted such as for chemotherapy or other hazardous orders

64. Pharmacist Involvement

- Pharmacists should actively participate in medication management systems
  - Use a system approach-most errors are made by long term employees with unblemished records
  - It is the system that leads to the error
- Many errors from the medication process
- Need to recognize the important role of the pharmacist
- Review of order by pharmacist before administration reduces errors
- Make rounds with physicians in ICU

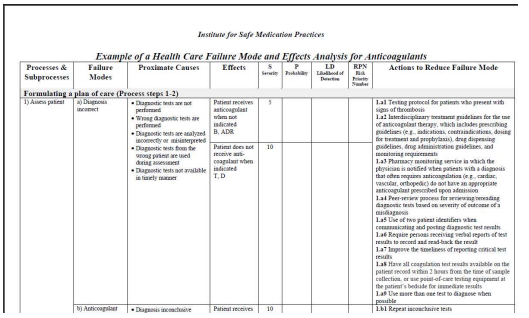
Pharmacist Involvement

- Inspect medication storage areas
- Work with others to identify work environment including limiting distractions, and interruptions, accurate prescribing, dispensing and administration of drugs
- Pharmacist attend continuing education conferences and maintain awareness of safe practice literature
- Larger hospitals have pharmacist in the ED
- NQF 34 Safe Practices for Better Healthcare.

65. Do a FMEA on Anticoagulants

- Consider doing a failure mode and effect analysis on anticoagulants,
- Can help identify potential errors before they occur,
- 28 page one available off ISMP website,
  - www.ismp.org/Tools/FMEAofAnticoagulants.pdf
- Important since TJC anticoagulant NPSG.03.05.01 and frequent cause of error and adverse event,

ISMP FMEA Anticoagulants



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Example of a Health Care Failure Mode and Effects Analysis for Anticoagulants

Processes & Subprocesses	Failure Modes	Proximate Causes	Effects	S Severity	P Probability	LD Likelihood of Detection	RPN Risk Priority Number	Actions to Reduce Failure Mode
Formulating a plan of care (Process steps 1-2)								
1) Assess patient	a) Diagnosis incorrect	• Diagnostic tests are not performed • Wrong diagnostic tests are performed • Diagnostic tests are analyzed incorrectly or misinterpreted	Patient receives anticoagulant when not indicated B, ADR	5				**1.a1** Testing protocol for patients who present with signs of thrombosis **1.a2** Interdisciplinary treatment guidelines for the use of anticoagulant therapy, which includes prescribing guidelines (e.g., indications, contraindications, dosing for treatment and prophylaxis), drug dispensing guidelines, drug administration guidelines, and monitoring requirements **1.a3** Pharmacy monitoring service in which the physician is notified when patients with a diagnosis that often requires anticoagulation (e.g., cardiac, vascular, orthopedic) do not have an appropriate anticoagulant prescribed upon admission **1.a4** Peer-review process for reviewing misleading diagnostic tests based on severity of outcome of a misdiagnosis **1.a5** Use of two patient identifiers when communicating and posting diagnostic test results **1.a6** Require persons receiving verbal reports of test results to record and read-back the result **1.a7** Improve the timeliness of reporting critical test results **1.a8** Have all coagulation test results available on the patient record within 2 hours from the time of sample collection, or use point-of-care testing equipment at the patient's bedside for immediate results **1.a9** Use more than one test to diagnose when possible
		• Diagnostic tests from the wrong patient are used during assessment • Diagnostic tests not available in timely manner	Patient does not receive anti-coagulant when indicated T, D	10				
	b) Anticoagulant	• Diagnosis inconclusive	Patient receives	10				**1.b1** Repeat inconclusive tests

Remember TJC Anticoagulant Therapy 03.05.01

Requirement: Reduce the likelihood of patient harm associated with the use of anticoagulation therapy.

