AHC Media

October 10, 2016

Hospital CMS CoPs Made Easy
The Series Part 3

Speaker

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Objectives

- Describe where to locate a copy of the current CMS CoP manual.
- Discuss the importance of a current history and physical for any patient undergoing elective surgery.
- Review why all verbal orders must be signed off with the corresponding date and time.
- Summarize the restraint standards hospitals must follow.
- Reinforce why hospitals need grievance policies and procedures.
- Discuss the requirements for documentation when interpreters are involved.
- Discuss the many pharmacy policies required by government bodies.
- Explain why care plans and protocols must be maintained in the medical record.
- Verify why hospitals must have approved policies and related staff education in place.
- Discuss how to communicate policies on infection control and discharge.
- Advise staff on the hospital organ donation policy.
- Outline the required documentation regarding post-anesthesia assessment.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

Location of CMS Hospital CoP Manual

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

New website

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

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

CoP Manual Also Called SOM

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

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

Transmittals for Appendix A

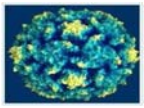
Survey Protocol

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

Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module
Inpatient Rehabilitation Unit Survey Module
Hospital Swing-Bed Survey Module
Regulations and Interpretive Guidelines

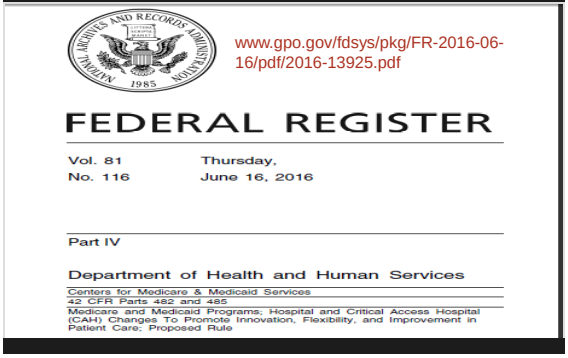
www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.p

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



CMS Proposed Changes to the CoPs on Nursing

June 16, 2016 Federal Register



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

FEDERAL REGISTER

Vol. 81 Thursday,
No. 116 June 16, 2016

Part IV

Department of Health and Human Services

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

CMS Proposed Changes to Nursing

- Would clarify that need nursing supervisor and enough staff immediate availability of RN at the bedside to respond when needed
- Must include in policy all the outpatient areas and which ones need a RN
  - Policy must be approved by the MEC
- Must have current nursing care plan
- Must have evidence of reassessment and include patient goals
- All nurses, including agency, must follow P&Ps

CMS Proposed Changes to Nursing

- CNO must evaluate all clinical activities of nurses including agency nurses and other staff
- Must have P&P prohibiting discrimination
  - Can't discriminate against race, color, orientation, disability, etc.
  - Must inform the patient in writing, and in a language they can understand, of their right to be free from discrimination
- Need an order for drugs
- Want to refer to CNO as nursing leadership

CMS Hospital Nursing CoPs

Nursing Services 0385

- Must have an organized nursing service that provide 24 hour nursing services
- Must have at least one RN furnishing or supervising 24 hours
- SSA at 1861 (b) states you must have a RN on duty at all times (except small rural hospitals under a waiver)
- Survey procedures-determine nursing services is integrated into hospital PI
- Make sure there is adequate staffing
- Survey procedure - look for job descriptions including director of nursing

Director of Nursing Service

- DON must be RN, A-386
  - Often referred to as chief nursing officer or CNO
- CNO responsible for determining types and numbers of nursing personnel
- CNO responsible for operation of nursing service
- Survey procedure-look at organizational chart
- May read job description of DON to make sure it provides for this responsibility
- May verify CNO approves patient care P&P's

Nurse Staffing 392

- Nursing service must have adequate number of nurses and personnel to care for patients
  - Answer call lights timely and check on patient if cardiac monitor alarms
- Must have nursing supervisor
- Every department or unit must have a RN present (not available if working on two units at same time)
- Survey procedure-look at staffing schedules that correlate number and acuity of patients

Nurse Staffing 392

- There are 3 recent evidenced based studies that show the importance of having adequate staffing which results in better outcomes
- Study said patients who want to survive their new hospital visit should look for low nurse-patient ratio
- Nurse Staffing and Quality of Patient Care, AHRQ, Evidence Report/Technology Report Number 151, March 2007, AHRQ Publication No. 07-E005[1]

[1]http://www.ahrq.gov/downloads/pub/ evidence/pdf/nursestaff/nursestaff.pdf

Nursing Linked to Safety

- IOM study also linked adequate staffing levels to patient outcomes
- Limits to number of hours worked to prevent fatigue
- Suggests no mandatory overtime for nurses
- Never work a nurse over 12 hours or 60 hours in one week (or will have 3 times the error)

Nursing Linked to Safety

- Also showed medication error rate, falls, pressure ulcers, UTI, surgery site infections, gastric ulcers, codes, LOS, increased unnecessary readmissions, patient experience or satisfaction rates etc. linked to staffing
  - Important in value based purchasing
- Redesigning the work force
- See Keeping Patients Safe: Transforming the Work Environment of Nurses 2004[1]

[1]www.nap.edu/openbook/0309090679/html/23/html

Nursing Staffing Linked to Safety

- AHRQ 2008 has published 3 volume, 51 chapter handbook for nurses at no cost
- Great resource that every hospital should have
- Nurse Staffing and Patient Care Quality and Safety
- Again shows that patient safety and quality is affected by short staffing
- Patient Safety and Quality: An Evidence-Based Handbook for Nurses, 2008[1]
- [1]http://www.ahrq.gov/qual/nurseshdbk

Verify Licensure 394

- Must have procedure to ensure nursing personnel have valid and current license
- Survey procedure-review licensure verification P&P
- Can verify licensure on line by most state boards of nursing online
  - Considered primary source verification
  - Can print out information for employee file

RN for Every Patient 395

- A RN must supervise and evaluate the nursing care for every patient
- RN must do admission assessment
- Must use acceptable standard of care
- Evaluation would include assessing each patient's needs, health status and response to interventions

Nursing Care Plan 396 2013

- Hospital must ensure that nursing staff develop and keeps a current, nursing care plan for each patient
  - If nursing participates in interdisciplinary care plan then do not have to have separate nursing plan of care
- Starts upon admission, includes discharge planning, physiological and psychosocial factors
- Based on assessing the patient's needs
- Care plan is part of the patient's medical records and must be initiated soon after admission, revised and implemented

Agency Nurses 398

- Agency nurses or traveling nurses (CMS calls them non-employee nurses) must adhere to P&P's
- CNO must provide adequate supervision and evaluate (once a year) activities of agency nurses
- Includes other personnel such as volunteers
- Orientation must include to hospital and to specific unit, emergency procedures, nursing P&P, and safety P&P's

Preparation/Admin of Drugs 405

- Drugs must be prepared and administered according to state and federal law
  - 404 deleted and combined with 405
- Need an practitioner's **order**
  - CMS changes to allow other practitioners who are allowed to order to sign off order such as PharmD as allowed by P&P and state scope of practice and MS bylaws/RR
- Surveyor will observe nurse prepare and pass medications
- Medications must be prepared and administered with acceptable national standards of practice (TJC MM chapter), manufacturer's directions and hospital policy

CMS Changes to Medication Administration

- CMS issued a survey and certification memo dated 11-18-11, 6-7-13 and March 14, 2014
  - Tag 405 use to say that all medications must be given within 30 minutes of the scheduled time
  - Now three blocks of time to give medications
  - Included section on standing orders but most sections moved to tag 457

CMS Changes to CoPs

- Changed tag 405 which deals with orders of drugs and biologicals and **safe opioid use**
- Most sections on standing orders section was moved to 457
- Added information on age and weight of patient especially weight based doses for children
- All drugs are administered under the supervision of nursing or other personnel
- Five rights of medication administration: right patient, medication, dose, route and time and references nine rights

Pharmacy Should Prepare Piggybacks & IVs

For Information – Not Required/Not to be Cited

Although the regulation addresses both preparation and administration of drugs and biologicals and does not prohibit preparation of drugs by nursing staff, to improve patient safety it is generally preferable for hospitals to avoid nurse preparation of drugs in patient care areas, and instead rely upon pharmacy IV admixture systems and/or commercially available unit dose products.

Administration of Meds 0405

- Medication management is a hot topic with CMS and TJC
- All drugs administered under the supervision of nursing or other personnel if permitted by law
- In accordance with approved medical staff P&P's, state & federal laws, MS bylaws and R/R and scope of practice
- Surveyor will review sample of medication records to ensure it conforms to physician's order

Administration of Meds 405

- Need to have an **order**, make sure compliant with state and federal laws, and acceptable standards of practice
- Need to have a P&P with three time frames on timing of medications
- Must educate staff and policy must comply with the 10 page memo issued
- Include medications not eligible for scheduled dosing such as stat drugs, PRN, loading doses, drugs for scheduled procedure etc.

