Preparing Radiology/Nuclear Medicine to Comply with The Joint Commission Accreditation Standards

Jeffrey P. Norenberg, PharmD, PhD, BCNP, FASHP, FAPhA
Professor and Director of Radiopharmaceutical Sciences
Professor of Anesthesiology & Critical Care Medicine
University of New Mexico Health Sciences Center
and
Executive Director and Chairman
National Association of Nuclear Pharmacies

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Learning Objectives

• List the three Joint Commission (TJC) medication-related standards scored as non-compliant on surveys in imaging areas.
• Cite a common cause of non-compliance in imaging areas for each of the above three standards.
• List five specific strategies to improve compliance with TJC medication-related standards in imaging areas.
Self-Assessment Questions

True or False:
1. Medication storage is one of the top cited TJC standards in imaging areas.
2. The use of pharmacy bulk packages of contrast for multiple patients in radiology is prohibited by the Joint Commission.
3. It is permissible for imaging to prepare sterile IV’s rather than the pharmacy because they are procedural areas.
Medicare Deemed Status

- Implications of the Medicare Improvements for Patients and Providers Act of 2008
  - TJC standards aligned with Medicare Conditions of Participation (COP)
  - TJC interpretation based on CMS interpretation
  - CMS input into standard & survey process changes
  - New EP’s based on language specificity in COP
    - “For hospitals that use Joint Commission accreditation for deemed status purposes:”

EP = Elements of Performance
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Medication Storage

- Medication Security
  - EP 3. Stores all medications in a secure area
  - EP 6. Prevents unauthorized individuals from obtaining medications

- Issues:
  - Medication carts (code carts) in an area accessible to unescorted visitors/patients, or not in view of staff
  - Staff (janitors, maintenance) have access to medication areas without being authorized to do so in policy
  - Medications accessible unaccompanied public/visitors
    - lying around, rooms left unlocked -including wasted drugs
Medication Security

- Procedural areas are secure if active and staffed
- Mobile Carts (incl. crash carts)
  - Due to mobility, must be in a locked room in a secure area or under constant surveillance when not in use.
- Automated Dispensing Cabinets (ADCs)
  - Considered locked, but must be in secure area.
- Must have policy on which staff can have access
- Litmus test: Can visitors access the medications?

Revised Interpretive Guidelines for Hospital COP.
CMS Memo S&C-08-12, February 8, 2008
Medication Storage Issues

- EP 7*: Stored medications (and components used in their preparation) not labeled with contents, expiration date, and any applicable warnings
  
  - Issue:
  
  - No or wrong expiration date on products
    
    - If not labeled with an expiration date by manufacturer, then one must be assigned
    
    - Once opened or stored in different conditions (e.g., warmer) must be assigned a revised beyond use date

* = direct impact EP
Beyond Use Date

• The Joint Commission requires organizations to re-label all drugs with a “beyond use date” once the original manufacturer’s container is opened
  – Includes IV’s stored after the overwrap is removed and contrast in warmers
  – Date must be the last date that the product is to be used – cannot be the date opened – see FAQ
  – If manufacturer specifies a beyond use date in the package insert, subsequent labeling must use same or less
    • Otherwise pharmacy specifies (from standards of practice)
Beyond Use Date

• For sterile injectable multi-dose vials, the Joint Commission requires a revised expiration date of 28 days from the date of opening or puncture except when:
  – Original expiration date is shorter
  – Where manufacturer specifies otherwise in the package insert

• **Issue:** Non-contrast medications in Nuclear Medicine, Interventional Radiology, Cardiac Stress Lab

*Joint Commission Perspectives June 2010*
Medication Storage

• EP 2: Stores medications according to the manufacturers’ recommendations or, in the absence of such recommendations, according to a pharmacist’s instructions
• EP 8: Removes all expired, damaged, and/or contaminated medications and stores them separately from medications available for administration
• EP 18: Periodically inspects all medication storage areas
Medication Storage

• **Issues:**
  – Expired medications stored in areas for patient use
  – Products stored under conditions not allowed in package insert
    • Cannot store contrast in warmer if manufacturer does not specify the storage condition in package insert, or other document from manufacturer
    • Cannot store at room temperature if manufacturer specifies product must be refrigerated
CDC Safe Injection Practices

