TJC Medication Standards 2014

Friday, October 3rd, 2014

The information provided in AHC Media Webinars does not, and is not intended to constitute medical or legal advice. Opinions, references and links provided by our speakers are provided for your convenience and do not represent our endorsement of such opinions, products or services.
Speaker

Sue Dill Calloway RN, Esq
AD, BA, BSN, MSN, JD CPHRM

President of Patient Safety and Health Care Consulting

Board Member
Emergency Medicine Foundation

614 791-1468
sdill1@columbus.rr.com
Call with questions, no emails
1. Recall TJC’s definition of what constitutes a medication.

2. Review hospital requirements for self-administered medications.

3. Describe problematic medication management standards for hospitals.

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

5. Evaluate compliance requirements and penalties.
TJC MM Standards

- Understanding and implementing the Joint Commission’s Medication standards continue to be a challenge for some hospitals.

- These standards are very important from a patient safety perspective.

- The medication management standards are often scored as noncompliant during the hospital surveys.

- There are 3 top problematic standards in the Medication Management (MM) chapter and one in the National Patient Safety Goals (NPSG).
Top Problematic Standards for Hospitals

- Three of the Medication Management (MM) and 1 NPSG standards are problematic for hospitals
  - MM.03.01.01 The hospital safely stores medications.
  - MM.04.01.01 Medication orders are clear and accurate.
  - MM.05.01.01 Pharmacist reviews appropriateness of all medications dispensed in the hospital
  - NPSG.03.04.01 Label all medications, containers, and other solutions on and off the sterile field
Sample Medications 2014

- TJC standards apply to sample medications effective July 1, 2014
- Many hospitals quit providing sample medications years ago because of legal and regulatory issues
- TJC said they are not endorsing the use of sample medications
- Rather they have had many questions and have now determined which standards will apply to sample medications
- Rare instance it is used for inpatient but if so all the MM standards apply
Sample Medications

Applicability of MM Standards to Sample Medications

Effective July 1, 2014, several Medication Management (MM) requirements will include applicability to the management of sample medications for the ambulatory care, behavioral health care, critical access hospital, home care, hospital, and office-based surgery programs.

In response to increasing customer concerns regarding compliance and sample medications, The Joint Commission conducted an in-depth review of MM elements of performance (EPs) and selected several that were applicable to sample medications.

After the selected MM EPs were evaluated with stakeholders, by professional and technical advisory Committees, and through a field review, The Joint Commission determined that the EPs listed in the box at right are applicable to sample medications.

Each of the EPs selected as applicable to sample medications will be clarified with the following Note:

"Note: This element of performance is also applicable to sample medications."

This Note will appear the MM chapter in the spring 2014 Edition® and the 2014 Update 1 to the Comprehensive Accreditation Manuals for the programs listed above. The requirements will also be available on The Joint Commission website at http://www.jointcommission.org/standards_information/prepublication_standards.aspx and will be in the spring 2014 Edition® as well as the 2014 update to the Comprehensive Accreditation Manuals.

A Note on Applicability

Please note that, in making this clarification, The Joint Commission is not endorsing the use of sample medications. The purpose of this Note is to clarify which MM EPs are applicable to sample medications for organizations that permit their use. MM EPs that do not have this Note are not applicable to sample medications.

In addition, The Joint Commission determined that in the rare event a sample medication is used in an inpatient setting, the sample medication is subject to the complete MM standards like any other inpatient medication. The accreditation manuals will address this with a clarification to the MM Chapter Overview.

Questions about this clarification may be directed to Kelly Podgorny DNP, RN, project director, Department of Standards and Survey Methods, at kpodgorny@jointcommission.org.
The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online E-dition®), accredited organizations and paid subscribers can also view them in the monthly periodical The Joint Commission Perspectives®. To begin your subscription, call 800-746-6578 or visit http://www.jcrinc.com.

Revised Requirements for the Hospital Accreditation Program

Medication Management (MM)

Standard MM.04.01.01
Medication orders are clear and accurate.

Element of Performance for MM.04.01.01
A 14. The hospital requires an order from a doctor of medicine or osteopathy, or, as permitted by law and regulation, a hospital–specific protocol(s) approved by a doctor of medicine or osteopathy, to administer influenza and pneumococcal polysaccharide-vaccines.
Safe MM System Addresses 8 Areas

- Planning
- Selection and procurement
- Storage
- Ordering
- Preparing and dispensing
- Administration
- Monitoring
- Evaluation
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.05.01.17, MM.05.01.19) (MM.05.01.15 is not applicable to hospitals)

VI. Administration (MM.06.01.01, MM.06.01.03, MM.06.01.05)

VII. Monitoring (MM.07.01.03) (MM.07.01.01 is not applicable to hospitals)

VIII. Evaluation (MM.08.01.01)
Goal of the MM Chapter

- To provide a framework for an effective and safe medication management (MM) system
- Manage high-alert and hazardous medications
- Select, procure, and storing medications
- Manage emergency medications
- Controlling medications brought into the hospital by patients, families, or LIPs
- Managing medication orders
- Preparing, labeling and dispensing medications
Goal of MM Chapter

- Administering medications
- Retrieving recalled or discontinued medications
- Managing investigational medications
- Monitoring patients’ reactions to medications
- Responding to real or potential adverse drug events, adverse drug reactions, and medication errors
  - CMS, Tag 508, requires definition of medication errors, ADR, and drug incompatibility and must include near miss in the definition
Some overlap of medication management standards and National Patient Safety Goals (NPSGs)

Introduction to the NPSGs and Elements of Performance

Labeling of Medications under NPSG.03.04.01 and reducing harm from anticoagulants under NPSG

Medication reconciliation has five EPs under NPSG.03.06.01
Goal 3
Improve the safety of using medications.

**NPSG.03.04.01**
Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings.
Note: Medication containers include syringes, medicine cups, and basins.

---Rationale for NPSG.03.04.01---
Medications or other solutions in unlabeled containers are unidentifiable. Errors, sometimes tragic, have resulted from medications and other solutions removed from their original containers and placed into unlabeled containers. This unsafe practice neglects basic principles of safe medication management, yet it is routine in many organizations.

The labeling of all medications, medication containers, and other solutions is a risk-reduction activity consistent with safe medication management. This practice addresses a recognized risk point in the administration of medications in perioperative and other procedural settings. Labels for medications and medication containers are also addressed at MM.05.01.09.

**Elements of Performance for NPSG.03.04.01**

1. In perioperative and other procedural settings both on and off the sterile field, label medications and solutions that are not immediately administered. This applies even if there is only one medication being used.
   - Note: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process. Refer to NPSG.03.04.01, EP 5, for information on timing of labeling.

2. In perioperative and other procedural settings both on and off the sterile field, labeling occurs when any medication or solution is transferred from the original packaging to another container.

3. In perioperative and other procedural settings both on and off the sterile field, medication or solution labels include the following:
   - Medication name
   - Strength
   - Quantity
   - Diluent and volume (if not apparent from the container)
   - Expiration date when not used within 24 hours
Medication Reconciliation NPSG.03.06.01

- Revised July 1, 2011 and 5 EPs
- Obtain information from the patient on the medication he or she is currently taking
- Define the types of medication information to be collected in non-24 hours settings such as ED, radiology, ambulatory surgery etc.
- Compare medication taken with those ordered to be sure you are not missing any
- Provide patient with written information on medication when discharged and explain importance of managing medication information
Reconciling Medication Information
Hospital Accreditation Program

NPSG.03.06.01
1 Maintain and communicate accurate patient medication information.

Elements of Performance for NPSG.03.06.01

1. Obtain information on the medications the patient is currently taking when he or she is admitted to the hospital or is seen in an outpatient setting. This information is documented in a list or other format that is useful to those who manage medications.
   Note 1: Current medications include those taken at scheduled times and those taken on an as-needed basis. See the Glossary for a definition of medications.
   Note 2: It is often difficult to obtain complete information on current medications from a patient. A good faith effort to obtain this information from the patient and/or other sources will be considered as meeting the intent of the EP.

2. Define the types of medication information to be collected in non-24-hour settings and different patient circumstances.
   Note 1: Examples of non-24-hour settings include the emergency department, primary care, outpatient radiology, ambulatory surgery, and diagnostic settings.
   Note 2: Examples of medication information that may be collected include name, dose, route, frequency, and purpose.

3. Compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies.
   Note: Discrepancies include omissions, duplications, contraindications, unclear information, and changes. A qualified individual, identified by the hospital, does the comparison. (See also HR.01.06.01, EP 1)

4. Provide the patient (or family as needed) with written information on the medications the patient should be taking when he or she is discharged from the hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose).
   Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications. For more information about communications to other providers of care when the patient is discharged or transferred, refer to Standard PC.04.02.01.

5. Explain the importance of managing medication information to the patient when he or she is discharged from the hospital or at the end of an outpatient encounter.
   Note: Examples include instructing the patient to give a list to his or her primary care physician; to update the information when medications are discontinued, doses are changed, or new medications (including over-the-counter products) are added; and to carry medication information at all times in the event of emergency situations. (For information on patient education on medications, refer to Standards MM.06.01.03, PC.02.03.01, and PC.04.01.05.)
Medication Management FAQs

- TJC has a section called Standards FAQs
  - Not called JCAHO anymore
  - Will call TJC
- There are 9 FAQs under Medication Management (MM)
- Updated periodically
# Medication Management FAQs

<table>
<thead>
<tr>
<th>Topic</th>
<th>Status</th>
<th>Publish Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Define Concentrated KCL</td>
<td>Revised</td>
<td>November 24, 2008</td>
</tr>
<tr>
<td>Emergency Cart Security</td>
<td>New</td>
<td>October 23, 2013</td>
</tr>
<tr>
<td>Medication Refrigeration Temperature Logs</td>
<td>Updated</td>
<td>November 24, 2008</td>
</tr>
<tr>
<td>Monitoring Patient Response</td>
<td>Updated</td>
<td>November 24, 2008</td>
</tr>
<tr>
<td>Multi-dose Vials</td>
<td>Current</td>
<td>July 20, 2010</td>
</tr>
<tr>
<td>Pharmacy Review for Licensed Independent Practitioner (LIP) Controlled Medication</td>
<td>Revised</td>
<td>November 24, 2008</td>
</tr>
<tr>
<td>Sample Medications</td>
<td>Updated</td>
<td>November 24, 2008</td>
</tr>
<tr>
<td>Security of Anesthesia Cart Medications</td>
<td>Updated</td>
<td>November 24, 2008</td>
</tr>
<tr>
<td>Strength and Dosage Form Listing</td>
<td>Updated</td>
<td>November 24, 2008</td>
</tr>
</tbody>
</table>
Safe Injection Practices

- TJC has FAQ on multidose vials
- This is part of the safe injection practices
- Safe injection practices is being hit hard by both TJC and CMS
- CDC has ten standards on this such as one needle, one syringe for every patient
- CMS has a revised worksheet on infection control which contains a section on this and memo on this
- Free memo summarizes and hospitals should have P&P and staff on safe injection practices
Safe Injection Practices

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 and control is an important issue in today’s healthcare environment. It is important to accreditation organizations like the Joint Commission (TJC). The Joint Commission has eight pages of standards in the chapter on Infection Prevention and Control (IC).

Infection prevention and control is also important to the Centers for
### Section 2. B Injection Practices and Sharps Safety (Medications, Saline, Other Infusates)

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 communicable disease including the following:

<table>
<thead>
<tr>
<th>Elements to be assessed</th>
<th>Manner of Assessment Code (check all that apply) &amp; Surveyor Notes</th>
<th>Manner of Assessment Code (check all that apply) &amp; Surveyor Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>[ ] Yes, 1 [ ] No, 2 [ ] N/A, 3</td>
<td>[ ] Yes, 4 [ ] No, 5</td>
</tr>
<tr>
<td>2. B.2 Needles are used for only one patient.</td>
<td>[ ] Yes, 1 [ ] No, 2 [ ] N/A, 3</td>
<td>[ ] Yes, 4 [ ] No, 5</td>
</tr>
<tr>
<td>2. B.3 Syringes are used for only one patient (this includes manufactured prefilled syringes and insulin pens).</td>
<td>[ ] Yes, 1 [ ] No, 2 [ ] N/A, 3</td>
<td>[ ] Yes, 4 [ ] No, 5</td>
</tr>
</tbody>
</table>

Interview = 1 Observation = 2 Infection Control Document Review = 3 Medical Record Review = 4 Other Document Review = 5
Center for Clinical Standards and Quality/ Survey & Certification Group

DATE: November 9, 2012
TO: State Survey Agency Directors
FROM: Director
Survey & Certification Group

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 Workshop Model: Public Working group has worked in the pilot site...
Sample Medication FAQ

Medication Management (CAMH / Hospitals)

Sample Medications

Q. What issues must our organization consider relating to sample medications?

A. The following issues:

- Patient-specific medication information must be available in some fashion (MM.01.01.01)
- Medication must be safely stored (MM.03.01.01)
- Medication orders or prescriptions are clear and accurate (MM.04.01.01)
- The patient record contains information that reflects the patients care, treatment or services (RC.02.01.01)
- Medications are labeled, (MM.05.01.09)
- The organization follows a process to retrieve recalled or discontinued medications (MM.0501.17).
- The organization monitors patients to determine the effects of their medications (MM.07.01.01).
- The organization responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors (M.07.01.03).
- The organization provides patient education and training based on each patient's needs and abilities (PC.02.03.01).
Medication Management Chapter

- This chapter is important
- Every nurse, physician, and pharmacist should know what is in this section
- MM is one of the 14 priority focus areas
- There is a medication management tracer
- Will look at medication labels and medication process during tracers
- Tracer includes patients on high risk medications
Definition of Medication

For the purposes of these standards, medication includes (found in glossary):

- Product designated by FDA as a drug
- Prescription medications and sample medications
- Herbal remedies, vitamins, and nutriceuticals (nutritional supplements)
- Over-the counter drugs
- Vaccines and diagnostic and contrast agents (radioactive meds)
- Respiratory therapy treatments and parenteral nutrition
Definition of Medication

- Blood derivatives
- IV solution plain, with electrolytes and or drugs
- The pharmacy does not have to control all of these things
- However, the MM standards still apply
- Lab may handle blood derivatives so make sure they know the standards
- Nuclear med department may handle radioactive material
Definition Does NOT Include:

- Enteral nutrition- as these as food products
- Oxygen
- Medical gases
Eight Sections of MM Chapter

- Planning
- Selection and procurement
- Storage
- Ordering and transcribing
- Preparing and dispensing
- Administration
- Monitoring
- Evaluation
Planning MM.01.01.01

- **Standard**: Hospital plans its MM process

- **Rationale** addresses issues that MM is a complicated area

- MM involves many people to manage quality and safety
  - Such as physicians, ward clerk, pharmacist techs, nurses etc.
  - Each part has to be planned to ensure safety and quality is maintained

- There are two EPs
EP1 P&P is required to make sure information is accessible for those who need to use it:

- Age, sex, and diagnoses
- Allergies and sensitivities
- Current medications
- Height and weight when necessary
  - Recommend weigh children in kg for only
- Pregnancy and lactation when necessary
- Lab results when indicated
- Any additional information required by hospital
Planning

- EP2- The hospital implements its policy and procedure (P&P) so that the information is available to those who need to use it like LIP and staff.

