

Medication Management and
CONTRAST MEDIA

Discussion Guide



Developed by ASHP Advantage

DISCLAIMER: The information contained in this discussion guide is constantly evolving because of ongoing research and changes in regulatory standards and is subject to the professional judgment and interpretation of the practitioner, given the uniqueness of each practice site. The writer, reviewers, editors, and ASHP have made reasonable efforts to ensure the accuracy and appropriateness of the information presented in this document. However, any reader of this information is advised that the writer, reviewers, editors, and ASHP are not responsible for the continued currency of the information, for any errors or omissions, or for any consequences arising from use of the information in the document in any and all practice settings. Any reader of this document is cautioned that ASHP makes no representation, guarantee, or warranty, express or implied, as to the accuracy and appropriateness of the information contained in this document and will bear no responsibility or liability for the results or consequences of its use.

Medication Management and Contrast Media Discussion Guide

Howard I. Cohen, R.Ph., M.S., FASHP

EXECUTIVE SUMMARY

When the Joint Commission explicitly defined medications to include contrast agents, many health systems found themselves out of compliance with certain medication management (MM) standards and the National Patient Safety Goal (NPSG) for medication reconciliation. The most troublesome standards involve pharmacist review of orders (MM 4.10) and medication storage (MM 2.20).

In the past, most radiology and pharmacy departments had limited contact. The radiology department typically handled the purchasing, storage, preparation, and administration of contrast media. The pharmacy department interacted with the radiology department only if other, noncontrast medications were used in the radiology department. Radiology and pharmacy departments must work together to become compliant with the MM standards and meet the NPSG for medication reconciliation.

In devising strategies for complying with the standards and meeting the medication reconciliation NPSG, health systems must consider several issues. Institutions must decide whether pharmacists or licensed independent practitioners (LIPs) shall perform medication order review for contrast media, since the Joint Commission allows the latitude to make this choice. Institutions also must

decide whether the radiology or pharmacy department should purchase and store contrast media. Requirements for meeting the medication reconciliation NPSG differ between the inpatient and outpatient settings. Considerations in planning for collaboration between the pharmacy and radiology departments include how the departments currently function, how well current practices comply with the Joint Commission MM standards and medication reconciliation NPSG and promote patient safety, the available options for improving processes and systems, the types of education that will be required, and how the effects of changes in processes and systems will be monitored and improved upon in the future.

This discussion guide explores some of the factors to be considered in devising strategies for complying with the Joint Commission standards and meeting the medication reconciliation NPSG. Options are described and their implications discussed. No single strategy is effective for all health systems; each health system must customize its approach, keeping in mind that the goal is to improve the quality and safety of patient care as well as meet accreditation standards.

PURPOSE

This discussion guide is intended as a basic tool for health professionals to use in reviewing the Joint Commission medication management (MM) standards and National Patient Safety Goals (NPSGs) for contrast media use and considering the issues to be addressed as the pharmacy and radiology departments collaborate to meet the requirements.

This document is not intended to provide a comprehensive review of contrast media or Joint Commission requirements pertaining to contrast media. Rather, it has been developed to generate ideas that health practitioners can use in their institutions.

INTRODUCTION

Providing high quality patient care and maximizing patient safety in all aspects of health care are of paramount importance to all health care practitioners today. In the mid 1990s, the Institute of Medicine (IOM) evaluated the quality of medical care in the United States and released three major reports revealing serious problems in America's health systems.¹⁻³ Motivated in part by these reports, health systems increased their voluntary reporting of errors through various reporting systems, including the United States Pharmacopeia (USP) MedMARx medication error reporting system. In 2004, USP's *Patient Safety CAPSLink* newsletter reported briefly on five years' worth of errors connected to radiology departments and cardiac catheterization laboratories: 16.3% of the errors linked to radiological services had harmed patients—eight times the overall frequency of harm from errors reported to the MedMARx database.⁴ These findings of disproportionate harm from medication use in the radiology department are part of what prompted the Joint Commission to include contrast media in the definition of medication in its MM standards in 2004. The Joint Commission also established NPSGs to address safety problems identified by IOM and other groups; the goals are updated annually.

The preamble of the MM chapter in the Joint Commission's *Comprehensive Accreditation Manual for Hospitals* includes an explicit definition of the products to which the standards apply: "...diagnostic and contrast agents, radioactive medications...and any product designated by the Food and Drug Administration (FDA) as a drug."⁵ Thus, the MM standards apply to contrast media as well as any other medications stored, dispensed, or administered in the radiology department. Radiology departments typically are out of compliance with the standards and NPSGs listed in Table 1.

The main intent of the MM standards and NPSGs is to improve the quality of care, including patient safety, in all patient care areas, including the radiology department. The need to meet the requirements of the MM standards and NPSGs that relate to contrast media presents an opportunity to focus on the development of protocols, policies, and procedures that will have a positive effect on

TABLE 1
Standards and National Patient Safety Goals that are Problematic for Radiology Departments*

Medication Management (MM)

- MM 2.20—Storage of medications
- MM 4.10—Pharmacist review of orders
- MM 4.30—Medication labeling

Provision of Care, Treatment, and Services (PC)

- PC 5.10—Use of at least two patient identifiers
- PC 13.20—Moderate sedation

National Patient Safety Goals (NPSGs)

- NPSG 1—Time out process (i.e., immediate pre-operative pause to ensure active communication among surgical team members)
- NPSG 8—Medication reconciliation

*For a complete list of Joint Commission standards and National Patient Safety Goals, see the Joint Commission Web site (www.jointcommission.org) and publications.

patient care and safety above and beyond fulfilling Joint Commission requirements.