• TJC requires adherence to CDC Safe Injection Practices guidelines
  – IC.01.05.01, EP 1 – Must incorporate CDC Safe Injection Guidelines in P&P
  – IC.02.01.01, EP 2* – Must follow CDC Safe Injection Guidelines in practice
    • Joint Commission Perspectives - October 2010
  – For CDC guidelines see:
    • http://www.cdc.gov/injectionsafety/unsafePractices.html

IC = Infection Control
CDC Safe Injection Practices

• Examples from CDC Guidelines:
  – “Do not administer medications from single-dose vials or ampules to multiple patients”
    • propofol, contrast
  – “Do not use bags or bottles of IV solution as a common source of supply for multiple patients”
    • cardiac cath, IR, procedural areas, nuclear med
  – “Pre-spiking IV bags”
• Examples from CDC Guidelines (continued):
  – If used for multiple patients, “Do not store multi-dose vials (MDV) in the immediate patient treatment area”
    • OR suite, patient room, procedure room, patient bay
    • If MDV used for multiple patients, medication from MDV must be drawn up outside of the immediate treatment area or MDV must be discarded after treatment (used for only one patient)
      – Cardiac Cath Lab, Cardiac Stress, IR, Nuclear Medicine
When: April 2012 - Arizona
Who: Three patients who received pain remediation and contrast injections
Breaches: Use of single-dose/single-use vials of contrast media and saline solution for multiple patients and failure to wear facemasks during injection procedures
Patient Impact: Three patients admitted to the hospital for severe infections including mediastinitis, bacterial meningitis, epidural abscess, and sepsis. A fourth patient who received contrast from the same vial was found deceased at home. Invasive MRSA infection could not be ruled out.
The Bulk Contrast Vial Issue
Pharmacy Bulk Package

• These are NOT multi-dose vials – there is no such thing as a multi-dose vial of IV contrast!

• Wording in Package Insert:
  – “The transfer is restricted to a suitable work area, such as a laminar flow hood”
  – “Once the pharmacy bulk package is punctured, it should not be removed from the aseptic work area during the entire period of use”
Pharmacy Bulk Package

• FDA interpretation (10/31/2011)
  – “An aseptic area is one that meets the following criteria:
    • Engineering controls such as HEPA-filtered laminar air flow that meets the standards for ISO Class 5
    • Appropriate cleaning and disinfecting procedures
    • Periodic microbiological monitoring of the area”
  – “We do not regard PBP’s as appropriate for use in the CT suite unless the suite meets these specific criteria”
    • Sterile tubing does not constitute an aseptic area
Current Status

• FDA
  – Requiring equipment manufacturers to prove sterility when used in their equipment
    • If not done, approval could be withdrawn
  – Creating a new category of vial for multiple patient use in radiology that is not a “pharmacy bulk package”
    • Contrast manufacturers to create new packaging for multiple patient use
Current Status

• Joint Commission
  – Not surveying use of pharmacy bulk package in multiple patients, providing risk assessment by organization done
  – Will cite if bulk package not stored properly and/or used within beyond use date

• Still at Legal Risk of Lawsuit
  – if not treated as single dose vials outside of the hood
    • ISMP *Medication Safety Alert!,* September 20, 2012
    • Package Insert
Footnote:
- Radiology: Pharmacist review of contrast orders (including radiopharmaceuticals) is exempted. However, the hospital is expected to define, through protocol or policy, the role of the LIP in the direct supervision of a patient during and after IV contrast media is administered.

- See ACR guidelines for IV contrast administration
- Issue: IV contrast administered per protocol without specifying role of MD in supervision of patient before and during IV contrast administration in the policy or protocol
• **Issue:** No pharmacist review when required
  – Non-contrast medications in diagnostic areas for scheduled cases when no LIP at the patient bedside during administration of the drug
  – Non-profiled ADCs for all drugs
    • Cardiac Stress: dobutamine, Lexiscan, adenosine
    • Nuclear Medicine: furosemide, etc.
    • Radiology: lorazepam, others given by RN

ADCs = Automated dispensing/distribution cabinets
Drug Preparation

- EP 1* - A pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations except in urgent situations in which a delay could harm the patient or when the product’s stability is short.
  - Presence of LIP (or admixture performed by LIP) is not an exception! Neither is being a “procedural area”.
  - Issues: Heparin drips, irrigations and other IV admixtures often non-standard concentration