- This EP does not apply in an emergency situation when time does not permit like a code.

- This is talking about the minimal amount of information that would have to be available to those in the MM process including the pharmacist.
So What’s in Your Policy?

LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER - SHREVEPORT

CONTROL OF MEDICATIONS

Purpose:

To define, control, and secure the handling of all medications, including controlled substances, in each patient care area, so as to conform to the policies of the Pharmacy and Therapeutics Committee, JCAHO, and Federal and State Regulations.

Policy:

Medications stocked in a patient care area should be secured in a locked Automated Drug Distribution System (ADS). This includes DEA Schedule II, III, IV and V Controlled Substances.

I. Departments with Automated Dispensing Machines

A. User Access

1. Only individuals authorized to administer, dispense or stock medications will be given access to the system.

   B. Safeguarding medications
   C. Management of medications
   D. Documentation of medications
Patient Specific Information

- Major cause of error is lack of information
- Need lab for patients on Heparin and Coumadin, Dig level for patient on Lanoxin, weight for pediatric patient (use Kg only), BUN and creatinine on elderly patient when prescribing certain antibiotics
- Need to create an accurate medication history and current list of medication
  - Medication reconciliation as part of NPSG
High Alert Medication  MM.01.01.03

- **Standard:** Hospital needs to safely manage both high alert and hazardous medications

- **Rationale:** High alert medications are those that account for a large number of medication errors and sentinel events

- ISMP has a list of high alert medications

- IHI has how to guide to prevent harm from high alert medications

- Four elements of performance
Hazardous Medications

- **Hazardous Medications** are those that studies in animals or humans indicate that exposure to them have the potential for causing
  - Cancer
  - Developmental or reproductive toxicity
  - Harm to organ
- NIOSH has a list of hazardous medications
  - Including resources on hazardous exposure in health care
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 care receiving personnel.

It seems counter-intuitive that the health care industry, whose mission is to combat disease, is itself a "high-hazard" industry for the workers it employs. In fact, it has become increasingly clear that workplace exposures to hazardous drugs can cause toxic effects such as skin rashes, adverse reproductive outcomes (including abortions, and congenital malformations), and possibly leukemia. 

Workers can be protected from exposures to hazardous drugs through engineering controls, administrative controls, and proper protective equipment.
NIOSH Hazardous Drugs

NIOSH Hazardous Drugs List

- Previous update was Dec 2010
- Updated in 2012 (FR June 27, 2012) and proposed changes 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

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.
NIOSH List of Hazardous Drugs

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012
<table>
<thead>
<tr>
<th>Established Name</th>
<th>Proprietary Name</th>
<th>Drug Class</th>
<th>Formulation(s)</th>
<th>Dosage</th>
<th>FDA pregnancy Category</th>
<th>Drug Package Insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>abacavir</td>
<td>Ziagen</td>
<td>antiviral</td>
<td>tablets, oral solution</td>
<td>600mg</td>
<td>C</td>
<td>PI</td>
</tr>
<tr>
<td>abiraterone acetate</td>
<td>Zytiga</td>
<td>antineoplastic; CYP17 inhibitor</td>
<td>tablets</td>
<td>1000mg</td>
<td>X</td>
<td>PI</td>
</tr>
<tr>
<td>apomorphine</td>
<td>Apokyn</td>
<td>dopamine agonist</td>
<td>SQ</td>
<td>2-6mg</td>
<td>C</td>
<td>PI</td>
</tr>
<tr>
<td>bevacizumab</td>
<td>Avastin</td>
<td>monoclonal antineoplastic</td>
<td>IV</td>
<td>5-15mg/kg</td>
<td>C</td>
<td>PI</td>
</tr>
<tr>
<td>crizotinib</td>
<td>Xalkori</td>
<td>antineoplastic</td>
<td>capsules</td>
<td>250mg</td>
<td>D</td>
<td>PI</td>
</tr>
<tr>
<td>deferiprone</td>
<td>Ferriprox</td>
<td>FE chelator</td>
<td>tablets</td>
<td>25-30mg/kg</td>
<td>D</td>
<td>PI</td>
</tr>
<tr>
<td>dexmedetomidine</td>
<td>Precedex</td>
<td>alpha and renergic antagonist</td>
<td>IV</td>
<td>0.2-1mcg/kg</td>
<td>C</td>
<td>PI</td>
</tr>
<tr>
<td>eribulin mesylate</td>
<td>Halaven</td>
<td>antineoplastic; microtubule inhibitor</td>
<td>IV</td>
<td>1.4mg/m2</td>
<td>D</td>
<td>PI</td>
</tr>
<tr>
<td>erlotinib</td>
<td>Tarceva</td>
<td>antineoplastic</td>
<td>tablets</td>
<td>150mg</td>
<td>D</td>
<td>PI</td>
</tr>
<tr>
<td>ezogabine</td>
<td>Potiga</td>
<td>anticonvulsant</td>
<td>tablets</td>
<td>100-150mg</td>
<td>C</td>
<td>PI</td>
</tr>
<tr>
<td>fingolimod</td>
<td>Gilenya</td>
<td>biological response modulator; sphingosine-1 phosphate recpt. modulator</td>
<td>capsules</td>
<td>0.5mg</td>
<td>C</td>
<td>PI</td>
</tr>
</tbody>
</table>
High Risk Meds  01.01.03

- EP1 Define your list high alert medicines and hazardous medications in writing
  - EC.02.02.01 EP 8 Hospital minimizes risks associated with disposing of hazardous medications
- EP2 Define a process for managing high alert and hazardous drugs
  - MM.03.01.01 EP 9 Concentrated electrolytes are only in patient care units where necessary and precautions are taken
High Risk Medications

- Hospital needs to develop its own list of high risk or high alert drugs and hazardous medications
  - KCl, Concentrated NaCl over 0.9%, Chemo, Insulin, paralytic agents, etc.

- Examples include medications not FDA approved, investigational drugs, new ones, controlled substances, LASA, ones with narrow therapeutic range such as Coumadin, Theophylline, and Digoxin
High Risk Meds  MM.01.01.03

- EP3  Implement your process for high alert and hazardous medications
  - EC.02.02.01 EP1 Hospital maintains current inventory of hazardous material and waste that is uses, stores, or generated
  - Inventory only materials required by law
  - EC.02.02.01 EP8 Hospital minimizes risk with disposing of hazardous materials
  - Do you do double checks or bar coding?
CMS High Risk Drugs

- Do performance evaluation of pharmacist include for high risk activities such as compounding hazardous medications (CMS 492)

- CMS requires system to minimize ADE in high risk medications (CMS Tag 500)

- CMS says high risk drugs are
  - Includes investigational drugs, controlled medications, medications not on the approved FDA list, medications with a narrow therapeutic range, psychotherapeutic medications and look-alike/sound-alike medications and those new to the market or new to the hospital
APPENDIX A
DRUGS CONSIDERED HAZARDOUS
General Approach to Handling Hazardous Drugs

In this Alert, NIOSH presents a standard precautions or universal precautions approach to handling hazardous drugs safely. That is, NIOSH recommends that all hazardous drugs be handled as outlined in this Alert. Therefore, no attempt has been made to perform drug risk assessments or propose exposure limits. The area of new drug development is rapidly evolving as unique approaches are being taken to treat cancer and other serious diseases.

Defining Hazardous Drugs

Hazardous drugs include those used for cancer chemotherapy, antiviral drugs, hormones, some bioengineered drugs, and other miscellaneous drugs. The definition of hazardous drugs used in this Alert is based on an ASHP definition that was originally developed in 1990 [ASHP 1990]. Thus the definition may not accurately reflect the toxicity criteria associated with the newer generation of pharmaceuticals entering the health care setting. For example, bioengineered drugs target specific sites in the body, and although they may or may not be toxic to the patient, some may not pose a risk to health care workers.

NIOSH and other organizations are still gathering data on the potential toxicity and health effects related to highly potent drugs and bioengineered drugs. Therefore, when working with any hazardous drug, health care workers should follow a standard precautions approach along with any recommendations included in the manufacturer's MSDSs.

ASHP Definition of Hazardous Drugs

The ASHP defines hazardous drugs in their 1990 revision of Technical Assistance Bulletin on Handling Hazardous Drugs [ASHP 1990]. The bulletin gives criteria for identifying potentially hazardous drugs that should be handled in accordance with an established safety program [McDermid et al. 1993; Armitage and McDermid 1993]. The criteria are prioritized to reflect the hierarchy of potential toxicity described below. Since the hazardous drugs covered by this Alert were designed as therapeutic agents for humans, human toxicity profiles should be considered superior to any data from animal models or in vitro systems. Additional guidance for defining hazardous drugs is available in the following citations: carcinoma [81 Fed. Reg. 17960–18011 (1986)]; IARC 2004; teratogenicity [56 Fed. Reg. 63758–63760].
High Risk Meds  MM.01.01.03

- EP5 Hospital must report abuses and losses of controlled substances to pharmacy department and, as appropriate, to the CEO (DS)
  - This for hospitals that use TJC for deemed status so it is most hospitals except VA and Shiners
  - This is a CMS CoP requirement for hospitals
  - CMS also requires a high risk policy in the hospital CoPs (490)
How to Comply

- Include in getting, storing, transcribing, preparing etc.
  - Such as two nurses will check before giving chemo, insulin, or Heparin, chemo certified nurses only

- Tell you to more frequently monitor BP if on this drug

- Example, separate storage and different label (flashing lights) for paralytic drugs

- Separate insulin and mark well and have two nurses check dose, bottle, and order
Policy on High Alert Medications

- Have a policy on high alert meds,

- Digoxin IV, Heparin, adrenergic agonists, concentrated electrolytes and chemo have highest risk of injury (ISMP)

- Insulin, Opiates and Narcotics, injectible KCL, Heparin, and NaCl over 0.9% were most commonly ones involved in error

- CMS amends CoPs and is focusing on safe use of opioids
Policy on High Alert Medications

- If select insulin have vials in different bins or sections of box

- Use tall man lettering such as NovaLog and NovaLIN

- High alert may include: Epidural infusions, Fentanyl, Heparin over 1000 units, insulin, Lidocaine with Epi vials, neuromuscular blockers, PCA, TPN, moderate sedation, anesthetic agents (propofol), and adrenergic agonists (phenylephrine)
MODEL HIGH-ALERT MEDICATIONS POLICY & PROCEDURES

PURPOSE

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

DEFINITION

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

POLICY

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

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.
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
**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).

<table>
<thead>
<tr>
<th>Classes/Categories of Medications</th>
<th>Specific Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>adrenergic agonists, IV (e.g., epinephrine, phenylephrine, norepinephrine)</td>
<td>colchicine injection</td>
</tr>
<tr>
<td>adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)</td>
<td>eprostenol (Flolan), IV</td>
</tr>
<tr>
<td>anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)</td>
<td>insulin, subcutaneous and IV</td>
</tr>
<tr>
<td>antiarrhythmics, IV (e.g., lidocaine, amiodarone)</td>
<td>magnesium sulfate injection</td>
</tr>
<tr>
<td>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)</td>
<td>methotrexate, oral, non-oncologic use</td>
</tr>
<tr>
<td>cardioprotective solutions</td>
<td>oxytocin, IV</td>
</tr>
<tr>
<td>chemotherapeutic agents, parenteral and oral</td>
<td>nitroprusside sodium for injection</td>
</tr>
<tr>
<td>dextrose, hypertonic, 20% or greater</td>
<td>potassium chloride for injection concentrate</td>
</tr>
<tr>
<td>dialysis solutions, peritoneal and hemodialysis</td>
<td>potassium phosphates injection</td>
</tr>
<tr>
<td>epidural or intrathecal medications</td>
<td>promethazine, IV</td>
</tr>
<tr>
<td>hypoglycemics, oral</td>
<td>sodium chloride for injection, hypotonic (greater than 0.9% concentration)</td>
</tr>
<tr>
<td>inotropic medications, IV (e.g., digoxin, milrinone)</td>
<td>sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more</td>
</tr>
<tr>
<td>liposomal forms of drugs (e.g., liposomal amphotericin B)</td>
<td></td>
</tr>
<tr>
<td>moderate sedation agents, IV (e.g., midazolam)</td>
<td></td>
</tr>
<tr>
<td>moderate sedation agents, oral, for children (e.g., chloral hydrate)</td>
<td></td>
</tr>
<tr>
<td>narcotics/opiates, IV, transdermal, and oral (including liquid concentrates, immediate and sustained-release formulations)</td>
<td></td>
</tr>
</tbody>
</table>

**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-
**Standard:** The hospital addresses the safe use of look-alike/sound-alike (LASA) medications

- It is a much bigger problem according to recent research so USP has database hospitals can check for LASA drugs

- 8th Annual MedMaRX report issued in 2008 shows problems with 3,170 drug pair names which is doubled number since 2004

- Oxycontin confused with oxycodone

- Cerebyx confused with celebrex
EP1  The hospital develops a list of LASA medications it stores, dispenses, or administers

- ISMP publishes a list of LASA drugs at www.ismp.org
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 is the list of confused drug names:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Confused Drug Name</th>
<th>ISMP Medication Safety Alert® Acute Care Edition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABELCET**</td>
<td>amphotericin B**</td>
<td>Vol. 8, Issue 13, 6/26/03</td>
</tr>
<tr>
<td>ACCUPRIL</td>
<td>ACIPHEX</td>
<td>Vol. 5, Issue 9, 5/3/00</td>
</tr>
<tr>
<td>acetazolamide**</td>
<td>acetohexamide**</td>
<td>Vol. 5, Issue 12, 6/14/00</td>
</tr>
<tr>
<td>acetohexamide**</td>
<td>acetazolamide**</td>
<td>Vol. 5, Issue 12, 6/14/00</td>
</tr>
<tr>
<td>ACIPHEX</td>
<td>ARICEPT</td>
<td>Vol. 5, Issue 24, 11/29/00</td>
</tr>
<tr>
<td>ACIPHEX</td>
<td>ACCUPRIL</td>
<td>Vol. 5, Issue 9, 5/3/00</td>
</tr>
<tr>
<td>ACTIVASE</td>
<td>TNKase</td>
<td>Vol. 8, Issue 11, 5/29/03</td>
</tr>
<tr>
<td>ACTONEL</td>
<td>ACTOS</td>
<td>Vol. 9, Issue 13, 7/1/04</td>
</tr>
<tr>
<td>ACTOS</td>
<td>ACTONEL</td>
<td>Vol. 9, Issue 13, 7/1/04</td>
</tr>
<tr>
<td>ADDERALL</td>
<td>INDERAL</td>
<td>Vol. 1, Issue 4, 2/28/96</td>
</tr>
<tr>
<td>ADVACOR</td>
<td>ASTACOR</td>
<td>Vol. 7, Issue 8, 5/4/00</td>
</tr>
</tbody>
</table>
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.)