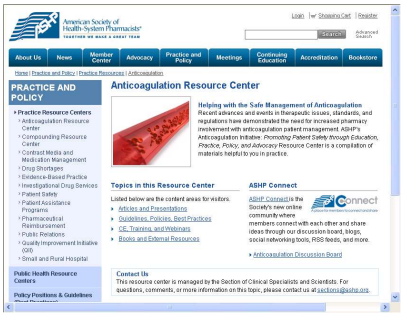
Rationale:

- Applies to hospitals that provide anticoagulant therapy or long term prophylaxis for things like atrial fib
- Does not apply to routine situations in which short term prophylactic use for prevention of DVT related to procedure or hospitalization

Anticoagulants Recommendations

- Use only unit dose products, prefilled syringes, or premixed infusion bags
- Use approved protocols such as IV Heparin protocol
- Check INR on patients on Coumadin
- Manage food and drug interactions on patients on Coumadin
- Use IV pump for IV Heparin
- Have P&P for baseline and lab tests for Heparin and LMW Heparin
- Provide education to staff and patients
- Evaluate anticoagulant safety practices

Many Great Anticoagulant Resources



www.ashp.org/Import/PRACTICEANDPOLICY/PracticeResourceCenters/Anticoagulation.aspx

Anticoagulant Toolkit PaPSA

SEA Preventing Anticoagulant Errors

66. Be Aware of Problematic Standards

- TJC lists the most problematic standards every year and the following are the ones regarding medication issues,
- It has already been discussed that MM 03.01.01, is a top problematic standard regarding storage and security of medications
- Verbal orders related to medication is a problematic standard
- The do not use abbreviation was moved to the IM chapter from a NPSG by TJC
- Medication reconciliation

IHI How to Guide Medication Reconciliation

www.ihi.org/NR/rdonlyres/98096387-C903-4252-8276-5BFC181C0C7F/0/ADEHowtoGuide.doc

67. Use Standardized Medication Labeling

- Standardize methods for labeling and packaging of medications
- Also a TJC standard and NPSG
- Labeling of medication on and off the sterile field
- Discusses what label should contain; drug name strength, amount, expiration date if not used within 24 hours, etc.
- Use tall man lettering Humu**BID** or Humu**LOG**

Medication Labeling 05.01.09

Medications are labeled appropriately;

•Having a standardized method for labeling all meds will reduce errors

•Label in standardized form as per your hospital policy and standards of practice

•Must be labeled if it is prepared but not administered immediately

•See also NPSG.03.04.01 and MM standard

Medication Labeling

What must the label include:

- Drug name, strength and amount (if not apparent),
- Expiration date when not used within 24 hours,
- Expiration date when not used<24 hours,
- IV admixtures-date prepared the diluents,
- Plain IVs do not have to have label
  - Do not spike IVs more than an hour in advance
  - Medications should not be prepared more than one hour in advance unless prepared in pharmacy

68. Have Medication Board on Every Unit

- Considering having a medication board on every unit
- Every month new articles are placed on it
- Information about new drugs
- Get great articles from the AHRQ PSNet website
- ISMP has free monthly newsletter for nurses at www.ismp.org
- ISMP has many tool and toolkits such as neonatal drug infusions and confused drug names
- Include list of confused drug names

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ISMP's List of *Confused* Drug Names

This list of confused drug names, which includes look-alike and sound-alike name pairs, consists of those name pairs that have been published in the *ISMP Medication Safety Alert!*® and the *ISMP Medication Safety Alert!*® Community/Ambulatory Care Edition. Events involving these medications were reported to ISMP through the ISMP National Medication Errors Reporting Program (ISMP MERP).

We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as: using both the brand and generic names; including the purpose of the medication on prescriptions; configuring computer selection screens to prevent look-alike names from appearing consecutively; and changing the appearance of look-alike product names.

Updated through June 2011

Drug Name	Confused Drug Name
Abelcet	amphotericin B
Accupril	Aciphex
acetaZOLAMIDE	acetoHEXAMIDE
acetic acid for irrigation	glacial acetic acid
acetoHEXAMIDE	acetaZOLAMIDE
Aciphex	Accupril
Aciphex	Aricept
Activase	Cathflo Activase
Activase	TNKase
Actonel	Actos
Actos	Actonel
Adacel (Tdap)	Daptacel (DTaP)
Adderall	Inderal

Drug Name	Confused Drug Name
amLODIPine	aMILoride
amphotericin B	Abelcet
amphotericin B	Ambisome
Anacin	Anacin-3
Anacin-3	Anacin
antacid	Atacand
Antivert	Axert
Anzemet	Avandamet
Apresoline	Priscoline
argatroban	Aggrastat
argatroban	Orgaran
Aricept	Aciphex
Aricept	Azilect

