Medication Security and Storage

CMS and Joint Commission Standards
What You Need to Know to Make Sure Your Hospital is in Compliance!
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Objectives

- Recall that both the Joint Commission and CMS have standards on medication security
- Discuss that drugs, biologicals, and controlled substances must be stored to prevent diversion
- Describe that both CMS and Joint Commission require the hospital to have a written policy to address the security of medications
- Discuss the requirement that medication storage areas must be periodically inspected
- Recall that CMS requires that only authorized individuals have access to locked areas
Letter from ASA to Joint Commission Urges Action on Medication Management Concerns

By Rachel Fields | December 28, 2010

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

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

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

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

Read more about anesthesia.
December 21, 2010

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

Re: Medication Management and Anesthesia Practice

Dear Dr. Chassin,

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

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

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

- Prohibition on pre-labeled syringes
- Labeling of spinal and epidural anesthetics and analgesics
April 26, 2011

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Dear Anesthesia Providers:

Thank you for your letter dated December 21, 2010, seeking information about and clarification of several of The Joint Commission Medication Management standards and how they apply to the practice of anesthesia.

You bring up several issues that I will address individually.
Letter From TJC Dated April 26, 2011

- TJC requires under NPSG.03.04.01 that all syringes must be labeled.
- TJC has removed the prohibition against pre-labeling.
- Have pulled the FAQ on this off their website.
- One exception exists
  - Unlabeled syringe can be used only if no break in the process meaning the person who draws it up administers the medication.
Letter From TJC

- Labeling is not required during the administration of epidural and spinals.

- However, if the person performing the procedure draws up the medication and lays it on the sterile field then there is a break in the process and it must be labeled.

- Second situation is when syringe is filled by a person who is not performing the procedure and lays it on the sterile field, this would also be a break in the process and must be labeled.
The prohibition against using a syringe which does not have a label on it is embedded in the safety culture.

TJC said aware that many kits now have a manufacturer's label.

- If kit has more than two medications then must be labeled so there is no mix up of the medications.

Kept the section that 2 people are needed to verify the filling of a medication if the person preparing it is not the one who will administer it.

- TJC plans to further investigate the issue.
Letter From TJC

- TJC will allow practitioners to carry medications in their pocket if there is a written policy on this.
- TJC standard aligns with CMS that medications be secured or in a secure area.
  - And only authorized persons have access to the medications.
- TJC said not aware of any incidents in which hospital was cited for MM.06.01.01 EP9 for inadequately explaining medications used in the practice of anesthesia.
CMS Hospital CoP Regulations and Interpretive Guidelines on Selected Topics Including Security and Storage of Medication
You Don’t Want One of These From CMS
CMS The Conditions of Participation CoPs

- CMS stands for the Center for Medicare and Medicaid Services.
- Any hospital that accepts Medicare or Medicaid payment must follow the standards contained in this 422 page manual.
- The standards must be followed for all patients in the hospital and not just Medicare or Medicaid patients.
  - PPS hospitals use the manual labeled Appendix A.
  - Critical access hospitals use Appendix W which are C numbered standards.
The regulations were first published in 1966

- Many revisions in past year with final interpretive guidelines December 22, 2011
- Anesthesia, Respiratory and Rehab Orders, Visitation, Telemedicine, Pharmacy, Blood Transfusions and IV Medications, 30 minute medication rule and standing orders

First regulations are published in the Federal Register first then publishes Interpretive Guidelines and some have survey procedures

- Hospitals should check the CMS Survey and certification website once a month for changes

Location of all of the CMS CoP Manuals

Medicare State Operations Manual
Appendix

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.

- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the red button in the 'Download' column to see any available file in PDF.

- To return to this page after opening a PDF file on your desktop, use the browser "back" button. This is because closing the file usually will also close most browsers.


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

Table of Contents

(Rev. 74, 12-02-11)
(Rev. 75, 12-02-11)
(Rev. 77, 12-22-11)
(Rev. 78, 12-22-11)

Transmittals for Appendix A

Survey Protocol

Introduction

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

Psychiatric Hospital Survey Module

Policy & Memos to States and Regions

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

Select From The Following Options:
- Show all items

- Show only (select one or more options):
  - Show only items whose [ ] is within the past [ ]
  - Show only items whose Fiscal Year is [ ]
  - Show only items containing the following word [ ]

Show Items

There are 455 items in this list.
Pharmacy Section Starts at Tag 490

A-0469

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

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

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

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

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

Survey Procedures §482.24(c)(2)(viii)

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

A-0490

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

§482.25 Condition of Participation: Pharmaceutical Services

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug
Pharmacy Tag 508 Revised May 20, 2011

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

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

DATE: May 13, 2011
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group

SUBJECT: State Operations Manual (SOM) Hospital Appendix A Update
*** In the attached SOM Transmittal, the reference to 484.24 is changed to 482.24 for Tag A-1164. The change is highlighted in yellow color. ***

Memorandum Summary

SOM Hospital Appendix A Updated
- Revisions have been made to reflect regulation changes governing orders for rehabilitation (42 CFR 482.56) and respiratory care services (42 CFR 482.57)
- Clarifications have been made for provisions related to:
  - Nursing requirements related to blood transfusions and intravenous medications (42 CFR 482.23(c)(3))
  - Immediate reporting of medication administration errors, adverse events, and incompatibilities (42 CFR 482.25(b)(6))
§482.25(b)(6) - Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

Interpretive Guidelines §482.25(b)(6)

Hospitals are required to ensure that the attending physician is made immediately aware of drug administration errors, adverse drug reactions, and incompatibilities. When the attending physician is unavailable, the covering physician must be notified. When the covering physician must be notified, the patient’s attending physician must be notified as soon as he/she is available. In addition, when appropriate, such events must also be reported to the hospital-wide Quality Assessment and Performance Improvement (QAPI) program.

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

- Drug administration error:

  The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is “Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and...
Many ASA members have struggled to comply with the hospital requirement that anesthesia carts be locked between cases. Over the last several years, surveyors from the Joint Commission and from state health agencies have surprised quite a few departments by insisting on an extremely strict interpretation of the old Medicare regulation that provided, “Drugs and biologicals shall be kept in a locked storage area” (Conditions of Participation, 42 C.F.R. §462.25(b)).

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

It was the intention of CMS to give hospitals more flexibility in their policies on the storage of noncontrolled substances. Drug Enforcement Administration (DEA) Schedule II, III, IV and V drugs must continue to be kept locked even within a “secure area” such as an operating room (O.R.) suite. (Schedule V drugs are not used in anesthesia practice.) Only authorized personnel may have access to these medications. Hospitals that store anesthesia carts in an operating room will need continued access to resuscitation drugs and also acknowledging the need to set up anesthesia carts in preparation for use in the O.R. or labor and delivery unit. The position statement provides that “Anesthesia carts and anesthesia machines may remain unlocked, and 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 O.R. suite.”

ASA members should consult the Position Statement on Medication Security, which is available at www.ASAhq.org/clinical/LockedCartPolicyFinalOct2003.pdf, in assisting their hospitals to update their own medication security policies.

Sample Policy Language

In the discussion accompanying the Federal Register notice regarding the revision to the regulation, CMS emphasized flexibility in allowing hospitals to determine their own medication security and storage policies. Thus there are several approaches, concepts and phrases that each hospital, in order to comply with the Medicare Conditions of Participation (42 C.F.R. §482.25 (b)),
ASA Sample Policy and Procedure

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

Pharmaceutical Services

Policies and Procedures — Security of Anesthesia Medications

Preamble
Anesthesiologists use medications both to sedate or anesthetize patients and to relieve pain, most commonly with controlled substances from DEA Schedules II, III and IV. Anesthesiologists also administer medications to manage the neuromuscular system, cardiovascular system and pulmonary system. Drugs used for these purposes must be made immediately available at all times in any active anesthetizing location. Limiting access to these resuscitation drugs even for a few seconds could seriously compromise patient safety. Any protocols or procedures designed to prevent tampering with or diversion of anesthesia medications must permit immediate access to resuscitation drugs, consistent with federal regulations (42 C.F.R. § 482.25 (b) (2)) that were revised effective January 28, 2007.

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

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

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

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

Procedures and Definitions

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

"Secure Area": Surgery, Intensive Care Unit, Emergency Room, Operating Room.
APSF Hosts Medication Safety Conference

Consensus Group Defines Challenges and Opportunities for Improved Practice

by John H. Eichhorn, MD

Overview

On January 26, 2010, the Anesthesia Patient Safety Foundation (APSF) convened a consensus conference of 100 stakeholders from many different backgrounds to develop new strategies for “predictable prompt improvement” of medication safety in the operating room. The proposed new paradigm to reduce medication errors causing harm to patients in the operating room is based on Standardization, Technology, Pharmacy/Prefilled/Premixed, and Culture (STPC). This new paradigm goes far beyond the important but traditional emphasis on medication label format and the admonition to “always read the label.” Small group sessions on each of the 4 elements of the new paradigm (STPC) debated and formulated specific recommendations that were organized and prioritized by all the attendees.
### Table 1: Consensus Recommendations for Improving Medication Safety in the Operating Room

#### Standardization

1. High alert drugs (such as phenylephrine and epinephrine) should be available in standardized concentrations/diluents prepared by pharmacy in a ready-to-use (bolus or infusion) form that is appropriate for both adult and pediatric patients. Infusions should be delivered by an electronically-controlled smart device containing a drug library.