<table>
<thead>
<tr>
<th>Accolate</th>
<th>Accupril</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accolate</td>
<td>Accutane</td>
</tr>
<tr>
<td>Accupril</td>
<td>AcipHex</td>
</tr>
<tr>
<td>Accupril</td>
<td>Accolate</td>
</tr>
<tr>
<td>Accupril</td>
<td>Acetate</td>
</tr>
<tr>
<td>Accupril</td>
<td>Aricept</td>
</tr>
<tr>
<td>Accupril</td>
<td>Monopril</td>
</tr>
<tr>
<td>Accutane</td>
<td>Accolate</td>
</tr>
<tr>
<td>Accutane</td>
<td>Accupril</td>
</tr>
<tr>
<td>Acelbutolol</td>
<td>Albuterol</td>
</tr>
<tr>
<td>Acetaminophen and Codeline</td>
<td>Acetaminophen and Hydrocodone</td>
</tr>
<tr>
<td>Acetaminophen and Codeline</td>
<td>Acetaminophen and Oxycodeone</td>
</tr>
</tbody>
</table>

| Acyclovir | Famciclovir |
| Acylate | Amlodin |
| Adalat CC | Aldomet |
| Adalat CC | Allegra |
| Adderall | Floternal |
| Adenosine | Adenosine Phosphate |
| Adenosine Phosphate | Adenosine |
| Adifex-P | AcipHex |
| Adriamycin | Arebia |
| Adriamycin | Idamycin |
| Advair | Advicer |
| Advicer | Advair |
| Aggrastat | Aggrenox |
| Aggrastat | Argatroban |
| Aggrenox | Aggrastat |
| Alpurine | Atropine |

| Altace | Accupril |
| Altace | Amaryl | Amerge |
| Altace | Artane |
| Altace | Norvasc |
| Aupept | Atrovent |
| Amantadine | Amlodarone |
| Amantadine | Ranitidine | Rimantadine |
| Amaryl | Altace | Amerge |
| Amaryl | Avandia |
| Amaryl | Reminyl |
| Amaryl | Symmetry |
| Ambien | Amen |
| Ambien | Ativan |
| Ambien | Coumadin |
| Amen | Ambien |
EP2 The hospital takes action to prevent errors involving the interchange of the medications on its list of LASA medications

EP3 The hospital annually reviews and, as necessary, revises its list LASA medications

So in your policy include precautions for LASA medications
- Heparin mix up
- Bottles looked alike
- Bottles were stored next to each other
- Red warning labels should be placed on neuromuscular blockers
Compliance  LASA Drugs

- CPOE helps to prevent illegible handwriting
- Implement storage processes in the pharmacy and other facility medication storage areas that physically separate or differentiate products with similar names
- Use proven technologies like Robotic Fills and Bar Code Medication Administration (BCMA)
- Include a purpose on all prescriptions
- Provide education to facility on products that have been confused
- Tall man lettering in software and labeling
How to Comply LASA Drugs

- Implement read backs and spell backs
- Track medication errors caused by LASA and identify most frequent medications
- Make sure patients get counseled by pharmacist and use correct pronunciation for the new drugs
- Include a line on prescription pads on indication for the drug and discuss if indication does not match what patient expects to see
Selection and Procurement MM.02.01.01

Standard: The hospital needs to select and obtain medications

This means that the medications available for dispensing are selected, listed and procured based on criteria

- This is the first step in the medication process
- You need to figure out what medications you need and how to get them to your hospital
- There are 15 EPs
In 2010 The Joint Commission began the process of reviewing hospital standards and survey processes to customize requirements for specific types of hospitals and patient populations. The new “Standards Applicability Grid” (SAG) chapter in the Comprehensive Accreditation Manual for Hospitals (CAMH), for example, lists relevant elements of performance (EOPs) based on a hospital’s services and includes applicability for acute care, psychiatric, surgical specialties, and now long-term acute care hospitals. As a result of the continuing efforts toward customization.

The Joint Commission’s Board of Commissioners recently approved a revision to “Medication Management” (MM) Standard MM.02.01.01, EP 2, expanding the criteria for selecting medications to include the populations served.

The revision, which becomes effective July 1, 2012, will appear in the 2012 Update 1 to the CAMH (scheduled for publication in March) and in the B-dition® (scheduled for release in April). The standard and the revised EP are shown in the box below; the new text is underlined.

**Approved: Updated Medication Selection Criteria for Hospitals**

**Effective July 1, 2012**

**Standard MM.02.01.01**
The hospital selects and procures medications.

**Element of Performance for MM.02.01.01 A 2.** The hospital develops and approves criteria for selecting medications, which, at a minimum, include the following:
- Effectiveness
- Drug interactions
- Potential for errors and abuse
- Adverse drug events
- Sentinel event advisories
- Population(s) served (for example, pediatrics, geriatrics)
- Other risks
- Costs
Select and Procure Medications 02.01.01

- **EP1** Develop written criteria for determining which medications are available for dispensing or administration
- This must be developed with input from medical staff, LIPs, pharmacist, and staff

- **EP2**- The written criteria should include indications for use, effectiveness, drug interactions, ADE, possibility of medication error or other risk, abuse potential, sentinel event advisories, population served (such as kids and geriatric patients) and cost

- **MM.05.01.01 EP 10** Medications are reviewed if variation from the hospital’s indications for use
Medication New to Hospital

- EP3- A process must be established to monitor patient response when a new drug is used
  - Talking about when a new medicine is made available to your hospital and placed on the formulary
  - How it is monitored such as INR for Coumadin or patient on Metformin having CT with contrast with history of severe renal failure when these drugs first came out
  - FAQ that says before you add medication to your formulary, be sure staff and LIPs are trained on the effects of the medication and the monitoring requirements
  - Hospital must have access to appropriate lab or diagnostic test to monitor effectiveness
New Medications Added to the Formulary

- When drugs are added how do you educate staff about the new drug and when lab or other tests may be needed to monitor the drug (FAQ)?
- Do staff document this process?
- CMS in hospital CoP also has first dose rule and new medication added
This is the **FIRST DOSE** Of This MEDICATION

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

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

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

CHECK ALL THAT APPLY:

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

__________ The patient exhibited or described the following side-effects: __________________________

____________________________________

__________ Physician Notified. Name of Dr. ______________________ Date & Time ________________

LIST ANY INTERVENTIONS: ______________________________________________________

_____________________________________________________________________________

Nurse signature: __________________________ Date & Time ______________ Place in Progress Notes

Patient Sticker
Formulary

- **EP4** The hospital maintains a formulary and this must contain the dosages and strengths
  - Formulary may be your list of what is available in your hospital but must have strength and dose (FAQ)
  - Sample medications are not required to be on your list

- **EP5** Formulary is available to those involved in medication management
Formulary

- The formulary is synonymous with the list of medications available for use in the hospital so staff will know what is available.

- Lots of questions on this standard such as if you need a lab test to monitor the effects of the drug, like a WBC, or other diagnostic testing, make sure you can do this before the drug is included in your formulary.

- TJC has FAQ that states the formulary should be a resource for prescribers and staff to know which products, strengths and dosage forms are available.
Formulary Management

Medications Derived from Biologic Sources (0809)

Source: Council on Pharmacy Practice

To encourage pharmacists to take a leadership role in their health systems for all aspects of the proper use of medications derived from biologic sources, including preparation, storage, control, distribution, administration procedures, safe handling, and therapeutic applications; further,

To facilitate education of pharmacists about the proper use of medications derived from biologic sources.

(Note: Section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] defines biological product as follows: a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine [or any other trivalent organic arsenic compound], applicable to the prevention, treatment, or cure of a disease or condition of human beings.)

This policy supersedes ASHP policy 0316.

Gene Therapy (0103)

Source: Council on Administrative Affairs

To declare that health-system decisions on the selection, use, and management of gene therapy agents should be based on the same principles as a medication formulary system in that (1) decisions are based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, and pharmacoeconomic factors that result in optimal patient care, and (2) must include the active and direct involvement of physicians, pharmacists, and other appropriate health care professionals; further,

To declare that decisions on the management of a medication formulary system should not be based solely on economic factors.

This policy was reviewed in 2005 by the Council on Administrative Affairs and by the Board of Directors and was found to still be appropriate.

Generic Substitution of Narrow Therapeutic Index Drugs (0817)
EP6 Hospital standardizes and limits the number of drug concentrations to meet the patient’s need

- For example use unit dose, premixed IV products and don’t send gallon bottles as floor stock anymore
- If Lidocaine will get 2 grams in 500 cc IV and no other concentration is available
KCl Piggybacks  FAQ

- No concentrated electrolytes in patient care areas such as concentrated KCl or solution over 0.9% NaCl

- FAQ: Can have 100ml bags of KCL with this in it but not 20 or 40 mEq vials
KCl Piggybacks

Medication Management (CAMH / Hospitals)

Define Concentrated KCL

Q: What is considered "concentrated" in terms of potassium chloride? We have 100ml bags of potassium chloride in strengths of 20 and 40 mEq. The bag label states that it is concentrated. Must these be kept out of patient care areas? What is considered concentrated in terms of sodium chloride?

A: For potassium chloride, strengths of 2 mEq/ml or greater (specifically, vials of 20mEq/10ml and 40mEq/20ml) are considered concentrated. The bags noted above are not considered concentrated and may be stored in patient care areas. For sodium chloride, or NaCL, strengths greater than 0.9% are considered concentrated.

Can have 100ml bags of KCL with this in it but not 20 or 40 mEq vials
Standardize Concentration and Rule of 6

- Standardize and limit the number of IV concentrations
  - Like only get 20,000 units of Heparin in 1000cc

- Rule of 6 violates this which is common practice in pediatrics that allows a nurse to quickly approximate dose of a vasopressors agent by using a factor of six to adjust concentration of the drug while keeping the rate constant—significant risk of error
Broselow-Luten Pediatric Tape

- Make sure you have one of the newer ones or you will be cited
- Make sure staff know how to use it correctly
- There is a 24 pages long study packet for the correct use of the Broselow Pediatric emergency tape available at no charge at http://dukehealth1.org/deps/Study_Packet_v2_0_rev_may2006.pdf
- Place on flat surface, red end of tape is even with top of patient’s head, remember red to head, stop free hand at bottom of patient’s heel (not toes)
- Free hand indicate weight in kg and the patient’s color zone
Medications Not on the Formulary

- EP7 Hospital has a process to select, approve, and get the medications that are **not** on the formulary

- With medication reconciliation process have seen increase in this

- Need process and mini approval process for these non formulary drugs like certain minor ones pharmacist can decide or go to the department director

- This standard applies to sample medication (SM)
Medications Not on the Formulary

- EP8 Hospital implements their process to select, approve, and procure medications not on their formulary
  - For example, patient takes Allegra for allergies and hospital substitutes a drug that contains something the patient is allergic to
  - Applies to sample medications (SM)
- There is a policy and staff knows how to follow it like meds locked in patient room, counted, and nurse opens and gives patient one and documents it
**Annual Review of Formulary Drugs**

- EP9  Review yearly the list of medications that are on the formulary and available to be dispensed or administered

- This is done to look at emerging safety and efficacy information

- Is the drug in the class not as safe based on new information and rethink if this drug should be in your formulary as FDA continually to publish new warnings
Drug Shortage Management

- EP10 Need a process to communicate shortages and outages to LIP and staff who participate in MM
- EP 11 Hospital implements this process for shortages and outages
- EP12 Hospital develops and approves written protocols to be used if shortage or out of drug

- Shortage has become a significant problem lately including shortages of cardiovascular drugs, anesthetic and central nervous system drugs and anti-infective drugs
Medications Substitution Policies/Shortages

- EP13 Hospital implements approved medication substitution protocols
- EP14 Hospital has a process to communicate about medication substitution for shortages or outages
- EP15 Hospital implements the process to communicate shortages and outages
- ASHSP found shortages lead to medication errors and significant issue lately
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.
Drug Shortages

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

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

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

MANUAL OF POLICIES AND PROCEDURES
CENTER FOR DRUG EVALUATION AND RESEARCH

POLICY AND PROCEDURES
OFFICE OF NEW DRUGS
Drug Shortage Management

Table of Contents

PURPOSE ................................................................. 1
BACKGROUND .......................................................... 1
POLICY ................................................................. 2
RESPONSIBILITIES AND PROCEDURES .................. 3
REFERENCES ......................................................... 7
DEFINITIONS ........................................................ 7
EFFECTIVE DATE .................................................... 8
ATTACHMENT 1 ....................................................... 9
ATTACHMENT B ...................................................... 18


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
Drug Shortages

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

Subscribe to RSS ▶️ | Report a Drug Shortage

FIND DRUG SHORTAGES

Search by Generic Drug Name... Find OR Search by Drug Shortage List...
ASHP Managing Drug Shortages
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. Nevertheless, these drug product shortages have been increasing in frequency and severity since the late 1990s. 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.

Strategies for dealing with drug product shortages are similar to disaster planning and risk management contingencies for major snowstorms, mass casualty events, temporary wholesale shutdowns, and evacuations made for the Year 2000.

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 are from a single manufacturer or the raw material used by multiple manufacturers.
GAO Drug Shortage Better but Still Continue

United States Government Accountability Office

Report to Congressional Addressees


February 2014

DRUG SHORTAGES

Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability
Storage of Medications MM.03.01.01

- Standard The hospital must safely store medications

- Rationale This is important to maintain the drug’s integrity, minimize diversion, reduce errors and to ensure medications are available when they are needed

- There are 19 EPs but only 11 apply to hospitals

- Top problematic standard for hospitals

- FAQ states do not have to temperate logs for refrigerators and freezers however……..