ISMP Institute for Safe Medication Practices

Vermont Oxford Network

Standard Concentrations of Neonatal Drug Infusions

A collaborative effort between the Institute for Safe Medication Practices (ISMP) and Vermont Oxford Network (VON)

The drug concentrations provided below are the result of a national effort to create standard concentrations for typical neonatal drug infusions that could be used across all US hospitals for at least 80% of neonatal infusions. (The other 20% of infusions may require different concentrations based on the unique needs of the neonate.) ISMP and the Vermont Oxford Network (VON), a nonprofit voluntary group of healthcare professionals working to improve newborn care, collaborated with representatives from neonatal intensive care units in the US to identify and promote the standard concentrations of typical neonatal drug infusions listed in the table that follows. Some drugs include two standard concentrations to accommodate various weights of neonates, including low-birth-weight infants.

The safety benefits of all hospitals using the same standard concentrations whenever possible for neonates are vast and include the following:

- Reduce medication error risk when critically-ill neonates are transferred from one facility to another
- Stimulate development of standardized infusion device drug libraries
- Provide the demand necessary for manufacturers to offer commercially prepared standard solutions (if not already available), thereby reducing the risk of extemporaneous compounding errors within hospitals.

We urge all hospitals where neonates are treated to join our national effort to reduce the risk of harmful errors when caring for our tiniest patients!

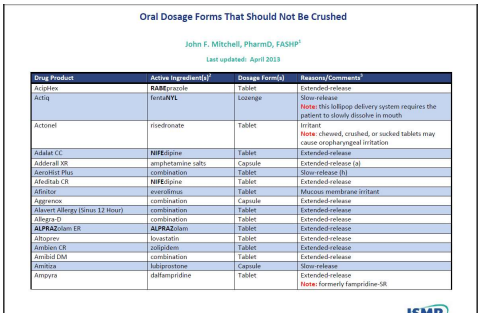
Standard Concentrations of Neonatal Drug Infusions

Drug	Type(s) of Infusions	Recommended Concentrations*
acyclovir	intermittent infusion**	7 mg/mL
alprostadil	continuous infusion	10 mcg/mL
amphotericin B	intermittent infusion**	0.1 mg/mL
amphotericin B liposomal	intermittent infusion**	1 mg/mL
ceFAZolin	intermittent infusion**	100 mg/mL
cefotaxime	intermittent infusion**	100 mg/mL
clindamycin	intermittent infusion**	6 mg/mL

69. Train on Do Not Crush Medication

- Should have list for staff of meds that should not be crushed, have in a book or on the wall in the ED
- Aciphex, actonel, accutane, Toporol XL, Prilosec, Procardia XL, aprevacide, Plendil, OxyContin, Oramorph SR, Opana ER (causes fatal OD) and 16 pages
- Especially enteric coated, drugs with ER or SR since slow release
- Wall chart can be purchased from www.factsandcomparisons.com/hospitalpharm/
- Free list available at www.ismp.org/Tools/DoNotCrush.pdf
- ED should put chart in medication room
- See Identified safety risks with splitting and crushing oral medications. Paparella S. J Emerg Nurs. 2010;36:156-158

Do Not Crush List



Oral Dosage Forms That Should Not Be Crushed

John F. Mitchell, PharmD, FASHP[1]

Last updated: April 2013

Drug Product	Active Ingredient(s)[2]	Dosage Form(s)	Reasons/Comments[3]
Aciphex	RABEprazole	Tablet	Extended-release
Actiq	fentaNYL	Lozenge	Slow-release Note: this lollipop delivery system requires the patient to slowly dissolve in mouth
Actonel	risedronate	Tablet	Irritant Note: chewed, crushed, or sucked tablets may cause oropharyngeal irritation
Adalat CC	NIFEdipine	Tablet	Extended-release
Adderall XR	amphetamine salts	Capsule	Extended-release (a)
AeroHist Plus	combination	Tablet	Slow-release (h)
Afeditab CR	NIFEdipine	Tablet	Extended-release
Afinitor	everolimus	Tablet	Mucous membrane irritant
Aggrenox	combination	Capsule	Extended-release
Alavert Allergy (Sinus 12 Hour)	combination	Tablet	Extended-release
Allegra-D	combination	Tablet	Extended-release
ALPRAZolam ER	ALPRAZolam	Tablet	Extended-release
Altoprev	lovastatin	Tablet	Extended-release
Ambien CR	zolpidem	Tablet	Extended-release
Ambid DM	combination	Tablet	Extended-release
Amitiza	lubiprostone	Capsule	Slow-release
Ampyra	dalfampridine	Tablet	Extended-release Note: formerly fampridine-SR

