

Elevate Your Medication Management: Tips from the HHS, CMS, TJC & IOM

Tuesday, June 30th, 2015



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Objectives

- Describe ways to reduce medication errors in your facility.
- Explain why medication errors are the most common type of medical error.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

Headlines We Don't Want to See

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

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

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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.

 Tweet

7

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."

 +1

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

According to the report, the family of the deceased is not yet sure if they will pursue legal action.

Medication Errors

- Medication errors are the most common type of medical errors
 - CMS, in hospital CoP, says drug related adverse outcomes were noted in 1.9 million inpatient stays, which is 4.7% of all stays (April 15, 2015 Manual)
 - 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

Many Resources on ADE PSH for Patients

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Resources

Adverse Drug Events (ADE)



The information contained in these resources does not necessarily reflect the views of the Partnership for Patients, the Centers for Medicare and Medicaid Services, The United States Department of Health and Human Services, nor the United States government.

Title	Description
"How-to Guide: Prevent Adverse Drug Events (Medication Reconciliation)" (Institute for Healthcare Improvement [IHI])	This how-to guide 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.
"How-to Guide: Prevent Adverse Drug Events (Medication Reconciliation) — Pediatric	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

http://partnershipforpatients.cms.gov/p4p_resources/tsp-adversedrugsade.html

<p>“How-to Guide: Prevent Adverse Drug Events (Medication Reconciliation) — Pediatric Supplement” (IHI)</p>	<p>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.</p>
<p>“Preventing Adverse Drug Events (Medication Reconciliation): Patient and Family Fact Sheet” (IHI)</p>	<p>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.</p>
<p>“Reducing Medication Errors” (Massachusetts Coalition for the Prevention of Medical Errors)</p>	<p>A Web site listing initiatives to reduce medication errors in anticoagulation medicine, ambulatory settings, acute care facilities, long-term care facilities, and consumer safety.</p>
<p>“MATCH Medication Reconciliation Toolkit” (IHI)</p>	<p>The medication reconciliation initiative at Northwestern Memorial Hospital, called MATCH, included development of a toolkit to help hospital and outpatient practice staff.</p>
<p>“Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs” (U.S. Department of Health & Human Services, Agency for Healthcare Research and Quality [AHRQ])</p>	<p>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.</p>
<p>“Preventable Adverse Drug Reactions: A Focus on Drug Interactions” (U.S. Department of Health & Human Services, U.S. Food and Drug Administration [FDA])</p>	<p>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.</p>
<p>“Safe Use Initiative: Collaborating to Reduce Preventable Harm from Medications” (FDA)</p>	<p>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.</p>

<p>"ISMP" (Institute for Safe Medication Practices)</p>	<p>A comprehensive Web site with medication safety tools, reports, resources, products, alerts, and videos.</p>
<p>"NCC MERP" (The National Coordinating Council for Medication Error Reporting and Prevention)</p>	<p>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.</p>
<p>"Adverse Drug Reaction Surveillance: Practical Methods for Developing a Successful Monitoring Program" (Medscape from WebMD)</p>	<p>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.</p>
<p>"Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention" (Journal of the American Medical Association)</p>	<p>Article. Assessment of the incidence and preventability of adverse drug events (ADEs) and potential ADEs, with analysis of preventable events to develop prevention strategies.</p>
<p>"MedWatch: The FDA Safety Information and Adverse Event Reporting Program" (FDA)</p>	<p>FDA gateway for clinically important safety information and for reporting serious problems with human medical products.</p>
<p>"Adverse Event Reporting System (AERS)" (FDA)</p>	<p>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.</p>

ISMP Medication Safety Practices for Hospitals

The screenshot displays the ISMP website's navigation menu at the top, including links for Home, Support ISMP, Newsletters, Webinars, Report Errors, Educational, Store, Consulting, FAQ, Tools, About Us, and Contact Us. A search bar and social media icons are also present. The main content area features a large banner for the 2014-15 Targeted Medication Safety Best Practices for Hospitals, accompanied by an image of the document. Below the banner, a paragraph explains the purpose of the best practices, and a 'DOWNLOAD' button is provided with a link to the document. A 'Resources' sidebar on the right lists links to the TMSBP Main Page, the 2014-15 Targeted Medication Safety Best Practices for Hospitals, Educational Programs, Frequently Asked Questions, and Baseline Survey. The footer contains additional navigation links, contact information, and copyright notices.

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2014-15 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 on specific medication safety issues that continue to cause fatal and harmful errors in patients, despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts over the next two years. While targeted for the hospital based setting, some may be applicable to other healthcare settings. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the ISMP Medication Safety Alert¹ are referenced after each best practice.

DOWNLOAD <http://www.ismp.org/Tools/BestPractices/default.aspx>

Resources

- [TMSBP Main Page](#)
- [2014-15 Targeted Medication Safety Best Practices for Hospitals](#)
- [Educational Programs](#)
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1. Are Errors Rampant and Under-reported?

The screenshot shows the AHRQ PSNet website. At the top, there is a blue header with the U.S. Department of Health & Human Services logo and the URL www.hhs.gov. Below that is a yellow banner with the AHRQ logo and the text "Agency for Healthcare Research and Quality" and "Advancing Excellence in Health Care". The main navigation bar is dark blue with the PSNet logo and a search box. The "The Collection" tab is selected. The main content area features a news article titled "Prescription mistakes are rampant and under-reported." with a sub-headline "Download: Adobe Reader" and "Email". The article text begins with "This news piece discusses pharmacy medication dispensing errors and describes how patients can help prevent them." Below the article is a "Free full text" link. To the right of the article is a "Find Related Resources by..." section with categories: Resource Type (Newspaper/Magazine Article), Setting of Care (Outpatient Pharmacy), Target Audience (Patients), Clinical Area (Pharmacy), Safety Target (Dispensing Errors), Error Types (Cognitive Errors ("Mistakes")), and Approach to Improving Safety. At the bottom left, there is a "Related Resources" section with an "AUDIOVISUAL" link and a news article titled "NJ CVS mixed up cancer meds with kids' fluoride." with a sub-headline "Greenblatt M. ABC News. March 3, 2012." and a "NEWSPAPER/MAGAZINE ARTICLE" link.

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

AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care www.ahrq.gov

PSNet patient safety network

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morbidity & mortality rounds on the web

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Prescription mistakes are rampant and under-reported. Download: Adobe Reader Email

LaGrone K. WPTV.com. April 30, 2012.

This news piece discusses pharmacy medication dispensing errors and describes how patients can help prevent them.

[Free full text](#)

Related Resources

AUDIOVISUAL

NJ CVS mixed up cancer meds with kids' fluoride.

Greenblatt M. ABC News. March 3, 2012.

NEWSPAPER/MAGAZINE ARTICLE

Find Related Resources by...

Resource Type

- Newspaper/Magazine Article

Setting of Care

- Outpatient Pharmacy

Target Audience

- Patients

Clinical Area

- Pharmacy

Safety Target

- Dispensing Errors

Error Types

- Cognitive Errors ("Mistakes")

Approach to Improving Safety

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 that patients suffer an ADE?
- IHI has a free trigger tool to help hospitals measure these rates if they are not currently doing this
- Includes how to measure the number and degree of harmful medication events
 - www.ihl.org/resources/Pages/Tools/TriggerToolforMeasuringAdverseDrugEvents.aspx



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IHI Trigger Tool for Measuring Adverse Drug Events

Institute for Healthcare Improvement (in partnership with Premier, Inc., San Diego, California, USA)
Cambridge, Massachusetts, USA

The use of "triggers," or clues, to identify adverse drug events (ADEs) is an effective method for measuring the overall level of harm from medications in a health care organization. The Trigger Tool for Measuring Adverse Drug Events provides instructions for conducting a retrospective review of patient records using triggers to identify possible ADEs. This tool includes a list of known ADE triggers and instructions for measuring the number and degree of harmful medication events. The tool provides instructions and forms for collecting the data you need to measure [ADEs per 1,000 Doses](#) and [Percent of Admissions with an ADE](#).

Read the related article about using the Trigger Tool:

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 lovastatin. 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 safety concerns for their patients can reduce potential adverse

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
- Focuses on opportunities for federal engagement: surveillance, prevention, incentives and oversights, and research
- Want to work with public sector in action plan
- 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 and private sector organizations, and communities who can organize and take action towards preventing high-priority ADEs.

National Action Plan for ADE

National Action Plan for Adverse Drug Event Prevention



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

HHS National Action Plan for ADE

National Action Plan for Adverse Drug Event Prevention

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

Contents

Foreword.....	iii
Contents.....	iv
List of Acronyms	viii
Executive Summary.....	1
Introduction	4
Adverse Drug Events: Magnitude of the Problem.....	5
Federal Interagency Steering Committee and Workgroups for ADEs.....	10
References.....	14
Section 1: National Action Plan Scope and Development.....	17
Scope of the National Action Plan for ADE Prevention.....	17
Framework for the National Action Plan for ADE Prevention.....	18
Development Process for the National Action Plan for ADE Prevention	19
References.....	22
Section 2: Surveillance Resources	23
Considerations for Choosing Surveillance Data Sources and Metrics.....	23
Federal Systems that Conduct ADE Surveillance.....	27
Future Considerations for Optimizing Federal ADE Surveillance Efforts	30
References.....	32
Section 3: Prevention Approaches	33
Key Determinants of ADEs.....	33
Affordable Care Act—Health Care Delivery Models	35
References.....	36
Section 4: Incentives and Oversight Opportunities	38
Regulatory Oversight.....	38
Value-based Purchasing Financial Incentives.....	41
Transparency and Associated Incentives	46

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
- 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

Antibiotic Stewardship Program

- CDC aims to cut C-diff 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

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_antibiotic-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



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Antimicrobial Stewardship

User Guide

The toolkit is composed of three sections:

- **Hospital and Health System Resources** - includes a readiness assessment tool, the starting point in developing or enhancing a successful Antimicrobial Stewardship Program (ASP). The tool, a checklist developed by the CDC, should be shared with senior management, a senior leader for quality, purchasing directors, clinic managers, nurse managers, key physician leaders, risk managers, pharmacy leaders, infection preventionists and hospital epidemiologists, laboratory staff and information technology staff. For ease of use, it is divided into two sections, one for those just beginning a program, the other for those who wish to enhance an existing program.
- **Clinician Resources** - includes webinars, clinical evidence supporting appropriate use of antibiotics, implementation guides and related articles.
- **Patient Resources** - includes frequently asked questions, pamphlets and handouts on how patients can best engage in their care and resources on appropriate use of antibiotics.

The CDC Assessment Tool

This checklist will assist hospitals in assessing key elements needed for creating a program that ensures optimal antibiotic prescribing and appropriate use. The key elements of a successful ASP include leadership commitment, accountability, drug expertise, action, tracking, reporting and education. To access the checklist, [click here](#) »

Hospital and Health System Resources

GETTING STARTED

CDC Core Elements of Hospital Antibiotic Stewardship Programs

This document summarizes core elements of successful hospital ASPs. It complements existing guidelines on ASPs from organizations including the IDSA in conjunction with SHEA, ASHP and The Joint Commission. Experience demonstrates that antibiotic stewardship programs can be implemented effectively in a wide variety of hospitals and health systems and that success is dependent on defined leadership and a coordinated multidisciplinary approach. To download, [click here](#) »

Antibiotic Rx in Hospitals: Proceed with Caution

This fact sheet from CDC illustrates how antibiotics save lives, but poor prescribing practices put patients at unnecessary risk for preventable allergic reactions, super-resistant infections and deadly diarrhea. Errors in prescribing decisions also contribute to

www.ahaphysicianforum.org/resources/appropriate-use/antimicrobial/index.shtml



Download the Antimicrobial Stewardship Toolkit

The Hospital's Role

The misuse or overuse of antibiotics remains a global public health concern, contributing to antibiotic resistance and increased patient morbidity and mortality. Hospital antimicrobial stewardship programs have proven effective in improving appropriate antibiotic use, reducing adverse events and enhancing quality

Antimicrobial Stewardship Toolkit

Greater New York Hospital Association
United Hospital Fund

www.shea-online.org/Portals/0/GNYHA_Antimicrobial_Stewardship_Toolkit_FINALv2%20Dec2011.pdf

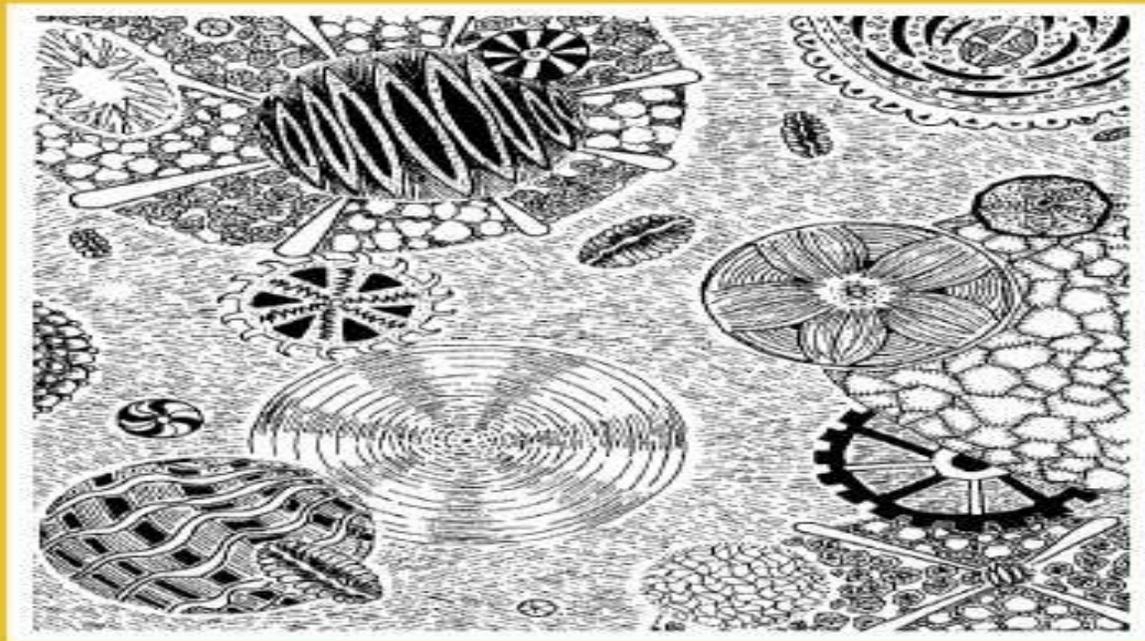


ANTIMICROBIAL STEWARDSHIP TOOLKIT

BEST PRACTICES FROM THE GNYHA/UHF ANTIMICROBIAL STEWARDSHIP COLLABORATIVE

Follow Antibiotic Guidelines

Antibiotic Guidelines 2014-2015



**Treatment Recommendations
For Adult Inpatients**

Also available online at
insidehopkinsmedicine.org/amp

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

CDC Toolkit on Antibiotic Prescribing

Vital Signs

- Preventing Melanoma
- About Vital Signs
- Vital Signs Social Media
- Other Vital Signs Issues

Related Links

- Download this factsheet [PDF - 1.44 MB]
- en Español [PDF - 1.13 MB]
- CDC Digital Press Kit
- [Read the MMWR»](#)
- [Science Clips»](#)

www.cdc.gov/vitalsigns/antibiotic-prescribing-practices/index.html



Making Health Care Safer

Antibiotic Rx in Hospitals: Proceed with Caution
March 2014

Vital^{CDC}signs™



1 in 2
More than half of all hospital patients receive an antibiotic.



3x
Doctors in some hospitals prescribed 3 times as many antibiotics as doctors in other hospitals.



30%
Reducing the use of high-risk antibiotics by 30% can lower deadly diarrhea infections by 26%.

Antibiotics save lives, but poor prescribing practices are putting patients at unnecessary risk for preventable allergic reactions, super-resistant infections, and deadly diarrhea. Errors in prescribing decisions also contribute to antibiotic resistance, making these drugs less likely to work in the future.

To protect patients and preserve the power of antibiotics, hospital CEOs/medical officers can:

- Adopt an antibiotic stewardship program that includes, at a minimum, this [checklist](#):
 1. Leadership commitment: Dedicate necessary human, financial, and IT resources.
 2. Accountability: Appoint a single leader responsible for program outcomes. Physicians have proven successful in this role.
 3. Drug expertise: Appoint a single pharmacist leader to support improved prescribing.

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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
- 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		Sum
<p>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).</p>	<input type="radio"/> Yes <input type="radio"/> No	
<p>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.</p>	<input type="radio"/> Yes <input type="radio"/> No	
<p>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.</p>	<input type="radio"/> Yes <input type="radio"/> No	
<p>If no to any part of 1.C.1 through 1.C.3, cite at 42 CFR 482.42(a) (Tag A-0749)</p>		
<p>1.C.4 The hospital can provide a list of target MDROs.</p> <p>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</p>	<input type="radio"/> Yes <input type="radio"/> No	
<p>1.C.5 The hospital can demonstrate the criteria used to determine epidemiologically important MDROs on their list.</p>	<input type="radio"/> Yes <input type="radio"/> No	
<p>1.C.6 The hospital can provide justification for any epidemiologically important organisms not on their list and otherwise not targeted in their hospital.</p>	<input type="radio"/> Yes <input type="radio"/> 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

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

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 in hospitals when assessing compliance with any of these three CoPs.
- **Final Worksheets Made Public:** Via this memorandum we are making the worksheets publicly available. The hospital industry is encouraged, but not required, to use the worksheets as part of their self-assessment tools to promote quality and patient safety.

Ca First State to Enact Antimicrobial Stewardship Program



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Search
 This site California

- Home
- Programs
- Services
- Health Information
- Certificates & Licenses
- Publications & Forms
- Data

Home > Programs > Healthcare Associated Infections Program > Antimicrobial Stewardship Program Initiative

The California Antimicrobial Stewardship Program Initiative

The use of antibiotics is the most important factor in the development of antimicrobial resistance. Antimicrobial stewardship programs aim to promote and measure use of the appropriate agent, dose, duration, and route of administration of antimicrobial agents, in order to improve patient outcomes while minimizing adverse events including toxicity, *Clostridium difficile* infections and the emergence of antimicrobial resistant organisms. Antimicrobial stewardship programs improve the quality of patient care and patient safety, and can also reduce excessive costs attributable to inappropriate antimicrobial use.

California is the first and remains the only state to enact antimicrobial stewardship legislation. Since 2008 California law required that general acute care hospitals develop a process for monitoring the judicious use of antibiotics and that the results are monitored by quality improvement committee(s). In September 2014, California Senate Bill 1311 was signed into law, further requiring hospitals to adopt and implement an antimicrobial stewardship policy in accordance with guidelines established by federal government and professional organizations, and to establish a physician-supervised multidisciplinary antimicrobial stewardship committee with at least one physician or pharmacist who has undergone specific training related to stewardship. Nationally, a presidential Executive Order - Combatting Antibiotic-Resistant Bacteria, also issued in September 2014, requires federal agencies to review existing regulations and propose new regulations or other actions to require hospitals to implement robust stewardship programs that adhere to best practices; agencies will also be required to define, promulgate and implement stewardship programs in other settings such as long-term care facilities and outpatient settings.

The CDPH HAI Program California Antimicrobial Stewardship Program Initiative provides guidance and support for California hospitals and other healthcare facilities to implement these important local programs.

California Antimicrobial Stewardship Program Initiative activities:

- **New** [Practical Antimicrobial Stewardship: Implementation and Expansion in Healthcare Facilities](#) presented by IDAC and CDPH on July 18, 2015 in Irvine, CA
- **New** [CDPH Antimicrobial Stewardship Program \(ASP\) Toolkit 2015](#)
- The HAI Program has launched a statewide [Antimicrobial Stewardship Program \(ASP\) Collaborative](#), with the goal of ensuring that all California hospitals have a functional and robust ASP to promote patient safety and to decrease antimicrobial resistance. The Collaborative will extend for 1 year, from January through December 2015.
- **Updated** The Spotlight on Antimicrobial Stewardship Programs project, helps define antimicrobial stewardship programs and activities, and spotlights volunteer hospitals that wish to highlight their programs and share their progress with others. The [Spotlight on ASP Project Invitation 2014](#) remains open to allow additional hospitals to participate.
- Use results from a statewide assessment of antimicrobial stewardship programs conducted during May 2010-September 2011 ([The State of Antimicrobial Stewardship in California](#)) to provide evidence-based recommendations for implementing or strengthening antimicrobial stewardship programs depending on facility attributes and resources.
- Develop recommendations with the [Antimicrobial Stewardship Subcommittee](#) of the California HAI Advisory Committee.
- Define activities that comprise antimicrobial stewardship programs in California hospitals.

