



University HealthSystem Consortium

University HealthSystem Consortium Best Practice Recommendation

Safe Use of Imaging Contrast
Agents and Radiopharmaceuticals

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THE POWER OF COLLABORATION

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About UHC

The University HealthSystem Consortium (UHC), formed in 1984, is an alliance of 102 academic medical centers and 184 of their affiliated hospitals representing approximately 90% of the nation's nonprofit academic medical centers. UHC offers its members specific programs and services to improve clinical, operational, and patient safety performance. The mission of UHC to advance knowledge, foster collaboration, and promote change to help members succeed in their respective markets.

Introduction

Imaging medications have always carried the prescription legend, but historically these agents have not been handled like other medications within either imaging areas or health care organizations themselves. In 2004, The Joint Commission (TJC) mandated that contrast agents and radiopharmaceuticals be treated as medications,¹ subject to the scrutiny of Medication Management (MM) Standards and medication related National Patient Safety Goals (NPSGs). This change ensures that the same controls that exist for other medications within the organization in regards to prescribing, dispensing, storage, security, administration, and monitoring must also be in place for contrast agents and radiopharmaceuticals.

As with any new regulatory requirement, challenges are expected, and ongoing action plans are being developed to address those challenges. Meeting these new requirements in most imaging areas requires significant cultural change. Although compliance with the standards is clearly in the best interest of patient safety, even something as simple as using the word *medication* in place of *dye* has been a difficult transition for both patients and staff. Ensuring compliance with the standards also necessitates a closer working relationship between the Departments of Pharmacy and Imaging, a collaboration that has not previously existed in many health care organizations.

The MMs and NPSGs continue to present challenges for radiology and nuclear medicine areas, and most notable are those associated with MM.05.01.01 (formerly MM 4.10) element of performance (EP) 1. These challenges have been the subject of concern and debate across the country—within institutions and across pharmacy, radiology, nuclear medicine, and other imaging professional societies.

MM.05.01.01 EP1 specifically requires a pharmacist to review all prescriptions or medication orders before dispensing with the following 2 exceptions: (1) When the medication is urgently needed or (2) when a licensed independent practitioner (LIP) controls the ordering, preparation, and administration of the medication. TJC has consistently stated that the second exception requires the LIP to remain with the patient during administration of the medication. In January 2007, TJC modified this interpretation for radiology services only: Effective January 1, 2007, a hospital's radiology services will be allowed to

define, through protocol or policy, the role of the LIP in the direct supervision of a patient during and after imaging medication is administered. The protocol/policy must be approved by the medical staff and the role of the LIP must be defined so that there can be timely intervention by the LIP in the event of a patient emergency. TJC recommends that organizations refer to the American College of Radiology Practice Guidelines for the Use of Intravascular Contrast Media during development of the protocol/policy.²

A field review of MM 4.10 (now MM.05.01.01) was conducted in December 2006 that included questions related to hospital imaging settings. Many of the responses supported the use of protocols, developed with the participation of a pharmacist, for contrast agents and radiopharmaceutical administration.³

Based on the recommendations from the field review, TJC staff conducted discussions with multiple professional societies to investigate the safety issues related to the administration of contrast agents and radiopharmaceuticals and the use of protocols in place of a pharmacist's prospective review of contrast agent medication orders. These discussions were held with the following organizations:

- American College of Radiology
- American Society of Echocardiography
- American Society of Health-System Pharmacists
- Society of Nuclear Medicine
- Society of Radiologists in Ultrasound⁴

The outcome of this investigation has resulted in proposed revisions to MM 4.10 EP1 and MM 8.10 (now MM.08.01.01) EP1. The MM 4.10 revision includes 6 proposed EPs permitting the use of medication protocols in place of medication orders for the administration of contrast agents in radiology, magnetic resonance imaging (MRI), echocardiography, and ultrasound and for the administration of radiopharmaceuticals. The 8.10 EP1 revisions focus on the evaluation of safety trends or issues identified from the use of protocols in the above-mentioned areas.⁵