In the past, radiology and pharmacy departments in most health systems had limited contact. In some institutions, the radiology department ordered its own contrast agents, had them delivered directly to the department, and had a concierge service stock the shelves. Contact with the pharmacy department was limited to the ordering and delivery of other medications stocked in the radiology department. Pharmacy departments typically had little contact with radiology departments because contrast agents were not considered medications and no pharmacy involvement was necessary for radiology to perform its day-to-day operations. The radiology department was able to fulfill Joint Commission requirements for participation in pharmacy and therapeutics (P&T) committee activities without working closely with the pharmacy department. Current Joint Commission standards and NPSGs require that the radiology and pharmacy departments work together.

MEDICATION MANAGEMENT STANDARD MM 4.10—PHARMACIST REVIEW OF ORDERS

Standard MM 4.10 states that all medication orders are to be reviewed by a pharmacist prior to administration, implying a patient-specific review for every order. Two exceptions are allowed: (1) “in urgent situations when the resulting delay would clinically harm the patient” and (2) “a Licensed Independent Practitioner (LIP) controls the ordering, preparation, and administration of the medication.”⁶ Initially, the Joint Commission stated that the LIP must be present “at the bedside” for this control to be exercised.⁶

In June 2005, the Joint Commission clarified its requirements for the use of oral contrast media.⁷ Although review by a pharmacist remains “a recommended safety step,” the administration of oral contrast media is considered safe in both inpatient and outpatient settings as long as specific safeguards (Table 2) are followed. In August 2006, the exception for oral contrast media and the safeguards were extended to the rectal administration of contrast media.⁸ Rectal administration of contrast media is considered safe as long as the same safeguards required for oral agents are used. The exception does not apply to any other medications or contrast media administered through any other natural orifice.

A modification in the interpretation of standard MM 4.10 element of performance 1 regarding LIPs for radiology was made in January 2007.⁶ A hospital’s radiology services may “define, through protocol or policy, the role of the licensed independent practitioner in the direct supervision of a patient during and after IV contrast media is administered.” The policy or protocol is to be approved by the medical staff, and the role must be defined so that there can be timely intervention by an LIP in the event of a patient emergency. The Joint Commission recommended that health systems refer to the American College of Radiology (ACR) Practice Guideline for the Use of Intravascular Contrast Media in developing the policy or protocol.⁹ This guideline states that “the supervising physician, or his or her physician designee, must be immediately available to respond promptly to an adverse effect.” Thus, the requirement for presence of the LIP at the bedside was clarified to allow for his or her presence

TABLE 2
**Oral and Rectal
Contrast Media Safeguards^{7,8}**

1. The organization adopts clinical practice guidelines or approved screening tools to address the safe administration of contrast media. For hospitals, these must be approved by both the medical staff and pharmacy.
2. Only trained, designated individuals retrieve medications from a limited set of medications (MM 4.50, EP 2).*
3. The appropriateness of the medication (contrast agent) is reviewed by a qualified health care professional (MM 4.10, EP 3).
4. The organization implements quality control procedures to prevent retrieval errors (MM 4.50, EP 2).
5. A pharmacist is available on call if needed (MM 4.50, EP 2).
6. The organization retrospectively evaluates its system by sampling records of cases in which contrast media were administered without prior pharmacy review to determine whether the system functions as designed or has opportunities for improvement (MM.8.10).

*EP = element of performance.

nearby but not necessarily at the bedside, provided that there is a mechanism for timely intervention in the event of a problem.

TWO APPROACHES TO COMPLIANCE

There two approaches to complying with standard MM 4.10. An institution can implement a protocol that defines the role of the LIP, or it can implement a system in which a pharmacist reviews orders for contrast media prior to the imaging study. If an institution adopts a protocol defining the role of the LIP in the direct supervision of patients before and after the administration of intravenous contrast media, pharmacist review of orders for contrast media is not required. Such a protocol essentially addresses the proper screening of patients scheduled to receive intravenous contrast media, ensures that the medication is ordered properly, and defines how the protocol will be

reviewed to ensure effectiveness, among other things. Pharmacy and radiology departments must collaborate on the development of the protocol, and the protocol must be approved by the medical staff. Otherwise, a system must be implemented in which a pharmacist reviews every order for contrast media prior to each imaging study.

There is no right or wrong answer to the question of who (i.e., the pharmacist or LIP) should review contrast media orders for appropriateness. The decision should be based on the needs of the individual health care facility. Some institutions have chosen to have a pharmacist review all orders for nonoral and nonrectal contrast media. Policies and procedures have been developed to address how pharmacists will obtain the order, communicate the results of their review to the radiology department, and document the review in the medical record, and the pharmacists have been educated to conduct a complete and thorough review of orders for contrast media. Other health systems have found that the most efficient and cost-effective approach is to implement a protocol that defines the role of the LIP. Regardless of the approach that an institution selects, the pharmacy and radiology departments must collaborate in the design, implementation, and assessment of order review procedures.

ELEMENTS OF THE REVIEW

The protocols, policies, and procedure developed to meet standard MM 4.10 should address in detail what constitutes a complete review of medication orders, as well as follow-up procedures to ensure that the system is working as well as possible. Key elements of a medication order review include the patient's history of adverse drug reactions, current renal function, and potential drug interactions.

Adverse Reactions

All patients who receive contrast media need to be screened for a history of adverse reactions to contrast media, allergies to other drugs and substances, and other risk factors for adverse reactions (Table 3). Patients with these risk factors are more likely to experience adverse reactions to contrast media; depending on institutional policy, they might require pre-procedure medications, hydration or other measures, and a discussion with the ordering physician to help minimize risk.

TABLE 3

Risk Factors for Adverse Reactions to Contrast Media¹⁰⁻¹⁵

- History of adverse reaction to intravascular iodinated contrast media
- History of asthma
- Previous serious allergic reaction to materials (including seasonal and food allergies) other than contrast agents
- Known cardiac dysfunction, including recent or potentially imminent cardiac decompensation, severe arrhythmias, unstable angina pectoris, recent myocardial infarction, and pulmonary hypertension
- Renal insufficiency

More information about adverse reactions to contrast media can be found in the *Quick Guide to Contrast Media (Quick Guide)* available on the ASHP Web site.