Storage of Medications MM.03.01.01

- EP2 Medications must be stored according to the manufacturers instructions and if none according to a pharmacist’s instructions
  - Refrigerated, keep out of light, room temperature etc.

- EP3 Drugs, biologicals and controlled scheduled drugs are stored to prevent diversion and locked as necessary and as required by law
  - Schedules drugs are Schedule II-V of the Comprehensive Drug Abuse Prevention and Control Act

- CMS made changes in the hospital CoP
Medication Management (CAMH / Hospitals)

Medication Refrigeration Temperature Logs

Q: Are we required to maintain temperature logs for medication storage refrigerators and freezers?

A: Joint Commission does not specifically require temperature logs for refrigerators and freezers used for medication storage. Standard MM.03.01.01, EP2 requires that medications be stored according to manufacture's recommendations. Additionally, EC. 01.01.01 requires that organization describes and implement processes to maintain and monitor equipment performance. If your organization chooses to use temperature monitoring to achieve this, the monitoring method must track temperature in an ongoing fashion to indicate whether or not internal temperature has deviated from the required ranges for all drugs stored. In addition, the organization should have a defined process outlining disposition of medication from a refrigerator or freezer which has deviated from the recommended temperature range.
Storage of Medications  P&P

- EP4- A written policy is needed to address control of medication across the continuum
  - Such as receipt of drug, administration of the medication including safe storage, handling, and return to storage

- EP5  Hospital implements its policy addressing the control of medications between receipt by the provider and its administration (SM)
Storage of Medications MM.03.01.01

- EP6 Unauthorized individuals are prevented from obtaining medications in accordance with policy and law (SM)

- EP7 All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings (SM)
  - Multidose vials expires 28 days after opening so label bottle with expiration date
  - TJC has FAQ on multi-dose vials
Safe Injection Practices Toolkit

The resources in this toolkit may only be used for internal improvement and education efforts. They may not be used for commercial purposes.

Safe injection practices are crucial to basic levels of patient safety and provider protection. Hepatitis C virus, hepatitis B virus, and HIV can be spread from patient to patient when safe injection practices are not used.

The ASC Quality Collaboration has assembled a variety of resources and information that may be used to supplement your current processes to enhance existing injection practices.

The BASIC Safe Injection Practices Toolkit includes three essential resources:

- Safe Injection Practices: What CMS Surveyors Are Looking For
- One Needle, One Syringe, One Time Poster
- Injection Practices Policy and Procedure Template

The EXPANDED Safe Injection Practices contains both essential resources and a broader array of materials, including:

- Assessment Tools
- Implementation Aids
- Training Materials
- Monitoring Tools
- Workplace Reminders

http://ascquality.org/SafeInjectionPracticesToolkit.cfm
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
Office of Clinical Standards and Quality/Survey & Certification Group

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
Medication Management (CAMH / Hospitals)

Multi-dose Vials

Q. What types of vials are considered to be “multi-dose?”

A. According to Safe Injection Practices Coalition (2010): A multi-dose vial is a bottle of liquid medication (injectable) that contains more than one dose of medication and is approved by the Food and Drug Administration (FDA) for use on multiple persons. A new, sterile needle and syringe should always be used to access the medication in a multi-dose vial. The reuse of needles or syringes to access multi-dose vial medication can result in contamination of the medicine with microbes that can be spread to others when the medicine is used again. (Retrieved on June 18, 2010 from http://www.oneandonlycampaign.org/Post/sections/8/Files/SIPCProviderBrochure.pdf)

Q. When do multi-dose vials that have been punctured or opened need to be discarded?

A. Multi-dose vials are to be discarded 28 days after first use unless the manufacturer specifies otherwise (shorter or longer). Manufacturers are only required by law to test the effectiveness of the bacteriostatic agent used in the multi-dose vial for a period of 28 days. Manufacturers are allowed by the FDA to provide extended dating in the package insert if they have conducted testing beyond the 28 days. Multi-dose pens, such as those used to inject medications such as insulin and Byetta, are included.

Q. Does the multi-dose vial need to be labeled with a new expiration date once it is opened or punctured?

Yes. Standard MM.03.01.01, EP 7 requires that all stored medications are labeled with the expiration date. The Joint Commission defines the expiration date as “the last date that the product is to be used”. The manufacturer's expiration date is based on the fact that the product has not been opened. Once the vial cap is removed or the vial is punctured, the manufacturer’s expiration date is no longer valid and a revised date (also called the “beyond use date” in pharmaceutical terminology) needs to be determined. To be in compliance with MM.03.01.01 EP 7, The Joint Commission requires organizations to re-label multi-dose vials with a revised expiration date once the multi-dose vial is opened or punctured.

If the manufacturer’s original expiration date is shorter than the revised expiration date then the shorter date must be used. Also, if sterility is questioned or compromised the multi-dose vials should be discarded regardless of the date.
If the manufacturer’s original expiration date is shorter than the revised expiration date then the shorter date must be used. Also, if sterility is questioned or compromised the multi-dose vials should be discarded regardless of the date.

Labeling the multi-dose vial with the date opened will not meet the intent of this requirement.

Q. Do vaccines need to follow the 28 day rule?

Currently, vaccines are exempted from this requirement. The CDC Immunization Program states that vaccines are to be discarded per the manufacturer’s expiration date. The Joint Commission is applying this approach to all vaccines (whether a part of the CDC or state immunization program or purchased by healthcare facilities) with the understanding that the vaccines are stored and handled appropriately (correct temperature is maintained, frequency of temperature checks, etc.). Following the guidelines provided in the package insert is very important to assure integrity of the vaccine.

The CDC has excellent resources regarding the use, storage and handling of vaccines.

Where can I locate additional information on safe medication practices for multi-dose vials?

The Safe Injection Practices Coalition has developed the One and Only Campaign which is: “A public health campaign, led by the Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC), to raise awareness among patients and healthcare providers about safe injection practices. The campaign aims to eradicate outbreaks resulting from unsafe injection practices”. The website for this campaign provides excellent resources for staff and patients.
One and Only Campaign

www.oneandonlycampaign.org/

About the Campaign

The One & Only Campaign is a public health campaign led by the Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC) to raise awareness among patients and healthcare providers about safe injection practices. The campaign aims to eradicate outbreaks resulting from unsafe injection practices.

Watch Training Video
Not All Vials Are Created Equal

**SINGLE-DOSE OR MULTI-DOSE?**

**NOT ALL VIALS ARE CREATED EQUAL.**

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

*This information can literally save a life.*

---

[One Needle, One Syringe, Only One Time.]

Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

---

ONEANDONLYCAMPAIGN.ORG
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 and control is an important issue in today’s healthcare environment. It is important to accreditation organizations like the Joint Commission (TJC). The Joint Commission has eight pages of standards in the chapter on Infection Prevention and Control (IC).

Infection prevention and control is also important to the Centers for...
Identify Risks for Transmitting Infections

- Hospital and ASC in Colorado where surgery tech with Hepatitis C infection steals Fentanyl and replaces it with used syringes of saline infecting 17 patients as of December 11, 2009 and 5,970 patients tested (total 36 for 3 facilities)

- Kristen Diane Parker in 2010 gets 30 years for drug theft and needle swap scheme

- Worked at Denver’s Rose Medical Center and Colorado Springs’ Audubon Surgery Center

1 www.krdo.com/Global/link.asp?L=399119
Kristen Parker Sentenced for Fentanyl Theft

January 18th, 2010  By LucyC

About a year ago a woman named Kristen Diane Parker, a surgery tech who worked in hospitals the Denver area, made the news, including on LawyersAndSettlements.com. I wrote a couple of short pieces about her. She was addicted—maybe still is—to Fentanyl.

Also known as Duragesic, Fentanyl is a prescription pain medication—quite a strong one—and quite an addictive one by all accounts. Kristen Parker was so addicted to the stuff that she would steal syringes from hospital surgery carts where she worked—syringes that were filled with Fentanyl—and inject herself. She would then fill the used syringes with saline and replace them. Just in case this isn’t crystal clear—post-operative patients were being administered saline in used syringes instead of their prescribed pain medication.

Ah, but it gets worse. Parker ended up infecting some 36 people with hepatitis C, a currently incurable viral infection which leads to chronic liver inflammation, and in some cases liver cancer. Parker, who shared needles when injecting heroine, is hepatitis C positive—something she claims she didn’t know when she was fixing her needles.

Thankfully, Ms. Parker got careless, and she got caught. No surprise there, given the state she must have been in: Fentanyl is 80 to 100 times stronger than morphine. Eventually,
Pleads Guilty

- 34 yo pleads guilty
- He pleads guilty to 16 federal drug charges
- He worked as cardiac tech and former lab tech in 18 hospitals in 7 states
- 46 patient confirmed with his strain of Hepatitis C
- 32 in New Hampshire, 7 in Maryland, 6 in Kansas, and 1 in Pennsylvania
- Stole fentanyl and replaced it with saline and used dirty needle
  - Stealing drugs since 2002 and pleads guilty Aug 2013
CONCORD, N.H. — Patients at a New Hampshire hospital who were infected with hepatitis C by a traveling medical technician with a drug problem are pleased with his guilty plea but are still pushing to hold others accountable.

David Kwiatkowski, 34, pleaded guilty last week to 16 federal drug charges under an agreement that calls for him to spend 30 to 40 years in prison. He admitted stealing painkiller syringes from hospitals where he worked and replacing them with saline-filled syringes tainted with his blood.

Before he was hired at Exeter Hospital in New Hampshire in 2011, Kwiatkowski worked as a cardiac technologist in 18 hospitals in seven states, moving from job to
Remove Expire Drugs/ Concentrated Lytes

- EP8 All expired, damaged, or contaminated medications are removed (SM)
  - These should be stored separately from medications available for administration

- EP9 Concentrated electrolytes are kept in patient care areas only when patient safety necessitates their immediate use
  - Precautions are used to prevent inadvertent administration
Storage of Medications MM.03.01.01

- EP10  Medication should be in the most ready to administer forms that are commercially available (SM)
  - In unit doses that have repackaged by the pharmacist or licensed repackager
  - Anticoagulants use see NPSG.03.05.01

- EP18  Hospital inspects medication storage areas periodically
Supervise Drug Storage Areas

- EP19- Must have a director of pharmacy by a registered pharmacist or a supervised drug storage area (DS)
  - This must in accordance with law and regulation
  - This is for hospitals that used TJC for deemed status
  - This is a CMS CoP requirement
  - Applies to sample medication (SM)
Storage of Medications MM.03.01.01

- EP 24 The hospital maintains records of the receipt and disposition of radiopharmaceuticals
- Effective July 2, 2014
Storage of Medications MM.03.01.01

- This is a common problematic standard for hospitals
- Should stock only approved medication that are on your formulary
- Exception is medications brought to hospital by the patient which is MM.03.01.05
- Store medication under appropriate circumstances such as refrigerate or keep out of light
- No medications lying on ledge of the dumb waiter or shelf of tube system in hallways
Storage of Medications

- Make sure the hospital’s P&P contains all the elements required by this standard and by the CMS CoP policy requirements

- Schedule II-IV medications must be locked

- Should do hazard vulnerability analysis (HVA) on the location of all carts and places where medications are stored including crash carts

- Make sure medicine carts are locked in OB for stat C-sections
Storage Issues

- Have monthly inspections and all expired, damaged, or contaminated medications are removed.
- Medications that are easy to confuse should be separated, like sound alike or look alike drugs (LASA) Celebrex and Celexia since many go alphabetically.
- Be sure to separate insulin and mark it with tall man lettering so similar names are not confusing.
Medication Management

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-
Medications in the OR  ASA Position


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
Emergency Medications  MM.03.01.03

- Standard  Hospital needs to safely manage emergency medications

- Rationale  Emergency medications must be treated with the same care for safety as in other non-emergency settings

- Hospital needs to decide which medications and supplies are needed

- Hospital needs to plan how it will address patient emergencies
Emergency Medications  03.01.03

- EP1  Hospital leadership and MS and LIPs decide which emergency medications will be accessible based on the population served

- EP2 Emergency medications and supplies are readily accessible in patient care areas
  - Often referred to as the crash cart standard
  - Crash carts can be locked with plastic lock, under constant surveillance, or with real lock based on HVA
  - Schedule II-V must be locked
Emergency Cart Security  FAQ Oct 2013

- Medicine must be stored in secure manner to prevent tampering, theft or diversion
- Balance security with need to have drugs and supplies readily available
- Padlocks are discouraged and don’t want to create a barrier
- Do a risk assessment to make decisions
- In ED permissible to use breakaway lock since staffed 24 hours as long as process in place to monitor the integrity of the breakaway lock
Crash Cart Security

Medication Management (CAMH / Hospitals)

Emergency Cart Security

Q: Please clarify the issue of emergency cart security. Is the use of a breakaway tag that includes a numeric identification number and a defined process to monitor cart integrity considered an acceptable approach to maintaining security of emergency carts strategically located and readily available for use in emergent situations in patient care areas staffed 24/7.

A: The Joint Commission requires that medications are stored in a secure manner to prevent tampering, theft or diversion in accordance with law and regulation. Considering the intended nature and use of emergency carts, organizations must balance security with the requirement that emergency medications and their associated supplies are readily available (i.e. MM.03.01.03 EP 2) when needed.