This best practice recommendation for the safe use of contrast agents and radiopharmaceuticals is offered as a guide to UHC members, TJC, professional societies, and health care institutions. It is designed to improve safety with the use of contrast agents and radiopharmaceuticals, as well as to educate TJC and professional societies regarding the unique challenges and considerations for using these agents within health care institutions. This document clarifies what is considered “best practice” in terms of the MMs

and the NPSGs to make implementation of these safety measures both practical and easy.

A multidisciplinary team of health care professionals from 15 UHC hospitals from across the United States and a representative from the Society of Nuclear Medicine collaborated to create this best practice recommendation.

Definitions

A **medication**, as defined by TJC, is “any product designated by the Food and Drug Administration (FDA) as a drug, as well as any sample medications, herbal remedies, vitamins, nutraceuticals, over the counter drugs, vaccines, diagnostic and contrast agents, respiratory therapy treatments, parenteral nutrition, blood derivatives, and intravenous solutions (plain, with electrolytes and /or drugs). This definition of medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases.”¹

TJC defines a **medication error** as a preventable event resulting in incorrect use of a medication or harm to the patient.¹

TJC defines the phrase **adverse drug event (ADE)** as any event resulting in injury to the patient. Injury may be due to a reaction to a normal dose or a reaction due to an error.¹

An **adverse drug reaction (ADR)**, per TJC, results in “unintended, undesirable, or unexpected effects of prescribed medications or of medication errors” requiring dose alterations, medication discontinuation, hospitalization, further treatment with a prescription medication or causing disability, cognitive impairment or death.¹

Contrast medications or contrast agents are medications used in imaging procedures to facilitate the differentiation of body tissues. The most common contrast agents are iodine-containing contrast and barium used in x-ray imaging; gadolinium-containing contrast agents (GCCA) used in magnetic resonance imaging (MRI); and microbubble contrast used in echocardiography and ultrasound imaging. Iodine-containing contrast and barium contrast act by absorbing or attenuating the x-ray beam as it passes through the tissue. Gadolinium is a paramagnetic element; GCCA alters the local magnetic field of water protons in the body area being scanned, facilitating a rapid release of absorbed energy that results in a stronger signal and a brighter image. Microbubble contrast, also called perfluorocarbon microsphere contrast, interacts with the ultrasound wave, resulting in harmonic echoes that are unique to these agents.

Radiopharmaceuticals are used in the diagnosis and treatment of disease by allowing a scanner to trace (capture) the radiopharmaceutical through physiologic, biochemical, or molecular processes thus allowing functional visualization at the organ, tissue, or cellular level.

The term *imaging medications*, when used alone, indicates inclusion of both contrast agents and radiopharmaceuticals.

The term *technologists*, when used alone, indicates inclusion of radiologic, ultrasound and nuclear medicine technologists.

A **licensed independent practitioner (LIP)** is any individual permitted by law and by the organization to provide imaging care and services, without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges. Examples include a radiologist or other board-certified imaging physician, medical resident, physician assistant, or nurse practitioner. Imaging interpretation and approval of variations to a protocol can only be performed by a physician with clinical privileges to do so.

TJC has defined a **protocol** as a standardized specification for care of an individual in a specific clinical situation that has been developed through a formal interdisciplinary process that incorporates the best scientific evidence of effectiveness. This definition includes protocols that require medications. Protocols that include medications are to be developed with the participation of a pharmacist and approved by the medical staff. Standing medical orders are not included in this definition of a protocol.

The **Pharmacy and Therapeutics Committee** is a medical staff committee. For the purposes of this paper, any protocol approved by this committee has the approval of the medical staff and radiology and pharmacy leadership.