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

AHRQ C-Diff Toolkits



Agency for Healthcare Research and Quality
Advancing Excellence in Health Care



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Previous Page Table of Contents Download Next Page

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

- Clinicians & Providers
- Education & Training
- Hospitals & Health Systems
- Prevention & Chronic Care
- Quality & Patient Safety**
 - AHRQ's Healthcare-Associated Infections Program
 - Comprehensive Unit-based Safety Program (CUSP)
 - Partnership for Patients
 - Patient and Family Engagement
 - Patient Safety Measure Tools & Resources

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

Publication # 12-0082-EF

[Go to Online Store](#)

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

Antimicrobial stewardship for reducing C. difficile offers a potentially promising path for facilities invested in and committed to the effort. Developing and implementing a successful ASP will involve structural, process, and cultural changes in your organization. To effect the changes needed in clinical practice, organizations require multiple adjustments in roles, responsibilities, workflow, decisionmaking, and communication.

Failure to assess your organization's readiness for the change at multiple levels can lead to unanticipated implementation challenges. Bringing about organizational change of any type is difficult. You will not want to move ahead until you are confident of your organization's readiness. Even then, it will be important to balance the need to proceed thoughtfully with the need to move quickly enough to show progress and maintain momentum.

Consider the following questions as you evaluate your organization's readiness and identify action steps to prepare.

1.1. Do we have the appropriate ASP foundation on which to build?

This toolkit assumes that your hospital already has an ASP or the foundation for an ASP from which to launch the ASP

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
- 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



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-15-Hospital

DATE: March 14, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

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

Final for IV Medication, Opioid

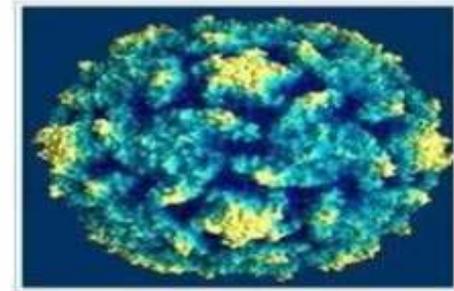
State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

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-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

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

MEDICAL CENTER HOSPITAL
500 - 600 W. 4TH STREET ODESSA, TEXAS PH. 335-7111

FOR Varguez Ramon AGE _____
ADDRESS 1150 W. 4th St DATE 6/23/95

NO REFILLS Plendil 20mg # 120 -
20mg P.O. Q6hr
REFILLS Ferron sulfate 300mg # 100
300mg P.O. TID c meals
LABEL Humulin N
30 units SQ QAM
Ram/Colm

PRODUCT SELECTION PERMITTED DISPENSE AS WRITTEN

D.E.A. #

728 037 2-88 04 88-270

(Ref. BMJ 1999; 319: 1456)

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Write Legibly

- Nephrologist 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 professionals should have known better than to believe anyone would prescribe such

9. Writing Letters and Numbers

- FDA and ISMP note four most common mistakes and helpful in writing prescriptions
 - Between the letter “I” 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 www.jointcommission.org/ealerts/

The screenshot shows the website header with the logo and navigation links. The main navigation bar includes 'Accreditation', 'Certification', 'Standards', 'Measurement', 'Topics', 'About Us', and 'Daily Update'. The page title is 'Topic Details' and the breadcrumb is 'Home > Topic Details'. A sidebar on the left contains a 'Sign up for News and Alerts' box with a 'Sign up here' button. The main content area is titled 'Topic Library Item' and features the article 'Joint Commission Website E-Alerts' dated April 1, 2013. The article text describes the e-alert service and provides a link to sign up. A right-hand sidebar contains social media sharing icons for Twitter, Facebook, Google+, and LinkedIn, along with a 'Share' button and a counter showing '0'.

The Joint Commission

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Topic Details Saturday 3:25 CST Jul 13 2013

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Topic Library Item

Joint Commission Website E-Alerts

April 1, 2013

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

New - E-alerts now available for Joint Commission Podcasts - update your subscription to sign up today!

[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, and podcasts
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TJC Website Has all SEAs

The screenshot displays the homepage of The Joint Commission website, specifically the Sentinel Event Alert section. The header includes the logo and navigation links such as 'Log In | Request Guest Access', 'Contact Us | Careers | JCR Web Store | Press Room', and a search bar. The main navigation bar features categories like Accreditation, Certification, Standards, Measurement, Topics, About Us, and Daily Update. The breadcrumb trail reads 'Home > Topics > Sentinel Event - Sentinel Event Alert'. The main content area is titled 'Sentinel Event' and features a link to 'www.jointcommission.org/sentinel_event.aspx'. The primary article is 'Patient Safety Systems Chapter and the Sentinel Event Policy', which discusses the relationship between accreditation and patient safety. A quote from Ronald M. Wyatt, MD, MHA, is included. Below the article are sections for 'Sentinel Event Alert', 'Sentinel Event Alert Webinar Replays', and 'Statistics'. A sidebar on the right contains a 'Sign up for Sentinel Event Alert' box with 213 shares, 'Quick Safety' links, and 'Patient Safety Systems' resources. Social media sharing icons for Twitter, Facebook, Google+, and Print are visible at the top right of the article area.

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Accreditation Certification Standards Measurement **Topics** About Us Daily Update

Home > Topics > Sentinel Event - Sentinel Event Alert Twitter Facebook Google+ Share Print

Sunday 8:08 CST, June 14, 2015

Sentinel Event

www.jointcommission.org/sentinel_event.aspx

Sentinel Event Alert

- Sentinel Event Alert 54: Safe use of health information technology
- Sentinel Event Alert 53: Managing risk during transition to new ISO tubing connector standards

[View More](#)

Sentinel Event Alert Webinar Replays

- Sentinel Event Alert Issue 51: Preventing unintended retained foreign objects
- Sentinel Event Alert Issue 50: Medical device alarm safety in hospitals

Statistics

- Sentinel Event Data
- Sentinel Event Data

Patient Safety Systems Chapter and the Sentinel Event Policy

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.

Both the Patient Safety Systems Chapter and the Sentinel Policy are designed to be used together.

- [Patient Safety Systems Chapter](#)
- [Patient Safety Systems Chapter](#)

Sign up for Sentinel Event Alert

213 [Share](#)

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Quick Safety

- Quick Safety - Issue Thirteen, May 2015
- Quick Safety - Issue Two April 2015

[View More](#)

Patient Safety Systems

- Patient Safety Systems Chapter for the Hospital program

Forms and Tools

- Framework for Conducting a Root Cause Analysis and Action Plan

TJC Sentinel Event Alerts on Medications

- SEA Managing Risks during transition to new tubing connectors
- SEA 49 Safe Use of Opioids
- 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

Sentinel Event Alert

- [Sentinel Event Alert Issue 49: Safe use of opioids in hospitals](#)
- [Sentinel Event Alert Issue 48: Health care worker fatigue and patient safety](#)

[View More](#)

Statistics

- [Sentinel Event Data Summary](#)
- [Sentinel Event Data - General Information](#)
- [Sentinel Event Data - Event Type by Year](#)

[< Back](#)

Topic Library Item

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.



Opioids Toolkit PaPSA



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

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

Educational Tools

Opioids



There are many published studies and reported events that demonstrate potential gaps in the knowledge regarding the use of opioids. Assessment of knowledge in a healthcare facility, such as through the assessment tool included below, and analysis may be helpful in identifying knowledge gaps and in developing improvement strategies to reduce medication errors associated with opioid use.

Prevention Program Tools



[Opioid Knowledge Self-Assessment](#)

Articles

[Results of the PA-HEN Organization Assessment of Safe Practices for a Class of High-Alert Medications](#)

As a part of the Pennsylvania Hospital Engagement Network (HEN) adverse drug event collaboration, Authority analysts developed an assessment tool to help participating hospitals assess the safety of opioid practices in their facilities and identify opportunities for improvement.

[Results of the Opioid Knowledge Assessment from the PA Hospital Engagement Network Adverse Drug Event Collaboration](#)

To address opioid knowledge gaps among Pennsylvania practitioners, facilities may consider assessing staff understanding of opioids and providing training, specifically regarding assessment of patients for adverse drug reactions, recognizing advancing sedation, and making timely adjustments to the plan of care based on the patient's risk.

11. Implement a Safe Process for Opioids

- Hot issues in the news right now for many reasons
- July 5, 2013 CDC issued memo and found high rate of fatal drug overdose and drug misuse
 - In 2010, total of 15,323 deaths due to drug overdose
 - Deaths increased fivefold for women
 - More women die from drug OD than motor vehicles accidents
 - In 2010 there were 943,365 visits by women for drug misuse
- Many emergency departments have new policy on prescribing but don't post in ED lobby due to EMTALA

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 main management specialist or pharmacist of pain management plan and ensure staff is aware

Overdose of Rx Opioid Pain Relievers

CDC Home



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

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

Morbidity and Mortality Weekly Report (MMWR)

www.cdc.gov/mmwr/preview/mmwrhtml/mm6226a3.htm?s_cid=mm6226a3_w



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Vital Signs: Overdoses of Prescription Opioid Pain Relievers and Other Drugs Among Women – United States, 1999-2010

Weekly

July 5, 2013 / 62(26);537-542

On July 2, this report was posted as an MMWR Early Release on the MMWR website (<http://www.cdc.gov/mmwr>).

Abstract

Background: Overdose deaths have increased steadily over the past decade. This report describes drug-related deaths and emergency department (ED) visits among women.

Methods: CDC analyzed rates of fatal drug overdoses and drug misuse- or abuse-related ED visits among women using data from the National Vital Statistics System (1999–2010) and the Drug Abuse Warning Network (2004–2010).

Results: In 2010, a total of 15,323 deaths among women were attributed to drug overdose, a rate of 9.8 per 100,000 population. Deaths from opioid pain relievers (OPRs) increased fivefold between 1999 and 2010 for women; OPR deaths among men increased 3.6 times. In 2010, there were 943,365 ED visits by women for drug misuse or abuse. The highest ED visit rates were for cocaine or heroin (147.2 per 100,000 population), benzodiazepines (134.6), and OPR (129.6). ED visits related to misuse or abuse of OPR among women more than doubled between 2004 and 2010.

Conclusions: Although more men die from drug overdoses than women, the percentage increase in deaths since 1999 is greater among women. More women have died each year from drug overdoses than from motor vehicle–related injuries since 2007. Deaths and ED visits related to OPR continue to increase among women. The prominent involvement of psychotherapeutic drugs, such as benzodiazepines, among overdoses provides insight for prevention opportunities.

Implications for Public Health Practice: Health-care providers should follow guidelines for responsible prescribing, including screening and monitoring for substance abuse and mental health problems, when prescribing OPR. Health-care providers who treat women for pain should use their state's

Many States are Taking This Initiative

Ohio.gov State Agencies | Online Services



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

Drug Overdose

Prescription for Prevention Campaign

Drug Overdose Data and Publications

Violence and Injury Prevention Program

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

The Governor's Cabinet Opiate Action Team (GCOAT) was established in the fall of 2011 to address the continuing epidemic of misuse and abuse and overdose from prescription opioids. The GCOAT consists of five working groups: (1) Treatment--includes Medication Assisted Treatment; (2) Professional Education; (3) Public Education; (4) Enforcement; and (5) Recovery Supports.

Under the leadership of Dept. of Health Director Dr. Ted Wymyslo and Department of Aging Director Bonnie Kantor-Burman, the Opioids and other Controlled Substances guidelines were developed through a multidisciplinary effort involving many state medical and health care associations, emergency departments and acute care facilities, state agencies and boards, as well as individual physicians, nurses and other clinicians.



Professional Education
Workgroup

Guidelines

[Prescribing Guidelines](#)

[Patient Handout](#)

[Frequently Asked Questions](#)

Background Document

[Background Document](#)

www.healthyohioprogram.org/ed/guidelines

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.
 - b. Receive the right to request a photo ID to
4. Obtain a photo ID from the patient or family member.
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 safely prescribe
 - Risk Evaluation and Mitigation Strategy (REMS)



SEARCH

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- [Medical Devices](#)
- [Radiation-Emitting Products](#)
- [Vaccines, Blood & Biologics](#)
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www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm



FDA NEWS RELEASE

For Immediate Release: Sept. 10, 2013

Media Inquiries: Morgan Liscinsky, 301-796-0397, morgan.liscinsky@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

[En Español](#)

FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics

New boxed warning to include neonatal opioid withdrawal syndrome

The U.S. Food and Drug Administration today announced class-wide safety labeling changes and new postmarket study requirements for all extended-release and long-acting (ER/LA) opioid analgesics intended to treat pain.

"The FDA is invoking its authority to require safety labeling changes and postmarket studies to combat the crisis of misuse, abuse, addiction, overdose, and death from these potent drugs that have harmed too many patients and devastated too many families and communities," said FDA Commissioner Margaret A. Hamburg, M.D. "Today's action demonstrates the FDA's resolve to reduce the serious risks of long-acting and extended release opioids while still seeking to preserve appropriate access for those patients who rely on these medications to manage their pain."

Given the serious risks of using ER/LA opioids, the class-wide labeling changes, when final, will include important new language to help health care professionals tailor their prescribing decisions based on a patient's individual needs.

The updated indication states that ER/LA opioids are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

The updated indication further clarifies that, because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, these drugs should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain; ER/LA opioid analgesics are not indicated for as-needed pain relief.

"The FDA's primary tool for informing prescribers about the approved uses of medications is the product labeling," said Douglas Throckmorton, M.D., deputy director for regulatory programs in the FDA's Center for Drug Evaluation and Research. "These labeling changes describe more clearly the risks and safety concerns associated with ER/LA opioids and will encourage better, more appropriate, prescribing, monitoring and patient counseling practices involving these drugs."

Recognizing that more information is needed to assess the serious risks associated with long-term use of ER/LA opioids, the FDA is requiring the drug companies that make these products to conduct further studies and clinical trials. The goals of these postmarket requirements are to further assess the known serious risks of misuse, abuse, increased sensitivity to pain (hyperalgesia), addiction, overdose, and death.

The FDA is also requiring a new boxed warning on ER/LA opioid analgesics to caution that chronic maternal use of these products during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening and require management according to protocols developed by neonatology experts. NOWS can occur in a newborn exposed to opioid drugs while in the mother's womb. Symptoms may include poor feeding, rapid breathing, trembling, and excessive or high-pitched crying.

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/signForNews.aspx
- 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

The screenshot shows the AHRQ PSNet website. At the top, there is a blue header with the U.S. Department of Health & Human Services logo and the URL www.hhs.gov. Below this is a yellow banner with the AHRQ logo and the text "Agency for Healthcare Research and Quality" and "Advancing Excellence in Health Care". The main content area has a blue background with the PSNet logo and "patient safety network". A search bar with a "SEARCH" button is visible. A navigation menu includes "Home", "What's New", "The Collection", "Patient Safety Primers", "Glossary", "Subscribe", "My PSNet", and "About". A "webM&M" logo with the text "Visit Now morbidity & mortality rounds on the web" is also present. The main content area features a "Subscribe to Newsletter" section with the URL www.psnet.ahrq.gov/newsletter.aspx. Below this, there are two subscription options, each with a "Yes" radio button selected and a "No" radio button unselected. The first option is for the "AHRQ PSNet newsletter" and the second is for the "AHRQ WebM&M newsletter".

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

AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care www.ahrq.gov

AHRQ PSNet patient safety network

SEARCH

webM&M Visit Now
morbidity & mortality rounds on the web

Home What's New The Collection Patient Safety Primers Glossary **Subscribe** My PSNet About

Subscribe to Newsletter www.psnet.ahrq.gov/newsletter.aspx

I want to subscribe to the AHRQ PSNet newsletter
 Yes No

The **AHRQ PSNet** email newsletter offers you the latest patient safety information and news every week.

I want to subscribe to the AHRQ WebM&M newsletter
 Yes No

The **AHRQ WebM&M** email newsletter alerts you when the latest issue of the monthly journal of cases, commentaries, and perspectives on medical error is available.



SEARCH

webM&M Visit Now
morbidity & mortality rounds on the web

The Collection > Medication Errors/Preventable Adverse Drug Events

www.psnet.ahrq.gov/collectionBrowse.aspx?taxonomyID=416
Click on The Collection and then Medication Error



PATIENT SAFETY PRIMERS
Medication Errors

Narrow By

clear selections 1 - 20 of 1664

Show Excerpt Don't Show Excerpt

Sort by date ▾

Safety Target

< All

Medication Errors/Preventable Adverse Drug Events

- Ordering/Prescribing Errors (325)
- Transcription Errors (44)
- Dispensing Errors (104)
- Administration Errors (363)
- Monitoring Errors and Failures (24)

Origin/Sponsor

- Africa (3)
- Asia (37)
- Australia and New Zealand (54)
- Central and South America (9)
- Europe (257)
- North America (1240)

Resource Types

- Audiovisual (24)
- Award (4)
- Book/Report (37)

UPCOMING MEETING/CONFERENCE

Measuring medication safety: using the right data for the best results.

Institute for Safe Medication Practices. July 18, 2013; 1:30–3:00 PM (Eastern).

STUDY

Return on investment for vendor computerized physician order entry in four community hospitals: the importance of decision support.

Zimlichman E, Keohane C, Franz C, et al. Jt Comm J Qual Patient Saf. 2013;39:312-318.

STUDY

Clinical relevance of and risk factors associated with medication administration time errors.

Teunissen R, Bos J, Pot H, Pluim M, Ramers C. Am J Health Syst Pharm. 2013;70:1052-1056.

REVIEW

Information technology interventions to improve medication safety in primary care: a systematic review.

Lainer M, Mann E, Sönnichsen A. Int J Qual Health Care. 2013 Jun 15; [Epub ahead of print].

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

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

The screenshot shows the FDA website's 'Safe Use Initiative' page. At the top, the FDA logo and 'U.S. Food and Drug Administration' are displayed, along with navigation links for 'A to Z Index', 'Follow FDA', and 'En Español'. A search bar is present. Below the navigation menu, the 'Drugs' section is active. The main content area features a large blue banner with the 'SAFE USE' logo and the text 'collaborating to reduce preventable harm from medications'. Below this, a paragraph explains the initiative's goal: to reduce preventable harm from medications by identifying risks and developing interventions. A 'Spotlight' section highlights a 'Funding and Support Update' with a 'New!!' tag. A 'Contact FDA' section provides the phone number 301-796-7600, email CDERPASE@fda.hhs.gov, and the address of the Safe Use Initiative Team. A sidebar on the left contains links for 'Safe Use Initiative - Current Projects', 'Safe Use Initiative - Completed Projects', 'Funding and Support', and 'Resources for You'.

Safe Use Initiative

Collaborating to Reduce Preventable Harm from Medications

SAFE USE collaborating to reduce preventable harm from medications

Today, tens of millions of people in the United States depend on prescription and OTC medications to sustain their health—more than four billion prescriptions are written annually. Too many people, however, suffer unnecessary injuries, and some die as a result of preventable medication errors. The U.S. Food and Drug Administration (FDA) believes that many of these medication-related risks are manageable if parties committed to the safe use of medications work together.

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.

Spotlight

- **Funding and Support Update**
New!!

Contact FDA

301-796-7600
CDERPASE@fda.hhs.gov

Safe Use Initiative Team
Professional Affairs and Stakeholder Engagement (PASE)
Office of the Center Director
WO 51-2341
10903 New Hampshire Avenue
Silver Spring, MD 20993

Resources for You

- [Professional Affairs and Stakeholder Engagement](#)

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

Current Projects of Safe Use Initiative



U.S. Food and Drug Administration

Search FDA



[← back to Drug Safety and Availability](#)

Safe Use Initiative - Current Projects

- [Acetaminophen](#)
- [Atypical antipsychotic medication use in pediatric populations](#)
- [Epidural steroid injections](#)
- [Medication adherence](#)
- [Nonsteroidal anti-inflammatory drugs for the treatment of pain in geriatric patients](#)
- [Opioid misuse and abuse](#)
- [Opioid patient-prescriber agreement](#)
- [Opioid safe prescribing](#)
- [Preventing surgical fires](#)
- [Safe injection practices](#)
- [Unintentional medication overdoses in children](#)

Acetaminophen



Drugs

[Home](#) [Drugs](#) [Drug Safety and Availability](#) [Safe Use Initiative](#)

Drug Safety and Availability

[Safe Use Initiative](#)

[Safe Use Initiative Fact Sheet](#)

[Opportunities for Collaboration](#)

[Novel Interventions and Collaborations to Improve the Safe Use of Medications-- Cooperative Agreements](#)

[Acetaminophen Toxicity](#)

[Preventing Surgical Fires](#)

Acetaminophen Toxicity

Acetaminophen is one of the most commonly used medicines in the United States. When used according to the label directions, it has a well-established record of safety and efficacy. Although acetaminophen overdose is very rare in the context of its broad usage, overdose can be toxic and lead to acute liver failure.