Renal Function

Renal function should be assessed as part of the medication order review, since patients with compromised renal function are at greater risk for adverse events associated with contrast media. Nephrotoxicity following the administration of contrast media accounts for more than 10% of hospital-acquired renal failure and is a leading cause of acute renal failure.^{16,17} Contrast-induced nephropathy (CIN) is defined as an increase in serum creatinine by 25% or more than 0.5 mg/dL within 72 hours after contrast media administration.¹⁷ Patients with normal renal function are at low risk for developing CIN, but the risk of CIN increases as the estimated glomerular filtration rate decreases.¹⁸ Nevertheless, all patients should be screened for risk factors for CIN (Table 4). ACR and the Consensus Panel for CIN have developed specific precautions for patients at risk for CIN.^{10,18} These precautions are listed in the *Quick Guide*.

Generally, renal function is assessed by estimating the glomerular filtration rate using a recent serum creatinine concentration and the Cockcroft-Gault or Modification of Diet in Renal

TABLE 4
Risk Factors for
Contrast-Induced Nephropathy^{10,19}

- Renal insufficiency
- Diabetes mellitus
- Dehydration
- Cardiovascular disease
- Age >70 years
- Myeloma
- Hypertension
- Hyperuricemia

Disease formula.²⁰ Although many radiology departments use blood urea nitrogen and serum creatinine levels to assess renal function, estimated glomerular filtration rate is preferred. Some institutions are required by state law to have an estimated glomerular filtration rate documented in the chart for every patient. Other factors that could affect renal function should be considered as well, such as recent administration of medications that have the potential to reduce renal function (e.g., cancer chemotherapies, diuretics) and medications that suggest the presence of compromised renal function (e.g., epoetin alfa). The patient's state of hydration also should be considered.

Nephrogenic systemic fibrosis (NSF) is a rare scleroderma-like condition that has been reported in patients with renal insufficiency who received gadolinium-based contrast media for magnetic resonance (MR) imaging.^{21,22} FDA is investigating the association between NSF and gadolinium-based contrast media. The agency recently called for inclusion of a black-box warning in the prescribing information for all gadolinium-based contrast agents.²³ ACR also updated its guidance document for safe MR imaging practices.²⁴ These practices include screening patients who are scheduled for MR imaging for a history of renal disease and dialysis. See the *Quick Guide* for a more in-depth discussion of NSF. Information about the causes of NSF is evolving rapidly, and

any order review system that is established should include a mechanism for ensuring that it reflects the most recent recommendations.

Drug Interactions

Contrast media can interact with other medications, so patients should be screened for potential drug interactions as part of the contrast media order review. Intravascular administration of iodinated contrast media (see the *Quick Guide* for a table of contrast media) to patients who are taking metformin has been associated with lactic acidosis. The danger is that if the contrast agent impairs renal function and prevents the elimination of metformin, lactic acidosis can occur.²⁵ More details about the interaction are available in the *Quick Guide*.

Gadobenate dimeglumine is a substrate for the hepatic canalicular multispecific organic anion transporter (cMOAT, also referred to as MRP2 or ABCC2) and may compete with other drugs for cMOAT sites.²⁶ Caution is necessary when gadobenate dimeglumine is administered to patients who are taking other drugs that are substrates for this transporter or who have certain underlying metabolic disorders. See the *Quick Guide* for a more in-depth discussion of the interaction and a list of these medications and disease states.

OBTAINING NEEDED INFORMATION FOR ORDER REVIEW

Medication lists, clinical histories, and laboratory values generally are readily available for hospital inpatients. However, obtaining this information for radiology outpatients can be more difficult. Outpatients often come to the radiology department for a diagnostic imaging study bringing little or no medication or clinical information with them and follow-up care is conducted at a clinic or physician's office outside the health system, sometimes a considerable distance away. As such, radiology and pharmacy departments are often unable to access the necessary patient information needed to perform the contrast media order review. This issue must be addressed.

Every health system will need to develop methods of obtaining the information needed to review contrast media orders. To evaluate medication contraindications and potential drug interactions, some institutions use an initial screening form (i.e., questionnaire) that is mailed to

the patient for completion prior to the scheduled appointment for a diagnostic imaging study involving contrast media and is returned by mail or brought to the appointment. The form asks for a list of all medications the patient takes, which is required as part of the medication reconciliation standard. The form can be reviewed by a nurse under protocol when an LIP is present, or it can be reviewed by a pharmacist who conveys relevant information to the radiologist as necessary. Health care practitioners may conduct a patient interview to clarify or augment information collected on the screening form.

The greatest difficulty in obtaining the information needed for contrast media order review lies in assessing an outpatient's renal function. A review of the patient's medication list may suggest that renal function is poor. However, the assessment is not complete unless a recent (as defined by the institution's policy; for example, within 60 days) serum creatinine concentration is available. Some health systems have dealt with this by requiring outpatients to have serum creatinine concentration determined by a laboratory before their scheduled radiology appointment. Orders for the lab test are mailed to the patient before the appointment, and the patient is expected to have the test before the radiology appointment. Other institutions are exploring the use of portable, point-of-care laboratory devices that can measure serum creatinine concentration within approximately 15 minutes from only a few drops of blood. The potential use of these devices should be explored in collaboration with the institution's clinical laboratory personnel, because the device must be validated and the validation must be documented. Another consideration is how to integrate the use of portable, point-of-care laboratory devices into the billing and reimbursement system.