While organizations are responsible for ensuring the security of the contents of an emergency cart, use of devices (padlocks, etc) that could create delays or barriers to immediate access to emergency medications and supplies is discouraged and could potentially be interpreted as ‘not available for use’ (see PC.02.01.11 EP 2). When security devices are used, the intent would be to use an appropriate device that allows the organization to detect tampering while not creating a barrier or delay in the staff’s ability to access the emergency supplies contained within the cart. It is most helpful for organizations to conduct a risk assessment in order to identify risks associated with various options available for securing emergency cart contents. The results of the risk assessment will enable leaders to make decisions and design processes that best serve the delivery of safe, quality emergency care while maintaining the integrity of emergency supplies.
Crash Cart Standard

- PC.03.01.01 EP 8 Need resuscitation equipment when doing operative, high risk procedures, or moderate sedation since can lose protective reflexes

- Many consider the ACLS changes to ensure emergency drugs on their crash carts and recommendations from organizations like ENA and ACEP (www.acep.org and www.ena.org)

- American Academy of Pediatrics, Committee on Pediatric Emergency Medicine has list of recommendations (www.aap.org)
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
Emergency Medications  03.01.03

- EP3 Emergency medications need to be available in unit dose, age specific, and ready to administer forms
  - Remember pediatric doses previously discussed
  - Emergency ACLS drugs like Atropine or EPI should be in its ready to use injectible form during a code
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
Restock Crash Carts

- EP6: Hospital replaces emergency medications or supplies when they are used to maintain a full stock
  - Careful when replacing crash carts as to make sure medications are secure
  - Don’t want surveyor to find crash cart not restocked after it was used
  - Some of the larger ED are putting pharmacist on staff in the ED
  - Make sure top of crash cart is not dusty
ASHP Statement on Pharmacy Services to the Emergency Department

Position

The American Society of Health-System Pharmacists (ASHP) believes every hospital pharmacy department should provide its emergency department (ED) with the pharmacy services that are necessary for safe and effective patient care. Although the nature of these services will vary with each institution’s needs and resources, the pharmacist’s role may include:

- Working with emergency physicians, emergency nurses, and other health care professionals to develop and monitor medication-use systems that promote safe and effective medication use in the ED, especially for high-risk patients and procedures;
- Collaborating with emergency physicians, emergency nurses, and other health care professionals to promote medication use in the ED that is evidence-based and aligned with national quality indicators;
- Participating in the selection, implementation, and monitoring of technology utilized in the medication-use process;
- Providing direct patient care as part of the interdisciplinary emergency care team.

Pharmacy services in the ED have been documented since the 1970s. These services initially focused on inventory control, cost containment, and participation on resuscitation teams but have since expanded to include clinical pharmacy services. The effectiveness of clinical pharmacy services has been well documented in other settings. The participation of pharmacists in intensive care units and on internal medicine teams has improved patient outcomes by reducing preventable ADEs by 66% and 78%, respectively. Similar effectiveness with pharmacist participation on emergency medicine teams has also been documented. Despite this evidence, the 2005 ASHP national survey found that only 3.5% of the hospitals surveyed had a pharmacist assigned to the ED for any period of time, and only 5% had a formal policy requiring that pharmacists review and approve medication orders before administration in EDs.

Pharmacy Services to the ED

All health care professionals share a commitment to and responsibility for providing safe and effective patient care. These shared objectives provide strong incentives for collaboration. Pharmacists can deliver on these incentives by:

1. Participating in the development and implementation of medication-use systems that reduce the risk of ADEs;
2. Collaborating with emergency physicians, nurses, and other health care professionals to promote safe and effective medication use in the ED;
3. Using evidence-based practices to improve patient outcomes;
4. Providing direct patient care as part of the interdisciplinary emergency care team.

These strategies can help ensure that patients receive the highest quality of care possible in the ED.
ED Pharmacist Research Center AHRQ

The Emergency Pharmacist Research Center: A Safety Measure in Emergency Medicine

Description

These side presentations and other related tools can assist hospitals, pharmacists, and emergency departments in their efforts to describe, justify, and implement new emergency pharmacist programs.

The slide presentations, which are accompanied by associated tools, include the following sections:

- Justification
  - Provides a review of the literature that helps justify the need for an emergency pharmacist program
- Role of the emergency pharmacist
Welcome

This website provides the resources and results associated with the AHRQ-funded research program aimed at increasing the use of clinical pharmacists in emergency medicine. The project goals include providing a body of evidence to demonstrate the value of using emergency pharmacists in the emergency department.

New Items

New!!! The American Society of Health-System Pharmacists is providing a FIFTH year of the ASHP Patient-Care Impact Program for 2011. [CLICK HERE FOR MORE INFORMATION] a 6-month, practice-based mentorship program for new or current emergency pharmacists or those (administrators or pharmacists) starting new clinical pharmacy programs in an emergency department. The 2011 kickoff will occur at the June ASHP meeting in Denver, with a newly expanded session, and will culminate at the midyear meeting with a poster session in New Orleans. Over 50 Emergency Pharmacist programs have been initiated through the PCIP mentorship program. Click [here] to download a recently published paper describes the first program.

New. Dr. Fairbanks has taken a new position as Director of the National Center for Human Factors Engineering in Healthcare, in Washington DC. The Center, part of the MedStar Institute for Innovation, focuses on applying system safety engineering methods to healthcare. More information is available at www.MedicalHumanFactors.net.

In related news, we have recently co-authored a paper describing the first year of the PCIP Emergency Pharmacist program, in the American Journal of Health System Pharmacy. [link to article] (access required) or email us to request reprint.
MM.03.01.01 Effective July 2, 2014

- EP 24 The hospital maintains records for the receipt and disposition of radiopharmaceuticals
  - For hospitals with deemed status
  - Also note a change in the federal law effective July 11, 2014

- Allow in-house preparation of radiopharmaceuticals by trained nuclear medicine technicians in hospitals on off hours without a physician or a pharmacist being present
  - Removed the wording of direct supervision but still under their supervision
Medications Brought In MM.03.01.05

- **Standard** Hospital safely controls medications brought in by patients, families, or LIPs

- **Rationale** The hospital needs to control medications brought in to protect the safety and quality of care

- Also when medication reconciliation is done and hospital does not carry like vitamins and OTC

- Patient may be allergic to the drug in substitutions
Medications from Home

- There are a number of reasons for allowing patients to bring in medications especially with the medication reconciliation process as may not have a non-formulary drug or herbal agent.

- Another valid reasons for allowing includes avoiding interruption of medications or lack of alternatives.

- May be used for observation patients since Medicare does not pay for their oral drugs.

- All 3 EPs apply to sample medication.
Medications Brought In 03.01.05

- **EP1** Hospital defines when medications are brought in by patients, families, or LIPs can be administered

- **EP2** Hospital identifies all medication brought in prior its use and the medication needs to be visually evaluated to determine the medication’s integrity

  - Example are medications in the correct bottle with all same type of pills, not outdated, and labeled?
MEDICATIONS BROUGHT IN 03.01.05

- EP3 Hospital needs to inform patients, families, and LIPs when medications are not permitted

- So develop your process is to safety manage medications brought from home
  - Signed form by patient, counted by staff, locked in drawer, physician order, integrity of bottle, medications clearly labeled by a pharmacist, medication in original bottle, medication not outdated, no state law prohibitions etc.
The policy must address the safety and use of the medication acquired by a practitioner from sources other than the organization for use in patient care.

Will you allow this and what is your policy and be sure physicians and LIP know what your P&P is.

For example, Botox is brought in by patient to be given for migraine headaches by neurologist in the outpatient department.
Medication Orders MM.04.01.01

- Standard- Medication orders have to be clear and accurate
- There are 14 EPs but only 12 apply to hospitals
- EP1 Hospital has to have a written policy to include specific types of medication orders that are acceptable
  - As needed (PRN) orders, automated stop orders
  - Standing orders
    - A pre-written medication order and specific instructions from the LIP to administer a medication to a person in clearly defined circumstances
Medication Orders  MM.04.01.01

- Written policy to include the following
  - Titrating and range orders
  - Orders for compounded drugs or drug mixtures not commercially available
  - Orders for medication related devices (nebulizers, catheters)
  - Orders for investigational medications or herbal agents
  - Orders for medication at discharge or transfer
Medication Orders P&P

- **EP2** Policy needs to include elements of a complete medication order
  - Drug, dose, frequency, route, etc.

- **EP3** Policy on medication use needs to include indication for use and when it is required
  - What is the diagnosis or condition for each drug unless obvious such as antibiotic for pneumonia patient
  - Can be on med reconciliation form, H&P or other place in chart so can tell why patient takes that med
**Diagnosis, Condition, Indication-For-Use In Order**

Q: Does every medication order need to contain a diagnosis, condition, or indication-for-use?

A: No. Standard MM.04.01.01 requires that there be documented justification for all medications ordered. That justification can be in the form of lab values, diagnoses, progress note entries, etc. In other words, the documented justification must be evident somewhere in the medical record.

Standard MM.04.01.01. EP 3 requires organizational policy to designate whether or when indication for use is required as an element of a medication order (e.g., PRN orders). In this situation, organizations must be in compliance with policies.
EP4- Policy need to includes precautions for LASA medications

- It is a much bigger problem according to recent research so USP has database hospitals can check for LASA drugs

- 8th Annual MedMaRX report issued in 2008 shows problems with 3,170 drug pair names which is doubled number since 2004

- Discussed previously
Incomplete or Illegible Orders

- EP5  Policy needs to include actions to take when medication orders are incomplete, illegible or unclear
  - Nurse contacts ordering practitioner when this occurs
  - Consider adding clarification information in nurses notes and on order sheet
  - Lasix order clarified with Dr. Smith 4/25/00 1100 and is 20 mg PO once a day
  - Asked during medication management tracer
Verbal Orders

- EP6 Hospital minimizes the use of verbal and telephone orders for medications
  - Big issue with both CMS and TJC
  - No verbal orders if standing in the nursing station absent a code or emergency
  - Limited to situations like orders needed and doctor at home or in office
  - Remember to make sure all verbal orders are written down, read back, signed off, dated and timed
Indication for the Medication

- There is **documented diagnosis**, condition, or indication for each med ordered,

- Consider new form- why do you take Pepcid-is it to prevent stress ulcer?

- May be in history and physical or admission orders or on medication reconciliation form,

- Why is the patient getting this drug?

- Okay if clear such as antibiotic for pneumonia,
Preprinted Order Sheets

- EP7 Hospital reviews and updates preprinted orders within time frame identified or sooner if based on current or new evidence
  - Consider adding review date to preprinted orders
  - May sure is drafted based on evidenced based medicine
  - Remember CMS Cop to have practitioner sign this is page 3 of 3 and to initial any additions or deletions and June 7, 2013 Changes see EP15
- CMS says protocols must be approved by the MS and entered as an order in the chart
  - Tag 405, 405, 450 and 457
Resume Previous Medications

- EP8  Hospital prohibits summary (blanket) orders to resume previous medications
  
  - So physician cannot writing an admitting order that says “Resume all home meds” or “Resume preop drugs” after surgery

- EP9  Each medication ordered need a diagnosis, condition or indication for use
  
  - Can be in history and not on the order itself
Medication Orders

- EP10  Define in writing when weight based dosing is required for pediatric patients (SM)
  - Only use kg for children
- EP13  Hospital implements its policies for medication orders
- EP14  Hospital requires a physician approved protocol to administer flu and Pneumovac or order
Applicable to Hospitals

Effective Immediately

Medication Management (MM)

Standard MM.04.01.01
Medication orders are clear and accurate.

Element of Performance for MM.04.01.01

A 14. The hospital requires an order from a doctor of medicine or osteopathy, or, as permitted by law and regulation, a hospital-specific protocol(s) approved by a doctor of medicine or osteopathy, to administer influenza and pneumococcal polysaccharide vaccines.
Standing Orders 2013

- EP 15 Preprinted Orders, Electronic Standing Orders, Order Sets, and Protocols for Medication Include the following: (DS)
  - To comply with CMS CoP Changes
  - Must be reviewed and approved by MS (MEC) in conjunction with nursing and pharmacy
  - Evaluate to make sure consistent with evidence-based guidelines and nationally recognized standards
Standing Orders  2013

- Must regularly review standing orders and protocols to make sure they are current, useful, and safe
  - This must be approved by the Medical Staff (such as MEC) in coordination with nursing and pharmacy

- Standing orders and protocols have to still be signed off, dated and times by the ordering practitioner or practitioner responsible for the care of the patient
  - In accordance with hospital P&P, MS by-laws or Rules and Regulations and law
  - Make sure order is placed in chart so it can be signed off
CMS Requirements on Order Sets, Protocols, Preprinted Orders, and Standing Orders

Sue Dill Calloway RN MSN JD

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

The development of protocols and standings orders is better described as a journey. Initially CMS said that a physician order was needed first and that standing orders had
Medical Homes EHR Prescribing

- EP 21 The primary care medical home uses an electronic prescribing process
- This standard applies only to hospitals that elect the TJC primary care medical home option
Pharmacist Review MM.05.01.01

- **Standard** - A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital

- There are 11 EPs but only 10 apply to hospitals

- This has been a problematic standards for hospitals and source of frequent questions

- All prescriptions or medication orders are reviewed for appropriateness by the pharmacist before the **first dose** is given for safety reasons
Pharmacist Review before First Dose

- EP1 Pharmacist reviews all medication orders or prescriptions prior to dispensing or removing medications from the floor stock
  - Exception is made if LIP controls the ordering, preparation and administration (such as in radiology, endoscopy, or the ED)
  - Radiology service must define, through protocol or policy, the role of the LIP to directly supervise the patient during and after IV contrast is administered in case of a patient emergency
    - Author suggest you make it a policy in light of CMS protocol IG
Pharmacist Review before First Dose

- ACR has contrast manual at www.acr.org
- Exception is made if delay would cause the patient harm in an urgent situation
  - Patient in the ED needs tPa for heart attack or Morphine for pain
- CMS hospital CoP Tag 500
- Necessary to prevent backup in the ED
- ED must have LIP available in the unit who is available for immediate intervention should patient have an ADE
LIP Order in the ED Exception

- If the patient is still in the ED and a bed is not going to be available for 12 hours and patient needs their daily medication, there is time to have the pharmacist do a review of their medication before giving them their daily medications.

- Example is patient is admitted to the medical unit for pneumonia and nurse cannot just go to the automated dispensing unit and get meds until pharmacy has reviewed the list.
Pharmacy Closed

- EP2- If the pharmacy is not open 24 hours a day then a healthcare professional determined to be qualified reviews the medication order in the pharmacist absence
  - Many hospitals have the nurse supervisor access the night cabinet and then reviews with RN who will give
  - Many hospitals provide additional medication training to the supervisor who has to pull drugs from the night cabinet and consider bar coding
  - Some hospitals fax the medication order to a pharmacist as part of tele-pharmacy process
Pharmacist Retrospective Review

- EP3- The pharmacist conducts a retrospective review of all medication orders during this period as soon as a pharmacist is available or the pharmacy opens
  - The nurse supervisor or physician should only pull the drugs that are needed during the time there is no pharmacist
  - The pharmacist needs to review all the drugs that were given from the night cabinet when they come in that morning
Review Medications First Dose Rule

- EP4-9 The following is a list of things that the pharmacist needs to review before the first dose is given:
  - Allergies or potential sensitivities
  - Existing or potential interactions between the medication ordered and food and
  - Medications the patient is currently taking
First Dose Review by Pharmacist

- EP4-9 The following is a list of things that the pharmacist needs to review before the first dose is given (Continued);
  - Appropriateness of the medication, dose, frequency, and route of administration
  - Current or potential impact as indicated by laboratory values
  - Therapeutic duplication and other contraindications
Clarify Any Unclear Orders

- EP11- Concerns, issues, or questions are clarified with the individual prescriber before dispensing
  - This issue is discussed during medication management tracer so make sure staff know what to do if order is unclear or illegible
  - Should document clarification in the medical record and CMS CoP standard
DELETED: Requirement for Pharmacist Review of Off-Label Medication Use

The Joint Commission’s Board of Commissioners approved the deletion of Element of Performance (EP) 10 for “Medication Management” (MM) Standard MM.05.01.01 for behavioral health care, critical access hospitals, home care, hospitals, and long term care. This EP required a pharmacist to review all medication orders for variation from the organization’s indications for use. The deletion is effective immediately.

