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JCAHO Med Management

Meeting the Standards for Emergency Medications and Labeling

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This continuing feature highlights the experiences of various health care organizations regarding the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) Medication Management Standards and National Patient Safety Goals implementation. Practical information on what worked and how organizations have been surveyed regarding the standards and goals will be provided along with updates on revisions and recommendations being established by JCAHO. To share your success stories, contact Sondra K. May, PharmD, Department of Pharmacy Services, University of Colorado Hospital, 4200 East Ninth Avenue, Box A-027, Denver, CO 80262. E-mail: sondra.may@uch.edu.

Abstract — The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Medication Management Standards and certain National Patient Safety Goals (NPSG) contain specific requirements aimed at promoting medication safety. Medication Management Standard 2.30 requires that emergency medications are consistently available, controlled, and secured. Changes made in 2004 in the CMS Interpretive Guidelines for hospital Conditions of Participation deal with security of mobile carts. Since JCAHO requires compliance with applicable federal and state laws and regulations, these CMS regulations need to be considered when designing and controlling emergency medication supplies. Medication Management standard 4.30 requires that medications are labeled. A new 2006 NPSG details requirements for medication labels on and off the sterile field.

EMERGENCY MEDICATIONS

JCAHO Medication Management (MM) 2.30 states, "emergency medications and/or supplies, if any, are consistently available, controlled, and secured."[1] Additionally, elements of performance from MM.2.20, concerning proper and safe medication storage, apply to all medications—including those for emergencies.

A standard stock of medications and supplies for the crash carts used within the organization must be developed. This should be re-evaluated periodically to ensure that the medications and supplies are appropriate, consistent with current guidelines, and meet the needs of the clinicians and patients.

Dosage Forms in Crash Carts

Most of the infusions used during codes can be purchased as premixed solutions, avoiding the need for personnel to mix the solutions during the emergency situation. National Patient Safety Goal (NPSG) 3B requires that the organization standardize and limit the number of drug concentrations available in the organization and MM.2.20 element of performance 3 requires that emergency medications are available in ready-to-administer forms whenever possible. Dopamine, dobutamine, lidocaine and other cardiovascular infusions should be available in crash carts in the premixed forms and in the standardized concentrations approved by the Pharmacy and Therapeutics Committee.

Other Emergency Medication Supplies

Pharmacy should control all emergency drug supplies. Though crash carts are often tightly controlled, many times other emergency supplies have developed without the input of pharmacy. Tackle boxes and other containers of emergency medications need to be under the same control as crash carts, including:

- Approval of contents by a medical staff committee
- Security
- Documentation of integrity of the contents

Table 1 lists common types of emergency stock maintained in hospitals. The procedures used for determining contents, locations, and the security and documentation for each emergency container should be consistent and under

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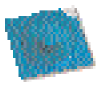

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Table 1. Types of Emergency Medication Stock

Crash cart – adult
Crash cart – pediatric
Crash cart – neonatal
Rapid sequence intubation kits
Hyperthermia cart
Perfusion cart
Epidural cart
Toxemia box
Thrombolytic box
Transport box
Imaging box
Dialysis box

control of the pharmacy department.

Be sure that nursing and other clinical staffs are aware that these are evaluated as emergency medications during surveys. Many sites find it helpful to perform a "fresh eyes" walk-through periodically to ensure that all medications are properly controlled.

Table 2. CMS Interpretive Guideline Concerning Security

§482.25(b)(2) Drugs and biologicals must be kept in a locked storage area.
§482.25(b)(2) Interpretive Guidelines

All drugs and biologicals must be kept in a locked room or container. If the container is mobile or readily portable, when not in use, it must be stored in a locked room, monitored location, or secured location that will ensure the safety of the drugs or biologicals.

All drugs and biologicals must be stored in a manner to prevent access by non-authorized individuals.

Persons without legal access to drugs and biologicals cannot have unmonitored access to drugs or biologicals.