EDUCATING THE REVIEWER

Not all personnel may have the knowledge base for reviewing orders to ensure that contrast media administration is safe. It may be necessary to educate staff members about contrast media, renal function assessment, drug interactions or contraindications, and relevant past medical history before they can assume responsibility for contrast media order review. Educational plans should include pharmacists, nurses, radiological technologists, and radiologists.

PROTOCOL FOR LICENSED INDEPENDENT PRACTITIONERS

If an institution decides to develop a protocol defining the role of the LIP, the following must be considered:

1. **Protocol Development.** The radiology and pharmacy departments collaborate on the development of the protocol. The protocol must be approved the medical staff.
2. **Elements of a Protocol.** The protocol should address the following issues:
 - a. **Role of the LIP:** Define the responsibilities of the LIP in protecting the safety of patients scheduled for radiology procedures and in intervening in emergent situations. The supervising physician or his or her physician designee must be familiar with contraindications and relevant risk factors that might increase the likelihood of adverse effects associated with contrast administration. Furthermore, the practitioners are responsible for reviewing indications for the examination and for determining the appropriateness of the type, timing, dosage, rate, and route of administration of contrast media. There are numerous other considerations in defining the role of the LIP. It is recommended that institutions refer to the ACR Practice Guideline for the Use of Intravascular Contrast Media in developing the policy or protocol.⁹
 - b. **Patient Assessment:** The existing systems should be reviewed to determine how patients are best assessed to determine if the contrast agent and dose ordered can be safely administered and to ensure that current practices are consistent with the goal of the protocol. Also important is how the assessment will be documented (e.g., using a computerized form or process, a preprinted order form, screening form for patients scheduled for a procedure, or other method).
 - c. **System Assessment:** How will the system be reviewed to ensure its effectiveness and identify opportunities for improvement? Who will be responsible for conducting the periodic assessment, and how will it be documented?

PHARMACIST REVIEW OF ORDERS

If an institution does not develop a protocol defining the role of the LIP, then the pharmacy will be responsible for review of orders for contrast media and the following must be considered:

1. How does the pharmacist obtain the order?
 - a. Workflow
 - b. Computer systems
 - c. Transmission of faxed or scanned orders
2. How can the orders be reviewed in a timely fashion?
3. How many contrast agents and other medications are used by the radiology department?
4. How much additional staffing (i.e., hours) will be required?
5. What elements should be part of the order review process to determine whether the contrast agent may be safely administered to the patient?
 - a. What information is needed to determine whether the agent may be safely administered?
 - i. History of adverse drug reactions
 - ii. Current renal function
 - iii. Potential drug interactions
 - b. How will the information needed for order review be obtained?
 - i. Medication lists
 - ii. Laboratory values
 - iii. Patient clinical history
6. What type of education will be required to train staff to appropriately review orders?

Obtaining the Order

Analysis of current workflow in both the pharmacy and radiology departments is a logical place to begin analyzing the process for order review. Both departments probably have workflow patterns that are efficient and minimize interruptions that could compromise patient safety. The current workflow should be diagrammed, using flow charts or other means, so that it is well understood by both departments. A thorough understanding of workflow facilitates the design of systems and processes for medication order review that improve on, rather than detract from, departmental efficiency.

Whether the health system has a computerized prescriber order entry (CPOE) system and whether the system interfaces with the radiology department as well as the pharmacy department (i.e., whether radiology orders are routinely seen by pharmacy) is a consideration. If the pharmacy and radiology computer systems do not routinely interface, steps may be taken to establish an interface so that pharmacy can routinely receive every medication order. In institutions where computer systems already are interfaced and pharmacy receives radiology orders, a limited amount of additional effort may be needed for pharmacy personnel to review contrast media orders. If it is not possible for pharmacy to routinely receive radiology orders by computer, the question of how pharmacy can receive orders must be addressed. Options include having radiology personnel fax or scan and transmit orders for contrast media to the pharmacy department. Because oral and rectal contrast media are exempted from the Joint Commission requirement for pharmacist order review, the policy for transmitting orders by these rather cumbersome methods might be limited to intravascular contrast media.

Timeliness of Order Review

Review of contrast media orders has the potential to introduce delays in workflow within the radiology department. The patient scheduling process and the percentages of scheduled versus emergency cases, the point in the scheduling process at which the decision to use contrast media is made, and the amount of time required for a pharmacist to review contrast media orders are considerations. In some health systems, radiology cases are scheduled 24 hours in advance, which may give the pharmacy department a reasonable amount of time to review orders. The means of communicating to the radiology department about contrast media orders, especially if questions or concerns arise, is another factor to consider.

Various methods may be used to communicate with the radiology department about problems with contrast media orders. Some pharmacists telephone the radiologist about concerns, and others use a written form highlighting the concern for radiologist review. The form is attached to the order in question and sent to the prescriber; telephone calls are reserved for urgent concerns (e.g., allergies to contrast media), since it is often

difficult to contact radiologists in a timely fashion. In some cases, the pharmacy communicates directly with a radiologic technologist to ensure that the study is postponed until concerns are resolved.

Several tools that can be used to evaluate the efficiency of order review and communication are available in the quality improvement literature and may be accessed through the American Society of Health-System Pharmacists (ASHP) Quality Improvement Initiatives Resource Center by going to www.ashp.org.

Number of Medications Used in Radiology

There are several agents available that can be used for CT and MR procedures. The selection of the available agents should be driven by safety, adverse effects, and cost and available purchase contracts. In addition, the medications that manage adverse effects or reduce the risk for adverse events in patients receiving contrast media should be considered (e.g., steroids, antihistamines, narcotics, anxiolytic agents).

For some institutions it has proved helpful to limit the number of contrast agents and other medications available within the radiology department. For example, a radiology department may stock a preferred CT agent, a preferred MR agent, and agents reserved for patients with reduced renal function. Narrowing the field of available products can possibly make the initial education process easier, simplify the screening process, and minimize the opportunity for mistakes.