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

3. **Additional Ideas:**
   a. Interdisciplinary and uniform curriculum for medication administration safety to be available to all training programs and facilities.
   b. No concentrated versions of any potentially lethal agents in the operating room.
   c. Required read-back in an environment for extremely high alert drugs such as heparin.
   d. Standardized placement of drugs within all anesthesia workstations in an institution.
   e. Convenient required method to save all used syringes and drug containers until case concluded.
   f. Standardized infusion libraries/protocols throughout an institution.
   g. Standardized route-specific connectors for tubing (IV, arterial, epidural, enteral).

#### Pharmacy/Prefilled/Premixed

1. Routine provider-prepared medications should be discontinued whenever possible.

2. Clinical pharmacists should be part of the perioperative/operating room team.

3. Standardized pre-prepared medication kits by case type should be used whenever possible.

4. **Additional Ideas:**
   a. Interdisciplinary and uniform curriculum for medication administration safety for all anesthesia professionals and pharmacists.
   b. Enhanced training of operating room pharmacists specifically as perioperative consultants.
   c. Deployment of ubiquitous automated dispensing machines in the operating room suite (with communication to central pharmacy and its information management system).

#### Technology

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

#### Culture

1. Establish a “just culture” for reporting errors (including near misses) and discussion of lessons learned.

2. Establish a culture of education, understanding, and accountability via a required curriculum and CME and dissemination of dramatic stories in the APSF Newsletter and educational videos.

3. Establish a culture of cooperation and recognition of the
Hospital must have a pharmacy to meet the patient’s needs and need to promote safe medication use process

Must be directed by registered pharmacist or drug storage area under constant supervision

MS is responsible for developing P&P to minimize drug error

Function may be delegated to the pharmacy service
Provide medication related information to hospital personnel

Medication Management is important to CMS and TJC

Contains list of functions of the pharmacist (collect patient specific information, monitor effects, identify goals, implement monitoring plan with patient, etc.)

- Add to pharmacy director job description

Flag new types of mistakes

- Hospital went completely computerized and found 22 new types of errors
CMS Pharmacy Policies Include:

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

- Drug recalls
- Patient specific information that should be readily available (TJC tells you exactly what this is, like age, sex, allergies, current medications, etc.)
- Means to incorporate external alerts and recommendation from national associations and government for review and policy revision (Joint Commission, ISMP, FDA, IHI, AHRQ, Med Watch, NCCMER, MEDMARX)
  - If medication management committee can assign each to one of the members to report at monthly meeting
Pharmacy Policies 490

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

- Problematic standard with both CMS and TJC

This includes compliance with state laws (pharmacy laws), and federal regulations (USP 797), standards by nationally recognized organizations (ASHP, FDA, NIH, USP, ISMP, etc.)

Pharmacy director must review P&P periodically and revise

- Remember to date policy to show last review and include sources such as CMS CoP or TJC standard
Pharmacy Management 491

- Drugs stored as per manufacture’s recommendations
- Pharmacy employees provide services within the scope of their licensure and education
  - Some states allow only pharmacist to do compounding
- Sufficient pharmacy records to follow flow from order to dispensing/administration
- Maintain control over floor stock
  - Make sure no expired medications and make sure all labeled
Pharmacist A-491

- Ensure drugs are dispensed only by licensed pharmacist
  - Pharmacist dispense and nurse administers
- Must have pharmacist to develop, supervise, and coordinate activities of pharmacy
- Can be part time, full time or consulting
- Single pharmacist must be responsible for overall administration of pharmacy
Pharmacist A-491

- Job description should define development, supervision, and coordination of all activities
- Must be knowledgeable about hospital pharmacy practice and management
- Must have adequate number of personnel to ensure quality pharmacy service, including emergency services
- Sufficient to provide services for 24 hours, 7 days a week
  - This means patients get stat drugs within time frame set
Pharmacy Delivery of Service 500

- Keep accurate records of all scheduled drugs
- Need policy to minimize drug diversion
- Drugs and biologicals must be controlled and distributed to provide patient safety
- In accordance with state and federal law and applicable standards of practice
- Accounting of the receipt and disposition of drugs subject to COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970
Pharmacist and hospital staff and committee develop guidelines and P&P to ensure control and distribution of medications and medication devices.

System in place to minimize high alert medication (double checks, dose limits, pre-printed orders, double checks, special packaging, etc.)

And on high risk patients (pediatric, geriatric, renal or hepatic impairment)

High alert meds may include investigational, controlled meds, medicines with narrow therapeutic range and sound alike/look alike.
Delivery of Service 500

- All medication orders must be reviewed by a pharmacist before **first dose** is dispensed.
- Includes review of therapeutic appropriateness of medication regime.
- Therapeutic duplication.
- Appropriateness of drug, dose, frequency, route and method of administration.
- Real or potential med-med, med-food, med-lab test, and med-disease interactions.
- Allergies or sensitivities and variation from organizational criteria for use.
Delivery of Service 500

- Sterile products should be prepared and labeled in suitable environment
- Pharmacy should participate in decisions about emergency medication kits (such as crash carts)
  - Remember issue of security of crash carts
  - Do HVA (hazard vulnerability analysis) to determine if under constant supervision or location of cart is safe such as just outside nurses station
- Medication stored should be consistent with age group and standards (such as pediatric doses for pediatric crash cart)
Delivery of Service 500

- Must have process to report serious adverse drug reactions to the FDA
  - Such as on Med Watch form
- Policy to address use of medications brought in
  - Policy, count drugs, patient signs release, locked in drawer, will help with medication reconciliation to bring in
- P&P to ensure investigational meds are safely controlled and administered
- Medications dispensed are retrieved when recalled or discontinued by manufacturer or FDA (eg. Vioxx)
Delivery of Service 500

- System in place to reconcile medication that are not administered and that remain in medication drawer when pharmacy restocks

- Will ask why it was not used?

- Not the same as medication reconciliation as in the TJC NPSG which all hospitals should still do from a patient safety perspective even if not TJC accredited

- TJC published revised Medication Reconciliation changes with 5 EPs which went into effect July 1, 2011
Reconciling Medication Information

Hospital Accreditation Program

NPSG.03.06.01
Maintain and communicate accurate patient medication information.

Elements of Performance for NPSG.03.06.01

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

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

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

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

5. Explain the importance of managing medication information to the patient when he or she is discharged from the hospital or at the end of an outpatient encounter.
   Note: Examples include instructing the patient to give a list to his or her primary care physician; to update the information when medications are discontinued, doses are changed, or new medications (including over-the-counter products) are added; and to carry medication information at all times in the event of emergency situations. (For information on patient education on medications, refer to Standards MM.06.01.03, PC.02.03.01, and PC.04.01.05.)
Compounding of Drugs  CMS A-501

- All compounding, packaging, and disposal of drugs and biologicals must be under the supervision of pharmacist

- Must be performed as required by state of federal law

- Staff ensure accuracy in medication preparation

- Staff uses appropriate technique to avoid contamination
Compounding of Drugs 501

- Use a laminar airflow hood to prepare any IV admixture, any sterile product made from non-sterile ingredients, or sterile product that will not be used within 24 hours (see USP 797)

- Meds should be dispensed in a safe manner and to meet the needs of the patient

- Quantities are minimized to avoid diversion, dispensed timely, and if feasible in unit dose

- All concerns, issues, or questions are clarified with the individual prescriber before dispensing
Locked Storage Areas A-502

- Drugs and biologicals must be kept in a secure and locked area when appropriate
  - Would be considered a secure area if staff actively providing care so before or after a case like in surgery
  - But not on a weekend when no one is around so you would lock up the anesthesia cart

- Schedule II, III, IV, and V must be kept locked within a secure area (see also 503)
  - This means all these scheduled drugs are locked up
  - Anesthesia usually does not give schedule V drugs
  - Only authorized person can get access to locked areas
Locked Storage Areas A-502

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

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

- May allow patients to have access to urgently needed drugs such as Nitro and inhalers
- CMS previously did not allow but changed their guidelines
- Need P&P on competence of patient, patient education and must meet elements in TJC MM standard on self administration
  - CMS mentioned TJC standard in Federal Register but not in interpretive guidelines
- Measures to secure bedside medications
Locked Storage Areas

- Saline flushes need to be secure to prevent tampering so under constant supervision or locked up
  - Should now have safe injection practice policy and follow CDC 10 requirements
  - CMS gets 50 million dollars to enforce infection control standards
  - Recommend even though FDA does not classify as medication

- If medication cart is in use and unlocked, then someone with legal access must be close by and directing monitoring the cart, like when the nurse is passing meds

- Need policy for safeguarding, transferring and availability of keys
Security of Medications In the Operating Room
American Society of Anesthesiologists
Position Statement
Approved by the ASA Executive Committee - October 2003

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

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

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

- This position statement is from American Society of Anesthesiologists

- Security of Medications in the Operating Room
  - All hospitals should also have a copy of the annual book published by AORN on Perioperative Standards and Recommended Practices and has Medication Safety section available for purchase at www.aorn.org
  - These are available off the ASA website¹

- Security of medications in the operating room

¹http://www.asahq.org/publicationsAndServices/sgstoc.htm
Policy and Procedure

- CMS states that they expect hospital P&P to address

- The security and monitoring of any carts including whether locked or unlocked if contains drugs and biologicals
  - TJC recommends hazard vulnerability analysis to evaluate location and safety of all carts containing medications

- In all patient care areas to ensure safe storage and patient safety

- P&P to keep drugs secure, prevent tampering, and diversion
Self administered medications are safely and accurately administered

If you allow self administration, need procedure to manage, train, supervise, and document process

TJC MM stands for medication management standard MM.06.01.03

If non-staff member administers (patient or family) must train and make sure competent to do so (give info on nature of med, how to administer, side effects, and how to monitor effects)

Patient has to be determined to be competent before allowed to self administer
Outdated or Mislabeled Drugs 505

- Outdated, mislabeled or otherwise unusable drugs and biologicals must not be available for patient use
- Hospital has a system to prevent outdated or mislabeled drugs
- Surveyor will spot check individual drug containers to make sure have all the required information including lot and control number, expiration date, strength, etc.
No Pharmacist on Duty A-0506

- If no pharmacist on duty, drugs removed from storage area are allowed only by personnel designated in policies of MS and pharmacy service
- Must be in accordance with state and federal law
- Routine access to pharmacy by non-pharmacist for access should be minimized and eliminated as much as possible
  - E.g. night cabinet for use by nurse supervisor
  - Need process to get meds to patient if urgent or emergent need
  - TJC does not allow nurse supervisor in pharmacy so would need to call in the on call pharmacist
No Pharmacist on Duty A-0506

- Access is limited to set of medications that has been approved by the hospital and only trained prescribers and nurses are permitted access.

