AHC Media

Getting the Right Prescription: CMS Medication and Pharmacy Standards

Thursday,
October 2nd, 2014

Speaker

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- Board Member
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Learning Objectives

1. Recall why hospitals receiving Medicare/Medicaid reimbursement must follow CMS medication guidelines even if the hospital has deemed status.

2. Review the three timeframes in which all medications must be given.

3. Describe the policy CMS requires for high-risk drugs such as double checks or dose limits.

4. Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.

5. Evaluate compliance requirements and penalties

You Don’t Want One of These From CMS

TJC Revised Requirements

- Joint Commission has made many changes in the past and these are to bring their standards into closer compliance with the CMS CoP
- TJC has had a chapter on Medication Management standards since 2004
  - Has 8 sections and 20 elements of performance and very detailed
- TJC also has FAQs on medication management
  - Some standards are the same but others are different and all hospitals should consider adopting since important in reducing medication errors

TJC Medication Management Chapter

Chapter Outline:

I. Planning
   A. Medication Planning (MM.01.01.01, MM.01.01.03) *(MM.01.01.05 is not applicable to hospitals)*
   B. Look-alike/Sound-alike Medications (MM.01.02.01)

II. Selection and Procurement (MM.02.01.01)

III. Storage (MM.03.01.01, MM.03.01.03, MM.03.01.05)

IV. Ordering and Transcribing (MM.04.01.01)

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.05.01.15, 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.07.01.01, MM.07.01.03)

VIII. Evaluation (MM.08.01.01)

Letter to TJC Regarding Anesthesia Issues

- Four anesthesia groups sent a letter to TJC
- TJC responded to the letter
- All Joint Commission hospitals should consider keeping copies of these correspondences
- Copies are available off the ASA website
- Discusses many important issues such as using pre-labeled stickers, informing patients of first dose of drugs, carrying medications in your pocket, preparing medication for surgery, and preparing a medication that is immediately given

An Era of Concerns

Letter from ASA to Joint Commission Urges Action on Medication Management Concerns

By Rachel Fields | December 28, 2010

The American Society of Anesthesiologists, along with the American Association of Nurse Anesthetists, the American Academy of Anesthesiologist Assistants and the Anesthesia Patient Safety Foundation, has sent a joint letter to The Joint Commission, urging action on a number of concerns related to medication management.

The letter addressed several issues, such as the labeling of syringes and containers, medications for patients in transport to recovery areas, medication security and locked carts and informed consent. The letter cited concerns with the prohibition pre-labeled syringes, which the organizations believe actually decrease medication errors, and the Joint Commission's position on labeling of spinal anesthetics.

The letter also asked The Joint Commission to provide written confirmation that its standards do not prohibit anesthesia professionals from carrying medications on their person when indicated or necessary for patient safety and in accordance with institutional policy.

Read the letter from the ASA and other organizations to the Joint Commission.

Read more about anesthesia:

TJC Response Medication Security

www.asahq.org/.../For%20Members/Advocacy/ASA%20in%20Washington/TJC%20Med%20Mgmt%20Letter%2012-21-10.ashx

December 21, 2010

Mark Chassin, MD, MPP, MPH
President
The Joint Commission
One Renaissance Blvd.
Oakbrook Terrace, IL 60181

Re: Medication Management and Anesthesia Practice

Dear Dr. Chassin,

The American Society of Anesthesiologists (ASA), representing over 44,000 members, the American Association of Nurse Anesthetists (AANA), representing more than 40,000 members, the American Academy of Anesthesiologist Assistants (AAAA), representing 900 members, and the Anesthesia Patient Safety Foundation (APSF) are pleased to submit this joint letter to summarize our collective and unified thoughts on relevant medication management issues that continue to persist.

Our societies and members take very seriously medication management issues, especially as they relate to patient safety. We also recognize that such issues and their respective standards and regulations should be evidence-based, when possible, and feasible for all anesthesia providers to efficiently and effectively perform their job and deliver high quality, safe patient care. We are pleased to know that The Joint Commission agrees that standards should be evidence-based and is working to eliminate those that fail to achieve this goal.

Labeling of Syringes and Containers

Our members support the need for labeling medications appropriately and are working to promote the most effective means of eliminating medical errors in the operating room, both on and off the sterile field. However, we still have outstanding concerns with respect to the following issues:

- Prohibition on pre-labeled syringes
- Labeling of spinal and epidural anesthetics and analgesics
- Label verification requirements when two individuals are involved

The Conditions of Participation (CoPs)

- Regulations first published in 1986
  - Many revisions in recent past to luer misconnections, visitation, IV medication and blood, anesthesia, pharmacy, insulin pens, timing of medication, safe injection practices, standing orders, self administered medication and telemedicine
  - Manual updated June 6, 2014
  - This latest manual included changes related to IV medication, blood, and **safe opioid** use under tags 405, 409, 412 and 957
- First regulations are published in the **Federal Register** then CMS publishes the **Interpretive Guidelines** and some have **survey procedures** [2]
  - Hospitals should check this website once a month for changes

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

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 all manuals

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

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

The Revised Final CoPs

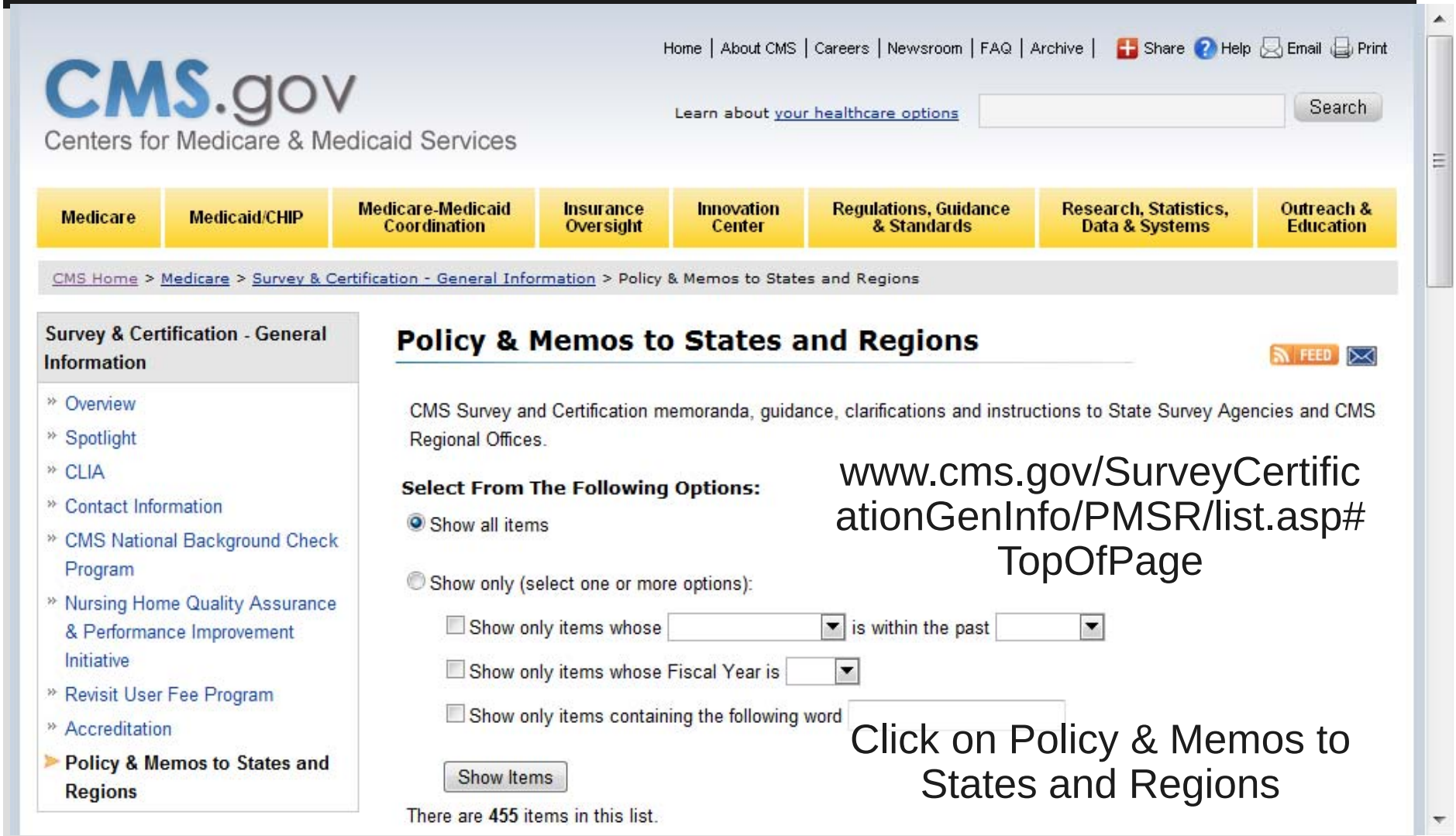
- Every hospital should have a copy of the hospital CoP manual and consider placing it on hospital intranet [1]
- Slides have tag number so you can go back and review each section
- Check CMS website once a month for changes [3]

[1]www.cms.hhs.gov/transmittals/downloads/R37SOMA.pdf

2 http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf

3http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

CMS Survey and Certification Website



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

Click on Policy & Memos to States and Regions

Policy & Memos to States and Regions

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

Show entries: 10

Filter On:

Title	Memo #	Posting Date	Fiscal Year
Access to Statements of Deficiencies (CMS-2567) on the Web for Skilled Nursing Facilities, Nursing Facilities, Hospitals,& Critical Access Hospitals	13–21- ALL	2013-03-22	2013
AHRQ Common Formats - Information for Hospitals and State Survey Agencies (SAs) - Comprehensive Patient Safety Reporting Using AHRQ Common Formats	13-19-HOSPITALS	2013-03-15	2013
Guidance for Hospitals, Critical Access Hospitals (CAHs) and Ambulatory Surgical Centers (ASCs) Related to Various Rules Reducing Provider/Supplier Burden	13-20-Acute Care	2013-03-15	2013
Luer Misconnection Adverse Events	13-14-ALL	2013-03-08	2013
Physician Delegation of Tasks in Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs)	13-15-NH	2013-03-08	2013
F tag 155-- Advance Directives- Revised Advance Copy	13-16-NH	2013-03-08	2013
F tag 322—Naso-Gastric Tubes - Revised Advance Copy	13-17-NH	2013-03-08	2013
Revised Roll-Out of the New End Stage Renal Disease (ESRD) Core Survey Process	13-18-ESRD	2013-03-08	2013
Notice -Ninth Opportunity National Background Check Program Funding	13-12- NH	2013-03-01	2013
Information Only: New Dining Standards of Practice Resources are Available Now	13-13-NH	2013-03-01	2013

CMS Hospital Worksheets Third Revision

- October 14, 2011 CMS issues a 137 page memo in the survey and certification section
  - Memo discusses surveyor worksheets for hospitals by CMS during a hospital survey
- Addresses discharge planning, infection control, and QAPI and includes section on safe injection practices and preventing MDRO and antibiotic use (at end)
- It was pilot tested in hospitals in 11 states and on May 18, 2012 CMS published a second revised edition
  - Piloted test each of the 3 in every state over summer 2012
  - November 9, 2012 CMS issued the third revised worksheet which is now 88 pages and some revisions expected 2014

Third Revised Worksheets

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: 13-03-Hospital

DATE: **November 9, 2012**

TO: State Survey Agency Directors

FROM: Director
Survey & Certification Group

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

SUBJECT: Patient Safety Initiative FY 2013 Pilot Phase – Revised Draft Surveyor Worksheets

Memorandum Summary

- *Patient Safety Initiative*: The Centers for Medicare & Medicaid Services (CMS) is continuing to test revised surveyor worksheets for assessing compliance with three hospital Conditions of Participation (CoPs): Quality Assessment and Performance Improvement (QAPI), Infection Control, and Discharge Planning. We are focusing on compliance with these CoPs as a means to reduce hospital-acquired conditions (HACs), including healthcare associated infections (HAIs), and preventable readmissions.
- *Draft Worksheets Made Public:* Via this memorandum we are making the revised draft worksheets publicly available. As was the case previously, there may be additional revisions to the worksheets at the end of FY 2013.

Patient Safety Initiative Pilot Phase

The Survey & Certification Group (SCG) Patient Safety Initiative is continuing to pilot test three revised surveyor worksheets designed to help surveyors assess compliance with the hospital CoPs for QAPI, infection control, and discharge planning. In S&C-12-01 released October 14, 2011 and in S&C-12-32 released May 18, 2012, we made available to the public copies of the initial and revised draft surveyor worksheets. These worksheets were used during the pre-test and pilot phases of the SCG initiative, from September 2011 through September 2012.

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)
- 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

Single Dose Medication June 18, 2012

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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 drugs from one SDV to multiple patients without adhering to USP <797>***

CMS Memo on Safe Injection Practices

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

CMS Memo on Safe Injection Practices

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

CMS Memo on Safe Injection Practices

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

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- Bar Code Guide
- My Medicine List™
- Outsourcing Sterile Products Preparation: Contractor Assessment Tool
- Pharmacy Practice Model Initiative

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www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx

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

CMS Memo on Insulin Pens

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

Insulin Pens

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

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-30-ALL

DATE: **May 18, 2012**

TO: State Survey Agency Directors

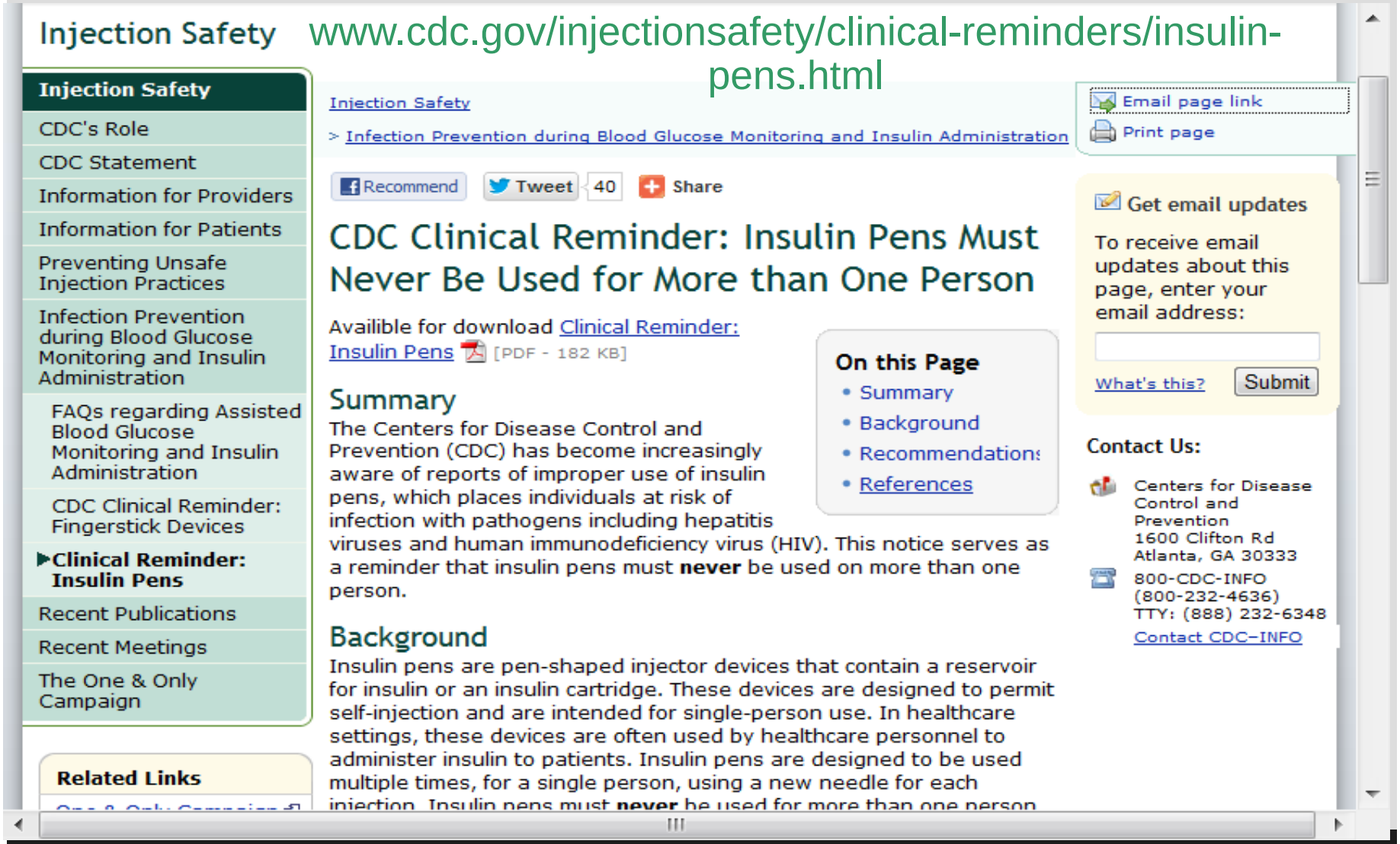
FROM: Director
Survey and Certification Group

SUBJECT: Use of Insulin Pens in Health Care Facilities

Memorandum Summary

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

CDC Reminder on Insulin Pens



CDC Has Flier for Hospitals on Insulin Pens

CDC CLINICAL REMINDER

Insulin Pens
Must Never Be Used for More than One Person

Summary

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

Background

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times, for a single person, using a new needle for each injection. Insulin pens must **never** be used for more than one person. Regurgitation of blood into the insulin cartridge can occur after injection [1] creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed.

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

Recommendations

VA Alert on Insulin Pens

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

VA Issues Alert 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

VA Alert on Insulin Pens

- Decided to prohibit multi-dose insulin pen injectors on all patient units except the following:
  - Patients being educated prior to discharge to use a insulin pen injector
  - Eligible patient is self medication program
  - Patient needing treatment and no alternative formulation is available
  - Patients participating in a research protocol requiring an insulin pen
  - Pen injectors dispensed directly to patients as an outpatient prescription

FDA Issues An Alert in 2009

U.S. Food and Drug Administration

Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens

FDA ALERT [03/19/2009]: The FDA is issuing this alert to remind healthcare providers and patients that insulin pens and insulin cartridges* (see description below) are never to be shared among patients. Sharing of insulin pens may result in transmission of hepatitis viruses, HIV, or other blood-borne pathogens.

The FDA has received information that insulin pens may have been shared among numerous patients (two thousand or more) in one hospital in the United States from 2007-2009 (http://www.wbamc.amedd.army.mil/[1]), and in a smaller number of patients in at least one other hospital. Although the disposable needles in the insulin pens were reportedly changed for each patient, there is still a risk of blood contamination of the pen reservoir or cartridge. Patients who were treated with insulin pens at the hospitals in question are being contacted by the hospitals, and are being offered testing for hepatitis and HIV. Some of the potentially exposed patients have reportedly tested positive for hepatitis C; however it is not known if the hepatitis infection occurred through insulin pen sharing, or if those who tested positive had previously undiagnosed hepatitis C.

Insulin Pen Posters and Brochures Available

ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.
Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

About the Campaign | Safe Injection Practices | Healthcare Provider Information | Patient Information | Campaign Resources | News | Contact Us

Insulin Pen Safety – One Insulin Pen, 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

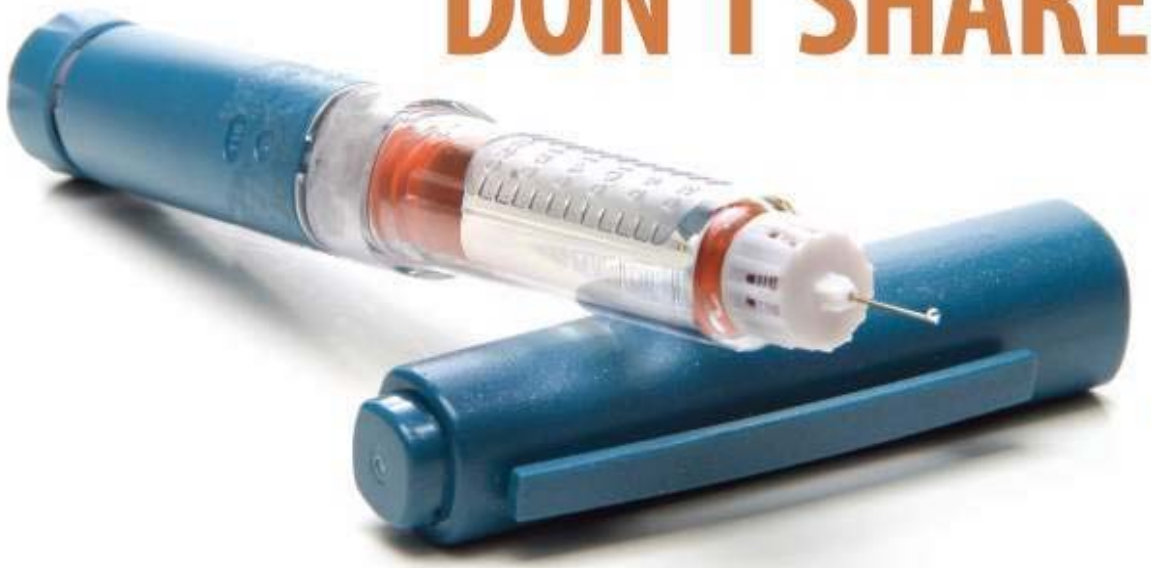
- Poster
- Brochure

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

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.

1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

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

ONE INSULIN PEN, ONLY ONE PERSON

Recommendations for Safe Insulin Pen Use

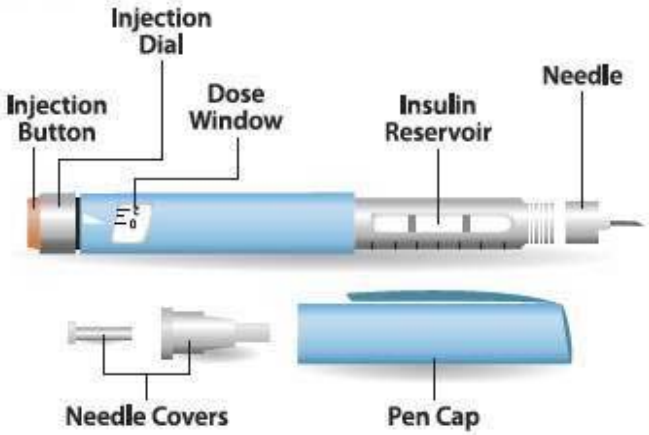
Protection from infection is a basic expectation anywhere healthcare is delivered. Use of insulin pens and other injection equipment for more than one person poses unacceptable risks and should be considered a "never" event.

- Insulin pens and other injection equipment containing multiple doses of medication are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens and other injection equipment should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

These recommendations apply to any setting where insulin pens and other injection equipment are used, including assisted living or residential care facilities, skilled nursing facilities, clinics, health fairs, shelters, detention facilities, senior centers, schools, and camps as well as licensed healthcare facilities.

Insulin Administration

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. They 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 for a single person multiple times, using a new needle for each injection.

Back flow of blood into the insulin reservoir can occur during an injection. This creates a risk of bloodborne and bacterial pathogen transmission if the pen is used for more than one person, even when the needle is changed.

The Safe Injection Practices Coalition created an easy to use check list for facilities. Similar to a risk assessment, the list contains the necessary components of injection safety for facilities to quickly assess their practices.

A copy of the checklist can be found at: www.cdc.gov/injectionsafety/Checklist

Timing of Medications

- Nursing tag number 405 use to say all medications had to be given within 30 minutes of scheduled time
- Now **three** time frames to give medications
  - 30 minutes- some medications are critical and must be given timely such as fast acting insulin with meal or antibiotic in surgery within 1 hour
  - Meds given twice a day or more, such as tid, bid, qid, every 6 hours) give 1 hour before or after so 2 hour window
  - More than once a day, such as once a week, month, year, give 2 hours before or after so 4 hour window

Timing of Medications & Standing Orders

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality / Survey & Certification Group

Ref: S&C-12- 05-Hospital

DATE: **November 18, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Updated Guidance on Medication Administration, Hospital Appendix A of the State Operations Manual (SOM)

Memorandum Summary

- ***Medication Administration Guidance Updated***: SOM Appendix A guidance concerning medication administration in hospitals is being updated to:
  - Reflect current standards of practice related to timeliness of medications. Hospitals are expected to establish policies and procedures for the timing of medication administration that appropriately balance patient safety with the need for flexibility in work processes.
  - Incorporate policy regarding standing orders from S&C-09-10.
- ***ASPEN Changes***: Tags A-404 and A-405 have been combined. It will take time for this guidance to be incorporated into a future ASPEN release. Prior to this conversion citations should be made only to Tag A-404.

Medication Timing Transmittal Dec 22, 2011

CMS Manual System
Pub. 100-07 State Operations
Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 77	(Advance Copy)	Date: December 22, 2011

SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for 42 CFR 482.23(c), concerning medication administration.

REVISED MATERIAL - EFFECTIVE DATE*: December 22, 2011
IMPLEMENTATION DATE: December 22, 2011

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/§482.23(c) Standard: Preparation and Administration of Drugs/A-0405

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

A-0405

(Rev. 77, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§482.23(c) Standard: Preparation and Administration of Drugs

2014 Changes Safe Use of Opioids

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-15-Hospital

DATE: **March 14, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

Memorandum Summary

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

Luer Misconnections Memo

- CMS issues memo March 8, 2013
- 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

Luer Misconnections Memo

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

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-14-ALL

DATE: **March 8, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Luer Misconnection Adverse Events

Memorandum Summary

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

June 2010 Pa Patient Safety Authority

Tubing Misconnections: 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 misconnections becomes more prevalent. Tubing misconnections can occur with intravenous catheters, feeding tubes, hemodialysis tubes, and tracheostomy coils, among other devices. One of the main reasons for tubing misconnections is that many types of tubing for different types of medical devices incorporate luer connectors. These connectors contribute to misconnections because they allow luer-to-luer dissimilar tubes or catheters to be connected together. Between January 2008 and September 2008, 36 events of tubing misconnections were reported to the Pennsylvania Patient Safety Authority involving various types of misconnections. Methods for reducing the likelihood of tubing misconnections include equipment design solutions and administrative controls (policies and work practices). Equipment design solutions either prevent the user from making a misconnection or prompt the user to make the correct connection. Administrative controls are policies and practices that reduce the risk of misconnections such as tracing lines back to their sources. (Pa Patient Saf Advis 2010 Jun;7(2):41-5.)

Introduction

Depending on acuity level, patients may have many tubing lines connecting them to medical devices only or 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 misconnections can occur with potentially fatal results.[1] Misconnections have been recognized as a serious problem for many years. One of the earliest published reports of misconnections was the inadvertent delivery of breast milk via intravenous (IV) administration in 1972.[2] However, misconnections have garnered more attention in recent years, especially in the United States, due in part to the tubing misconnection Sentinel Event Alert issued by the Joint Commission in April 2006.[3]

for IV delivery connected to nasogastric tubes.[4] The Alert offers risk reduction strategies and recommendations, which are included in the overall risk reduction strategies below.