Liver injury from acetaminophen overdose remains a serious public health problem despite ongoing regulatory and educational efforts over the past several years to improve the safe use of medicines that contain acetaminophen. Patients can take too much if they take more than the labeled dose of one acetaminophen medicine, or if they take more than one medicine containing acetaminophen (for example, an over-the-counter [OTC] medicine that contains acetaminophen with a prescription medicine that contains acetaminophen).

To prevent acetaminophen overdose, consumers need to be able to read labels and recognize when their medicines contain acetaminophen. The active ingredients in OTC medicines are clearly listed on the label, but the container labels on prescription medicines that contain acetaminophen may not clearly identify acetaminophen as an active ingredient.

Under the leadership of the National Council for Prescription Drug Programs (NCPDP), FDA's Safe Use Initiative and a broad group of stakeholders came together to form the Acetaminophen Best Practices Task Group, which produced the white paper, "[NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen \(PDF- 974KB\)](#)." (For a list of Task Group members, see Appendix D, "Contributors to this White Paper.")

These recommendations are intended to make it easier for consumers to: 1) identify that their prescription pain reliever contains acetaminophen. 2) compare active ingredients on their prescription and over-the-

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, VinCRISTine 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 <i>Maximum 5 doses in 24 hours</i>		Infants' Concentrated Drops 80 mg/ 0.8 mL Dropperful (Use only the dropper provided)	Children's Suspension Liquid 160 mg/ 5 mL Teaspoon (tsp)	Children's Soft Chews Chewable 80 mg each Tablet	Junior Strength Chewable 160 mg each Tablet	Adult Regular Strength 325 mg each Tablet
Weight	Age					
6-11 lbs	0-3 mos	$\frac{1}{2} = 0.4 \text{ mL}$				
12-17 lbs	4-11 mos	1 = 0.8 mL	$\frac{1}{2} \text{ tsp}$			
18-23 lbs	12-23 mos	$1 \frac{1}{2} = 0.8 + 0.4 \text{ mL}$	$\frac{3}{4} \text{ tsp}$			
24-35 lbs	2-3 yrs	2 = 0.8 + 0.8 mL	1 tsp	2	1	
36-47 lbs	4-5 yrs		1 $\frac{1}{2}$ tsp	3	1 $\frac{1}{2}$	
48-59 lbs	6-8 yrs		2 tsp	4	2	
60-71 lbs	9-10 yrs		2 $\frac{1}{2}$ tsp	5	2 $\frac{1}{2}$	1
72-95 lbs	11 yrs		3 tsp	6	3	1 $\frac{1}{2}$
96 lbs +	12 yrs +		4 tsp	8	4	2

Ibuprofen Dosing Chart

Ibuprofen (Motrin, Advil) Dose every 6 to 8 hours <i>Maximum 4 doses in 24 hours</i>		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.
- ¹ 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



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

EPOCRATES® ONLINE



DRUGS

DISEASES

m ✓

PILL ID

MEDCALC

TABLES

Drug Lookup:

Browse:

Drugs

[Alt Meds](#)

Select formulary:

No Formulary Selected

Drug Names

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

2-PAM (common name)
3TC (common name)
8-MOP
A+D Cream
A+D Ointment
A/B Otic
abacavir
abacavir/lamivudine
abacavir/lamivudine/zidovudine

close

Epocrates Online drug and disease reference provides:

- Access to extensive disease database
- Dosing for 3,300+ brand and generic drugs
- MultiCheck drug interaction checker
- 600 alternative medicines, including interactions*
- Pill identifier*

<http://www.epocrates.com/>

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
- 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.
- Syringes is marked “oral use only not for IV” and oral syringes are different **color** so nurse does not make 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

511

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.

Keep Current Copy of the CMS Hospital Manual

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

Table of Contents
(Rev. 137, 04-01-15)

[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

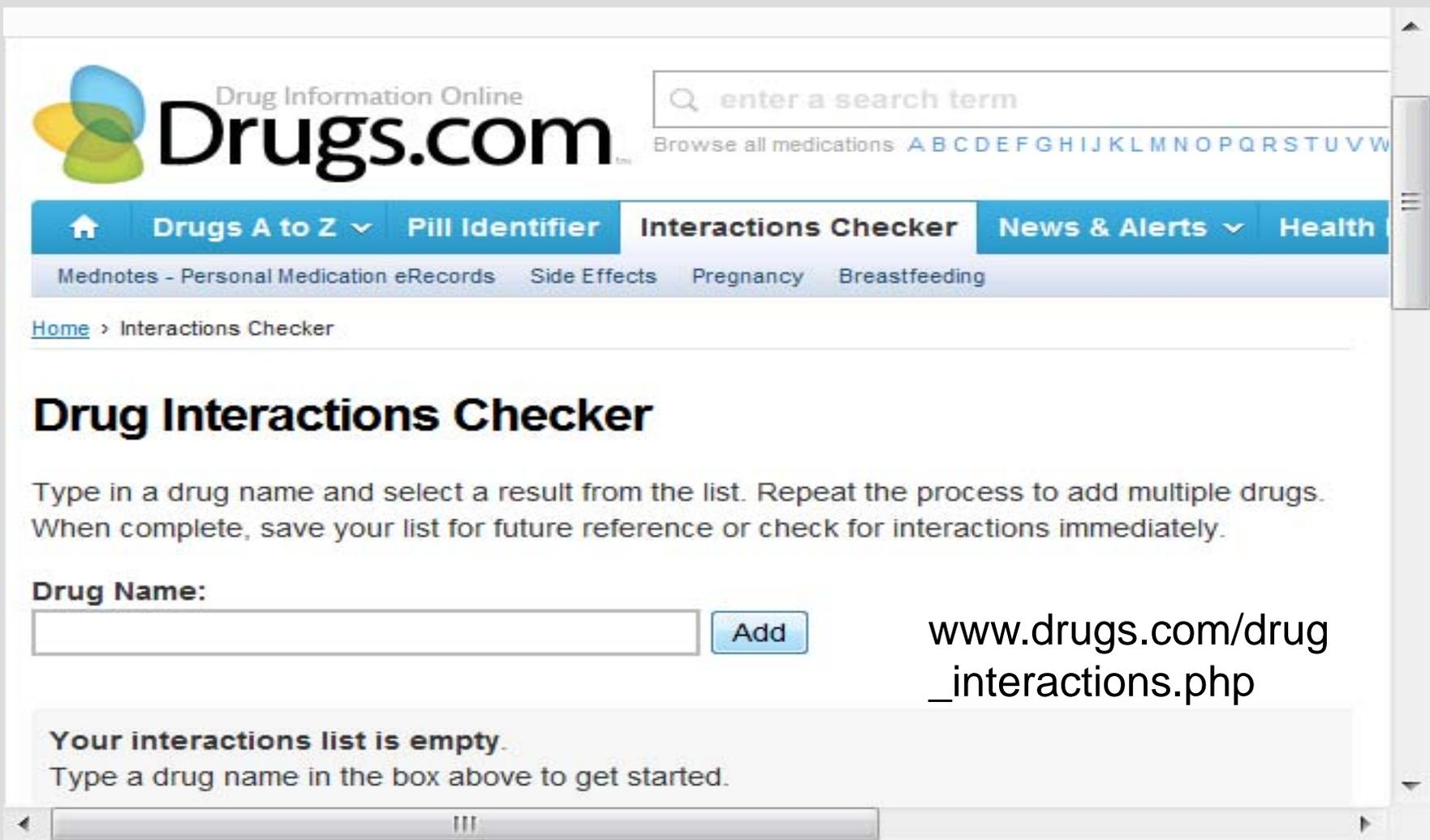
All the manuals are
located at

www.cms.hhs.gov/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
- Many good resources on drug on the internet which can also drug interactions

Drug Interactions Checker



The screenshot shows the Drugs.com website interface. At the top left is the Drugs.com logo with the tagline "Drug Information Online". To the right is a search bar with the placeholder text "enter a search term" and a magnifying glass icon. Below the search bar is a navigation menu with tabs for "Drugs A to Z", "Pill Identifier", "Interactions Checker" (which is highlighted), "News & Alerts", and "Health". Underneath the navigation menu are links for "Mednotes - Personal Medication eRecords", "Side Effects", "Pregnancy", and "Breastfeeding". A breadcrumb trail shows "Home > Interactions Checker". The main heading is "Drug Interactions Checker". Below this is a paragraph of instructions: "Type in a drug name and select a result from the list. Repeat the process to add multiple drugs. When complete, save your list for future reference or check for interactions immediately." There is a "Drug Name:" label followed by an empty text input field and an "Add" button. To the right of the input field is the URL "www.drugs.com/drug_interactions.php". Below the input field is a message box that says "Your interactions list is empty. Type a drug name in the box above to get started." At the bottom of the page is a horizontal scrollbar.

Drug Information Online
Drugs.com[™]

enter a search term

Browse all medications: [A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#) [H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#)

Home > Interactions Checker

Drug Interactions Checker

Type in a drug name and select a result from the list. Repeat the process to add multiple drugs. When complete, save your list for future reference or check for interactions immediately.

Drug Name:

www.drugs.com/drug_interactions.php

Your interactions list is empty.
Type a drug name in the box above to get started.

Drug Interaction Checker

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REFERENCE & Procedures

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Drug Interaction Checker

Print

Add a Drug

Use the search field to add a drug, OTC, or herbal.

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

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When should you
order stress testing?

Learn about the uses for stress MPI

Drug Interaction & Drug Information

ePOCRATES
an athenahealth company

Have an account? SIGN IN

DRUGS

DISEASES

INTERACTION CHECK

PILL ID

CALCULATORS

TABLES

PATIENT RESOURCES

Search. Diagnose. Treat.

Search Epocrates

<https://online.epocrates.com/>

Clinical Updates

Stay informed about important medical developments and current drug information.

» Read more

Patient Resources

View links to free patient education materials selected by the Epocrates clinical team.

» Read more

athenahealth Insights

Stay up-to-date on clinical data trends and thought leadership from our parent company.

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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 inform 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

Children Medications and Policies in the ED

American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

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 WORD

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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<http://pediatrics.aappublications.org/content/124/4/1233.full.pdf+html?sid=169edc0d-e224-4a05-ad3c-a71f3567e4de>

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 Surgical Association, Brain Injury Association of America, Child Health Con

<http://aappolicy.aappublications.org/cgi/reprint/pediatrics;124/4/1233.pdf>

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

IVMedication Compatibility Charts

- IV Medication Compatability Chart
- Low Vitamin D Symptoms
- Low Blood Pressure
- High Blood Pressure Medication
- IV Medication Compatibility Chart Privacy Policy
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	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)	Pancuronium (Pavulon)	Pantoprazole (Protonix)	
Albumin	Y						Y													Y										
Alteplase (Activase, rTPA)		Y						N	N							N			Y			Y								
Amiodarone (Cordarone)			Y	N	Y	Y	Y	Y	Y	Y	Y	Y		Y	!	N	Y	Y	Y	Y	!	Y	Y	Y	Y		Y		N	
Argatroban			N	Y	Y		Y	Y	Y					Y	Y				Y			Y	Y	Y	Y		Y			
Atropine			Y	Y	Y	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	Y	Y	Y	Y		N	Y	Y	Y			Y		N	
Cisatracurium (Nimbex)						Y	Y	Y	Y	Y	Y	Y		Y	!	!		Y	Y	Y	Y			Y			Y		N	
Diltiazem (Cardizem)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	N	!	!	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
Dobutamine (Dobutrex)		N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	!	!	!	Y	Y	Y	Y	Y	Y	Y	Y	??	Y	Y	Y	N
Dopamine		N	Y	Y	Y	Y	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	??	Y	Y	Y	Y
Esmolol (Brevibloc)			Y		Y	Y	Y	Y	Y	Y	Y	Y		Y	N	!	Y	Y	Y		Y	Y		Y		Y	Y	Y	Y	N
Etomidate (Amidate)					Y								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	Y	Y	N
Furosemide (Lasix)			!	Y	Y	Y	!	N	!	!	Y	N		Y	Y	Y	Y	Y	Y	!	Y	Y	!	Y	N	!	N	N	!	Y
Heparin		N	N		Y	Y	!	!	!	Y	Y	!		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	!	Y	Y	Y
Insulin, regular			Y		Y	Y	!	!	!	!	Y			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	!	N		!		Y	
Isoproterenol (Isuprel)			Y		Y	Y	Y	Y	Y	Y	Y	Y		Y	!	Y	N	Y	Y	Y	Y	Y	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	??	Y	Y		N	
Lorazepam (Ativan)	Y		Y			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y				Y	Y	Y	Y	Y	Y	Y	Y	Y	N	
Magnesium sulfate			!		Y	N	Y	Y	Y	Y	Y	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	Y	Y	Y	Y	Y	N	
Milrinone (Primacor)			Y	Y		Y	Y	Y	Y					Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	
Morphine			Y	Y	Y	Y	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	??	Y	Y	Y	Y		
Nicardipine (Cardene)							Y	Y	Y	Y	Y	Y		Y	N	!			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	
Norepinephrine (Levophed)			Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	!	Y	!	Y	Y	Y	Y	Y	Y	Y	Y	??	Y	Y	!	
Pancuronium (Pavulon)							Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
Pantoprazole (Protonix)			N			N	N	N	N	V	V	N		N	V	V	V	V	V	N	N	V	N	N	I		N	I	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

v03
10/01/2008



Getting Started Kit: Prevent Harm from High-Alert Medications

How-to Guide

A national initiative led by IHI, the 5 Million Lives Campaign aims to dramatically improve the quality of American health care by protecting patients from five million incidents of medical harm between December 2006 and December 2008. The How-to

www.ihl.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 its 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 include meds not FDA approved, investigational drugs, new ones, controlled substances, look-alike, ones with narrow therapeutic range

ISMP High Alert Medication Tool

ISMP Institute for Safe Medication Practices
A Nonprofit Organization Educating the Healthcare Community and Consumers About Safe Medication Practices

20 YEARS ADVANCING MEDICATION SAFETY

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2014-15 Targeted Medication Safety Best Practices for Hospitals

REVIEW DOCUMENTS

2014 Medication Safety Intensive

April 10 and 11, 2014 Washington, DC
May 30 and 31, 2014 Las Vegas, NV
October 2 and 3, 2014 Nashville, TN
December 5 and 6, 2014 Anaheim, CA

Click here for details

UPCOMING WEBINARS

Addressing Safety Challenges with U-500 Insulin (And did you know U-200 and U-300 insulin)

Education & Awareness

- Newsletters
- Consulting Services
- Educational Programs
- Let ISMP be your PSO
- Professional Development
- Self Assessments
- Consumers

Medication Safety Tools & Resources

Featured Tools

- New standards for healthcare connectors – the "Stay Connected" program
- The Root Cause Analysis Workbook for Community/ Ambulatory Pharmacy
- Special Error Alerts
- 2014-15 Targeted Medication Safety Best Practices for Hospitals
- ISMP Guidelines
- High-Alert Medications
- Confused Drug Name List
- Community Pharmacy Medication Safety Tools and Resources
- Error-Prone Abbreviation List

Report Medication Errors or Safety Concerns

Research-based Medication Safety Tools

FREE

- Consumer medication leaflets
- Risk-reduction scorecards software
- Bar-coding readiness assessment

Long-Term Care AdviseERR

NEW medication safety newsletter for LTC facilities.

SUBSCRIBE

Quarter Watch

http://www.ismp.org/tools/stayconnectedprogram.aspx

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
adrenergic agonists, IV (e.g., EPINEPH rine, phenylephrine, norepinephrine)
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)
antiarrhythmics, IV (e.g., lidocaine, amiodarone)
antithrombotic agents, including: <ul style="list-style-type: none"> ■ 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)
cardioplegic solutions

Specific Medications
epoprostenol (Flolan), IV
magnesium sulfate injection
methotrexate, oral, non-oncologic use
opium tincture
oxytocin, IV
nitroprusside sodium for injection
potassium chloride for injection concentrate
potassium phosphates injection
promethazine, IV

Have a Clear Policy on High Risk Meds



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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.¹

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)
- Anticonvulsants

- 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.

POLICY

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- Epidural infusions
- Fentanyl
- Heparin (>100 units, flushes exempt)
- Insulin (including regular, aspart, NPH, and glargine)
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- 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)
- 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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The Wisconsin Patient Safety Institute enhances and promotes patient safety by advocating for the adoption of safe practices in health care organizations throughout Wisconsin.

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

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 ⁴ daily
Obesity (wt ≥ 99kg)	1mg/kg ¹ q12h	100 units/kg ³ q12h
Moderate renal impairment	0.85mg/kg ¹ q12h	200 units/kg ² daily

Great Resource on Anticoagulants

DRUGS

Apixaban (Eliquis)	▶
Bivalirudin (Angiomax)	▶
Dabigatran (Pradaxa)	▶
Edoxaban (Savaysa)	▶
Fondaparinux (Arixtra)	▶
Heparin	▶
Low molecular weight heparins (LMWH)	▶
Rivaroxaban (Xarelto)	▶
Warfarin (Coumadin)	▶

CONDITIONS

Alternative monitoring of antithrombotic therapy	▶
Anticoagulation and neuraxial anesthesia	▶
Bleeding Risk Assessment	▶
Central venous catheter management	▶
Chronic antithrombotic therapy	▶
Guidelines for reversal of anticoagulation	▶

About UW Medicine Anticoagulation Services

The Anticoagulation Services program at UW Medicine is operated by the UW Medicine Department of Pharmacy.

Services encompass the management of anticoagulant therapy in pharmacist-managed anticoagulation clinics at the University of Washington Medical Center (UWMC), Seattle Cancer Care Alliance (SCCA) and Harborview Medical Center (HMC) as well as coordination of the use of antithrombotic agents in the inpatient setting.

Pharmacist providers are involved in clinical practice, training and education, and research activities consistent with the mission of UW Medicine and the Department of Pharmacy.

"The goals of pharmacist-managed anticoagulation services include treatment and prevention of thromboembolic disease and minimization of complications of antithrombotic therapy."

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[Read more](#)

NEW GUIDELINES for Conversion ("Switching") From One Anticoagulant to Another

In June 2015, UW Medicine Anticoagulation Services posted guidelines for converting from one anticoagulant to another. See the recommendations under the new purple tab titled "Anticoagulant Conversions ("Switching")" in the upper right hand corner of the home page.

[Read more](#)

NEW GUIDELINES for Management of Superficial Vein Thrombosis

In May 2015, new UW Medicine Guidelines for Management of Superficial Vein Thrombosis were approved. The new guidelines can be found in the VTE section of this website



MOST POPULAR

- Suggestions for converting to/from rivaroxaban
- Warfarin maintenance dosing nomogram
- UW Medicine alternative monitoring for antithrombotic agents
- Suggestions for converting to/from apixaban
- LMWH dosing guidelines
- Neuraxial guidelines
- Antithrombotic reversal guidelines
- Warfarin teaching booklets
- Refer a patient
- Washington State Anticoagulation Clinics

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
> 200	If < 6 hours since most recent bolus or rate change	Continue infusion at current rate, and repeat PTT at the appropriate time.
		1. TURN OFF HEPARIN INFUSION



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 standing orders is better described as a journey

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,

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

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 acs 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 it 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
- Hospitals must provide patient education and training on safe medication use
- This standard requires documentation of the response to the medications; pain medication relieved pain to 1/10, nausea medication resulted in no nausea or vomiting, etc.,
- Address any concerns with MD before administering
- Discuss any unresolved significant concerns about the medication with the prescriber

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,

26. 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

- 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 was April 1, 2015
- Anesthesia updates four times and has section on what is an anesthesia and analgesic
 - Has 486 pages and Tag 0001 to 1164
 - Pharmacy standards start at Tag A-0490
 - 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
- All CMS manuals are available at

Location of CMS Hospital CoP Manuals

Medicare State Operations Manual Appendix

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

CMS Hospital CoP Manuals **new** address

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

App. No.	Description	PDF File
A	Hospitals	 2.185 KB
AA	Psychiatric Hospitals	 606 KB

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 Dg only
- 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
- Surveyors to look at medications and if a risk for falls and unsteady gait
- 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

27. 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 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



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Drugs

- Home
- Drugs
- Drug Safety and Availability
- Drug Shortages

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



Drug Safety and Availability

- Drug Shortages
- Current Drug Shortages
- How to Report a Shortage or Supply Issue
- Resolved Drug Shortages
- Drugs to be Discontinued
- Frequently Asked Questions About Drug Shortages

Resources for You

- Drug Shortage Manual of Policies and Procedures (MaPP) (PDF - 149KB)
- Biologic Product Shortages

Drug Shortages

FDA takes great efforts, within its legal authority, to address and prevent drug shortages, which can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. The agency works closely with manufacturers of drugs in short supply to communicate the issue and to help restore availability. FDA also works with other firms who manufacture the same drug, asking them to increase production, if possible, in order to prevent or reduce the impact of a shortage.