Administration of Meds 405

- Medications that are eligible for scheduled times
- P&P to include time-critical scheduled medications given in 30 minutes with one hour window
- P&P that are non-time-critical scheduled medications
  - 2 hours for medications prescribed more frequently than daily, but no more frequently than every 4 hours and
  - 4 hours for medications prescribed for daily or longer administration intervals
- P&P on missed or late medications

Assessment & Monitoring of Patients

- Patients on medications needed to be carefully monitored
  - May need clinical and lab data to evaluate medication
  - Monitor respiratory status, pulse ox BP, end tidal CO2 with patients on **opioids**
  - Evaluate clinical signs such as confusion, agitation, unsteady gait, itching etc.
  - Know high risk medications policy and safe practices
  - Know risk factors for ADE such as patient has liver or kidney failure, history of sleep apnea, obesity, smoking, drug-drug interaction and first time medication use

ISMP List of High Alert Medication

ISMP's List of *High-Alert* Medications

Printer friendly version

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

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

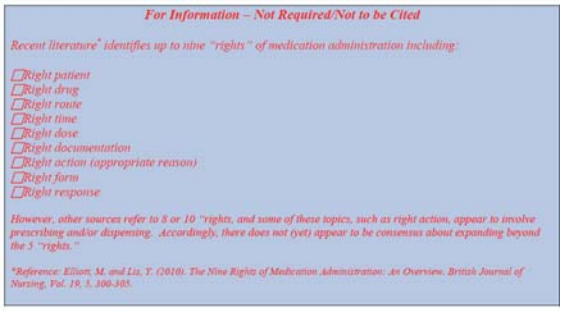
Assessment & Monitoring of Patients

- ADE, such as anaphylaxis or opioid-induced respiratory depression may require timely and appropriate
- Post-medication monitoring in case of a high alert medication may include regular assessment of VS, pulse ox, and sedation levels of post surgery patient on PCA
- Such as Richmond agitation sedation scale (RASS) or the Pasero Opioid-Induced sedation scale (POSS), Inova Sedation Scale (ISS), Ramsey scale, Aldrete Scoring system

Assessment & Monitoring of Patients

- Staff are expected to include patient reports of his experience with medication's effect
- Patient should be instructed to notify nurse if there is difficulty breathing or a reaction to the medication
- Hospital needs P&P to address the manner and frequency of monitoring
- P&P should include information to be communicated at shift change
- Should include patient's risk factors
- **Document** after medication administered

9 Rights of Medication Administration



For Information – Not Required/Not to be Cited

Recent literature identifies up to nine "rights" of medication administration including:*

- ☐ *Right patient*
- ☐ *Right drug*
- ☐ *Right route*
- ☐ *Right time*
- ☐ *Right dose*
- ☐ *Right documentation*
- ☐ *Right action (appropriate reason)*
- ☐ *Right form*
- ☐ *Right response*

However, other sources refer to 8 or 10 "rights, and some of these topics, such as right action, appear to involve prescribing and/or dispensing. Accordingly, there does not (yet) appear to be consensus about expanding beyond the 5 "rights."

**Reference: Elliott, M. and Liu, Y. (2010). The Nine Rights of Medication Administration: An Overview. British Journal of Nursing, Vol. 19, 5, 300-305.*

Safe Injection Practices

- Must ensure staff follow SOP to prevent HAI related to medication preparation
  - References infection control worksheet
  - Assessed under infection control section
- Compounded sterile preparations (CSP) can cause HAI if proper precautions are not followed such as following the USP standards
- Nurses may prepare sterile medication for immediate use
- CMS mentions the following apply

Compounding 2016

- Must only involve simple transfer of not more than 3 commercially manufactured, sterile, nonhazardous products from the manufacturer's original container
- And not more that two entries into any one container including a vial or an IV bag
- Administration must be within one hour following the preparation
- Must follow aseptic technique during all phases of preparation

Compounding

- Must label it unless your prepare it and immediately administer it to the patient
- CSP label must include: patient identification, name and amount of ingredients, name or initial of person who prepared it, and exact one hour BUD
- Drug is outdated after its expiration date or BUD
  - BUD is December 2017 but multi-dose vial expires in 28 days when opened unless sooner by manufacturer
- Need P&P to give clear directions to staff on how to determine BUD date if not available from manufacturer

Physician Order 406

- Standard: Drugs and biologicals must be prepared on the order contained within preprinted and electronic standing orders, order sets, and protocols if meet the standards in tag 457
- Orders for drugs can be documented and signed by other practices if acting in scope of practice, state law, P&P, and MS bylaws and R/R
- CMS issues standing order memo 10-24-08
- Also includes standing orders, preprinted orders and use of rubber stamps

Physician Order 406

- Flu and pneumovax can be given by protocol approved by the MS after assessment of contraindications
- Orders for drugs must be documented and signed by practitioners allowed to write them
- Doctors and if allowed NP and PAs
- Rubber stamps - will not be paid for order for M/M patients and some insurance companies so many hospitals do not allow rubber stamps

Physician Order 406

- Order must have name of patient, age and weight (if applicable), date and TIME of order, drug name, strength, frequency, dose, route, quality and duration, and special instructions for use, and name of pre scriber
- Have a culture so can ask questions
- Now allowed to have written protocol or standing orders with drugs and biologicals that have been approved by MS
- Can implement them but be sure provider signs, dates, and times the order

Physician Order 406

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

Preprinted Order Sets

- Must date and time when the order set is signed
- Must indicate on last page the total number of pages in the order set
- If want to strike out something in the order sheet or delete it or add order on blank line then physician needs to initial each place
- Should add this to the MR audit sheet to make sure there is compliance with this guideline
- Standing orders must address well-defined clinical scenarios involving medication
- Refers to tag 457 and 450 for more information

Verbal Orders 407 and 408

- Verbal orders are a patient safety issue
- Have lead to many errors
- Hospital must describe situations in which they can be used as well as limitations
- Must establish the identity and author of all orders
- Rewrite your P&P and Medical staff by-laws to be consistent with these standards
- Repeated VO section in MR starting with tag 454 and reiterated area of verbal orders offer too much room for error

Verbal Orders

- Must follow state law for time period to sign off such as 24 or 48 hours
  - If no state law do **not** have to sign off in 48 hours anymore
- Must sign off orders within time frame set by hospital policy
- Many hospitals **without** a state law can choose to have signed off in policy but
  - But still try and get them **signed off ASAP**
- Must still sign name and date and time the order

CMS Verbal Orders

- Emphasizes to be used infrequently and never for convenience of the physicians
- This means that physician should not give verbal orders in nursing station if he or she can write them
- Can be used in emergency or if surgeon is scrubbed in during surgery
- Regulation broadens category of practitioners who can sign orders off such as PA or NP
- Renewed any physician can sign off for any other physician on the case

Verbal Orders P&P Should Include

- Limitations or situation on not using VO such as not for chemotherapy
- List the elements for a complete VO (such as patient name, drug, dose, frequency, name of person giving and taking order, et al.)
- Define who can receive VO and the method to ensure authentication
- Provide guidelines for clear and effective communications

Signing Off Verbal Orders

- Person taking VO must document it in the chart
- Physician must sign off a verbal order, **date,** and **time** it when signed off
- Any physician on the case can sign off any VO
- This practice must be addressed in the hospital's P&P
- Now a NP or PA may sign off a verbal order, if within their scope (where they had authority to write order) and allowed by state law, hospital policy and delegated to this by the physician

Verbal Orders

- Regulation states that verbal orders should be authenticated based on state law
- Some states require order to be signed off in 24 hours or 48 hour and if no state law then no longer a set 48 hours but what your hospital P&P dictate
- Need hospital P&P to reflect these guidelines
- Write it down and repeat it back

Joint Commission Verbal Orders

- RC.02.03.03 (IM 6.50) requires that qualified staff receive and record VO
- Define in writing who can receive and record VO
- Date and document identity of who gave, received, and implemented the order
- Authenticated within time frame law/regulation
- Write it down and read back the completed order or test result (NPSG 2009)

Blood Transfusions and IVs 409

- Standard: Blood transfusions and IV medications must be administered with state law and MS P&P
- Use to require special training for this and there was a long list of things that nurses had to be trained on
- CMS eliminated the regulations mandating training for non-physicians who administer IV medication and blood and blood products
  - CMS says because this training is already standard practice but must still be competent in those areas
  - Must follow your P&P and state scope of practice

Blood and IV Medication Training

- Must still follow **state law requirements**
  - In some states an LPN can not hang blood
  - Or the LPN can not push certain IV medications in some states
  - Must show they are competent
- Must still have approved **Medical Staff Policies** and Procedures in place
- Staff must follow these which have most of the things that were previously required