There are many types of misconnections; however, this article will focus on liquid-to-liquid and liquid-to-gas misconnections because these misconnections 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 nutrition 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 misconnections can result in a liquid substance entering the wrong body part or the wrong substance entering the patient. Liquid-to-gas misconnections are incorrect connections that can result in gas introduced into patients' blood vessels or liquid entering patients' respiratory tracts.[5]

A common reason for tubing misconnections, whether liquid-to-liquid or liquid-to-gas, is that some types of tubing lines for different medical devices incorporate common luer connectors. The International Organization for Standardization (ISO) characterizes a luer connector as a conical fitting with a 6% (Luer) taper for syringes, needles, and other medical equipment.[6] The luer connection system consists of male and female counterparts that are joined together either by push-thru slip or screw-in threaded (luer lock) fittings. Luer connectors contribute to misconnections because they easily allow functionally dissimilar tubes or catheters to be connected together.[7]

Misconnections in Pennsylvania

Between January 2008 and September 2008, 36 tubing misconnection events were reported to the Authority: 35 liquid-to-liquid events and 1 liquid-to-gas event. (See the Table for a breakdown of the types of misconnections reported.) Examples of the serious illness and incidents involving misconnections reported to the Authority include the following:

> The patient is a 4-month-old infant admitted . . . to determine renal function. The physician ordered a 22 mL bolus of 50% [normal saline]. A . . . nurse connected the bag of NS to the patient's [central] line. . . .

June 2010 Pa Patient Safety Authority

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> The patient is a 4-month-old infant admitted . . . to determine renal function. The physician ordered a 22 mL bolus of 50% [normal saline]. A . . . nurse connected the bag of NS to the patient's [central venous catheter] . . .

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 gastrointestin disorder, died at a pediatric care center. A suspension of **QUESTRAN** (cholestyramine) was accidentally given via a central line intravenous catheter instead of through an enteral feeding tube.

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

Luer connector systems, common to many healthcare catheters, tubes, administration sets, extension sets, and syringe have been at the heart of many catheter/tubing misconnections. At the center of one of the most commonly reported problems is the fact that some manufactured enteral catheters still have ports that only accept parenteral administratio sets and syringes. So, even if a liquid medication is prepared in an oral syringe, the medication must be transferred to 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 whic we've described in this newsletter since publication began in 1996:

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

FDA Luer Misconnections

U.S. Food and Drug Administration

Search FDA

Tubing and Luer Misconnections: Preventing Dangerous Medical Errors

Patients in health care settings receive medications and other therapies through a variety of tubes and catheters. These delivery systems often use parts called small-bore connectors to link various components. Small-bore refers to the small size of the opening of the connector. Luer connectors are a commonly used type of small-bore connector and throughout this website the term Luer will be used to describe both Luer and other types of small-bore connectors.

Because these connectors are compatible between different delivery systems, patient injuries and deaths have occurred when medicines, liquid feeding formulas, or air were accidentally delivered through the wrong tubing. These errors are sometimes called tubing misconnections, wrong route errors, catheter misconnections or Luer misconnections. It is vitally important that all health care clinicians receive appropriate orientation and training that emphasizes the risk of tubing misconnections. This includes not only acute care settings, but, long-term care, rehabilitation facilities, home health care, physician offices, and any non-clinical settings in which a small-bore connector may be used on a patient.

This website explains how misconnections occur, provides real-life examples of misconnections, and offers tips and additional resources for preventing them. Guidance for manufacturers of enteral feeding systems is also provided.

www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm

Luer Lock (left) and Luer Slip (right)

New Standards Prevent Tubing Misconnections

- New and unique international standards being developed in 2014 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

New standards to prevent tubing misconnections will have unprecedented impact on supply chain and patient safety

What if you could no longer connect any of the equipment that you have in stock to give enteral feedings (e.g., feeding sets, tubes, oral syringes). That is the likely scenario - once new standards to prevent tubing misconnections are released - without a carefully crafted implementation plan across all settings where care is delivered.

The very simple and universal design of most *connectors* in all of health care creates a serious risk that tubes from totally unrelated systems can be inadvertently connected leading to patient death or serious injury. This means that an enteral feeding tube could be accidentally connected to an IV line, delivering formula into a vein with fatal consequences. An international group of stakeholders are working together to solve this problem by developing unique design standards for every delivery system so that unrelated systems can never be mistakenly connected together.

What do these new standards mean for healthcare

New and unique international standards are being developed for connectors for each gas and liquid delivery system in healthcare to make it virtually impossible to connect unrelated systems[1]. These new connector standards will include new designs for connectors of enteral, respiratory, limb cuff inflation, neuraxial, and intravascular systems. It is anticipated that the standards for enteral connectors will be the first to be released in 2014. There will be a phase-in period for product development, market release and implementation guided by the FDA, existing state legislation, suppliers, and national organizations working together.

www.premierinc.com/tubingmisconnections/

Self Administered Meds Tag 412 and 413

A-0412
(Rev. 84, Issued: 06-07-13, Effective: 06-07-13, Implementation: 06-07-13)

§482.23(c)(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self -administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.

(i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.

(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).

(C) Instruct the patient (or the patient's support person where appropriate) in the safe and accurate administration of the specified medication(s).

(D) Address the security of the medication(s) for each patient.

(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

4th Anesthesia Changes January 14, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 02-02-38
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C-11-10-Hospitals

DATE: **January 14, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp

SUBJECT: Revised Hospital Anesthesia Services Interpretive Guidelines—State Operations Manual (SOM) Appendix A

Memorandum Summary

Revisions to Recently Updated Interpretive Guidelines for Anesthesia Services: The Centers for Medicare & Medicaid Services (CMS) has revised the guidelines concerning the anesthesia services Condition of Participation (CoP) at 42 CFR 482.52.

- Hospitals are expected to develop and implement policies and procedures that address the clinical circumstances under which medications that fall along the analgesia-anesthesia continuum are considered anesthesia, and specify the qualifications of practitioners who can administer analgesia.
- Additional clarifications related to pre- and post-anesthesia evaluation requirements are provided.
- Frequently Asked Questions (FAQs) are also attached.

On December 11, 2009 CMS released updated Interpretive Guidelines for the Anesthesia Services Condition of Participation (CoP) for Hospitals as an attachment to S&C memo 10-09. Among other things, this guidance was a response to requests for clarification of the distinction between analgesia and anesthesia, given that the regulation at 42 CFR 482.52(a) limits the administration of anesthesia

Access to Hospital Complaint Data

- CMS issued Survey and Certification memo on March 22, 2013 regarding access to hospital complaint data
- Includes deficiency in the pharmacy standards
  - Includes acute care and CAH hospitals
  - Does not include the plan of correction but can request
  - Questions to bettercare@cms.hhs.com
- This is the CMS 2567 deficiency data and lists the tag numbers
  - Will update quarterly
  - Available under downloads on the hospital website at www.cms.gov

Access to Hospital Complaint Data

- There is a list that includes the hospital's name and the different tag numbers that were found to be out of compliance
  - Many on restraints and seclusion, EMTALA, infection control, patient rights including consent, advance directives and grievances
- Two websites by private entities also publish the CMS nursing home survey data
  - The ProPublica website for LTC
  - The Association for Health Care Journalist (AHCJ) websites for hospitals

Access to Hospital Complaint Data

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: 13-21- ALL

DATE: **March 22, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Access to Statements of Deficiencies (CMS-2567) on the Web for Skilled Nursing Facilities, Nursing Facilities, Hospitals, & Critical Access Hospitals

Memorandum Summary

- ***Survey Findings Posted on*** *http://www.cms.gov:* In July 2012, the Centers for Medicare & Medicaid Services (CMS) began posting redacted Statements of Deficiencies (CMS-2567s) for skilled nursing facilities and nursing facilities on *Nursing Home Compare*. In March 2013, CMS began posting CMS-2567s for short-term acute care hospitals and critical access hospitals (CAHs) for surveys based on complaint investigations. This memorandum describes the contents and location of these files.
- ***Other Web-based Tools Based on These Data:*** At least two additional websites, provided by private parties (*ProPublica* and the Association for Health Care Journalists), publish information based on the CMS-2567 data. These websites are independent of CMS. CMS does not endorse or sponsor any particular private party application.
- ***Plans of Correction (POC):*** The posted CMS data do not contain any POC information. State Survey Agencies (SAs) and CMS Regional Offices (RO) may see an increase in requests for both the CMS-2567 and any associated POCs.
- ***Question & Answers:*** We plan to issue an update to this memorandum that will include an attachment of frequently asked questions in order to provide answers to other queries that may arise.

Background – Nursing Home Survey Findings

In July 2012, CMS began posting nursing home statements of deficiencies, derived from the Form

Pharmacy Deficiencies Total 528

Administration of drugs	Tags 404 and 405 (Nursing)	Nov 2013 156 cited	Mar 2014 263
Pharmacy Administration	Tag 491	25 cited	34
Delivery of Drugs Pharmacy Drug Records	Tag 500 Tag 494	37 cited 0	45 12
Pharmaceutical Services Formulary	Tag 490 Tag 511	18 cited 0	42 2
Pharmacist Responsibility Pharmacy Personnel	Tag 492 Tag 493	16 cited 0	17 5
Pharmacist Supervision	Tag 501	10 cited	14
Access to Locked Area Reporting Adverse Events	Tag 504 Tag 508	2 cited 0	5 18
After Hours Access to Drugs Secure Storage Unusable Drug Stop Orders	Tag 506 Tag 502 Tag 505 Tag 507	1 cited 15 cited 25 Cited 0	4 25 41 1

CMS Hospital CoPs

- Hospital Conditions of Participation are called the CoPs for short
- It is Appendix A and is 471 pages long
- Manuals amended more frequently now
- Is called the state operations manual or SOM
- Has section numbers called tag numbers and go from Tag A-**0001** to A-**1164**
- Pharmacy section at tag **490-511**

[1]

[2]http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf

Pharmacy Section Starts a Tag 490

A-0469

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

[All records must document the following, as appropriate:]

§482.24(c)(2)(viii) - Final diagnosis with completion of medical records within 30 days following discharge.

Interpretive Guidelines §482.24(c)(2)(viii)

All medical records must contain a final diagnosis. All medical records must be complete within 30 days of discharge or outpatient care.

Survey Procedures §482.24(c)(2)(viii)

Select a sample of patients who have been discharged for more than 30 days. Request their medical records. Are those records complete? Does each record have the patient's final diagnosis?

A-0490

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

§482.25 Condition of Participation: Pharmaceutical Services

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug

Pharmaceutical Services 490

- Standard: Hospital must have a pharmacy to meet the patient's needs and need to promote safe medication use process
- Must be directed by registered pharmacist or drug storage area under constant supervision
- MS is responsible for developing P&P to minimize drug error
- Function may be delegated to the pharmacy service

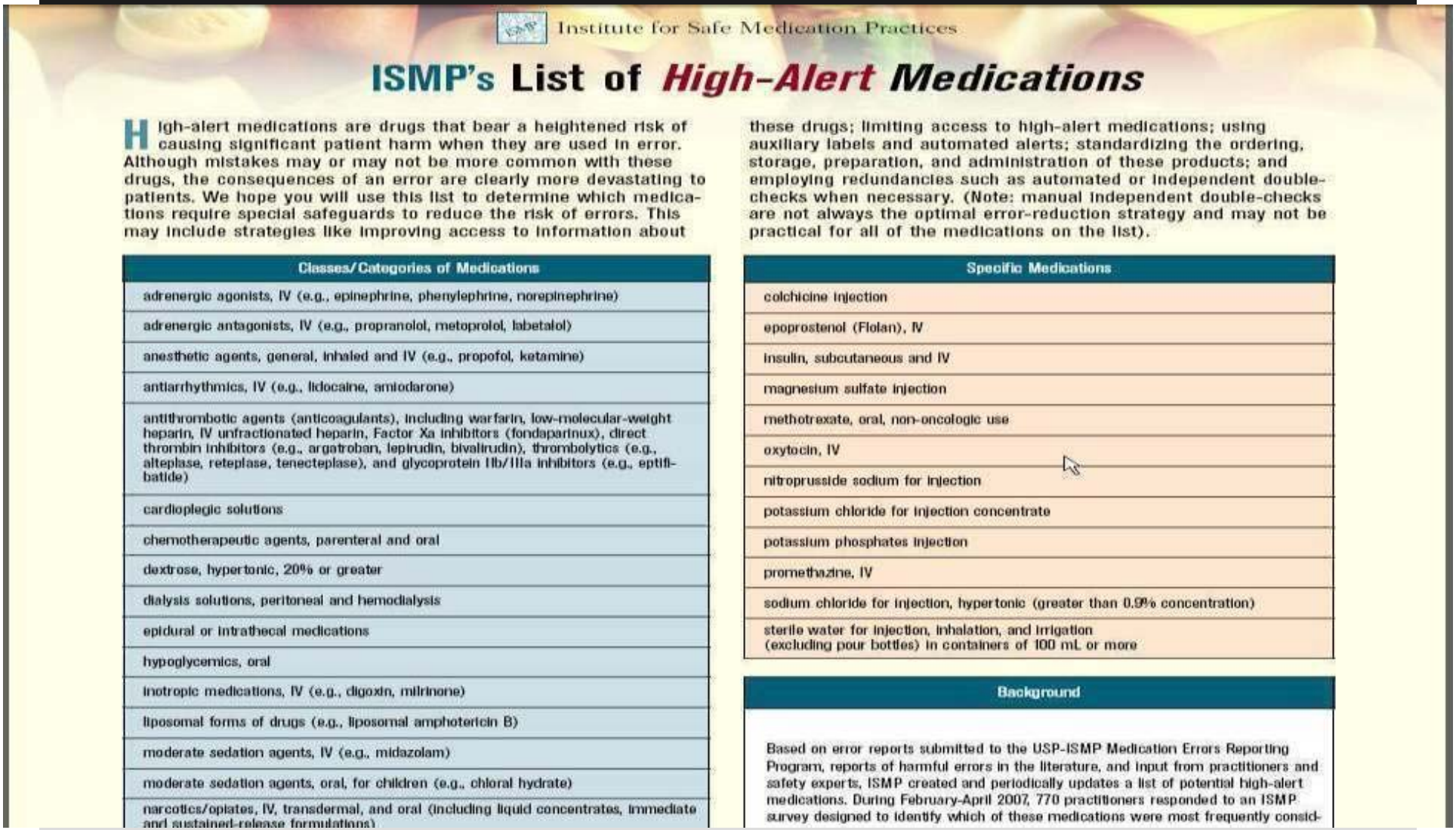
Pharmacy 0490

- Provide medication related information to hospital personnel
- Medication Management is important to CMS and TJC and TJC has a medication management chapter
- Contains list of functions of the pharmacist (collect patient specific information, monitor effects, identify goals, implement monitoring plan with patient, etc.)
  - Add to pharmacy director job description
- Flag new types of mistakes
  - Hospital went completely computerized and found 22 new types of errors

Pharmacy Policies Include:

- High alert medication-dosing limits-packaging, labeling and storage (TJC MM.01.01.03)
  - ISMP (Institute for Safe Medication Practice) and USP have list of high alert medications)
- Limiting number of medication related devices and equipment-no more that **2 types** of infusion pumps (490)
- Availability of up to date medication information
- Pharmacist on call if not open 24 hours

What Are Your 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 like improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; standardizing the ordering, storage, preparation, and administration of these products; 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., epinephrine, 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 (anticoagulants), including warfarin, low-molecular-weight heparin, IV unfractionated heparin, Factor Xa inhibitors (fondaparinux), direct thrombin inhibitors (e.g., argatroban, lepirudin, bivalirudin), thrombolytics (e.g., alteplase, reteplase, tenecteplase), and glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)
cardioplegic solutions
chemotherapeutic agents, parenteral and oral
dextrose, hypertonic, 20% or greater
dialysis solutions, peritoneal and hemodialysis
epidural or intrathecal medications
hypoglycemics, oral
inotropic medications, IV (e.g., digoxin, milrinone)
liposomal forms of drugs (e.g., liposomal amphotericin B)
moderate sedation agents, IV (e.g., midazolam)
moderate sedation agents, oral, for children (e.g., chloral hydrate)
narcotics/opiates, IV, transdermal, and oral (including liquid concentrates, immediate and sustained-release formulations)

Specific Medications
colchicine injection
epoprostenol (Flolan), IV
insulin, subcutaneous and IV
magnesium sulfate injection
methotrexate, oral, non-oncologic use
oxytocin, IV
nitroprusside sodium for injection
potassium chloride for injection concentrate
potassium phosphates injection
promethazine, IV
sodium chloride for injection, hypertonic (greater than 0.9% concentration)
sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more

Background

Based on error reports submitted to the USP-ISMP Medication Errors Reporting Program, reports of harmful errors in the literature, and input from practitioners and safety experts, ISMP created and periodically updates a list of potential high-alert medications. During February-April 2007, 770 practitioners responded to an ISMP survey designed to identify which of these medications were most frequently consid-

So What's In Your Policy?

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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.[i]

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.

High Alert How to Guide IHI

v03
10/01/2008

PROTECTING 5 Million lives FROM HARM IHI.org

Getting Started Kit:
Prevent Harm from High-Alert Medications

How-to Guide

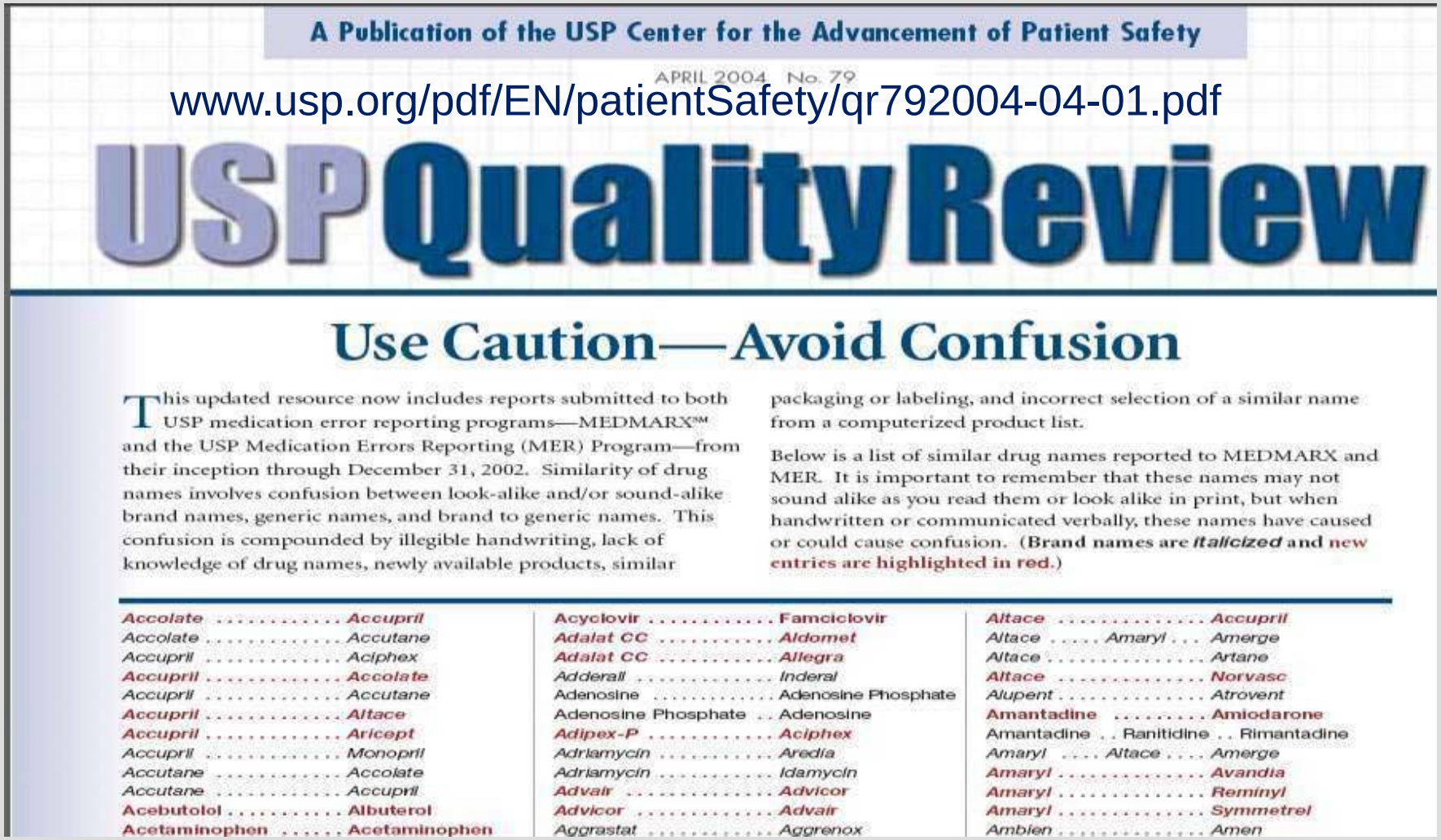
A national initiative led by IHI, the 5 Million Lives Campaign aims to dramatically improve the quality of American health care by protecting patients from five million incidents of medical harm between December 2006 and December 2008. The How-to

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

Pharmacy Policies

- Avoid dangerous abbreviations (TJC IM.02.02.01)
- All elements of order; dose, strength, route, units, rate, frequency
- Alert system for sound alike/look alike (LASA) and also TJC standard MM.04.01.01 and NPSG.03.03.01
  - 8th Annual MedMaRX report issued in 2008 shows problems with 3,170 drug pair names which is doubled number since 2004
  - USP has website to check LASA drugs
- Use of facility approved pre-printed order sheets whenever possible

USP Confused Name List



A Publication of the USP Center for the Advancement of Patient Safety

APRIL 2004 No. 79

www.usp.org/pdf/EN/patientSafety/qr792004-04-01.pdf

USP Quality Review

Use Caution—Avoid Confusion

This updated resource now includes reports submitted to both USP medication error reporting programs—MEDMARX™ and the USP Medication Errors Reporting (MER) Program—from their inception through December 31, 2002. Similarity of drug names involves confusion between look-alike and/or sound-alike brand names, generic names, and brand to generic names. This confusion is compounded by illegible handwriting, lack of knowledge of drug names, newly available products, similar packaging or labeling, and incorrect selection of a similar name from a computerized product list.

Below is a list of similar drug names reported to MEDMARX and MER. It is important to remember that these names may not sound alike as you read them or look alike in print, but when handwritten or communicated verbally, these names have caused or could cause confusion. (**Brand names are *italicized*** and **new entries are highlighted in red.**)

Accolate . . . . . *Accupril*	*Acyclovir* . . . . . Famciclovir	*Altace* . . . . . *Accupril*
Accolate . . . . . *Accutane*	*Adalat CC* . . . . . *Aldomet*	*Altace* . . . . . *Amaryl* . . . *Amerge*
Accupril . . . . . *Aciphex*	*Adalat CC* . . . . . *Allegra*	*Altace* . . . . . *Artane*
Accupril . . . . . *Accolate*	*Adderall* . . . . . *Inderal*	*Altace* . . . . . *Norvasc*
Accupril . . . . . *Accutane*	Adenosine . . . . . Adenosine Phosphate	*Alupent* . . . . . *Atrovent*
Accupril . . . . . *Altace*	Adenosine Phosphate . . Adenosine	*Amantadine* . . . . . *Amiodarone*
Accupril . . . . . *Aricept*	*Adipex-P* . . . . . *Aciphex*	Amantadine . . Ranitidine . . Rimantadine
Accupril . . . . . *Monopril*	*Adriamycin* . . . . . *Aredia*	*Amaryl* . . . . *Altace* . . . . *Amerge*
Accutane . . . . . *Accolate*	*Adriamycin* . . . . . *Idamycin*	*Amaryl* . . . . . *Avandia*
Accutane . . . . . *Accupril*	*Advair* . . . . . *Advicor*	*Amaryl* . . . . . *Reminyl*
Acebutolol . . . . . *Albuterol*	*Advicor* . . . . . *Advair*	*Amaryl* . . . . . *Symmetrel*
Acetaminophen . . . . . *Acetaminophen*	*Aggrastat* . . . . . *Aggrenox*	*Ambien* . . . . . *Amen*

Institute for Safe Medication Practices

ISMP's List of *Confused Drug Names*

This list of confused drug names, which includes look-alike and sound-alike name pairs, consists ***only*** of those name pairs that have been involved in medication errors published in the *ISMP Medication Safety Alert!®* The errors involving these medications were reported to ISMP through the USP-ISMP Medication Errors Reporting Program (MERP).

The Joint Commission (TJC) established a National Patient Safety Goal that requires each accredited organization to identify a list of look-alike or sound-alike drugs used in the organization. Those names that appear on TJC's list of look-alike or sound-alike names have been noted with a double asterisk (**) below.

Drug Name	Confused Drug Name	*ISMP Medication Safety Alert!®* Acute Care Edition
ABELCET**	amphotericin B**	Vol. 8, Issue 13, 6/26/03
ACCUPRIL	ACIPHEX	Vol. 5, Issue 9, 5/3/00
acetazolamide**	acetohexamide**	Vol. 5, Issue 12, 6/14/00
acetohexamide**	acetazolamide**	Vol. 5, Issue 12, 6/14/00
ACIPHEX	ARICEPT	Vol. 5, Issue 24, 11/29/00
ACIPHEX	ACCUPRIL	Vol. 5, Issue 9, 5/3/00
ACTIVASE	TNKase	Vol. 8, Issue 11, 5/29/03
ACTONEL	ACTOS	Vol. 9, Issue 13, 7/1/04
ACTOS	ACTONEL	Vol. 9, Issue 13, 7/1/04
ADDERALL	INDERAL	Vol. 1, Issue 4, 2/28/96
ADVICOR	AITOCOR	Vol. 7, Issue 9, 5/1/02

Pharmacy Policies

- "Resume preop orders" is prohibited
- Voluntary, non-punitive reporting system to monitor and report adverse drug events
  - System analysis theory recognizes most errors are a system problem and not due to bad practitioner
  - Many hospitals balance with Just Culture
  - TJC has the same standard
- Preparation, distribution, administration and disposal of hazardous medications (chemotherapy)

NIOSH Hazardous Drugs

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Workplace Safety & Health Topics www.cdc.gov/niosh/topics/hazdrug/

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- ▶**Hazardous Drug Exposures in Healthcare**
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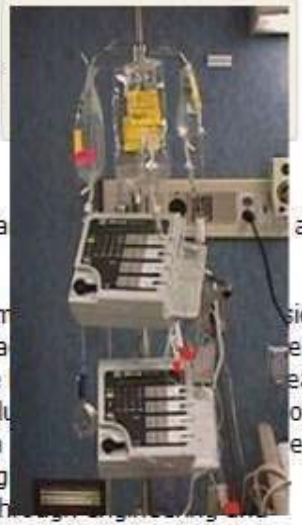
- Health Care Workers
- Antineoplastic Drugs

NIOSH > Workplace Safety and Health Topics > Hazards & Exposures

HAZARDOUS DRUG EXPOSURES IN HEALTH CARE

Health care workers who prepare or administer hazardous drugs (e.g., those used for cancer therapy, and some antiviral drugs, hormone agents, and bioengineered drugs) or who work in areas where these drugs are used may be exposed to these agents in the workplace. About 5.5 million U.S. health care workers are potentially exposed to hazardous drugs, including pharmacy and nursing personnel, physicians, environmental services workers, workers in research laboratories, veterinary ca and receiving personnel.