* = direct impact EP
Drug Preparation

- **Intravenous admixture**: addition of a measured amount of drug to a 50mL or greater bag or bottle of fluid given by any sterile route.
  - Pre-packaged Add-a-Vial® systems, syringes and reconstitution of vials exempt

CAMH = Comprehensive Accreditation Manual For Hospitals
• EP 2* - Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas dedicated solely for IV product preparation
• EP 4* - Any compounded sterile product that is not used within 24 hours must be prepared by the pharmacy in an ISO Class 5 environment
A Word about USP 797

• TJC Does NOT survey against USP 797
  – Compliance not required unless required by state law or regulation
  – If not required by state law or regulation, required to evaluate against most current USP 797 and develop action plan for implementation of any changes they feel are necessary to improve process. (MM.08.01.01)
    • Can choose to do something different
    • Decision process is important
    • No maximum timeline – hospital specifies
    • Only survey if evaluation done & plan present
Contracted Pharmacy Services

• LD.04.03.09: Care, treatment, and services provided through contractual agreement are provided safely and effectively
  – Vendors selection must have input of the medical staff
  – Must establish expectations for the performance of the contracted services
  – Must communicate the expectations in writing to the provider of the contracted services
  – Must monitor contracted services by evaluating these services in relation to the hospital’s expectations
  – Must take steps to improve contracted services that do not meet expectations
Contracted Pharmacy Services

- Applies to:
  - Unit dose radiopharmaceuticals (patient-specific)
  - Outsourced sterile pharmacies that are not manufacturers or FDA registered

- Does not apply to:
  - Bulk Radiopharmaceuticals, Kits
  - Medications from a FDA registered as a “Human Drug Compounding Outsourcing Facility”
Use of Radiopharmaceuticals

• Obtained from
  – Manufacturer is a registered “Drug Establishment”
  – Licensed by NRC
  – Procurement of radiopharmaceuticals (10 CFR 35.100)

• Prepared by
  – Authorized Nuclear Pharmacist (10 CFR 35.55)
  – Authorized User Physician (10 CFR 35.57)
  – Supervised individual (10 CFR 35.27)
Copies of FDA-Approved Products

• FDC § 503A
  – May not compound “regularly or in inordinate amounts any drug products that are essentially copies of commercially available drug products.”
    • Exception for drugs on FDA shortage list
    • Exception where there is a change that produces for an individual patient a clinical difference, as determined by the prescriber, between the compounded drug and the approved drug

• S. 959
  – Radiopharmaceutical must be compounded using one or more FDA-approved RPs…

• APhA Radiopharmaceutical Compounding Guidelines
  – A RP may be compounded if the FDA-approved product cannot be obtained from a commercial source in time to meet urgent medical needs of identified patient

• CMS and State Medicaid Reimbursement
  – CMS allows reimbursement only for FDA-approved drugs
  – Compounded products must seek pre-authorization/approval
  – State Medicaid and Third Party Administrators follow CMS rules
Medication Labeling

• EP 1*- Medication containers are labeled whenever medications are prepared but not immediately administered
  – TJC defines an immediately administered medication as “one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process”
  • This is a different definition than USP 797

• EP 4*- All medications prepared are labeled with the expiration date when not used within 24 hours
Medication Labeling

• Issues:
  – Not all medications labeled after transfer to another container
    • Medication name and strength
    • Expiration date/time, if not used the same day
    • Patient name (if patient specific)
    • Diluent, Date Prepared (if IV admixture*)

* 50mL or greater volume bag/bottle.
Labeling in Procedures

- NPSG 03.04.01: Label all medications and solutions on and off the sterile field
  - Issues:
    - Not all solutions labeled
    - No strength on label
    - Actual containers not labeled
    - Not labeled immediately before or after addition of drug to the container
    - Verbal & visual check in 2 person handoff
    - Not discarding medications at end of procedure
    - Not discarding unlabeled medications
Medication Reconciliation

- EP 2: Define (in writing) the types of medication information to be collected in non–24-hour settings and different patient circumstances
  - OP Radiology, Diagnostics
  - Can say no drug information collected for oral contrast, or only check if on metformin and similar drugs for IV contrast
  - Can say only drug name – no dose, route, etc for ED