- Quality control procedures are in place like second check by another or secondary verification like bar coding.

- Pharmacist reviews all medications removed and correlates with order first thing in the morning.
DATE: May 13, 2011
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group

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

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

Memorandum Summary

SOM Hospital Appendix A Updated

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

Background

The final FY 2011 Inpatient Prospective Payment System (IPPS) rule was published on August 16, 2010 (75 FR 50042) and effective on October 1, 2010. The FY 2011 IPPS final rule contained revisions to the Hospital Conditions of Participation (CoPs) governing rehabilitation
Pharmacy CoP Tag 508

- Must have definition of medication errors, ADR, and drug incompatibility
- Any unexpected reaction that occurs between the IV medications must also be reported
- Must have up to date information on drug incompatibilities
- If harm to patient on any of three must notify doctor immediately
- Need policy on when to notify immediately and when to notify later and document in chart
Pharmacy CoP Tag 508

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

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

www.drugs.com/drug_interactions.php
Drug Interaction Checker

Bisphosphonate Dosing

- Examine the evidence supporting the proven dosing schedule

Drug Interaction Checker


When should you order stress testing?
Learn about the uses for stress MPI
Pediatric Drug Interaction Checker

Drug Interaction Calculator

Enter up to 10 generic drugs in a prescription and get the various drug interactions that can occur.

Drug 1: ___________________________ Drug 2: ___________________________
Drug 3: ___________________________ Drug 4: ___________________________
Drug 5: ___________________________ Drug 6: ___________________________
Drug 7: ___________________________ Drug 8: ___________________________
Drug 9: ___________________________ Drug 10: ___________________________

Submit Details  Reset
Drug Interaction Checker

Drug Interactions

<table>
<thead>
<tr>
<th>Drug × Drug</th>
<th>Drug × Food</th>
<th>Drug × Lab Test</th>
<th>Drug × Herb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Websites</td>
<td>Websites</td>
<td>Print &amp; Electronic Resources</td>
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<td>Dynamic Searches</td>
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</tr>
</tbody>
</table>

Drug-Drug Interactions

Websites:

General Interactions:

- Current Topics in Drug Interactions (Hansten & Horn)
- Cytochrome P450 Drug Interaction Table (Indiana University School of Medicine)
- Cytochrome P450 Drug Interaction Table (InterMED-Rx) - $
- Drug Interaction Checker (DrugDigest)
- Drug Interaction Checker (Medscape, registration required)

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

IVMedication Compatibility Charts

- IV Medication Compatibility Chart
- Low Vitamin D Symptoms
- Low Blood Pressure
- High Blood Pressure Medication
- IV Medication Compatibility Chart Privacy Policy
- Contact Us At IVMedication Compatibility Chart

Site Map

Pharmaceutical Admixtures www.PharMEDIum.com
Quality IV & Epidural Preparations. View Our Selection Online Today!

Effective Drug Treatment www.TheRecoveryPlace.net/Treatment
Drug Treatment and Rehabilitation Programs. Call (888) 494-8536!

LYRICA® (pregabalin) CV www.PfizerPro.com/Lyrica
Get Prescribing Information And Other Resources At PfizerPro.com.

#1 Addiction Rehab Center TransformationsTreatment.co
Adult, Addiction Rehab & Detox All Private Rooms,

www.ivmedicationcompatibilitychart.com/
| Drug Name                      | Albumin | Alteplase (Activase, rTPA) | Amiodarone (Cordarone) | Atropine | Calcium chloride | Cisatracurium (Nimbex) | Diltiazem (Cardizem) | Dobutamine (Dobutrex) | Dopamine | Epinephrine (Adrenalin) | Esmolol (Brevibloc) | Etomidate (Amidate) | Fentanyl (Sublimaze) | Furosemide (Lasix) | Heparin | Insulin, regular | Isoproterenol (Isuprel) | Lidocaine (Xylocaine) | Lorazepam (Ativan) | Magnesium sulfate | Metoprolol (Lopressor) | Mirilimone (Primacor) | Morphine | Nesiritide (Natrecor) | Nicardipine (Cardene) | Norepinephrine (Levophed) | Pancuronium (Pavulon) | Pantoprazole (Protonix) |
|-------------------------------|---------|----------------------------|------------------------|----------|-----------------|-----------------------|----------------------|----------------------|----------|-----------------------|-------------------|------------------|---------------------|----------------|---------|----------------|----------------------|----------------------|----------------|-----------------|----------------------|-----------------------|----------------|----------------|----------------|----------------------|----------------|----------------|----------------|----------------------|----------------|----------------|----------------|----------------------|
Hospital Policies and Procedures (P&P) 508

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

- Non-punitive environment so staff will report
- Many hospitals balance the non-punitive environment with Just Culture

Should focus on system analysis theory and system issues and not individual staff

- The majority of medication errors are made by long term employees with unblemished records
- It is a system that allows the error to occur
Hospital Requirements  A-508

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

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

www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/#Trigger
Trigger Tool for Measuring Adverse Drug Events

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

NOTE: You can use this tool in conjunction with the interactive Trigger Tool for Measuring ADEs in the Workspace area on IHI.org. Enter your detailed data from all of your ADE Patient Record Review Sheets into the interactive Trigger Tool for Measuring ADEs. The Tool will automatically calculate and graph two measures: ADEs per 1,000 Doses and Percent of Admissions with an ADE.
Hospital must have a method to evaluate the effectiveness of its systems for identifying and reporting medication errors and ADEs to the PI program.

- Methods could include the use of standardized benchmarks for size and scope of services provided.
  - Or studies on reporting rate published in peer review journals.
- CMS encourages hospitals to report ADE, medication errors, and incompatibilities.
Medication Error Reporting  A-0508

- Reporting is not limited to
- The Food and Drug Administration’s (FDA) MedWatch program
- The Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program (USP-ISMP MERP)
  - https://www.ismp.org/orderforms/reporterrortoismp.asp
- Any reports required by any specific state law requirement
Survey Procedure A-0508

- Surveyor is supposed to pull the policy and make sure there is a definition of medication errors, ADR, and DI

- P&P must discuss when to report these immediately to the attending physician and to PI program

- Surveyor to make sure all medication errors and suspected ADEs are documented in the medical record

- Will ask staff what they do when they become aware of the above 3 things
Survey Procedure A-0508

- Surveyor is to make sure staff are aware of the hospital’s P&P on reporting and documentation of all medication errors and ADEs

- Will ask how this information gets reported to the hospital PI program

- Surveyor is to make sure the hospital’s definition of ADR and medication error is based on national standards
  - These were provided by CMS in the interpretive guidelines
Medications Errors A-0509

- Hospital must proactively identify med errors and ADE and can not rely solely on incident reports

- Proactive includes observation of med passes, concurrent and retrospective review of patient’s clinical record, ADR surveillance, evaluation of high alert drugs and indicator drugs (Narcan, Romazicon, Benadryl, Digibind, et al) or generate a review for potential ADE

- Remember FMEA (failure mode and effect analysis) and IHI adverse event trigger tool is great

  - Has trigger tool for adverse drug events in hospitals, pediatrics and on the mental health unit at www.ihi.org
Trigger Tool for Measuring Adverse Drug Events (IHI Tool)

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

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

Read the related article about using the Trigger Tool:

For more general information on Trigger Tools and how to select...

www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/TriggerTool+for+Measuring+Adverse+Drug+Events+%28IHI+Tool+%29.htm
Abuses and Losses 509

- Abuses and losses of controlled substances must be reported pharmacist and CEO and in accordance with any state or federal laws
- Surveyor will interview pharmacist to determine their understanding of controlled substances policies
- What is procedure for discovering drug discrepancies?
- Remember state board of pharmacy rules on abuses and losses
Drug Interaction Information 510

- Information on drug interactions and information on drug side effects, toxicology, dosage, indication for use and routes of administration must be available to staff

- Texts and other resources must be available for staff at nursing stations and drug storage areas

- Staff development programs on new drugs added to the formulary and how to resolve drug therapy problems
Drug Identification and Interactions

- Drug interaction checker available at www.drugs.com/drug_interactions.php
- Pill wizard to identify medication with pictures at www.drugs.com/pill_identification.html
- You can search more than 3,700 drugs for dose, interactions etc. at https://online.epocrates.com/
- FDA announced on May 26, 2010 that they are collaborating with drugs.com to expand access for consumer to FDA consumer information
Drug Interactions Checker

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

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

Please sign in to view previously saved lists.