It seems counter-intuitive that the health care industry, whose m sick, is itself a "high-hazard" industry for the workers it employs. In fa e shown that workplace exposures to hazardous drugs can cause ealth effects such as skin rashes, adverse reproductive outcomes (inclu ous abortions, and congenital malformations), and possibly leukemia ealth risk depends on how much exposure a worker has to these drug Workers can be protected from exposures to hazardous drugs th administrative controls, and proper protective equipment.



Muti-channel infusion

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National Institute for Occupational Safety and Health (NIOSH)
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348
24 Hours/Every Day
cdcinfo@cdc.gov

NIOSH Hazardous Drugs 2012 List

- Previous update was Dec 2010
- Updated in 2012 (FR June 27, 2012) and proposed in 2014
- NIOSH reviewed 70 new drugs that received FDA approval
- NIOSH reviewed 180 drug that received new special warnings (usually black box warnings)
- Found 26 of these that were added to the list
- Removed 15 drugs that are no longer available in the ED

List of Hazardous Drugs in Healthcare

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

All CDC Topics | Choose a topic above | SEARCH

A-Z Index for All CDC Topics

NIOSH Publications and Products www.cdc.gov/niosh/docs/2012-150/ NIOSH

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- NIOSH-Issued Publications
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NIOSH > NIOSH Publications & Products > NIOSH-Issued Publications

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DHHS (NIOSH) Publication Number 2012-150 June 2012

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012

The National Institute for Occupational Safety and Health (NIOSH) Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings was published in September 2004 (http://www.cdc.gov/niosh/docs/2004-165/). In Appendix A of the Alert, NIOSH identified a sample list of major hazardous drugs. The list was compiled from information provided by four institutions that have generated lists of hazardous drugs for their respective facilities and by the Pharmaceutical Research and Manufacturers of America (PhRMA) from the American Hospital Formulary Service Drug Information (AHFS DI) monographs

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NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Proposed Additions and Deletions to the NIOSH Hazardous Drug List 2014						
Established Name	**Proprietary Name**	**Drug Class**	**Formulation(s)**	**Dosage**	**FDA pregnancy Category**	**Drug Package Insert**
Drugs Recommended by NIOSH to be Added to the 2012 Hazardous Drug List						
abacavir	Ziagen	antiviral	tablets, oral solution	600mg	C	PI
abiraterone acetate	Zytiga	antineoplastic; CYP17 inhibitor	tablets	1000mg	X	PI
apomorphine	Apokyn	dopamine agonist	SQ	2-6mg	C	PI
bevacizumab	Avastin	monoclonal antineoplastic	IV	5-15mg/kg	C	PI
crizotinib	Xalkori	antineoplastic	capsules	250mg	D	PI
deferiprone	Ferriprox	FE chelator	tablets	25-30mg/kg	D	PI
dexmedetomidine	Precedex	alpha andrenergic antagonist	IV	0.2-1mcg/kg	C	PI
eribulin mesylate	Halaven	antineoplastic; microtubule inhibitor	IV	1.4mg/m2	D	PI
erlotinib	Tarceva	antineoplastic	tablets	150mg	D	PI
ezogabine	Potiga	anticonvulsant	tablets	100-150mg	C	PI
fingolimod	Gilenya	biological response modulator; sphingosine-1 phosphate recpt. modulator	capsules	0.5mg	C	PI

Pharmacy Policies

- Drug recalls
- Patient specific information that should be readily available (TJC tells you exactly what this is, like age, sex, allergies, current medications, etc.)
- Means to incorporate external alerts and recommendation from national associations and government for review and policy revision (Joint Commission, ISMP, FDA, IHI, AHRQ, Med Watch, NCCMER, MEDMARX)
  - If medication management committee can assign each to one of the members to report at monthly meeting

FDA has a List of Drug Recalls

FDA Drug Recalls Website

Sign Up to Get Recall Alerts from FDA

Pharmacy Policies 490

- Identification of weight based dosing for pediatric populations
  - May also require weights for elderly patients in renal failure on antibiotics
- Requirements for review based on facility generated reports of adverse drug events and PI activities
- Policy to identify potential and actual adverse drug events
  - IHI trigger tool for peds, hospitals and mental health unit, concurrent review, observe med passes etc.
- Must periodically review all P&P's

Use Kg and Not Pounds for Children

Acetaminophen Dosing Chart

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

Ibuprofen Dosing Chart

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

Trigger Tool for Measuring Adverse Drug Events

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 collecting the data you need to measure the number of ADEs per 1,000 doses and the percentage of admissions with an ADE.

NOTE: You can use this tool in conjunction with the interactive Trigger Tool for Measuring ADEs in the Workspace area on IHI.org. Enter your detailed data from all of your ADE Patient Record Review Sheets into the interactive Trigger Tool for Measuring ADEs. The Tool will automatically calculate and graph two measures: ADEs per 1,000 Doses and Percent of Admissions with an ADE.

This tool contains:

- Background
- List of ADE Triggers
- General Instructions
- Case Studies
- ADE Patient Record Review Sheet
- Pediatric ADE Patient Record Review Sheet
- ADE Monthly Summary Sheet (*Use interactively on IHI.org)

IHI Trigger Tools

IHI Adverse Drug Event Trigger Tool

Trigger Tool for Measuring Adverse Drug Events

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- Case Studies
- ADE Patient Record Review Sheet
- Pediatric ADE Patient Record Review Sheet
- ADE Monthly Summary Sheet (*Use interactively on IHI.org)

www.ihi.org/ihi/workspace/tools/trigger/CreateTool.aspx

Pharmacy Policies

- Need a multidisciplinary committee - committee of medicine, nursing, administration, and pharmacy to develop P&P
- MS must develop P&P or have policy that this function is fulfilled by pharmacy
- Surveyors will make sure staff is familiar with all the medication P&P's
- Need policies to minimize drug error

Pharmacy Management 0491

- Pharmacy or drug storage must be administered in accordance with professional principles
  - TJC 03.01.01 and problematic standard
- This includes compliance with state laws (pharmacy laws), and federal regulations (USP 797), standards by nationally recognized organizations (ASHP, FDA, NIH, USP, ISMP, etc.)
- Pharmacy director must review P&P periodically and revise
  - Remember to date policy to show last review and include sources such as CMS CoP or TJC standard

Pharmacy Management 491

- Drugs stored as per manufacturer's recommendations
- Pharmacy employees provide services within the scope of their licensure and education
  - Some states allow only pharmacist to do compounding
- Sufficient pharmacy records to follow flow from order to dispensing/administration
- Maintain control over floor stock
  - Make sure no expired medications and make sure all labeled

Pharmacist 491

- Ensure drugs are dispensed only by licensed pharmacist
  - Pharmacist dispense and nurse administers
- Must have pharmacist to develop, supervise, and coordinate activities of pharmacy
- Can be part time, full time or consulting
- Single pharmacist must be responsible for overall administration of pharmacy

Pharmacist 491

- Job description should define development, supervision, and coordination of all activities
- Must be knowledgeable about hospital pharmacy practice and management
- Must have adequate number of personnel to ensure quality pharmacy service, including emergency services
- Sufficient to provide services for 24 hours, 7 days a week
  - This means patients get stat drugs within time frame set

Pharmacy Delivery of Service 500

- Keep accurate records of all scheduled drugs
- Need policy to minimize drug diversion
- Drugs and biologicals must be controlled and distributed to provided patient safety
- In accordance with state and federal law and applicable standards of practice
- Accounting of the receipt and disposition of drugs subject to COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

Pharmacy Delivery of Service 500

- Pharmacist and hospital staff and committee develop guidelines and P&P to ensure control and distribution of medications and medication devices
- System in place to minimize high alert medication (double checks, dose limits, pre-printed orders, double checks, special packaging, etc.)
- And on high risk patients (pediatric, geriatric, renal or hepatic impairment)
- High alert meds may include investigational, controlled meds, medicines with narrow therapeutic range and sound alike/look alike

Delivery of Service 500 First Dose Rule

- 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

Delivery of Service 500

- Sterile products should be prepared and labeled in suitable environment
- Pharmacy should participate in decisions about emergency medication kits (such as crash carts)
  - Remember issue of security of crash carts
  - Do HVA to determine if under constant supervision or location of cart is safe such as just outside nurses station
- Medication stored should be consistent with age group and standards
  - Such as pediatric doses for pediatric crash cart

Delivery of Service 500

- Must have process to report serious adverse drug reactions to the FDA
  - Such as on Med Watch form
- Policy to address use of medications brought in
  - Policy, count drugs, patient signs release, locked in drawer, will help with medication reconciliation to bring in
- P&P to ensure investigational meds are safely controlled and administered
- Medications dispensed are retrieved when recalled or discontinued by manufacturer or FDA (eg. Vioxx)

Delivery of Service 500

- System in place to reconcile medication that are not administered and that remain in medication drawer when pharmacy restocks
- Will ask why it was not used?
- Not the same as medication reconciliation as in the TJC NPSG which all hospitals should still do from a patient safety perspective
  - Except in CMS worksheet it is refers to medication reconciliation as required by TJC
- TJC medication reconciliation 5 elements of performance became effective July 1, 2011

TJC Medication Reconciliation

Reconciling Medication Information

Hospital Accreditation Program

NPSG.03.06.01

Maintain and communicate accurate patient medication information.

Elements of Performance for NPSG.03.06.01

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

Compounding of Drugs 501

- All compounding, packaging, and disposal of drugs and biologicals must be under the supervision of pharmacist
- Must be performed as required by state or federal law
- Staff ensure accuracy in medication preparation
- Staff uses appropriate technique to avoid contamination

Compounding of Drugs 501

- Use a laminar airflow hood to prepare any IV admixture, any sterile product made from non-sterile ingredients, or sterile product that will not be used within 24 hours (see USP 797)
- Meds should be dispensed in safe manner and to meet the needs of the patient
- Quantities are minimized to avoid diversion, dispensed timely, and if feasible in unit dose
- All concerns, issues, or questions are clarified with the individual prescriber before dispensing

Locked Storage Areas 502

- Drugs and biologicals must be kept in a secure and locked area
- Would be considered a secure area if staff actively providing care but not on a weekend when no one is around
- Schedule II, III, IV, and V must be kept locked within a secure area (see also 503)
- Only authorized person can get access to locked areas
  - See tag 406(drugs and biologicals) and 412 and 413 also (self administered drugs) in nursing section

Locked Storage Areas A-502

- Persons without legal access to drugs and biologicals can have not have unmonitored access
- They can not have keys to storage rooms, carts, cabinets or containers with unsecured medications (housekeeping, maintenance, security)
- Critical care and L&D area staffed and actively providing care are considered secure
- Setting up for patients in OR is considered secure such as the anesthesia carts but after case or when OR is closed need to lock cart

Securing Medications

- So all controlled substances must be locked
- Hospitals have greater flexibility in determining which non controlled drugs and biologicals must be kept locked
- Medications should not be stored in areas readily accessible to unauthorized persons such in a private office unless visitors are not allowed without supervision of staff
- P&P need to address security of any carts containing drugs

Securing Medications

- May allow patients to have access to urgently needed drugs such as Nitro and inhalers
- Need P&P on competence of patient, patient education and must meet elements in TJC MM standard on self administration
  - CMS mentioned TJC standard in Federal Register
  - Tag 412 and 413 on June 7, 2013 and 2014
- Measures to secure bedside medications
- Make sure medication carts in OB to do stat C-sections is locked

Locked Storage Areas

- If medication cart is in use and unlocked, then someone with legal access must be close by and directing monitoring the cart, like when the nurse is passing meds
- Need policy for safeguarding, transferring and availability of keys
- Should now have safe injection practice policy and follow CDC 10 requirements
- CMS gets 50 million dollars to enforce infection control standards and is making infection control visits to hospitals

Medications in the OR ASA Position

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

American Society of Anesthesiologists®

STATEMENT ON SECURITY OF MEDICATIONS IN THE OPERATING ROOM

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

Preamble

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

Recommended Policies

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

Rationale

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

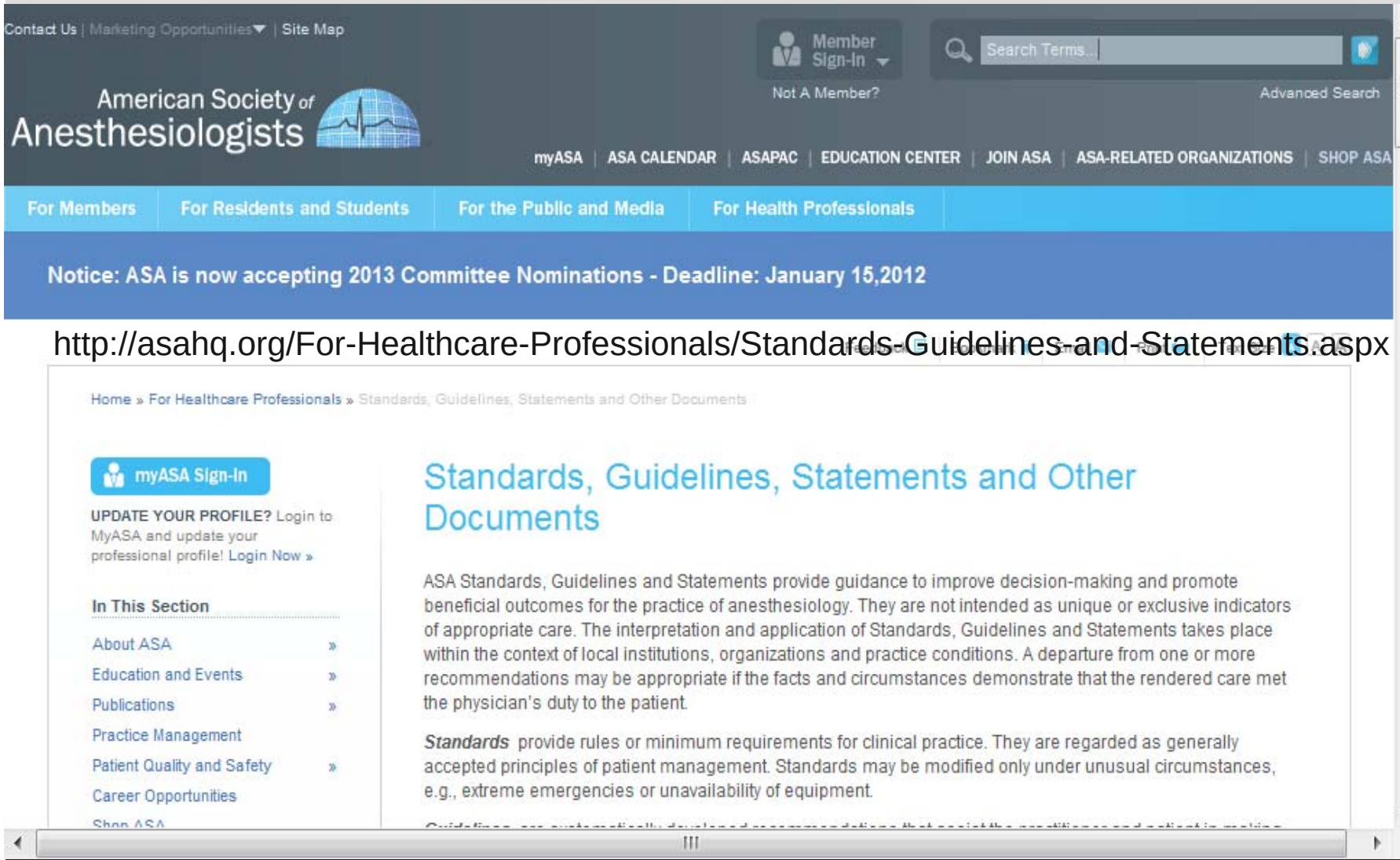
B. At the end of anesthesia cases, when patients are particularly vulnerable, anesthesia

ASA Standards, Guidelines, Statements

- This position statement is from American Society of Anesthesiologists
- Security of Medications in the Operating Room
  - All hospitals should also have a copy of the annual book published by AORN on Perioperative Standards and Recommended Practices and has Medication Safety section
- These are available off the ASA website[1]
- Security of medications in the operating room

[1]http://www.asahq.org/publicationsAndServices /sgstoc.htm

ASA Guidelines and Statements



Recommendation on Medications in the OR

The Official Journal of the Anesthesia Patient Safety Foundation

apsf www.apsf.org NEWSLETTER Spring 2010

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

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Accidental Intrathecal Injection of Tranexamic Acid

APSF Hosts Medication Safety Conference

Consensus Group Defines Challenges and Opportunities for Improved Practice

by John H. Eichhorn, MD

Overview

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

The resulting consensus recommendations include:

Standardization

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

Table 1:
Consensus Recommendations for Improving Medication Safety in the Operating Room

Standardization

1. High alert drugs (such as phenylephrine and epinephrine) should be available in standardized concentrations/diluents prepared by pharmacy in a ready-to-use (bolus or infusion) form that is appropriate for both adult and pediatric patients. Infusions should be delivered by an electronically-controlled smart device containing a drug library.
2. Ready-to-use syringes and infusions should have standardized fully compliant machine–readable labels.
3. *Additional Ideas:*
   a. Interdisciplinary and uniform curriculum for medication administration safety to be available to all training programs and facilities.
   b. No concentrated versions of any potentially lethal agents in the operating room.
   c. Required read-back in an environment for extremely high alert drugs such as heparin.
   d. Standardized placement of drugs within all anesthesia workstations in an institution.
   e. Convenient required method to save all used syringes and drug containers until case concluded.
   f. Standardized infusion libraries/protocols throughout an institution.
   g. Standardized route-specific connectors for tubing (IV, arterial, epidural, enteral).

Technology

1. Every anesthetizing location should have a mechanism to identify medications before drawing up or administering them (bar code reader) and a mechanism to

Pharmacy/Prefilled/Premixed

1. Routine provider-prepared medications should be discontinued whenever possible.
2. Clinical pharmacists should be part of the perioperative/operating room team.
3. Standardized pre-prepared medication kits by case type should be used whenever possible.
4. *Additional Ideas:*
   a. Interdisciplinary and uniform curriculum for medication administration safety for all anesthesia professionals and pharmacists.
   b. Enhanced training of operating room pharmacists specifically as perioperative consultants.
   c. Deployment of ubiquitous automated dispensing machines in the operating room suite (with communication to central pharmacy and its information management system).

Culture

1. Establish a *"just culture"* for reporting errors (including near misses) and discussion of lessons learned.
2. Establish a culture of education, understanding, and accountability via a required curriculum and CME and dissemination of dramatic stories in the *APSF Newsletter* and educational videos.

ASA Standard Guidelines and Statements

Ambulatory Anesthesia and Surgery, Guidelines for (2008)

Anesthetic Care During Interventional Pain Procedures for Adults, Statement on (2010)

Anesthesia Care Team, The (2009)

Anesthesia Consultation Program (2008)

ASA Statement Comparing Anesthesiologist Assistant and Nurse Anesthetist Education (2007)

Avoidance of Medication Errors in Neuroxial Anesthesia, Statement on Standard Practice for (2010)

Basic Anesthetic Monitoring, Standards for (2005)

Basic Anesthetic Monitoring, Standards for (Effective July 1, 2011)

Clinical Privileges in Anesthesiology, Guidelines for Delineation of (2008)

Conflict of Interest, Statement on (2008)

Continuing Medical Education in Anesthesiology, Guidelines for Minimally Acceptable (2005)

Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia (2009)

Critical Care and Trauma Medical Services, Statement of Principles (2006)

Critical Care by Anesthesiologists, Guidelines for the Practice of (2009)

Distinguishing Monitored Anesthesia Care From Moderate Sedation/Analgesia (Conscious Sedation) (2009)

Documentation of Anesthesia Care (2008)

Economic Credentialing, Statement on (2008)

End-of-Life Care, Statement on Quality of (2008)

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

Use of Propofol

STATEMENT ON SAFE USE OF PROPOFOL

Committee of Origin: Ambulatory Surgical Care

(Approved by the ASA House of Delegates on October 27, 2004, and amended on October 21, 2009)

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Due to the potential for rapid, profound changes in sedative/anesthetic depth and the lack of antagonist medications, agents such as propofol require special attention. Even if moderate sedation is intended, patients receiving propofol should receive care consistent with that required for **deep sedation**.

The Society believes that the involvement of an anesthesiologist in the care of every patient undergoing anesthesia is optimal. However, when this is not possible, non-anesthesia personnel who administer propofol should be qualified to **rescue*** patients whose level of sedation becomes deeper than initially intended and who enter, if briefly, a state of general anesthesia.**

- The physician responsible for the use of sedation/anesthesia should have the education and training to manage the potential medical complications of sedation/anesthesia. The physician should be proficient in airway management, have advanced life support skills appropriate for the patient population, and understand the pharmacology of the drugs used.

  The physician should be physically present throughout the sedation and remain immediately available until the patient is medically discharged from the post procedure recovery area.
- The practitioner administering propofol for sedation/anesthesia should, at a minimum, have the education and training to identify and manage the airway and cardiovascular changes which occur in a patient who enters a state of general anesthesia, as well as the ability to assist in the management of complications.

  The practitioner monitoring the patient should be present throughout the procedure and be completely dedicated to that task.
- During the administration of propofol, patients should be monitored without interruption to

Good Article from ASA

http://www.asahq.org/For-Members/Practice-Management/~/media/For%2520Members/Practice%2520Management/PracticeManagementNewsletterArticles/2007/pm0207.ashx

Anesthesia Carts: New Federal Regulation Aligns With ASA Policy

Karin Bierstein, J.D., M.P.H.
Associate Director of Professional Affairs

Many ASA members have struggled to comply with the hospital requirement that anesthesia carts be locked between cases. Over the last several years, surveyors from the Joint Commission and from state health agencies have surprised quite a few departments by insisting on an extremely strict interpretation of the old Medicare regulation that provided, "Drugs and biologicals shall be kept in a locked storage area" (Conditions of Participation, 42 C.F.R. §462.25(b)).

As a result of a lengthy ASA campaign to change the so-called "locked cart rule," the Centers for Medicare & Medicaid Services (CMS) revised the regulation effective January 26, 2007. The regulation now states that *"All drugs and biologicals must be kept in a secure area, and locked when appropriate."*

It was the intention of CMS to give hospitals more flexibility in their policies on the storage of noncontrolled substances. Drug Enforcement Administration (DEA) Schedule II, III, IV and V drugs must continue to be kept locked even within a "secure area" such as an operating room (O.R.) suite. (Schedule V drugs are not used in anesthesia practice.) Only authorized personnel may have access to

have access to resuscitation drugs and also acknowledging the need to set up anesthesia carts in preparation for use in the O.R. or labor and delivery unit. The position statement provides that "Anesthesia carts and anesthesia machines may remain unlocked, and noncontrolled ... 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 O.R. suite." ASA members should consult the Position Statement on Medication Security, which is available at www.ASAhq.org/clinical/LockedCartPolicyFinalOct2003.pdf, in assisting their hospitals to update their own medication security policies.

Sample Policy Language

In the discussion accompanying the *Federal Register* notice regarding the revision to the regulation, CMS emphasized flexibility in allowing hospitals to determine their own medication security and storage policies. Thus there are several approaches, concepts and phrases that each hospital, in order to comply with the Medicare Condi-

ASA Sample Policy and Procedure

Figure 1. Sample Language for a Hospital Policy on Anesthesia Medication Security

Pharmaceutical Services

Policies and Procedures — Security of Anesthesia Medications

Preamble

Anesthesiologists use medications both to sedate or anesthetize patients and to relieve pain, most commonly with controlled substances from DEA Schedules II, III and IV. Anesthesiologists also administer medications to manage the neuromuscular system, cardiovascular system and pulmonary system: drugs used for these purposes must be immediately available at all times in any active anesthetizing location. Limiting access to these resuscitation drugs even for a few seconds could seriously compromise patient safety. Any protocols or procedures designed to prevent tampering with or diversion of anesthesia medications must permit immediate access to resuscitation drugs, consistent with federal regulations (42 C.F.R. §462.25(b) (2)) that were revised effective January 26, 2007.

Purpose

This policy provides that medications shall be stored securely to protect the safety of patients and the public health while allowing appropriate access by authorized personnel.

Pharmacy Policies

Pharmacy is ultimately responsible for the storage, dispensing and inventory control of all perioperative medications.

Coordination with Anesthesiology Policies

The Department of Anesthesiology is responsible for the safety of patients under its care. Pharmacy and Anesthesiology will together ensure that medication security policies proposed by either service (1) maintain patient safety, (2) do not conflict with each other and (3) comply with federal and state regulations.

Controlled and Noncontrolled Medications

Drugs used in anesthesiology are divided into controlled (DEA Schedules II, III and IV) and noncontrolled substances. (For the purpose of this policy on medication security, ephedrine and propofol are treated like controlled substances.)

Procedures and Definitions

1. **All anesthesia medications will be kept in a secure area.**
2. **Controlled substances must be locked within a secure area.**

"Secure Area"

- Surgical Intensive Care Unit

Policy and Procedure

- CMS states that they expect hospital P&P to address
- The security and monitoring of any carts including whether locked or unlocked if contains drugs and biologicals
- In all patient care areas to ensure safe storage and patient safety
- P&P to keep drugs secure, prevent tampering, and diversion

TJC Self Administered Meds

- Self administered medications are safely and accurately administered
  - If you allow self administration, need procedure to manage, train, supervise, and document process
  - Remember CMS Tag 412 and 413
- TJC MM stands for medication management standard MM.06.01.03
  - If non-staff member administers (patient or family) must train and make sure competent to do so (give info on nature of med, how to administer, side effects, and how to monitor effects)
  - Patient has to be determined to be competent before allowed to self administer

Outdated or Mislabeled Drugs 505

- Outdated, mislabeled or otherwise unusable drugs and biologicals must not be available for patient use
- Hospital has a system to prevent outdated or mislabeled drugs
- Surveyor will spot check individual drug containers to make sure have all the required information including lot and control number, expiration date, strength, etc.