  • Issue: Many have changed practice but not policy
Other Standard Issues

• MM.02.01.01 – Selection of Medications
  – EP 1-5: Formulary Process
  – EP 9: Annual review process based on safety and efficacy
    • Above include contrast, radiopharmaceuticals, other diagnostics
  – EP 6*: Standardizes and limits the number of drug concentrations available

• MM.03.01.03 – Emergency Drugs
  – EP 2*: Emergency medications and associated supplies are readily accessible in patient care areas
    • Includes diagnostic & procedural areas

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Other Standard Issues

• MM.05.01.11 – Safely Dispenses Medications
  – EP 2: Hospital dispense medications and maintain records according to law, regulation & standards of practice
  • Issue: Dispensing practices not the same as the pharmacy (e.g. lack of control records; labeling with patient name, directions, warnings, etc.)
    – Dispensing oral contrast (legend drug) by radiology to outpatients to take home
Other Standard Issues

- MM.06.01.01 – Safely administers medications
  - Defines in policy, who can administer medications
  - Must include appropriate personnel for contrast, adjuvant drugs, etc.
Other Standard Issues

• NPSG 01.01.01: Uses at least two patient identifiers when administering medications
  – Issue: Done on entry to department – and not prior to each medication or contrast administration, as required
• MM.07.01.03 – Adverse drug event reporting
  – EP 6: Medication administration errors, adverse drug reactions, and medication incompatibilities as defined by the hospital are reported to the attending physician or clinical psychologist, immediately when possible, and as appropriate to the organization-wide PI program
• CMS interpretation – 11/18/11
  – The immediate reporting requirement applies to drug administration errors, adverse drug reactions or incompatibilities that have harmed or have the potential to harm the patient. If the outcome of the drug administration error is unknown, the physician must also be notified without delay
• There must be policies and procedures related to immediate reporting of these events to the attending (including timeframe) and ensure staff are aware of the process
• All errors must be documented in the medical record and reported to the hospitals tracking/reporting system for PI purposes
• Allergic reactions and idiosyncratic reactions included. Specific definitions of medication errors, ADR and incompatibilities included in interpretative guidelines

Also very prescriptive training/competence assessment requirements for staff who administer IV’s
Other Standard Issues

• MM. 08.01.01 –Evaluation of the effectiveness of the medication management system
  – EP 1 - Data collected on performance of MM system
  – EP 3 - Data analyzed to identify risk points
  – EP 5 - Improvements identified based on data analysis, literature, best practices
    • ISMP Medication Safety Alert!
    • Issue: Not including diagnostic areas in data collection or evaluation
Other CMS Requirements

• PC.02.01.01, EP 15
  – IV medications are administered in accordance with state law and approved medical staff P&P.

• MM.05.01.07 Medication Preparation
  – EP 6: In-house preparation of radiopharmaceuticals is done by, or under the supervision of, an appropriately trained registered pharmacist or doctor of medicine or osteopathy.
Parting Suggestions

• Periodic review of all areas where medications are used
• Be sure to address hot patient safety issues in media
• Work with your Joint Commission Coordinator
• Don’t panic – focus on big issues not the obscure
“Safety in health care depends more on dynamic harmony among actors than on reaching an optimum level of excellence at each separate organizational level.”

René Amalberti, MD, PhD
Sources of Information

• www.jointcommission.org
  – FAQ for current standards
  – FAQ for current NPSG
  – Copy of 2009 NPSG
  – Current and Past Copies of:
    • Sentinel Event Alert
    • Joint Commission Online
  – Pre-publication Standards
Questions

• For questions about the interpretation of Joint Commission standards, organizations (or the public) can submit their questions by either:
  – Calling the Standards Interpretation Unit at 630-792-5900
  – Submitting the question in writing by using the following on-line form:
    http://www.jointcommission.org/Standards/OnlineQuestionForm/
Self-Assessment Questions

True or False:

1. Medication storage is one of the top cited TJC standards in medical imaging areas.

2. The use of pharmacy bulk packages of contrast for multiple patients in radiology is prohibited by The Joint Commission.

3. It is permissible to prepare sterile IV’s in imaging areas rather than the pharmacy because they are procedural areas.