Manufacturers are not required to report information, such as reasons for shortages or the expected duration of shortages. However, many companies voluntarily provide shortage information that FDA posts on its website. FDA encourages and appreciates all reporting of shortages by manufacturers. Shortage notifications and updates may be reported to FDA at drugshortages@fda.hhs.gov.

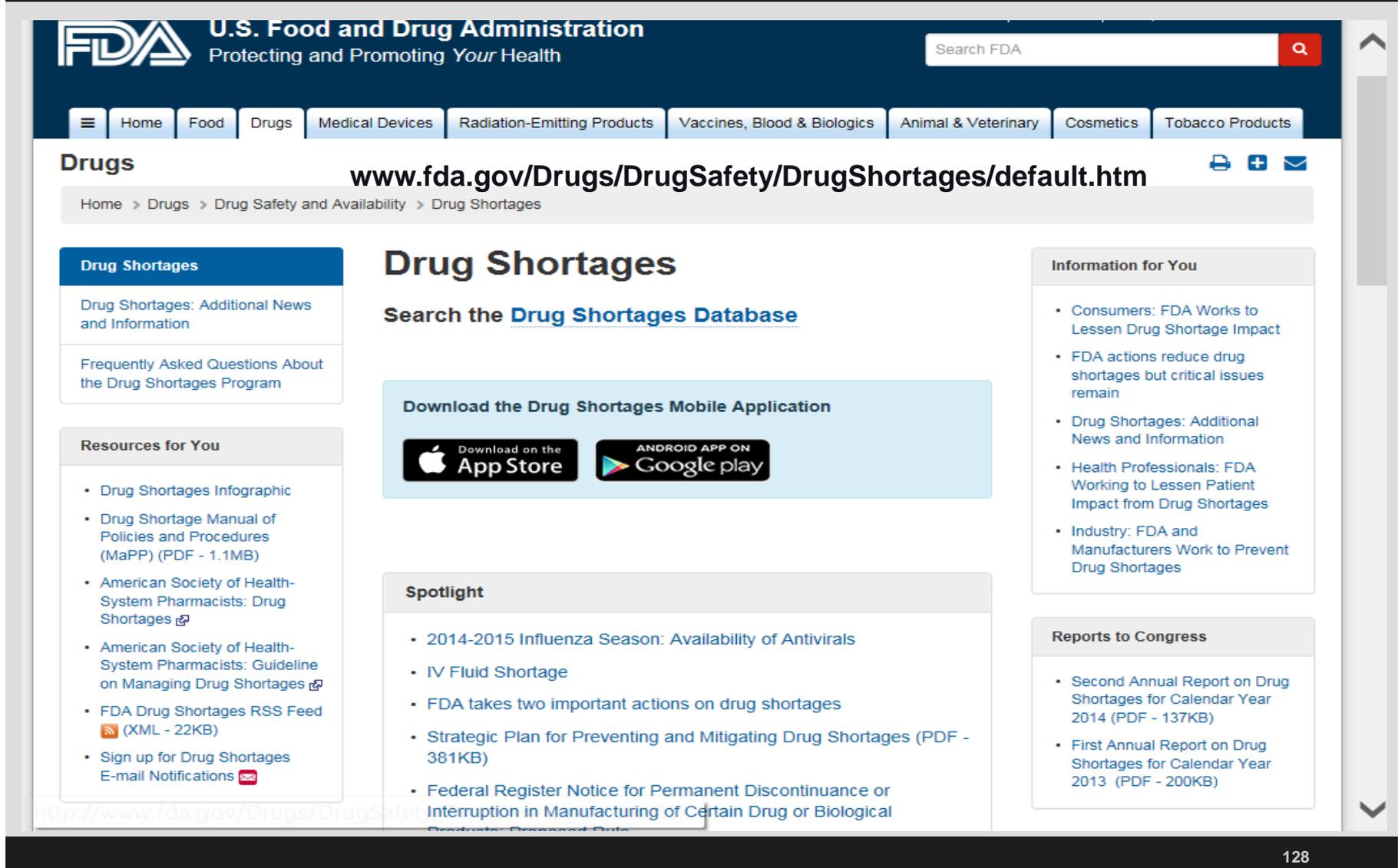


Drug Shortages Information

Spotlight

- FDA acts to bolster supply of critically needed cancer drugs
- Notification to FDA of Issues that May Result in a Prescription Drug or Biological Product Shortage (PDF - 226KB)
- Bedford Product Availability
- FDA Report: A Review of FDA's Approach to Medical Product Shortages
- Statement from FDA and HHS on Drug Shortages

FDA Drug Shortages Website



The screenshot shows the FDA Drug Shortages website interface. At the top, the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health" are visible. A search bar is located in the top right corner. Below the header is a navigation menu with tabs for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The "Drugs" tab is selected, and the page title is "www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm". The breadcrumb trail reads "Home > Drugs > Drug Safety and Availability > Drug Shortages".

Drug Shortages

Drug Shortages: Additional News and Information

Frequently Asked Questions About the Drug Shortages Program

Resources for You

- Drug Shortages Infographic
- Drug Shortage Manual of Policies and Procedures (MaPP) (PDF - 1.1MB)
- American Society of Health-System Pharmacists: Drug Shortages
- American Society of Health-System Pharmacists: Guideline on Managing Drug Shortages
- FDA Drug Shortages RSS Feed (XML - 22KB)
- Sign up for Drug Shortages E-mail Notifications

Drug Shortages

Search the [Drug Shortages Database](#)

Download the Drug Shortages Mobile Application

Download on the App Store | ANDROID APP ON Google play

Spotlight

- 2014-2015 Influenza Season: Availability of Antivirals
- IV Fluid Shortage
- FDA takes two important actions on drug shortages
- Strategic Plan for Preventing and Mitigating Drug Shortages (PDF - 381KB)
- Federal Register Notice for Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products

Information for You

- Consumers: FDA Works to Lessen Drug Shortage Impact
- FDA actions reduce drug shortages but critical issues remain
- Drug Shortages: Additional News and Information
- Health Professionals: FDA Working to Lessen Patient Impact from Drug Shortages
- Industry: FDA and Manufacturers Work to Prevent Drug Shortages

Reports to Congress

- Second Annual Report on Drug Shortages for Calendar Year 2014 (PDF - 137KB)
- First Annual Report on Drug Shortages for Calendar Year 2013 (PDF - 200KB)

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



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www.accessdata.fda.gov/scripts/drugs-shortages/default.cfm



FDA Drug Shortages

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Current and Resolved Drug Shortages and Discontinuations Reported to FDA

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Search by Generic Name or Active Ingredient:

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- Therapeutic Categories
- New and Updated

Current and Resolved Shortages Listed by Generic Name or Active Ingredient

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A drug receives Resolved status when the Drug Shortages Staff (DSS) determines that the market is covered, based on information from all manufacturers. The market is considered covered when supply is available from at least one manufacturer to cover total market demand. However, some manufacturers may not have all presentations available. DSS monitors the supply of products with Resolved status. For the most current supply information, contact the manufacturers.

Generic Name or Active Ingredient	Status
Acetohydroxamic Acid (Lithostat) Tablets	Currently in Shortage
Amikacin Injection	Resolved
Ammonium Chloride Injection	Currently in Shortage
Atropine Sulfate Injection	Currently in Shortage
Azathioprine Tablet	Currently in Shortage
Barium Sulfate for Suspension	Resolved
Bupivacaine Hydrochloride (Marcaine, Sensorcaine) Injection	Currently in Shortage
Caffeine Anhydrous (125mg/ml) Sodium Benzoate (125mg/ml) Injection	Currently in Shortage

Sign Up for Information on Drug Shortages



U.S. Food and Drug Administration
Protecting and Promoting *Your Health*

https://public.govdelivery.com/accounts/USFDA/subscriber/new?pop=t&topic_id=USFDA_22

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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

Drug Shortages

- > Current Shortages
- > Drugs No Longer Available
- > No Commercially Available Preparations
- > Resolved Shortages
- > Guidelines and Resources
- > Report a Drug Shortage

Drug Shortages

Welcome to the ASHP Drug Shortages Resource Center, the first stop for information and resources on drug product shortages and management. Drug shortages can adversely affect drug therapy, compromise or delay medical procedures, and result in medication errors. ASHP and its partners work to keep the public informed of the most current drug shortages.

[Subscribe to RSS](#)  | [Report a Drug Shortage](#) | [Join Our Community](#)



FIND DRUG SHORTAGES

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Search by Generic Drug Name...

OR

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Important Updates

- > [ASHP Speaks to I.V. Saline & Other Drug Shortages on Marketplace Radio](#)

Manage Drug Shortages



[Conservation Strategies for IV Fluids](#)

Help and Support

- > [Guided Tour](#) [PDF]
- > [Frequently Asked Questions](#)
- > [Sample Annotated Drug Shortage Monograph](#) [PDF]

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]

Other Drug Shortage Resources

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.³⁻⁵ 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.⁶ 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



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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 period¹. If the past trend holds true, the problem is getting worse. Manufacturers voluntarily reported 56

GAO Drug Shortages Number Still High



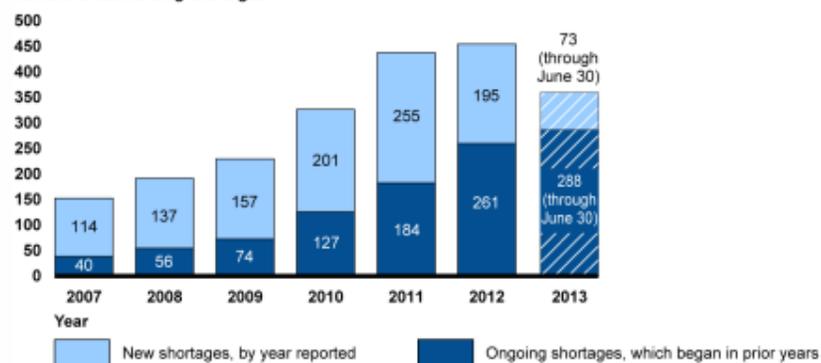
United States Government Accountability Office
Report to Congressional Addressees

February 2014

DRUG SHORTAGES

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

Number of active drug shortages



Source: GAO analysis of University of Utah Drug Information Service data.

GAO-14-194

28. 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, MEDMARX, 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

Have the Patient Get a DMM

DESIGNATED MEDICATION MANAGER CAMPAIGN (DMM)

We can all help stop medication errors and medication abuse. Join the fight to reduce medication misuse.

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



An estimated 1.5 million people are injured by medication errors in the United States each year. It is said that about 22.5 million Americans use illicit drugs. A medication taken by a person for whom it was not prescribed, or in dosages other than prescribed, can have serious adverse effects on health. Causes of medication error and abuse include (but aren't limited to) surgery-related depression, mental confusion, and the use of prescription painkillers. But medication errors can be greatly reduced and the best person to help a patient do that is a trusted relative or friend of the patient.



Medication errors and abuse can be minimized before a prescription is filled: by designating a Medication Manager or intervention support person (often a close family member or friend) to help getting materials to educate the patient in correct use of the medication.

While any medications are being taken: by providing a support person and monitoring system for the patient.

At any time: by helping patients eliminate the risk of medication overuse or misuse.



The Designated Medication Manager (DMM) campaign was developed to assist individuals taking any medication. A DMM, assigned by the patient before medication use begins, helps patients with prescription drug, over the counter drug or vitamin and herbal intake and watches out for mistakes, misuse, and signs of addiction. The campaign encourages the recruitment of DMMs and suggests programs and literature to assist them in the skills they will need.

References: Substance Abuse and Mental Health Administration, 2012/ <http://www.samhsa.gov/>; National Institute on Drug Abuse, 2012. / <http://www.drugabuse.gov/>; Long Island Council on Alcohol and Drug Dependence, 2012 / <http://www.licadd.com/>

29. 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
- 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

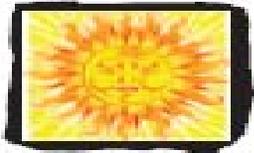
NPSG.03.06.01

1 Maintain and communicate accurate patient medication information.

Elements of Performance for NPSG.03.06.01

- 2 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
3 setting. This information is documented in a list or other format that is useful to those who manage medications.
4 Note 1: Current medications include those taken at scheduled times and those taken on an as-needed basis. See the Glossary for a definition
5 of medications.
6 Note 2: It is often difficult to obtain complete information on current medications from a patient. A good faith effort to obtain this information
7 from the patient and/or other sources will be considered as meeting the intent of the EP.
- 8 2. Define the types of medication information to be collected in non-24-hour settings and different patient circumstances.
9 Note 1: Examples of non-24-hour settings include the emergency department, primary care, outpatient radiology, ambulatory surgery, and
10 diagnostic settings.
11 Note 2: Examples of medication information that may be collected include name, dose, route, frequency, and purpose.
- 12 3. Compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to
13 identify and resolve discrepancies.
14 Note: Discrepancies include omissions, duplications, contraindications, unclear information, and changes. A qualified individual, identified by
15 the hospital, does the comparison. (See also HR.01.06.01, EP 1)
- 16 4. Provide the patient (or family as needed) with written information on the medications the patient should be taking when he or she is
17 discharged from the hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose).
18 Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include
19 only those medications. For more information about communications to other providers of care when the patient is discharged or transferred,
20 refer to Standard PC.04.02.01.
- 21 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
22 outpatient encounter.
23 Note: Examples include instructing the patient to give a list to his or her primary care physician; to update the information when medications
24 are discontinued, doses are changed, or new medications (including over-the-counter products) are added; and to carry medication
25 information at all times in the event of emergency situations. (For information on patient education on medications, refer to Standards
26 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



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- ▶ [Quality Indicators™ Toolkit for Hospitals](#)
- ▶ [Transforming Hospitals: Designing for Safety and Quality](#)

Project RED (Re-Engineered Discharge) Training Program



The Project RED (Re-Engineered Discharge) training program is designed to help hospitals re-engineer their discharge process. Using the study modules and supporting materials, hospitals will become familiar with Project RED's processes and components, determine metrics for evaluating impact, and learn how to implement Project RED.

This content was developed from an AHRQ project that ran from 2009 to 2012 and is based on an early version of the RED Toolkit. Select for the latest version of the [RED Toolkit](#).

Introduction

The Project RED (Re-Engineered Discharge) intervention is a patient-centered, standardized approach to discharge planning. Initially developed through research conducted by Dr. Brian Jack of the Boston University Medical Center and funded by the Agency for Healthcare Research and Quality (AHRQ), Project RED improves patient preparedness for self care and reduces preventable readmissions.

This training program is designed to help you implement Project RED program within your hospital. Using the study modules and supporting materials, you will:

- Become familiar with Project RED's processes and components.
- Determine metrics for evaluating the impact of the intervention.
- Learn how to implement Project RED.

30. 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

Page 1 of 12

[Table of Contents](#) [Download](#)

[Next Page](#)

Clinicians & Providers

Education & Training

▸ Continuing Education

Curriculum Tools

▸ Diabetes Planned Visit Notebook

▸ Advancing Pharmacy Health Literacy Practices Through Quality Improvement

▸ TeamSTEPPS

▸ Staying Healthy Through Education and Prevention (STEP)

▸ Chronic Care Model

▸ CLABSI Tools

▸ CUSP Toolkit

Hospitals & Health Systems

Prevention & Chronic Care

Quality & Patient Safety

Advancing Pharmacy Health Literacy Practices Through Quality Improvement

Publication # 12-M013-EF

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Curricular Modules for Faculty

Advancing Pharmacy Health Literacy Practices Through Quality Improvement: Curricular Modules for Faculty is a set of modules to help pharmacy faculty integrate health literacy and health literacy quality improvement into courses, experiential education, and projects for PharmD students and pharmacy residents. The curricular modules can be used for lectures, seminars, laboratory classes, and experiential education. The modules consist of 17 activity guides with 4 accompanying PowerPoint® presentations. Each activity guide includes a list of further resources.

Investigators:

Sarah J. Shoemaker, Pharm. D., Ph.D., Abt Associates, Inc.
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Contents

[Acknowledgements](#)

[Overview](#)

[Using the Curricular Modules](#)

[Are These Modules for You?](#)

[Adapting the Curricular Modules to Meet Your Needs](#)

[Accreditation Council for Pharmacy Education \(ACPE\) Standards](#)

[PowerPoint® Slide Decks](#)

[Activity Guides](#)

[Increasing Awareness of Health Literacy in Pharmacy \(Guides 1-7\)](#)

[Improving Communication in Pharmacy \(Guides 8-11\)](#)

[Assessing the Health Literacy Practices of Pharmacies \(Guides 12-15\)](#)

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

30. 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.

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

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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

31. ASHP Common Causes of Medication Errors

- Get a copy of the ASHP 9 page document on Guidelines on Preventing Medication Errors in Hospitals
- States many medication errors are undetected
- List common cause of medication errors
 - Ambiguous strength designation on labels
 - Look-alike or sound alike drugs
 - Illegible handwriting, inappropriate abbreviations
 - Excessive workloads, medication unavailable
 - Inaccurate dosage calculations

ASHP Guidelines on Preventing Medication Errors in Hospitals

www.ashp.org/s_ashp/docs/files/MedMis_Gdl_Hosp.pdf

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 (D&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

Also ASHP Guidelines on ADRs

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."

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."

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

32. 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):

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

If Drug Used as Restraint:

Drug Name	Dosage
-----------	--------

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,

32. 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
- There are 20 standards in 8 different areas
- 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)

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)

33. 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 last year were 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

The Joint Commission

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

**Survey Activity Guide
For Health Care Organizations**

2015

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
- Access to meds when pharmacy is closed and night 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

34. 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



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

35. 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

35. Do RCA for Medication Sentinel events

- Do a thorough and credible root cause analysis
- TJC requires a **RCA** 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

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 unintended act, either of omission or commission, or an act that does not achieve its 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:

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 hr 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	Unintended Retention of foreign body	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.

(5) Includes selection & procurement, storage, ordering & transcribing, preparing & dispensing, administration, and monitoring.

TJC Framework for Conducting RCA

The screenshot displays the website for The Joint Commission. At the top left is the logo and name 'The Joint Commission'. To the right are links for 'Log In | Request Guest Access', 'Forgot password? | Log In Help', and 'Contact Us | Careers | Press Room'. A search bar is located on the right side. Below the header is a navigation menu with tabs for 'Accreditation', 'Certification', 'Standards', 'Measurement', 'Topics', 'About Us', and 'Daily Update'. The 'Topics' tab is selected. The breadcrumb trail reads 'Home > Topics > Sentinel Event - Sentinel Event Alert'. There are social media sharing buttons for Twitter, Facebook, Google+, and a general 'Share' button, along with a 'Print' button. The date 'Monday 10:38 CST, August 6, 2012' is shown. The main content area features a 'Sentinel Event Alert' sidebar with three items: 'Issue 48: Health care worker fatigue and patient safety', 'Issue 47: Radiation risks of diagnostic imaging', and 'Issue 46: A follow-up report on preventing suicide: Focus on medical/surgical units and the emergency department'. The main article is titled 'Framework for Conducting a Root Cause Analysis and Action Plan', dated 'April 1, 2009'. It includes a 'Download This File' button and a description: 'A Framework for a Root Cause Analysis and Action Plan In Response to a Sentinel Event'. A 'Podcasts' sidebar lists two items: 'Sentinel Event Alert, Issue 41: Preventing errors relating to commonly used anticoagulants' and 'Sentinel Event Alert, Issue 40: Behaviors that undermine a culture of safety'. A 'Forms and Tools' sidebar contains 'Affirmation Statement' and 'Alternatives for Sharing Sentinel Event Related Information with The...'. A blue URL 'www.jointcommission.org/sentinel_event.aspx' is overlaid on the page.