No Pharmacist on Duty 0506

- If no pharmacist on duty, drugs removed from storage area are allowed only by personnel designated in policies of MS and pharmacy service
- Must be in accordance with state and federal law
- Routine access to pharmacy by non-pharmacist for access should be minimized and eliminated as much as possible
  - E.g. night cabinet for use by nurse supervisor
  - Need process to get meds to patient if urgent or emergent need
  - TJC does not allow nurse supervisor in pharmacy so would need to call the on call pharmacist

No Pharmacist on Duty 0506

- Access is limited to set of medications that has been approved by the hospital and only trained prescribers and nurses are permitted access
- Quality control procedures are in place like second check by another or secondary verification like bar coding
- Pharmacist reviews all medications removed and correlates with order first thing in the morning

Joint Commission

- The Joint Commission (TJC) has a similar standard in the hospital manual
- It is located in PC.02.01.01 EP 15
- This section says the hospital must provide care and treatment for each patient
- This section requires that blood transfusions and IV medication must be administered in accordance with state law and approved medical staff policies and procedures
- This is for hospitals that use TJC for deemed status

Pharmaceutical Services 0508 2013

- Standard: Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician
  - If appropriate also to the QAPI program
- Hospitals are required to make sure the attending doctor is immediately aware of the following:
  - Medication errors or drug errors
  - Adverse drug reactions (ADRs)
  - Drug incompatibilities (DI)

CMS Changes to Tag 508

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 02-02-38
Baltimore, Maryland 21244-1850

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-28-Hospitals
REVISED 05.20.11

DATE: **May 13, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: State Operations Manual (SOM) Hospital Appendix A Update

***** In the attached SOM Transmittal, the reference to 484.24 is changed to 482.24 for Tag A-1164. The change is highlighted in yellow color*****

Memorandum Summary

SOM Hospital Appendix A Updated

- Revisions have been made to reflect regulation changes governing orders for rehabilitation (42 CFR 482.56) and respiratory care services (42 CFR 482.57)
- Clarifications have been made for provisions related to:
  - Nursing requirements related to blood transfusions and intravenous medications (42 CFR 482.23(c)(3))
  - Immediate reporting of medication administration errors, adverse events, and incompatibilities (42 CFR 482.25(b)(6))

Background

The final FY 2011 Inpatient Prospective Payment System (IPPS) rule was published on August 16, 2010 (*75 FR 50042*) and effective on October 1, 2010. The FY 2011 IPPS final rule contained revisions to the Hospital Conditions of Participation (CoPs) governing rehabilitation and respiratory care services. SC-11-04-ALL summarized these changes, which are now being incorporated into Appendix A of the SOM.

Pharmacy CoP Tag 508

- If attending physician is unavailable can notify covering physician
  - However, important to note that when covering physician is notified, the attending must still be notified as soon as he or she is available
- Hospital must have P&P on reporting to the attending physician and to the PI program
  - Hospitals have incident reporting systems which often go to risk management and to the hospital wide PI committee
- CMS has a definition of all 3 and hospitals should include definition in their P&P

Medication Error 2013

- The National Coordinating Council Medication Error Reporting and Prevention definition is
- Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. 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.
- In this content drug error is limited to those errors that actually reach the patient

Tag 508 2013

The hospital must adopt policies and procedures that identify the types of events that must be reported immediately to the attending physician, as well as those to be reported to the QAPI program.

- Drug administration error:

  The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. 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." *In the context of this regulation, however, "drug administration error" is limited to those errors in administration that actually reach the patient, i.e., a medication actually is administered to a patient when it should not be, or the wrong dose is administered, or the wrong root of administration is used, etc., or a medication that should have been administered to the patient has not been administered in a timely manner, as discussed in the medication administration standard at 42 CFR 482.23(c).*

- Adverse drug reaction:

  The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as "Any unexpected, unintended, undesired, or excessive response to a drug that:

  - Requires discontinuing the drug (therapeutic or diagnostic)
  - Requires changing the drug therapy;

ADR Definition by ASHP

An ADE is 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)
4. Necessitates being admitted to the hospital
5. Prolongs stay in a health care facility

ADR Definition by ASHP (Continues)

6. Necessitates supportive treatment

7. Significantly complicates diagnosis

8. Negatively affects prognosis, or

9. Results in temporary or permanent harm, disability, or death

- Also includes an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug)
- And an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual)

Drug Incompatibilities Definition

- A drug incompatibility (DI) occurs when drugs interfere with one another chemically or physiologically
- Drugs known to be incompatible must not be mixed, administered together,
  - Or administered within a timeframe where they will interfere with each other
- If IV medications are administered with known incompatibility then a medication errors has occurred
  - Therefore, it must be reported to the physician

Drug Incompatibilities

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

Reporting to the Attending

- An immediate report must be made to the attending if medication error, ADE, or DI harmed or has the potential to harm the patient
- If outcome of medication error is unknown then physician must be notified
  - Be sure the incident report is filled out and document in the incident report that the attending physician was notified
  - Document notification of the attending physician in the patient's medical record

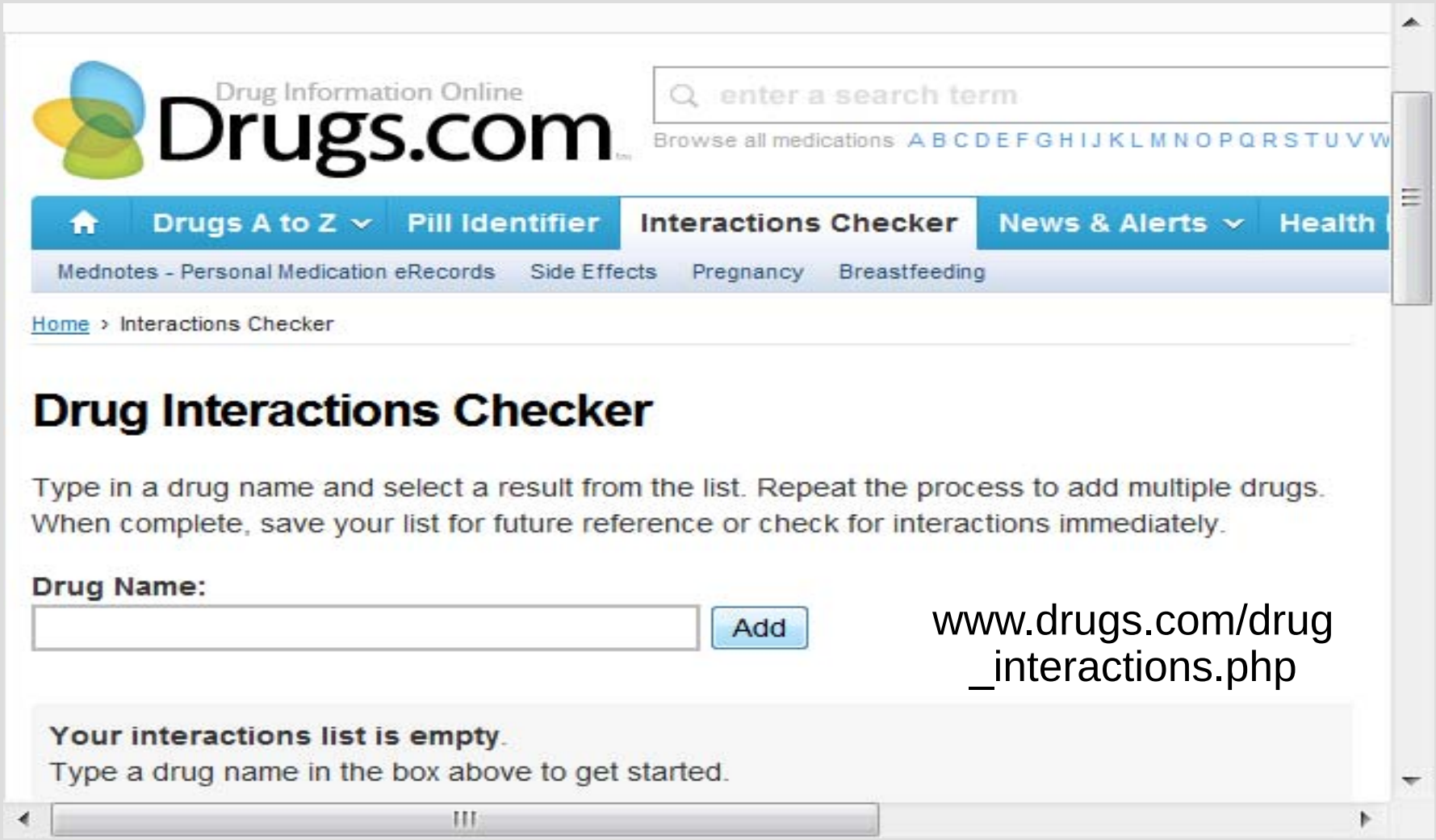
Medication Errors With No Harm 0508

- Medication errors that do not result in harm or insignificant harm to the patient must be documented in the medical record
- These do not require immediate reporting to the attending physician
- Example, nurse forgets to give an analgesic dose during the night shift
  - It can be reported first thing in the morning
  - No need to wake up the physician during the night since no harm done

Drug Administration Errors

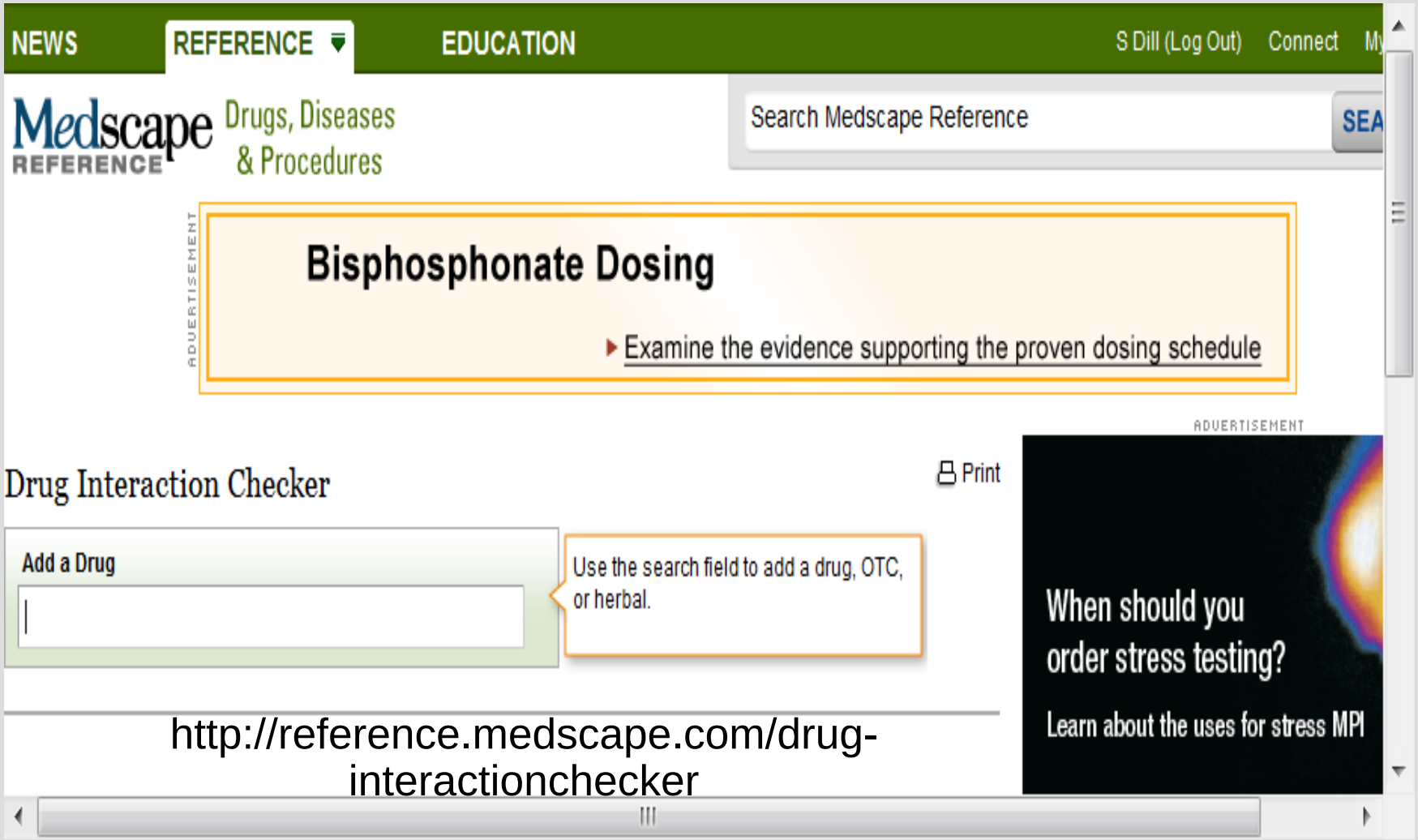
- CMS says hospital staff are expected to use their best clinical judgment in determining whether immediate reporting is required
  - Based on patient's presentation and assessment
  - This must be done in accordance with the hospital P&P
- PI program must track and report medication errors and near misses
  - Must also track suspected ADRs
  - To determine system errors and prevent future errors

Drug Interactions Checker



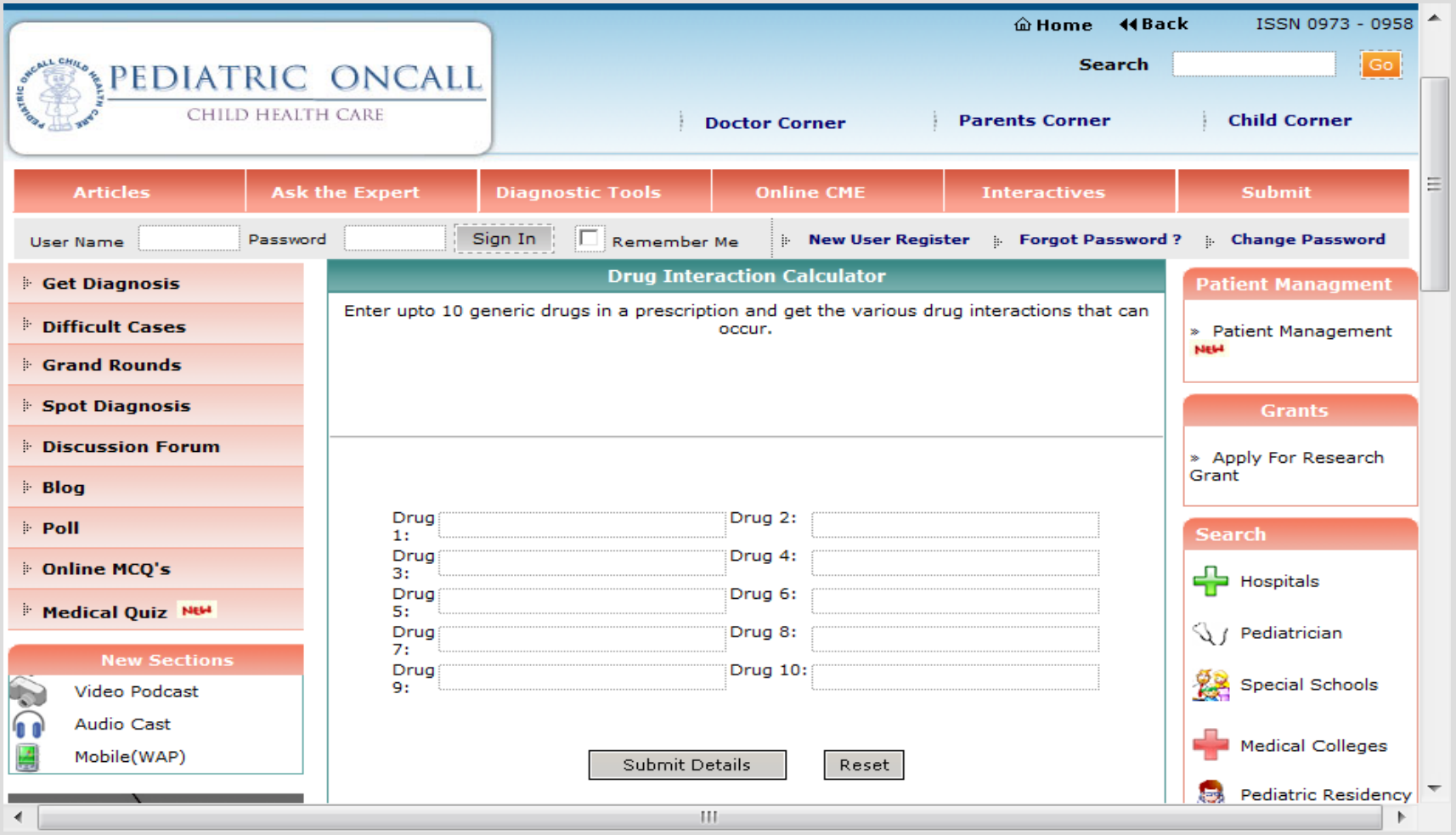
www.drugs.com/drug_interactions.php

Drug Interaction Checker



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

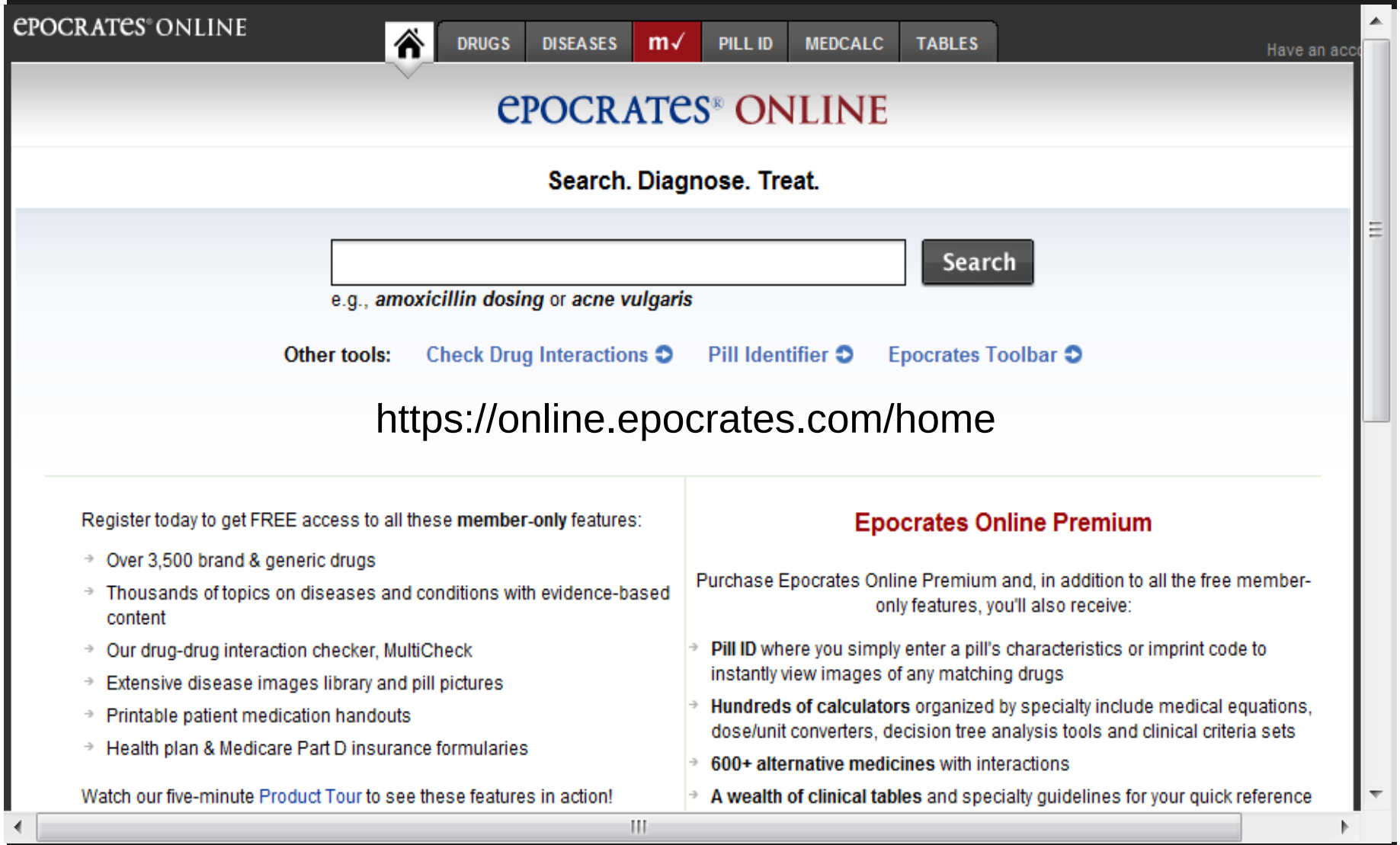
Pediatric Drug Interaction Checker



Drug Interaction Checker

http://dir.pharmacy.dal.ca/drugprobinteraction.php

Epocrates Online Checker



When Is An Interaction Likely to Cause Harm

When Is an Interaction Likely to Cause Harm?

John R. Horn, PharmD, FCCP, and Philip D. Hansten, PharmD

Past columns have discussed various drug interaction properties that need to be considered when assessing a specific patient for the presence of a drug interaction. Once the potential for an interaction is established, the next question is usually: "What is the risk that the interaction will cause an observable change in this patient's response to the object drug?" A few tools can help assess the risk of a potential drug interaction that is caused by inhibition of the object drug's elimination.

CHANGES IN DRUG CLEARANCE VS PLASMA CONCENTRATIONS

The first thing to consider is how much change in the plasma concentration of the object drug is likely to occur. Often the magnitude of a drug interaction will be described as an average change in area under the concentration time curve (AUC) or drug clearance (Cl). If the dosage interval and bioavailability are kept constant, the AUC and average steady-state plasma concentration (Css) will be determined by the dose of drug and its clearance. The AUC and Css indicate the total exposure to a drug and are usually related to the drug's response. An increase in Cl will decrease AUC and a decrease in Cl increases AUC. If a study determines that the mean AUC of the object drug is increased by 50%, that value will approximate the mean change in the average plasma concentration and the patient's exposure to the drug.

If a study reports that the mean clearance of the object drug is decreased by 50%, this indicates that the mean AUC will increase by 100%, or will double in value. The relationship between change in clearance and AUC is shown in the Table.

As can be seen from the Table, a decrease in the clearance of a drug produces a larger relative change in the AUC. A decrease in clearance ≥25% produces at least a 33% increase in the plasma concentration of the object drug. For most drugs that have linear kinetics, a 25% decrease in clearance is equivalent to increasing the dose of the object drug by 33%, because dose changes will produce equivalent changes in AUC.

ASSESSING THE RISK ASSOCIATED WITH A CHANGE IN CL

Once the mean change in the concentration of the object drug is determined, one needs to consider how that degree of change relates to the usual therapeutic range of the drug. For many drugs, a change in dose of 30% to 50% will produce a change in response. For this reason, a decrease in clearance exceeding 25% to 35% is often used as an indication that a patient may experience an adverse outcome from the interaction.

If the object drug has a wide therapeutic dosage range that does not cause toxicity (ie, diazepam), larger changes in clearance may be well tolerated. Of course, patient-specific factors, such as concurrent diseases or drugs, must be considered when assessing the risk to a patient of a potential drug interaction. It is important to keep in mind that the usual interpatient variation in the magnitude of a drug interaction can be 5- to 6-fold under controlled study conditions.

By doing some simple calculations based on the reported magnitude of an interaction, it is possible to make an estimate about the potential risk to a patient. Based on the degree of risk and the benefit of administering the drugs, appropriate management options can then be selected. ***PT***

Table

RELATIONSHIP BETWEEN CHANGE IN CL AND AUC OF OBJECT DRUG

Decrease in Cl (%)	Increase in AUC (%)	Increase in Cl (%)	Decrease in AUC (%)
10	11	10	9
20	25	20	17
25	33	25	20
30	43	30	23
50	100	50	33
75	300	75	43

> Web

http://www.hanstenandhorn.com/news.htm

How to Address a Drug Interaction Alert

Drug Interactions

How to Address a Drug Interaction Alert

John R. Horn, PharmD, FCCP, and Philip D. Hansten, PharmD

Pharmacists are faced with frequent drug interaction (DI) alerts. Assessing the risk of these potential interactions to the patient is the first step that must be taken, prior to acting on the alert. When it becomes necessary to intervene to prevent patient harm, every pharmacy practice setting should have a uniform approach to DI alerts. The response to a potential DI will depend on several factors, including who is seeing the alert, the level of access to prescribers and patients, the perceived severity of the risk, and potential management options. As we have previously covered options for dealing with inappropriate alerts, we will assume the DI alert is appropriate and represents some risk of harm to the patient.

BASIC INFORMATION NEEDED

have discussed many of these factors (eg, degree of first-pass metabolism, genetics, concomitant diseases, dose of drug, and route of administration) that alter the magnitude of an interaction.

AGREE ON CERTAIN HIGH-RISK DIS

It is a good exercise to have all the pharmacists at your practice site agree on a list of particularly "risky" drugs commonly prescribed to your patients (eg, those with narrow therapeutic range or high first-pass metabolism) and determine how to respond. This list of interactions should be based on the potential for severe adverse outcomes and would likely be fairly short.

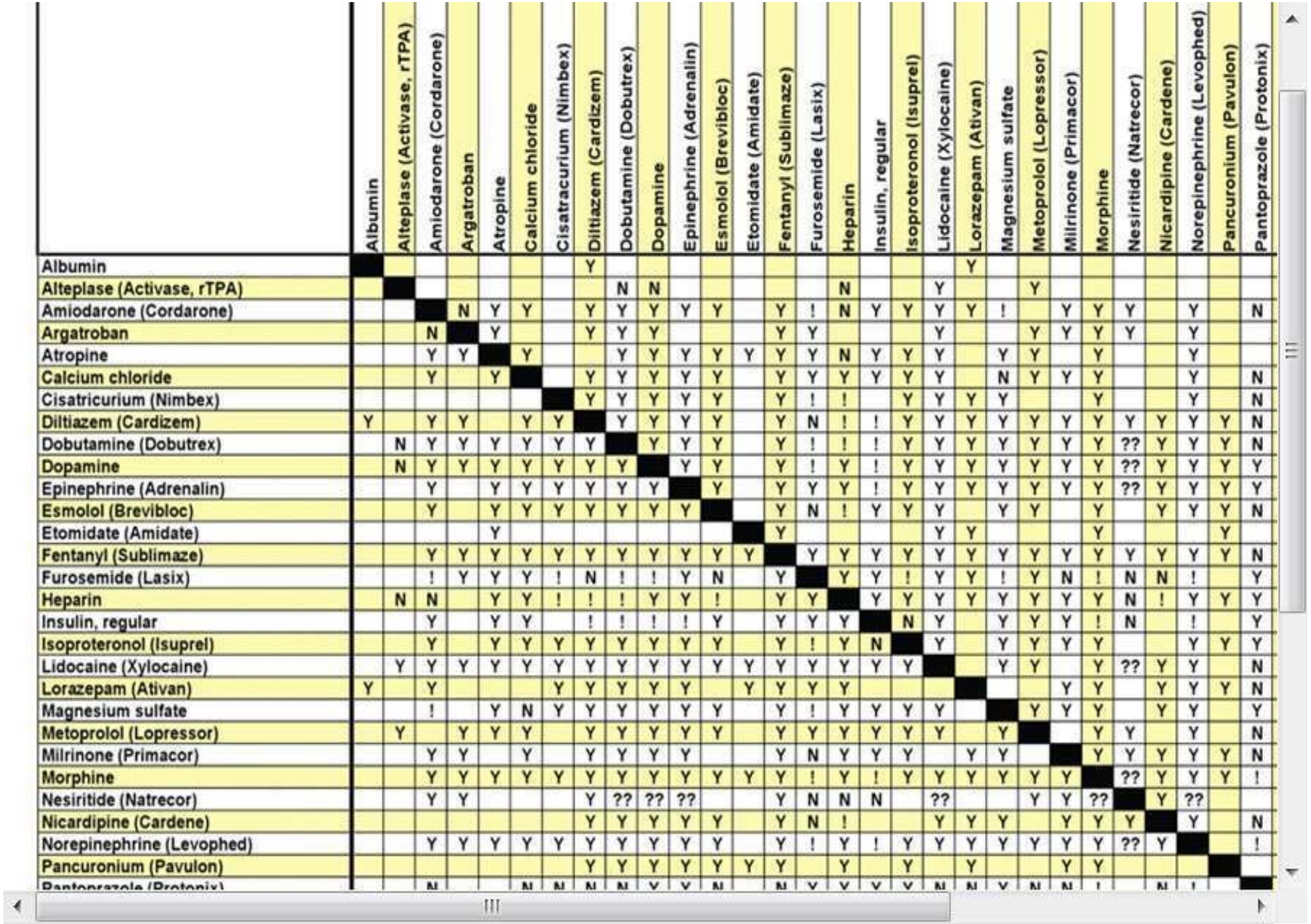
For example, prescriptions for warfarin plus CYP2C9 inhibitors or colchicine and CYP3A4 or P-glycoprotein inhibitors might always require a prescriber contact

prescriber a therapeutic alternative for one of the interacting drugs, particularly when 2 different prescribers are involved. Physicians will rarely make recommendations regarding drugs prescribed by another physician. Alternatives will have similar pharmacologic properties but lack the interaction risk.