Staffing Considerations

The amount of additional personnel time required for review of contrast media orders and the ability of current staff to absorb the added workload are considerations in deciding whether a pharmacist or LIP should perform order review and how the system for reviewing orders will be designed. The amount of time required for order review will affect staffing requirements. For example, a teaching institution may perform approximately 80,000 imaging studies with contrast each year. If only 2 minutes is spent reviewing each order, the time required to prospectively review all orders for contrast media amounts to one full-time equivalent.

Some health systems have found that they are best served by reorganizing and adding personnel in the radiology department to provide LIP oversight for all imaging areas where intravascular contrast media are used. This arrangement is feasible because the Joint Commission does not require the LIP to be present at the bedside as long as there is a mechanism for timely intervention in the event of a patient emergency.⁶ Technology should be leveraged to the extent possible to maximize efficiency.

MEDICATION MANAGEMENT STANDARD MM 2.20—MEDICATION STORAGE

The radiology department is required to comply with standard MM 2.20 requirements for medication storage. Some aspects of concern in this standard are listed in Table 5. All contrast media as well as other medications used in the radiology department must be approved through the formulary process. Medications in the radiology department are to be stored in secured areas at all times, with access limited to personnel authorized by law, policy, or regulation. Routine inspection of storage areas is required. Requirements for medication security and temperature control apply to warmers used for CT intravascular contrast media.

ONLY FORMULARY DRUGS TO BE ROUTINELY STOCKED

Standard MM 2.20 requires that only formulary drugs be routinely stocked in radiology. As with any other medication, all contrast media must be evaluated and approved through the appropriate committee (e.g., P&T committee) formulary process. Health systems need to review the formulary status of all contrast agents used in the institution and ensure that any nonformulary agents undergo the review process for addition to the formulary.

MEDICATION SECURITY AND TEMPERATURE CONTROL

Another requirement of standard MM 2.20 is that all medications be stored in secure locations. This standard does not necessarily imply that contrast media must be stored and dispensed for individual patients by the pharmacy department. Whether contrast agents are best stored in the pharmacy or radiology department depends on the needs of the institution.

TABLE 5

Medication Management Standard MM 2.20 Requirements of Concern in Radiology Departments

- Only formulary drugs (including contrast media) are routinely stocked
- Appropriate temperature monitoring is provided for medication storage areas, including computed tomography contrast media warmers
- Security for medications, including those stored in crash carts, is provided
- Persons not authorized by policy, law, or regulation do not have access to medications
- Narcotic control is provided
- Periodic inspections of storage areas are conducted, and these inspections include checks of expiration dates

In one scenario, the pharmacy department could store all contrast media and other medications used by the radiology department and dispense them for specific patients after receipt of an order. This scenario has the potential for significantly disrupting the flow of patients and work in the radiology department, and it is likely to consume a substantial amount of staff time because of the large volume of imaging studies performed in most institutions. An automated dispensing machine (e.g., smart cabinet linked with the hospital information system) with access limited to authorized persons could be placed in the radiology department to reduce the disruption.

In an alternative scenario, all contrast media and other medications used by the radiology department would be stored in locked areas in the department, with access limited to authorized personnel. One thing to consider in developing a plan for medication storage and security is that CT contrast media warmers are considered storage areas. Therefore, warmers must be locked at all times (i.e., 24 hours/day, 7 days/week) unless they are under the direct supervision of authorized personnel.

CT warmers need to be monitored for temperature control, and temperature logs must be maintained. Additionally the shelf life of the contrast once placed in the warmer must be determined for stability. The *Quick Guide* provides a list of appropriate temperature ranges for various contrast media. Whether this temperature monitoring is performed by pharmacy or radiology personnel is at the discretion of the health system.

ORDERING CONTRAST MEDIA

An interesting question that has been raised in the context of medication storage and security is whether contrast agents should be purchased by the pharmacy or radiology department. However, pharmacy is responsible for medication ordering and contrast agents are clearly defined as a medication. In the past, many radiology departments purchased contrast media using their own budget lines, and pharmacy played no role in the purchasing process. Institutions may need to evaluate whether this approach to purchasing contrast media remains optimal. The pharmacy department may be able to arrange purchasing agreements with discounts and better prices than what the radiology department can obtain. Pharmacy may be able to place orders daily rather than weekly or monthly, thereby minimizing space required for inventory storage.

AUTHORIZATION FOR MEDICATION ACCESS

Another requirement of standard MM 2.20 is that only persons authorized by policy, law, or regulation have access to medications; this standard applies to contrast media. Pharmacists, radiologists, radiology nurses, and radiologic technologists are authorized to have access to contrast media and prepare and label doses. Intravascular contrast media may be administered by radiology nurses and radiologists. Radiologic technologists also may administer intravascular contrast media in accordance with current ACR policy statements, state law, and institutional policies and procedures. ACR supports the use of certified or licensed radiologic technologists for the administration of intravascular contrast media under the direct supervision of a radiologist or his or her physician designee if the practice is in compliance with institutional policies and state regulations.^{9,10}

Prior written approval must be obtained from the medical director of the radiology department.¹⁰ Radiologic technologists must participate in and maintain documentation of continuing education related to the materials injected and the procedures performed.¹⁰ ACR policy statements do not address the practice by radiologic technologists of preparing, labeling, or administering medications other than contrast media. Radiology department policies and procedures may need to be revised to comply with the aspect of the standard that applies to medications other than contrast media.

Some intravascular contrast media are available in bulk containers with multiple doses. Individual doses must be prepared and labeled for a specific patient. The requirements of USP chapter 797, “Pharmaceutical Compounding—Sterile Preparations,” which was revised in December 2007, may need to be followed.²⁷ The Web-based ASHP Compounding Resource Center provides information about the USP requirements.