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Accreditation Certification Standards Measurement **Topics** About Us Daily Update

Home > Topics > Sentinel Event - Sentinel Event Alert

Twitter Facebook Google+ Share Print

Monday 10:38 CST, August 6, 2012

Sentinel Event

Sentinel Event Alert

- Sentinel Event Alert Issue 48: Health care worker fatigue and patient safety
- Sentinel Event Alert, Issue 47: Radiation risks of diagnostic imaging
- Sentinel Event Alert, Issue 46: A follow-up report on preventing suicide: Focus on medical/surgical units and the emergency department

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Topic Library Item

Framework for Conducting a Root Cause Analysis and Action Plan

April 1, 2009

[Download This File](#)

A Framework for a Root Cause Analysis and Action Plan In Response to a Sentinel Event

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Podcasts

Sentinel Event Alert, Issue 41: Preventing errors relating to commonly used anticoagulants

By Joint Commission

Sentinel Event Alert, Issue 40: Behaviors that undermine a culture of safety

By Joint Commission

[View More](#)

Forms and Tools

Affirmation Statement

Alternatives for Sharing Sentinel Event Related Information with The...

TJC Sentinel Event Policy with Matrix

Topic Library Item

Sentinel Event Policy and Procedures

November 19, 2014

The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help hospitals that experience serious adverse events improve safety and learn from those sentinel events. Careful investigation and analysis of Patient Safety Events (events not primarily related to the natural course of the patient's illness or underlying condition), as well as evaluation of corrective actions, is essential to reduce risk and prevent patient harm. 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.

A sentinel event is a Patient Safety Event that reaches a patient and results in any of the following:

- Death
- Permanent harm
- Severe temporary harm and intervention required to sustain life

An event can also be considered sentinel event even if the outcome was not death, permanent harm, severe temporary harm and intervention required to sustain life. See list below.

Such events are called "sentinel" because they signal the need for immediate investigation and response. Each accredited organization is strongly encouraged, but not required, to report sentinel events to The Joint Commission. Organizations benefit from self-reporting in the following ways:

- The Joint Commission can provide support and expertise during the review of a sentinel event.
- The opportunity to collaborate with a patient safety expert in The Joint Commission's Sentinel Event Unit of the Office of Quality and Patient Safety.
- Reporting raises the level of transparency in the organization and promotes a culture of safety.
- Reporting conveys the health care organization's message to the public that it is doing everything possible, proactively, to prevent similar patient safety events in the future.

138

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2015 TJC Sentinel Event Policy & Procedure

Sentinel Events (SE)

I. Sentinel Events

The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help hospitals that experience serious adverse events improve safety and learn from those sentinel events. Careful investigation and analysis of patient safety events, as well as evaluation of corrective actions, 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

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 YES 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):	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5

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

Page 15 of 21

36. 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
 - Remind family members and visitors
 - TJC has SEA 33 issued December 20, 2004,
- Carefully monitor patients and ensure pulse ox and or ETCO₂ monitors



Authorized and Unauthorized (“PCA by Proxy”) Dosing of Analgesic Infusion Pumps

Position Statement:

The American Society for Pain Management Nursing (ASPMN) recognizes the need for prompt, safe, and effective pain relief for all and supports the use of Authorized Agent Controlled Analgesia (AACA) for the patient who is unable to self administer analgesics using an analgesic infusion pump. The ASPMN does not support the use of "PCA by Proxy" in which an **unauthorized** person activates the dosing mechanism of an analgesic infusion pump and delivers analgesic medication to the patient, thereby increasing the risk for potential patient harm.

ASPMN further delineates that support for AACA is contingent upon a health care agency having in place clear guidelines outlining the conditions under which such practice may be implemented, including monitoring procedures that will insure safe use of the therapy.

Ethical Tenets:

The ethical principles of beneficence (the duty to benefit another) and non-maleficence (the duty to do no harm) oblige health care professionals to provide pain management and comfort to all patients, including those individuals who are vulnerable to the under treatment of pain, unable to speak for themselves, and lack the ability to self administer medications. In situations where a person is unable to self administer analgesics due to cognitive or physical limitations a consistent care provider can be educated to assist or to administer analgesics.

Providing quality and comparable pain management to individuals who cannot self

37. 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
- 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
Center for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-23-18
Baltimore, Maryland 21244-1890



Center for Clinical Standards and Quality / Survey & Certification Group

Re: 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.

June 2010 Pa Patient Safety Authority

Tubing Mismatches: Making the Connection to Patient Safety

ABSTRACT

Some patients may have multiple tubing lines connected to them for reasons such as delivery of medication and nutrition therapy. With these multiple lines, the potential for tubing mismatches becomes more prevalent. Tubing mismatches can occur with intravenous catheters, feeding tubes, peritoneal dialysis tubes, and tracheostomy cuffs, among other devices. One of the main reasons for tubing mismatches is that many types of tubing for different types of medical devices incorporate lock connectors. These connectors contribute to mismatches because they often have normally dissimilar tubes or catheters to be connected together. Between January 2008 and September 2009, 38 events of tubing mismatches were reported to the Pennsylvania Patient Safety Authority involving various types of mismatches. Methods for reducing the likelihood of tubing mismatches include equipment design solutions and education. New controls (guidance and lock protection), equipment design solutions either prevent the user from making a mismatch or prompt the user to make the correct connection. Administrative controls are policies and practices that reduce the risk of mismatches such as tracing lines back to their source. (Pa Patient Saf Act 2010 Jun;7(2):41-5.)

Introduction

Depending on acuity level, patients may have multiple lines connecting them to medical devices used for delivering medication or nutrition therapy. Medical devices connected to patients may also have tubing lines connecting the devices with other medical devices. Under these circumstances, tubing mismatches can occur with potentially fatal results. Mismatches have been recognized as a serious problem for many years. One of the earliest published reports of mismatches was the tragic incident delivery of breast milk via intravenous (IV) administration in 1972.¹ However, mismatches have garnered more attention in recent years, especially in the United States, due in part to the tubing mismatched Neutralizer Alert issued by the Joint Commission in April 2006.²

for IV delivery connected to nasogastric tubes.³ The Alert offers risk reduction strategies and recommendations, which are included in the overall risk reduction strategies below.

There are many types of mismatches; however, this article will focus on liquid-to-liquid and liquid-to-gas mismatches because these mismatches can pose the most serious harm to patients and are the most frequently reported to the Pennsylvania Patient Safety Authority. Liquid lines are typically those that administer medications or nutrient but can also include solution lines such as flush lines. Medical gas lines are typically used for respiratory support or to power pneumatic medical devices. Liquid-to-liquid mismatches can result in a liquid substance entering the wrong body part or the wrong substance entering the patient. Liquid-to-gas mismatches are incorrect connections that can result in gas entering liquid line patients' blood vessels or liquid entering patients' respiratory tracts.⁴

A common cause for tubing mismatches, whether liquid-to-liquid or liquid-to-gas, is that many types of tubing lines for different medical devices incorporate common lock connectors. The International Unit system for Standardization (ISO) designates a line connector as a central fitting with a 19° Bevel taper that engages, needles, and other medical equipment.⁵ The line connector system consists of male and female counterparts that are joined together either by push (they slip or screw-in threaded their lock) fittings. Lock connectors contribute to mismatches because they easily allow functionally dissimilar tubes or catheters to be connected together.⁶

Mismatches in Pennsylvania

Between January 2008 and September 2009, 38 tubing mismatch events were reported to the Authority. 35 liquid-to-liquid events and 3 liquid-to-gas events. (See the Table for a breakdown of the types of mismatches reported.) Examples of the Serious Events and Incidents involving mismatches reported to the Authority include the following:

The patient is a 68-year-old female admitted . . . to determine need for surgery. The physician ordered a 72 ml bolus of 20% intralipid. A . . . nurse connected the bag of 20% to the patient's lower "Y" on

ISMP Tubing Misconnections

www.ismp.org

ISMP Medication Safety Alert! Acute Care

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 gastrointestinal 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. *AJ Health-Syst Pharm.* 2010;67:734-36). The patient, a 17-month-old child, had a central venous catheter (CVC) in place for 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 3 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 administration sets and syringes. So, even if a liquid medication is prepared in an oral syringe, the medication must be transferred to a 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 which 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
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- 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.

Managing Risk During the Transition

Sentinel Alert *Event*

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

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

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

Managing risk during transition to new ISO tubing connector standards

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

The first new ISO connector standard (ANSI/AAMI/ISO 80369-1) has been adopted and others are expected to be introduced and adopted through 2014 and 2015. Health care organizations should begin preparing for changes in connectors and devices as early as possible during the transitional period to avoid

Misconnections & How to Prepare

Sentinel Event Alert, Issue 53
Page 2

There are various types of misconnections posing dangers, including the following:^{3,9}

Types of misconnections		
Enteral feeding tube	connected to	IV (such as <i>The New York Times</i> example) ^{6,10,11}
Limb cuff inflation device	connected to	IV (For example, a 71-year-old woman died post-operatively after a blood pressure cuff was accidentally connected to her IV line, causing an air embolism.) ⁷
Epidural solution (intended for epidural administration)	connected to	Peripheral or central IV catheter ¹⁰
Epidural line	connected to	IV infusion ^{10,11}
Bladder irrigation solution using primary IV tubing (connected as secondary infusion)	connected to	Peripheral or central IV catheter ^{10,11}
IV infusion (intended for IV administration)	connected to	Indwelling bladder (foley) catheter ^{10,11}
IV infusion (intended for IV administration)	connected to	Nasogastric (NG) tube ^{10,11}
Primary IV tube	connected to	Blood product (intended for transfusion) ^{10,11}
Enteral feeding (gastric or nasal)	connected to	Tracheostomy tube ³
IV solution	administered via	Blood administration set ^{10,11}
Primary IV solution	administered via	Various functionally dissimilar catheters (such as external dialysis catheter, ventriculostomy port, amnio-infusion catheter, distal port of pulmonary artery catheter) ^{10,11}

New Standards Prevent Tubing Misconnections

- New and unique international standards being developed in 2015 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

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- **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

June 2010 Pa Patient Safety Authority

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ISMP Tubing Misconnections www.ismp.org

ISMP Medication Safety Alert! Acute Care

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TJC Sentinel Event Alert #36

www.jointcommission.org

The screenshot shows the homepage of The Joint Commission website. At the top left is the logo for The Joint Commission. To the right of the logo are links for "Log In | Request Guest Access" and "Forgot password? | Log in Help". Further right are links for "Contact Us | Careers | JCR Web Store | Press Room". Below these links is a search bar with the word "Search" and a "Go" button. A navigation menu below the search bar includes "Accreditation", "Certification", "Standards", "Measurement", "Topics", "About Us", and "Daily Update". Below the navigation menu is a breadcrumb trail "Home > Topic Details" and a date "Monday, 9/14/2015, April 23". A sidebar on the left contains a "Sign up for News and Alerts" box with a "Sign up here" button. The main content area is titled "Topic Library Item" and features the headline "Sentinel Event Alert, Issue 36: Tubing misconnections—a persistent and potentially deadly occurrence" with a date of "April 3, 2015". Below the headline is a "Download This File" button. The text below the button reads: "Tubing and airway misconnection errors are an important and under-reported problem in health care organizations. In addition, these errors are often caught and corrected before any injury to the patient occurs. Given the reality of and potential for life-threatening consequences, increased awareness and analysis of these errors—including avoided errors—can lead to dramatic improvement in patient safety." To the right of the text is an image of a tangled piece of clear medical tubing. On the far right of the page is a social media sharing sidebar with icons for Twitter, Facebook, LinkedIn, and a "More" button.

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www.premierinc.com/quality-safety/tools-services/safety/topics/tubing-misconnections/resources.jsp

Resources

Enteral Feeding Misconnections: A Consortium Position Statement

[PRINT PAGE](#)[EMAIL PAGE](#)

IN: *The Joint Commission Journal on Quality and Patient Safety*, May 2008

Authors: Peggi Guenther (American Society for Parenteral and Enteral Nutrition), Rodney Hicks (United States Pharmacopeia), Debora Simmons (MD Anderson Cancer Center), Jay Crowley (Food and Drug Administration), Richard Croteau (The Joint Commission), Cathie Gosnell (Safety Institute, Premier Inc) and Timothy Vanderveen (Cardinal Health)

- [Download Enteral feeding misconnections](#)

NEW FDA: Letter to Enteral Feeding Tube Manufacturers

- [Download FDA July 2010 Letter](#)

Avoid Tubing Misconnections

- TJC **SE Alert 36** reported eight deaths and 300 from USP
- Includes misconnection from central intravenous catheters, peripheral intravenous catheters, nasogastric feeding tubes, percutaneous enteric feeding tubes, peritoneal dialysis catheters, tracheostomy cuff inflation tubes, and automatic blood pressure cuff insufflation tubes
- Actually case where enteric feeding into IV catheters (4), injection of barium sulfate into central line catheter, BP insufflator tube connected into IV catheter (2 cases),

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,

38. Prevent Vincristine Errors

- Errors are related to inadvertent administration of vin**CRIST**ine intrathecally (into subarachnoid space)
 - TJC Sentinel Event Alert 34
 - 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: <i>Undiluted</i>		Column B: <i>Diluted</i>		
	Yes	No	25 mL	50 mL	Other
a. What is the typical volume of solution administered for each dose of IV vincristine in your facility?			18%	44%	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?	96%	4%	80%	20%	
c. Are you aware of any extravasations that have occurred within the past 2 years related to administration of undiluted IV vincristine?	5%	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:

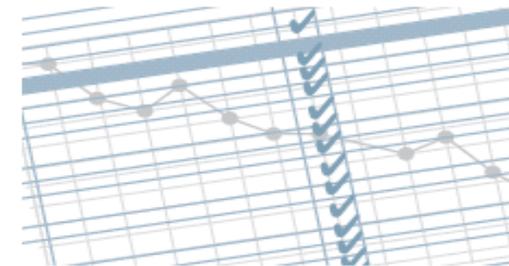
The goal of this best practice is to prevent errors involving inadvertent daily dosing of oral methotrexate both in the inpatient setting and after discharge. Since early 1996 and as recently as 2013, fatal errors have been reported to ISMP about the accidental daily dosing of oral methotrexate that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

39. 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



**INSTITUTE FOR
HEALTHCARE
IMPROVEMENT**



Innovation Series 2009

IHI Global Trigger Tool for Measuring Adverse Events

Second Edition

www.ihl.org/knowledge/Pages/Tools/IntrotoTriggerToolsforIdentifyingAEs.aspx

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Introduction to Trigger Tools for Identifying Adverse Events



Institute for Healthcare Improvement
Cambridge, Massachusetts, USA

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

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

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

More on This Topic

• [Passport Exclusive: Improvement Skills to Empower Front Line Nurses I](#)

• [Passport Exclusive: Improvement Skills to Empower Front-Line Nurses II](#)

• [Saving lives by studying deaths: Using standardized mortality reviews to improve inpatient safety](#)

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Featured Content

• [IHI Global Trigger Tool for Measuring Adverse Events](#)

• [IHI Trigger Tool for Measuring Adverse Drug Events](#)

• [Improvement Tip: Focus on Harm, Not Errors](#)

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,

40. 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 is reached at 3 days

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	
	<i>Patient should NOT receive <u>transdermal fentanyl</u> if any of the following criteria are met.</i>
<input type="checkbox"/>	Use of <u>transdermal fentanyl</u> is for any of the following: (1) mild pain; (2) breakthrough or intermittent pain (i.e., for as-needed / <u>p.r.n.</u> 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).
<input type="checkbox"/>	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 <u>oxycodone</u> daily, 8 mg of oral <u>hydromorphone</u> daily, or an <u>equianalgesic</u> dose of another opioid, for less than one week.
<input type="checkbox"/>	Hypersensitivity to <u>fentanyl</u> or local hypersensitivity reaction to any components of the patch that is not adequately controlled with topical medications (e.g., corticosteroids).
<input type="checkbox"/>	Patient has a contraindication to opioids (e.g., significant respiratory depression, acute or severe bronchial asthma or <u>hypercarbia</u> , or known or suspected paralytic <u>ileus</u>).
Inclusion Criteria	
	<i>Patient must meet all of criteria A–D to use <u>transdermal fentanyl</u> patches. These criteria apply to new starts only; patients stable on <u>transdermal fentanyl</u> should not be required to discontinue it or switch to another opioid unless there is a clinical reason for doing so.</i>
<input type="checkbox"/>	A. Patient requires around-the-clock analgesia for moderate to severe, <i>persistent</i> chronic pain
<input type="checkbox"/>	B. Patient is followed by a VA or VA-contracted provider for management of <u>transdermal fentanyl</u> therapy.
<input type="checkbox"/>	C. <u>Transdermal fentanyl</u> is <i>initially</i> prescribed and titrated by a VA or VA-contracted provider who has experience in dosing <u>transdermal fentanyl</u> or is in consultation with a VA or VA-contracted organized pain clinic or local pain management expert with experience in dosing <u>transdermal fentanyl</u> .
<input type="checkbox"/>	D. Patient meets at least one of the following conditions: <ul style="list-style-type: none"> — 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 <i>chronic and relatively stable</i> 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 <p><i>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 aggressive use of laxatives; or nausea inadequately controlled by antiemetics or gradual dose titration)</i></p>

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.

- 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



For Consumers

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www.fda.gov/Drugs/DrugSafety/SafeUse/initiative/default.htm

Second Safety Warning on Fentanyl Skin Patch

Search Consumer Updates go

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 approved 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 medicine 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 not well controlled with other pain medicines. The patches are not to be used to treat sudden, occasional, or mild pain, or pain after surgery.
- Be aware of the signs of fentanyl overdose: trouble breathing, or slow or shallow breathing; slow heartbeat; severe sleepiness; cold, clammy skin; trouble walking or talking; or feeling faint, dizzy, or confused. If these signs occur, get medical attention right away.

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

Disposal of Unused Medications

The screenshot shows the FDA website's 'Drugs' section. At the top, the FDA logo and 'U.S. Food and Drug Administration' are displayed, along with the tagline 'Protecting and Promoting Your Health'. A search bar and 'Most Popular Searches' are also visible. The main navigation bar includes links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The 'Drugs' section is active, with a breadcrumb trail: Home > Drugs > Resources for You > Information for Consumers (Drugs). A left sidebar contains two 'Resources for You' boxes. The top box lists: Information for Consumers (Drugs), Buying & Using Medicine Safely, Ensuring Safe Use of Medicine, and Safe Disposal of Medicines. The bottom box lists: How to Dispose of Unused Medicines, Medication Disposal: Questions and Answers, and Fentanyl Patch Can Be Deadly to Children. The main content area features the title 'Disposal of Unused Medicines: What You Should Know' and a 'Topics on this Page' list: Overview, List of Medicines Recommended for Disposal by Flushing, and Questions and Answers about Medication Disposal. Below this is an 'Overview' section explaining the importance of proper disposal. It is followed by 'Medicine Take-Back Programs', which describes how to use local programs. The final section is 'Disposal in Household Trash', which provides simple steps for disposal when no take-back program is available. A large graphic on the right side of the page asks 'Got Drugs?' and promotes a collection event on Saturday, April 27th, from 10 a.m. to 2 p.m. The graphic shows several pills, one of which is a blue capsule with 'dispose' written on it, and a white tablet with 'Rx' on it. A call to action says 'Click here for a collection site near you.' At the bottom of the page, a URL is visible: <https://www.deadiversion.usdoj.gov/NTBI/NTBI-PUB.pub?jsessionid=E57FF3A66EBF04FB6...>

Resources for You

- Information for Consumers (Drugs)
- Buying & Using Medicine Safely
- Ensuring Safe Use of Medicine
- Safe Disposal of Medicines

Resources for You

- How to Dispose of Unused Medicines
- Medication Disposal: Questions and Answers
- Fentanyl Patch Can Be Deadly to Children

Disposal of Unused Medicines: What You Should Know

Topics on this Page

- Overview
- List of Medicines Recommended for Disposal by Flushing
- Questions and Answers about Medication Disposal

Overview

Medicines play an important role in treating many conditions and diseases, but when they are no longer needed it's important to dispose of them properly to avoid harm to others. Below, we list some disposal options and some special disposal instructions for you to consider when throwing out expired, unwanted, or unused medicines.