Blood Transfusions and IVs

- Hospital P&P for blood and IV medication must be based on state law and MS P&P and must address the following:
  - Vascular access route such as central line, peripheral or implanted port and what medications can be given IV and via what type of access devices
  - Basic safety practices for medication administration
    - Tracing line and tubes prior to administration to be sure proper route
    - Verify proper programming of infusion devices

Blood Transfusions and IVs

- Patient Monitoring
  - Monitor for the effects of the medication since IV medications have a more rapid effect
  - Monitoring to include assessment of risk factors that would influence type and frequency of monitoring
  - Such as patient with renal failure on Vancomycin and dose is based on lab test
- P&P expected to address
  - Monitoring for fluid and electrolyte balance
  - Monitor patients on high alert meds including **opioids** and evaluate for over-sedation and respiratory depression

Blood Transfusions and IVs

- Risk factors for patients receiving **opioids** include
  - Snoring or history of sleep apnea
  - No recent opioid use or first-time use of IV opioids
  - Increased opioid dose requirement or opioid habituation
  - Longer length of time receiving general anesthesia during surgery
  - Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other CNS depressants
  - Preexisting pulmonary or cardiac disease
  - Thoracic or other surgical incisions that may impair breathing

Blood Transfusions and IVs

- P&P must include who can conduct the assessments
- The frequency and duration of the assessments
- Under what circumstances practitioners prescribing IV opioids are allowed to establish protocols that differ from hospital P&P
- Assessment includes VS (TPR and BP), pain level, respiratory status, sedation level and ETCO2
- Also mentions APSF monitoring of opioids including ETCO2

For Information – Not Required/Not to be Cited

Institute for Safe Medication Practices Guidelines for PCA Monitoring

Assessment of Opioid Tolerance	Vital Signs	Pain	Sedation	Respiratory		
				Rate	Quality	SPO_2* &/or $ETCO_2$**
Baseline Assessment before PCA	X	X	X	X	X	X
PCA Initiation or Change in Drug/Syringe Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
PCA Dose Change or Bolus Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
Adverse Event or Patient Deterioration (e.g., adverse change in sedation score) Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
Hand-offs/Shift Change	X	X	X	X	X	X

Institute for Safe Medication Practices (ISMP). Medication Safety Alert – Fatal PCA Adverse Events Continue to happen…Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013 ISMP adapted these recommendations from the San Diego Patient Safety Council

* SPO_2: Saturation of peripheral oxygen via pulse oximetry

Blood Transfusions

- Confirm correct patient
- Verify correct blood product
- Standard calls for two qualified persons, one who is administering the transfusion
- Document monitoring
- P&P include how frequent you monitor the patient and do vital signs
- How to identify and treat and report any adverse transfusion reaction

Blood Transfusions

- Staff must be competent in venipuncture
- Competent in using vascular access devices
- Trained in early detection and intervention for opioid over-sedation
- Must document competency
- So make sure nursing education is aware and staff trained in orientation periodically
- Make sure staff educated on P&P

Blood Transfusions and IVs

- Is there evidence that staff competent in;
- Maintaining fluid and electrolyte balance
- Venipuncture techniques
- Blood transfusion: blood components, administration policy, national standards of practice, patient monitoring requirements including frequency, documentation, verifying correct blood and patient
- Transfusion reactions; Identification, treatment and reporting requirements

Incident Reports Transfusions

- There must be procedure for reporting transfusion reactions, adverse drug reactions and errors in administration of drugs (410)
- Survey procedure - request procedure for reporting-they may review the incident reports or other documentation through QAPI program
  - But must have a hospital P&P for reporting transfusion reactions such as an incident reporting system
  - See tag number 508

ADE and Drug Administration 410

- Mentions similar standard in pharmacy section which is in tag 508
- Wants to be all drug errors and ADE are reported
- This includes any blood transfusions AE
- Discusses symptoms of a transfusion reaction
- Need P&P for internal reporting of transfusion reactions since be life threatening
- Must be immediately reported to the practitioner responsible for the patient's care and documented in the medical record and report to PI

Self Administration of Medication 412

- Standard: Hospital may allow a patient or caregiver to self administer both hospital issued medication and the medication the patient brought from home
  - As specified in the hospital P&P
- Revise your policy to include this section
- Add this to the education of your nursing and pharmacy staff

Self Administration of Medication 412

- Must have an order, must make sure patient is competent to do, must educate the patient
- P&P must address security of medication for each patient
- Must document in the MR so patient must let nurse know
- Visually inspect medication for integrity
- Previously this section was in the pharmacy section 502

OIG Report January 22, 2015

Why Changes Were Made to the Pharmacy Standards

Surveyor Training on Compounding

- The OIG issued a report regarding a recommendation that which called on CMS to ensure hospital surveyors are trained on nationally recognized compounding practices
- Recommend it change the CoPs interpretive guidelines to address hospital contracts with stand-alone compounding pharmacies
- OIG said the lack of surveyor training preventing the oversight entities from effective evaluating the hospital's use of CSP or compounded sterile preparations

OIG Report on Oversight of Hospital Pharmacies

OFFICE OF
INSPECTOR GENERAL

http://oig.hhs.gov/oei/reports/oei-01-13-00400.pdf

MEDICARE'S OVERSIGHT OF COMPOUNDED PHARMACEUTICALS USED IN HOSPITALS

Daniel R. Levinson
Inspector General

The OIG Report Jan 2015

- May find the surveyor may review the contracts of the stand alone compounding pharmacy
- This includes surveyors from TJC, DNV, AOA (AAAHC) HCAP, and CIHQ
- Surveyors will likely be more aware of standards with additional training and more likely to discover if hospital is not doing safe compounding practices
  - Discussed the 64 deaths from the fungal meningitis case from NECC
  - Made 55 recommendations on overseeing CSPs in hospitals

Table A1: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to the Hospital Physical Plant and Environmental Quality

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors request a copy of the hospital's pharmacy cleaning logs?	1	4	0
Do surveyors request a copy of the hospital's pharmacy environmental sampling logs?	0	5	0
If the hospital prepares CSPs onsite, do surveyors assess whether the area of preparation is appropriate for all CSP risk levels compounded at the hospital?	2	3	0
If the hospital prepares hazardous CSPs onsite, do surveyors assess the appropriateness of the physical area where hazardous CSPs are compounded?	3	2	0
If the hospital prepares CSPs onsite, do surveyors assess the environmental quality and control in the area of preparation?	3	2	0
If always or some of the time, do surveyors assess the adequacy of the environmental quality and control for each risk level of CSP prepared at the hospital?	2	3	0
If the hospital prepares CSPs onsite, do surveyors review the hospital's written procedures outlining the following:			
Cleaning and disinfecting of the compounding areas?	1	4	0
Personnel hand hygiene and garbing in compounding areas?	3	2	0
Employee aseptic technique in compounding areas?	2	3	0
Environmental sampling in compounding areas?	0	5	0
Facility and engineering control testing and certification in compounding areas?	0	4	1
If the hospital prepares CSPs onsite, do surveyors assess the adequacy of personnel protective equipment for compounding CSPs, including applicable	2	3	0

CMS Pharmacy Section

Pharmaceutical Services 489

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

Meet Needs of the Patients 490

- **Standard:** The hospital must have pharmacy services that meet the needs of the patients
- Includes providing medication related information to staff
- Scope and complexity of services is consistent with volume and types of patients served
- If reports of frequent delays then surveyor is to talk further with the pharmacy director
- Surveyor will ask how hospital has determined that the services meet the needs of patients

P&P and Drug Storage 491

- **Standard:** The MS is responsible for developing P&P that minimize drug errors
- This function can be delegated to the pharmacy
- Many P&Ps required
- **Standard**: The pharmacy or drug storage area must be administered in accordance with accepted professional principles
- This is TJC 03.01.01 and a problematic CMS standard

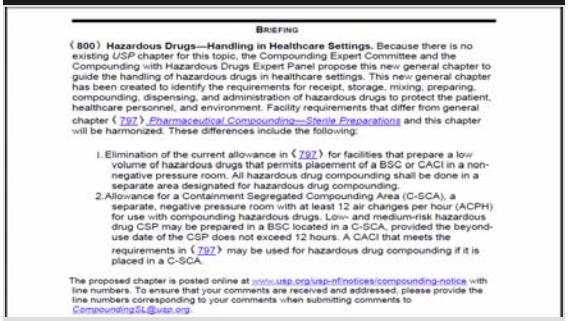
Pharmacy Management 0491

- Must ensure safe and appropriate procurement, storage, preparation, dispensing, use, tracking, control, and disposal of medications
  - Includes medication devices
- Must be administered in accordance with accepted professional principles
- This includes compliance with state laws (pharmacy laws), and federal regulations (USP 797, USP 800 hazardous drugs), standards by nationally recognized organizations (ASHP, FDA, NIH, USP, ISMP, etc.)