MEDICATION MANAGEMENT STANDARD MM 4.30—MEDICATION LABELING

Standard MM 4.30 requires that medications that are mixed or transferred from a bulk container but not administered immediately be labeled in a standardized way, according to organizational policy, applicable laws and regulations, and standards of practice, to minimize errors. Labels must contain the drug name, strength, and amount; the expiration date if not used within 24 hours after preparation; the expiration time if expiration occurs within 24 hours after preparation; and the date prepared. If the person preparing the medication is not the person administering the medication or if individualized doses for multiple patients are prepared, the label must also contain the patient’s name and location or address, directions for use, and any applicable cautionary statements.²⁸

The two main issues inherent in this standard are (1) correct labeling of medications, including contrast media, that are administered in the radiology department and (2) correct labeling of any medications sent home with a patient from the radiology department.

LABELING IN THE RADIOLOGY DEPARTMENT

Any contrast media mixed in the radiology department but not administered immediately

must be labeled according to standard MM 4.30. For example, if a dose is mixed before the patient arrives, the labeling requirements apply. Radiology policies and procedures need to be evaluated to determine whether they are consistent with standard MM 4.30 for medication labeling. Radiology personnel may need to be educated about the standard.

MEDICATIONS SENT HOME FROM RADIOLOGY

Another potential problem occurs when the radiology department sends contrast media or other medications home with the patient for use before or after a scheduled appointment. If medications are provided to a patient or sent home with a patient for use outside the facility, they must be labeled with the patient’s name, location or address, directions, and cautionary statements as well as the drug name, strength, amount, and expiration date or time. One way to ensure that proper labeling is provided for contrast media and other medications is to write prescriptions for them and have the pharmacy, rather than the radiology department, dispense the medication.

NATIONAL PATIENT SAFETY GOAL 8—MEDICATION RECONCILIATION

NPSG 8 on medication reconciliation requires three steps: (1) obtain and document a complete list of the patient’s current medications on entry to the system, (2) compare the medications the organization provides with those on the list and resolve any discrepancies, and (3) communicate the current medication list to the next provider.

The issues involved in providing medication reconciliation differ between inpatients and outpatients, and policies and procedures or protocols need to be developed for both settings. When inpatients go to the radiology department for a diagnostic imaging study, this is considered a simple transfer. When an outpatient undergoes a diagnostic imaging study, a different set of requirements apply.

INPATIENT TRANSFER TO RADIOLOGY FOR DIAGNOSTIC IMAGING

The transfer of a hospital inpatient to the radiology department for a diagnostic imaging study requires transfer of the current medication list. This can be done by computer (i.e., access by an authorized practitioner in the radiology department to the

patient medication profile through the computer suffices). A radiologist or radiology nurse should review the medication list for any potential problems (e.g., history of adverse reaction to contrast media, use of contraindicated medications or medications that suggest the presence of renal dysfunction). Review of this list can be an integral part of the order review conducted to fulfill standard MM 4.10. After completion of the diagnostic imaging study, a medication list must accompany the patient when he or she returns to the patient care area. If the radiologist orders new medications for the patient after the study, they must be added to the list; however, it is not necessary to reorder all medications. The use of CPOE is acceptable for meeting the medication reconciliation requirements of NPSG 8.

OUTPATIENT MEDICATION RECONCILIATION

For an outpatient arriving at the radiology department, a medication list must be generated on entry to the health system if medications might be administered or prescribed or the patient's medications might affect the results of a diagnostic imaging study. For example, a complete medication list would need to be compiled for an outpatient arriving for an interventional radiology procedure or CT or MR imaging with contrast. However, no list would be needed for an outpatient having an X-ray.

A questionnaire (screening form) can be sent to the patient prior to the appointment to obtain the medication list, or the list can be obtained in a patient interview at the time of the appointment. The list must be placed in a highly visible location for review by the radiologist, radiology nurse, or pharmacist prior to the diagnostic imaging study. The listed medications are to be reviewed for any potential problems or interactions with the medications (particularly contrast media) that might be administered during the study. This review can become part of the medication order review process conducted to fulfill standard MM 4.10.

After completion of the diagnostic imaging study, a complete medication list must be sent with the patient to the next provider. However, the Joint Commission has made provisions for exemptions to this requirement (Table 6).²⁹ Most diagnostic imaging studies appear to fall into the exempt category, although each case must be individually

TABLE 6
Criteria for Exemption from Requirement to Send a Medication List to Next Provider²⁹

- The encounter is brief and on an outpatient basis
- Medications that act locally with negligible systemic effects are used
- No other medications are used during the procedure
- No new medications are prescribed for or provided to the patient for use after discharge
- No changes are made to the patient's current medications
- Any provider of care to whom the patient is referred already has the patient's current medication information

evaluated to determine whether a medication list should be generated for the next provider. If a list is needed, the decision on whether the pharmacy or radiology department should generate it is best left to the individual institution.

ELEMENTS OF A SUCCESSFUL PROGRAM

The intent of the MM standards and medication reconciliation NPSG is to improve patient safety and quality of care. Creation of a multidisciplinary team tasked with ensuring that the health system complies with the MM standards and meets NPSGs, educating key personnel, and measuring and analyzing outcomes can help improve patient care and safety. Members of other disciplines who should be considered for the collaborative effort include representatives from the nursing, clinical laboratory, information technology, purchasing, and nephrology departments.

MULTIDISCIPLINARY TEAMS

Pharmacy and radiology staff could independently revise their policies and procedures to comply with Joint Commission requirements, but the common goal of improving patient safety and quality of care might not be met. Experience from the quality improvement movement suggests that

accomplishing this goal requires collaboration.

Support from the health-system administration is necessary for any radiology–pharmacy collaboration to be successful. Administrators can delegate responsibility and authority to the team for the implementation of new policies, procedures, and protocols. Financial and human resources for team functions (e.g., providing overtime payments and freeing personnel from other duties to focus on team responsibilities) also may be provided by the administration.