Medicine Take-Back Programs

Medicine take-back programs for disposal are a good way to remove expired, unwanted, or unused medicines from the home and reduce the chance that others may accidentally take the medicine. Contact your city or county government's household trash and recycling service to see if there is a medicine take-back program in your community and learn about any special rules regarding which medicines can be taken back. You can also talk to your pharmacist to see if he or she knows of other medicine disposal programs in your area or visit the U.S. Drug Enforcement Administration's website for information on [National Prescription Drug Take-Back Events](#).

Disposal in Household Trash

If no medicine take-back program is available in your area, you can also follow these simple steps to dispose of most medicines in the household trash:¹

- Mix medicines (do NOT crush tablets or capsules) with an unpalatable substance such as kitty litter or used coffee grounds.

Got Drugs?

Turn in your unused or expired medication for safe disposal
Saturday, April 27th, 10 a.m. – 2 p.m.

Click here for a collection site near you.

FDA Initiative on Fentanyl Patches



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993



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.

Fentanyl skin patches are to be worn for up to 3 days and then removed for disposal.

41. 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

42. 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 be 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

43. Use Saline instead of Heparin Flushes

- American Society of Health-System Pharmacists published a position statement on this
- Use 0.9% saline to maintain patency of peripheral indwelling intermittent infusion devices and not heparin
- 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

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 PIID patency 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.⁷⁻¹⁶ In several randomized, double-blind studies in which PIIDs composed principally of fluoropolyethylene 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.¹⁰⁻¹² The frequency of phlebitis associated with the use of these solutions was also similar.^{7,8,17-19} 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.^{8,10} Several studies provide a scientific basis for using heparin flush,^{6,20,21} 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

43. Saline Flushes Single Use Only

- Saline flushes should be unit dose
 - CDC requirement and one of ten safe injection practices
 - If manufacturer makes it in a single dose then need to buy it in a single dose
 - 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 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

44. Follow Safe Injection Practices



- CMS had a 50 million dollar grant to enforce infection control standards so surveyors more knowledgeable and HHS 1 billion
- 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 that one patient only
 - Multi-dose vials for one patient if possible
 - If not mark and do not use after 28 days
 - Clean glucometers after each use and single use lancets

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



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 CO₂ 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:

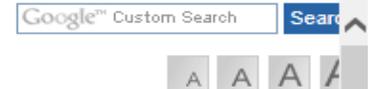
Standardization

- High alert drugs (such as phenvlephrine 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.

45. 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
7000 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1882



Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-30-ALL

DATE: May 18, 2012

TO: State Survey Agency Directors

[www.cms.gov/Medicare/Provider-Enrollment-and-](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html)

FROM: Director
Survey and Certification Group

[Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html)

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 than one patient/resident. The reuse of insulin pens, including the reuse of needles, can result in cross-contamination and the transmission of blood-borne viruses.

CDC Reminder on Insulin Pens

Injection Safety [www.cdc.gov/injectionsafety/clinical-reminders/insulin-](http://www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html)

[pens.html](http://www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html)

Injection Safety

CDC's Role

CDC Statement

Information for Providers

Information for Patients

Preventing Unsafe Injection Practices

Infection Prevention during Blood Glucose Monitoring and Insulin Administration

FAQs regarding Assisted Blood Glucose Monitoring and Insulin Administration

CDC Clinical Reminder: Fingerstick Devices

► **Clinical Reminder: Insulin Pens**

Recent Publications

Recent Meetings

The One & Only Campaign

[Injection Safety](#)

> [Infection Prevention during Blood Glucose Monitoring and Insulin Administration](#)

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CDC Clinical Reminder: Insulin Pens Must Never Be Used for More than One Person

Available for download [Clinical Reminder: Insulin Pens](#) [PDF - 182 KB]

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.

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Contact Us:

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

 800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348

[Contact CDC-INFO](#)

Related Links

[One & Only Campaign](#)

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 in 2013

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 2008 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

Insulin Pen Posters and Brochures Available



About the Campaign

Safe Injection Practices

Healthcare Provider Information

Patient Information

Campaign Resources

News

Contact Us



Insulin Pen Safety – One Insulin Pen, One Person

BE AWARE
DON'T SHARE



ONE INSULIN PEN,
ONLY ONE PERSON

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

The Safe Injection Practices Coalition created an insulin pen poster and brochure for healthcare providers as a reminder that insulin pens and other injectable medications are meant for one person and should never be shared. PDFs of these educational materials are linked below:

Specific Materials for Safe Use of Insulin Pens – for Clinicians and Patients

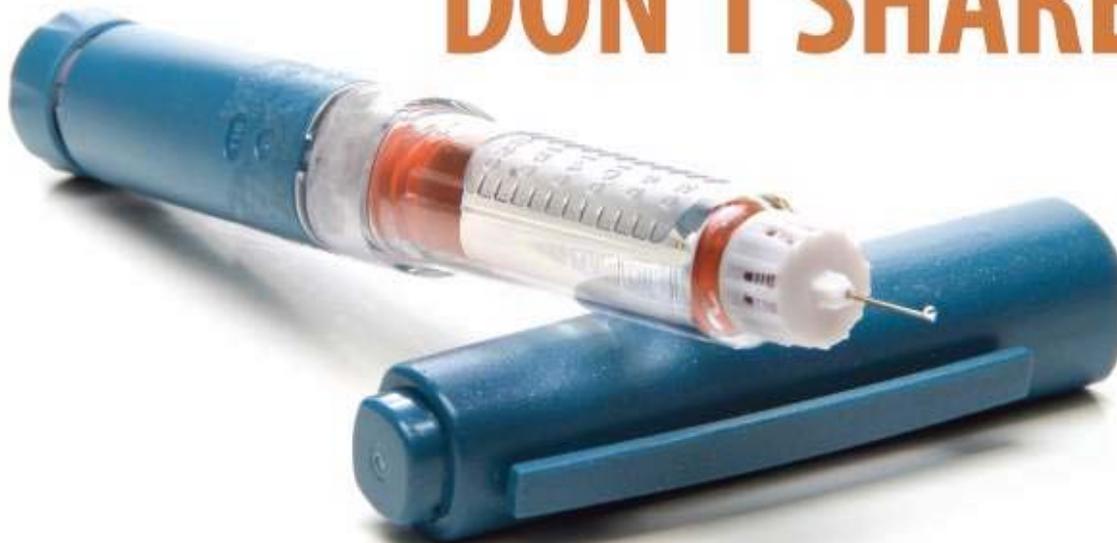
- [Poster](#)
- [Brochure](#)

[Click here](#) to order free copies of these materials from the Centers for Disease Control and Prevention (CDC) (publication numbers 22-1501 and 22-1503).

Additional Resources

- [VA Patient Safety Alert: Multi-Dose Pen Injectors](#) (Department of Veterans Affairs, January 2013)

BE AWARE DON'T SHARE



Insulin pens that contain more than one dose of insulin are only meant for one person.

They *should never be used for more than one person*, even when the needle is changed.

**ONE INSULIN PEN,
ONLY ONE PERSON**

The One & Only Campaign is a public health campaign aimed at raising awareness among the general public and healthcare providers about safe injection practices.

For more information,
please visit:
www.ONEandONLYcampaign.org

Insulin Pen Brochure

DON'T DO IT

Sharing Insulin Pens and Other Injection Equipment Jeopardizes Patients

In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration issued an alert for healthcare professionals reminding them that insulin pens are meant for use on a single person only and are not to be shared. Unfortunately, there have been continuing reports of persons placed at risk of bloodborne and bacterial pathogen transmission through sharing of insulin pens.

A SIMPLE RULE

Injection equipment (e.g., insulin pens, needles and syringes) should **never** be used for more than one person.



About the Safe Injection Practices Coalition

The Safe Injection Practices Coalition (SIPC) is a partnership of healthcare-related organizations led by the Centers for Disease Control and Prevention that was formed to promote safe injection practices in all U.S. healthcare settings. The SIPC has developed the One & Only Campaign – a public health education and awareness campaign – aimed at both healthcare providers and patients to advance and promote safe injection practices.

For more information,
please visit:

www.ONEandONLYcampaign.org

BE AWARE DON'T SHARE



ONE INSULIN PEN, ONLY ONE PERSON



What Every
Healthcare Professional
Needs To Know

46. 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
- Mark it expires in 28 days unless sooner by manufacturer

CMS Safe Injection Practices

DEPARTMENT OF HEALTH & HUMAN SERVICES
Center for Medicare & Medicaid Services
1100 Security Boulevard, Mail Stop C2-21-18
Baltimore, Maryland 21244-1880



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 adhering to USP <797>*

CMS Memo on Safe Injection Practices

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

CMS Memo on Safe Injection Practices

- Bottom line is you can not use a single dose vial on multiple patients
- CMS requires hospitals to follow nationally recognized standards of care like the CDC guidelines
- SDV typically lack an antimicrobial preservative
- Once the vial is entered the contents can support the growth of microorganisms
- The vials must have a beyond use date (BUD) and storage conditions on the label

Safe Injection Practices

- 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 AOA HFAP
- CMS has a list and any breaches should be referred
- Referral is to the state authority such as the state epidemiologist or State HAI Prevention Coordinator

Infection Control Breaches

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



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



EMERGENCY
MEDICINE
PATIENT SAFETY
FOUNDATION

Safe Injection Practices Patient Safety Brief Emergency Medicine Patient Safety Foundation

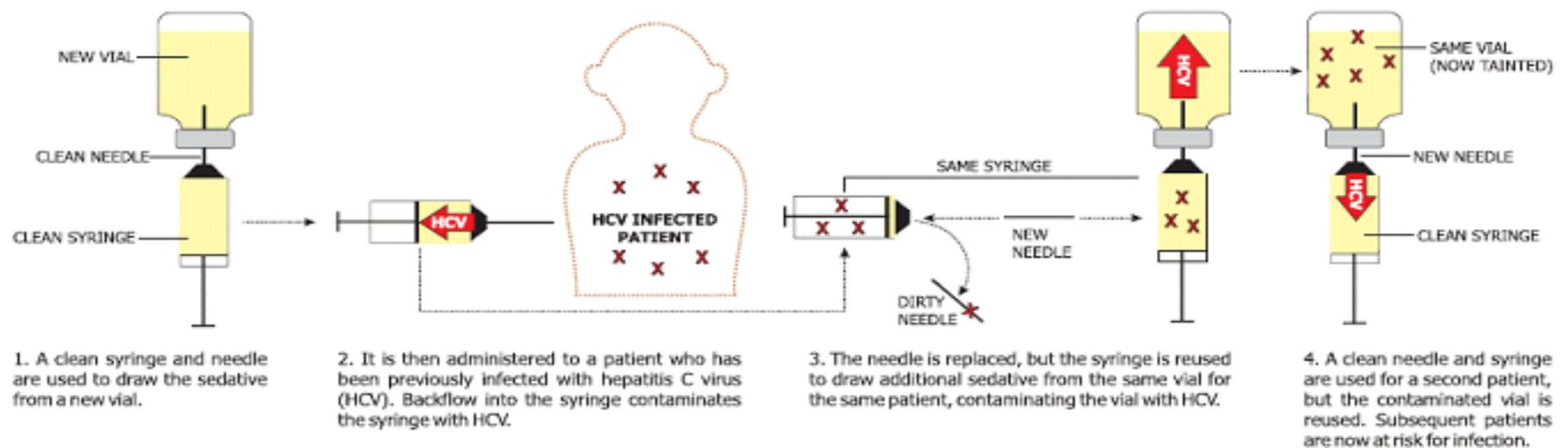
By: Sue Dill Calloway RN MSN JD CPHRM
Ruth Carrico PhD RN FSHEA CIC

July 2012



Unsafe Injection Practices and Disease Transmission

Reuse of syringes combined with the use of single-dose vials for multiple patients undergoing anesthesia can transmit infectious diseases. The syringe does not have to be used on multiple patients for this to occur.



Source: www.southernnevadahealthdistrict.org



Not All Vials Are Created Equal

SINGLE-DOSE OR MULTI-DOSE?

NOT ALL VIALS ARE CREATED EQUAL.

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

This information can literally save a life.



ONEANDONLYCAMPAIGN.ORG

ASHP Has SDV Crosswalk

ASHP Crosswalk of Guidances and Standards for Managing Single (SDV) and Multi-Dose Vials (MDV)

July 2013



This guide is an ASHP member resource prepared jointly by the **Section of Pharmacy Practice Managers Advisory Group on Quality and Compliance** and **ASHP's Division on Medication Safety and Quality**.

Contact:

David Chen

Director, Pharmacy Practice Sections
and Section of Pharmacy Practice Managers
DChen@ashp.org

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46. 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



The screenshot displays the Patient Safety Authority website. At the top left is the logo for the Patient Safety Authority, Commonwealth of Pennsylvania. Below the logo is a navigation menu with the following items: HOME, PATIENT SAFETY AUTHORITY, PA-PSRS and PASSKEY, PATIENT SAFETY ADVISORIES, PATIENTS AND CONSUMERS, NEWS AND INFORMATION, COLLABORATIONS, EDUCATIONAL TOOLS, and AUTHORITY EVENTS. The main content area features a header image of healthcare professionals, a search bar, and a section titled "Educational Tools". The "Contrast-Induced Nephropathy" section includes a flowchart, a text paragraph, and three sub-sections: "Educational Resources" (with links to a video, an algorithm, and a poster) and "Articles" (with a link to an article titled "Contrast-Induced Nephropathy: Can This Iatrogenic Complication of Iodinated Contrast be Prevented?").

PATIENT SAFETY AUTHORITY
Commonwealth of Pennsylvania

HOME
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PATIENT SAFETY ADVISORIES ▶
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COLLABORATIONS ▶
EDUCATIONAL TOOLS ▶
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ADDRESS:
Patient Safety Authority
333 Market Street
Lobby Level
Harrisburg, PA 17120

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

Educational Tools

Contrast-Induced Nephropathy

Contrast-induced nephropathy cannot be viewed as a treatable or acceptable complication of iodinated contrast-related procedures. Yet, fear of renal failure should not dictate avoidance of diagnostic studies using iodinated contrast.

Educational Resources

Contrast-Induced Nephropathy
This educational video discusses the complication of contrast-induced nephropathy and is appropriate for clinicians.

Management of Patients Undergoing Iodinated Contrast-Related Procedures
This stand-alone algorithm can help institutions to identify patients with risk factors for contrast-induced nephropathy.

Management of Patients Undergoing Iodinated Contrast-Related Procedures
This educational poster includes an algorithm to identify patients with risk factors for contrast-induced nephropathy, premedication regimen information, and reference tables for calculating estimated glomerular filtration rates.

Articles

Contrast-Induced Nephropathy: Can This Iatrogenic Complication of Iodinated Contrast be Prevented?
Because of its serious consequences, contrast-induced nephropathy cannot be viewed as a treatable or acceptable complication of iodinated contrast-related procedures.

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

47. 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 standards for 2015
- See ACR MRI Safety Guideline issued 2013,

ACR MR Safe Practices 2013

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

JOURNAL OF MAGNETIC RESONANCE IMAGING 37:541-551 (2013)

Special Communication

ACR Guidance Document on MR Safe Practices: 2013

Expert Panel on MR Safety: Emanuel Kanal, MD,^{1*} A. James Barkovich, MD,² Charlotte Bell, MD,³ James P. Borgstede, MD,⁴ William G. Bradley Jr, MD, PhD,⁵ Jerry W. Froelich, MD,^{6*} J. Rod Gimbel, MD,⁷ John W. Gosbee, MD,^{8*} Elissa Kuhn-Kaminski, RT,¹ Paul A. Larson, MD,⁹ James W. Lester Jr, MD,¹⁰ John Nyenhuis, PhD,^{1,11} Daniel Joe Schoeler, PhD,^{1,2} Elizabeth A. Sabek, RN, BSN,¹ Jeffrey Weinreb, MD,^{1,2} Bruce L. Wilkoff, MD,^{1,2} Terry O. Woods, PhD,^{1,2} Leonard Lucey, JD,^{1,12} and Dina Hernandez, BSRT^{1,13}

Because there are many potential risks in the MR environment and reports of adverse incidents involving patients, equipment and personnel, the need for a guidance document on MR safe practices emerged. Initially published in 2004, the ACR MR Safe Practices Guidelines established de facto industry standards for safe and responsible practices in clinical and research MR environments. As the MR industry changes, the document is reviewed, modified and updated. The most recent version will reflect those changes.

Key Words: MR safety; MR; MR safe practices
J. Magn. Reson. Imaging 2013;37:541-551.
© 2013 Wiley Periodicals, Inc.

THERE ARE POTENTIAL risks in the MR environment, not only for the patient (1,2) but also for the accompanying family members, attending health care professionals, and others who find themselves only occasionally or rarely in the magnetic fields of MR scanners, such as security or housekeeping personnel, firefighters, police, etc. (3-6). There have been reports in the medical literature and print-media detailing Magnetic Resonance Imaging (MRI) adverse incidents involving patients, equipment and personnel that spotlighted the need for a safety review by an expert panel. To this end, the American College of Radiology originally formed the Blue Ribbon Panel on MR Safety. First constituted in 2004, the panel was charged with reviewing existing MR safe practices and guidelines (2-6) and issuing new ones as appropriate for MR environments. Published initially in 2002 (4), the ACR MR Safe Practices Guidelines established de facto industry standards for safe and responsible practices in clinical and research MR environments. These were subsequently reviewed and updated in May of 2004 (3). After reviewing substantial feedback from the field and installed base, as well as changes that had transpired throughout the MR industry since the publication of the 2004 version of this document,

¹Department of Radiology, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, USA.

²Department of Radiology and Biomedical Imaging, University of California, San Francisco, California, USA.

³United Anesthesiologists, Miami, California, USA.

⁴University of Colorado, Denver, Colorado, USA.

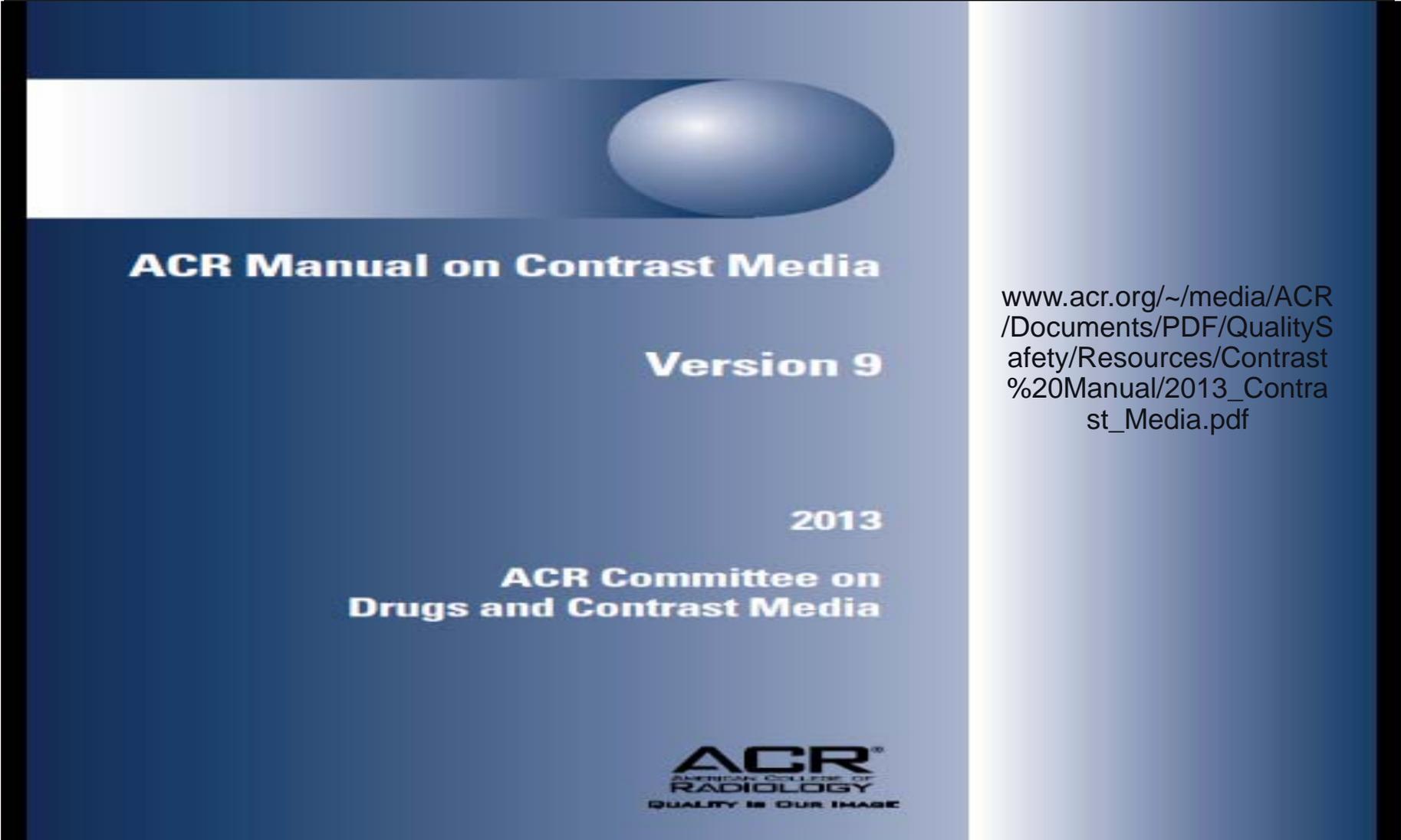
⁵Department of Radiology, University of California San Diego Medical Center, San Diego, California, USA.