If it is not possible to switch one of the interacting drugs, and the decision is made to administer both drugs to the patient, a monitoring plan should be devised to detect any evidence of an adverse drug reaction and respond appropriately. Monitoring could be as simple as measuring vital signs, plasma drug concentrations, or a specific pharmacodynamic parameter such as international normalized ratio or electrocardiogram. It is important to consider the time course of the interaction so that monitoring is

Incompatibility Charts

www.ivmedicationcompatibilitychart.com/



	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	Isoproteronol (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										
Alteplase (Activase, rTPA)									N	N						N			Y			Y							
Amiodarone (Cordarone)				N	Y	Y		Y	Y	Y	Y	Y		Y	!	N	Y	Y	Y	Y	!		Y	Y	Y		Y		N
Argatroban			N		Y			Y	Y	Y				Y	Y				Y			Y	Y	Y	Y		Y		
Atropine			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		N	Y	Y	Y			Y		N
Cisatricurium (Nimbex)								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	N	!	!	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	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
Epinephrine (Adrenalin)			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	N	!	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	N
Furosemide (Lasix)			!	Y	Y	Y	!	N	!	!	Y	N		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	N	!	Y	Y	Y
Insulin, regular			Y		Y	Y		!	!	!	!	Y		Y	Y	Y		N	Y		Y	Y	Y	!	N		!		Y
Isoproteronol (Isuprel)			Y		Y	Y	Y	Y	Y	Y	Y	Y		Y	!	Y	N		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		N
Lorazepam (Ativan)	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
Metoprolol (Lopressor)		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			Y	N	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	!
Nesiritide (Natrecor)			Y	Y				Y	??	??	??			Y	N	N	N		??			Y	Y	??		Y	??		
Nicardipine (Cardene)								Y	Y	Y	Y	Y		Y	N	!			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			!
Pancuronium (Pavulon)								Y	Y	Y	Y	Y	Y	Y		Y		Y		Y			Y	Y					
Pantoprazole (Protonix)			N			N	N	N	N	Y	Y	N		N	Y	Y	Y	Y	N	N	Y	N	N	!		N	!		

Hospital Policies and Procedures (P&P) 508

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

Non-punitive Environment 0508

- Hospitals are encouraged by CMS to adopt a non-punitive environment
  - Non-punitive environment so staff will report
  - Many hospitals balance the non-punitive environment with Just Culture
- Should focus on system analysis theory and system issues and not individual staff
  - The majority of medication errors are made by long term employees with unblemished records
  - It is a system that allows the error to occur

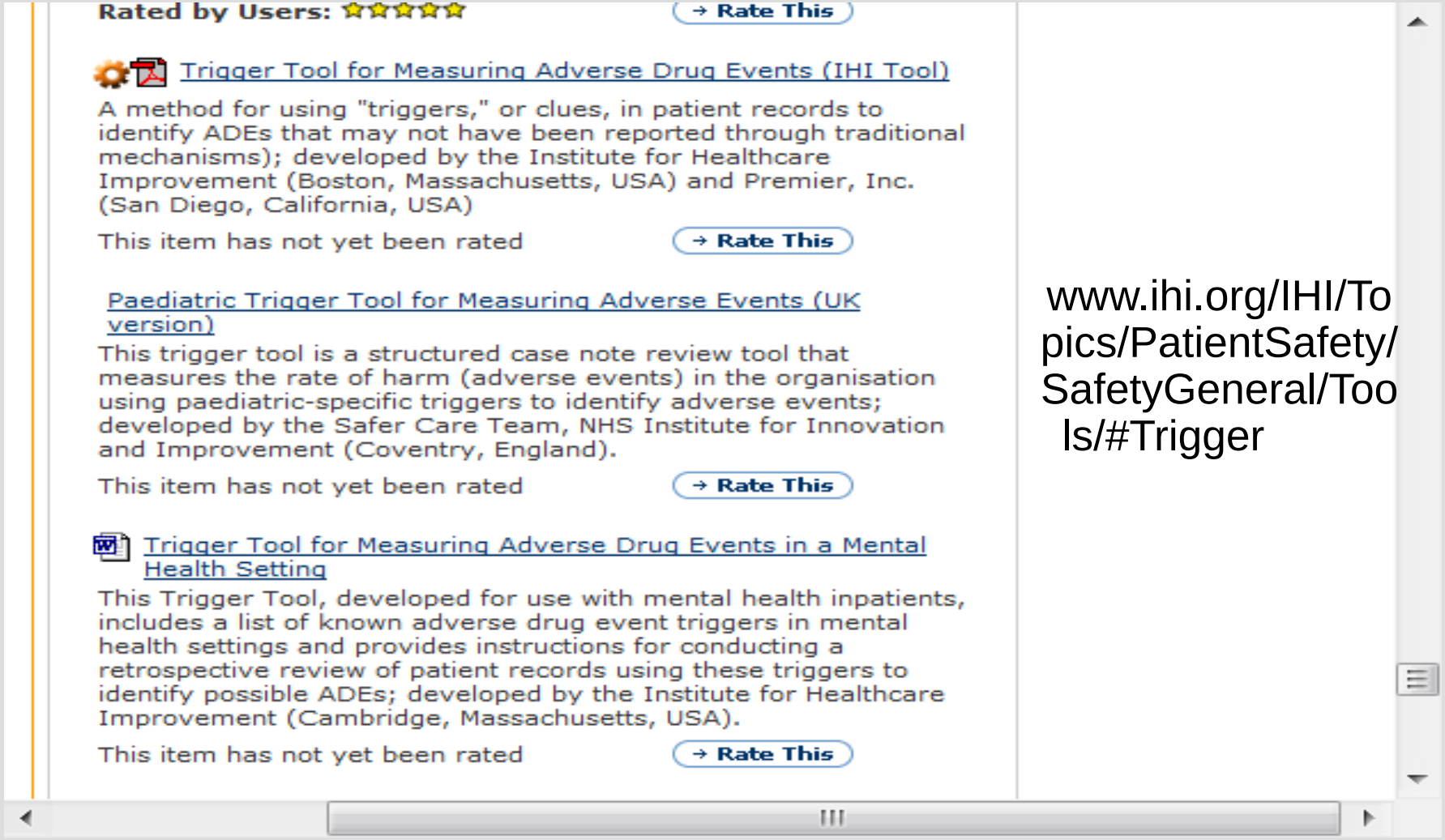
Hospital Requirements 508

- The hospital can not just rely on incident reports
- Additional steps must be taken besides
  - Encouraging reporting
  - Adopting a broad definition of medication error and
  - PI reporting
- Incident reports fail to identify most errors and ADEs

Proactive Identification

- Proactive identification could include
  - Observe medication passes by nurse
  - Concurrent and retrospective review of patient medical record
  - ADR surveillance team
  - Implementation of medication usage evaluations for high-alert drugs
  - Identification of indicator drugs (trigger drugs)

IHI Has Three Trigger Tools for ADEs



www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/#Trigger

Trigger Tool for ADE

Trigger Tool for Measuring Adverse Drug Events

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 collecting the data you need to measure the number of ADEs per 1,000 doses and the percentage of admissions with an ADE.

NOTE: You can use this tool in conjunction with the interactive Trigger Tool for Measuring ADEs in the Workspace area on IHI.org. Enter your detailed data from all of your ADE Patient Record Review Sheets into the interactive Trigger Tool for Measuring ADEs. The Tool will automatically calculate and graph two measures: ADEs per 1,000 Doses and Percent of Admissions with an ADE.

Mental Health ADE Trigger Tool

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

www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/#Trigger

Institute for Healthcare Improvement
November 2008
Version 2

Pediatric Trigger Tool for ADE

NICU Trigger Tool:
Measuring Adverse Events in the Neonatal Intensive Care Unit

Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit

The use of "triggers," or clues, to identify adverse events (AEs) is an effective method for measuring the overall level of harm in a health care organization. This Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit provides instructions for conducting a retrospective review of patient records using triggers to identify possible AEs in the **Neonatal Intensive Care Unit (NICU).** This tool includes a list of potential AE triggers and instructions for collecting the data you need to measure the rate of AEs in your NICU (the total number of AEs per 100 admissions), and the percentage of admissions with an AE) in your NICU. A full test of these triggers was conducted in order to construct a valid neonatal Trigger Tool. The details of this study can be found in the following article:

Sharek PJ, Horbar JG, Mason W, et al. Adverse events in the neonatal intensive care unit: Development, testing, and findings of a NICU-focused Trigger Tool to identify harm in North American NICUs. *Pediatrics.* 2006;118(4):1332-1340.
http://pediatrics.aappublications.org/cgi/content/abstract/118/4/1332

This NICU Trigger Tool contains:

Measure of Effectiveness 508

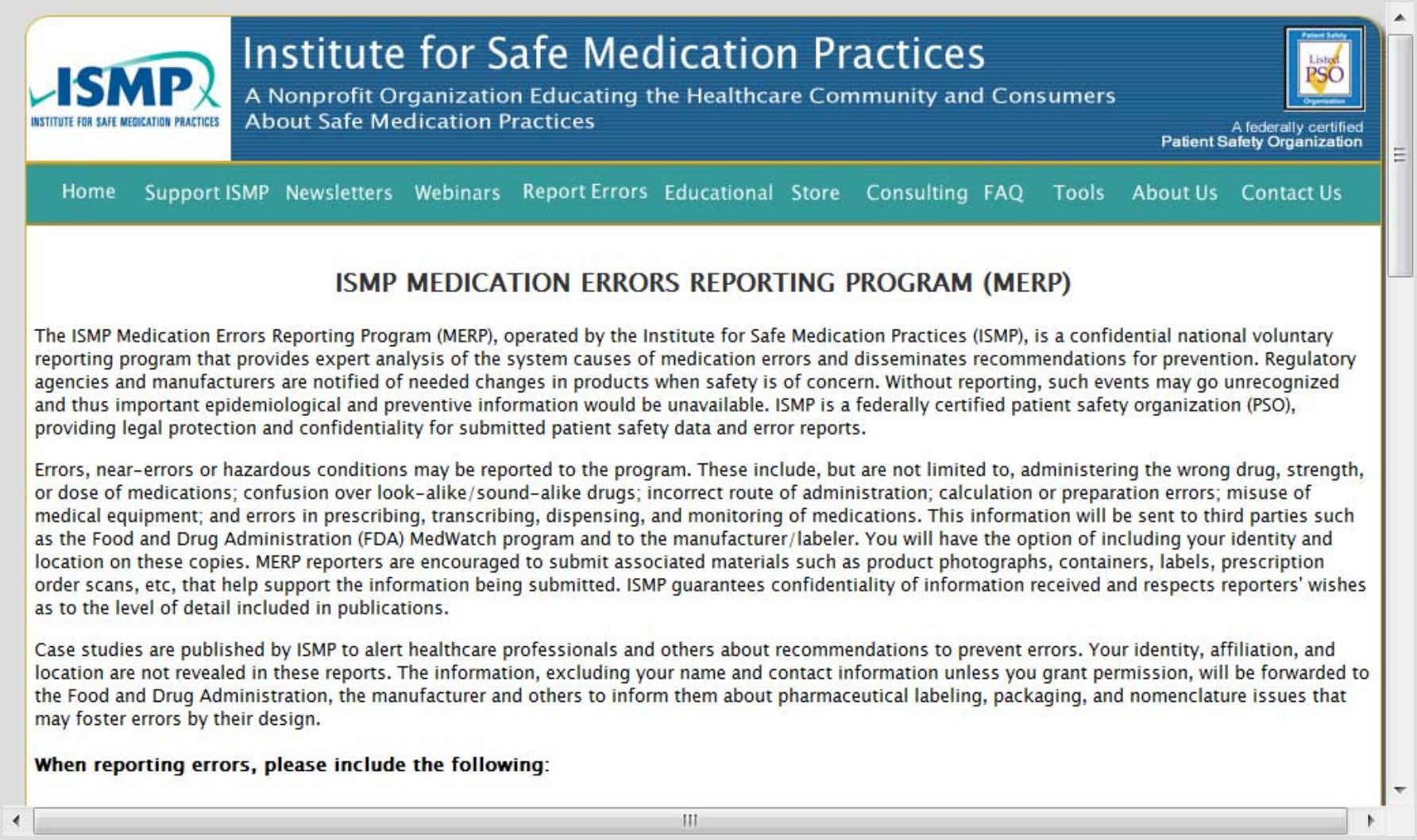
- Hospital must have a method to evaluate the effectiveness of its systems for identifying and reporting medication errors and ADEs to the PI program
- Methods could include the use of standardized benchmarks for size and scope of services provided
  - Or studies on reporting rate published in peer review journals
- CMS encourages hospitals to report ADE, medication errors, and incompatibilities

Medication Error Reporting 0508

- Reporting is not limited to
- The Food and Drug Administration's (FDA) MedWatch program
  - http://www.fda.gov/Safety/MedWatch/default.htm
- The Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program (USP-ISMP MERP)
  - https://www.ismp.org/orderforms/reporterrortoismp.asp
- Any reports required by any specific state law requirement

FDA Med Watch Program

ISMP Medication Error Reporting Program



Institute for Safe Medication Practices

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

A federally certified Patient Safety Organization

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ISMP MEDICATION ERRORS REPORTING PROGRAM (MERP)

The ISMP Medication Errors Reporting Program (MERP), operated by the Institute for Safe Medication Practices (ISMP), is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern. Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. ISMP is a federally certified patient safety organization (PSO), providing legal protection and confidentiality for submitted patient safety data and error reports.

Errors, near-errors or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications. This information will be sent to third parties such as the Food and Drug Administration (FDA) MedWatch program and to the manufacturer/labeler. You will have the option of including your identity and location on these copies. MERP reporters are encouraged to submit associated materials such as product photographs, containers, labels, prescription order scans, etc, that help support the information being submitted. ISMP guarantees confidentiality of information received and respects reporters' wishes as to the level of detail included in publications.

Case studies are published by ISMP to alert healthcare professionals and others about recommendations to prevent errors. Your identity, affiliation, and location are not revealed in these reports. The information, excluding your name and contact information unless you grant permission, will be forwarded to the Food and Drug Administration, the manufacturer and others to inform them about pharmaceutical labeling, packaging, and nomenclature issues that may foster errors by their design.

When reporting errors, please include the following:

Survey Procedure 0508

- Surveyor is suppose to pull the policy and make sure there is a definition of medication errors, ADR, and DI
- P&P must discuss when to report these immediately to the attending physician and to PI program
- Surveyor to make sure all medication errors and suspected ADEs are documented in the medical record
- Will ask staff what they do when they become aware of the above 3 things

Survey Procedure 508

- Surveyor is to make sure staff are aware of the hospital's P&P on reporting and documentation of all medication errors and ADEs
- Will ask how this information gets reported to the hospital PI program
- Surveyor is to make sure the hospital's definition of ADR and medication error is based on national standards
  - These were provided by CMS in the interpretive guidelines

Abuses and Losses 509

- Abuses and losses of controlled substances must be reported pharmacist and CEO and in accordance with any state or federal laws
- Surveyor will interview pharmacist to determine their understanding of controlled substances policies
- What is procedure for discovering drug discrepancies?
- Remember state board of pharmacy rules on abuses and losses

Drug Interaction Information 510

- Information on drug interactions and information on drug side effects, toxicology, dosage, indication for use and routes of administration must be available to staff
- Texts and other resources must be available for staff at nursing stations and drug storage areas
- Staff development programs on new drugs added to the formulary and how to resolve drug therapy problems

Drug Interaction Information 510

- Information on drug interactions and information on drug side effects, toxicology, dosage, indication for use and routes of administration must be available to staff
- Texts and other resources must be available for staff at nursing stations and drug storage areas
- Staff development programs on new drugs added to the formulary and how to resolve drug therapy problems

Formulary 0511

- Formulary system must be established by the MS to ensure quality pharmaceuticals at reasonable cost
- Formulary lists the drugs that are available
- Processes to monitor patient responses to newly added medication
- Process to approve and procure meds not on the list
- Process to address shortages and outages including communication with staff, approving substitution and educating everyone on this, and how to obtain medications in a disaster

Medications Shortages

- FDA has a website on current shortages and can sign up to get this information sent via email
- FDA drug shortage program designated by Center for Drug Evaluation and Research (CDER) Center Director
- FDA also has list of drugs to be discontinued
- Sign up to get email notification at www.fda.gov/cder/drug/shortages/default.htm

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www.fda.gov/cder/drug/shortages/default.htm

Drugs

Home › Drugs › Drug Safety and Availability › Drug Shortages

Drug Safety and Availability

- Drug Shortages
- Current Drug Shortages Index
- Current Drug Shortages A - D
- Current Drug Shortages E - K
- Current Drug Shortages L - N
- Current Drug Shortages O - R
- Current Drug Shortages S - Z
- Resolved Drug Shortages
- Drugs to be Discontinued
- How to Report a Shortage or Supply Issue
- Frequently Asked Questions About Drug Shortages

Drug Shortages

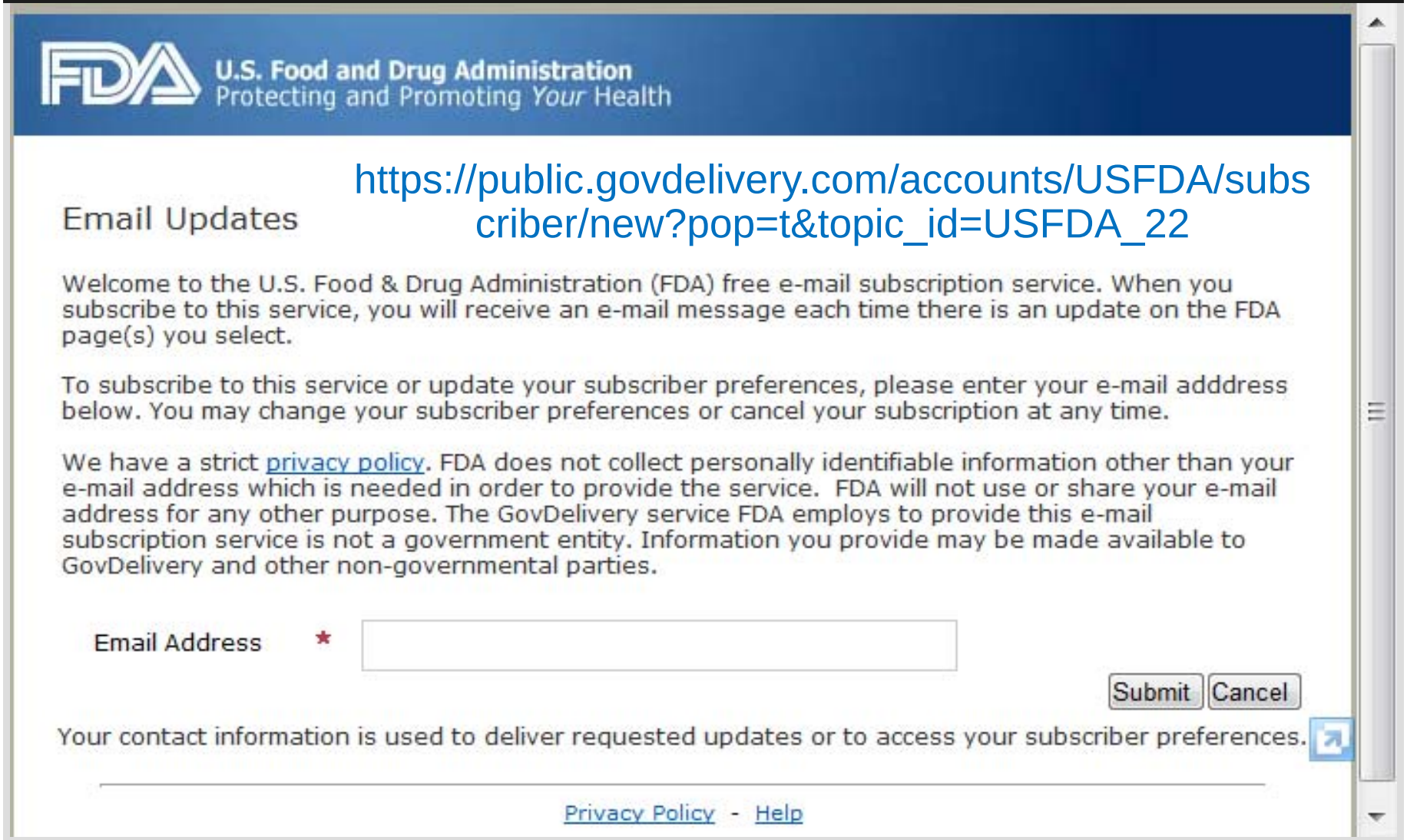
FDA takes great efforts, within its legal authority, to address and prevent drug shortages, which can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. The agency works closely with manufacturers of drugs in short supply to communicate the issue and to help restore availability. FDA also works with other firms who manufacturer 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.

Spotlight

- Meningitis Outbreak: Voriconazole and Liposomal Amphotericin B Availability Information
- Fact Sheet: Drug Products in Shortage in the United States
- FDA acts to bolster supply of critically needed cancer drugs
- FDA Report: A Review of FDA's Approach to Medical Product Shortages
- Statement from FDA and HHS on Drug Shortages

Sign Up To Get Drug Shortage Information



Drug Shortage Manual

MANUAL OF POLICIES AND PROCEDURES

CENTER FOR DRUG EVALUATION AND RESEARCH MAPP 6003.1

POLICY AND PROCEDURES

OFFICE OF NEW DRUGS

Drug Shortage Management

Table of Contents

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POLICY 2
RESPONSIBILITIES AND PROCEDURES 3
REFERENCES 7
DEFINITIONS 7
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www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

PURPOSE

- This MAPP establishes the Center for Drug Evaluation and Research (CDER) procedures for notification, evaluation, and management of drug shortage situations for all CDER products (e.g., investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), and critical products from any source)

ASHSP Drug Shortage Website

- American Society of Health System Pharmacist has website on current shortages and drugs no longer available
- Has other resources such as articles and news on drug shortages
- Has two articles on understanding and managing drug product shortages which you can use to help draft this required P&P
- http://www.ashp.org/shortages

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HOME > DRUG SHORTAGES

www.ashp.org/shortages

Drug Shortages

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

Drug Shortages

Print Share

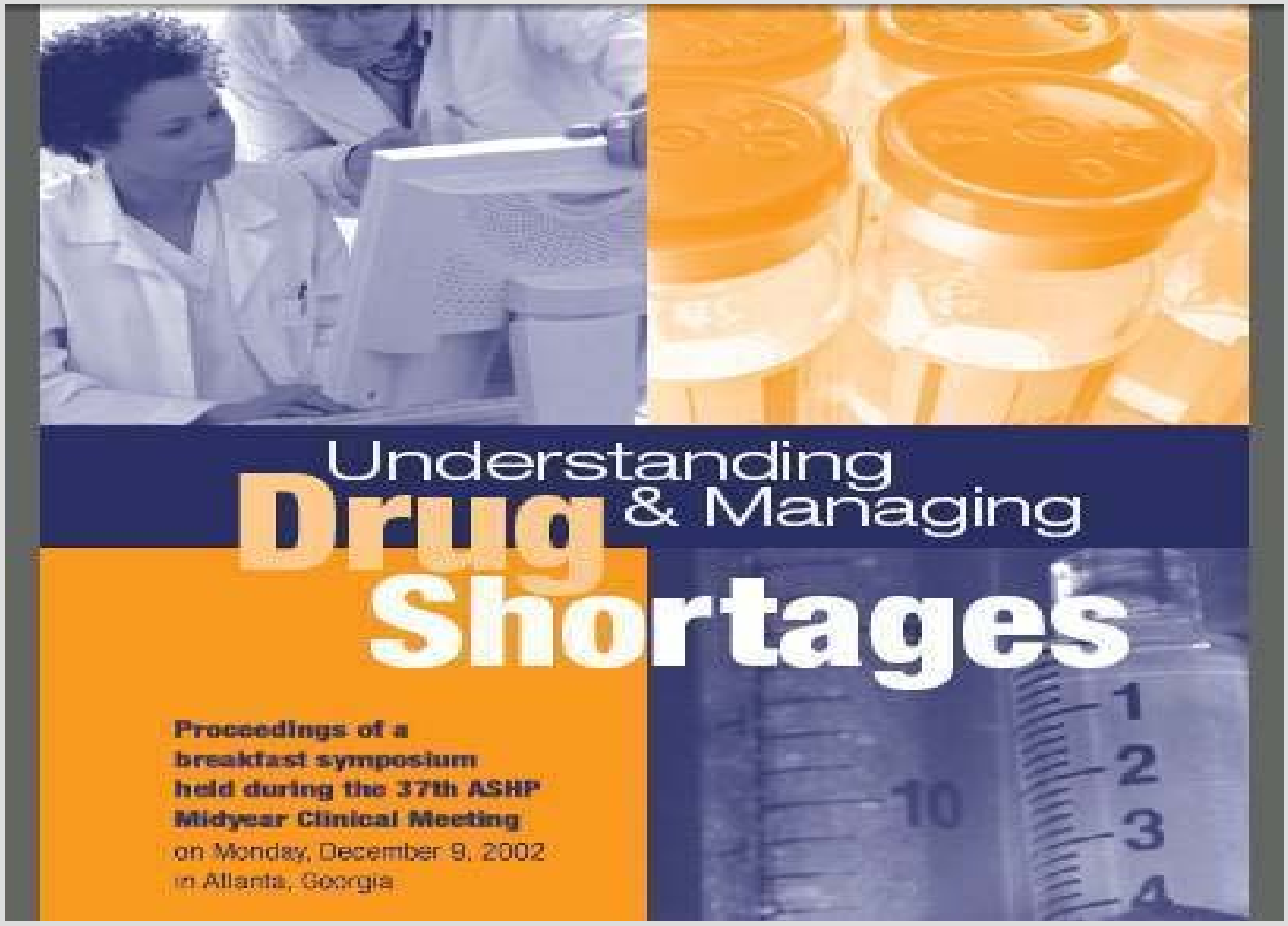
Welcome to the ASHP Drug Shortages Resource Center, the first stop for information and resources on drug product shortages and management. Drug shortages can adversely affect drug therapy, compromise or delay medical procedures, and result in medication errors. ASHP and its partners work to keep the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

Subscribe to RSS | Report a Drug Shortage

FIND DRUG SHORTAGES

Search by Generic Drug Name... Find OR Search by Drug Shortage List...