USP 800 Hazardous Drugs in Hospitals

- February 1, 2016 USP published the new standards
- Will apply to hospitals effective July 1, 2018
- That handle drugs identified as hazardous or potentially hazardous by NIOSH
- Done to help protect healthcare workers
  - For more information go to www.usp.org/news/usp-publishes-standard-handling-hazardous-drugs-healthcare-settings
  - FAQ at www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings

USP 800 Hazardous Drugs



BRIEFING

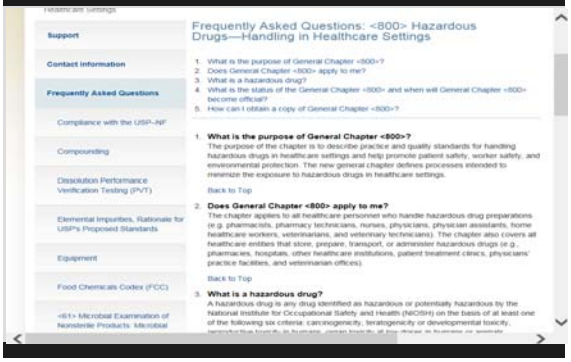
〈800〉 **Hazardous Drugs—Handling in Healthcare Settings.** Because there is no existing *USP* chapter for this topic, the Compounding Expert Committee and the Compounding with Hazardous Drugs Expert Panel propose this new general chapter to guide the handling of hazardous drugs in healthcare settings. This new general chapter has been created to identify the requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs to protect the patient, healthcare personnel, and environment. Facility requirements that differ from general chapter 〈797〉 *Pharmaceutical Compounding—Sterile Preparations* and this chapter will be harmonized. These differences include the following:

1. Elimination of the current allowance in 〈797〉 for facilities that prepare a low volume of hazardous drugs that permits placement of a BSC or CACI in a non-negative pressure room. All hazardous drug compounding shall be done in a separate area designated for hazardous drug compounding.
2. Allowance for a Containment Segregated Compounding Area (C-SCA), a separate, negative pressure room with at least 12 air changes per hour (ACPH) for use with compounding hazardous drugs. Low- and medium-risk hazardous drug CSP may be prepared in a BSC located in a C-SCA, provided the beyond-use date of the CSP does not exceed 12 hours. A CACI that meets the requirements in 〈797〉 may be used for hazardous drug compounding if it is placed in a C-SCA.

The proposed chapter is posted online at www.usp.org/usp-nf/notices/compounding-notice with line numbers. To ensure that your comments are received and addressed, please provide the line numbers corresponding to your comments when submitting comments to CompoundingSL@usp.org.

www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf

USP 800 Hazardous Drugs



Support

Contact Information

Frequently Asked Questions

Compliance with the USP–NF

Compounding

Dissolution Performance Verification Testing (PVT)

Elemental Impurities, Rationale for USP's Proposed Standards

Equipment

Food Chemicals Codex (FCC)

<61> Microbial Examination of Nonsterile Products: Microbial

Frequently Asked Questions: <800> Hazardous Drugs—Handling in Healthcare Settings

1. What is the purpose of General Chapter <800>?
2. Does General Chapter <800> apply to me?
3. What is a hazardous drug?
4. What is the status of the General Chapter <800> and when will General Chapter <800> become official?
5. How can I obtain a copy of General Chapter <800>?

1. **What is the purpose of General Chapter <800>?**
The purpose of the chapter is to describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection. The new general chapter defines processes intended to minimize the exposure to hazardous drugs in healthcare settings.

Back to Top

2. **Does General Chapter <800> apply to me?**
The chapter applies to all healthcare personnel who handle hazardous drug preparations (e.g. pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians). The chapter also covers all healthcare entities that store, prepare, transport, or administer hazardous drugs (e.g., pharmacies, hospitals, other healthcare institutions, patient treatment clinics, physicians' practice facilities, and veterinarian offices).

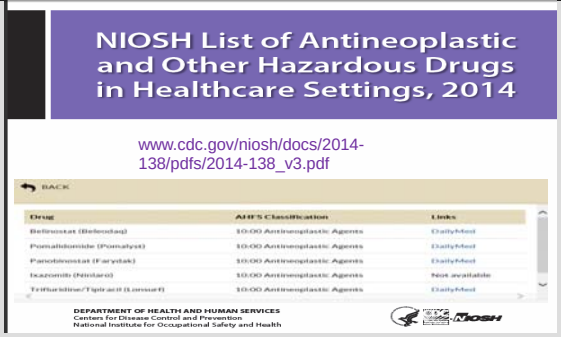
Back to Top

3. **What is a hazardous drug?**
A hazardous drug is any drug identified as hazardous or potentially hazardous by the National Institute for Occupational Safety and Health (NIOSH) on the basis of at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity,

NIOSH Hazardous Drugs

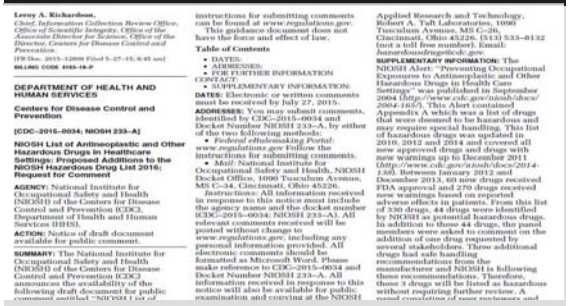
- Updated in 2014 and proposed additions in 2016 as published in the Federal Register
- NIOSH reviewed 70 new drugs that received FDA approval in 2014 updates
- NIOSH reviewed 180 drug that received new special warnings (usually black box warnings)
- Found 26 of these that were added to the list
- Removed 15 drugs that are no longer available in the ED

NIOSH List of Hazardous Drugs



www.cdc.gov/niosh/docs/2014-138/pdfs/2014-138_v3.pdf

Hazardous Update List 2016



www.cdc.gov/niosh/docket/review/docket233a/pdfs/233a_2015-12857.pdf

P&P and Drug Storage 491

- May use unit dose, floor stock, individual prescriptions or a combination
- Hospitals with drug storage areas only must use pre-packaged drugs that require no further preparation
- MS is responsible for P&Ps but can delegate it to pharmacy
- Hospital 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 or cite the source

P&P and Drug Storage 491

- Must train staff on P&Ps
- Must monitor to make sure P&Ps are being followed
- P&Ps for Minimizing Drug Errors
  - Need to take steps to prevent, identify, and minimize drug errors
  - This includes ensuring that the pharmacy process conforms to accepted standards of pharmacy practice

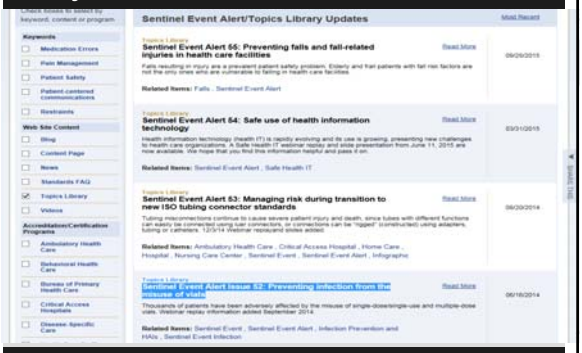
P&Ps for Minimizing Drug Errors

- Must proactively identify and review ADEs
- Must be aware of external alerts to real or potential pharmacy related problems
- Many organization issues sentinel event alerts or alerts
  - Such as 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
- Has a list of policies that are expected to be addressed

National Coordinating Council

Pharmacy Alerts NAN

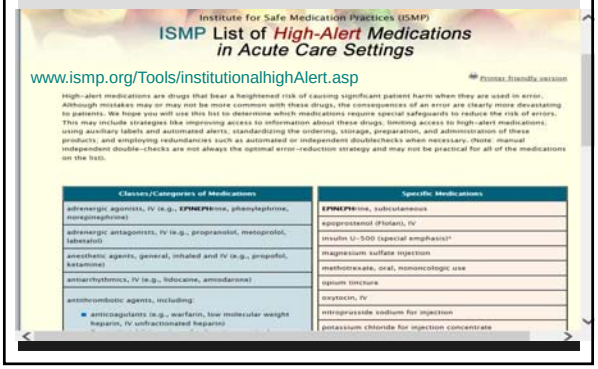
Many TJC SEAs are Medication Related



Required Policies and Procedures 491

- High alert medications
  - Include LASA meds (look alike-sound alike)
  - Includes meds with narrow therapeutic range (Warfarin), psychotherapeutic medications
  - Ways to minimize include dosing limits, packaging, guidelines, labeling and storage (TJC MM.01.01.03)
  - ISMP (Institute for Safe Medication Practice) and USP have list of high alert medications)

ISMP High Alert Medications


Institute for Safe Medication Practices (ISMP)