⁶Department of Radiology, University of Minnesota, Minneapolis, Minnesota, USA.

⁷Radiology Associates of E. Tennessee, Knoxville, Tennessee, USA.

⁸University of Michigan Health System and Ford Motor (Cleveland) LLC,

ACR Contrast Manual

The image shows the cover of the 'ACR Manual on Contrast Media, Version 9, 2013'. The cover has a blue gradient background with a white horizontal bar at the top. A blue sphere is positioned on the right side of the white bar. The text is centered and reads: 'ACR Manual on Contrast Media', 'Version 9', '2013', 'ACR Committee on Drugs and Contrast Media', and the ACR logo at the bottom. The logo includes the text 'ACR', 'AMERICAN COLLEGE OF RADIOLOGY', and 'QUALITY IS OUR IMAGE'.

ACR Manual on Contrast Media

Version 9

2013

**ACR Committee on
Drugs and Contrast Media**

ACR[®]
AMERICAN COLLEGE OF
RADIOLOGY
QUALITY IS OUR IMAGE

www.acr.org/~media/ACR/Documents/PDF/QualitySafety/Resources/Contrast%20Manual/2013_Contrast_Media.pdf

48. Prevent Betadine Burns in the OR

- Pa Safety Authority received dozens of reports of betadine 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

49.. 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

SAFETY AUTHORITY
Commonwealth of Pennsylvania

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Educational Tools

Insulin Therapy

In events involving insulin reported to the Pennsylvania Patient Safety Authority, more than half led to situations in which a patient may have or actually received the wrong dose or no dose of insulin, which could lead to difficulties in glycemic control. Strategies to address these problems include limiting the variety of insulin products, developing standardized protocols and a standardized prescription format, avoiding the use of abbreviations, and requiring an independent double check of all doses before dispensing and administering intravenous insulin.

Browse by Topic

- Discipline
- Audience
- Care Setting
- Event
- Patient Safety Focus
- Hospital-Acquired Condition

Educational Resources

Insulin Measures Worksheet
This sample worksheet may be used for documenting facility-specific process and outcome measures involving the use of insulin.

Articles

Medication Errors with the Dosing of Insulin: Problems across the Continuum
In reported events involving the use of insulin products, 52% of the events led to situations in which a patient may have or actually received the wrong dose or no dose of insulin.

Spotted Again: Insulin/TB Syringe Confusion
An event report about insulin and tuberculin syringe confusion prompts revisiting this topic, which was first highlighted in the October 28, 2004, supplementary Advisory.

Complexity of Insulin Therapy
Nearly 16% of Serious Events submitted through PA-PSRS involved the use of insulin, a high-alert medication.

Follow-up on Previous Advisory Articles
Patient Safety Officers share feedback and follow-up on two topics of previous Advisory issues (i.e., insulin and tuberculin syringe confusion, time out processes).

Overdoses Caused by Confusion Between Insulin and Tuberculin Syringes
Errors in which tuberculin syringes were used in place of insulin syringes may be attributable to a resemblance in packaging of the two syringes.

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PPSA Insulin Measures Worksheet

Measures	TIME PERIOD:			TIME PERIOD:			TIME PERIOD:		
	INCIDENCE	TOTAL PATIENTS	PERCENTAGE	INCIDENCE	TOTAL PATIENTS	PERCENTAGE	INCIDENCE	TOTAL PATIENTS	PERCENTAGE
Outcome Measures									
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									
Monitoring									
	NUMBER	TOTAL		NUMBER	TOTAL		NUMBER	TOTAL	

51. 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

Definitions

Harm

Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring

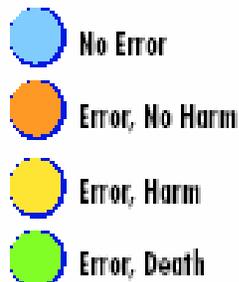
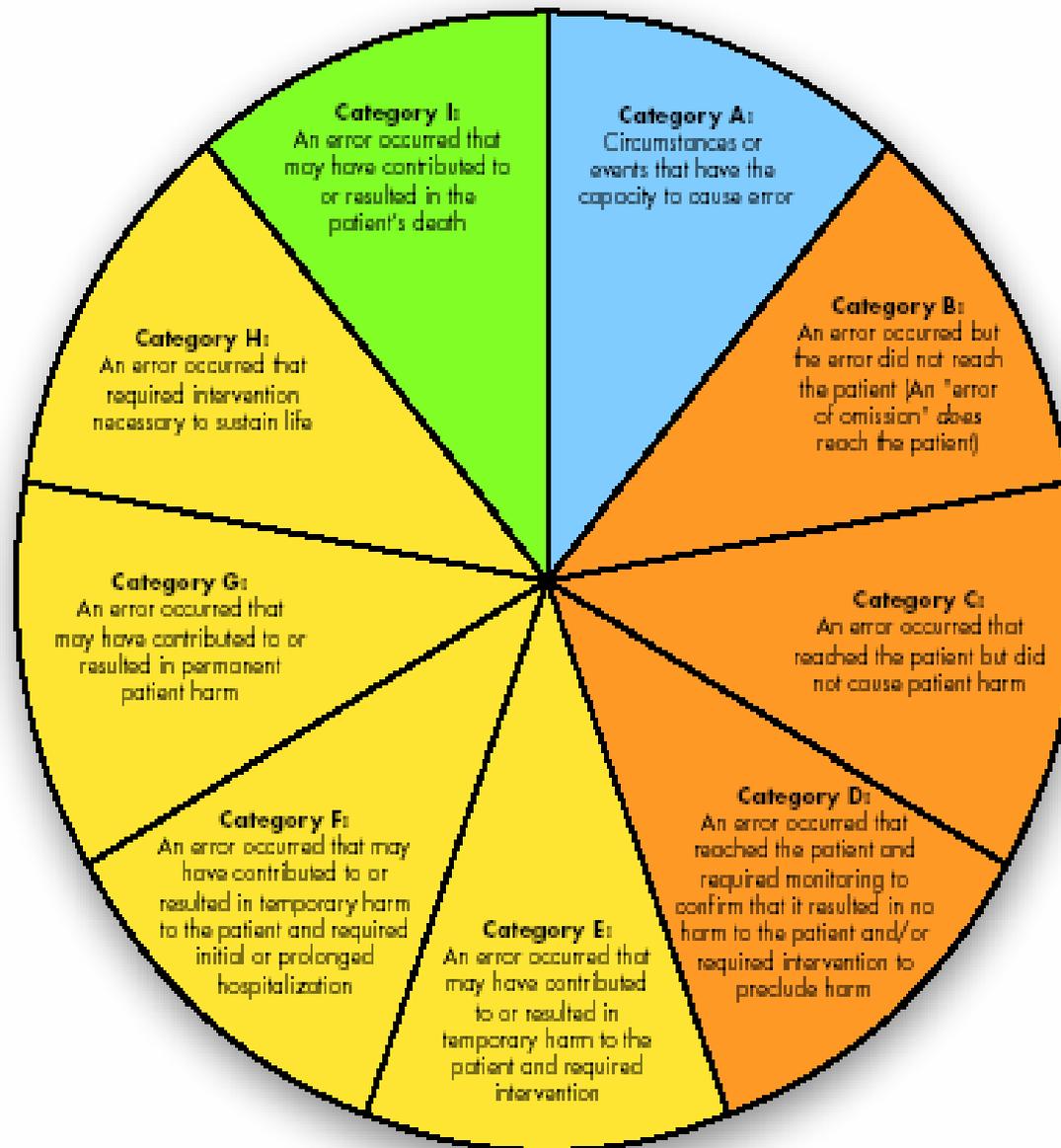
To observe or record relevant physiological or psychological signs.

Intervention

May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)



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.

51. 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;

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

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | FDA Voice Blog

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Regulatory Information

Home Regulatory Information Guidances

Guidances

- FDA Guidance Documents: General and Cross-Cutting Topics
- Advisory Committee Guidance Documents
- Clinical Trials Guidance Documents
- Combination Products Guidance Documents
- Import and Export Guidance Documents
- International Conference on Harmonisation (ICH) Guidance Documents
- Veterinary International Conference on Harmonization (VICH) Guidance Documents

"Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet

Guidance for Institutional Review Boards and Clinical Investigators

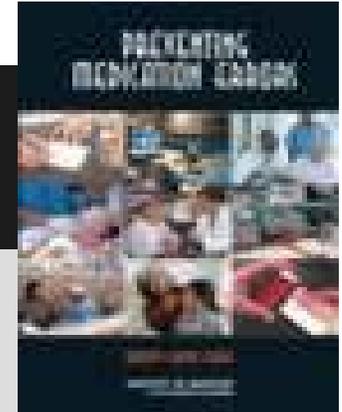
Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgement. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner *when the intent is the "practice of medicine"* does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB). However, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight.

Investigational Use of Marketed Drugs, Biologics and Medical Devices

The investigational use of approved, marketed products differs from the situation described above. "Investigational use" suggests the use of an approved product in the context of a clinical study protocol [see 21 CFR 312.3(b)]. When the principal intent of the investigational use of a test article is to develop information about the product's safety or efficacy, submission of an IND or IDE may be required. However, according to 21 CFR 312.2(b)(1), the clinical investigation of a marketed drug or biologic does not require submission of an IND if all six of the following conditions are met:

- it is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug;
- it is not intended to support a significant change in the advertising for the product;
- it does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
- it is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively];
- it is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]; and
- it does not intend to invoke 21 CFR 50.24

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



Preventing Medication Errors

- Preventing Medication Errors: Quality

Chasm Series,

- 4 out 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 benchmark and be aware of studies on the number of errors

52. 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 if in a hallway or tube system
- Drugs and biologicals must be kept in a secure and locked area
- Also strictly enforced by CMS under tag 502
- Make 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

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



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

ASA Guidelines and Statements

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For Members | For Residents and Students | For the Public and Media | For Health Professionals

Notice: ASA is now accepting 2013 Committee Nominations - Deadline: January 15, 2012

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

Home » For Healthcare Professionals » Standards, Guidelines, Statements and Other Documents

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Standards, Guidelines, Statements and Other Documents

ASA Standards, Guidelines and Statements provide guidance to improve decision-making and promote beneficial outcomes for the practice of anesthesiology. They are not intended as unique or exclusive indicators of appropriate care. The interpretation and application of Standards, Guidelines and Statements takes place within the context of local institutions, organizations and practice conditions. A departure from one or more recommendations may be appropriate if the facts and circumstances demonstrate that the rendered care met the physician's duty to the patient.

Standards provide rules or minimum requirements for clinical practice. They are regarded as generally accepted principles of patient management. Standards may be modified only under unusual circumstances, e.g., extreme emergencies or unavailability of equipment.

Guidelines are systematically developed recommendations that are intended to assist in the decision-making process.

Recommendation on Medications in the OR

The Official Journal of the Anesthesia Patient Safety Foundation



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 CO₂ 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 phenvlephrine and epinephrine) should be available in

53. 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" List¹

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 "l"	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	

Do Not Use Abbreviation

<i>Set</i>	<i>Item</i>	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 MSO₄ MgSO₄	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

Institute for Safe Medication Practices

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 commu-

nicating 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
µg	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	Half-strength	Mistaken as bedtime	Use "half-strength" or "bedtime"
hs	At bedtime, hours of sleep	Mistaken as half-strength	
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"

54. 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

55. “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),
- Also confusion between epinephrine and ephedrine (look alike names),
- Have a P&P, Communicate issues to staff especially ED and ICU and CCU staff,

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.”

56. 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, ETCO₂, 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.

57. 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

58. 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.

58. 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

Institute for Safe Medication Practices

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	<ul style="list-style-type: none"> Diagnostic tests are not performed Wrong diagnostic tests are performed Diagnostic tests are analyzed incorrectly or misinterpreted Diagnostic tests from the wrong patient are used during assessment Diagnostic tests not available in timely manner 	<p>Patient receives anticoagulant when not indicated B, ADR</p> <p>Patient does not receive anti-coagulant when indicated T, D</p>	5				<p>1.a1 Testing protocol for patients who present with signs of thrombosis</p> <p>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</p> <p>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</p> <p>1.a4 Peer-review process for reviewing/rereading diagnostic tests based on severity of outcome of a misdiagnosis</p> <p>1.a5 Use of two patient identifiers when communicating and posting diagnostic test results</p> <p>1.a6 Require persons receiving verbal reports of test results to record and read-back the result</p> <p>1.a7 Improve the timeliness of reporting critical test results</p> <p>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</p> <p>1.a9 Use more than one test to diagnose when possible</p>
	b) Anticoagulant	<ul style="list-style-type: none"> 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

The screenshot shows the ASHP website's Anticoagulation Resource Center. At the top, the ASHP logo and name are displayed, along with navigation links for Login, Shopping Cart, and Register. A search bar is also present. Below the header is a navigation menu with tabs for About Us, News, Member Center, Advocacy, Practice and Policy, Meetings, Continuing Education, Accreditation, and Bookstore. The main content area is titled "Anticoagulation Resource Center" and features a red pill graphic. The page is organized into several sections: a left sidebar with "PRACTICE AND POLICY" and "Public Health Resource Centers"; a main content area with a description of the resource center and a list of topics; and an "ASHP Connect" section on the right. A "Contact Us" box is located at the bottom of the main content area.

ASHP American Society of Health-System Pharmacists®
TOGETHER WE MAKE A GREAT TEAM

Login | Shopping Cart | Register

Search Advanced Search

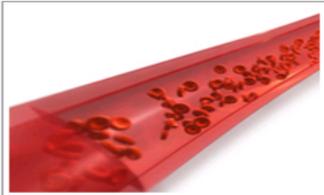
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Home | Practice and Policy | Practice Resources | Anticoagulation

PRACTICE AND POLICY

- ▶ Practice Resource Centers
 - > Anticoagulation Resource Center
 - > Compounding Resource Center
 - > Contrast Media and Medication Management
 - > Drug Shortages
 - > Evidence-Based Practice
 - > Investigational Drug Services
 - > Patient Safety
 - > Patient Assistance Programs
 - > Pharmaceutical Reimbursement
 - > Public Relations
 - > Quality Improvement Initiative (QII)
 - > Small and Rural Hospital

Anticoagulation Resource Center



Helping with the Safe Management of Anticoagulation
Recent advances and events in therapeutic issues, standards, and regulations have demonstrated the need for increased pharmacy involvement with anticoagulation patient management. ASHP's Anticoagulation Initiative: *Promoting Patient Safety through Education, Practice, Policy, and Advocacy* Resource Center is a compilation of materials helpful to you in practice.

Topics in this Resource Center

Listed below are the content areas for visitors.

- ▶ [Articles and Presentations](#)
- ▶ [Guidelines, Policies, Best Practices](#)
- ▶ [CE, Training, and Webinars](#)
- ▶ [Books and External Resources](#)

ASHP Connect

ASHP Connect is the Society's new online community where members connect with each other and share ideas through our discussion board, blogs, social networking tools, RSS feeds, and more.

▶ [Anticoagulation Discussion Board](#)

Contact Us

This resource center is managed by the Section of Clinical Specialists and Scientists. For questions, comments, or more information on this topic, please contact us at sections@ashp.org.

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

Anticoagulant Toolkit PaPSA



The screenshot displays the Patient Safety Authority website. At the top left is the logo for the Patient Safety Authority, Commonwealth of Pennsylvania. A navigation menu on the left lists: HOME, PATIENT SAFETY AUTHORITY, PA-PSRS and PASKEY, PATIENT SAFETY ADVISORIES, PATIENTS AND CONSUMERS, NEWS AND INFORMATION, COLLABORATIONS, EDUCATIONAL TOOLS, and AUTHORITY EVENTS. The main content area features a header image of healthcare professionals, a search bar, and a section titled "Educational Tools". The primary focus is on the "Anticoagulation Management Service" section, which includes a video thumbnail and a descriptive paragraph. Below this are sub-sections for "Educational Tools" (with links to research posters and a video), "Articles" (with a link to an article on safer care), and "Companion Online Information" (with a link to a failure mode analysis).

PATIENT SAFETY AUTHORITY
Commonwealth of Pennsylvania

HOME
PATIENT SAFETY AUTHORITY ▶
PA-PSRS and PASKEY ▶
PATIENT SAFETY ADVISORIES ▶
PATIENTS AND CONSUMERS ▶
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AUTHORITY EVENTS ▶

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

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

Analyzing, Educating for Patients

Search

Educational Tools

Anticoagulation Management Service



The complexity of anticoagulants has resulted in patient safety compromise. Healthcare organizations have increasingly recognized the benefits of anticoagulation management services (AMS) in the inpatient and outpatient settings. This collection of resources about AMS may help facilities outline the positive impact that an AMS program will have to provide safer care and maximize patient outcomes.

Educational Tools

[Anticoagulation Management Service: Providing Safer Care Along the Continuum](#)
This research poster illustrates key components to consider when developing an anticoagulation management service.

[Anticoagulation Management Service: Safe Care, Maximizing Outcomes](#)
This brief informational video about the benefits of an anticoagulation management service can be used for educational purposes.

Articles

[Anticoagulation Management Service: Safer Care, Maximizing Outcomes](#)
Healthcare organizations have increasingly recognized the benefits of anticoagulation services in the inpatient and outpatient settings.

Companion Online Information

[Example of Health Care Failure Mode and Effects Analysis for Anticoagulants](#)
This online information produced by the Institute for Safe Medication Practices is a link to a sample failure mode and effects analysis about anticoagulants.

SEA Preventing Anticoagulant Errors

Topic Details

Sunday 12:42 CST, June 17, 2012

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News and Alerts

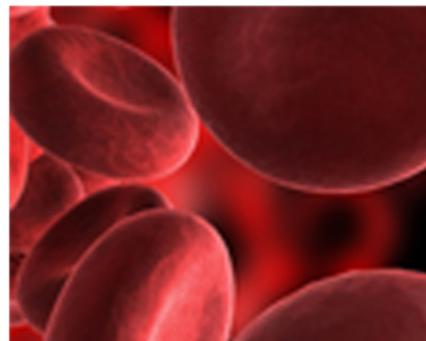
Sign up here

Topic Library Item

Sentinel Event Alert, Issue 41: Preventing errors relating to commonly used anticoagulants

September 24, 2008

Download This File



Reports of accidental deaths and overdosing due to the improper use of anticoagulant drugs have received significant public attention. Anticoagulants have been identified as one of the top five drug types associated with patient safety incidents in the United States. In the United Kingdom, anticoagulants are one of the classes of drugs commonly associated with fatal medication errors.

[Download complete issue.](#)

59. 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

v06
10/01/2008



Getting Started Kit: Prevent Adverse Drug Events (Medication Reconciliation)

How-to Guide

A national initiative led by IHI, the 5 Million Lives Campaign aims to dramatically improve the quality of American health care by protecting patients from five million incidents of medical harm between December 2006 and December 2008. The How-to Guides associated with this Campaign are designed to share best practice knowledge on areas of focus for participating organizations. For more information and materials, go to www.ihl.org/IHI/Programs/Campaign.

This How-to Guide is dedicated to the memory of David R. Calkins, MD, MPP (May 27, 1948 – April 7, 2006) –

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

60. 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

61. 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

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

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

62. 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, FASHP¹

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
Amibid 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



The End! Questions?