ASHP Managing Drug Shortages



www.ashp.org/s_ashp/docs/files/BP07/Procure_Gdl_Shortages.pdf

ASHP Guidelines on Managing Drug Product Shortages

Purpose

Short-term back orders and long-term unavailability of drug products have been a challenge to pharmacy managers for many years.[1] Nevertheless, these drug product shortages have been increasing in frequency and severity since the late 1990s.[2–4] The causes are varied and involve all segments of the "supply chain." Changes in policies and practices among these segments individually and collectively contribute to drug product shortages. The challenge for pharmacy managers is to enable the provision of seamless equivalent drug therapy at comparable costs.

Managing drug product inventories and supply situations is particularly complex for health care organizations because of the large number of monotherapies and monoproducts available. Drug product shortages can delay and compromise patient care and increase total costs, including those of alternative therapies, delivery devices, and staff training. The department of pharmacy should take a leadership role in managing shortages by developing appropriate strategies and an awareness campaign.[5]

Strategies for dealing with drug product shortages are similar to disaster planning and risk management contingencies for major snowstorms, mass casualty events, temporary

Shortages can be the result of one, several, or any combination of factors throughout the supply chain. For the purposes of this guideline, the supply chain includes sources of raw materials, manufacturers, regulators, wholesalers, prime vendors, buying groups, and end-user health care organizations. The "just-in-time" approach to procurement and inventory management among manufacturers, distributors, and end-users has reduced the ability of the supply chain to maintain drug product availability during disruptions. Many end-user health care organizations have reduced on-hand inventories to the extent that they are dependent on daily replenishments from suppliers. Inventories no longer provide an adequate buffer and, under some circumstances, a temporary back order becomes a critical drug product shortage for the end-user. The factors that follow contribute to disruptions in the availability of drug products.

Raw and Bulk Material Unavailability. Disruptions can occur in the availability of raw and bulk materials to manufacturers of finished drug products. This is especially problematic when multiple manufacturers make a drug product with material available from only one source (e.g., the sole source for bulk penicillin G sodium) that discontinues production. Availability problems arise when raw materials

GAO Drug Shortage Better but Still Continue

United States Government Accountability Office

GAO

Report to Congressional Addressees

www.gao.gov/assets/670/660785.pdf

February 2014

DRUG SHORTAGES

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

CMS Manual

- There are other reference to medication besides the pharmacy/medication section
- In the survey process, surveyor should look for outdated medication in the pharmacy
- Mentions psychiatric advance directives and use of medication
- Discusses medications and if a risk for falls or an unsteady gait
- Tag 160 regarding use of medications and when it is a restraint

CMS 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 be administered within **certain time limits** of the scheduled time and nurse must remain with patient until taken (Tag 405, Revised 12-22-2011)

CMS Manual

- 3 timeframes to administer medications under 405
- Must monitor medications as part of PI process including errors (Tag 405) and safe use of Opioids
- 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 have education on blood and IV medications (Tag 409 and amended June 20, 2011 and changed in FR July 16, 2012 to have P&P and follow state law)
- 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)

So What's In Your Policy?

POLICY AND PROCEDURE MANUAL

Medication Security and Storage Policy

Purpose:
This policy promotes patient safety by ensuring compliance with State and Federal laws as well as Joint Commission and Aspen regulations while limiting the opportunity for unauthorized use of loss of medication.
Definitions:
A listing of definitions of key terms is provided in Appendix A of this policy.

This policy separates medication security and storage into eight distinct pieces:

1) Receipt
2) Storage – pharmacy
3) Transportation
4) Storage – unit
5) Medication Removal
6) Waste
7) Inspection of Units
8) Disposal

Pharmacy Receipt of Medication

The process of receiving medications must include the proper checks and balances to insure accuracy of products received and their security.

Specifically, JDH will ensure proper handling of medications by allowing only Pharmacist/Pharmacist technicians to receive deliveries of medications.

Controlled substances may only be handled by authorized Pharmacy personnel and must be processed in accordance with Pharmacy procedure C-009.
Additional procedures over the receipt of medications may be found in Pharmacy Manual

Storage of Medication Policy

Storage of Medications

Pharmacy:
JDH should seek to control both access to and storage conditions of medications at all times.

Medications should be stored in accordance with manufacturer recommendations and/or based on pharmacist experience and instructions. Pharmacy access should be restricted at all times based on employee identification.

Controlled substances must be secured in a locked room inside the pharmacy and held in a secured device or refrigerator. Personnel gain access to the controlled substance devices via password authentication.

Transportation and Delivery of Medications

Transportation: Medications may only be transported via prescribed manners.

Different types of medications are transported in different ways:

Controlled substances may be transported in one of three ways:

- By pharmacist or pharmacist tech
- Controlled substances can be picked up by licensed personnel at the pharmacy and then transported to units.
- Off site locations may receive medications via JDH transports

Medications not containing controlled substances medications may be transported by pharmacy staff, Hospital staff, or volunteers.

For additional information on Pharmacy transportation see Pharmacy manual C-011 and C-012

Delivery:

Controlled substances must be delivered to the appropriate Pyxis machine or double locked facility. (For additional details see Pharmacy manual C-009)
When a pharmacist or pharmacist tech delivers medication it may be delivered to either the

The End! Questions??

- Sue Dill Calloway RN, Esq. CPHRM, CCMSCP
- AD, BA, BSN, MSN, JD
- President of Patient Safety and Education
- 614 791-1468
- sdill1@columbus.rr.com
- See resource material including Tag 406 and 412 and 413

Tag 406 Revised March 15, 2013 Drugs

A-0406

(Rev.)

§482.23(c)(1) (ii)– Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of §482.24(c)(3).

§482.23(c)(*3*) - With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and and who is responsible for the care of the patient as specified under §482.12(c)…

§482.23(c)(3)(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under §482.12(c) only if such practitioners are acting in accordanc with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

Physician Order 406 2013

- Orders for drugs must be documented and signed by practitioners allowed to write them
  - Or signed by practitioners as allowed by state law, state scope of practice, hospital P&P and MS bylaws and R/Rs
- Doctors can write orders and if allowed NP and PAs
- Removed section about use of rubber stamps which is medical record chapter anyway
- Adds a section that talks about standing orders

Standing Orders 406

- Nurses or others authorized by hospital P&P and state law may
  - Administer drugs and biologicals in accordance with pre-printed and electronic standing orders, order sets, and protocols
  - CMS collectively just refers to these as standing orders
- Need to address well defined clinical scenarios involving medication administration
- Refers to tag 457 for requirements on standing order P&Ps

Examples of Standing Orders 2013

- Practitioner must still sign off, date, and time
- Chest pain protocol or asthma protocol with Albuterol and Atrovent are an example of initiation of orders
- Code teams gives ACLS drugs in an arrest
- Timing of orders should not be a barrier to effective emergency response
- Preprinted order
  - Should send memo so doctors and providers are aware of new guidelines

CMS Adds New Tag Numbers 412 & 413

A-0412

§482.23(c)(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self -administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.

(i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.
(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).
(C) Instruct the patient (or the patient's support person where appropriate) in the safe and accurate administration of the specified medication(s).
(D) Address the security of the medication(s) for each patient.
(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

Self-Administer Medications 2013

- CMS added new tag numbers 412 and 413
- Previously, the only section on self administered medications was in the pharmacy standard under tag 502
- Standard: The hospital may allow a patient or caregiver/support person to self administer medications in accordance with hospital P&P
  - This includes hospital issued medication and patient's own medication brought in
- These are very long sections so need to read

Self-Administer P&P Must Include

- Self administer P&P **must** include:
  - Need an order
  - Make sure assess capacity and document
    - Is the patient competent and not confused
  - Instruct the person on how to give safely
  - Address the security of the medication
  - Document when given in the medical record

Self-Administer Medications

- Not required to do
  - Could be beneficial to some patients
- Generally applies to inpatients but may find appropriate situations for outpatients
  - Hospital does for observation patients on Medicare since does not pay for oral medications
  - Asthma patient has inhaler at bedside or patient has hemorrhoid cream or patient learns to give subq Heparin
- Teaching patient to use their medications could avoid readmissions or returns to the ED

Self-Administer Medications

- Some cases nurse may need to supervise
- May want to include in the P&P when supervision by the nurse is needed
- May exclude certain medications from self administration
- Medical staff, nursing and pharmacy departments must collaborate in developing P&P
- Surveyor will assess carefully to ensure these standards and policy requirements are met

Self Administer Medications 413

- New tag number in 2013
- Standard: The hospital may allow a patient or caregiver to self administer own medication or hospital issued medications as defined by P&P
- Must have policies to include:
  - Need an order which is consistent with P&P
  - Assess capacity of the patient and document
  - Evaluate the medicine for integrity
  - Address security of the medication
  - Document each medicine given

System to Prevent MDRO & Antibiotic Use

- This is from the CMS worksheets for hospitals, 3rd revision, and is on systems to prevent the transmission of MDRO and promote antibiotic stewardship (1 C)
- MDRO is multidrug-resistant organisms such as C-diff, MRSA, or VRE
- Hospital has P&P to minimize risk of transmission of MDRO?
  - There are many free toolkits online for MDRO and CDC has tons of excellent resources at www.cdc.gov/nhsn/ such as MDRO modules

Standing Order Moved from 405 and Now 457

A-0457

(Rev.)

§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-printed and electronic standing orders, order sets, and protocols. However, we note that the lack of a standard definition for these terms and their interchangeable and indistinct use by hospitals and health care professionals may result in confusion regarding what is or is not subject to the requirements of §482.24(c)(3), particularly with respect to "order sets."

- *Not all pre-printed and electronic order sets are considered a type of "standing order" covered by this regulation. Where the order sets consist solely of menus of treatment or care options designed to facilitate the creation of a patient-specific set of orders by a physician or*

Tag 457 Standing Orders 2013

- Standard: hospitals can use preprinted and electronic standing orders, order sets, and protocols for patient orders only if the hospital has the following 4 things:
- Make sure the orders and protocols have been reviewed and approved by the MS (such as the MEC) and the hospital's nursing and pharmacy leadership
- Demonstrate that the orders and protocols are consistent with nationally recognized and evidenced based guidelines

Tag 457 Standing Orders

- No standard definition of standing orders
- For brevity CMS uses standing orders to include pre-printed orders, electronic standing orders, order sets and protocols
  - Said these are forms of standing orders
- States lack of standard definition may result in confusion
- Not all preprinted and electronic order sets are considered a standing order covered by this regulation

Tag 457 Standing Orders

- Example; doctor or qualified practitioner picks from an order set menu and treatment choices can not be initiated by nurses or other non-practitioner staff then menus are not standing orders covered by this regulation
- Menu options does not create an order set subject to these regulations
- The physician has the choice not to use this menu and could create orders from scratch or modify it

Tag 457 Standing Orders 2013

- In cases, where a nurse can initiate without a prior specific order,
  - Then policy and practice must meet these regulations
  - Doesn’t matter what it is called
  - Must meet certain pre-defined clinical situations
  - Emergency response or part of an evidenced-based treatment where it is NOT practical for a nurse to obtain a written order or verbal order
- Hybrids still require compliance with this section
  - Order set has a protocol for nurse initiated such as KCL

Standing Order Requirements 457

- Must be well-defined clinical situations with evidence to support standardized treatments
- Appropriate use can contribute to patient safety and quality care
- Can be initiated as emergency response
- Can be initiated as part of an evidenced based treatment regime where not practicable to get a written or verbal order
- Must be medically appropriate such as RRT

Standing Order Requirements 457

- Triage and initialing screening to stabilize ED patients presenting with symptoms of MI, stroke, asthma
- Post-operative recovery areas like PACU
- Timely provisions of immunizations
- Can’t be used when prohibited by state or federal law so no standing orders on R&S
- CMS has set forth a number of minimum requirements for standing orders that must be present for a well-defined clinical scenario

Minimum Requirements for Standing Orders

- Must be approved by MS, nursing and pharmacy leadership
- P&P address how it is developed, approved, monitored, initiated by staff and signed off or authenticated
- Must have specific criteria identified in the protocol for the order for a nurse or other staff to initiate
  - Such as a specific clinical situation, patient condition or diagnosis
- Must include process to have them signed off

Minimum Requirements for Standing Orders

- Hospital must document standing order is consistent with nationally recognized and evidenced based guidelines
- Burden is on the hospital to show there is sound basis for the standing order
- Must have regular review to ensure its still useful and a safe order
- P&P address how to correct it, revise or modify
- Must be placed in the order section of the chart
- Must be dated, timed, and signed

Tag 457 Standing Orders 2013

- Make sure there is periodic and regular review of the orders and protocols conducted by the MS, nursing and pharmacy leadership to determine the continued usefulness and safety
- Make sure they are dated, timed, and authenticated promptly in the medical record
  - Signed off by the ordering practitioner of another practitioner on the case
  - Could be signed off by non-physician if allowed by hospital policy, state law, the person state law scope of practice, and MS bylaws or R/R

Subq Insulin Order Set

www.hospitalmedicine.org/AM/Template.cfm?Section=QI_Clinical_Tools&Template=/CM/HTMLDisplay.cfm&ContentID=4239

Insulin Drip Protocol

THE *NEW** YALE INSULIN DRIP PROTOCOL

The following insulin drip protocol is intended for use in hyperglycemic adult patients in an ICU setting, but is not specifically tailored for those individuals with diabetic emergencies, such as diabetic ketoacidosis (DKA) or hyperglycemic hyperosmolar syndrome (HHS). When these diagnoses are being considered, or if BG≥ 500 mg/dL, an MD should be consulted for specific orders. Also, please notify an MD if the response to the insulin drip is unusual/unexpected, or if any situation arises that is not adequately addressed by these guidelines. The starting dose, adjustments, and glucose targets have been intensified.

Initiating An Insulin Drip

1.) **INSULIN INFUSION**: Mix 1 units Regular Human Insulin per 1 cc 0.9 % NaCl. Administer via infusion pump (in increments of 0.5 U/hr).
2.) **PRIMING**: Flush 50 cc of Insulin/NS drip through all IV tubing, before infusion begins (to saturate the insulin binding sites in the tubing)
3.) **THRESHOLD**: IV insulin is indicated in any critically ill patient with persistent BG ≥ 140 mg/dl; consider use if BG ≥ 110 mg/dl.
4.) **TARGET BLOOD GLUCOSE (BG) LEVELS: 90-119 mg/dL***.
5.) **BOLUS & INITIAL INSULIN DRIP RATE**: If initial BG ≥ 150, divide initial BG level (mg/dL) by 70, then round to nearest 0.5 units for bolus AND initial drip rate. If initial BG < 150 mg/dl, divide by 70 for initial drip rate only (i.e., NO bolus)
   Examples: 1) Initial BG 335 mg/dL: 335 ÷ 70 4.78, rounded ↑ to 5: 5 units IV bolus + start drip @ 5 units/hr.
   2) Initial BG 148 mg/dL: 148 ÷ 70 2.11, rounded ↓ to 2: start drip @ 2 units/hr (NO bolus)

Fingerstick (FS) Blood Glucose Monitoring

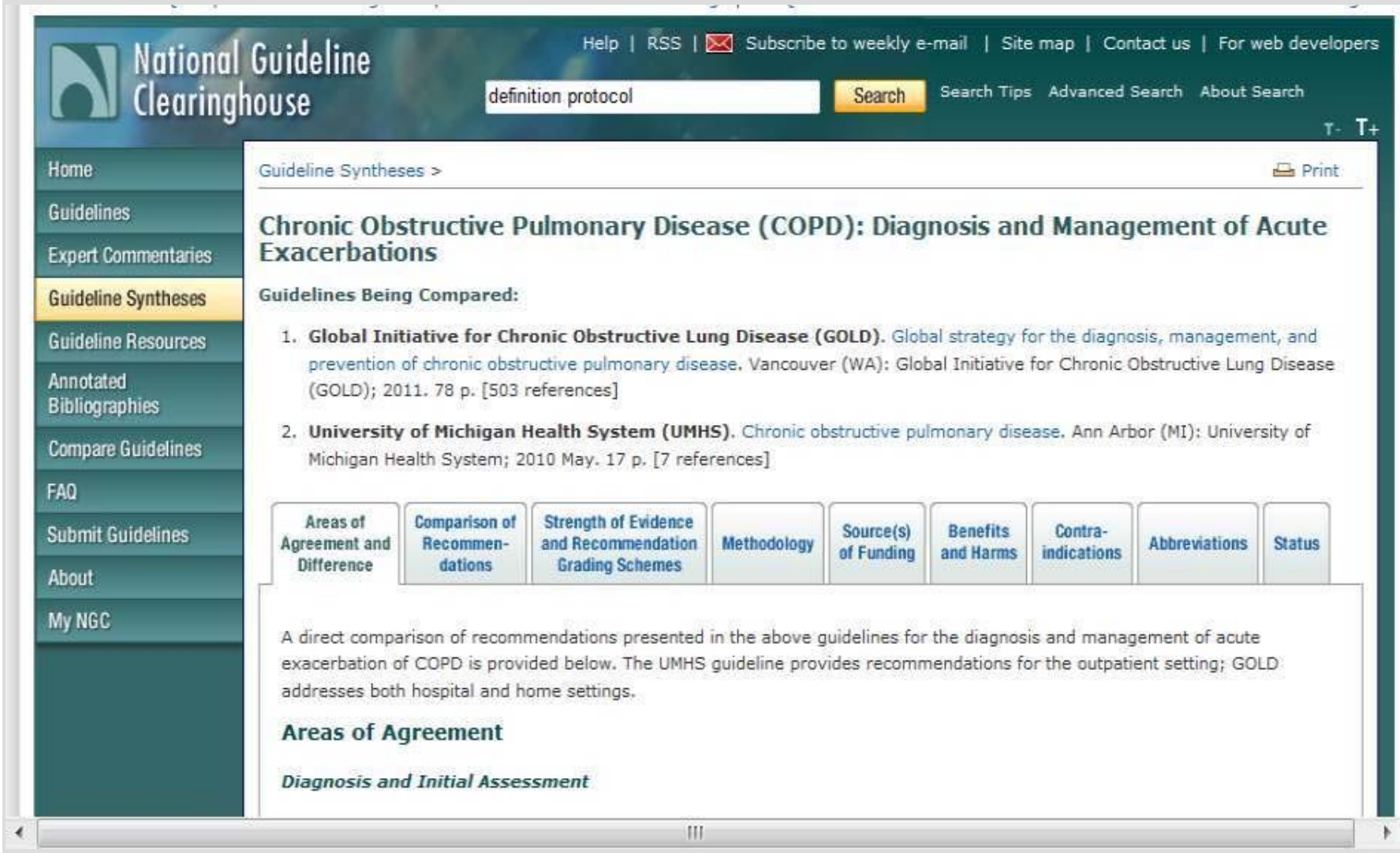
1.) Check FS hourly until stable (defined as 3 consecutive values in target range). In hypotensive patients, capillary blood glucose (i.e.,fingersticks) may be inaccurate and obtaining a blood sample from an indwelling vascular catheter may be preferable.
2.) Once stable, check FS q 2 hours; once stable x 12-24 hours, FS checks can be spaced to q 4 hours **IF**:
   a) no significant change in clinical condition AND b) no significant change in nutritional intake
3.) If any of the following occur, consider the temporary resumption of hourly FS monitoring, until BG is again stable:
   a) any change in insulin drip rate (i.e. BG out of target range) b) significant changes in clinical condition
   c) initiation or cessation of pressor or steroid therapy d) initiation or cessation of dialysis or CVVH
   e) initiation, cessation, or rate change of nutritional support (TPN, PPN, tube feedings, etc.)

Changing the Insulin Drip Rate

If BG < 50 mg/dL:
D/C INSULIN DRIP **Give 1 Amp (25 g) D50 IV; recheck BG q 15 minutes**
⇒ When BG ≥ 90 mg/dL, wait 1 hour, recheck BG, then restart drip at 50% of most recent rate (if BG still ≥ 90 mg/dL

If BG 50-69 mg/dL:
D/C INSULIN DRIP If symptomatic (or difficult to assess), give 1 Amp (25 g) D50 IV; recheck BG q 15 minutes

Guidelines www.guidelines.gov



CDC Healthcare Safety Network

System to Prevent MDRO & Antibiotic Use

- Hospital has multidisciplinary process in place to review antimicrobial use, local susceptibility patterns, and antimicrobial agents in the formulary?
- Are patients with MDRO identified?
- Are there P&P to prevent the development and transmission of MDRO?
- Is there a system in place to prompt clinicians to use the right antibiotic?
  - Could include CPOE, susceptibility reports, notifications from pharmacy, comments in microbiology report, evidenced based guidelines, etc.

System to Prevent MDRO & Antibiotic Use

- Is there a mechanism in place to prompt clinicians to review antibiotics use after 72 hours?
- Do antibiotic orders include an indication for use?
- Is there a mechanism in place to identify patients getting IV antibiotics that could be eligible to receive oral antibiotics?
- Is there a system with clinical microbiology lab that ensures prompt notification if there is a novel resistance pattern detected?
- Are patients or healthcare staff who are colonized or infected with MDRO identified and isolated according to the P&P

System to Prevent MDRO & Antibiotic Use

- Is there a system to identify those present on admission (POA) infections in order to control the spread?
- Can the IP provide an updated list of the reportable diseases to the local or state department of health?
- Can the IP provide evidence that all reportable diseases are reported and documented as required (tag 749)
  - Every state has a list of things that must be reported such as HIV, C-diff, hepatitis B, hepatitis C, etc

AHRQ Agency for Healthcare Research and Quality

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You Are Here: AHRQ Home > Patient Safety & Medical Errors > ERASE *C. difficile* Project Toolkit > Questions To Consider

Toolkit for Reduction of *Clostridium difficile* Infections Through Antimicrobial Stewardship

The Evaluation and Research on Antimicrobial Stewardship's Effect on *Clostridium difficile* (ERASE *C. difficile*) Project

www.ahrq.gov/qual/cdifftoolkit/cdiffl1qu.htm

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

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 targeted to promote appropriate antibiotic use and potential *C.*

Injection Practices & Sharps Safety

- Next section is on injection practices and sharps safety
- This includes medications, saline, and other infusates
- Injections are given and sharps safety is managed in a manner consistent with IC P&P
- CDC has standards on self injection practices
- Injections are prepared using aseptic technique
- One needle, one syringe for every patient and includes insulin pens (CMS issues memo May 18, 2012)

Section 2. B Injection Practices and Sharps Safety (Medications, Saline, Other Infusates)

Elements to be assessed		Manner of Assessment Code (check all that apply) & Surveyor Notes			Manner of Assessment Code (check all that apply) & Surveyor Notes	
Injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:						
2. B.1 Injections are prepared using aseptic technique in an area that has been cleaned and free of visible blood, body fluids, or contaminated equipment.	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5		☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	
2. B.2 Needles are used for only one patient.	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5		☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	
2. B.3 Syringes are used for only one patient (this includes manufactured prefilled syringes and insulin pens).	☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5		☐ Yes ☐ No ☐ N/A	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	

Interview = 1 Observation = 2 Infection Control Document Review = 3 Medical Record Review = 4 Other Document Review = 5

11.00 x 8.50 in

Injection Practices & Sharps Safety 2 B

- Injections prepared using aseptic technique in area cleaned and free of blood and bodily fluids
- Is rubber septum disinfected with alcohol before piercing?
- Are single dose vials, IV bags, IV tubing and connectors used on only one patient?
- Are multidose vials dated when opened and discarded in 28 days unless shorter time by manufacturer?
- Make sure expiration date is clear as per P&P
- If multidose vial found in patient care area must be used on only one patient

Safe Injection Practices Patient Safety Brief

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

www.empsf.org

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

The Centers for Disease Control and Prevention (CDC) says there are 1.7 million healthcare-associated infections in the US every year. Of these, it is estimated that about 99,000 deaths occur as a result. Infection prevention

Injection Practices & Sharps Safety

- Are all sharps disposed of in resistant sharps container?
- Are sharp containers replaced when fill line is reached?
  - Are sharps disposed of in accordance with state medical waste rules
  - Hospitals should have a system in place where someone has the responsibility to check these and ensure they are replaced when they are full

CMS Anesthesia Standards Changes

- The anesthesia standards should also be reviewed as they discuss things in the pain bucket (analgesia) and in the anesthesia bucket
- There are four things in the pain bucket that are addressed by CMS and these include moderate sedation, minimal sedation, topical and locals
- There are four things in the anesthesia bucket; general, epidural and spinal (regional), MAC, and deep sedation
- Sets forth the requirements and policies required for all the above

CMS Anesthesia Standards Changes

- Hospitals are expected to have P&P on when medications that fall along the analgesia-anesthesia continuum are considered anesthesia
  - P&P must be based on nationally recognized guidelines
- Must specify the qualifications of practitioners who can administer analgesia
- CMS further clarified pre-anesthesia and post-anesthesia evaluations
- CMS added FAQs which are very helpful
  - Hospitals should review these as many changes and clarifications were made

CMS Anesthesia Standards Changes

- CMS has added additional requirements for the definition and use of analgesia (pain) through out the hospital
- These are less prescriptive than the prior changes
- CMS requires the hospital to develop policies on specific clinical privileges involving anesthesia and analgesia (pain)
- Must specify the qualifications for each category of practitioners who administer analgesia
- Strong emphasis on rescue capacity of hospitals

Procedural Sedation

- Medical staff and board must approve C&P of physicians including emergency department and GI physicians
- If ED physicians give a medication such as propofol, Ketamine etc. must be based on a national standard of care such as an ACEP position statement
- ACEP allows this
- FDA and package inserts says only CRNA or anesthesiologist can give Propofol but not a CMS issue anymore

CMS Added FAQs

Attachment 2

FAQs for Revisions to Anesthesia Services Interpretive Guidelines

The revised interpretive guidelines (IG) require each individual hospital to develop its own internal policies and procedures as to what medications, under what circumstances, constitute anesthesia and therefore require administration by an anesthesia professional as delineated at 42 CFR 482.52(a). The IG also requires that hospitals base their policies on nationally recognized guidelines.

The following questions and answers are provided to facilitate understanding of the revised guidance:

Q1: How can the same drug be used at the same facility for general anesthesia in the operating room and for a sedative in the emergency department or a procedure room?