Persons without legal access to drugs or biologicals cannot have keys to medication storage rooms, carts, cabinets, or containers. Whenever persons without legal access to the drugs or biologicals have unmonitored access to or could gain access to the drugs or biologicals stored in an area, the hospital is not in compliance with the requirement to store all drugs and biologicals in a locked storage area.

Nursing Medication, Anesthesia, and Other Medication Carts

When not in use, nursing medication, anesthesia, and other medication carts (hereafter referred to as "carts") containing drugs or biologicals must be locked or kept in a locked storage room. However, due to the mobility of carts, when not in use, locked carts that contain drugs or biologicals must be stored in a locked room or secure location. If a cart containing drugs or biologicals is in use and unlocked, someone with legal access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with state and federal law and hospital policy has legal access to the drugs and biologicals in the cart. That person must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

Security of Crash Carts and Other Emergency Drug Supplies

In May 2004, CMS published Interpretive Guidelines for Hospital Conditions of Particpation.[2] §482.25(b)(2) requires that drugs and biologicals must be kept in a locked storage area. The section specifically notes that mobile carts and other containers must be stored in a locked room or secure location. The specific Interpretive Guideline is listed in Table 2.

Examine your placement of carts and other mobile containers such as tackle boxes. Ensure that they are secure based on the CMS Interpretive Guidelines.

Pediatric Dosing

The Rule of Six, a calculation method to prepare weight-based infusions, has gained attention since it conflicts with the JCAHO mandate to standardize concentrations of infusions. JCAHO requires that this controversial dosing method be eliminated, since it is based on varying the concentration of infusions rather than varying the rate of a standardized concentration. Hospitals that continue to use the Rule of Six must apply to JCAHO to request approval of an alternative approach, meet all the criteria developed by JCAHO,[3] and eliminate the method no later than December 31, 2008.

Some organizations use a pediatric emergency tape to calculate dosages of medications during codes. The newest version of the *Broselow* tape (New Edition 2002) provides information that uses standardized infusion concentrations; older versions used patient-specific concentrations based on the Rule of Six. Some organizations have developed supplements to these tapes to further clarify standard concentrations used in their organizations.[5]

Other Emergency Medication Related Standards

Emergency medication stocks in other non-acute areas of an organization need to be considered. Many organizations have a variety of non-acute care, including ambulatory surgery, behavioral health, home care, and long-term care. Standard MM.3.20 applies to each of these accredited areas. Coordination through pharmacy

offers a consistent approach and guidance in meeting the requirements.

Environment of Care standard (EC) 4.10 requires that the hospital address emergency management. Part of the plan for managing emergency conditions includes logistics for managing critical supplies including pharmaceuticals. Be sure that your plan for emergency preparedness includes provision of appropriate medications and supplies, and is consistent with MM.3.20.

LABELING

JCAHO MM.4.30 states, "medications are labeled."[1] Though this standard and related elements of performance have not changed since 2004, an additional requirement of NPSG 3 has been clarified and added for 2006: "label all medication containers (eg, syringes, medicine cups, basins) or other solutions on and off the sterile field in perioperative and other procedural settings."[7,8]

Procedural Settings

Procedural settings include the surgical suite as well as areas such as imaging, endoscopy units, cardiac catheterization labs, physicians' offices, and even the patient's bedside. Keep in mind that:

- The definition includes medications, chemicals, reagents, cleansers, saline, and water
- All containers must be labeled, even if there is only one medication or solution
- Labeling must occur whenever any medication or solution is transferred from the original package to another container
- The medication or solution should be labeled one at a time
- The label must include the drug name, strength, amount (if not evident from the container), expiration date if not used within 24 hours, and expiration time if it occurs in less than 24 hours
- Two qualified individuals must visually and verbally verify the labels, when the person preparing the medication is not the same as the one administering the medication
- The container itself must be labeled. A label below the container is not sufficient; neither is taping a vial to the syringe to act as a label

Accurate and complete labeling is a basic medication safety issue. Various organizations have published information on fatal errors related to lack of labeling medications in procedural areas:

- A JCAHO Sentinel Event Alert from February 2001[9] highlighted an error where a basin thought to contain lidocaine 1% with epinephrine 1:100,000 actually contained topical epinephrine 1:1,000
- The Institute for Safe Medication Practices (ISMP) reported on a mixup of chlorhexidine with contrast media in December 2004[10]
- The Association of periOperative Registered Nurses (AORN) published a Guidance Statement: Safe Medication Practices in Perioperative Practice Settings[11] that supports complete labeling

Be sure that all procedural areas are aware of the expectations and are compliant with complete labeling.[12] Sterile labels can be obtained from various suppliers.