Disclaimer: Every effort has been made to ensure that the information provided by Multum is accurate, up-to-date, and complete, but no guarantee is made to that effect. In addition, the drug information contained herein may be time sensitive and should not be utilized as a reference resource beyond the date hereof. Multum’s drug information does not endorse drugs, diagnose patients, or recommend therapy. Multum’s drug information is a reference resource designed as supplement to, and not a substitute for, the expertise, skill, knowledge, and judgement of healthcare practitioners in patient care. The absence of a warning for a given drug or drug combination in no way should be construed to indicate that the drug of drug combination is safe, effective, or appropriate for any given patient. Multum Information Services, Inc. does not assume any responsibility for any aspect of healthcare administered with the aid of information Multum provides. Copyright 2000-2010 Multum Information Services, Inc. The information contained herein is not intended to cover all possible uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the drugs you are taking, check with your doctor, nurse, or pharmacist.
Epocrates Online drug and disease reference provides:

- Access to extensive disease database
- Dosina for 3,300+ brand and generic drugs
- MultiCheck drug interaction checker
- Hundreds of brand name OTC drug products
- 600 alternative medicines, including interactions
- Pill identifier
- Hundreds of calculators and clinical criteria

*Available with Epocrates Online Premium

Select a medication above to begin
The Joint Commission Standards on Selected Standards on Medication Security and Storage
Storage of Medications MM.03.01.01

- Joint Commission (TJC) has a standard on storage of medications in Medication Management 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
- Law and regulation (CMS Hospital CoPs) and manufacturers' guidelines further define the hospital’s approach to medication storage
<table>
<thead>
<tr>
<th>Description</th>
<th>MOS</th>
<th>Cr</th>
<th>PFA</th>
<th>Doc</th>
<th>SC</th>
<th>ESP</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 The hospital stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.</td>
<td>IM, MM, PE, Staffing</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>3 The hospital stores all medications and biologicals, including controlled (scheduled) medications, in a secured area to prevent diversion, and locked when necessary, in accordance with law and regulation.</td>
<td>MM, OS, PE</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>4 The hospital has a written policy addressing the control of medication between receipt by an individual health care provider and administration of the medication, including safe storage, handling, security, disposition, and return to storage.</td>
<td>IM, MM</td>
<td></td>
<td></td>
<td></td>
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<td>ESP-1</td>
</tr>
<tr>
<td>5 The hospital implements its policy addressing the control of medication between receipt by an individual health care provider and its administration.</td>
<td>IM, MM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 The hospital prevents unauthorized individuals from obtaining medications in accordance with its policy and law and regulation.</td>
<td>MM, OS, PE</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>7 All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.</td>
<td>IM, MM, SE</td>
<td></td>
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<tr>
<td>8 The hospital removes all expired, damaged, and/or contaminated medications and stores them separately from medications available for administration.</td>
<td>MM, PE, SE</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>9 The hospital keeps concentrated electrolytes present in patient care areas only when patient safety necessitates their immediate use, and precautions are used to prevent inadvertent administration. <em>(See also MM.01.01.03, EP 2)</em></td>
<td>MM, PE, SE</td>
<td></td>
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</tr>
<tr>
<td>10 Medications in patient care areas are available in the most ready-to-administer forms commercially available or, if feasible, in unit-doses that have been repackaged by the pharmacy or a licensed repackager.</td>
<td>MM, SE</td>
<td></td>
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<tr>
<td>11 The hospital periodically inspects all medication storage areas.</td>
<td>MM, PE</td>
<td></td>
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</tr>
<tr>
<td>19 For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital has a pharmacy directed by a registered pharmacist or a supervised drug storage area, in accordance with law and regulation.</td>
<td>MM, OT, Staffing</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Storage of Medications MM.03.01.01

- There are 19 EPs but only 11 apply to hospitals
  - Top problematic standard for hospitals
- This standard says that the hospital safety stores medication
- This standard has a rationale
- Storage of medication is to maintain integrity of the medications
- Storage of medication is also to minimize the risk of medication diversion
- Also to reduce potential dispensing errors
EP2  Medications must be stored according to the manufacturers instructions

- If none then according to a pharmacist’s instructions

- Examples include some medications must be kept out of light or refrigerated and include this in your P&P such as

- “Medications which require special storage such as Protect from Light or Do Not Refrigerate should be labeled, packaged and stored accordingly
Storage of Medications MM.03.01.01

- Make sure refrigerators for medications say “For Medication Only. No Food Allowed”
- Monitor the temperature of the refrigerators
- Know what to do if the temperature deviates from the normal temperature such as discard medications
- Note TJC FAQ on this from November 24, 2008
  - TJC does not specifically require temperature logs for refrigerators used for medication storage
Storage of Medications MM.03.01.01

- Must store medications according to manufacturer recommendation

- EC.01.01.01 requires to have a process to maintain and monitor equipment performance

- Include in your policy storage requirements such as Refrigeration: 36-46F, Freezer: 4-14F, Cool Place: 46-59F, Room Temperature: 59-86F

- Have director of pharmacy or qualified designee inspect monthly all nursing care units or other units where medications are dispensed and make sure no expired medications
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.
Pharmacy Storage and Retrieval System

- Automated system for storing and dispensing medications
- Dual temperature boxes allow automatic storage and picking of temperature sensitive drugs within one compact unit
So What’s In Your Policy?

- DEPARTMENT OF PHARMACY
- MEDICATION STORAGE

I. Drug storage and preparation areas within the pharmacy and throughout the hospital are under the supervision of the Director of Pharmacy

II. ALL MEDICATIONS ARE TO BE STORED IN STRICT COMPLIANCE WITH THE MANUFACTURERS DIRECTIONS FOR STORAGE AND/OR USP STANDARDS FOR STORAGE PRIOR TO USE.
So What’s In Your Policy?

III. Floor stock medications are to be housed in locked floor stock cabinets located in the Medication Rooms or are contained in the Acudose cabinets. Unused and unopened medications must be returned to the Automated Dispensing Machine or the pharmacy. Access to the medication rooms and the Automated Dispensing Machine are limited to authorized personnel only.

IV. Narcotic medication floor stock are to be housed in locked Narcotic drawers in the medication rooms or contained in the Automated Dispensing Machine. Unused and unopened medications must be returned to the Automated Dispensing Machine or
Storage of Medications MM.03.01.01

- EP3 Drugs, biologicals and controlled scheduled drugs are stored to prevent diversion and locked as necessary and as required by law
  - Scheduled drugs are Schedule II-V of the Comprehensive Drug Abuse Prevention and Control Act
  - So these Drug Enforcement Administration (DEA) scheduled drugs must be locked up
  - CMS made changes in the hospital CoP and now says all drugs and biologicals must be kept in a secure area and locked when appropriate
Medication Security and Storage Policy

**Purpose:**
This policy promotes patient safety by ensuring compliance with State and Federal laws as well as Joint Commission and Aspen regulations while limiting the opportunity for unauthorized use of loss of medication.

**Definitions:**
A listing of definitions of key terms is provided in Appendix A of this policy.

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

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

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

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

Controlled substances may only be handled by authorized Pharmacy personnel and must be processed in accordance with Pharmacy procedure C-009.

Additional procedures over the receipt of medications may be found in Pharmacy Manual
Storage of Medications

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

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

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

Transportation and Delivery of Medications

Transportation: Medications may only be transported via prescribed manners.

Different types of medications are transported in different ways:

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

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

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

Delivery:

Controlled substances must be delivered to the appropriate Pyxis machine or double locked facility. (For additional details see pharmacy manual C-009)

When a pharmacist or pharmacist tech delivers medication it may be delivered to either the
Storage of Medications

- EP4- A written policy is needed to address control of medication across the continuum

- This would start when the medication are received by the hospital and through administration of the medications

  - Must also include safe storage, handling, security, disposition, and return to storage

  - Want to have proper checks and balances to insure accuracy of medications received and their security
Storage of Medications MM.03.01.01

- EP5  Hospital implements its policy addressing the control of medications between receipt by the provider and its administration

- EP6  Unauthorized individuals are prevent from obtaining medications in accordance with policy and law
  - Hospital need to prevent drug diversions
  - Automated dispensing units and software can help track medication used in the hospitals
  - Co-signatures when wasting narcotics on the Narcotic and Controlled Drug Administration record and make sure witnessed the destruction
Security of Medications MM.03.01.01

- Housekeeping, security, and maintenance do not have unsupervised access in medications in the pharmacy
  - Access to pharmacy is limited to authorized pharmacy personnel
  - Pharmacy volunteers can be authorized to deliver medications

- Lock carts in the OB where C-sections are done when not in use

- Lock anesthesia carts at night and when there an active case is not going on

- Don’t have medications on top of carts that can be taken when not in a secured area
Security of Medications MM.03.01.01

- Watch wasted medications and have a system to deposit
- Diversion programs generally focus on narcotics and other controlled substances but other drugs can be involved
- Make sure drugs are not sent on freight dumbwaiters and tube systems that come out in unsecured areas
- Run reports to see who removes what drugs
  - One hospital that ran a report found they were losing 10,000 tablets per month of Lomotil so now they lock it up
  - Can run a report to track practitioner use and can show if pulling more doses than the patient received
  - Hospital should keep a discrepancy monitoring log to track it
Pay attention to anesthesia and respiratory therapy drugs

Nursing medication carts and cabinets that contain medications must be locked when not in use

If nurse is passing medication from a med cart (not an automatic dispensing cabinet or ADC) then need to keep cart in line of vision

Medication from automated dispensing cabinet should be given asap after removal and not left unattended

Remove all expired, damaged, and or contaminated medications and store them separately and place in pharmacy return bin
Security of Medications MM.03.01.01

- Nursing staff should be familiar with the policy on proper disposal of medication and medication waste along with policy on security of medications.