After careful review, The Joint Commission believes this EP is a redundant requirement because Standard MM.05.01.01 contains other requirements that meet the intent of EP 10:

- All medication orders are reviewed for the appropriateness of the medication, dose, frequency, and route of administration. (EP 6)
- After the medication order has been reviewed, all concerns, issues, or questions are clarified with the individual prescriber before dispensing. (EP 11)

Also, Standard MM.04.01.01, EP 9, requires every medication that is ordered to include an indication for use. This EP states that a diagnosis, condition, or indication for use exists for each medication ordered. A note for this EP assures that this information can be anywhere in the medical record and does not need to be on the order itself. For example, it might be part of the medical history.
Safe Preparation of Medication MM.05.01.07

- **Standard-** The hospital safely prepares medications

- **EP1** A pharmacist or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparation
  - An exception would be in an urgent situation where a delay could harm the patient
  - Remember the USP 797 standards where piggybacks and IVs need to be made under laminar hood etc.

- **Must follow any specific state law**
Separate Area to Prepare Medications

- EP2- Staff need to use clean or sterile technique and maintain a clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications
  - Separate medication room or something that is mounted to wall and folds down like a Wallaroo
  - CMS requirement also
Inspect Medication & USP 797

- **EP3** Staff visually inspect the medication for particulates, discoloration, or other loss of integrity during preparation.

- **EP4** The hospital uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous (IV) admixture or any sterile product that will not be used within 24 hours.

EP5 Need an order for medications (DS)

- Medications are prepared in accordance with an order and in accordance with P&P, MS R/R and by-laws and regulations.

- CMS CoP states need an order for any drug or biological, updated June 7, 2013 in Tag 405 (2014 changes on medications & opioid use) and 406.

- May use protocols for emergency situations such as ED nurse starts IV on patient thought to be a MI patient after approval by MEC.

- Nurse needs to enter the order in the order sheet and have physician or LIP sign the order.
Radiopharmaceuticals

- EP6 In-house preparation of radiopharmaceuticals is done by, or under the supervision of an appropriately trained registered pharmacist or doctor (DS)
  - This is a requirement under the CMS CoP for hospitals but proposes to change in 2014
  - July 11, 2014 change that allows radiology tech to do on off hours without a physician or pharmacist present
Radiopharmaceuticals  CMS

- In nuclear medicine radioactive substances are used to diagnose and treat disease
  - The medical imaging use radioactive isotopes (radionuclides) to locate organs or cellular receptors
  - The radiopharmaceuticals are taken IV or orally
  - An example is a myocardial perfusion scan or pulmonary ventilation and perfusion (V/Q) scan
- CMS revised the nuclear medicine CoP to remove the requirement from “direct supervision” from the in-house preparation supervision requirement
Radiopharmaceuticals CMS

- **Direct** supervision meant that the pharmacist or physician had to be physically located inside the hospital and immediately available during the preparation of the radiopharmaceutical.

- This was extremely burdensome on off hours.

- The rule adopted the proposed changes to revise to supervision instead of direct supervision so appropriately trained staff can prepare in-house pharmaceuticals under the oversight of a registered pharmacist or physician.
Radiopharmaceuticals CMS

- This means that now on off hours, such as evenings and weekends, a pharmacist or MD/DO does not have to be present to do nuclear medicine tests
- CMS received information that there is minimal in-house preparation required for radiopharmaceuticals
  - Many are batch prepared by the manufacturer
  - This was based on the recommendation of the Society of Nuclear Medicine and Molecular Imaging (SNMMI)
Radiopharmaceuticals  CMS

- Hospitals need to have a P&P on supervision of nuclear medicine personnel and in-house preparation

- CMS said they expect hospitals to follow the Society of Nuclear Medicine and Molecular Imaging recommendations on this issue

- This includes emergency performance of diagnostic procedures such as CAD, pulmonary emboli, stroke, and testicular torsion

- All comments were supportive of this change
ACR PRACTICE GUIDELINE FOR THE USE OF INTRAVASCULAR CONTRAST MEDIA

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology. The express or implied limitations of the guidelines should not be construed to diminish the wisdom of the practitioner who deviates from any recommendation contained herein.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline has been developed to promote the safe and effective administration of intravascular contrast media used for imaging studies.

Intravascular contrast media are used for a wide variety of imaging studies. The majority of intravascular contrast-enhanced imaging examinations involve iodinated contrast media, but other contrast media may be used for magnetic resonance imaging (MRI), ultrasonic imaging, and angiography.

Harriet G. Evans, MD
IV Contrast

- April 2007 changed the requirement that pharmacist had to do a retrospective review of all ED drugs within 48 hours but still requires IV contrast protocol or P&P
  - A hospital’s radiology department will be allowed to define, through a policy or protocol, the role of LIP’s in the direct supervision of patients during and after administration of IV contrast media
  - If radiologist not present when IV contrast is given, ED physician would be present to administer to ED patient
  - FAQ discusses medication administered under an LIP and states pharmacist may want to later assess risk points by randomly sampling and reviewing the LIP orders
IV Contrast

- Hospitals should refer to the American College of Radiology practice guidelines for the use of intravascular contrast media
- Also a number of guidelines for contrast in pediatric patients and contrast for MRI
- Exception for oral and rectal contrast media see August 2006 edition of The Joint Commission Perspectives.
ACR Contrast Manual

ACR Manual on Contrast Media

Version 9


2013

ACR Committee on Drugs and Contrast Media
Safe Preparation of Medications

- Suggest use premixed when available as safer than mixing up on the floor
- Suggest do not add drugs to Buritol or bags when pharmacist on duty
- Pharmacist needs to prepare piggybacks when on duty unless short half life or urgent need
Labeling of Medications  MM.05.01.09

- **Standard**  All medications must be labeled

- **Rationale**  It has been a long standing standard of practice that all medications must be labeled as is required by law and regulation

- A standardized method of labeling can promote medication safety

- 12 EPs

- Labels for medications are discussed under NPSG.03.04.01
Labeling of Medications  MM.05.01.09

- **EP1** A medication must be labeled when prepared if not immediately given (SM)
  - Exception is nurse in ED prepares Phenergan 12.5 mg to be given IV and immediately goes to the bedside and administers it slowly over 3 minutes
  - There is no break in the process and prepared and administered by the same person
- **EP2** Information on the label is displayed in standardized format
Medication Labels Must Contain

- EP3 to EP6  The medication label must contain:
  - Medication name, strength, and amount
  - Expiration date when not used within 24 hours
  - Expiration time when expiration occurs in less than 24 hours
  - The date prepared and the diluent for all compounded
  - Intravenous admixtures and parenteral nutrition formulas
    - Plain IVs do not need a label
Labeling of Medications

- EP7 to EP9 Label must contain the following when preparing individualized medications for multiple patients
  - Patient's name
  - The location where the medication is to be delivered
    - Location not used as identifier during administration
  - Directions for use and applicable accessory and cautionary instructions
    - Such as keep out of light, refrigerate, give over 2 minutes, dilute in 5 ml 0.9% NaCl
  - Same as when pharmacist prepares for the nurse
Labeling of Medications

- EP10 to EP 12  When preparing individualized medication by someone other than the person administering (pharmacist prepares for nurse) the label must include:

  - The patient's name
  - The location where the medication is to be delivered
  - Directions for use and applicable accessory and cautionary instructions
Dispensing Medications MM.05.01.11

- **Standard:** The hospital safely dispenses medications
  - **EP1** Quantities dispensed are consistent with patient needs
    - Hospital does not want to dispense large numbers of medication unnecessarily as it could lead to diversion
Dispensing Medications

- EP2 Medications are dispensed in accordance with professional standards of care and records maintained in accordance with law and regulation (SM)
  - Include anti-diversion strategies
  - There are many standards such as those set out by professional organizations like ASHSP, ISMP, APIC, IHI, FDA, and USP
  - There are many state regulations like those from the state pharmacy board
  - There are many federal laws/regulations such as the USP 797
Dispensing Medications

- EP3 Hospital dispenses within time frames it defines to meet the patient needs
  - If physician orders medication stat what is the time frame to administer it to patient such as 20 minutes
  - If physician orders medication ASAP what is the hospital’s time frame such as 2 hours
Dispensing Medications

- EP4 Medications are dispensed in the most ready-to-administer forms commercially available, and, if feasible, in unit doses that have been repackaged by the pharmacy or licensed repackaged
  - Drugs in unit dose
  - Solutions like cough syrup in individual unit dose containers and not in big bottle
  - Drugs in crash cart are most readily available such as individual injectibles for EPI and Atropine
Pharmacy is Closed  MM.05.01.13

- **Standard**: The hospital obtains medications safety when the pharmacy is closed

- **Rational**: If pharmacy not open 24 hours a day patients may still need medications

- Hospital needs to provide for urgent or emergent needs when the pharmacy is closed

- This standard does not affect hospitals that have a pharmacist on duty 24 hours a day

- 7 EPs
Night Cabinet Standard

- **EP1** Hospital has a process to meet the patient’s need when pharmacy is closed
  - For example, nurse supervisor gets needed meds out of the night cabinet

- **EP2** When non-pharmacist is allowed to obtain meds after hours, medications are limited to those approved by the hospital
  - For example, hospitals have a list of the drugs in the night cabinet that can be accessed after hours and periodically review to see if you add or delete drugs
Pharmacy is Closed  Night Cabinet

- EP3 These medications must be stored outside the pharmacy
  - Like in the night cabinet
  - TJC does not want supervisor going into the pharmacy to get drugs when it is closed
  - Several hospitals report being cited by CMS for not having pharmacist do first dose review when pharmacy closed and not using telepharmacy

- EP4 Only trained, designated prescribers and nurses can access these approved medications
Pharmacy is Closed Night Cabinet

- EP5 Need to have a quality control procedure such as an independent check by another nurse or secondary verification system like bar coding to prevent retrieval errors
- EP6 Pharmacist needs to be on call or available to answer questions or retrieval medications not in night cabinet
- EP7 Hospital needs to implement its process when the pharmacy is closed
Recalled/Discontinued Medication MM.05.01.17

- **Standard**: The hospital follows a process to retrieve recalled or discontinued medications (all 4 EPs SM)

- **EP1**: The hospital has a written P&P that outlines what to do in the event a medication is recalled or discontinued for safety reason by the FDA
  - See EC.02.01.01 EP 11 The hospital responds to product notices and recalls
  - Send notices to nursing units
  - Hospitals can sign up on the FDA website to get notices of drug recalls and discontinued medications
Recalled/Discontinued Medication

- EP2 The hospital implements its P&P when a drug is recalled or discontinued for safety reasons
- EP3 Hospital must notify the prescribers when there is a drug is recalled or discontinued
  - For example, when Vioxx and Darvocet N recalled hospital had process to notify doctors and what would be substituted
- EP4 Hospital notifies patient that their medication has been recalled or discontinued by the FDA when required by law or your P&P
Standard: Hospital safely manages returned medications

Rationale- Medications may be returned to the pharmacy when allowed by law or regulation

Previously unused, expired, or returned medications need to be accounted for, controlled and disposed of to keep patient safe and to prevent diversion

4 EPS and all apply to sample medications (SM)
EP1 The hospital determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy

- For example, the patient is discharged and unused medications are returned to pharmacy
- For example, Dilaudid outdates tomorrow so nurse sends it back to pharmacy

EP2 The hospital has a process for returning medications to the pharmacy’s control which includes P&P to prevent diversion
Returned Medications  05.01.19

- EP3 Hospital determines if and when outside sources are used for destruction of medication.

- EP4 Hospital implements its process for managing unused, expired, or returned medications.
  - What is the hospital P&P to return and destroy these drugs?
  - Are they flushed or incinerated (p-waste)?
  - What is the process to document wasted drugs?
Administration of Meds MM.06.01.01

- Standard: The hospital safety administers medications
  - Pharmacist dispense the medication
  - It is the nurse’s role to safety administer that medication
  - There are 9 EPs
EP1 The hospital defines in writing, LIPS or clinical staff who are allowed to administered medication

- This includes with or without supervision
- It must be in accordance with law and regulation
- Example would be medication technicians with a certificate to pass certain medications in LTC in Ohio
- Nursing students in their program can administer medications
Administration of Medications by Nurse

- EP2 LIPS and clinical staff who are authorized are the only ones who can administer medications except self administration when permitted
  - So a nurse could not delegate to the nursing assistant to give the patient this medication in a cup when they come back from the bathroom
  - Many states require LPN to have medication course before being able to administer medications
  - Example would be only RNs can administer blood and many nurse practice acts restrict LPN role such as may be able to irrigate central line
Administration of Medications

- EP3 to EP9  Prior to administration the individual must:
  - Verifies that the medication selected matches the medication order and product label
  - Visually inspects the medication for particulates, discoloration, or other loss of integrity
  - Verifies the medication has not expired and there are no contraindications
Administration of Medications

- EP3 to EP9 - Prior to administration the individual must (Continued):
  - Verifies the medication is being administered at the proper time, in the prescribed dose, and by the correct route
  - Discusses any unresolved concerns about the medication with the patient’s prescriber
  - The patient or family is informed about any potential clinically significant adverse drug reactions or other concerns regarding administration of a **new** medication
Administration of Medications

- Remember **PC.02.03.01 EP10** that requires education and training to provided to the patient on the safe and effective use of medication
  - Use teach base to make sure patient understands and understand issue of low health literacy
  - Make sure use an interpreter if patient has limited English proficiency
- This section also references **MM.06.01.03 EP 3-6** about self administration of medication by patients
- CMS Tag 412 and 413 in Nursing section and Tag 502 in Pharmacy
Administration of Medications