www.ismp.org/Tools/DoNotCrush.pdf

70. Reduce Deaths by Reducing Medications

- Article suggests that hospitals should reduce the number of medications a patient takes to improve patient safety
  - Fewer the medications, the less chance of errors
- Suggests doctor should stop all home medications when a patient is admitting unless a compelling reason to continue
- When patient is discharged suggest doctor not resume any medications unless compelling reason to do so
  - IOM study found one error per patient per day

Hospitals can reduce deaths by reducing medication

By Bruce L. Lambert, William Galanter, and Robert McNutt | June 15, 2015

More harm than good? (Reuters/John Sommers II)

At their best, hospitals are places where doctors bring babies safely into the world and bring gravely ill people back from the brink of death. But at their worst, they are dangerous places where patients are vulnerable to hospital-acquired infections and a host of harmful medical errors.

A recent analysis grading more than 2,500 US hospitals on safety

The Brief | Our Picks | Popular | Obsessions

71. Preventing Heparin Error

- Make sure not next to each other
- Consider double checks when filing cabinet
- Provide staff education about recent mix up with heparin in six infants in Riverside Methodist in Indiana and Dennis Quade twins
- Sleeve to provide information to prevent dangerous mix ups

Careful about Heparin LASA drug

Heparin Errors

- Medicare Patient Safety Monitoring System looked at 25,145 hospital visits
- 13% Heparin ADEs
- 8% patients had Warfarin ADEs
- 10.7% insulin/hypoglycemia
- 0.6% CDiff from antibiotics
- Source: Classen, David. JC Journal of Quality and Patient Safety, Vol. 36, No 1, Jan 2010, pp 12.

72. More on Medications

- Be aware of food-drug, drug-drug, drug-disease interactions
- Provide information on these to staff
- Good lightning in medication room and magnifier on cart
- Color coding or color matching of drugs

More on Medications

- Make sure everyone has access to a complete list of the medications, including herbals and OTC,
- Audit to be sure medication reconciliation is done and done correctly
- Use automated dispensing units,
- Red allergy bracelets on all patients and if no allergy write NKDA,
- Document specific reaction if patient is allergic to medication,
- Know CMS rules on protocols and standing orders

More on Medications

- Use tamper proof prescriptions
- Write purpose of drug on prescription
- Make sure phone number of prescriber on prescription so they will call if question
- Use two identifiers before administering medications
- Consider a smart pump
- Provide list of meds not to give elderly (Beer List)
- Provide chart on units of do not crush drugs

Beer's List Updated 2012

SPECIAL ARTICLES

American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults

The American Geriatrics Society 2012 Beers Criteria Update Expert Panel

Potentially inappropriate medications (PIMs) continue to be prescribed and used as first-line treatment for the most vulnerable of older adults, despite evidence of poor outcomes from the use of PIMs in older adults. PIMs now form an integral part of policy and practice and are incorporated into several quality measures. The specific aim of this project was to update the previous Beers Criteria using a comprehensive, systematic review and grading of the evidence on drug-related problems and adverse drug events (ADEs) in older adults. This was accomplished through the support of The American Geriatrics Society (AGS) and the work of an interdisciplinary panel of 11 experts in geriatric care and pharmacotherapy who applied a modified Delphi method to the systematic review and grading to reach consensus on the updated 2012 AGS Beers Criteria. Fifty-three medications or medication classes encompass the final updated Criteria, which are divided into three categories: potentially inappropriate medications and classes to avoid in older adults, potentially inappropriate

comes. Estimates from past studies in ambulatory and long-term care settings found that 27% of adverse drug events (ADEs) in primary care and 42% of ADEs in long-term care were preventable, with most problems occurring at the ordering and monitoring stages of care.[1,2] In a study of the 2000/2001 Medical Expenditure Panel Survey, the total estimated healthcare expenditures related to the use of potentially inappropriate medications (PIMs) was $7.2 billion.[3]