- Single dose medications can not be used on more than one patient so make sure staff understand the safe injection practices policy or waste policy.

- EP7 All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.
Medication Security in Hospitals

Goal:

Medications shall be stored in hospitals in a secure manner to protect public health and safety, and to promote patient care.

1. Medications stored in a hospital must be secured in accordance with federal, state, and local laws.
2. Department of Health oversight of hospital medication security by Facilities and Services Licensing, and the Board of Pharmacy, should be consistent and coordinated.
3. The Board of Pharmacy is the primary source of policy determination with respect to medication security.
4. Hospitals are expected to adopt appropriate, site-specific medication security procedures.

General requirements for medication security:

1. Procurement, preparation, storage, distribution, and control of all drugs throughout a hospital is the responsibility of the Director of Pharmacy.
2. The Director of Pharmacy is specifically responsible for the hospital medication security procedures and shall demonstrate they are appropriate to their facility and consistent with current standards of practice.
3. The hospital medication security procedures must both ensure that drugs are secure from the public and allow appropriate access by authorized personnel.
4. Hospital pharmacy directors must work with their counterparts in nursing, medicine and administration to ensure compliance with appropriate medication security policies and procedures.

Definition:

"Authorized personnel" will be defined by the Director of Pharmacy.
**Clarification: Expiration of Multi-dose Vials**

**Discard 28 Days after First Use**

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

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

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

**References**

2. APIC: APIC Position Paper: Safe Injection, Infusion and Medication Vial
Storage of Medications MM.03.01.01

- EP8 All expired, damaged, or contaminated medications are removed
  - 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
  - In unit doses that have repackaged by the pharmacist or licensed repackaged
  - Anticoagulants use see NPSG.03.05.01

- EP18  Hospital inspects medication storage areas periodically

- E19 Pharmacy is directed by registered pharmacist or you must have a supervised drug storage area, in accordance with law and regulation (Deemed Status)
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
- Should do hazard vulnerability analysis on the location of all carts and places where medications are stored including crash carts
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.

- TJC has a FAQ on the security of anesthesia carts.
Security of Anesthesia Cart Medications

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

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

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

Purpose

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

Background

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

The use of automated medication storage and distribution devices continues to evolve. Some health care organizations deploy one or several devices in selected areas, such as emergency rooms, that are floor-stock intensive and where lost charges can be substantial; or for selected categories of medications, such as controlled substances, that have time-
ISMP Self Assessment 2011

http://www.ismp.org

Here's what's new!

AHA Webinar on Drug Shortages and ISMP Self Assessment

FDA/ISMP Safe Medication Management Fellowship

Medication Safety Tools & Resources

• New Standard Concentrations of Neonatal Drug Infusions
• Articles of Interest
TEAM UP TO PREVENT ERRORS

2011 ISMP Medication Safety Self Assessment® for Hospitals Is Coming

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

The medication safety self assessment helps hospitals to:

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

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

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

For more information:
www.ismp.org
selfassess@ismp.org
215.947.7797
ISMP Neonatal Drug Infusions

Standard Concentrations of Neonatal Drug Infusions
A collaborative effort between the Institute for Safe Medication Practices (ISMP) and Vermont Oxford Network (VON)

The drug concentrations provided below are the result of a national effort to standardize typical neonatal drug infusions across all US hospitals. ISMP and the Vermont Oxford Network (VON), a nonprofit voluntary group of healthcare professionals working to improve newborn care, collaborated with representatives from neonatal intensive care units in the US to identify and promote the standard concentrations of typical neonatal drug infusions listed in the table that follows. Some drugs include two standard concentrations to accommodate various weights of neonates, including low-birth-weight infants.

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

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

We urge all hospitals that treat neonatal patients to consider adopting these standard drug concentrations. Join our national effort to reduce the risk of harmful errors when caring for our tiniest patients!

<table>
<thead>
<tr>
<th>Drug</th>
<th>Type(s) of Infusions</th>
<th>Recommended Concentrations*</th>
</tr>
</thead>
<tbody>
<tr>
<td>acyclovir</td>
<td>intermittent infusion**</td>
<td>7 mg/mL</td>
</tr>
<tr>
<td>alprostadil</td>
<td>continuous infusion</td>
<td>10 mcg/mL</td>
</tr>
<tr>
<td>amphotericin B</td>
<td>intermittent infusion**</td>
<td>0.1 mg/mL</td>
</tr>
<tr>
<td>amphotericin B liposomal</td>
<td>intermittent infusion**</td>
<td>1 mg/mL</td>
</tr>
<tr>
<td>ceFAZolin</td>
<td>intermittent infusion**</td>
<td>100 mg/mL</td>
</tr>
<tr>
<td>cefotaxime</td>
<td>intermittent infusion**</td>
<td>100 mg/mL</td>
</tr>
<tr>
<td>clindamycin</td>
<td>intermittent infusion**</td>
<td>6 mg/mL</td>
</tr>
<tr>
<td>diazepam</td>
<td>intermittent infusion**</td>
<td>20 mcg/mL</td>
</tr>
</tbody>
</table>
MM.03.01.03 Emergency Medications

- 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 4 EPs

- 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 or hazard vulnerability analysis
  - Schedule II-V must be locked
Accessible Emergency Medicines

- 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
Guidelines for Care of Children in the ED

http://www.acep.org/Content.aspx?id=29134&terms=Guidelines%20for%20Care%20of%20Children%20in%20the%20Emergency%20Department
### Table 1. Guidelines for Medications for Use in Pediatric Patients in EDs

<table>
<thead>
<tr>
<th>Resuscitation Medications</th>
<th>Other Drug Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atropine</td>
<td>Activated charcoal</td>
</tr>
<tr>
<td>Adenosine</td>
<td>Topical, oral and parenteral analgesics</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>Antimicrobials (parenteral and oral)</td>
</tr>
<tr>
<td>Antiemetics</td>
<td>Anticonvulsants</td>
</tr>
<tr>
<td>Calcium chloride</td>
<td>Antidotes (common antidotes should be accessible to the ED)</td>
</tr>
<tr>
<td>Dextrose (D10W, D50W)</td>
<td>Antipyretics</td>
</tr>
<tr>
<td>Epinephrine (1:1000; 1:10 000 solutions)</td>
<td>Bronchodilators</td>
</tr>
</tbody>
</table>
Appendix 2. Guidelines for Equipment and Supplies for Use in Pediatric Patients in the ED

General Equipment

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

Monitoring Equipment

- Blood pressure cuffs (neonatal, infant, child, adult-arm, and thigh)
- Doppler ultrasonography devices
- ECG monitor/defibrillator with pediatric and adult capabilities including pediatric-sized pads/paddles
- Hypothermia thermometer
- Pulse oximeter with pediatric and adult probes
- Continuous end-tidal CO₂ monitoring device

Respiratory Equipment and Supplies
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
EP3 Emergency medications need to be available in unit dose, age specific, and ready to administer forms

- Remember to ensure pediatric doses are available which is especially important in a code
- Make sure you have a current Broselow pediatric tape
- Emergency ACLS drugs like Atropine or EPI should be in its ready to use injectible form during a code
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
  - Make sure medications are secure when returning the used cart to the pharmacy to be restocked
  - Don’t want surveyor to find crash cart not restocked after it was used
MM.03.01.05 Medications Brought In

- **Standard** Hospital safety 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 they may not have a non-formulary drug or herbal agent.

- Another valid reason 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.
Medications Brought In 3 EPs

- EP1  Hospital defines when medications are brought in by patients 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 3 EPs

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

- So develop your process is to safety manage medications brought from home (signed form, counted, locked in drawer, physician order, integrity of bottle of medications clearly labeled by a pharmacist, medication not outdated, no state law prohibitions etc.)
Medication Brought in by LIP

- 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.
Goal 3: Improve the Safety of Using Medications

- The Joint Commission has a National Patient Safety Goal (NPSG) and Medication Management (MM) standard on labeling of medications

- There are 3 sections left in 2012 in this goal
  - This is NPSG.03.04.01 (3D) on labeling of medications
  - NPSG.03.05.01 (3E) on reducing harm from anticoagulants
  - Medication Reconciliation which became effective July 1, 2011

- TJC has a FAQ
Procedures outside of the OR
Q. Does NPSG.03.04.01 apply only in the operating room?

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

Immediate use of a medication or solution
Q. Is there an exception to the labeling requirement for immediate use?

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

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

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

- Made a decision that NPSG.03.04.01 no longer prohibits pre-labeling
- Should note both risks and benefits in pre-labeling syringes
- TJC has decided to change the interpretation of this goal
- For years prohibited this through a FAQ but this has now been removed
- If surveyor witnesses this will confirm hospital has made a deliberate decision to do this
  - Email from Kimberly Anderson-Drevs of the Standards Interpretation Group of the Joint Commission
Content of the label
Q. When labeling medications and solutions in the context of NPSG.03.04.01, what information must be on the label?

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

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

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

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

A. It is acceptable to purchase and use pre-filled, pre-labeled syringes such as on procedure trays. However prelabeling medication and solution containers is not acceptable. The label should be prepared and applied at the time the medication or solution is prepared. Applying the label immediately before drawing up the medication is acceptable and may make the process of checking the label against the original container more efficient. Engraving basins for use only with sterile saline or other routine solutions also carries risk of pouring a solution into a basin that is pre-labeled for a different solution; this approach is not considered acceptable.
Pre-labeled syringes
Q. It has been our practice to pre-label syringes for anesthesia medications for the anesthesia cart in the trauma room as a means of reducing the time it takes to prepare needed medications when faced with an emergency situation. Is this acceptable?