- Verify medication is stable by visually looking for particulates or discoloration in vial
- Make sure drug is not expired
- Verify no contraindications like allergies or sensitivities or drug not indicated with certain medical conditions
- Verify administered at proper time, dose, and route such as yes it is Lanoxin 0.125 mg orally and is to be given at 9 am
Administration of Medications

- Advise patient and when appropriate, family, about significant adverse reactions when giving a new medication
  - Watch out for hives or red neck syndrome for Vancomycin or this medication is a diuretic and will make you urinate frequently
- Address any concerns with physician before administering
- Discuss any unresolved significant concerns about the medication with the prescriber and document clarification on order sheet and in nurses notes when indicated
Self Administered Medications MM.06.01.03

- **Standard:** Self administered drugs are administered safety and accurately

- Self administered may refer to medications given to the patient themselves or by a family member

- Doctor writes an order for Nitro at the patient’s bedside or an inhaler

- 7 EPs

- CMS CoP 412, 412 and 502
Self Administered Medications

- **EP1** - Hospital can decide if self administration is allowed
  - If allowed, then need a written process to address training, supervision, and documentation to guide this process

- **EP2** - The hospital need to implement its written process (P&P) for self administered drugs
Self Administered Medications

- **EP3** Patients and families need to be educated on the medication name, type and reason for use,

- **EP4** Must include how to administer medication, including process, time, frequency, route, and dose (is it an oral drug, rectal suppository, given subq)

- **EP5** Must include anticipated actions and potential side effects of the medication
Self Administered Medications

- EP6  Must include information to patient and families involved on how to monitor the effects of the drug
  - Such as how to take their pulse before taking a dose of Digoxin

- EP7  Must ensure patient or family member is competent before being allowed to administer medications
  - Would not leave a bottle of Nitro at the bedside of a patient who had Alzheimer's disease
Investigational Drugs MM.06.01.05

- **Standard**: Hospital safely manages investigational medications

- **Rationale** Investigational drugs can be of great help to the patient

- The hospital contributes to the safety of patients participating in investigational or clinical medication studies by controlling and monitoring the use of these medications

- 4 EPs
Investigational Drugs  06.01.05

- EP1  Hospital needs written process (P&P) that addresses the use including review, approval, supervision, and monitoring

- EP2  There is a written process for use of investigational medications specifies that the pharmacy controls the storage, dispensing, labeling, and distribution of investigational medications
Investigational Drugs

- EP3 P&P specifies that when a patient is involved in an investigational protocol that is independent of the hospital.
- The hospital evaluates and, if no contraindication exists, accommodates the patient’s continued participation in the protocol.
- EP4 Hospital implements its process (P&P) for the use of investigational drugs.
Investigational Drugs

Investigational Meds need to be safety controlled and administered

- Have a clear P&P for the reviewing, supervising and monitoring their use

- Nurses who administer need information on drug and its side effects

- Problematic standard

- See ISMP recommendations on reducing errors in investigational drugs at http://www.ismp.org/pressroom/PR20071107_2.pdf
FOR IMMEDIATE RELEASE

November 7, 2007

CONTACT: Renee Brehio, Media Relations
704-831-8822
rbrehio@ismp.org

Product-Related Issues Lead to Potential Errors with Investigational Drugs

Huntingdon Valley, Pa.—Routine practices used to name, label, package, and store investigational drugs raise serious patient safety concerns, warns the Institute for Safe Medication Practices (ISMP). In the most recent issue of the ISMP Medication Safety Alert! newsletter, the Institute outlines some of those concerns and provides recommendations for safe use.

Safety Concerns

- **Drug names.** Investigational drugs are often identified by a number preceded by an abbreviation of the sponsoring company’s name. This may lead to mistakes, including similar names due to participation in multiple studies by same sponsor and truncation of long letter/number designations by pharmacy computer systems. Other mistakes could be due to products receiving a generic or common name during a study that remains on the product label, and changes in code names.

- **Drug labels.** Many investigational drugs are labeled using a very small font size with little use of
Safety Concerns

- **Drug names.** Investigational drugs are often identified by a number preceded by an abbreviation of the sponsoring company’s name. This may lead to mistakes, including similar names due to participation in multiple studies by same sponsor and truncation of long letter/number designations by pharmacy computer systems. Other mistakes could be due to products receiving a generic or common name during a study that remains on the product label, and changes in code names.

- **Drug labels.** Many investigational drugs are labeled using a very small font size with little use of bold type, color, tall-man letters, or other strategies to help differentiate products. This can lead to confirmation bias when products are selected from the shelf, since the packaging looks so similar.

- **Drug packaging.** Many oral investigational drugs are not supplied in unit-dose packages. Some parenteral drugs may require dozens of vials to prepare a single dose, which sensitizes practitioners to expect to use multiple vials during preparation and makes recognition of overdoses less likely.

- **Tablet markings.** Tablet strengths often look identical and have no markings to help differentiate the strengths. While this may be essential for blinded studies, the same batches of look-alike tablets may be used for open label studies where the tablet strength is known to all participants.

- **Expiration dates.** Some sponsors do not list an expiration date and one must be obtained by calling an interactive voice system. The lag time involved has resulted in expired drugs not being replaced in time, or required direct intervention with the sponsor to avoid dispensing a drug that would reach expiration during outpatient use.
Medication Errors       07.01.03

- Standard: The hospital responds to actual or potential adverse drug events (ADEs), significant adverse drug reactions, and medication errors
- There are 5 EPs
- EP 1, 2, 3, and 5 applies to sample medications
- Medication errors are the most common type of medical errors
- RCA and FMEA are patient safety tools used by hospitals
- CMS will ask for 3 RCAs in QAPI worksheet
Medication Errors  07.01.03

- EP1 Hospital needs a written process (P&P) to respond to actual or potential adverse drug events, significant ADRs, and medication errors (ME)
  - If a medication error occurs what do you want the nurse to do?
  - Serious ones may necessitate an immediate call to the physician and nurse supervisor
  - Some may need just to fill out the incident report
  - Some may be reported to ADE hotline
Medication Errors 07.01.03

- **EP2** Hospital has written process (P&P) that addresses prescriber notification in event of ADE
  - Physician or prescriber needs to know if patient vomited after pain medicine given or developed hives to new medication

- **EP3** Hospital complies with external and internal reporting requirements of ADE and ME
  - Such as reports to the FDA MedWatch and alerts from USP, the FDA Safety Series, ISMP, Pa Patient Safety Authority, IHI, ASHP, and others
Medication Errors 07.01.03

- EP5 The hospital implements its process for responding to ADE, significant adverse drug reactions, and medication errors
  - Make sure staff know the hospital’s policy and procedure?
  - Are incident reports filled out as required by the P&P?
  - Do you use IHI adverse event trigger tool to identify errors and look for opportunities?
Medication Errors

- EP6  Medication administration errors, ADRs, and drug incompatibilities are immediately reported to the attending physician
  - As defined by the hospital (use national definition)
  - And report to the hospital wide PI program
  - This is for hospitals that use the TJC for deemed status
  - CMS requires definition of each and P&P must state when immediate notification of physician as if harm to the patient under Tag 508
Evaluation of Medications MM.08.01.01

- Standard: The hospital evaluates the effectiveness of its medication management system
  - Evaluation includes reconciling medication information
- EP1  Hospital needs to collect data on the performance of its MM system
- EP2  This data needs to be analyzed
- EP3  The hospital compares data over time to identify risk points, levels of performance, patterns, trends, and variation of its medication management system
Evaluation of Medications

- EP4 The hospital reviews the literature and other external sources for new technologies and best practices

- EP5 The hospital identifies opportunities for improvement based on the data analysis, literature searches, evidenced based practice, and review of new technologies and best practices

- Do you have smart pumps, automated dispensing units, bar coding, CPOE etc.
Evaluation of Medications

- EP6 The hospital takes action on improvement opportunities identified as priorities for its MM system
- EP7 Need to evaluate when changes made to confirm that it resulted in an improvement
- EP8 If the improvement desired was not reached or sustained then need to take action
  - Back to the drawing board
- See Medication-Use Evaluation Guideline at www.ashp.org/
ASHP Guidelines on Medication-Use Evaluation

Medication-use evaluation (MUE) is a performance improvement method that focuses on evaluating and improving medication-use processes with the goal of optimal patient outcomes. MUE may be applied to a medication or therapeutic class, disease state or condition, a medication-use process (prescribing, preparing and dispensing, administering, and monitoring), or specific outcomes. Further, it may be applied in and among the various practice settings of organized health systems.

MUE encompasses the goals and objectives of drug-use evaluation (DUE) in its broadest application, with an emphasis on improving patient outcomes. Use of “MUE,” rather than “DUE,” emphasizes the need for a more multifaceted approach to improving medication use. MUE has a common goal with the pharmaceutical care it supports: to improve an individual patient’s quality of life through achievement of predefined, medication-related therapeutic outcomes. Through its focus on the system of medication use, the MUE process helps to identify actual and potential medication-related problems, resolve actual medication-

Steps of the MUE Process

While the specific approach varies with the practice setting and patient population being served, the following common steps occur in the ongoing MUE process:

- Establish organizational authority for the MUE process and identify responsible individuals and groups.
- Develop screening mechanisms (indicators) for comprehensive surveillance of the medication-use system.
- Set priorities for in-depth analysis of important aspects of medication use.
- Inform health care professionals (and others as necessary) in the practice setting(s) about the objectives and expected benefits of the MUE process.
- Establish criteria, guidelines, treatment protocols, and standards of care for specific medications and medication-use processes. These should be based on sound scientific evidence from the medical and pharmaceuti-
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 measuring the number and degree of harmful medication events. The tool provides instructions and forms for collecting the data you need to measure the number of ADEs per 1,000 doses and the percentage of admissions with an ADE.

This tool contains:
- Background
Resources

- Medication station-identifying risks in medication use process,
- Evaluating risk points in your MM system,
- Performing medication reconciliation in short stay areas,
- After hours medication needs,
- http://www.jointcommission.org/Pharmacists/journal_articles.htm
Center for Clinical Standards and Quality/Survey & Certification Group

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 receiving IV opioid medications.
The End! Questions???

Sue Dill Calloway RN, Esq
AD, BA, BSN, MSN, JD CPHRM

President of Patient Safety and Health Care Consulting

Board Member
Emergency Medicine Foundation
614 791-1468
sdill1@columbus.rr.com

TJC 9 do not use abbreviations
are in IM chapter, tracer and NPSG
medication information also attached
<table>
<thead>
<tr>
<th>Do Not Use</th>
<th>Potential Problem</th>
<th>Use Instead</th>
</tr>
</thead>
<tbody>
<tr>
<td>U, u (unit)</td>
<td>Mistaken for “0” (zero), the number “4” (four) or “cc”</td>
<td>Write &quot;unit&quot;</td>
</tr>
<tr>
<td>IU (International Unit)</td>
<td>Mistaken for IV (intravenous) or the number 10 (ten)</td>
<td>Write &quot;International Unit&quot;</td>
</tr>
<tr>
<td>Q.D., QD, q.d., qd (daily)</td>
<td>Mistaken for each other</td>
<td>Write &quot;daily&quot;</td>
</tr>
<tr>
<td>Q.O.D., QOD, q.o.d, qod (every other day)</td>
<td>Period after the Q mistaken for &quot;I&quot; and the &quot;O&quot; mistaken for &quot;I&quot;</td>
<td>Write &quot;every other day&quot;</td>
</tr>
<tr>
<td>Trailing zero (X.0 mg)*</td>
<td>Decimal point is missed</td>
<td>Write X mg</td>
</tr>
<tr>
<td>Lack of leading zero (X mg)</td>
<td></td>
<td>Write 0.X mg</td>
</tr>
<tr>
<td>MS</td>
<td>Can mean morphine sulfate or magnesium sulfate</td>
<td>Write &quot;morphine sulfate&quot;</td>
</tr>
<tr>
<td>MSO₄ and MgSO₄</td>
<td>Confused for one another</td>
<td>Write &quot;magnesium sulfate&quot;</td>
</tr>
</tbody>
</table>

¹ Applies to all orders and all medication-related documentation that is handwritten (including free-text computer entry) or on pre-printed forms.

*Exception:* A “trailing zero” may be used only where required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report size of lesions, or catheter/tube sizes. It may not be used in medication orders or other medication-related documentation.
Patient Flow  CAH and HAP Programs

- Surveyors are to interview staff during each of the individual tracers on what patient flow processes are being measured
- What other PI measures are in use
- What has the hospital learned?
- How has this data been used to make improvements
- Surveyor will look for variability in workload during the day and between days of the week
- Ask about wait, boarding, and turnaround times
## System Tracer – Medication Management

**Applies to:** All accreditation programs.

<table>
<thead>
<tr>
<th>Duration</th>
<th>60 minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants</strong></td>
<td>All surveyors available to participate</td>
</tr>
<tr>
<td><strong>Organization:</strong></td>
<td>Clinical and support staff involved in medication management</td>
</tr>
</tbody>
</table>

### Objectives

1. Learn about the organization’s medication management processes.
2. Evaluate the continuity of medication management from procurement of medications through monitoring.
3. Evaluate the medication reconciliation process during hand offs.

### Before

- Collect data from a high risk medication while conducting an individual patient tracer. You can use the attached medication management work-tool to help track medications.
- Seek an understanding of the medication management sub-processes (patient specific information, selection/procurement, storage, ordering/transcribing, preparing/dispensing, administration, monitoring and evaluation). This discussion should include pharmacy review, use of NPSG requirements, and assimilation of pertinent literature.
- Check the FDA website for safety alerts and recall notices: www.fda.gov/medwatch

### During

**Tracing (40-45 minutes)**

Using the patient’s experience on a high risk medication, trace the processes for managing that medication through the organization’s systems. This should include, when applicable, visits to:

- The unit where the patient is located
  - Ask about the last time the unit was informed of a drug recall; can the manager or staff remember how they were notified; ask to see any recent recall notices.
- The pharmacy
  - Explore the high risk medication’s procurement, storage and dispensing, investigating important issues, such as drug security.
Medication Management System Tracer

- Medication management will look at activity of tracing a patient who is receiving a high risk medication
  - Will go to the unit where the patient is located
- Will evaluate the process and 8 steps in the MM chapter such as patient specific information, select and procure the medication, ordering, transcribing, dispensing, administration etc.
- Will evaluate how the pharmacy reviews specific medications
Medication Management System Tracer

- Pharmacy
  - Will look at how pharmacy gets high risk medications and how they store it, and dispense it
  - Will evaluate drug security by the pharmacy
  - Will look at LASA issues
  - How does the pharmacy work with other departments and disciplines
  - How does pharmacy keep current on drug recalls
  - Will ask for copies of drug recall notices
Medication Management System Tracer

- **Lab**
  - Explore the role of the lab in evaluation of medication
  - Identify a trigger for lab testing (dig level for patient on dig, theophylline, INR for patient on warfarin, etc.)