Avoiding the use of inappropriate and high-risk drugs is an important, simple, and effective strategy in reducing medication-related problems and ADEs in older adults. Methods to address medication-related problems include implicit and explicit criteria. Explicit criteria can identify high-risk drugs using a list of PIMs that have been identified through expert panel review as having an unfavorable balance of risks and benefits by themselves and considering alternative treatments available. A list of PIMs was developed and published by Beers and colleagues for nursing

www.americangeriatrics.org/files/documents/beers/2012BeersCriteria_JAGS.pdf

Beers Criteria

Table 2. 2012 AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults

Organ System/ Therapeutic Category/Drug(s)	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation	References
Anticholinergics (excludes TCAs)					
First-generation antihistamines (as single agent or as part of combination products) • Brompheniramine • Carbinoxamine • Chlorpheniramine • Clemastine • Cyproheptadine • Dexbrompheniramine • Dexchlorpheniramine • Diphenhydramine (oral) • Doxylamine • Hydroxyzine • Promethazine • Triprolidine	Highly anticholinergic; clearance reduced with advanced age, and tolerance develops when used as hypnotic; increased risk of confusion, dry mouth, constipation, and other anticholinergic effects/toxicity. Use of diphenhydramine in special situations such as acute treatment of severe allergic reaction may be appropriate.	Avoid	Hydroxyzine and promethazine: high; All others: moderate	Strong	Agostini 2001 Boustani 2007 Guaiana 2010 Han 2001 Rudolph 2008
Antiparkinson agents • Benztropine (oral) • Trihexyphenidyl	Not recommended for prevention of extrapyramidal symptoms with antipsychotics; more effective agents	Avoid	Moderate	Strong	Rudolph 2008

More on Medications

- Take steps to reduce **fatigue** in staff with careful scheduling (no double shifts, resident hours, no more 60 hours a week for nurses and no more than 12 hour shifts),
- Calculate doses of Acetaminophen carefully for children-had dose card and instruct parents carefully on correct dose,
- Don't throw insulin into one bin- drawers with labeling and two licensed staff to check dosage,
- Remember trailing and leading zero.

More on Medications

- Use proper spelling and correct spacing in each order; for example, "propranolol20 mg" is easily misread as "propranolol 120 mg,"
- Avoid coined names, such as "magic mouthwash," or acronyms that can be misunderstood by those unfamiliar with them,
- Change the appearance of look-alike product names by using highlighting, bold face, color, circling, or Tallman lettering to emphasize parts of the names that are different like Novu**LIN** or Novu**LOG**
- Careful about Dilaudid use

Dilaudid Patient Safety Brief www.empsf.org

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.

Emergency Physicians Insurance eXchange

EPIX

EPIX Patient Safety Briefs

Preventing Dilaudid (HYDROmorphone) Adverse Drug Events

Revised and Updated by Sue Dill Calloway RN MSN JD
(Written by Jeanie Taylor RN BSN in 2012)

A hospitalized patient experiencing pain receives an overdose of intravenous Dilaudid (HYDROmorphone) after a physician prescribes the IV dose in the same amount as the oral dose the patient had been taking at home. Neither the pharmacist nor nurse captures the error. The nurse administers the wrong dose confusing it with morphine. These are not uncommon scenarios.

EPIX has seen a number of claims related to adverse drug events from Dilaudid (HYDROmorphone). Errors in the administration and dosage can be fatal. The Pennsylvania Patient Safety Authority (PA PSA) issued a memo after noting over 1694 reports of medication errors related to Dilaudid over a 20 month period. (1) A Canadian study reported 251 deaths from Dilaudid overdoses in the province of Ontario from 1985 to 2003. (2) Fatalities can occur at 51 ng/mL or more. (2) The FDA approved labeling was revised for Dilaudid* (1 mg/mL, 2 mg/mL, 4 mg/mL) and Dilaudid-HP (10 mg/mL) to help prevent associated medication errors. (3)