ISMP List of *High-Alert* Medications in Acute Care Settings

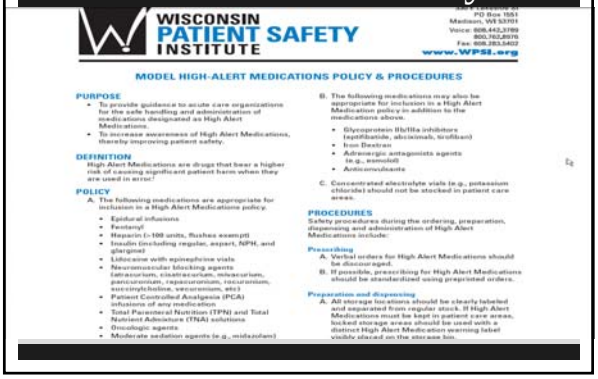
www.ismp.org/Tools/institutionalhighAlert.asp

Printer friendly version

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

Classes/Categories of Medications	Specific Medications
adrenergic agonists, IV (e.g., **EPINEPH**rine, phenylephrine, norepinephrine)	**EPINEPH**rine, subcutaneous
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)	epoprostenol (Flolan), IV
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)	insulin U-500 (special emphasis)*
antiarrhythmics, IV (e.g., lidocaine, amiodarone)	magnesium sulfate injection
antithrombotic agents, including:	methotrexate, oral, nononcologic use
▪ anticoagulants (e.g., warfarin, low molecular weight heparin, IV unfractionated heparin)	opium tincture
	oxytocin, IV
	nitroprusside sodium for injection
	potassium chloride for injection concentrate

So What's In Your Policy?


WISCONSIN PATIENT SAFETY INSTITUTE

www.WPSI.org

MODEL HIGH-ALERT MEDICATIONS POLICY & PROCEDURES

PURPOSE

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

DEFINITION

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

POLICY

A. The following medications are appropriate for inclusion in a High Alert Medications policy.

- Epidural infusions
- Fentanyl
- Heparin (>100 units, flushes exempt)
- Insulin (including regular, aspart, NPH, and glargine)
- Lidocaine with epinephrine vials
- Neuromuscular blocking agents (atracurium, cisatracurium, mivacurium, pancuronium, rapacuronium, rocuronium, succinylcholine, vecuronium, etc)
- Patient Controlled Analgesia (PCA) infusions of any medication
- Total Parenteral Nutrition (TPN) and Total Nutrient Admixture (TNA) solutions
- Oncologic agents
- Moderate sedation agents (e.g., midazolam)

B. The following medications may also be appropriate for inclusion in a High Alert Medication policy in addition to the medications above.

- Glycoprotein IIb/IIIa inhibitors (eptifibatide, abciximab, tirofiban)
- Iron Dextran
- Adrenergic antagonists agents (e.g., esmolol)
- Anticonvulsants

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

PROCEDURES

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

Prescribing

A. Verbal orders for High Alert Medications should be discouraged.

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

Preparation and dispensing

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

High Alert How to Guide IHI

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

Required Policies and Procedures 491

- Must follow standards of practice for all compounding, packaging, dispensing, and drug disposal
  - ASHP has sterile compounding resource center
- P&P to ensure investigational meds are safely controlled and administered
  - Written process to approve, review, supervise, and monitor investigational drugs
  - Pharmacy must control storage, dispensing, and labeling

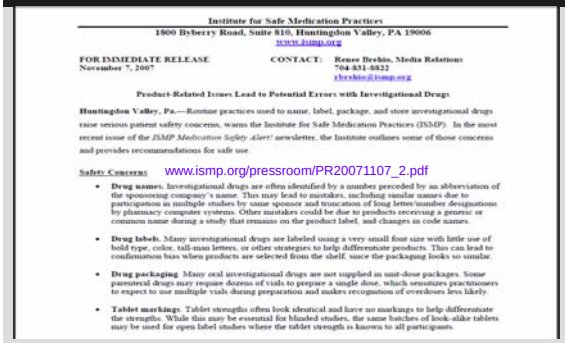
ASHP Sterile Compounding Resources

www.ashp.org/sterilecompounding

Outsourcing Vendor Assessment Tool

www.ashpfoundation.org/sterileproductstool

Safety Concerns of Investigational Meds



Institute for Safe Medication Practices
1800 Byberry Road, Suite 810, Huntingdon Valley, PA 19006
www.ismp.org

FOR IMMEDIATE RELEASE
November 7, 2007

CONTACT: Renee Brehio, Media Relations
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Product-Related Issues Lead to Potential Errors with Investigational Drugs

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

Safety Concerns

- **Drug names.** Investigational drugs are often identified by a number preceded by an abbreviation of the sponsoring company's name. This may lead to mistakes, including similar names due to participation in multiple studies by same sponsor and truncation of long letter/number designations by pharmacy computer systems. Other mistakes could be due to products receiving a generic or common name during a study that remains on the product label, and changes in code names.
- **Drug labels.** Many investigational drugs are labeled using a very small font size with little use of bold type, color, tall-man letters, or other strategies to help differentiate products. This can lead to confirmation bias when products are selected from the shelf, since the packaging looks so similar.
- **Drug packaging.** Many oral investigational drugs are not supplied in unit-dose packages. Some parenteral drugs may require dozens of vials to prepare a single dose, which sensitizes practitioners to expect to use multiple vials during preparation and makes recognition of overdoses less likely.
- **Tablet markings.** Tablet strengths often look identical and have no markings to help differentiate the strengths. While this may be essential for blinded studies, the same batches of look-alike tablets may be used for open label studies where the tablet strength is known to all participants.

www.ismp.org/pressroom/PR20071107_2.pdf

Required Policies and Procedures 491

- Standardize equipment and medication related devices
- CMS says can't have more than 1 or 2 types of infusion pumps
- Availability of up to date medication information
- Pharmacist on call if not open 24 hours
- "Resume previous orders" is prohibited
- Patient specific information that should be readily available (TJC tells you exactly what this is, like age, sex, allergies, current medications, etc.)

Standardize Rx & Communication Practices 491

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

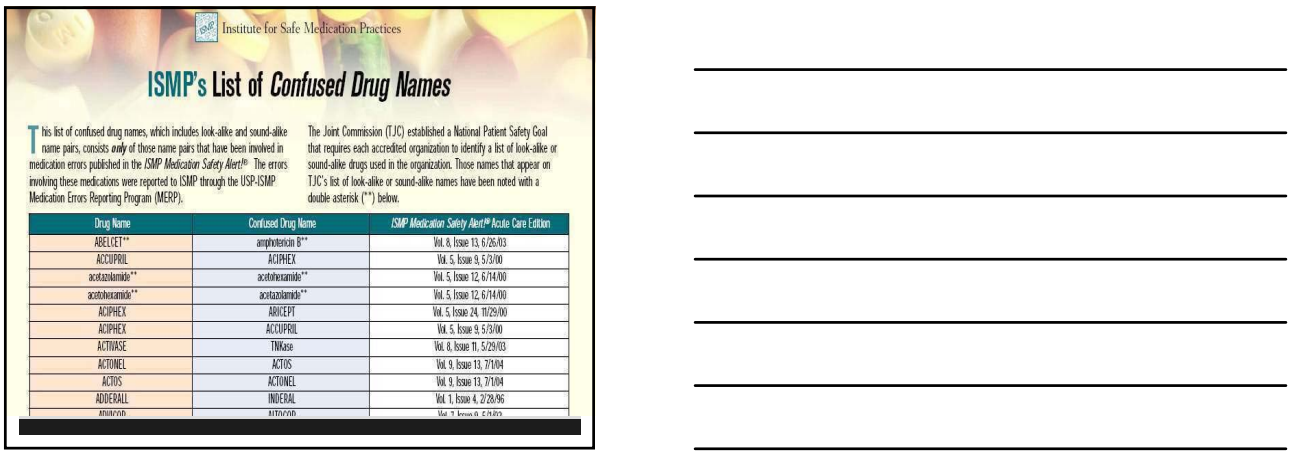
USP Confused Name List


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

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

USP Quality Review

Use Caution—Avoid Confusion


Institute for Safe Medication Practices

ISMP's List of *Confused Drug Names*

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

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

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

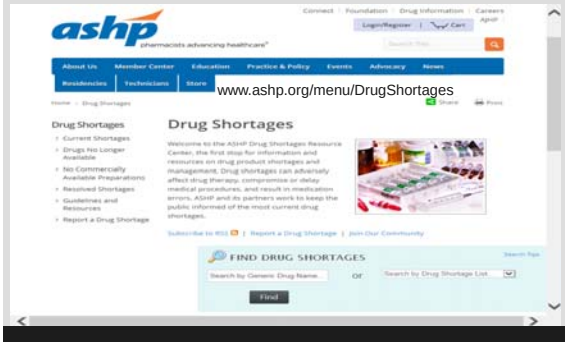
Required Policies and Procedures 491

- Be integrated into the hospital wide QAPI and flag new types of mistakes and continue to improve P&Ps as well as analyze errors and ADEs
  - RCA (systematic analysis) and FMEA are two tools
- Voluntary, non-punitive reporting system to monitor and report adverse drug events
  - System analysis theory recognizes most errors are a system problem and not due to bad practitioner
  - Many hospitals balance with Just Culture
  - TJC has the same standard