- **Dietary**
  - Review any dietary restrictions
  - Evaluate if any dietary interactions with medications
  - Is there a process in place to educate the patient

- May talk with a physician about prescribing issues
- Discuss communication during hand offs
Medication Management System Tracer

- Conference room discussion
  - May ask the hospital to describe their process of the medical management system
  - May ask to summarize their strengths, vulnerabilities and risk points

- Additional issues during tracer
  - How does the staff and others report medication errors and near misses
  - How does the hospital determine if there is a system breakdown
  - What data is collected?
Medication Management System Tracer

- What is process for reporting abuses and losses of controlled substances?
- What is process to override automated dispensing unit?
- What PI is collected related to medications?
- What is P&P for medications brought into the hospital by patients?
- How does the hospital educate the staff and patient about medication safety?
Medication Management System Tracer

- How are patients involved in safe medication management?
- What is the role of information management in the role of medication management?
- What is the process to report, respond, and analyzed medication errors, ADEs and drug incompatibilities?
- What is the process for implementing standing orders including how they are developed, approved and how are they regularly reviewed?
Medication Management Tracer

- When was the last time the unit was informed of a drug recall?
  - How were you notified
  - Surveyor will look for recent recall notices
- Will check the FDA website for safety alerts and recall notices at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)
  - You can sign up at FDA to get notices and ASHP has information on their website
# Medication Management Work Tool

## Medication Management – Work Tool

<table>
<thead>
<tr>
<th>Patient Identifier:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Medication Ordered</th>
<th>Date ordered</th>
<th>Time ordered</th>
<th>Amount Ordered</th>
<th>Frequency</th>
<th>Route</th>
<th>Pharmacy Review</th>
<th>Amount Administered</th>
<th>Time Administered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Blood Transfusion

- Will interview lab staff in the blood bank and the person hanging the blood about the following:
  - Protocol for unused blood products
  - Evaluation and maintenance of administration equipment
  - Data collection, communication and use
  - Storage when blood is not being used
NPSG Chapter Outline and Overview

Hospital

National Patient Safety Goals

I. Goal 1 – Improve the accuracy of patient identification.
   A. Use of Two Patient Identifiers (NPSG.01.01.01)
   B. Not applicable to hospitals
   C. Eliminating Transfusion Errors (NPSG.01.03.01)

II. Goal 2 – Improve the effectiveness of communication among caregivers.
    A. Not applicable to hospitals
    B. Not applicable to hospitals
    C. Timely Reporting of Critical Tests and Critical Results (NPSG.02.03.01)
    D. Not applicable to hospitals
    E. Not applicable to hospitals

III. Goal 3 – Improve the safety of using medications.
     A. Not applicable to hospitals
     B. Not applicable to hospitals
     C. Not applicable to hospitals
     D. Labeling Medications (NPSG.03.04.01)
     E. Reducing Harm from Anticoagulation Therapy (NPSG.03.05.01)

IV. Goal 4 – Not applicable to hospitals

V. Goal 5 – Not applicable to hospitals

VI. Goal 6 – Not applicable to hospitals

VII. Goal 7 – Reduce the risk of healthcare-associated infections.
     A. Meeting Hand Hygiene Guidelines (NPSG.07.01.01)
     B. Not applicable to hospitals
     C. Preventing Multidrug-Resistant Organism Infections (NPSG.07.03.01)
     D. Preventing Central Line–Associated Blood Stream Infections (NPSG.07.04.01)
     E. Preventing Surgical Site Infections (NPSG.07.05.01)

VIII. Goal 8 – Accurately and completely reconcile medications across the continuum of care. Note: All requirements for Goal 8 are not in effect at this time.
      A. Comparing Current and Newly Ordered Medications (NPSG.08.01.01)
      B. Communicating Medications to the Next Provider (NPSG.08.02.01)
      C. Providing a Reconciled Medication List to the Patient (NPSG.08.03.01)
      D. Settings in which Medications Are Minimally Used (NPSG.08.04.01)
Goal 3: Improve the Safety of Using Medications

- There are only 2 of the 5 sections left in and medication reconciliation now added
  - This is NPSG.03.04.01 (3D) on labeling of medications and
  - Also NPSG.03.05.01 (3E) on reducing harm from anticoagulants

- There are 8 elements of performance to NPSG.03.04.01
  - 2010 revision to include the preparation date and expiration date and time

- There are also 8 elements of performance to NPSG.03.05.01
Label all Medication

- Label all medications and medication containers (syringes, medicine cups, basins), and other solutions on and off the sterile field or procedural setting.
- EP1 In perioperative and other procedural setting you must label all medications and solutions that you are not going to immediately administer.
  - Need to do this even if only one medication is being used and even if obvious.
  - Immediately administered medicines is where you draw it up and take it directly to the patient without any break in the process.
Label all Medication and Solutions

2. In the perioperative and procedural setting, labeling occurs any time a medication or solution (normal saline) is transferred from the original packaging to another container.

3. Need name of medication on label, strength, amount, quantity, diluent and volume, preparation date, expiration date if not used within 24 hours and time if expires in less than 24 hours.
   - Preparation date was removed March 2010.
   - Expiration date and time are required.
Label all Medication and Solutions

4. All medications or solutions are verified by 2 persons verbally and visually if person preparing it will not be administering it.

5. Label each medication or solution as soon as it is prepared unless immediately administered.
   - Want you to prepare medications one at a time.

6. Discard any unlabeled medication or solution immediately.
Label all Medication and Solutions

7. Discard all labeled containers on the sterile field after surgery or procedure is done
   - This means you saved the original containers until you are done
   - Case of Ben Kolb who was given a concentrated dose of adrenaline instead of Lidocaine

8. Review all medication or solutions on and off the sterile field by entering and exiting staff responsible for MM
   - Such as at the change of shift
Label all Medications 03.04.01

- Use extended definition of medicine by TJC
- Applies to anesthesia meds, and other procedural settings and not just invasive procedures
- Pre-labeled empty syringes or containers are not acceptable
- Can purchase prefilled, pre-labeled syringes for procedure trays
Label all medications

- MM.05.01.09 EP 3 and 4 state what has to be on label
- Label to include name, strength, amount (if not apparent from the container), expiration date if not used within 24 hours or if it expires in less than 24 hours, IVs date prepared and diluent
- Label can be developed by the facility or commercially available, Sterile labels can be purchased
- All labels are verified both verbally and visually by two qualified persons
- No more than one medication or solution labeled at one time
- Shift change or break, all meds and solutions and their labels are reviewed by entering and exiting persons
- Focus on single dose vials and multi-dose vials now
Anesthesia

- Would not apply if anesthesiologist draws up medication and immediately gives it and disposed of entire content of syringe without leaving area
  - Remember USP 797 requirements that drugs should not be prepared more than an hour in advance unless prepared in pharmacy
- However, if medication is prepared and slowly administered over course of procedure must be labeled
- Must be labeled if prepared for bulk of day’s cases or if prepared by someone other than the administering provider
- Use preprinted adhesive labels that can be applied to syringes and checked against original container
- Meds prepared by pharmacist in the OR would not require second person to verify
Anticoagulant Therapy  03.05.01

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

Rationale:

- This only applies to hospitals that provide anticoagulation therapy and long term anticoagulant prophylaxis such as atrial fib

- Does not apply to routine situations in which short term anticoagulant prophylaxis is used to prevent DVT or PE related to procedures or hospitalization

- If the expectation is that lab values for coagulation will remain close or within normal limits
Anticoagulants

- There are 8 EPs

1. Use only oral unit dose products, prefilled syringes, and pre-mixed bags, when these products are available
   - Helps prevent compounding errors
   - Make sure preloaded syringes with pediatric doses for pediatrics patients when available
   - Big issue with the Joint Commission
Anticoagulants

2. Use approved protocols for the start and maintenance of anticoagulation therapy
   - Also appropriate to the condition being treated, and to the potential for drug interactions
   - Example would be Heparin protocol and Coumadin protocols

3. When starting a patient on Coumadin (Warfarin) you need to have a baseline INR and need INR on patients receiving this drug to adjust the dosage and document in the medical record
Anticoagulants

4. Use authoritative resources to manage potential food and drug interactions for patients taking Coumadin

5. Make sure all IV continuous Heparin is on an IV programmable pump in order to provide consistent and accurate dosing

6. Have a written policy that addresses baseline and ongoing lab tests that are required for anticoagulants

- August 2010 Perspective changed removed “Heparin and LMW (low molecular weight heparin) therapies” and replaced it with “anticoagulants”
Anticoagulants

7. Provide education regarding anticoagulation therapy to prescribers, staff, patients, and families

- Patient/family education includes the importance of follow-up monitoring, compliance issues, drug food interactions (dietary restrictions), and potential for ADR and interactions

- Added prescribers to the list of those who need educated as reported in the December 2009 Perspective
Anticoagulants

8. Evaluates anticoagulation safety practices and take action to improve practices and measure how effective those actions are in the time frame set by the hospital

- See MM.08.01.01
- Hospitals should evaluate the effectiveness of its medication management system
- This is an important thing to do
- Collecting data on the performance of the medication management system can tell you if the process is working well or not
Anticoagulant Therapy

- Need a policy and procedure and make sure staff educated on policy
- Policy should address what lab tests are required for heparin and LMW heparin and baseline
- Patients on Coumadin need current INR to monitor and adjust
- Use approved protocols for the initiation and management of anticoagulant therapy
Anticoagulant Therapy

- Consider high risk such as double checks, product selection, dose calculation, patient identification, settings on IV pump, and proper IV line

- Have a formalized education program for both staff and patients

- To reduce compounding and labeling errors use only oral and parental unit dose and premix infusions

- Make sure all concentrations available are really needed
Anticoagulant Therapy

- Make sure you have enough IV pumps
- Make sure no more than one or two types of IV pumps (CMS hospital CoP requirement)
- Follow anticoagulant safety practices
- Medications should be clearly labeled
- Separate LASA and the Heparin errors
- Computer order entry, bar coding with eMAR, and automated dispensing units may help
Medication Reconciliation .03.06.01

- Standard: Maintain and communicate accurate patient medication information

- EP1 Obtain a list of medications the patient is taking when admitted or treated as an outpatient
  - The medications the patient is taking can be documented in another format that is useful to the hospital
  - Current medications include PRN medications
  - It is often difficult to obtain complete information on medications from some patients but a good faith effort must be made to get the information from the patient or other source
EP2 The type of information to be obtained needs to be defined in non-24 hour settings and different patient circumstances

- Examples would include the emergency department, primary care, outpatient radiology, ambulatory surgery and diagnostic settings
- Medication information to be collected might include name, dose, route, frequency, and frequency
- Patients are to be educated on medications under MM.06.01.03, PC.02.03.01 and PC.04.01.05
Medication Reconciliation .03.06.01

- EP3 The medication information brought in by the patient needs to be compared with the medications ordered
  - A qualified person, who is determined by the hospital, has to do the comparison
  - Discrepancies would include omissions, duplications, contraindications, unclear information, and changes
  - References HR.01.06.01 Staff are competent to perform their responsibilities
EP4 Provide the patient with a list or written information on the medications they need to take when discharged from the hospital or at the end of the outpatient encounter

- An example would be to include the name of the medication, dose, route, frequency and purpose
- The information is given to the family when indicated
- Note: When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications
- References PC.04.02.01 about communicating to providers when the patient is discharged
EP5 Explain the importance of managing medication information

- This is to be done when the patient is discharged from the hospital
- This is also to be done at the end of the outpatient care provided
- This could be instructing the patient to give a list to their primary care physician
- Also to update the information list when medications are discontinued or added
- This should also include OTC medications
Medication Education

- MM.06.01.03 Self administered medications are administered safety and accurately (has 7 EPs)
- PC.02.03.01 The hospital provides patient education and training based on each patient’s needs and abilities (27 EPs but only 6 apply to hospitals)
- PC.04.01.05 The patient is informed and educated about follow-up care before discharge or transfer (8 EPs but only 6 apply to hospitals)
References

- Institute for Safe Medication Practices (ISMP) at [www.ismp.org](http://www.ismp.org)
- The Food and Drug Administration (FDA) at [www.fda.gov](http://www.fda.gov)
- The Institute for Healthcare Improvement (IHI) at [www.ihi.org](http://www.ihi.org)
- The Society of Health System Pharmacist (ASHSP) at [www.ashp.org](http://www.ashp.org)
Resources

- National Patient Safety Agency (NHS) at http://www.npsa.nhs.uk/
- American Society of Anesthesiologist (ASA) at http://www.asahq.org/
- Agency for Healthcare Research and Quality (AHRQ) at www.ahrq.gov
- Pa Patient Safety Authority (PPSA) at www.patientsafetyauthority.org
- Safe Medication at www.safemедication.com
Sound alike/ look alike drugs


- Drugs with similar names can lead to medication errors,

- This is a partial list

- A complete list is available from the USP Medication Errors Reporting (MER) Program.

- Confusion can be between similar brand names and similar generic drugs,

- Some may look alike when written or sound alike when communicated verbally.
Preventing Errors from LASA Drugs

- See article on this from ISMP at http://www.ismp.org/msaarticles/nameprint.htm,
- Look for possible name confusion when adding a new drug to the formulary
- When feasible, use magnifying lenses
- Have good lightening in nursing stations
- Have copyholders under good lighting to keep prescriptions and orders at eye level during transcription to improve the likelihood of proper interpretation of look-alike product names
TJC Clarifies Multi-dose Vials

**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 Pharmacopoeia (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 an 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.

USP® and APIC® now recommend that opened or punctured multi-dose vials be used for no more than 28 days 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.

Alternatively, 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 expiration 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**


This presentation is intended solely to provide general information and does not constitute legal advice. Attendance at the presentation or later review of these printed materials does not create an attorney-client relationship with the presenter(s). You should not take any action based upon any information in this presentation without first consulting legal counsel familiar with your particular circumstances.
Thank you for attending!!

- Sue Dill Calloway RN, Esq. CPHRM
- AD, BA, BSN, MSN, JD
- President
- Patient Safety and Healthcare Consulting
- 5447 Fawnbrook Lane
- Dublin, Ohio 43017
- 614 791-1468
- sdill1@columbus.rr.com