2018 Noninterpretive Skills

Study Guide

ABR | American Board of Radiology

This study guide is to be used in preparation for all Diagnostic Radiology Core and Certifying examinations administered during calendar year 2018.

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Introduction

This study guide has been created to assist examinees in preparing for the noninterpretive skills (NIS) section of the American Board of Radiology (ABR) Core and Certifying examinations administered between January 1 – December 31, 2018.

The guide has undergone significant revision compared with earlier versions, reflecting changes in NIS content on the examinations. The NIS Study Guide was reduced in size in 2017, necessitating limits on the breadth of material covered.

The determination of whether specific NIS topics merit inclusion in the study guide—and on the examinations—is based primarily on two factors. First, material contained in the NIS section should reflect knowledge that is needed to perform effectively in a modern radiology practice. Second, the public interest should be served by expecting the examinee to know the material.

Core Elements of Professionalism were deemed to merit inclusion because they reflect basic principles to which all physicians, including radiologists, should adhere. Core Concepts of Quality and Safety were included because they reflect underlying principles that drive quality and safety in any complex environment. Practical Quality and Safety Applications in Healthcare contain quality and safety strategies as they are applied to healthcare. Practical Safety Applications in Radiology focus on radiology-specific topics such as MR safety and management of intravenous contrast material. Reimbursement, Regulatory Compliance, and Legal Considerations in Radiology reflect mechanisms that external parties use to ensure quality and safety in radiology practice.

The guide covers the majority of general conceptual and practical NIS information contained in the Core and Certifying examinations. However, questions on important subspecialty-specific quality and safety knowledge and skills are also included on the examinations that are not included in this guide, especially those related to nuclear medicine and other procedure-based specialties. Examinees should be knowledgeable in basic quality and safety practices relevant to all subspecialties regardless of whether they are included in this study guide. Physics topics, including radiation safety, remain on the examination but are no longer included in the NIS section. Content related to research methodology and Bayesian statistics, included in previous versions, has been removed from the study guide and the examinations.

Examinees are expected to understand general NIS concepts rather than esoteric details. For example, examinees should understand the basics elements of regulatory requirements commonly found in radiology practice, as well as their underlying purpose. Less emphasis is placed on more superficial details, such as the names of the various regulatory agencies.

It is expected that this study guide will continue to evolve in future years to reflect continuing changes in the noninterpretive knowledge and skills needed to practice effectively in a modern radiology practice.

We also draw your attention to the references provided at the end of each chapter. We recommend that you consult these “deeper” resources, which provide perspective and depth of understanding of the concepts that are only superficially outlined in this study guide.

1 Core Elements of Professionalism

1.1 ABIM Physician Charter for Medical Professionalism in the New Millennium

Merriam-Webster defines a profession as "a calling requiring specialized knowledge and often long and intensive academic preparation." Professionalism, defined as "the conduct, aims, or qualities that characterize or mark a profession or a professional person," has been characterized as the basis of medicine's contract with society.

Several fundamental principles and physician responsibilities that apply to all professionals in medicine have been specified in a Physician Charter supported by the American Board of Internal Medicine (ABIM). Ten professional responsibilities support the following three fundamental principles of medical professionalism:

1. **Principle of primacy of patient welfare.** Physicians must be dedicated to serving the interest of the patient. Trust is central to the physician-patient relationship, which must not be compromised by market forces, societal pressures, or administrative exigencies.

2. **Principle of patient autonomy.** Physicians must be honest with their patients and empower them to make informed decisions about their treatment. Patients' decisions about their care must be paramount, as long as they are in keeping with ethical practice and do not lead to demands for inappropriate care.

3. **Principle of social justice.** The medical profession must promote the fair distribution of healthcare resources. Physicians should work actively to eliminate discrimination in healthcare.

The 10 professional responsibilities are summarized below:

1. **Commitment to professional competence.** Physicians must be committed to lifelong learning of medical knowledge and team skills necessary for the provision of quality care. More broadly, the profession as a whole must strive to see that all of its members are competent and must ensure that appropriate mechanisms are available for physicians to accomplish this goal.

2. **Commitment to honesty with patients.** Physicians must ensure that patients are completely and honestly informed before the patient has consented to treatment and after treatment has occurred. Medical errors should be communicated promptly to patients whenever injury has occurred. Physicians should be committed to reporting and analyzing medical mistakes to develop appropriate prevention and improvement strategies.

3. **Commitment to patient confidentiality.** Physicians are responsible for safeguarding patient information. Fulfilling this commitment is more pressing now than ever before, given the widespread use of electronic information systems. However, considerations of public interest may occasionally override this commitment, such as when patients endanger others.

4. **Commitment to maintaining appropriate relations with patients.** Given the inherent vulnerability and dependency of patients, certain relationships between physicians and patients must be avoided. In particular, physicians should never exploit patients for any sexual advantage, personal financial gain, or other private purpose.