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

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

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

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

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

- Under USP 797 if medications are prepared in pharmacy they are good for 48 hours unless state law is more restrictive

- The APSF hosts a medication safety conference and makes the following recommendations
  - Routine provider-prepared medications should be discontinued whenever possible
  - Clinical pharmacists should be part of the perioperative/operating room team
  - Standardized pre-prepared medication kits by case type should be used whenever possible
Anesthesia Patient Safety Foundation Report

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

APSF Hosts Medication Safety Conference
Consensus Group Defines Challenges and Opportunities for Improved Practice

by John H. Eichhorn, MD

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

- **Standardization**
  - High-alert drugs (such as chemotherapy and

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

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

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

institutions, professional organizations, and accreditation agencies.

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

CONFERENCE REPORT
Responder reports of medication errors among
NPSG On Medication Labeling

- There are 8 elements of performance to NPSG.03.04.01 on medication labeling
  - 2010 revision to include the preparation date and expiration date and time
- The standard requires hospital to do the following;
  - Label all medications and medication containers (syringes, medicine cups, basins), and other solutions on and off the sterile field or procedural setting
Label all Medication

- EP1 In the 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
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 data 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 NPSG.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
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
Pharmaceutical Compounding—Sterile Preparations

INTRODUCTION

The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from the following: 1) microbial contamination (nonsterility), 2) excessive bacterial endotoxins, 3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see “official” and “article” in the General Notices and Requirements) or 10% for nonofficial articles, 4) unintended chemical and physical contaminants, and 5) incorrect types and qualities of ingredients in Compounded Sterile Preparations (CSPs). Nonsterile CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints; and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins (see Bacterial Endotoxins Test §85), they are potentially most hazardous to
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
- See additional slides on the CDC 10 standards on safe injection practices
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**

- **Labels for medications are discussed under NPSG.03.04.01 and slides on this standard at the end of the presentation**
Labeling of Medications  MM.05.01.09

- EP1  A medication must be labeled when prepared if not immediately given
  - Exception is nurse in ED prepares Phenergan 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 (very few drugs)
  - The date prepared and the diluent for all compounded drugs
  - Intravenous admixtures and parenteral nutrition formulas (plain IVs do not need a label)
Labeling of Medications  MM.05.01.09

- 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
  - 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
Labeling of Medications

- 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
- Single dose vials used on one patient
- One single one needle every time
- Multidose only if single not available and mark expiration date on it which is usually 30 days
Labeling of Medications

- Do not need to label if you draw up medication and give it immediately

- If you remove from original container to use over the course of a procedure you must label it
  - This include saline, prep solutions, local anesthetics etc.

- Be sure what is on the label is consistent with MM.05.01.09 and NPSG.03.04.01
Labeling of Medications

- It is acceptable to buy and use the pre-filled and pre-labeled syringes
  - However, pre-labeling medications or containers in advance of putting in the medication or solution is not allowed
  - You must draw up one medication or solution at a time and affix the label and verify the label against the original container
  - You can not pre-label a bunch of empty syringes in advance to save time for anesthesia medication or in the trauma room
  - So buy the pre-filled and pre-labeled syringes
Labeling of Medications

- TJC FAQ also says you cannot tape a vial from which the medication was drawn to the syringe.
  - You must prepare a label for the syringe to include the required elements such as drug name, strength, amount (if not apparent from the container) and an expiration date if not used in 24 hours and any time one of the few medications has a short life and the expiration occurs in less than 24 hours.
- Medications prepared by the pharmacist who is assigned to the OR do not need a second person verification.
Additional Resources Provided

- TJC standard on standards when the pharmacy is closed which are similar to CMS
- Additional standard on medications from CMS found outside the pharmacy chapter such as the 30 minute rule to administer medications amended Dec 22, 2011
- More on safe injection practices
- Beer’s List of Medications on AHRQ website
- Pharmacist health literacy guide
The End! Questions??

- Sue Dill Calloway RN, Esq. CPHRM
- AD, BA, BSN, MSN, JD
- President of Patient Safety and Health Care Consulting
- Chief Learning Officer of the Emergency Medicine Patient Safety Foundation at www.empsf.org
- 614 791-1468
- sdill1@columbus.rr.com
- Additional resources follow
TJC Pharmacy Closed Standards

- The Joint Commission has standards on what to do when the pharmacy is closed.
- These are similar to the ones required by CMS that have been previously discussed.
- There have been several hospitals that have reported being cited by CMS for not having a pharmacist do a first review of medications when things are given by the nurse and nurse supervisor out of the night cabinet.
  - Consider telepharmacy where companies are now doing this since pharmacist can not be on call all the time.
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.**
Pharmacy is Closed

- **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

- 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

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

- 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 at another location to answer questions or retrieval medications not in night cabinet
- EP7 Hospital needs to implement its process when the pharmacy is closed
There are other references to medication besides the pharmacy/medication section.

Page 17 in the survey process is the section that surveyors should look for outdated medications in the pharmacy.

Page 79 discusses psychiatric advance directives and the use of medication.

Page 91 looks at medications and assesses risks for falls and unsteady gait.

Tag 160 discusses the use of medications and when it is appropriate to use restraints.
Physically holding to give a medication is a restraint (Tag 160)

Must assess medication in one hour face to face visit for patients who are V/SD (Tag 179)

Must include medications and allergies in H&P (Tag 358)

Surveyor to select patients and review all medication order and MARs (Tag 404)

Drugs must be administered under the supervision of nursing and with approved MS P&Ps (Tag 405)

Drugs must be administered within timeframe of 3 different ones and nurse must remain with patient until taken (Tag 405)
CMS Manual

- Must monitor medications as part of PI process including errors (Tag 405)
- Any questions on medications is resolved prior to administration (Tag 406)
- Need all elements of a complete drug order (Tag 406 and similar to questions asked on TJC Medication Management tracer)
- Verbal orders used infrequently and pose a risk of medication errors (Tag 407)
Staff must have education on blood and IV medications (Tag 409)

Medical record must contain response to medications (Tag 449 and 464)

Medical record must contain all medications given including any unfavorable reactions to drugs (Tag 467)

Diets must meet needs of patients including patients taking certain medications (Tag 628)

Adequate lighting in medication preparation areas (Tag 726)
 Patients must be counseled in timing and dosage of medications and effects for post hospital care (Tag 822)

Need policy on storage, access, control, and administration of medications and medications errors (Tag 1160)
Pharmacy Health Literacy Guide

- AHRQ has a free tool “Is Our Pharmacy Meeting Patients’ Needs?
- This is a Pharmacy Health Literacy Assessment Tool
- Includes introduction, survey of pharmacy staff section, assessment of the pharmacy, using assessment results etc
- Includes flow charts for conducting a health literacy assessment, guide, etc.
Beer’s List

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

## BEERS CRITERIA


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

<table>
<thead>
<tr>
<th>Drug Name or Class</th>
<th>Comments</th>
<th>Severity (High or Low)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-acting benzodiazepines:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Chlordiazepoxide (alone or in combination with Librium, Libranz, Libritabs)</td>
<td></td>
<td></td>
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<tr>
<td>- Diazepam (Valium)</td>
<td></td>
<td></td>
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<tr>
<td>- Quazepam (Doral)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Halazepam (Paculam)</td>
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<td></td>
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<tr>
<td>- Oxazepam (Talarnate)</td>
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<td></td>
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<tr>
<td>- Flurazepam (Dalmane)</td>
<td></td>
<td></td>
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<tr>
<td>These agents have very long half-lives, cause prolonged sedation and increase the risk of falls and fractures.</td>
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</tr>
<tr>
<td>- If sedative-hypnotic therapy is unavoidable, use short-acting agents.</td>
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<td></td>
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<tr>
<td>High</td>
<td></td>
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<tr>
<td>Short-acting benzodiazepines should rarely exceed the doses shown below:</td>
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<tr>
<td>- Lorazepam (Ativan) 3mg</td>
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<tr>
<td>- Oxazepam (S-over) 60mg</td>
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<td></td>
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<tr>
<td>- Triazolam (Halcion) 0.25mg</td>
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<tr>
<td>- Alprazolam (Xanax) 2mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Temazepam (Restoril) 1.5mg</td>
<td></td>
<td></td>
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<tr>
<td>This anxiolytic is highly sedating and addictive. All use should be avoided except in individuals who are physically dependent on it or who are being treated with short-course therapy for an acute condition.</td>
<td></td>
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<tr>
<td>High</td>
<td></td>
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<tr>
<td>Meperidine (Mylorid and Equanil)</td>
<td></td>
<td></td>
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<tr>
<td>High</td>
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<tr>
<td>Barbiturates except Phenobarbital for seizures</td>
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<tr>
<td>All use should be avoided except in patients who are physically dependent or for seizure disorder management. These are safer relative-depressants available.</td>
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<tr>
<td>High</td>
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<tr>
<td>Amitriptyline (Elavil), chlorpromazine, amitriptyline (Limbitrol), Amitriptyline-pentazocine (Triavil), doxepin (Sinequan)</td>
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<tr>
<td>Amitriptyline and doxepin are very sedating and anticholinergic, their use should be avoided.</td>
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<tr>
<td>High</td>
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<tr>
<td>Methyldopa (Aldomet)</td>
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<tr>
<td>Methyldopa-hydrochlorothiazide (Aldomet)</td>
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<tr>
<td>Reserpine at doses &lt; 0.25mg</td>
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<tr>
<td>All use should be avoided. Other antihypertensives are available.</td>
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<tr>
<td>Low</td>
<td></td>
<td></td>
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<tr>
<td>Indomethacin (Indocid and Indocin SR)</td>
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<tr>
<td>All use should be avoided. Other NSAIDs cause CNS toxic reactions less often.</td>
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<tr>
<td>High</td>
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<tr>
<td>Chlorpropamide (Diabinese)</td>
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<tr>
<td>Other oral hypoglycemics have shorter half-lives and do not cause SIADH.</td>
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<td>High</td>
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<tr>
<td>Pepsinase (Darvon) and combination products (Darvocet-N, Darvon-N, Darvon with ASA)</td>
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<tr>
<td>All use should be avoided. It has little advantage over acetaminophen. Other analgesics are safer and more effective.</td>
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<tr>
<td>Low</td>
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<tr>
<td>Pentolamine (Talwin)</td>
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<tr>
<td>All use should be avoided. Other narcotics are more effective and safer.</td>
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<tr>
<td>High</td>
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<td></td>
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<tr>
<td>Enzyt Myloids (Hyponge) and Cycloclamidate</td>
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<tr>
<td>All use should be avoided. Have not been shown effective in the doses studied.</td>
<td></td>
<td></td>
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<tr>
<td>Low</td>
<td></td>
<td></td>
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<tr>
<td>Diphenhydramine (Benadryl)</td>
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<tr>
<td>The only use in the smallest effective dose and only for emergency treatment of allergic reactions. Causes confusion and sedation.</td>
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<tr>
<td>High</td>
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</tbody>
</table>
Safe Injection Practices
 CDC Injections Safety for Providers