EDUCATION

Most radiology personnel know little about the Joint Commission MM standards and NPSGs or the workings of the pharmacy department. Most pharmacy personnel know little about contrast media and the workings of the radiology department. Therefore, members of both departments need to be educated.

Radiology personnel may need to be educated about the specifics of the Joint Commission requirements and their implications. This education may need to address how to store, prepare, label, and administer medications and the laws and regulations governing which personnel may legally perform those functions. Policies and procedures for medication storage may need to be revised or developed to address security and temperature control concerns. Policies and procedures for the review of medication orders and medication reconciliation need to be established, understood, and followed by personnel.

Pharmacists and pharmacy personnel may need to learn about contrast media and the essential elements of contrast media order review. Pharmacy personnel will also need to be educated about all new policies, procedures, and protocols for contrast media use. In addition, the pharmacy should develop a program to ensure that its staff members are competent to fulfill their role. The pharmacy should also institute reminders to include the radiology department in regularly scheduled medication inspections.

If a member of the health-system administration is not part of the multidisciplinary team, the administrative team should be kept informed of all developments so that it can help obtain the buy-in of staff throughout the institution.

The method for providing education is best determined by the individual institution according to its needs and resources. Some institutions may choose to use written communication or various electronic media; others may choose to provide live presentations tailored to a specific department or a more general audience of members of multiple departments.

OUTCOMES MEASUREMENT

No health system can claim to have improved patient care by implementing new policies and procedures unless it has documentation. It is helpful for pharmacy and radiology staff to establish a baseline measurement of current outcomes or practices associated with outcomes. For example, an institution may choose to measure the rate of adverse reactions, whether patient renal function is ascertained and patients received contrast while taking metformin, and whether the temperature in warmers is properly controlled, medication storage is secure, personnel who prepare and administer medications are authorized to do so, medications are properly labeled, and medication reconciliation is performed appropriately.

Monitoring should be continued on an ongoing basis to demonstrate that improvement achieved through the implementation of new policies and procedures has been maintained. This is a necessary step if an institution wants to demonstrate a favorable impact on patient care.

One part of monitoring that often is forgotten is the requirement in the oral and rectal contrast media safeguards for retrospective sampling of orders for oral and rectal contrast media that were not reviewed by a pharmacist (Table 2). This requirement might be accomplished in conjunction with other outcomes monitoring.

Whether monitoring is performed in real time using triggers programmed into the computer system or through prospective or retrospective review is at the discretion of the institution. It may not be possible to monitor the outcomes of all changes simultaneously, but it is important that monitoring of outcomes occurs. Pharmacy and radiology personnel can collaborate to set priorities for which aspect of care related to the MM standards and NPSGs requires attention first. Other aspects of care can be addressed as time and other resources become available.

CONCLUSION

Collaboration and communication among pharmacy and radiology personnel is needed to meet Joint Commission requirements pertaining to contrast

media use. The goal of improving patient safety and quality of care should be kept in mind in devising strategies to fulfill Joint Commission requirements.

REFERENCES

1. Kohn LT, Corrigan J, Donaldson MS, eds. To err is human: building a safer health system. Washington, DC: National Academy Press; 2000. www.nap.edu/openbook.php?isbn=0309068371.
2. Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academy Press; 2001. www.nap.edu/openbook.php?isbn=0309072808.
3. Aspden P, Wolcott JA, Bootman JL et al., eds. Preventing medication errors. Washington, DC: National Academies Press; 2007. http://books.nap.edu/openbook.php?record_id=11623&page=R1.
4. Thompson CA. Radiology errors are the worst, USP says. *Am J Health-Syst Pharm.* 2006; 63:402,406. www.ashp.org/s_ashp/article_news.asp?CID=167&DID=2024&id=14177.
5. Comprehensive accreditation manual for hospitals. Oakbrook Terrace, IL: The Joint Commission; 2008.
6. The Joint Commission. Approved: interim action for standard MM 4.10, element of performance 1, for critical access hospitals and hospitals: modifications for the emergency department and radiology practitioners. *Jt Comm Perspect.* 2007; 27(1):9.
7. Joint Commission on Accreditation of Healthcare Organizations. Clarifying information for MM 4.10 and oral contrast media. *Jt Comm Perspect.* 2005; 25(6):9.
8. Joint Commission on Accreditation of Healthcare Organizations. Clarifying information for MM 4.10 and rectal contrast media. *Jt Comm Perspect.* 2006; 26(8):9.
9. American College of Radiology. ACR practice guideline for the use of intravascular contrast media. www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/dx/iv_contrast.aspx (accessed 2008 Apr 2).
10. American College of Radiology Committee on Drugs and Contrast Media. Manual on contrast media. v.5.0. Reston, VA: American College of Radiology; 2004. www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual.aspx.
11. Debatin JF, Cohan RH, Leder RA et al. Selective use of low-osmolar contrast media. *Invest Radiol.* 1991; 26:17-21.
12. Enright T, Chua-Lim A, Duda E et al. The role of a documented allergic profile as a risk factor for radiographic contrast media reaction. *Ann Allergy.* 1989; 62:302-5.
13. Halpern JD, Hopper KD, Arredondo MG et al. Patient allergies: role in selective use of nonionic contrast material. *Radiology.* 1996; 199:359-62.
14. Kotlyarov E, Johnston GS, Mirvis S. Guidelines for use of nonionic contrast media. *AJR Am J Roentgenol.* 1991; 156:865-6.
15. Briguori C, Tavano D, Colombo A. Contrast agent-associated nephrotoxicity. *Prog Cardiovasc Dis.* 2003; 45:493-503.
16. McCullough PA, Wolyn R, Rocher LL et al. Acute renal failure after coronary intervention: incidence, risk factors, and relationship to mortality. *Am J Med.* 1997; 103:368-75.
17. Solomon R, Barrett B. Follow-up of patients with contrast-induced nephropathy. *Kidney Int Suppl.* 2006 Apr; (100):S46-50.
18. Solomon R, Deray G on behalf of the Consensus Panel for CIN. How to prevent contrast-induced nephropathy and manage risk patients: practical recommendations. *Kidney Int Suppl.* 2006 Apr; (100):S51-3.
19. Byrd L, Sherman RL. Radiocontrast-induced acute renal failure: a clinical and pathophysiologic review. *Medicine (Baltimore).* 1979; 58:270-9.
20. Johnson CA, Levey AS, Coresh J et al. Clinical practice guidelines for chronic kidney disease in adults: part II. Glomerular filtration rate, proteinuria, and other markers. *Am Fam Physician.* 2004; 70:1091-7. www.aafp.org/afp/20040915/1091.pdf.
21. Lin SP, Brown JJ. MR contrast agents: physical and pharmacologic basics. *J Magn Reson Imaging.* 2007; 25:884-99.
22. Marckmann P, Skov L, Rossen K et al. Nephrogenic systemic fibrosis: suspected causative role of gadodiamide used for contrast-enhanced magnetic resonance imaging. *J Am Soc Nephrol.* 2006; 17:2359-62.
23. U.S. Food and Drug Administration. Information for healthcare professionals: gadolinium-based contrast agents for magnetic resonance imaging (marketed as Magnevist, MultiHance, Omniscan, OptiMARK, ProHance). www.fda.gov/cder/drug/InfoSheets/HCP/gcca_200705.htm (accessed 2008 Apr 1).
24. Kanal E, Barkovich AJ, Bell C et al. ACR guidance document for safe MR practices: 2007. *AJR Am J Roentgenol.* 2007; 188:1447-74. www.ajronline.org/aheadofprint/06_06_1616.pdf.