Required Policies and Procedures 491

- Monitor drug alerts and recalls
- Need to incorporate external alerts and recommendations from national associations and governmental agencies
  - Need to revise policies
  - CMS says hospital should consider ISMP, NCCMERP, FDA, and MedWatch Program
- The FDA has a list of drug recalls and can sign up to receive alerts
- ASHP has resources on drug shortages and guidelines

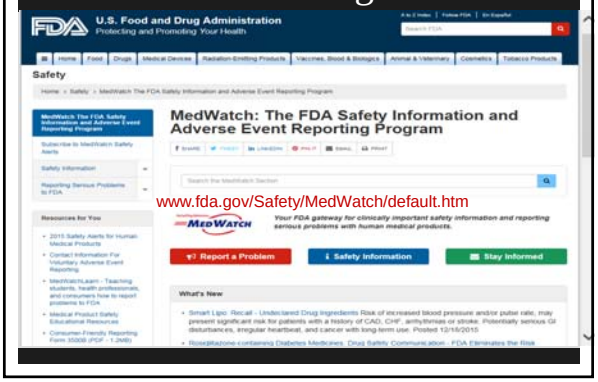
ASHP Website on Shortages



Sign Up to Get Recall Alerts from FDA

www.fda.gov/Safety/Recalls/default.htm

FDA MedWatch Program



www.fda.gov/Safety/MedWatch/default.htm

Required Policies and Procedures 491

- Identification of weight based dosing for pediatric populations
  - May also require weights for elderly patients in renal failure on antibiotics
  - Generally want to weigh babies in grams
  - Generally should weigh children in kg and not pounds or both
  - Weight based charts may help prevent medication errors in high risk medications

Use Kg and Not Pounds for Children

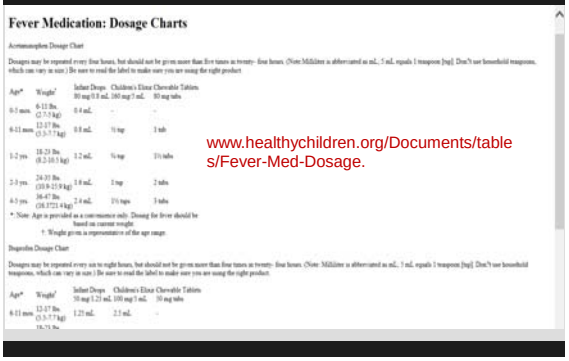
Acetaminophen Dosing Chart

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

Ibuprofen Dosing Chart

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

Acetaminophen& Ibuprofen Dosing Charts



Fever Medication: Dosage Charts

Acetaminophen Dosage Chart

Dosages may be repeated every four hours, but should not be given more than five times in twenty- four hours. (Note: Milliliter is abbreviated as mL; 5 mL equals 1 teaspoon [tsp]. Don't use household teaspoons, which can vary in size.) Be sure to read the label to make sure you are using the right product.

Age*	Weight†	Infant Drops 80 mg/0.8 mL	Children's Elixir 160 mg/5 mL	Chewable Tablets 80 mg tabs
0-3 mos	6-11 lbs. (2.7-5 kg)	0.4 mL	-	-
4-11 mos	12-17 lbs. (5.5-7.7 kg)	0.8 mL	½ tsp	1 tab
1-2 yrs	18-23 lbs. (8.2-10.5 kg)	1.2 mL	¾ tsp	1½ tabs
2-3 yrs	24-35 lbs. (10.9-15.9 kg)	1.6 mL	1 tsp	2 tabs
4-5 yrs	36-47 lbs. (16.3721.4 kg)	2.4 mL	1½ tsps	3 tabs

*Note: Age is provided as a convenience only. Dosing for fever should be based on current weight.

†Weight given is representative of the age range.

Ibuprofen Dosage Chart

Dosages may be repeated every six to eight hours, but should not be given more than four times in twenty- four hours. (Note: Milliliter is abbreviated as mL; 5 mL equals 1 teaspoon [tsp]. Don't use household teaspoons, which can vary in size.) Be sure to read the label to make sure you are using the right product.

Age*	Weight†	Infant Drops 50 mg/1.25 mL	Children's Elixir 100 mg/5 mL	Chewable Tablets 50 mg tabs
6-11 mos	12-17 lbs. (5.5-7.7 kg)	1.25 mL	2.5 mL	-

www.healthychildren.org/Documents/tables/Fever-Med-Dosage.

CDC Dosing Charts HIV Meds

www.cdc.gov/globalaids/docs/program-areas/pmtct/peds-dosing-guide.pdf

Peds Dosing Guide 22" x 10" 112706 11/27/06 11:10 AM Page 1

Weight range (kg)	Abacavir (Ziagen®, ABC)		Didanosine (Videx®, DDI)			Lamivudine (Epivir®, 3TC)		Stavudine (Zerit®, d4T)		Zidovudine (Retrovir®, ZDV, AZT)		
	8 mg/kg/dose TWICE daily		90-120 mg/m²/dose TWICE daily	120 mg/m²/dose TWICE daily	180-240 mg/m²/dose ONCE daily	4 mg/kg/dose TWICE daily		1 mg/kg/dose TWICE daily		180-240 mg/m²/dose TWICE daily		
	20 mg/ml solution	300 mg tablets	10 mg/ml suspension	25, 50, 100 mg chewable tablets	125, 200, 250, 400 mg EC capsules	10 mg/ml solution	150 mg tablets	1 mg/ml solution	15, 20, 30 mg capsules	10 mg/ml syrup	100 mg capsules	300 m tablet
5 - 5.9	2 ml		4 ml	25 mg + 25 mg tabs		3 ml		6 ml		6 ml		
6 - 6.9	3 ml		5 ml	25 mg + 25 mg tabs		3 ml		7 ml	10 mg (as 0.5 x 20 mg)	7 ml		
7 - 7.9	4 ml		6 ml	25 mg + 25 mg tabs		4 ml		8 ml	10 mg (as 0.5 x 20 mg)	8 ml		
8 - 8.9	4 ml		6 ml	25 mg + 25 mg tabs		4 ml		9 ml	10 mg (as 0.5 x 20 mg)	9 ml	1 cap	
									10 mg			

Pharmacist 492

- **Standard:** Must have pharmacy directed by a registered pharmacist or a drug storage under competent supervision
  - If has drug storage area instead of pharmacy still need to be under the direction of the pharmacist
- **Standard**: Must have pharmacist to develop, supervise, and coordinate activities of pharmacy
- Can be part time, full time or consulting
- Must have documented training or expertise in hospital pharmacy practice and management

Pharmacy Director 492

- Need to have written criteria for qualifications of the pharmacy director in accordance with scope of service
  - Most hospitals have a job description
  - Include responsible for supervision and coordination of all pharmacy services
  - Include active leadership of committees responsible for medication P&Ps
- Some small hospitals may not have a pharmacy but use a drug storage area for dispensing pre-packaged drugs

Pharmacist 492

- Must still make sure this area is under the supervision of a pharmacist or qualified person to ensure compliance with pharmacy requirements
  - Qualifications must be in writing, ensure security, access to locked areas and same is true if remote locations or satellites
- Has survey procedures and will ensure pharmacist has been appointed to be the director
- Will look at HR file to make sure qualified
- Will ask director how P&P developed, approved, and implemented

Enough Staff 493

- **Standard:** Must have adequate number of pharmacy staff to ensure quality pharmaceutical services
  - This include emergency services
- Need enough staff to meet the needs of the patient
- Must have sufficient staff in types, numbers, and training 24 hours 7 days a week
- Must have enough staff based on the scope and complexity of the hospital's pharmaceutical services
- Must participate in QAPI program

Pharmacy Delivery of Service 494

- **Standard:** Keep accurate records of receipt and disposition of all scheduled drugs
- Records must be current and accurate
- Must trace movement of scheduled drugs throughout the service
- Pharmacist must make sure records are reconciled
- Need policy to minimize drug diversion

Pharmacy Delivery of Service 500

- **Standard:** Drugs and biologicals must be controlled and distributed in accordance with federal and state law and standards of practice
- To prevent unauthorized use and distribution of medications
- To provide for an accounting of the receipt and distribution of drugs
  - Drugs subject to the Comprehensive Drug Abuse and Control Act of 1970
  - Law requires physical security of medications and strict record keeping for certain types of drugs such as controlled substances

Pharmacy Delivery of Service 500

- CMS specifically mentions ISMP, ASHP, USP, American College of Clinical Pharmacy (ACCP) and American Pharmacists Association (APA)
- CMS has blue boxes which are advisories
- Has a blue box on the USP's National Formulary
- Need a process where medication orders are received in the pharmacy and dispensed in a safe and timely manner
  - Pharmacists dispense and nurse administer medications
- Safe dispensing must be in accordance with SOP

Safe Dispensing of Medications 500

- Safe dispensing includes implementing systems such as dose limits, pre-printed orders, special labeling, double checks to minimize drug events
- Especially for high alert medications
- Ensure staff are aware of high alert medications and what the P&P says
- Need process to resolve questions with prescribing practitioner before medications are given
  - Need a culture of safety where staff feel comfortable
- Outcomes are documented in the chart

So What's In Your High Risk Med Policy?