- The CDC also issues Injection Safety for Providers
- Notes several investigations leading to transmission of Hepatitis C to patients
- Thousands of patients notified to be test for HVB, HCV, and HIV
- Referral of providers to the licensing boards for disciplinary actions
- Malpractice suits filed by patients
Infection Control Topics

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

Injection Safety Information for Providers

Released March 2008

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

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

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

- **never** administer medications from the same syringe to more than one patient, even if the needle is changed; and
CDC 10 Recommendations

- The CDC has a page on Injection Safety that contains the excerpts from the Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- Summarizes their 10 recommendations
Safe Injection Practices to Prevent Transmission of Infections to Patients


**III.A.1.b. Safe Injection Practices**

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

Whenever possible, use of single-dose vials is preferred over multiple-dose vials, especially when administering medications to multiple patients.
CDC Safe Injection Recommendations

- Use aseptic technique to avoid contamination of sterile injection equipment. Category 1A

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

- Needles, cannula and syringes are sterile, single-use items; they should not be reused for another patient nor to access a medication or solution that might be used for a subsequent patient. 1A
CDC Safe Injection Recommendations

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

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

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

- Wear a mask when placing a catheter or injecting material into the spinal canal or subdural space
  - Example, during myelograms, lumbar puncture and spinal or epidural anesthesia. 1B

- Worker safety; Adhere to federal (OSHA) and state requirements for protection of healthcare personnel from exposure to blood borne pathogens 1B
CDC has Injection Safety FAQs for Providers

- CDC has another resources with frequently asked questions
- What is injection safety?
- Incorrect practices identified in IV medications for chemotherapy, cosmetic procedures, and alternative medicine therapies
- Available at http://www.cdc.gov/ncidod/dhqp/injectionSafetyFAQs.html
Injection Safety

Frequently Asked Questions

Injection Safety FAQs for Providers
Released: March 2008

Questions addressed on this page

Overview

› What is injection safety?
› What is aseptic technique?
› What are some of the incorrect practices that have resulted in transmission of pathogens?
› For what types of procedures have these incorrect practices been identified?
› Can some of these incorrect practices also result in transmission of bacterial infections?
› Do medication vials have a preservative in them to prevent contamination?

Injection Procedures

› How should I draw up medications?
› Where should I draw up medications?
› What does single-use mean?
› Is it acceptable to combine leftover medication from single-use vials?
CDC has Injection Safety FAQs for Providers

- Also puts patients at risk for bacterial and fungal infections beside HIV and Hepatitis
- Single dose vials do not contain a preservative to prevent bacterial growth so safe practices necessary to prevent bacterial and viral contamination
- Proper hand hygiene before handling medications
- Make sure contaminated things are not placed near medication preparation area
October 14, 2011 CMS issues a 137 page memo

CMS is proposing to implement 3 surveyor worksheets for hospitals that would be completed during a hospital survey

One of these is on discharge planning, infection control, and QAPI

Will mostly likely see some changes in the final worksheet which will not be used before October 2012

However, hospitals should consider immediately reviewing these and implementing them into practice

Audit compliance
MEMORANDUM SUMMARY

*Focused Survey Initiative:* The Centers for Medicare & Medicaid Services (CMS) is testing three new surveyor worksheets for assessing compliance with three hospital Conditions of Participation (CoPs): Discharge Planning, Infection Control, and Quality Assessment and Performance Improvement (QAPI). A separate document containing instructions for the Infection Control worksheet is also included. We are focusing on compliance with these CoPs as a means to reduce healthcare-acquired conditions (HACs) and hospital readmissions.
DRAFT PRE-DECISIONAL SURVEYOR WORKSHEET
Assessing Hospital Compliance with the
Condition of Participation for Infection Control

Name of State Agency: ____________________________________________________________

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the Infection Control Condition of Participation. Items are to be assessed by a combination of observation, review of the hospital's infection control program documentation, interviews with hospital staff, patients and their family/support persons, and review of medical records.

The interviews should be performed with the most appropriate staff person(s) for the items of interest, as well as with patients, family members, and support persons.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on Form CMS-2567 when deficient practices are observed.

Section 1 Hospital Characteristics

1. Hospital name: ________________________________________________________________

2. Address, State, Zip Code: _____________________________________________________

3. CMS Certification Number (CCN): ____________

4. Date of site visit:
   ____________ / ____________ / ____________ to ____________ / ____________ / ____________
**Module 1: Interview Questions**

**Section 1. A. Infection control/prevention program and resources**

<table>
<thead>
<tr>
<th>Elements to be assessed</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A.1 The hospital has designated one or more individual(s) as its infection control officer(s)?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>If no, cite at 42 CFR 482.42(a) (Tag A-0748)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. A.2 The hospital has Infection Control policies and procedures developed and implemented by the infection control officer(s).</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>If no, cite at 42 CFR 482.42(a) (Tag A-0748)</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>1. A.3 The hospital has evidence that demonstrates the infection control officer(s) is qualified and maintains qualifications through education, training, experience or certification related to infection control consistent with hospital policy.</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>If no, cite at 42 CFR 482.42(a) (Tag A-0748)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. A.4 Hospital leadership ensures the hospital QAPI program effectively address identified problems in infection control on an ongoing basis.</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>If no, cite at 42 CFR 482.42(b)(1) (Tag A-0756)</strong></td>
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</tbody>
</table>
Infection Control Surveyor Worksheet

- Has section on injection practices and sharps safety
  - Single dose and multiple dose vials
  - One needle and one syringe
  - Replace sharps when fill line is reached
- Has section on environmental cleaning/disinfection
- Has section on personal protective equipment (PPE)
- Has section on point of care devices (glucose meter, INR, lancets)
- Reprocessing, single use devises (SUDs)
CDC has Injection Safety FAQs for Providers

- Single use parenteral medication should be administered to one patient only
- Pre-filled medication syringes should never be used on more than one patient
- A needed or other device should never be left inserted into a medication vial septum for multiple uses
  - This provides a direct route for microorganisms to enter the vial and contaminate the fluid
CDC has Injection Safety FAQs for Providers

- Multi-dose Vials
  - The safest thing to do is restrict each medication vial to a single patient, even if it's a multi-dose vial
  - Proper aseptic technique should always be followed
  - If multi-dose medication vials must be used for more than one patient, the vial should only be accessed with a new sterile syringe and needle
  - It is also preferred that these medications not be prepared in the immediate patient care area
CDC has Injection Safety FAQs for Providers

To help ensure that staff understand and adhere to safe injection practices, we recommend the following:

- Designate someone to provide ongoing oversight for infection control issues
- Develop written infection control policies
- Provide training
- Conduct performance improvement assessments
Center for Medicaid and State Operations/Survey and Certification Group

DATE: May 16, 2008

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Safe Injection Practices in Ambulatory Surgical Centers (ASCs)

Memorandum Summary

- **Safe Practices**: 42 CFR 416.44(a)(3) requires every ASC to establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

- **Alerts**: Recently the State of Nevada and federal epidemiologists identified a cluster of hepatitis C infections where the infected individuals all had procedures in the same ASC. Subsequent survey of that ASC identified unsafe injection practices.
II. Injection Practices (injectable medications, saline, other infusates)

Additional Instructions:

Observations are to be made of staff who prepare and administer medications and perform injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).

<table>
<thead>
<tr>
<th>Practices to be Assessed</th>
<th>Was practice performed?</th>
<th>Manner of confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Needles are used for only one patient</td>
<td>1 Yes 2 No 3 N/A</td>
<td>4 Observation 5 Interview 6 Both</td>
</tr>
<tr>
<td>B. Syringes are used for only one patient</td>
<td>1 Yes 2 No 3 N/A</td>
<td>4 Observation 5 Interview 6 Both</td>
</tr>
<tr>
<td>C. Medication vials are always entered with a new needle</td>
<td>1 Yes 2 No 3 N/A</td>
<td>4 Observation 5 Interview 6 Both</td>
</tr>
<tr>
<td>D. Medication vials are always entered with a new syringe</td>
<td>1 Yes 2 No 3 N/A</td>
<td>4 Observation 5 Interview 6 Both</td>
</tr>
<tr>
<td>E. Medications that are pre-drawn are labeled with the time of draw, initials of the person drawing, medication name, strength, and expiration date or time</td>
<td>1 Yes 2 No 3 N/A</td>
<td>4 Observation 5 Interview 6 Both</td>
</tr>
</tbody>
</table>

Note: A “No” answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs
F. Single dose (single-use) medication vials are used for only one patient (A “No” response must be cited in relation to 42 CFR 416.48(a).)