Background

Before outlining each of the safe practice recommendations, it is necessary to address some of the unique considerations and challenges associated with imaging and nuclear medicine areas: (1) the ongoing challenges that limit the ability of a prospective pharmacist review, (2) the important role of the technologists, (3) the requirement for direct supervision by an LIP, and (4) the importance of a multidisciplinary, collaborative approach to the safe use of contrast agents and radiopharmaceuticals.

A number of factors limit the feasibility of prospective pharmacist review of imaging medication orders. These factors include financial considerations for health care systems and an ongoing nationwide

pharmacist shortage. However, the primary concern is the potential negative impact that such a mandate would have on patient throughput in imaging areas, causing corresponding delays in patient care. Given the long-standing effectiveness of technologists and imaging nurses in pre-imaging patient screening, pharmacist involvement at a higher level may be more effective.

Another factor to note regarding prospective pharmacist review of orders is that most pharmacy curriculums do not provide focused education for contrast agents or radiopharmaceuticals. Radiopharmacology may be provided as an elective course, but primarily to those who choose to specialize in the field. On-the-job training is infrequent as well. Pharmacists must develop a more thorough knowledge base of contrast agents and radiopharmaceuticals in order to effectively contribute to medication safety in the use of these agents.

Technologists' core curriculum requires classes in imaging medication pharmacology, including contraindications and adverse drug reactions. They are also educated to effectively communicate with patients to obtain a pertinent medical history (including obtaining a medication list) and to screen for contraindications either based on the patient history or the properties of the medication being used. They are trained to contact the supervising physician if any contraindications or concerns arise—before moving forward with the protocol. They are trained to administer the medications ordered by the specified route within the scope of their practice.⁶⁻¹⁰ In addition to their certification curriculum, institutions provide on-site training upon hire, where technologists are trained to perform the aforementioned activities in accordance with institution specific policy and state rules and regulations.

In order to become board certified in radiology, medical school graduates must complete 1 year of clinical internship and 4 years in radiology. Most go on to a 1- to 2-year fellowship to specialize in a particular imaging modality and/or anatomical area. During this intensive training, much time is devoted to the understanding of contrast agents, their interaction with biological systems, and their effects on patients. Without this in-depth knowledge, accurate image interpretation and safe patient care would not be possible. Physicians in other medical specialties, such as cardiologists, also undergo this focused training if they elect to practice in the imaging sciences (e.g., cardiac catheterization lab).

Although radiologists and other imaging physicians have the most knowledge of imaging medication, many institutions across the country are faced with a shortage of trained radiologists.¹¹ As their expertise is critical to the interpretation of imaging and nuclear medicine exams, their responsibilities must be balanced to ensure that their time is spent only on activities that cannot reasonably be performed by other competent personnel. In the case of taking a patient history, screening for contraindications, and

administering a contrast agent or radiopharmaceutical, these functions can be effectively and competently performed by a technologist. Even in the event of an overabundance of radiologists, performing these functions is not a necessary or effective use of a radiologist's time.

It is the consensus of this best practice committee that the most effective way to comply with the MMs and NPSGs and to ensure safe use of contrast agents and radiopharmaceuticals is through a multi-disciplinary, collaborative approach that involves imaging physicians, nursing, pharmacy and imaging technical staff. Protocols that include medications should be developed by the imaging physicians to ensure maximum imaging resolution, reviewed by the Department of Pharmacy to ensure maximum patient safety, and approved by the medical staff. Staff should be appropriately educated, and individual responsibilities should be clearly defined by policy, including the role of the technologist, the nurse (where applicable), and the supervising physician. Quality monitors should be developed to ensure that the process provides for safe patient care and meets the requirements of the regulatory standards.

Safe Practice Recommendations

Patient-Specific Information— MM.01.01.01:

The organization plans its medication management processes.