General Hospital MEDICAL CENTER

HIGH ALERT MEDICATIONS

I. POLICY: To operate a safe medication administration and delivery system that will prevent the misuse medications and prevent misuse of a defined list of high-risk medications that have potential for significant harm.

II. PURPOSE: To reduce the potential for harm to patients by adopting and maintaining measures that specifically target medications with the highest risk of causing injury.

III. EQUIPMENT: A. High Alert Medication List
B. Medication Administration Record

IV. WHO DOES IT: A. Two licensed nurses, one being an RN

V. PROCEDURE: A. The high-alert list includes the medication groups that we determined were our highest risk medications. The list may be altered as necessary.

1. **Insulin, (subcutaneous,IV)**
2. **Heparin (LMWH, subcutaneous, IV)**
3. **Potassium chloride, for injection concentrate**

Delivery of Service 500 First Dose Rule

- **Standard**: 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

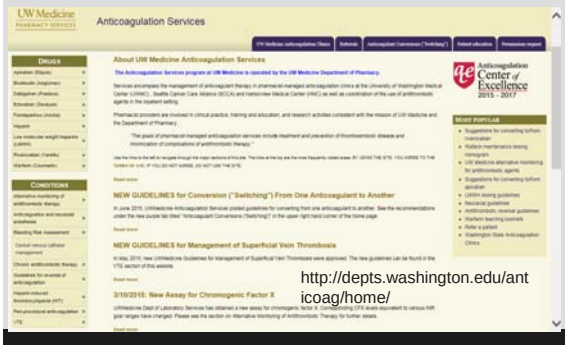
Pharmacy Delivery of Service 500

- Medications dispensed are retrieved when recalled or discontinued by manufacturer or FDA
  - Such as Vioxx or Darvocet
- Policy to address use of medications brought in
  - Policy, count drugs, patient signs release, locked in drawer
  - This will help with medication reconciliation
- Have a system in place to reconcile medications not administered
  - Such as left in drawer when pharmacy restocks or does inventory and determine if refused or not given by error

Monitoring Effects of Medication 500

- Must monitor medication effects as per policy to minimize ADE
- Usually with anticoagulants and antibiotics
- May request a pharmacy to dose order
- Monitoring effects of medication may include:
  - Clinical or lab data to evaluate dose, toxicity, or ADE
  - Physical signs and clinical symptoms
  - Assess patient's own perceptions about side effects
  - References nursing standards on monitoring of patients

Anticoagulant Resources UM



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

Compounding of Drugs 501

- **Standard:** All compounding, packaging, and disposal of drugs and biologicals must be under the supervision of pharmacist
- Must be performed as required by state or federal law
- Must have P&P to ensure all drugs are prepared by authorized staff
- Medications that need to be reconstituted or mixed are considered compounded preparations

Compounding of Drugs 501

- Some are compounded by pharmacy
- Some get them from manufacturer, registered outsourcing facility or compounding pharmacy
- Must meet standards for safe compounding to prevent contamination
- Drug Quality and Security Act (DQSA) has sections related to compounding
  - Signed into law Nov 27, 2013
  - Provides for oversight of compounding of drugs

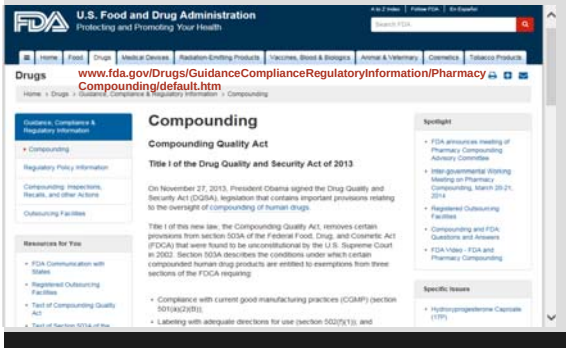
Compounding and Federal Law 501

- Under Section 503B a compounder can become an outsourcing facility
- Must register as one and comply with requirements, be inspected by the FDA, and provide AE information
- To be a registered outsourcing facility must comply with FDA's current good manufacturing practice (CGMP)
  - Has minimum requirements for manufacturer, processing, and packaging of drug product

Compounding and Federal Law 501

- As previously discussed, FDA wants hospitals to only use a registered outsourcing facility
- Pharmacies not registered as outsourcing facilities are called 503B pharmacies
  - These pharmacies are generally subject to oversight by the State Pharmacy board
- If hospital gets compounded medications from compounding pharmacy and not the manufacturer or a registered compounding pharmacy
  - Then hospital must demonstrate that compounded medicines have been prepared in accordance with SOC

FDA's Compounding Website



Use a Company that is Registered

www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm

Compounding and Federal Law 501

- So if hospital gets from compounding pharmacy then need to make sure they have access to quality assurance data
  - Hospital should get and review this data
- In the contract, the hospital would want to require that the compounding pharmacy meet the requirements of Section 503A of the FDCA
  - Remember ASHP Foundation has free toolkit to assess the contractors

Medication Compounded by Hospital 501

- Only the pharmacy compounds or admixes all sterile medications, IVs or other drugs
- Except in emergencies
  - There is a need for emergency or immediate patient administration
- All compounding must be done in accordance with SOP equivalent to the USP National Formulary
- Compounding is defined in USP 795 and includes reconstituting or manipulating commercial products by adding one or more ingredients

Medication Compounded by Hospital 501

- Compounded medication can result in contamination and unintended variations in strength
- Microbial contamination and bacterial endotoxins can be hazardous to patients
- USP 797 outlines SOP when preparing, storing, or transporting compounded sterile preparations (CSP)
  - This includes nasal inhalations, baths and soaks, injections, wound irrigation, eye drops and tissue implants
- Standard differs based on the level of risk
  - Low, medium or high risk level

Medication Compounded by Hospital 501

- This includes if the CSP must be sterilized before being used
- It includes how long it can be stored before it must be used
- Mentions the immediate use CSP standards which are published in the nursing section tag 405
- Some hospitals only prepare low-risk nonhazardous CSP from a physician's order for a specific patient and must be administered within 12 hours of preparation
  - Designated room with unidirectional airflow Class 5

Medication Compounded by Hospital 501

- The room can not be in an area with unsealed openings or openings to high traffic locations and only used to prepare low-risk CSPs
- If hospital preparing medium or high risk CSP with a BUD greater than 12 hours then must meet additional design and monitoring standards
  - Meet additional standards in the ante and buffer rooms
- USP 797 has separate standard for compounding of hazardous medications

Packaging and Labeling of Medications 501

- Proper packing and labeling is needed to reduce risk of error
- Each floor stock medication or unit dose must include:
  - Name, strength, lot and control number, and expiration date
  - If applicable must have a BUD
  - Multi-dose vials BUD is 28 days unless sooner by manufacturer
  - Make sure expiration date is on vial

Dispensing of Medications 501

- Meds should be dispensed in safe manner and to meet the needs of the patient
- Medications should be dispensed timely
  - Need system where medication orders get to the pharmacy and back to the patient promptly
- If feasible in unit dose
- In most ready to administer form
- Use the same dose packaging system
- Quantities are minimized to avoid diversion

FDA Resources on Drug Diversions

Dispensing of Medications 501

- Concerns must be clarified before dispensing
- Medications dispensed are retrieved when recalled and discontinued
  - Discussed previously under tag 491
- Medications must be available when pharmacy is not open and P&P on who can access
  - Often called the night cabinet standard
  - Can be from automated dispensing cabinets (ADC) outside the pharmacy
  - Contracted services with on-call pharmacists after hours

Locked Storage Areas 502 & 503

- **Standard:** Drugs and biologicals must be kept in a secure and locked area
- **Standard:** Schedule II-V drugs must be kept locked in secure area
  - Would be considered a secure area if staff actively providing care but not on a weekend when no one is around
  - Only authorized person can get access to locked areas
- P&P address self administration of drugs
  - See tag 406 (drugs and biologicals) and 412 and 413 also (self administered drugs) in nursing section