RELIAS | LEARNING 355

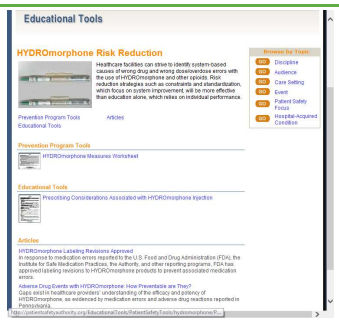
Risk Reduction Strategies

Storage

- **Store Dilaudid separately from morphine** in the automated dispensing cabinet (ADC) and take steps to ensure staff does not confuse the two drugs through distinct labeling.
- Do not store Dilaudid and morphine in the same strength. For example, store 2 mg (or less) vials of Dilaudid and 4 mg vials of morphine.
- Ensure that the pharmacy has a process in place to prevent them from mistakenly placing morphine in drug dispensing machines instead of Dilaudid.
- Always label as Dilaudid or Dilaudid (HYDROmorphone) to avoid confusion with morphine and use tall man lettering. Use both the brand name of Dilaudid and generic name on order sets, electronic orders, and medication administration records. Seventy percent of the wrong drug reports involved mix-ups with morphine. (1)
- **If narcotics are stored in an automated medication dispensing machine, allow emergency access to morphine, but consider requiring pharmacy review of all orders for Dilaudid prior to administration.** (1) This recommendation may not be practical in some facilities if it results in a delay in timely medicating a patient in need.
- Consider putting Dilaudid (HYDROmorphone) on the high-alert medication list. Some emergency departments require an independent double check when removed from the automated dispensing cabinet (ADC). Some ADCs may require a witness. Some ADCs have the capability of asking "This is DILAUDID. Is that correct?" when nurses retrieve it from the

RELIAS | LEARNING 356

Dilaudid HYDROmorphone Toolkit

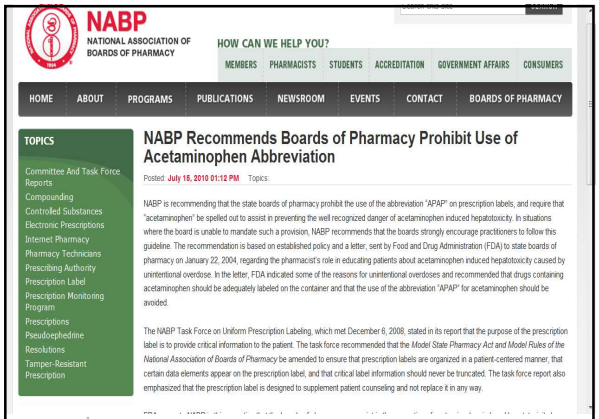


http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/hydromorphone/Pages/home.aspx

RELIAS | LEARNING 357

APAP Acetaminophen on the Label

- July 21, 2010, the National Association of the Boards of Pharmacy make a recommendation
- Pharmacist should not use APAP for acetaminophen on the label but should write it out
- To prevent the unintentional overdose that can result in hepatotoxicity
- Recommend state pharmacy boards try to incorporate it into state law



Dr Do Not Rx More than 325 mg per tablet

www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm381650.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

More on Medications

- Properly dispose of prescription drugs
- Do not flush down the toilet or hopper unless pharmacist has indicated it is permissible
- Attorney general in January 2010 fined two hospitals in NY for flushing drugs down the toilet
- FDA has a website on what can be flushed down the drain 1
- Some states have passed laws on this
- Cautus sink is an example
- Called p-waste
- 1www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf

Proper Disposal of Prescription Drugs

Office of National Drug Control Policy October 2009

Federal Guidelines:

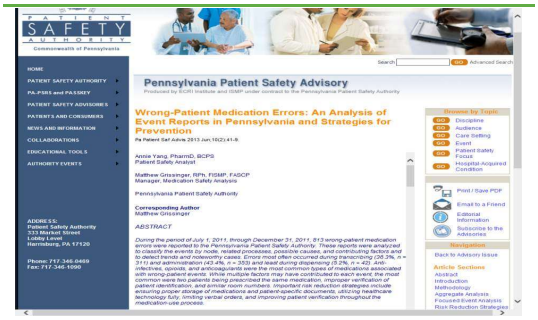
- Do not flush prescription drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so. For information on drugs that should be flushed visit the FDA's website.
- To dispose of prescription drugs not labeled to be flushed, you may be able to take advantage of community drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal. Call your city or county government's household trash and recycling service and ask if a drug take-back program is available in your community.
- If a drug take-back or collection program is not available:
  1. Take your prescription drugs out of their original containers.
  2. Mix drugs with an undesirable substance, such as cat litter or used coffee grounds.
  3. Put the mixture into a disposable container with a lid, such as an empty margarine tub, or into a sealable bag.