Recommendation:

Technologists or imaging nurses will be responsible for obtaining patient-specific information including age, sex, height, weight, pregnancy and lactation status, current medications, allergies and past sensitivities, relevant laboratory values, and relevant comorbidities, if not already available in the patient's chart. The information will be accessible when needed to the LIP and other health care staff in the imaging or nuclear medicine area.

Monitoring— MM.01.01.03:

The organization safely manages high-alert and hazardous medications.

Recommendation:

When imaging agents are added to formulary, both clinical risks and risk for error (i.e. look alike, sound alike) associated with the medication are evaluated.

To minimize clinical risk, appropriate screening and monitoring tools are put into place. Identified high-risk patients are brought to the attention of the LIP, and processes are in place that define alternatives,

such as dosage adjustments, other diagnostic treatment options, and/or post-exam therapies (e.g., dialysis).

Refer to NPSG.03.03.01 recommendation to minimize risk for error with imaging medications.

Selection and Procurement— MM.02.01.01:

The organization selects and procures medications.

Recommendation:

All imaging medications are subject to the same scrutiny with respect to selection and procurement as other medications used throughout the organization. They must be formally requested for addition to the formulary and criteria for consideration include indication for use, effectiveness, risks, and costs.

Annually the Pharmacy and Therapeutics Committee in collaboration with the Department of Imaging reviews the list of current formulary agents and makes recommendations to add or delete agents based on organizational need/experience and emerging safety evidence.

Storage— MM.03.01.01:

The organization safely stores medications.

Recommendation:

Policy and procedures for medication storage and security in the imaging and nuclear medicine areas are developed as a joint collaboration between the Departments of Pharmacy and Imaging, are consistent with other organizational policies for medication storage and security, and should be approved by the Pharmacy and Therapeutics Committee.

Storage— MM.03.01.03:

The organization safely manages emergency medications.

Recommendation:

Emergency medications are available in accordance with Pharmacy and Therapeutics Committee institutional policy for management of medical emergencies. Policy and procedures for adverse drug reactions to medications used in imaging and nuclear medicine areas are developed as a joint collaboration between the Departments of Pharmacy and Imaging and approved by the Pharmacy and Therapeutics Committee. Evidence-based guidelines are used to define the medications that are readily available.¹²

Ordering and Transcribing— MM.04.01.01:

Medication orders are clear and accurate.

Recommendation:

Orders for imaging medication may be defined by a protocol or may be written as individual medication orders. Variations to a protocol (e.g., patient does not meet criteria or physician chooses to modify a protocol) should be approved only by a physician with clinical privileges to do so. Protocols that include imaging medications are developed through collaboration between the Departments of Pharmacy and Imaging and are approved by the Pharmacy and Therapeutics Committee. Protocols for use of imaging medications must include the name of the imaging medication, dosage administration parameters, screening process (including contra-indications), and monitoring parameters. Technical procedures for image acquisition may be included in these protocols as well. The imaging medication administration parameters will include fixed or weight-based dosing, route, and infusion time, when appropriate.

Preparing and Dispensing— MM.05.01.01:

A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the organization.

Recommendation:

When imaging medications are administered according to a protocol, a prospective pharmacist review is not required. When a protocol is used, the technologist or imaging nurse is responsible for performing the patient screening (see MM.01.01.01) to ensure appropriateness. Any contraindications or significant risk factors to performing the exam are discussed with the LIP prior to administration of the imaging medication. If the LIP determines that the medication is still needed, organizational policy should indicate if a specific medication order is needed. An LIP is in the general vicinity while the exam is being performed and is immediately available if needed. Organizational leadership is responsible for ensuring that staff administering imaging medications are qualified and competent (as required in HR.01.02.01) and that those qualifications are specifically outlined in organizational policy. Any other medications administered to patients in an imaging area must comply with the requirements of MM.05.01.01 as written.

Preparing and Dispensing— MM.05.01.07:

The organization safely prepares medications.