Locked Storage Areas 504

- 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 (ES), maintenance, or security
- Critical care and L&D area staffed and actively providing care are considered secure
- Setting up for patients in OR is considered secure such as the anesthesia carts but after case or when OR is closed need to lock cart

Locked Storage Areas

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

Medications in the OR ASA Position

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

American Society of Anesthesiologists

STATEMENT ON SECURITY OF MEDICATIONS IN THE OPERATING ROOM

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

Preamble

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

Recommended Policies

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

Rationale

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

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

Recommendation on Medications in the OR

The Official Journal of the Anesthesia Patient Safety Foundation

apsf NEWSLETTER Spring 2010

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

In this issue:

APSF Hosts Medication Safety Conference

APSF Funds New Registry

Web Application to Track Patient Safety During Sedation

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

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

Hospital Coalition Group Endorses APSF Recommendations for PCA Monitoring

Letters to the Editor:

Accidental Intrathecal Injection of Tranexamic Acid

APSF Hosts Medication Safety Conference

Consensus Group Defines Challenges and Opportunities for Improved Practice

by John H. Eichhorn, MD

Overview

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

The resulting consensus recommendations include:

Standardization

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

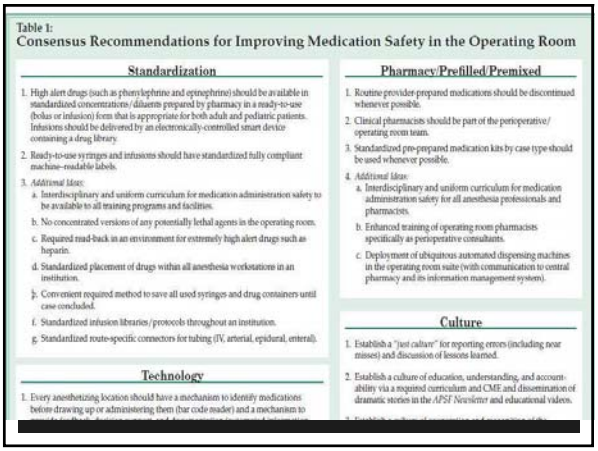


Table 1:
Consensus Recommendations for Improving Medication Safety in the Operating Room

Standardization

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

Technology

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

Pharmacy/Prefilled/Premixed

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

Culture

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

Policy and Procedure

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

Outdated or Mislabeled Drugs 505

- **Standard**: 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
- This include drugs that are recalled
- Drug can become unstable prior to expiration date if subject to conditions inconsistent with manufacturer's labeling

Outdated or Mislabeled Drugs 505

- Drug can be outdated before the BUD which can occur after the container is opened or while preparing during process if compounded
  - BUD is different from the expiration date
  - Expiration dates are given in years for commercial products
  - BUD is given or compounded preparations and are generally in hours or days
  - If compounded formulation is an official USP/NF the BUD in the monogram can be used or may be provided by manufacturer
  - BUD is the date and time after which a preparation must not be used or transported so use on patient before this date

Outdated or Mislabeled Drugs 505

- Hospital must have P&P to give clear direction to pharmacy staff on how to determine BUD if not available from the manufacturer
- P&P must be based on accepted professional principles equivalent to USP National Formulary
- Section in USP 797 entitled "Determining BUD"
  - Can be obtained through product specific experimental studies
  - Provides examples of issues a pharmacist can use to determine BUD in evaluating current literature

No Pharmacist on Duty 0506

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

No Pharmacist on Duty 0506

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

Automatic Stop Orders 507

- Standard: Drugs not specifically prescribed as to time and number must automatically be stopped after a reasonable time
- Commonly known as automatic stop orders
- Must follow acceptable SOP
- MS and pharmacy services determine automatic stop orders
- Hospital must monitor and enforce
- In EHR can have dose and time parameters build into the CPOE screens

Pharmaceutical Services 0508

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

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 Incompatibilities Definition

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

Drug Incompatibilities

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

Reporting to the Attending

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

Medication Errors With No Harm 0508

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

Drug Administration Errors

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

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

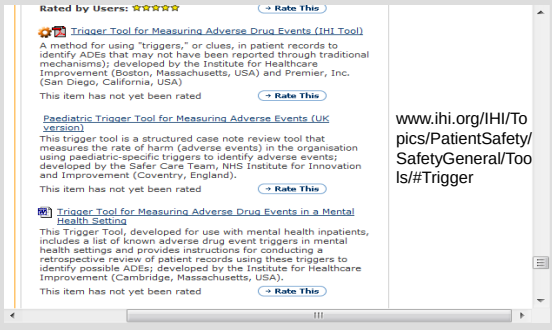
Hospital Requirements 508

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

Proactive Identification

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

IHI Has Three Trigger Tools for ADEs



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

Measure of Effectiveness 508

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

Medication Error Reporting 0508

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

Survey Procedure 0508

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

Abuses and Losses 509

- Standard: 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

Information Available to Staff 510

- Standard: Information must be available to staff
  - Drug interaction, side effects, toxicology, doses, indication for use and routes of administration
- Pharmacy must be a resource for medication related information to optimize outcomes
- Pharmacy may assist staff with following medication related functions;
  - Collect specific information such as allergies, height, and weight
  - Pharmacy therapeutic goals

Pharmacy Can Help Staff 510

- Identify any problems such as drug-drug interactions or excessive doses
- Monitor and adjust dose based on lab values such as Warfarin dosing
- Monitoring the plan as needed
- Practitioner may write pharmacy to dose and would calculate dose required
- CPOE may have build in functions for dosing, interactions but pharmacy responsible for accurate up to date information

Information Available to Staff 510

- Needs to have up to date resources whether in electronic or hard copy
- Pharmacist needs to be readily available by phone to respond to questions from nursing and other practitioners
- Surveyors will ask staff whether needed reference material is available to them
- Surveyors will ask nursing staff if reference material available when monitoring patients for medication therapies

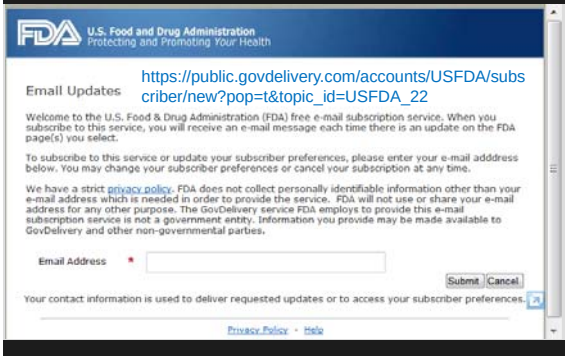
Formulary 0511

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

Medications Shortages

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

Sign Up To Get Drug Shortage Information



The End! Questions???

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Websites

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

Websites

- American College of Emergency Physicians ACEP - www.acep.org
- Joint Commission Joint Commission - www.JointCommission.org
- Centers for Medicare and Medicaid Services CMS - www.cms.hhs.gov
- American Association for Respiratory Care AARC - www.aarc.org
- American College of Surgeons ACS -www.facs.org
- American Nurses Association ANA - www.ana.org
- AHRQ is www.ahrq.gov
- American Hospital Association AHA - www.aha.org

Websites

- U.S. Pharmacopeia (USP) www.usp.org
- U.S. Food and Drug Administration MedWatch - www.fda.gov/medwatch
- Institute for Healthcare Improvement - www.ihi.org
- AHRQ at www.ahrq.gov
- Drug Enforcement Administration –www.dea.gov (copy of controlled substance act)
- US Pharmacopeia - www.usp.org, (USP 797 book for sale)
- National Patient Safety Foundation at the AMA -www.ama-assn.org/med-sci/npsf/htm
- The Institute for Safe Medication Practices - www.ismp.org

Websites

- CMS Life Safety Code page - http://new.cms.hhs.gov/CFCsAndCoPs/07_LSC.asp
- American College of Radiology- www.acr.org
- Federal Emergency Management Agency (FEMA)- www.fema.gov
- Sentinel event alerts at www.jointcommission.org
- American Pharmaceutical Association - www.aphanet.org
- American Society of Heath-System Pharmacists - www.ashp.org

Websites

- Enhancing Patient Safety and Errors in Healthcare - www.mederrors.com
- National Coordinating Council for Medication Error Reporting and Prevention - www.nccmerp.org,
- FDA's Recalls, Market Withdrawals and Safety Alerts Page: www.fda.gov/opacom/7alerts.html
- Association for Professionals in Infection Control and Epidemiology (APIC) infection control guidelines at www.apic.org
- Centers for Disease Control and Prevention - www.cdc.gov
- Occupational Health and Safety Administration (OSHA) at www.osha.gov

Infection Control Websites

- The National Institute for Occupational Safety and Health NIOSH at www.cdc.gov/niosh/homepage.html
- AORN at www.aorn.org
- Society for Healthcare Epidemiology of America (SHEA) at www.shea-online.org

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Thanks for attending! Questions???

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