Watch This Video WWW.safetyleaders.com

Labeling Injectible Drugs

- USP is advancing the new labeling of injectable
- To reduce the likelihood of patient death and disability resulting from errors
- The only information allowed will be vials to cautionary statements intended to prevent imminent life-threatening situations
- If none then nothing here including no company logos or company names
  - Requirements apply to the top circle surface of the ferrule and cap overseal of a vial with injectible meds

Keep Up With the Literature



www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2013/Jun;10(2)/Pages/41.aspx

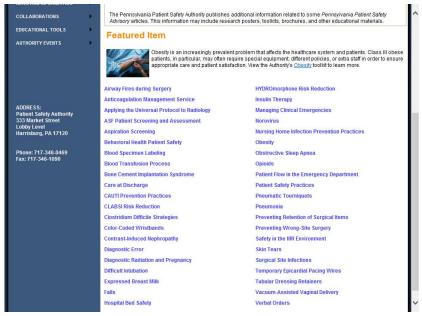
Risk Reduction Strategies

- Limit verbal orders
- Ensure proper storage of medications
  - Clearly label storage bins, standardize the labeling process, and remove meds when patient discharged
- Improve accuracy of patient identification
  - Confirm right patient and confirm with the MAR
- Use technology fully and properly
  - CPOE, continually examine CPOE, bar coding, prevent improper scanning, and ADC
- Empower the patient to prevent errors

Did You Know? FDA

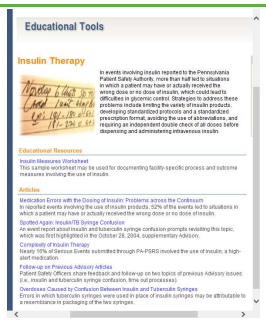
- Benzocaine can cause methemoglobinemia
  - Patients use it to relieve pain from teething, canker sores and irritation of the mouth and guns
- Mitoxantrone (Novantrone) use should monitor patient for cardiac function
  - Cardiac toxicity and heart failure is a side effect
  - Need to evaluate and have a baseline LVEF
  - MS patients are less likely to be monitored
- VinCRISTine should only be given IV
  - Severe neurologic damage if given in the spinal canal

Toolkits Pa PSA



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

Insulin Therapy Toolkit High Risk Drug



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

New Labeling of Injectables

RELIAS LEARNING 370

DTaP-Tdap Mix-ups

- ISMP Medication Errors Reporting Program database contains hundreds of cases of accidental mix-ups
- Between adult and pediatric products
- Used to immunize patients against diphtheria, tetanus, and pertussis
- Products are easy to confuse
- Tdap is a booster for older children and adults
- DTaP is active immunization for pediatric patients 6 months through 6 years

RELIAS LEARNING 371

DTaP-Tdap Mix-ups

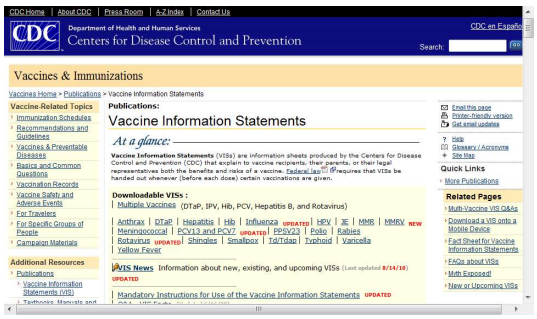
- DTaP has larger amount of antigen
- If adults get this will have a sore arm
- However, if a child gets the adult dosage it has less antigen and child may not respond appropriately
- Order vaccine by brand name and not vaccine abbreviation
- Separate the pediatric and adult formulation in the storage area
- CDC requires that vaccine information be given to patients before each vaccination

RELIAS LEARNING 372

DTaP-Tdap Mix-ups

- DTaP is sold under the brand names of
  - DAPTACEL
  - TRIPEDIA
  - INFANRIX
- Tdap is sold under the brand names of
  - BOOSTRIX
  - ADACEL

www.cdc.gov/vaccines/Pubs/vis/default.htm



Drug Identification and Interactions

- Drug interaction checker available at www.drugs.com/drug_interactions.php
- Pill wizard to identify medication with pictures at www.drugs.com/pill_identification.html
- You can search more than 3,700 drugs for dose, interactions etc. at https://online.epocrates.com/
- FDA collaborating with drugs.com to expand access for consumer to FDA consumer information