Recommendation:

Pharmacists, technologists, and imaging nurses involved in the preparation of imaging medications will annually demonstrate competency in sterile product preparation as defined by organizational policy. Wherever imaging medications are prepared, staff use techniques to ensure accuracy in preparation, avoid contamination by maintaining a clean, uncluttered area for product preparation, and use clean or sterile techniques as required by the institution's policy and applicable regulations.

Preparing and Dispensing— MM.05.01.09:

Medications are labeled.

Recommendation:

Imaging medications are labeled, if prepared but not administered immediately, when transferred from their original container to another container. Labels include the agent name, strength, and amount (if not apparent), expiration date only if it occurs in less than 24 hours or when the agent will not be used within 24 hours, date prepared, and diluent for all compounded admixtures. All labels are verified both verbally and visually by 2 qualified individuals when the person preparing the medication is not the person administering the medication. (Note: A 2-person verification is not required when imaging medications have been prepared and labeled in advance of a procedure by a pharmacist or nuclear medicine technologist.)

Administration— MM.06.01.01:

The organization safely administers medications.

Recommendation:

Prior to medication administration, a technologist or imaging nurse screens for potential drug interactions and contraindications specific to the imaging medication ordered as part of the protocol, per organizational policy. Organizational policy defines when and if a serum creatinine/GFR is required prior to the administration of an imaging medication. Prior to imaging medication administration, patients are provided with education specific to the imaging medication to be administered, including risks and benefits, anticipated side effects, after-procedure instructions, and any other pertinent information. Patient education is performed by technologists, imaging nurses, or LIPs. As with any medication, the 5 rights are performed prior to imaging medication administration (correct patient, medication, dose, route, and time).

Administration is performed only by those deemed competent to administer imaging medications and in accordance with state law and organizational policy.

Situations requiring informed consent (e.g., impaired renal function) are defined by organizational policy. Only an LIP may obtain an informed consent, which is signed by the patient and the LIP.

Monitoring— MM.07.01.01:

The organization monitors patients to determine the effects of their medication(s).

Recommendation:

The technologist or an imaging nurse monitors the patient for adverse drug reactions. Depending on the imaging medication to be administered, specific monitoring parameters are defined by protocol or organizational policy. Medications to treat extravasations and adverse drug reactions are readily available.

Monitoring— MM.07.01.03:

The organization responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors.

Recommendation:

The LIP is immediately notified in the event of an adverse drug event or medication error. An LIP or nurse is alerted to evaluate an extravasation. Appropriate measures are taken in accordance with organizational policy and by personnel deemed competent to administer treatments/medications as needed. Adverse drug events, including medication errors and extravasations, are documented according to organizational policy. Aggregate data are reported at least annually to the Pharmacy and Therapeutics Committee and sooner if adverse drug event trends are noted.

Evaluation— MM.08.01.01:

The organization evaluates the effectiveness of its medication management system.

Recommendation:

At least annually, the organization retrospectively evaluates its process by sampling records for cases in which contrast agents or radiopharmaceuticals were administered using a protocol to determine if the process is effective or if there are opportunities for improvement. Adverse drug reactions to imaging medications should be reported and tracked according to organizational policy.

Specific criteria to be evaluated include response to adverse drug reactions (including extravasations), compliance with defined screening processes, and adverse drug event/medication error trends. Data from this evaluation are reported to the Pharmacy and Therapeutics Committee.

NPSG.01.01.01: Improve the accuracy of patient identification.

Use at least 2 patient identifiers when providing care, treatment, and services.

Recommendation:

As with any other medication, 2 patient identifiers are used prior to administration of a contrast agent or radiopharmaceutical. Organizational policy defines which 2 patient identifiers may be used.

NPSG.03.03.01: Improve the safety of using medications.

The organization identifies and, at a minimum, annually reviews a list of lookalike/sound-alike medications used by the organization and takes action to prevent errors involving the interchange of these medications.