Labeling Medications in Anesthesia

Labeling a medication drawn up by an anesthesiologist or CRNA for immediate administration to a patient during surgery is not necessary. However, if another person draws up the medication prior to the case, or the syringe is prepared for gradual infusion during the case, it must be labeled appropriately.

Table 3. Safety Guidelines for Vincristine

Ensure proper labeling that includes: • Fatal if given intrathecally • For IV use only
Do not remove covering until moment of injection
Administer IT medications in a designated location at a standard time
Have the pharmacy prepare IT medications immediately before they are needed and deliver the drugs to the specific location
Never dispense or deliver IV medications along with IT medications
Require at least two health care professionals to independently verify and document the accuracy of IT doses before administration

IT = intrathecally

Labeling Vinca Alkaloids

Inadvertent administration of vincristine intrathecal (IT) continues to be reported. JCAHO published a Sentinel Event Alert[13] focused on this generally fatal error.

Be sure that doses of vinca alkaloids prepared in your pharmacy contain the FDA-required label stating: "Fatal if given intrathecally. For IV use only. Do not remove covering until moment of injection."

Suggestions to improve safety with vincristine[14] are listed in Table 3.

Labeling Oral Contrast Media

In many organizations, oral contrast media (barium, diatrizoate meglumine, and diatrizoate sodium solution) are distributed by the Department of Imaging. Be sure that the containers intended for patients are completely labeled, including:

- The hospital-approved two patient identifiers
- Drug name, strength, and amount (if not apparent from the container)
- The date prepared and the name or initials (depending on hospital policy) of the person who prepared the container
- Expiration date and time when not used within 24 hours
- Directions for use and any applicable cautionary statements