High Risk of Death and Adverse Events

- Tigecycline, a first-in-class board spectrum antibiotic, is approved for complicated intra-abdominal infections, complicated skin infections and community acquired pneumonia
- Usefulness of this drug for severe infections comes at a high risk of death and adverse events
- Tigecycline was associated with an increased incidence of all adverse events (including fever, headache, infection, abdominal pain, chills, and pain)
- Study at http://aac.asm.org/cgi/content/abstract/AAC.01402-10v1 Antimicrob. Agents Chemother. doi:10.1128/AAC.01402-10

Know Your Hospital's Error Rate

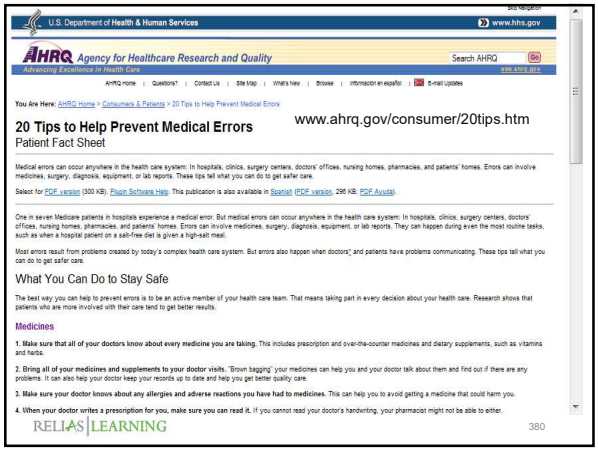
- Know benchmarking studies and how you compare as far as medication error rate
  - CMS now requires under tag 508 in the hospital CoP manual since amended 11-18-2011
  - See Preventing Medication Errors by IOM at www.iom.edu/CMS/3809/22526/35939.aspx
  - The hospital must have a method by which to measure the effectiveness of its systems for identifying and reporting to the PI program medication errors and ADRs
  - Such methods could include use of established benchmarks for the size and scope of services provided by the hospital, or studies on reporting rates published in peer-reviewed journals.

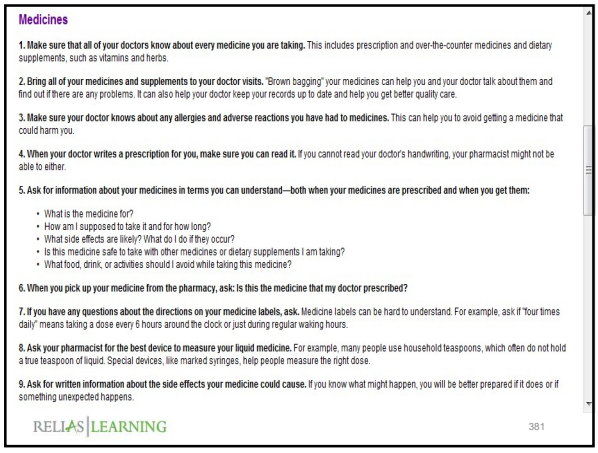
Give Patient a Brochure

- Consider giving patients a brochure on how to prevent medication errors
  - ISMP has a good 6 page one at www.ismp.org/pressroom/Patient_Broc.pdf
  - Do not save old medications
  - Tips to prevent errors with drug samples
  - Take all medications, including OTC, with you to the doctor and hospital
  - Have doctor write the reason for the medication on the prescription

Tips For Patients

- If use more than one pharmacy make sure they have a list of all of your medications
- Check the name on the prescription to make sure you did not get another patient's medication
- check to make sure the medication your were prescribed matches the label on the medication bottle
- Question any concerns immediately with the pharmacist such as why is this pill a different color or shape?





The End! Questions???

- Sue Dill Calloway RN Esq. CPHRM, CCMSCP, AD, BA, BSN, MSN, JD
- President Patient Safety and Healthcare Consulting
- 5447 Fawnbrook Lane
  Dublin, Ohio 43017
- 614 791-1468
  (Call with questions, no emails)
- sdill1@columbus.rr.com
- Email questions to CMS at hospitalscg@cms.hhs.gov

Medication Management

- Are you up to the challenge?
- What else should we add?

THANK YOU