- Sue Dill Calloway RN, Esq. CPHRM, CCMSCP
- AD, BA, BSN, MSN, JD
- President of Patient Safety and Education
- 5447 Fawnbrook Lane
- Dublin, Ohio 43017
- 614 791-1468 (Call with Questions, No emails)
- sdill1@columbus.rr.com
- Additional resources to follow

Careful about Heparin LASA drug



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,

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.

More on Medications



- Be aware of food-drug, drug-drug, drug-disease interactions,
- Provide information on these to staff,
- Good lighting 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

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

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

medications. 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

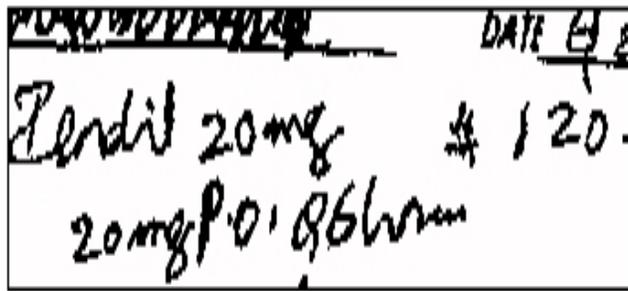
Avoiding the use of inappropriate and high-risk drugs is an important, simple, and effective strategy in reducing medication-related problems and ADEs in older adults. Methods to address medication-related problems include implicit and explicit criteria. Explicit criteria can identify high-risk drugs 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 home residents in 1991, and subsequently expanded and

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
<i>Anticholinergics (excludes TCAs)</i>					
First-generation antihistamines (as single agent or as part of combination products) <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Benztropine (oral) • Trihexyphenidyl 	Not recommended for prevention of extrapyramidal symptoms with antipsychotics; more effective agents available for treatment	Avoid	Moderate	Strong	Rudolph 2008

Illegible Handwriting



~~XXXXXXXXXX~~ DATE / /
Plendil 20mg \$ 120.
20mg PO q6h

Fig. 1. Poorly written prescription for Isordil seen as Plendil

- Patient got a prescription for Isordil 20 mg every 6 hours PO
- Pharmacist misread and gave Plendil (felodipine)
- Patient dies
- Physician and pharmacist sued

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.

51. 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



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.

Dilaudid HYDRomorphine Toolkit

Educational Tools

<http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/hydromorphine/Pages/home.aspx>

HYDRomorphine Risk Reduction



Healthcare facilities can strive to identify system-based causes of wrong drug and wrong dose/overdose errors with the use of HYDRomorphine and other opioids. Risk reduction strategies such as constraints and standardization, which focus on system improvement, will be more effective than education alone, which relies on individual performance.

[Prevention Program Tools Educational Tools](#)

[Articles](#)

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Prevention Program Tools



[HYDRomorphine Measures Worksheet](#)

Educational Tools



[Prescribing Considerations Associated with HYDRomorphine Injection](#)

Articles

[HYDRomorphine Labeling Revisions Approved](#)

In response to medication errors reported to the U.S. Food and Drug Administration (FDA), the Institute for Safe Medication Practices, the Authority, and other reporting programs, FDA has approved labeling revisions to HYDRomorphine products to prevent associated medication errors.

[Adverse Drug Events with HYDRomorphine: How Preventable are They?](#)

Gaps exist in healthcare providers' understanding of the efficacy and potency of HYDRomorphine, as evidenced by medication errors and adverse drug reactions reported in Pennsylvania.

<http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/hydromorphine/P...>

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



NABP

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

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BOARDS OF PHARMACY

TOPICS

Committee And Task Force Reports

Compounding

Controlled Substances

Electronic Prescriptions

Internet Pharmacy

Pharmacy Technicians

Prescribing Authority

Prescription Label

Prescription Monitoring Program

Prescriptions

Pseudoephedrine

Resolutions

Tamper-Resistant Prescription

NABP Recommends Boards of Pharmacy Prohibit Use of Acetaminophen Abbreviation

Posted: **July 15, 2010 01:12 PM** Topics:

NABP is recommending that the state boards of pharmacy prohibit the use of the abbreviation "APAP" on prescription labels, and require that "acetaminophen" be spelled out to assist in preventing the well recognized danger of acetaminophen induced hepatotoxicity. In situations where the board is unable to mandate such a provision, NABP recommends that the boards strongly encourage practitioners to follow this guideline. The recommendation is based on established policy and a letter, sent by Food and Drug Administration (FDA) to state boards of pharmacy on January 22, 2004, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. In the letter, FDA indicated some of the reasons for unintentional overdoses and recommended that drugs containing acetaminophen should be adequately labeled on the container and that the use of the abbreviation "APAP" for acetaminophen should be avoided.

The NABP Task Force on Uniform Prescription Labeling, which met December 6, 2008, stated in its report that the purpose of the prescription label is to provide critical information to the patient. The task force recommended that the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* be amended to ensure that prescription labels are organized in a patient-centered manner, that certain data elements appear on the prescription label, and that critical label information should never be truncated. The task force report also emphasized that the prescription label is designed to supplement patient counseling and not replace it in any way.

Dr Do Not Rx More than 325 mg per tablet

U.S. Department of Health and Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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

Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program > Safety Information

MedWatch The FDA Safety Information and Adverse Event Reporting Program

Safety Information

Safety Alerts for Human Medical Products

2014 Safety Alerts for Human Medical Products

2013 Safety Alerts for Human Medical Products

2012 Safety Alerts for Human Medical Products

2011 Safety Alerts for Human Medical Products

2010 Safety Alerts for Human Medical Products

2009 Safety Alerts for Human Medical Products

2008 Safety Alerts for Human Medical Products

Acetaminophen Prescription Combination Drug Products with more than 325 mg: FDA Statement - Recommendation to Discontinue Prescribing and Dispensing

[Posted 01/14/2014]

AUDIENCE: Consumer, Dentistry, Emergency Medicine, Internal Medicine, Pharmacy, Pain Management, Surgery

ISSUE: FDA is recommending health care professionals discontinue prescribing and dispensing prescription combination drug products that contain more than 325 milligrams (mg) of acetaminophen per tablet, capsule or other dosage unit. There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death.

Cases of severe liver injury with acetaminophen have occurred in patients who:

- took more than the prescribed dose of an acetaminophen-containing product in a 24-hour period;
- took more than one acetaminophen-containing product at the same time; or
- drank alcohol while taking acetaminophen products.

BACKGROUND: In January 2011 FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage which can result

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
- 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



The screenshot shows the SafetyLeaders.org website. At the top left is the TMIT Research Test Bed logo. The top right features the SafetyLeaders.org logo. A navigation bar contains several red buttons: LEAD Hospitals Initiatives, High Performer Survey & Resources, Research Programs, Workshops, Webinars & Meetings, Patient Programs, and Multimedia Center for PSOs. Below this is a secondary navigation bar with links for Home, Search, Web Meetings, New To SafetyLeaders?, About SafetyLeaders, and Login.

Dennis Quaid: Our New SafetyLeaders TMIT Teammate

The Quaid Foundation Has Merged with TMIT

As of April 12, 2010, The Quaid Foundation has merged with TMIT. The Quaid Foundation was formed by Dennis and Kimberly Quaid in 2007 after hospital personnel administered an overdose of heparin, a blood thinner, to their 12-day-old twins, putting their lives at great risk. The Quaid family is joining forces with TMIT to raise public awareness about our broken medical system, to eliminate human error, and to make caregivers aware that patients have the right to know all information that could have an impact on their health and well-being, with major focus on increasing awareness of the dangers of medication errors.

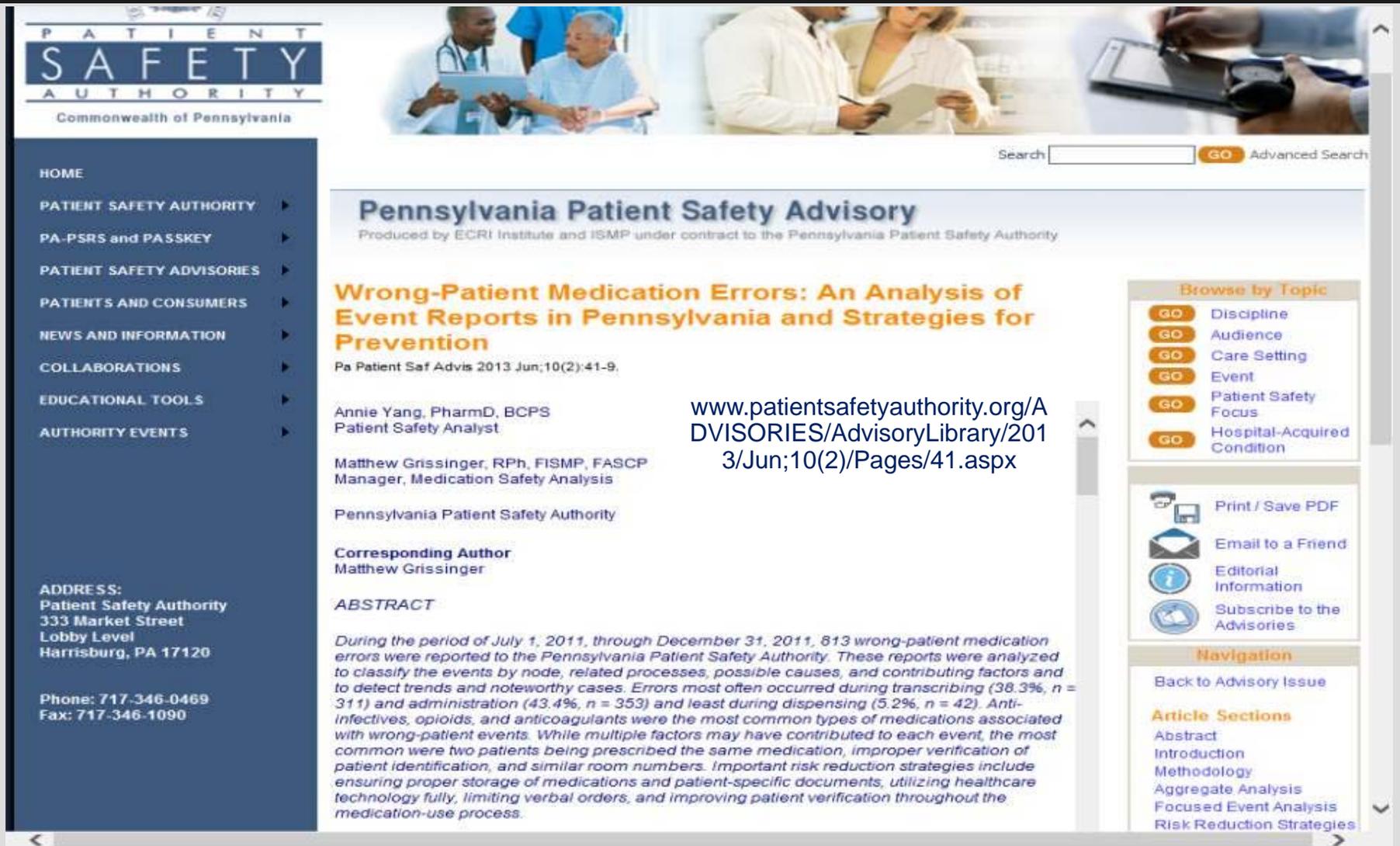
Over the last year, Dennis Quaid and TMIT have been actively involved in a number of other initiatives that have global reach and impact.

The video player shows two men sitting on a couch in an office setting, engaged in a conversation. The man on the right is gesturing with his hand while speaking. The video player interface includes a play button, a progress bar, and volume controls.

Labeling Injectable 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 injectable meds

Keep Up With the Literature



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Pennsylvania Patient Safety Advisory

Produced by ECRI Institute and ISMP under contract to the Pennsylvania Patient Safety Authority

Wrong-Patient Medication Errors: An Analysis of Event Reports in Pennsylvania and Strategies for Prevention

Pa Patient Saf Advis 2013 Jun;10(2):41-9.

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

Pennsylvania Patient Safety Authority

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ABSTRACT

During the period of July 1, 2011, through December 31, 2011, 813 wrong-patient medication errors were reported to the Pennsylvania Patient Safety Authority. These reports were analyzed to classify the events by node, related processes, possible causes, and contributing factors and to detect trends and noteworthy cases. Errors most often occurred during transcribing (38.3%, n = 311) and administration (43.4%, n = 353) and least during dispensing (5.2%, n = 42). Anti-infectives, opioids, and anticoagulants were the most common types of medications associated with wrong-patient events. While multiple factors may have contributed to each event, the most common were two patients being prescribed the same medication, improper verification of patient identification, and similar room numbers. Important risk reduction strategies include ensuring proper storage of medications and patient-specific documents, utilizing healthcare technology fully, limiting verbal orders, and improving patient verification throughout the medication-use process.

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Navigation

Back to Advisory Issue

Article Sections

- Abstract
- Introduction
- Methodology
- Aggregate Analysis
- Focused Event Analysis
- Risk Reduction Strategies

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 gums
- 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

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

Featured Item <http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx>



Obesity is an increasingly prevalent problem that affects the healthcare system and patients. Class III obese patients, in particular, may often require special equipment, different policies, or extra staff in order to ensure appropriate care and patient satisfaction. View the Authority's [Obesity](#) toolkit to learn more.

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[Expressed Breast Milk](#)

[Falls](#)

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[HYDROMorphone Risk Reduction](#)

[Insulin Therapy](#)

[Managing Clinical Emergencies](#)

[Norovirus](#)

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[Obesity](#)

[Obstructive Sleep Apnea](#)

[Opioids](#)

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[Pneumonia](#)

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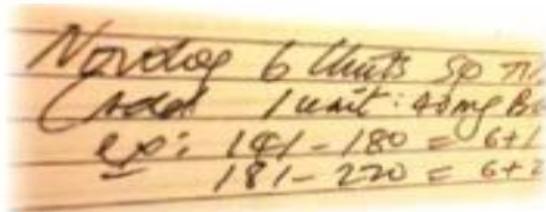
[Verbal Orders](#)

Insulin Therapy Toolkit High Risk Drug

Educational Tools

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

Insulin Therapy



In events involving insulin reported to the Pennsylvania Patient Safety Authority, more than half led to situations in which a patient may have or actually received the wrong dose or no dose of insulin, which could lead to difficulties in glycemic control. Strategies to address these problems include limiting the variety of insulin products, developing standardized protocols and a standardized prescription format, avoiding the use of abbreviations, and requiring an independent double check of all doses before dispensing and administering intravenous insulin.

Educational Resources

Insulin Measures Worksheet

This sample worksheet may be used for documenting facility-specific process and outcome measures involving the use of insulin.

Articles

Medication Errors with the Dosing of Insulin: Problems across the Continuum

In reported events involving the use of insulin products, 52% of the events led to situations in which a patient may have or actually received the wrong dose or no dose of insulin.

Spotted Again: Insulin/TB Syringe Confusion

An event report about insulin and tuberculin syringe confusion prompts revisiting this topic, which was first highlighted in the October 28, 2004, supplementary Advisory.

Complexity of Insulin Therapy

Nearly 16% of Serious Events submitted through PA-PSRS involved the use of insulin, a high-alert medication.

Follow-up on Previous Advisory Articles

Patient Safety Officers share feedback and follow-up on two topics of previous Advisory issues (i.e., insulin and tuberculin syringe confusion, time out processes).

Overdoses Caused by Confusion Between Insulin and Tuberculin Syringes

Errors in which tuberculin syringes were used in place of insulin syringes may be attributable to a resemblance in packaging of the two syringes.

New Labeling of Injectables



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

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

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



Vaccines & Immunizations

[Vaccines Home](#) > [Publications](#) > Vaccine Information Statements

Vaccine-Related Topics

- > [Immunization Schedules](#)
- > [Recommendations and Guidelines](#)
- > [Vaccines & Preventable Diseases](#)
- > [Basics and Common Questions](#)
- > [Vaccination Records](#)
- > [Vaccine Safety and Adverse Events](#)
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Additional Resources

- > [Publications](#)
- > [Vaccine Information Statements \(VIS\)](#)
- > [Textbooks, Manuals and](#)

Publications:

Vaccine Information Statements

At a glance:

Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. [Federal law](#) requires that VISs be handed out whenever (before each dose) certain vaccinations are given.

Downloadable VISs :

| [Multiple Vaccines](#) (DTaP, IPV, Hib, PCV, Hepatitis B, and Rotavirus)

| [Anthrax](#) | [DTaP](#) | [Hepatitis](#) | [Hib](#) | [Influenza](#) **UPDATED** | [HPV](#) | [JE](#) | [MMR](#) | [MMRV](#) **NEW**
| [Meningococcal](#) | [PCV13 and PCV7](#) **UPDATED** | [PPSV23](#) | [Polio](#) | [Rabies](#)
| [Rotavirus](#) **UPDATED** | [Shingles](#) | [Smallpox](#) | [Td/Tdap](#) | [Typhoid](#) | [Varicella](#)
| [Yellow Fever](#)

[VIS News](#) Information about new, existing, and upcoming VISs (Last updated **8/14/10**)

UPDATED

| [Mandatory Instructions for Use of the Vaccine Information Statements](#) **UPDATED**

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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 broad 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 you 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?



You Are Here: [AHRQ Home](#) > [Consumers & Patients](#) > [20 Tips to Help Prevent Medical Errors](#)

20 Tips to Help Prevent Medical Errors Patient Fact Sheet

www.ahrq.gov/consumer/20tips.htm

Medical errors can occur anywhere in the health care system: In hospitals, clinics, surgery centers, doctors' offices, nursing homes, pharmacies, and patients' homes. Errors can involve medicines, surgery, diagnosis, equipment, or lab reports. These tips tell what you can do to get safer care.

Select for [PDF version](#) (300 KB). [Plugin Software Help](#). This publication is also available in [Spanish \(PDF version, 296 KB; PDF Ayuda\)](#).

One in seven Medicare patients in hospitals experience a medical error. But medical errors can occur anywhere in the health care system: In hospitals, clinics, surgery centers, doctors' offices, nursing homes, pharmacies, and patients' homes. Errors can involve medicines, surgery, diagnosis, equipment, or lab reports. They can happen during even the most routine tasks, such as when a hospital patient on a salt-free diet is given a high-salt meal.

Most errors result from problems created by today's complex health care system. But errors also happen when doctors and patients have problems communicating. These tips tell what you can do to get safer care.

What You Can Do to Stay Safe

The best way you can help to prevent errors is to be an active member of your health care team. That means taking part in every decision about your health care. Research shows that patients who are more involved with their care tend to get better results.

Medicines

1. **Make sure that all of your doctors know about every medicine you are taking.** This includes prescription and over-the-counter medicines and dietary supplements, such as vitamins and herbs.
2. **Bring all of your medicines and supplements to your doctor visits.** "Brown bagging" your medicines can help you and your doctor talk about them and find out if there are any problems. It can also help your doctor keep your records up to date and help you get better quality care.
3. **Make sure your doctor knows about any allergies and adverse reactions you have had to medicines.** This can help you to avoid getting a medicine that could harm you.
4. **When your doctor writes a prescription for you, make sure you can read it.** If you cannot read your doctor's handwriting, your pharmacist might not be able to either.

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- 4. When your doctor writes a prescription for you, make sure you can read it.** If you cannot read your doctor's handwriting, your pharmacist might not be able to either.
- 5. Ask for information about your medicines in terms you can understand—both when your medicines are prescribed and when you get them:**
 - What is the medicine for?
 - How am I supposed to take it and for how long?
 - What side effects are likely? What do I do if they occur?
 - Is this medicine safe to take with other medicines or dietary supplements I am taking?
 - What food, drink, or activities should I avoid while taking this medicine?
- 6. When you pick up your medicine from the pharmacy, ask: Is this the medicine that my doctor prescribed?**
- 7. If you have any questions about the directions on your medicine labels, ask.** Medicine labels can be hard to understand. For example, ask if "four times daily" means taking a dose every 6 hours around the clock or just during regular waking hours.
- 8. Ask your pharmacist for the best device to measure your liquid medicine.** For example, many people use household teaspoons, which often do not hold a true teaspoon of liquid. Special devices, like marked syringes, help people measure the right dose.
- 9. Ask for written information about the side effects your medicine could cause.** If you know what might happen, you will be better prepared if it does or if something unexpected happens.

Medication Management

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



CDC Guidelines on Intravascular Catheters



Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011

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Thank you for attending!



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