A1: The physiological result in terms of level of sedation for a particular medication may vary based on dosage, route and timing of administration, the metabolism and interaction with other medications, the clinical status and body habitus of the patient, etc. However, there is neither a bright line nor predictability about when a patient will inadvertently convert from moderate to deep sedation, or how much medication will bring about the desired sedation state. In addition, for some medications there is no antidote that can quickly reverse its effects; rescue of an overly-sedated patient requires very specific skills in airway management and ventilation. For this reason the IG continues to require that hospitals ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than originally intended.

Q2: What nationally recognized guidelines are available for hospitals to use to develop their policies concerning what is anesthesia and what is analgesia and which procedures need which? What does "nationally recognized guidelines" mean?

A2: CMS' expectation is that such guidelines are issued by a national organization that has appropriate expertise and which has used consensus-setting process of professionals with appropriate expertise in developing its guidelines. We recognize that such organizations may not always fully agree with each other. Examples of organizations with guidelines related to anesthesia administration include, but not limited to, the following:

TJC Perspectives June 2010

Joint Commission Requirement

CLARIFICATION: Expiration of Multi-dose Vials

Discard 28 Days after First Use

Multiple outbreaks of infections associated with multi-dose vials have been reported in the scientific literature. Organizations such as the Association for Professionals in Infection Control and Epidemiology (APIC) and the United States Pharmacopeia (USP) have recently revised their guidelines as a result. The Joint Commission has also clarified its requirements for **ambulatory care, behavioral health, critical access hospital, home care, hospital,** and **long term care** programs pertaining to the use of multi-dose vials and their expiration dates; this clarification is **effective immediately**.

Medication Management (MM) Standard MM.03.01.01, Element of Performance (EP) 7, requires organizations to store all medications labeled with the expiration date. The Joint Commission defines *expiration date* as the last date that the product is to be used. The manufacturer bases the expiration date for all drug products on the fact that the product has not been opened. Once an individual removes a vial cap or punctures a vial, the expiration date is no longer valid and a revised expiration date (also called the "beyond-use date" in pharmaceutical terminology) needs to be identified. To comply with MM.03.01.01, EP 7, The Joint Commission requires organizations to re-label multi-dose vials with a revised expiration date (that is, a beyond-use date) once staff opens or punctures a multi-dose vial unless the manufacturer specifies otherwise. Therefore, The Joint Commission will require a 28-day expiration date for multi-dose vials from the date of opening or puncture, unless the manufacturer specifies otherwise. The Joint Commission bases this 28-day time frame on the fact that manufacturers are required by law to test the effectiveness of the bacteriostatic agent used in the multi-dose vial for a period of 28 days. The FDA allows manufacturers to provide extended dating in the package insert if they have conducted testing beyond the minimum 28 days.

Alternately, if the manufacturer identifies an original expiration date earlier than the revised expiration date, then the earlier date must be used. Also, if sterility is questioned or compromised, the multi-dose vial should be immediately discarded.

This dating expectation does not apply to vaccines in the Centers for Disease Control and Prevention and state immunization programs, which have separate requirements for when multi-dose vials must be discarded.

References

1. U.S. Pharmacopeia: *USP General Chapter 797 Frequently Asked Questions.* http://www.usp.org/audiences/pharmacist/797FAQs.html (Accessed April 13, 2010).
2. APIC: APIC Position Paper: *Safe Injection, Infusion and Medication Vial*

TJC FAQ on Anesthesia Cart

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Home > Accreditation Programs > Hospitals > Standards > 2009 Standards FAQs > Medication Management

Medication Management

Updated | November 24, 2008

Security of Anesthesia Cart Medications

Q: Can an anesthesia cart containing medication be left unlocked in an OR suite between cases?

A: If the individual operating room is part of a larger OR unit that is manned at all times in a fashion which monitors access to the operating room and assures constant surveillance of the anesthesia cart to prohibit access by unauthorized individuals - locking of the cart between cases would not be required.

After hours when the OR unit is not manned in a like manner, the carts must be properly secured. Whether the carts are locked or unlocked, they must be stored in a secured area which prohibits access and tampering by unauthorized individuals (e.g., in a separate locked room or in the secured OR unit where unauthorized access is prohibited.)

ASHP Guidelines on the Safe Use of Automated Medication Storage and Distribution Devices

Purpose

Automated medication storage and distribution devices are an increasingly prevalent component of the medication-use process in health care organizations. The pharmacy profession's transition to pharmaceutical care, changes in health care systems, and pressures to reduce costs have created interest in availability of and use of automated devices. ASHP supports the use of automated devices when it frees pharmacists from labor-intensive distributive functions, helps pharmacists provide pharmaceutical care, and improves the accuracy and timeliness of distributive functions. Experience with automated devices suggests that when they are used appropriately these benefits can be realized.[1–4] When automated devices are not used appropriately, their complexity, design and function variations, maintenance requirements, staff-training requirements, and other factors can have undesirable effects and compromise patient safety.[5,6] The National Association

Background

The appropriate, accurate, and timely distribution of medications to patients is a well-established responsibility of pharmacists. In acute care settings in particular, distribution systems have been developed that enable pharmacists to review medication orders and to oversee the preparation and packaging or selection of medication doses, as well as the delivery of doses to patient care units. Automation has evolved to ease fulfillment of pharmacists' distributive responsibilities, expand distribution-system capabilities, and improve efficiencies.

The use of automated medication storage and distribution devices continues to evolve. Some health care organizations deploy one or several devices in selected areas, such as emergency rooms, that are floor-stock intensive and where lost charges can be substantial; or for selected categories of medications, such as controlled substances, that have time-

ISMP Self Assessment

TEAM UP TO PREVENT ERRORS

2011 ISMP Medication Safety Self Assessment® for Hospitals Is Coming

An updated ISMP self assessment will be available online in early 2011. Plan now to make sure a team has been identified to help your hospital take advantage of this unique opportunity to improve medication safety.

The medication safety self assessment helps hospitals to:

- Evaluate their safety practices
- Identify opportunities for improvement
- Compare their experiences over time with those of similar organizations.

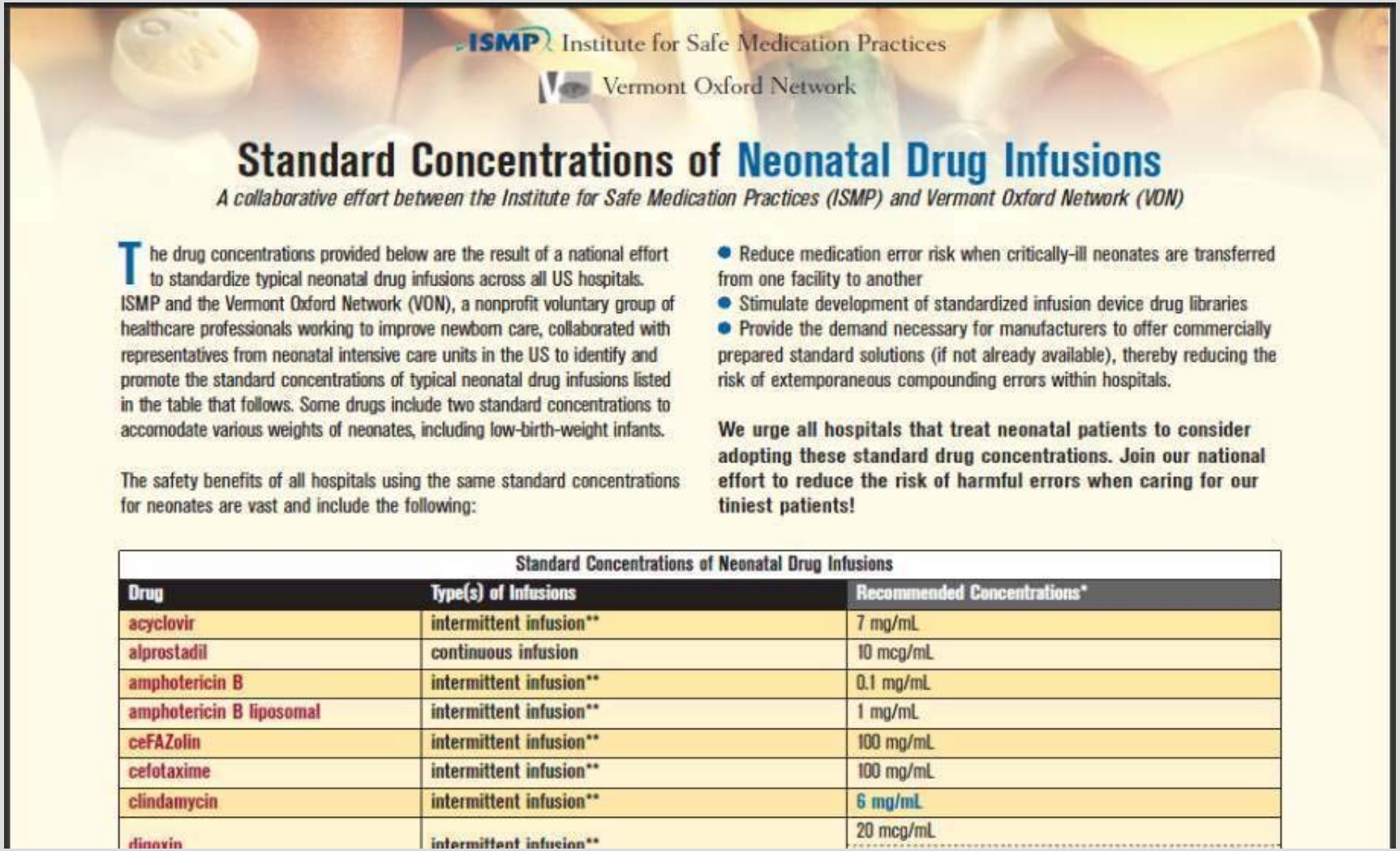
Previous ISMP self assessments were conducted in 2000 and 2004. The 2011 self assessment will document progress during the last five years of intense national attention to medication safety and identify the impact of emerging challenges, such as staffing shortages, shrinking reimbursement systems, and application of new technology.

ISMP is collaborating with the American Hospital Association (AHA) and Health Research & Educational Trust (HRET) on the new assessment. Support is being provided by the Commonwealth Fund.

For more information:
www.ismp.org
selfassess@ismp.org
215.947.7797

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

ISMP Neonatal Drug Infusions



ISMP Institute for Safe Medication Practices

Vermont Oxford Network

Standard Concentrations of Neonatal Drug Infusions

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

The drug concentrations provided below are the result of a national effort to standardize typical neonatal drug infusions across all US hospitals. 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 accomodate various weights of neonates, including low-birth-weight infants.

The safety benefits of all hospitals using the same standard concentrations 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 that treat neonatal patients to consider adopting these standard drug concentrations. 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
digoxin	intermittent infusion**	20 mcg/mL

AAP Policy

AMERICAN ACADEMY OF PEDIATRICS

American Academy of Pediatrics, Committee on Pediatric Emergency Medicine
and American College of Emergency Physicians, Pediatric Committee

Care of Children in the Emergency Department: Guidelines for Preparedness

ABSTRACT. Children requiring emergency care have unique and special needs. This is especially so for those with serious and life-threatening emergencies. There are a variety of components of the emergency care system that provide emergency care to children that are not limited to children. With regard to hospitals, most children are brought to community hospital emergency departments (EDs) by virtue of their availability rather than to facilities designed and operated solely for children. Emergency medical services (EMS) agencies, similarly, provide the bulk of out-of-hospital emergency care to children. It is imperative that all hospital EDs and EMS agencies have the appropriate equipment, staff, and policies to provide high quality care for children. This statement provides guidelines for necessary resources to ensure that children receive quality emergency care and to facilitate, after stabilization, timely transfer to a facility with specialized pediatric services when appropriate. It

Department of Health and Human Services, Health Resources and Services Administration and Maternal and Child Health Bureau. This statement has been reviewed by and is supported in concept by the Ambulatory Pediatric Association, American Association of Poison Control Centers, American College of Surgeons, American Hospital Association, American Medical Association, American Pediatric Surgical Association, American Trauma Society, Brain Injury Association Inc, Emergency Nurses Association, Joint Commission on Accreditation of Healthcare Organizations, National Association of Children's Hospitals and Related Institutions, National Association of EMS Physicians, National Association of EMTs, National Association of School Nurses, National Association of State EMS Directors, National Committee for Quality Assur-

Guidelines for Care of Children in the ED

Clinical & Practice Management

- Clinical Policies
- Policy Statements
- Resources
- EMS & Disaster Preparedness
- Find a Physician Group
- Residency Programs
- Journals and Publications

Guidelines for Care of Children in the Emergency Department

Approved April 2009

Revised and approved by the ACEP Board of Directors, the American Academy of Pediatrics Board of Directors, and the Emergency Nurses Association April 2009

Originally approved by the ACEP Board of Directors December 2000

Development of this statement was supported by the U.S. Department of Health and Human Services, Health Resources and Services Administration's Maternal and Child Health Bureau, the Emergency Medical Services for Children National Resource Center, and the Children's National Medical Center

ABSTRACT: Children requiring 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, therefore, imperative that all hospital EDs have the appropriate resources (medications,

Related Links

- Policy statements

http://www.acep.org/Content.aspx?id=29134&terms=Guidelines%20for%20Care%20of%20Children%20in%20the%20Emergency%20Department

Medications You Should Have in the ED

Table 1. Guidelines for Medications for Use in Pediatric Patients in EDs[a]

Resuscitation Medications	Other Drug Groups
Atropine	Activated charcoal
Adenosine	Topical, oral and parenteral analgesics
Amiodarone	Antimicrobials (parenteral and oral)
Antiemetics	Anticonvulsants
Calcium chloride	Antidotes (common antidotes should be accessible to the ED)[b]
Dextrose (D10W, D50W)	Antipyretics
Epinephrine (1:1000; 1:10 000 solutions)	Bronchodilators

Equipment and Supplies in the ED

place.

Appendix 2. Guidelines for Equipment and Supplies for Use in Pediatric Patients in the ED

General Equipment

- Patient warming device
- IV blood/fluid warmer
- Restraint device
- Weight scale, in kg only (no lb), for infants and children
- Tool or chart that incorporates both weight (kg) and length to assist physicians and nurses in determining equipment size and correct drug dosing (by weight and total volume), such as a length-based resuscitation tape
- Pain scale assessment tools appropriate for age

Monitoring Equipment

- Blood pressure cuffs (neonatal, infant, child, adult-arm, and thigh)
- Doppler ultrasonography devices
- ECG monitor/defibrillator with pediatric and adult capabilities including pediatric-sized pads/paddles
- Hypothermia thermometer
- Pulse oximeter with pediatric and adult probes
- Continuous end-tidal CO_2 monitoring device[a]

Respiratory Equipment and Supplies

January 2009 Perspective

Joint Commission Requirement

CLARIFICATION: Pediatric Emergency Medications and Immediate Threat to Life

The article titled "Improvements to the Decision Process" in the August 2008 issue of *The Joint Commission Perspectives*® described each level of criticality, including "Immediate Threat to Life" situations. A bulleted list on page 6 of the article provided examples of Immediate Threat to Life findings; among this list was the example "adult-strength medications on pediatric crash cart." Questions from the field have indicated that clarifying information on this example is needed. This information follows.

Not every case of adult-strength medications in pediatric crash carts represents an Immediate Threat to Life situation. The only time that the patient is at risk of significant harm (Immediate Threat to Life) is when only the higher (or adult) strength of a medication is stocked in a crash cart, **and** the organization's policy, protocol, dosing charts, or routine practice in handling pediatric codes is based on the less concentrated pediatric strength.

When both of these situations are present, a life-threatening overdose is a high probability. Consider the specific charts are on the cart, and the cart contains **only** a significantly higher adult concentration of the medication. This would also be true if such medication is in the pediatric section of a cart used to serve both adult and pediatric patients.

- All pediatric carts contain the pediatric strength, with the exception of one unit that has only the adult strengths. However, the policy, protocol, or standard practice in that hospital for handling a cardiac emergency is based on the pediatric strength. Staff responding to pediatric codes do so on all units, and might mistakenly administer adult doses or strengths when accustomed to pediatric doses or strengths.

The presence of an adult-strength medication in a pediatric crash cart does not automatically represent an Immediate Threat to Life situation. Please evaluate your organization's situation against the criteria outlined above.

For additional questions, please contact The Joint Commission's Standards Interpretation Group at

Labeling in Procedure Area TJC FAQ

Labeling in Procedural Area - NPSG - Goal 3 - 03.04.01

Revised | March 26, 2010

www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQId=176&StandardsFAQChapterId=77

Procedures outside of the OR

Q. Does NPSG.03.04.01 apply only in the operating room?

A. NPSG.03.04.01 applies to any surgical or other procedural setting and includes pre-, intra-, and post-operative/procedural components. Consequently, it applies not only to the surgical suite but also to prep areas, pre-op holding, and PACU. It also applies to medications used by anesthesia providers. In fact, it applies to all procedural areas that use medications or solutions including, but not limited to, radiology and other imaging services, endoscopy units, dental services, and patient care units where "bedside" procedures are done.

Immediate use of a medication or solution

Q. Is there an exception to the labeling requirement for immediate use?

A. If during the peri-operative or peri-procedural process, a solution or medication (either in the sterile field or out) is poured, drawn into a syringe, or otherwise used from its original container and immediately administered or disposed of labeling is not required. "Immediate administration" means with no intervening steps or functions prior to administration. However, if the medication or solution that has been removed from its original container will be used over the course of a procedure, for instance—prep solutions, normal saline used to rinse cardiac valves, local anesthetics, clotting agents, etc.—the receiving container must be labeled. Please also see MM.05.01.09.

This is also relevant to anesthesia services. If the anesthesia provider prepares a medication, immediately administers the medication, and the syringe or container is disposed of after the medication is adminstered, labeling the syringe or other container is not required. However, if the medication is prepared and slowly administered over the course of a procedure, if the medication is prepared by a staff member other than the administering provider, if the medication is prepared in bulk for the day's cases, or if the provider preparing the medication participates in another function prior to administration, the syringe or other container must be labeled.

If more than one medication is prepared, each would need to be labeled. Preparing two medications at the same time does not meet the above-stated definition of immediate use; therefore each would have to be labeled.

Content of the label

Q. When labeling medications and solutions in the context of NPSG.03.04.01, what information must be on the label?

A. The labeling expectations for this safety goal are consistent with the requirements of standard MM.05.01.09, which state the label must include:

- Drug name, strength, amount (if not apparent from the container)
- Expiration date when not used within 24 hours (this would be rare for procedures)
- Expiration time if less than 24 hours (applies to only a few drugs)
- Date prepared and the diluent for all compounded IV admixtures

In most cases of medications and solutions in the procedural setting, only the drug name, strength (concentration), and amount will be needed.

Pre-filled syringes

Q. We have discovered that pre-sterilized, pre-labeled syringes are now commercially available. Is this acceptable?

A. It is acceptable to purchase and use pre-filled, pre-labeled syringes such as on procedure trays. However prelabeling medication and solution containers is not acceptable. The label should be prepared and applied at the time the medication or solution is prepared. Applying the label immediately before drawing up the medication is acceptable and may make the process of checking the label against the original container more efficient. Engraving basins for use only with sterile saline or other routine solutions also carries risk of pouring a solution into a basin that is pre-labeled for a different solution; this approach is not considered acceptable.

Pre-labeled syringes

Q. It has been our practice to pre-label syringes for anesthesia medications for the anesthesia cart in the trauma room as a means of reducing the time it takes to prepare needed medications when faced with an emergency situation. Is this acceptable?

A. The basis of the current Joint Commission position prohibiting the pre-labeling of empty syringes is the established medication management principle that labeling is part of the medication preparation process and should be done at the same time the medication is prepared (drawn up into the syringe). The safest approach is to use manufacturer-prepared pre-filled, pre-labeled syringes. Pharmacy-prepared pre-filled, pre-labeled syringes would also be a safe approach but may not be practical for anesthesia services.

Prelabeling of Syringes

Q. Is it acceptable to "label" a syringe by taping the vial (from which the medication was drawn up) to the syringe?

A. No; it is not acceptable to label a syringe by taping the vial to the syringe.The label should include the drug name, strength, amount (if not apparent from the container), expiration date when not used wihin 24 hours and expiration time when expiration occurs in less than 24 hours.

Pharmacist-prepared medications and solutions

Q. We have a pharmacist assigned to the OR to assist in the preparation of medications and solutions. Do syringes prepared or mixed by the Operating Room Pharmacist require another individual to verify the labeling of the syringes?

A. Medications prepared and labeled by a pharmacist would not require a second person verification. One of the reasons for this NPSG requirement is that in procedural settings, the usual processes for preparing and dispensing medications often are not followed. Involving the pharmacists gets it back to the "usual processes" and their attendant safeguards.

Anesthesia Patient Safety Foundation Report

Volume 25, No. 1, 1-20 Circulation 84,122 Spring 2010

APSF Hosts Medication Safety Conference

Consensus Group Defines Challenges and Opportunities for Improved Practice

by John H. Eichhorn, MD

Overview

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

Standardization

- High alert drugs (such as phenylephrine and

- Ready-to-use syringes and infusions should have standardized fully compliant machine–readable labels.

Technology

- Every anesthetizing location should have a mechanism to identify medications before drawing up or administering them (bar code reader) and a mechanism to provide feedback, decision support, and documentation (automated information system).

Pharmacy/Prefilled/Premixed

- Routine provider-prepared medications should be discontinued whenever possible.
- Clinical pharmacists should be part of the perioperative/operating room team.
- Standardized pre-prepared medication kits by case type should be used whenever possible.

Culture

- Establish a *"just culture"* for reporting errors (including near misses) and discussion of lessons learned.

institutions, professional organizations, and accreditation agencies.

It was agreed that anesthesia professionals will likely surrender some of their "independence," adapting their medication preparation and delivery preferences and habits into more standardized practice patterns (involving guidelines and checklists), utilizing more standardized and premixed medications (input and supply by pharmacy services), and relying more on technology. Facilities and their administrators that are sensitive to the economic value of safety (return on investment) are critical to the effort, for both moral support to do the right thing and for provision of financial support for change. Practitioners in the operating room may take some convincing, but culture and patient safety can improve and medication errors causing morbidity and mortality can be dramatically reduced—just as happened with intraoperative monitoring years ago.

CONFERENCE REPORT

Persistent reports of medication accidents occur

Pharmacy Health Literacy Guide

- AHRQ has a free tool “Is Our Pharmacy Meeting Patients’ Needs?
- This is a Pharmacy Health Literacy Assessment Tool
- Available at http://www.ahrq.gov/qual/pharmlit/
- Includes introduction, survey of pharmacy staff section, assessment of the pharmacy, using assessment results etc
- Includes flow charts for conducting a health literacy assessment, guide, etc.

Is Our Pharmacy Meeting Patients' Needs? A Pharmacy Health Literacy Assessment Tool User's Guide

AHRQ
Agency for Healthcare Research and Quality

Beer's List Updated 2012!

- AHRQ has a number of other free toolkit
- One is the Beer's Criteria which is a list of medications that should not be prescribed for patients over the age of 65
- Some increase the fall risk in the elderly
- It lists the drugs or class of drugs and explains why it should not be use
- Also lists the severity such as low or high risk
- Available at http://www.qsource.org/topics/safetyprov.htm

Beer's List

BEERS CRITERIA Adapted from Fick, D M, et al. Updating the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. Archives of Internal Medicine 2003;163, DEC 8/22:2716-2724. Last updated 9/24/04.

The following medications should be avoided or used very cautiously in persons aged 65 years and over, independent of their health conditions and diagnoses.

Drug Name or Class	Comments	Severity (High or Low)
Long-acting benzodiazepines: • Chlordiazepoxide (alone or in combination: Librium, Librax, Limbitrol) • Diazepam (Valium) • Quazepam (Doral) • Halazepam (Paxipam) • Chlorazepate (Tranxene) • Flurazepam (Dalmane)	These agents have very long half-lives, cause prolonged sedation and increase the risk of falls and fractures. If benzodiazepine therapy is unavoidable, use short-acting agents.	High
Short-acting benzodiazepines should rarely exceed the doses shown below. • Lorazepam (Ativan) 3mg • Oxazepam (Serax) 60mg • Triazolam (Halcion) 0.25mg • Alprazolam (Xanax) 2mg • Temazepam (Restoril) 15mg	With rare exceptions, the agents should be used only in persons who are physically dependent or who are being treated with short-course therapy for an acute condition.	High
Meprobamate (Miltown and Equanil)	This anxiolytic is highly sedating and addictive. All use should be avoided except in individuals who are already physically dependent.	High
Barbiturates except Phenobarbital for seizures	All use should be avoided except in individuals who are physically dependent or for seizure disorder management. There are safer sedative-hypnotics available.	High
Amitriptyline (Elavil), chlordiazepoxide-amitriptyline (Limbitrol), Amitriptyline-perphenazine (Triavil), doxepin (Sinequan)	Aamitriptyline and doxepin are very sedating and anticholinergic, their use should be avoided.	High
Methyldopa (Aldomet) Methyldopa-hydrochlorothiazide (Aldoril)	All use should be avoided. Methyldopa causes bradycardia and can exacerbate depression in the elderly. Safer antihypertensives are available.	High
Reserpine at doses >0.25mg	All use should be avoided. Safer antihypertensives are available.	Low
Indomethacin (Indocin and Indocin SR)	All use should be avoided. Other NSAIDs cause CNS toxic reactions less often.	High
Chlorpropamide (Diabinese)	All use should be avoided. Other oral hypoglycemics have shorter half-lives and do not cause SIADH.	High
Propoxyphene (Darvon) and combination products (Darvocet-N, Darvon-N, Darvon with ASA)	All use should be avoided; it has little advantage over acetaminophen. Other analgesics are safer and more effective.	Low
Pentazocine (Talwin)	All use should be avoided. Other narcotics are more effective and safer.	High
Ergot Mesyloids (Hydergine) and Cyclandelate	All use should be avoided. Have not been shown effective in the doses studied.	Low
Diphenhydramine (Benadryl)	Use only in the smallest effective dose and only for emergency treatment of allergic reactions. Causes confusion and sedation.	High

CDC Injections Safety for Providers

- The CDC also issues Injection Safety for Providers
- Issued March 2008 at http://www.cdc.gov/ncidod/dhqp/ps_providerInfo.html
- Notes several investigations leading to transmission of Hepatitis C to patients
- Thousands of patients notified to be test for HVB, HCV, and HIV
- Referral of providers to the licensing boards for disciplinary actions
- Malpractice suits filed by patients

Injection Safety

Infection Control Topics

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

Injection Safety Information for Providers

Released March 2008

Several recent investigations undertaken by State and Local health departments and the Centers for Disease Control and Prevention (CDC) have identified improper use of syringes, needles, and medication vials during routine healthcare procedures, such as administering injections. These practices have resulted in one or more of the following:

- transmission of bloodborne viruses, including hepatitis C virus to patients;
- notification of thousands of patients of possible exposure to bloodborne pathogens and recommendation that they be tested for hepatitis C virus, hepatitis B virus, and human immunodeficiency virus (HIV);
- referral of providers to licensing boards for disciplinary action; and
- malpractice suits filed by patients.