<table>
<thead>
<tr>
<th></th>
<th>1 Yes</th>
<th>2 No</th>
<th>3 N/A</th>
<th>4 Observation</th>
<th>5 Interview</th>
<th>6 Both</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td></td>
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<td>b.</td>
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<td>c.</td>
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<td>d.</td>
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</tbody>
</table>

b. Manufactured prefilled syringes are used for only one patient

c. Bags of IV solution are used for only one patient

d. Medication administration tubing and connectors are used for only one patient

G. List all injectable medications/infusates that are in a vial/container used for more than one patient:

<table>
<thead>
<tr>
<th>Name of Medication</th>
<th>Average number of patients per vial/container</th>
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H. Multi-dose injectable medications are used for only one patient (Note: a “No” answer here is not necessarily a breach in infection control and does not result in a citation. However, a “No” response to the related questions I – K should be cited.

*Circle N/A if no multi-dose medications/infusates are used.*

If YES, please skip to “L”

If NO, please answer “I-K”:

1. The rubber septum on a multi-dose vial used for more than one patient is disinfected with alcohol prior to each entry

<table>
<thead>
<tr>
<th></th>
<th>1 Yes</th>
<th>2 No</th>
<th>3 N/A</th>
<th>4 Observation</th>
<th>5 Interview</th>
<th>6 Both</th>
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<tr>
<td>J. Multi-dose medications <strong>used for more than one patient</strong> are dated when they are first opened and discarded within 28 days of opening or according to manufacturer’s recommendations, whichever comes first</td>
<td>1 Yes 2 No 3 N/A</td>
<td>4Observation 5Interview 6Both</td>
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<tr>
<td>K. Multi-dose medications, <strong>used for more than one patient</strong>, are not stored or accessed in the immediate areas where direct patient contact occurs</td>
<td>1 Yes 2 No 3 N/A</td>
<td>4Observation 5Interview 6Both</td>
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<tr>
<td>L. All sharps are disposed of in a puncture-resistant sharps container</td>
<td>1 Yes 2 No 3 N/A</td>
<td>4Observation 5Interview 6Both</td>
<td></td>
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<tr>
<td>M. Sharps containers are replaced when the fill line is reached</td>
<td>1 Yes 2 No 3 N/A</td>
<td>4Observation 5Interview 6Both</td>
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<tr>
<td>N. Additional breaches in injection practices, not captured by the questions above were identified (If YES, please specify further in comments)</td>
<td>1 Yes 2 No 3 N/A</td>
<td>4Observation 5Interview 6Both</td>
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<tr>
<td>Comments:</td>
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</table>
USP 797

- USP published a revision to the USP general Chapter of 797
- These standards apply to pharmacy compounded sterile preparation
- This includes injections, nasal inhalations, suspensions for wound irrigations, eye drops etc.
- Applies to the pharmacy setting as well as to all persons who prepare medications that are administered
- And it applies to all healthcare centers
This chapter includes standards for preparing, labeling, and discarding prepared medications.

Pharmacies compound sterile preparations under laminar flow hoods with stringent air quality and ventilation to maintain the sterility of the drug (ISO class 5 setting).

If prepare outside the pharmacy then environment has particulates and microorganisms increasing the potential for contaminating the vial, IV solution or syringes.

- Need to wash hands before preparing medication outside the pharmacy.
Want to prepare IVs and piggybacks in the pharmacy when at all possible

Breathing over the sterile needle and vial stopper can create the potential for microbial contamination

USP exempts preparation outside the pharmacy for immediate use

  1 hour limit from completing preparation and this includes spiking an IV bag

Cost of medication disposal can be daunting if case not started within one hour which is why should consider pharmacy preparing under ISO class 5 environment
USP 797

- This way the drugs used for surgery are prepared by properly trained, cleansed, and garbed personnel to prolong the usability of the immediate use compounded sterile drugs (CSD)

- These can be stored for 48 hours

- Another option is to located a manufacturers injectable product (prepackaged syringe) that is discarded according to manufacturer expiration date

- APIC supports preparing parenteral medication as close as possible to the time of administration
USP 797 APIC Recommendations

- Make sure only trained staff are preparing medications.
- Need to prepared in a clean dry workspace that is free of clutter and obvious contamination sources like water, sinks.
- Medications should be stored in a manner to limit the risk of tampering.
- Should verify the competency of those preparing medications and monitor compliance with aseptic technique.
- 28 day discard date on multidose vials even though CDC says manufacturers recommendations.
APIC Recommendations

- APIC issues recommendations and key talking points for hospitals and healthcare facilities

- http://apic.informz.net/apic/archives/archive_272235.html

- The infection preventionist at our facility has designed a coordinated infection control program

- This is protect everyone coming in to our facility

- Our program implements evidenced based practices from leading authorities including the CDC
APIC Recommendations

- Cleanse the access diaphragm of vials using friction and a sterile 70% isopropyl alcohol, ethyl alcohol, iodophor, or other approved antiseptic swab
  - Allow the diaphragm to dry before inserting any device into the vial

- Never store or transport vials in clothing or pockets.

- Discard single-dose vials after use
  - Never use them again for another patient

- Use multi-dose medication vials for a single patient whenever possible
APIC Recommendations

- Never leave a needle, cannula, or spike device inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination
  - even if it has a 1-way valve
- Use a new syringe and a new needle for each entry into a vial or IV bag
- Utilize sharps safety devices whenever possible
- Dispose of used needles/syringes at the point of use in an approved sharps container
APIC position paper: Safe injection, infusion, and medication vial practices in health care

Susan A. Dolan, RN, MS, CIC,a Gwenda Felizardo, RN, BSN, CIC,b Sue Barnes, RN, BSN, CIC,c Tracy R. Cox, RN, CIC,d Marcia Patrick, RN, MSN, CIC,e Katherine S. Ward, RN, BSN, MPH, CIC,f and Kathleen Meahan Arias, MS, CICg
Washington, DC

Outbreaks involving the transmission of bloodborne pathogens or other microbial pathogens to patients in various types of health care settings due to unsafe injection, infusion, and medication vial practices are unacceptable. Each of the outbreaks could have been prevented by the use of proper aseptic technique in conjunction with basic infection prevention practices for handling parenteral medications, administration of injections, and procurement and sampling of blood. This document provides practice guidance for health care facilities on essential safe injection, infusion, and vial practices that should be consistently implemented in such settings.

Key Words: Bloodborne pathogens; injection; infusion; medication vial practices; aseptic technique; parenteral medications; administration of injections; procurement of blood.

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The transmission of bloodborne viruses and other microbial pathogens to patients during routine health care procedures continues to occur because of the use of unsafe and improper injection, infusion, and medication vial practices by health care professionals in various clinical settings throughout the United States.1–12 Breaches in safe injection, infusion, and medication vial practices continue to result in unacceptable and devastating events for patients. More than 35 outbreaks of viral hepatitis have occurred in the United States over the past 10 years because of these unsafe practices and other breaches of infection prevention procedures. These outbreaks have resulted in the exposure of >100,000 individuals to viral hepatitis and the transmission of either hepatitis B virus (HBV) or hepatitis C virus (HCV) to more than 500 patients.13 The unsafe practices used by health care personnel in these outbreaks can be categorized as (1) syringe reuse between patients during parenteral medication administration to multiple patients, (2) contamination of medication vials or intravenous (IV) bags after having been accessed with a used syringe and/or needle, (3) failure to follow basic injection safety practices when preparing and administering parenteral medications to multiple patients, and (4) inappropriate care/maintenance of finger stick devices and glucometer equipment between use on multiple patients.

In 2001, an anesthesiologist at a New York endoc-
Dear APIC Member:

Reports about syringe re-use and lax infection prevention and control practices at an endoscopy center in Nevada have prompted health officials to urge consumers to be proactive about impending surgical procedures. Due to these events, more than 40,000 patients have been notified regarding their possible risk of HCV transmission.

As a result, hospitals and clinics may receive increased phone calls about infection prevention policies and practices.

The following points are provided to assist in handling inquiries from concerned patients who call with questions or requests to receive a copy of the hospital's infection prevention and control policies.

**IMPORTANT NOTE.**

Prior to responding to calls from the public asking about your institution's infection prevention practices, be sure to talk with your risk management department to clarify your facility's stand regarding disclosure and release of information including policies, plans, and infection rates.

**KEY TALKING POINTS:**

- The infection prevention and control professionals at our facility have designed a coordinated
A Patient Safety Threat-Syringe Reuse

- CDC published a fact sheet called “A Patient Safety Threat- Syringe Reuse”
- It was published for patients who had received a letter stating they could be at risk due to syringe reuse
- Discusses the dangers of the reuse of syringes
- Discusses that multidose vial be assigned to a single patient to reduce the risk of disease transmission
1 Needle
1 Syringe
+ 1 Time

0 Infections
Advancing ASC Quality

- ASC Quality Collaboration has ASC tool kit for infection prevention
- Includes one on hand hygiene and safe injection practices
- Includes a basic and expanded version of the toolkit
- These are available at http://www.ascquality.org/advancing_asc_quality.cfm
Advancing ASC Quality

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

The following *ASC TIPS* are now available:

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

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