Recommendation:

Any imaging medications that have similar labeling but are of a different dose should be physically separated and distinctly and specifically identified. Imaging medications that could represent a risk include (but are not limited to):

- Visipaque versus Omnipaque (sound alike)
- Optimark 10 ml versus 20 ml (look alike)
- ^{99m}Tc sestamibi and ^{99m}Tc medronate diphosphate (MDP) (look alike)

NPSG 8: Accurately and completely reconcile medications across the continuum of care.**Outpatient Recommendations:**

During patient scheduling and when possible, patients are instructed to bring a copy of their medication list to their appointment. A technologist or imaging nurse documents the patient history, including current medications and allergies, and screens for contraindications or drug interactions with the specific imaging medication contained in the protocol. Any concerns are immediately addressed with the LIP.

Outpatient discharge information provided by the technologist or imaging nurse should include the name of the imaging medication received and any special post-procedure instructions such as adequate hydration or temporary discontinuation of a medication. If a change is made to the medication list by the LIP, then the patient must be provided with a copy of the revised medication list. A temporary discontinuation of a medication due to receipt of an imaging medication (e.g., discontinue metformin for 48 hours) does not necessitate that a revised medication list be provided to the patient.

The referring physician is alerted if a change is made to the medication list (as defined by organizational policy), and follow-up testing/treatment is recommended (e.g., creatinine) as needed. The name and dose of the imaging medication administered, including any pertinent information regarding response, must be documented in the patient's medical record and/or imaging report.

Inpatient Recommendations:

A technologist or imaging nurse accesses the patient's current medication and allergy list and screens for contraindications or drug interactions with the imaging medication contained in the protocol. Any concerns are immediately addressed with the LIP. The name and dose of the imaging medication administered, including any pertinent information regarding response, should be included in the handoff communication and documented in the patient's medical record and/or imaging report.

Conclusion

Medications used to enhance diagnostic imaging information must be appropriately administered. This requires communication and cooperation among various health care professionals, who by virtue of their training and perspective provide the necessary knowledge and expertise to ensure that this occurs in a timely and safe manner. This team, led by the imaging physician, must include pharmacists, technologists, and imaging nurses.

Pharmacists have demonstrated their ability to improve the safety of medication use in many areas of patient care. In order to effectively contribute to safe medication use in imaging areas, pharmacists must develop their knowledge base of contrast medications and radiopharmaceuticals. Continuing education opportunities are available and should be utilized to educate currently practicing health system pharmacists. Pharmacist involvement should include participation in the development of medication protocols or clinical care guidelines for the use of imaging medications, participation in formulary review of imaging medications, and assurance of appropriate medication storage in the imaging areas. Additionally, pharmacists should be involved in the monitoring of appropriate and off-label use, identification of drug interactions, identification of patients at risk for adverse drug events, and staff education.

Technologists, due to the specific nature of their specialty, have required training in the pharmacology of imaging medications, their contraindications, and potential adverse drug reactions. As they are typically the first caregiver to have direct contact with the patient in the imaging environment, they are in the best position to use a protocol to determine the appropriateness of imaging medication administration. Nurses, specifically trained in the imaging sciences are able to provide patient assessment and evaluation to ensure safe administration of imaging medications. By virtue of their training, they are in the best position

to provide first response medical care for an adverse drug reaction and can interact effectively in a life-threatening situation.

An imaging department that develops and implements policies and procedures using the expertise and guidance of imaging physicians, pharmacists, technologists, and imaging nurses provides a safe environment for its patients that will ensure accurate diagnostic information in a timely, efficient, and safe manner. Medication errors and adverse drug reactions will be minimized by taking advantage of the knowledge that these professionals contribute. A cooperative and collaborative approach by these caregivers will result in optimization of imaging medication use and improved patient safety.

Committee Members

UHC's best practice recommendation for the safe use of imaging contrast agents and radiopharmaceuticals was developed by a multidisciplinary committee.

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