These unfortunate events serve as a reminder of the serious consequences of failure to maintain strict adherence to safe injection practices during patient care. **Injection safety and other basic infection control practices are central to patient safety.** All healthcare providers are urged to carefully review their infection control practices and the practices of all staff under their supervision. In particular, providers should:

- **never administer medications from the same syringe to more than one patient, even if the needle is changed; and**

CDC 10 Recommendations

- The CDC has a page on Injection Safety that contains the excerps from the Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- Summarizes their 10 recommendations
- Available at http://www.cdc.gov/ncidod/dhqp/injectionSafetyPractices.html

Injection Safety

Safe Injection Practices to Prevent Transmission of Infections to Patients

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

III.A.1.b. Safe Injection Practices

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

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

Infection Control Topics

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

CDC Safe Injection Recommendations

- Use aseptic technique to avoid contamination of sterile injection equipment. Category 1A
- Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed.
  - Needles,cannula and syringes are sterile, single-use items; they should not be reused for another patient nor to access a medication or solution that might be used for a subsequent patient.1A

CDC Safe Injection Recommendations

- Use fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) for one patient only and dispose appropriately after use
- Consider a syringe, needle, or cannula contaminated once it has been used to enter or connect to a patient's intravenous infusion bag or administration set 1B

CDC Safe Injection Recommendations

- Use single-dose vials for parenteral medications whenever possible 1A
- Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use 1A
- If multidose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile 1A

CDC Safe Injection Recommendations

- Do not keep multidose vials in the immediate patient treatment area and store in accordance with the manufacturer's recommendations;
  - Discard if sterility is compromised or questionable 1A
- Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients 1B

CDC Safe Injection Recommendations

- Wear a mask when placing a catheter or injecting material into the spinal canal or subdural space
  - Example, during myelograms, lumbar puncture and spinal or epidural anesthesia. 1B
- Worker safety; Adhere to federal (OSHA) and state requirements for protection of healthcare personnel from exposure to blood borne pathogens 1B

Websites

- American Association for Respiratory Care AARC- www.aarc.org
- American College of Surgeons ACS- www.facs.org
- American Nurses Association ANA- www.ana.org
- AHRQ is www.ahrq.gov

Websites

- Center for Disease Control CDC – www.cdc.gov
- Food and Drug Administration- www.fda.gov
- Association of periOperative Registered Nurses at AORN- www.aorn.org
- American Institute of Architects AIA- www.aia.org
- Occupational Safety and Health Administration OSHA – www.osha.gov
- National Institutes of Health NIH-www.nih.gov

Websites

- United States Dept of Agriculture USDA- www.usda.gov
- Emergency Nurses Association ENA- www.ena.org
- American College of Emergency Physicians ACEP- www.acep.org
- Joint Commission Joint Commission- www.JointCommission.org,
- Centers for Medicare and Medicaid Services CMS- www.cms.hhs.gov

Websites

- American Hospital Association AHA- www.aha.org
- American College of Radiology- www.acr.org
- National Patient Safety Foundation at the AMA- www.ama-assn.org/med-sci/npsf/htm
- The Institute for Safe Medication Practices- www.ismp.org

Websites

- U.S. Pharmacopeia (USP) Convention, Inc.- www.usp.org
- U.S. Food and Drug Administration MedWatch- www.fda.gov/medwatch
- Institute for Healthcare Improvement- www.ihi.org
- Sentinel event alerts at www.jointcommission.org

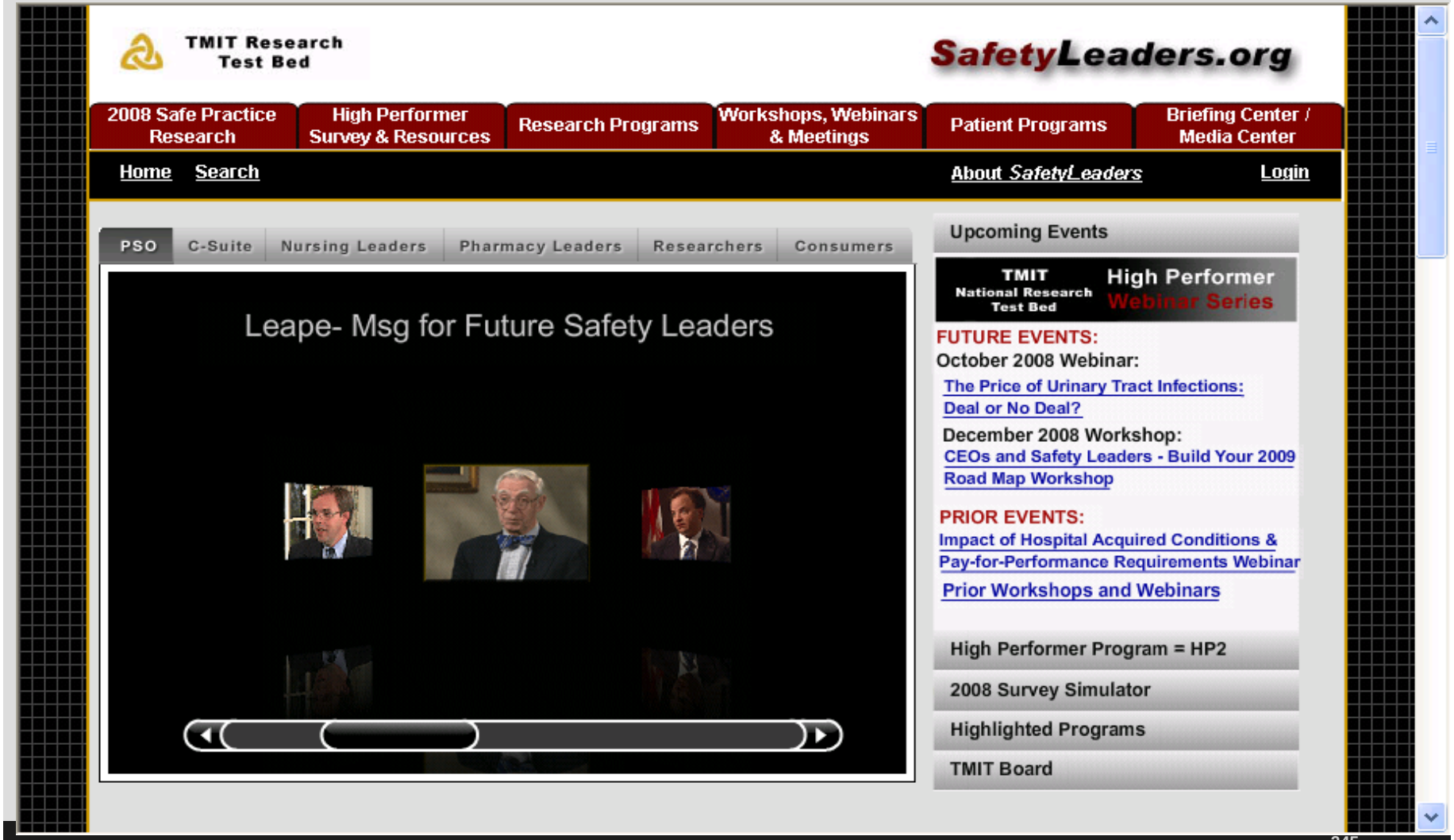
Websites

- American Pharmaceutical Association-www.aphanet.org
- American Society of Heath-System Pharmacists-www.ashp.org
- Enhancing Patient Safety and Errors in Healthcare-www.mederrors.com
- National Coordinating Council for Medication Error Reporting and Prevention-www.nccmerp.org
- FDA's Recalls, Market Withdrawals and Safety Alerts Page: http://www.fda.gov/opacom/7alerts.html

AHRQ Website http://www.ahrq.gov/qual/

IHI Website www.ihi.org/ihi

SafetyLeaders.org Website



AHRQ

- Medical Error and Patient Safety at http://www.ahrq.gov/qual/errorsix.htm, Web M&M, Mortality and Morbidity Monthly, at http://www.webmm.ahrq.gov/
- PSNet, AHRQ Patient Safety Network, http://psnet.ahrq.gov/, contains articles on medication errors and other patient safety issues that come out
- Are you signed up to get this? You can browse under medication errors/ADE topic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Morbidity & Mortality Rounds on the W
Search
GO
Advanced Search
Home > Safety Target > Medication Safety > Medication Errors/Preventable Adverse Drug Events (866)
Narrow your results:
Administration Errors (192)
Dispensing Errors (69)
Monitoring Errors and Failures (22)
Ordering/Prescribing Errors (191)
Transcription Errors (37)
Search within these results:
GO
Date
Show Summary
Medication Errors/Preventable Adverse Drug Events (1-20 of 866):
Next Page
How are these results ranked?
1. Commentary: Empiric Steroids: the Good, the Bad, and the Ugly
Harris ED. AHRQ WebM&M [serial online]. September 2008.

ISMP

- Institute for Safe Medication Practice is a rich source of information at www.ismp.org
- Has medication tools and resources such as high alert list, self assessment tools and error prone abbreviation
- FDA MedWatch
- Confused drug name list, anticoagulant safety
- Sign up nurses for free newsletter via email called Nurse Advise-ERR at https://www.ismp.org/orderforms/adviseERRsubscription.asp

The Institute for Safe Medication Practices

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

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Nursing Leadership Congress
For CNOs
September 15-17, 2008

Upcoming Teleconferences

Maximizing the Effectiveness of Your Medication Safety Team (A 2-part Teleconference Series)

Session 1: September 17, 2008
Session 2: October 23, 2008
from 1:30 to 3:00 p.m. ET

(Click for more information)

11th ANNUAL CHEERS AWARDS

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EDUCATION & AWARENESS

RESOURCES FOR HEALTHCARE PROVIDERS AND CONSUMERS

Newsletters	Professional Development
Consulting Services	Self Assessments
Educational Programs	Consumers

MEDICATION SAFETY TOOLS & RESOURCES

RESOURCES FOR IMPLEMENTING A STRATEGIC MEDICATION SAFETY PLAN

Quarterly Action Agenda (Free CE)	Error-Prone Abbreviation List
High-Alert Medication List	Pathways for Medication Safety
Confused Drug Name List	ISMP Guidelines
Textbook Errata	"Do Not Crush" List
Tools to Build a Community Pharmacy Medication Safety Program	Improving Medication Safety with Anticoagulant Therapy
Tall Man Letters	More Tools...

USP US Pharmacopeia

- Good source of information and have the MEDMARX program
- Have drug error finder for LASA,
- Revises heparin monograph at http://www.usp.org/hottopics/heparin.html?hlc.
- Has newletters at http://www.usp.org/aboutUSP/newsletter.html
- Has USP email notices –monthly updates,
- www.usp.org

ENGLISH ESPAÑOL FRANÇAIS DEUTSCH 中文 PORTUGUÊS Store Login Cart Support

U.S. PHARMACOPEIA

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- USP-NF
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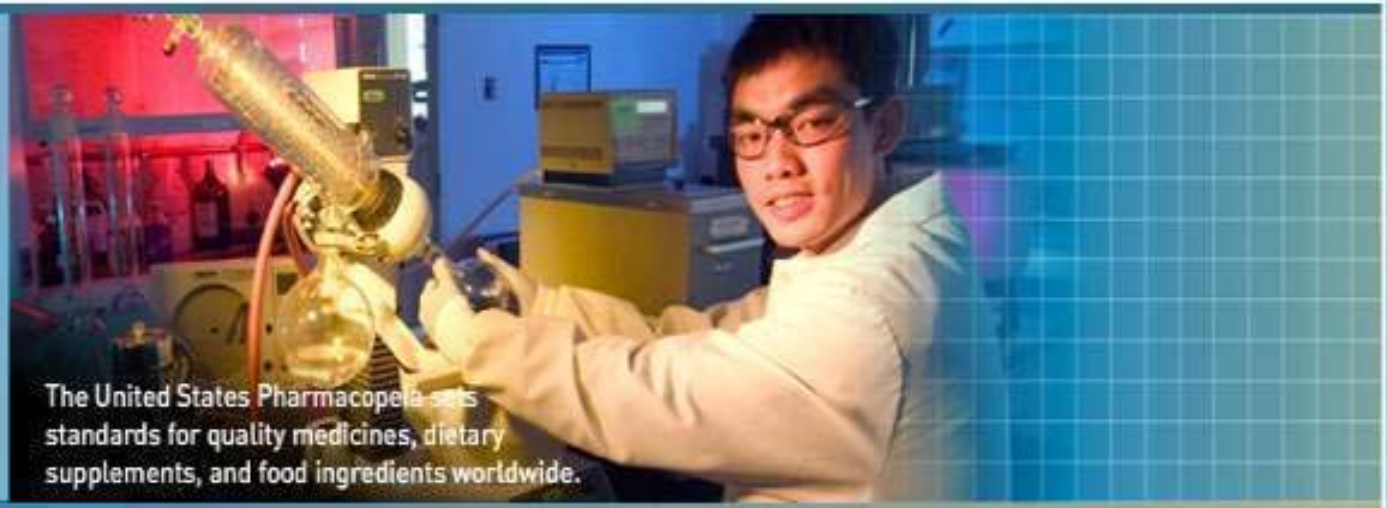
- MEETINGS
- PRODUCTS



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HotTopics

- USP Heparin Information
- USP Glycerin Information
- Food Ingredients

What's New | Compendial Notices | Press Releases

- USP's 2008 Annual Scientific Meeting to Convene Scientific Experts from Around the World (09/03/2008)
- USP Announces New Tool to Help Prevent Medication Mix-Ups Due to Look Alike/Sound Alike Drug Names (08/25/2008)
- USP's Keith Conerly Elected to ANAB Board of Directors (08/19/2008)
- USP Inaugurates New Facility in São Paulo (08/18/2008)
- USP Achieves ISO Accreditation for Certified Reference Materials (08/11/2008)
- U.S. Pharmacopeia Announces Revised Heparin Monographs and Reference Standards (06/23/2008)

Preview Course List: Navigating <467> Medication Safety

Upcoming Events

10/29/07–10/29/08
How to Develop a Monograph

08/20/08–08/20/09
How to Develop a Food Chemicals Codex Monograph

08/20/08–08/20/09
How to Use the FCC Forum

08/20/08–08/20/09
Introduction to the New Food Chemicals Codex

Calendar

Sign Up for FDA Alerts

- Sign up to get safety alerts from FDA
- At http://www.fda.gov/opacom/7alerts.html
- Example; Advil and ASA taken together- if heart patient takes ASA 81 mg for heart- ibuprofen can interfere with anti-platelet effect
- Take 30 minutes or longer and minimal risk with occasional use
- Lots of information on medications!
- See also Drug Safety newsletter at http://www.fda.gov/cder/dsn/2009_v2_no1/DSN_Vol2Num1.pdf

U.S. Food and Drug Administration

U.S. Department of Health and Human Services

FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA

Recalls, Market Withdrawals and Safety Alerts

Sign up for Recall email updates.

Recalls, Withdrawals and Alerts in the Last 60 Days:

This page includes the most significant product actions of the last 60 days, based on the extent of distribution and the degree of health risk. The recalls on the list are mainly Class I. A record of *all* recalls (Class I, II, and III) can be found in the FDA Enforcement Report. Definitions of Class I, II, and III recalls.

Search Only Class I Recalls

You can search by: brand, product, company

GO

View Recalls and Safety Alerts By Date

May 22, 2009

Fun Express Expands Nationwide Recall of Water-Based Face Paint

St. Bernadette Circle, St. Rose Church Recalls Pistachios-In Shell Dry Roasted and Salted Because of Possible Health Risk

In the Spotlight

- Amalgamated Produce, Inc. Recalls Sprouts in the North Eastern United States Because of Possible Health Risk
- Recall of Products Containing Peanut Butter: *Salmonella* Typhimurium
- FDA 101: Product Recalls -- From First Alert to Effectiveness Checks

Archive

- Class I Recalls, Withdrawals and Safety Alerts Archive

FDA Patient Safety News

- Mixups between insulin U-100 and U-500 which occurred when selecting from computer screens,
- Severe pain, muscle or joint pain, with osteoporosis drug with bisphosphate drugs such as Fosamax, Actonel, Boniva, and Reclast,
- More patients die with luer misconnections,
- Deaths from Fentanyl patches continue,
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm

FDA PATIENT SAFETY NEWS
http://www.fda.gov/psn

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FDA Patient Safety News

A Video News Show for Health Professionals

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CC Cable/DSL

Windows Media
CC Cable/DSL

Current Broadcast
Show #86, May. 2009

Podcast
Video Podcast (Instructions)

XML
RSS News Feed (Instructions)

New Medical Products

- FDA Approves First Human Drug from Genetically Engineered Animals

Recalls and Safety Alerts

- Safety Problems with Baxter Colleague Volumetric Infusion Pumps
- Warning on Metoclopramide
- Burns from Medicated Patches during MRI Exams

IHI Institute for Healthcare Improvement

- Excellent source of resources for patient safety and quality resources, toolkits, how to kits
- Prevent ADEs by implementing medication reconciliation
- Reduce harm from high alert medications
- Many resources related to medication issues at www.ihi.org


IHI.org
A resource from the Institute for Healthcare Improvement
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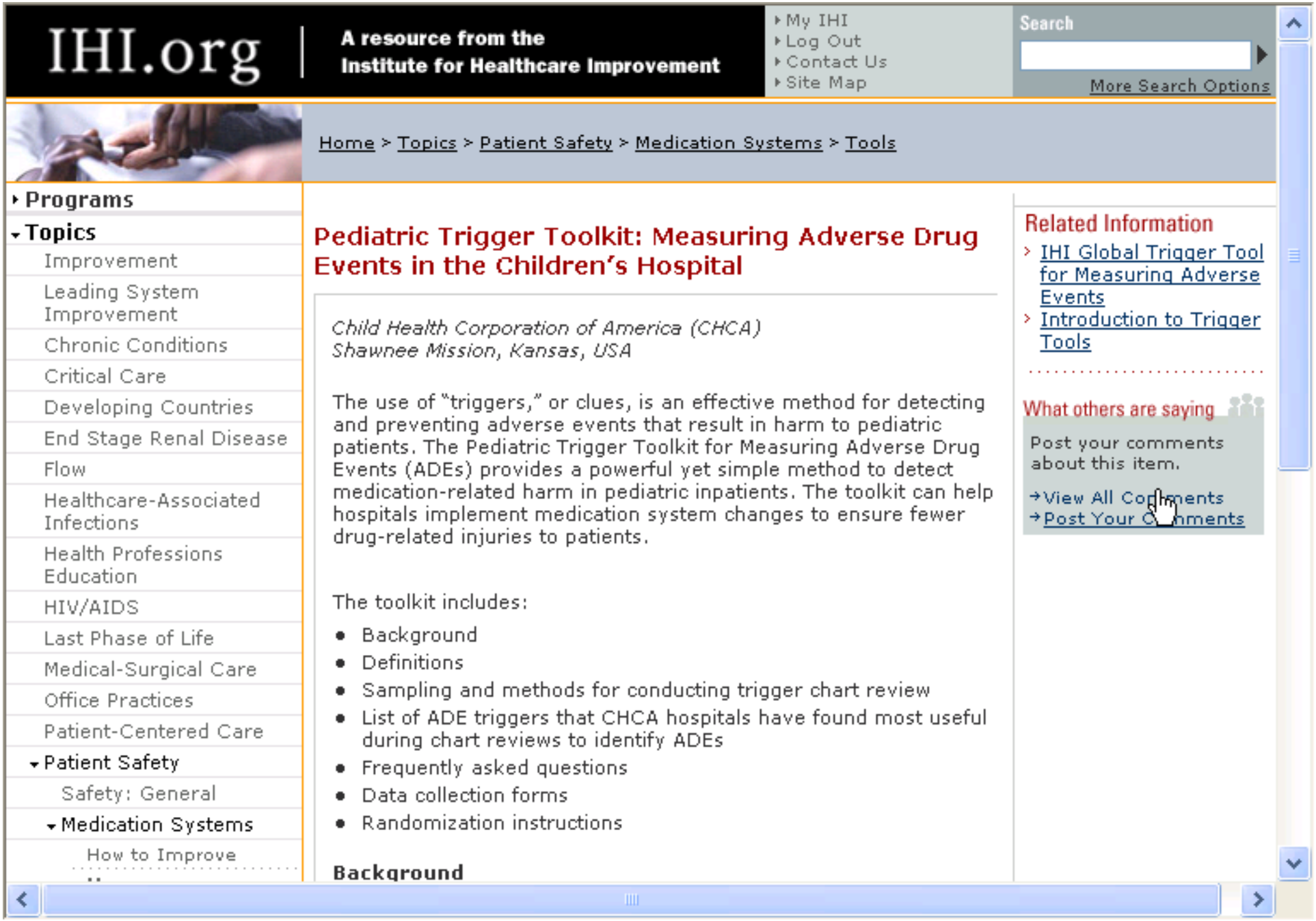
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Pediatric Trigger Toolkit: Measuring Adverse Drug Events in the Children's Hospital
Child Health Corporation of America (CHCA)
Shawnee Mission, Kansas, USA
The use of "triggers," or clues, is an effective method for detecting and preventing adverse events that result in harm to pediatric patients. The Pediatric Trigger Toolkit for Measuring Adverse Drug Events (ADEs) provides a powerful yet simple method to detect medication-related harm in pediatric inpatients. The toolkit can help hospitals implement medication system changes to ensure fewer drug-related injuries to patients.
The toolkit includes:
Background
Definitions
Sampling and methods for conducting trigger chart review
List of ADE triggers that CHCA hospitals have found most useful during chart reviews to identify ADEs
Frequently asked questions
Data collection forms
Randomization instructions
Background
Related Information
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Trigger Tool for Measuring Adverse Drug Events (IHI Tool)
Institute for Healthcare Improvement (in partnership with Premier, Inc., San Diego, California, USA)
Boston, 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:
Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: A practical methodology for measuring medication related harm. Quality and Safety in Health Care. 2003;12:194-200.
For more general information on Trigger Tools and how to select
Related Information
To Err Is Human
ADEs per 1,000 Doses
Trigger Tool for Measuring ADEs in a Mental Health Setting
Interactive Trigger Tool (ADEs)
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Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting

Institute for Healthcare Improvement (in collaboration with Noeleen Devaney, Director, Northern Ireland CSCG Support Team)
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 setting. The Trigger Tool methodology provides instructions for conducting a retrospective review of patient records using triggers to identify possible ADEs. This tool, a customization for psychiatry of the IHI Trigger Tool for Measuring Adverse Drug Events, was developed for use with mental health inpatients and includes a list of known ADE triggers in mental health settings, as well as instructions for collecting the data you need to measure the percentage of admissions with an ADE and the number of ADEs per 1,000 doses.

For more general information on Trigger Tools and how to select the appropriate one, see the Introduction to Trigger Tools page.

Background

The Institute for Healthcare Improvement formed the Idealized

Related Information
Introduction to Trigger Tools

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Leapfrog

- Represents half a million Americans by corporations that purchase health insurance
- Rewards for improving safety and quality
- Aims CPOE, 27 procedures to preventing medical errors, high risk treatments, ICU staffing with intensivists
- If 3 followed would prevent 907,600 medication errors, 65,341 lives and $41 billion dollars a year!
- www.leapfroggroup.org

National Quality Forum

- 34 Safe Practices published in April 2010 and section on SSI updated March 2011 at www.qualityforum.org
- Includes CPOE, unit dose, anticoagulant therapy, culture of safety, standardize labeling and storage of medication, identification of high alert medications, medication reconciliation
- Chapter 6 is on Medication Management

Safe Practice 29 Anticoagulant Therapy

- Organizations should implement practices to prevent patient harm due to anticoagulant therapy.
- TJC has anticoagulant NPSG
- University of Washington has excellent resources
- Number of other anticoagulant toolkits

29 Anticoagulant Therapy

- Need a defined anticoagulant management program to individualized the care
- Document patient's medication plan in the medication record
- Clinical pharmacy medication review is conducted to ensure safe selection and to avoid drug-drug interactions
- Use only oral unit dose products, prefilled syringes and premixed IV bags
- INR for patients starting on Coumadin

29 Anticoagulant Therapy

- Dietary is notified of patient getting Coumadin so food/medication interaction program
- Education is provided to all staff, prescribers and patients
- Need written policy for baseline lab tests for patients on Heparin and low molecular weight heparin therapies
- Hospital evaluates anticoagulation safety practices and takes action to improve its practice

Resources

- Source: AHRQ Press release, September 15, 2009, AHRQ Releases Two New Resources to Help Consumers and Clinicians Prevent Dangerous Blood Clots, at http://www.ahrq.gov/news/press/pr2008/blclotspr.htm
- The clinician's guide on Preventing Hospital-Acquired Venous Thromboembolism; A Guide for Effective Quality Improvement is available at http://www.ahrq.gov/qual/vtguide/
- Patient Guide to Preventing and Treating Blood Clots at http://www.ahrq.gov/consumer/bloodclots.htm

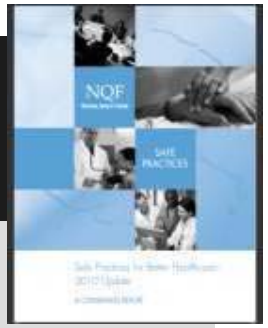
University of Washington Medical Center

- Some of the AHRQ resources were from U of Washington Medical Center
- Has an **excellent** website!
- Coumadin (Warfarin) teaching booklet in 5 languages
- Coumadin dosing charts, how to adjust, guidelines for dosing and monitoring Lovenox (Enoxaparin)
  - Treatment of VTE
  - Duration of anticoagulants, peri procedural anticoagulation
  - http://www.uwmcacc.org/index.html

Perdue Toolkit

- Anticoagulant Toolkit; Reducing Adverse Drugs and Potential Adverse Drug Events with Unfractionated Heparin, LMWH and Warfarin,
- Includes resource tools, self assessment, how to improve the process, improvement and sustaining improvement, physician order forms
  - Available at http://www.purdue.edu/dp/rche/pharmatap/toolkit.pdf

SP30 Contrast Induced Renal Failure



- SP is Contrast Media-Induced Renal Failure Prevention
- Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure
- and gadolinium-associated nephrogenic systemic fibrosis,
- and utilize a clinically appropriate method for reducing the risk of adverse events based on the patient's risk evaluations.
  - Pa Patient Safety Authority has toolkit

SP30 Contrast Induced Renal Failure

- Use evidenced based protocols that are approved by the MS for the prevention of CIN (contrast media-induced nephropathy)
  - based on the rapid evolution of contract agents and national guideline that is coming soon
- Monitor and document use of evidenced based protocols and document risk assessment in chart
- Document provider education
- Specify qualifications of staff allowed to initiate protocols for imaging

32 Glycemic Control

- Reconcile patient medication on discharge
- Education for newly diagnosed diabetics
- Include in their plan of care exercise, nutritional management, signs and symptoms of hyper or hypoglycemia
- Include instructions on use of blood glucose meter
- Sick day guidelines
- Who to contact in case of an emergency

Pa Patient Safety Authority

www.psa.state.pa.us/psa/site/default.asp

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Thank you for attending!!

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- Board Member
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