25. Glucophage (metformin hydrochloride tablets) and Glucophage XR (metformin hydrochloride extended-release tablets) prescribing information. Princeton, NJ; Bristol-Myers Squibb Co.: June 2006.
26. Pastor CM, Planchamp C, Pochon S et al. Kinetics of gadobenate dimeglumine in isolated perfused rat liver: MR imaging evaluation. *Radiology*. 2003; 229:119-25.
27. USP Chapter <797> Pharmaceutical compounding—sterile preparations. In: *The United States Pharmacopeia*, 31st rev., and the *National Formulary*, 26th ed. Rockville, MD: The United States Pharmacopeial Convention; 2008. www.usp.org/pdf/EN/USPNF/generalChapter797.pdf.
28. Rich DS. New JCAHO medication management standards for 2004. *Am J Health-Syst Pharm*. 2004; 61:1349-58.
29. The Joint Commission. FAQs for the Joint Commission's 2007 national patient safety goals. www.jointcommission.org/NR/rdonlyres/9ECF1ED6-E04E-41DE-B7BC-174590CEDF33/0/07_NPSG_FAQs_8.pdf (accessed 2008 Apr 1).

ADDITIONAL RESOURCES

- Kuo PH, Kanal E, bu-Alfa AK et al. Gadolinium-based MR contrast agents and nephrogenic systemic fibrosis. *Radiology*. 2007; 242:647-9.
- Morcus SK. Prevention of contrast media-induced nephrotoxicity after angiographic procedures. *J Vasc Interv Radiol*. 2005; 16:13-23.
- Runge VM. Safety of magnetic resonance contrast media. *Top Magn Reson Imaging*. 2001; 12:309-14.
- Shehadi WH. Death following intravascular administration of contrast media. *Acta Radiol Diagn (Stockh)*. 1975; 26:457-61.
- Shellock FG, Kanal E. Safety of magnetic resonance imaging contrast agents. *J Magn Reson Imaging*. 1999; 10:477-84.
- Solomon R. Contrast media nephropathy—how to diagnose and how to prevent? *Nephrol Dial Transplant*. 2007; 22:1812-5.
- Thomsen HS. European Society of Urogenital Radiology (ESUR) guidelines on the safe use of iodinated contrast media. *Eur J Radiol*. 2006; 60:307-13.
- Thomsen HS. Guidelines for contrast media from the European Society of Urogenital Radiology. *AJR Am J Roentgenol*. 2003; 181:1463-71.
- American College of Radiology. JCAHO approves interim provisions to medication management standard 4.10, encourages comments. www.acr.org/SecondaryMainMenuCategories/NewsPublications/FeaturedCategories/CurrentACRNews/archive/JCAHOApprovesInterimProvisionstoMedicationManagementStandard410EncouragesCommentsDoc193.aspx (accessed 2008 Apr 3).
- The Joint Commission. Urgent Bulletin—Update on standard MM 4.10. (accessed 2007 Jul 12). http://search.jointcommission.org/search?q=Urgent%20Bulletin%e2%80%94Update%20on%20standard%20MM%204.10.&site=EntireSite&client=jcaho_frontend&output=xml_no_dtd&proxystylesheet=jcaho_frontend

Organizations/Web Links

- American College of Radiology
www.acr.org
- American Hospital Association
www.aha.org
- American Society of Health-System Pharmacists
www.ashp.org
- American Society of Radiologic Technologists
www.ASRT.org
- Centers for Medicare and Medicaid Services
www.cms.hhs.gov
- The European Society of Urogenital Radiology
www.esur.org
- Institute of Medicine
www.iom.edu
- The Joint Commission
www.jointcommission.org
- Kidney International—Official Journal of the International Society of Nephrology
www.kidney-international.org
- National Coordinating Council for Medication Error Reporting and Prevention
www.nccmerp.org
- National Patient Safety Foundation
www.npsf.org
- U.S. Pharmacopeia MedMARx
www.medmarx.com