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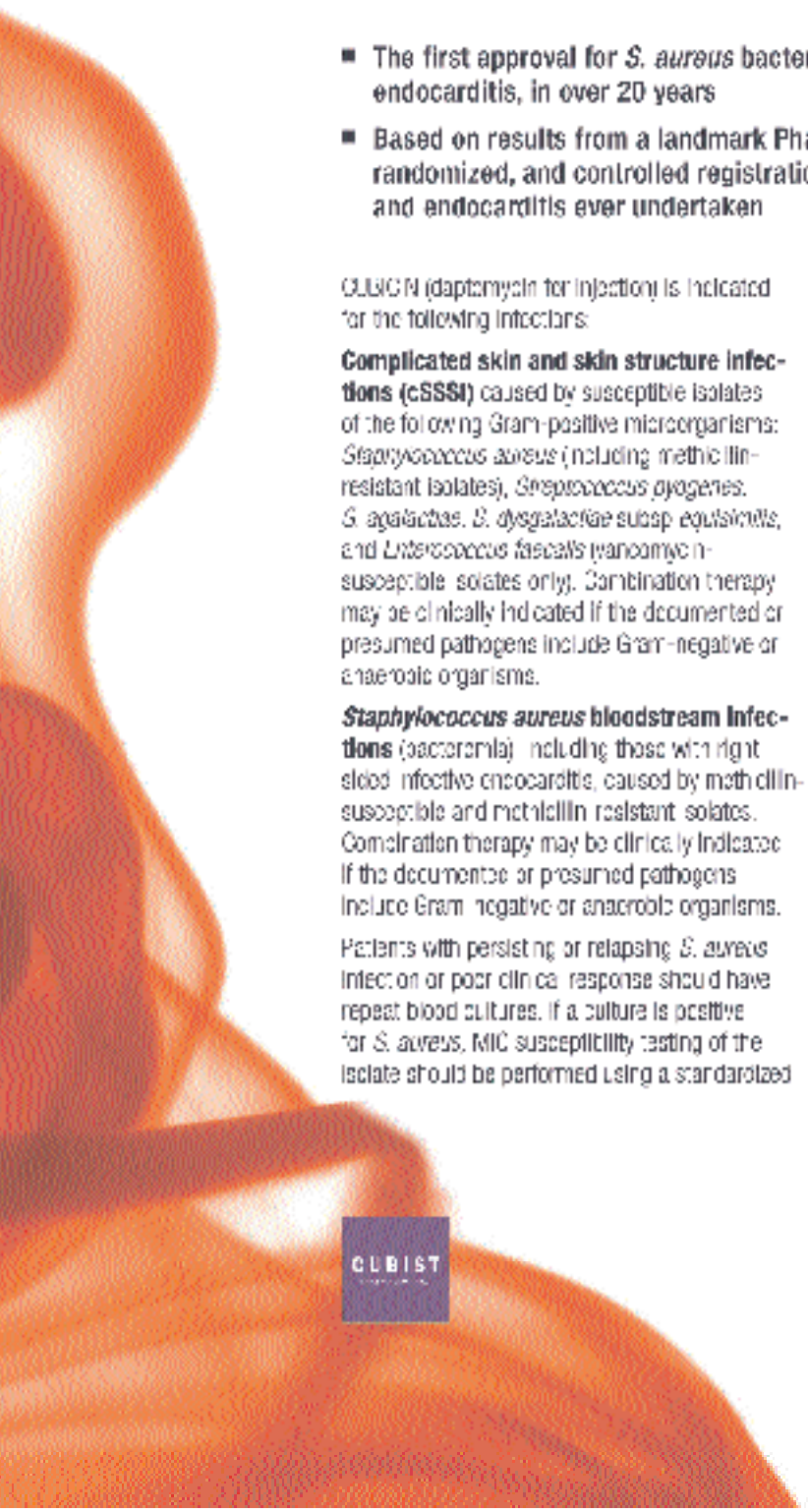
NEW INDICATION

CUBICIN 6 mg/kg once daily is now indicated for *S. aureus* bacteremia, including right-sided endocarditis, caused by MRSA and MSSA

- The first approval for *S. aureus* bacteremia, including right-sided endocarditis, in over 20 years
- Based on results from a landmark Phase 3 trial: the only prospective, randomized, and controlled registration trial of *S. aureus* bacteremia and endocarditis ever undertaken



CUBICIN (daptomycin for injection) is indicated for the following infections:

Complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant isolates), *Streptococcus pyogenes*, *S. agalactiae*, *S. dysgalactiae* subsp. *equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible isolates only). Combination therapy may be clinically indicated if the documented or presumed pathogens include Gram-negative or anaerobic organisms.

***Staphylococcus aureus* bloodstream infections** (bacteremia), including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates. Combination therapy may be clinically indicated if the documented or presumed pathogens include Gram-negative or anaerobic organisms.

Patients with persisting or relapsing *S. aureus* infection or poor clinical response should have repeat blood cultures. If a culture is positive for *S. aureus*, MIC susceptibility testing of the isolate should be performed using a standardized procedure, as well as diagnostic evaluation to rule out sequestered foci of infection. Appropriate surgical intervention (eg, debridement, removal of prosthetic devices, valve replacement surgery) and/or consideration of a change in antibiotic regimen may be required.

CUBICIN is not indicated for the treatment of pneumonia.

Patients receiving CUBICIN should be monitored for the development of muscle pain or weakness, particularly of the distal extremities. CPK levels should be monitored weekly, and any unexplained elevations should be monitored more frequently.

CUBICIN should be discontinued in patients with unexplained signs and symptoms of myopathy in conjunction with CPK elevation >1,000 U/L, or in patients without reported symptoms who have marked elevations in CPK (>10x U.L.N.).

Most adverse events reported in clinical trials were mild to moderate in intensity. The most common were anemia, constipation, diarrhea, nausea, vomiting, injection site reactions, and headache.

Please see brief summary of prescribing information on the next page.

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