5. **Commitment to improving quality of care.** Physicians should not only maintain clinical competence, but should work collaboratively with other professionals to continuously improve the quality of healthcare, including reducing medical errors, increasing patient safety, improving utilization of healthcare resources, and optimizing outcomes of care.

6. **Commitment to improving access to care.** Physicians should work individually and collectively toward providing a uniform and adequate standard of care and reducing barriers to equitable healthcare. These barriers may be based on education, laws, finances, geography, or social discrimination. This commitment entails the promotion of public health and preventive medicine, without promotion of the self-interest of the physician or the profession.

7. **Commitment to a just distribution of finite resources.** To provide cost-effective health care, physicians should work with other physicians, hospitals, and payers to develop evidence-based guidelines for effective use of healthcare resources. This includes the scrupulous avoidance of superfluous tests and procedures to reduce patient exposure to harm, decrease health expenses, and improve access to resources for patients who need them.

8. **Commitment to scientific knowledge.** Physicians should uphold scientific standards, promote research, and create new medical knowledge and ensure its appropriate use. The integrity of this knowledge is based on scientific evidence and physician experience.

9. **Commitment to maintaining trust by managing conflicts of interest.** Medical professionals and organizations can compromise their professional responsibilities by pursuing private gain or personal advantage, especially through interactions with for-profit companies. Physicians have an obligation to recognize, disclose to the general public, and deal with conflicts of interest that arise in the course of their professional duties and activities. Relationships between industry and opinion leaders should be disclosed, especially when physicians are determining criteria for conducting and reporting clinical trials, writing editorials or therapeutic guidelines, or serving as editors of scientific journals.

10. **Commitment to professional responsibilities.** Physicians have both individual and collective obligations to work collaboratively to maximize patient care, be respectful of one another, and participate in the processes of self-regulation, including remediation and discipline of members who have failed to meet professional standards. The profession should also define and organize the educational and standard-setting process for current and future members. These obligations include engaging in internal assessment and accepting external scrutiny of all aspects of their professional performance.

1.2 Ethical Considerations Specific to Radiology

The ABIM professional responsibilities largely overlap with the Code of Ethics as described in the American College of Radiology (ACR) Bylaws. However, several principles and rules of ethics apply specifically to the field of radiology, as stated by the ACR.

1. **Professional limitations.** The Bylaws state that radiologists should be aware of their limitations and to seek consultations in clinical situations where appropriate. Any limitations should be appropriately disclosed to patients and referring physicians.

2. **Reporting of illegal or unethical conduct.** To safeguard the public and the profession against physicians deficient in moral character or professional competence, radiologists are expected to report any perceived illegal or unethical conduct of medical professionals to the appropriate governing body.

3. **Report signature.** Radiologists should not sign a report or claim attribution of an imaging study interpretation that was rendered by another physician, making the reader of a report believe that the signing radiologist was the interpreter.

4. **Participation in quality and safety activities.** Radiologists who actively interpret images should participate in quality assurance, technology assessment, utilization review, and other matters of policy that affect the quality and safety of care.

5. **Self-referral.** Referring patients to healthcare facilities in which radiologists have a financial interest is not in the best interest of patients and may violate the Rules of Ethics.

6. **Harassment.** Radiologists are expected to relate to other members of the healthcare team with mutual respect and refrain from harassment or unfair discriminatory behavior.

7. **Undue influence.** Radiologists should seek to ensure that the system of healthcare delivery in which they practice does not unduly influence the selection and performance of appropriate available imaging studies or therapeutic procedures.

8. **Agreements for provision of high-quality care.** Radiologists should not enter into an agreement that prohibits the provision of medically necessary care or that requires care at below acceptable standards.

9. **Misleading billing arrangements.** Radiologists should not participate in billing arrangements that mislead patients or payers concerning the fees charged.

10. **Expert medical testimony.** Radiologists should exercise extreme caution to ensure that the testimony provided is nonpartisan, scientifically correct, and clinically accurate. Compensation that is contingent upon the outcome of litigation is unacceptable.

11. **Research integrity.** Radiologic research must be performed with integrity and be honestly reported.

12. **Plagiarism.** Claiming others' intellectual property as one's own is unethical. This includes plagiarism or the use of others' work without attribution.

13. **Misleading publicizing.** Radiologists should not publicize themselves through any medium or forum of public communication in an untruthful, misleading, or deceptive manner.

References

1. American Board of Internal Medicine Foundation. Medical Professionalism in the New Millennium: The Physician Charter. American Board of Internal Medicine Foundation Website. http://abimfoundation.org/what-we-do/medical-professionalism-and-the-physician-charter/physician-charter. Accessed October 1, 2016.

2. American College of Radiology. Code of Ethics. American College of Radiology Website. http://www.acr.org/~/media/ACR/Documents/PDF/Membership/Governance/2016_2017%20Code%20of%20Ethics.pdf. Accessed October 1, 2016.

2 Core Concepts of Quality and Safety

2.1 Core Concepts of Quality

2.1.1 Introduction to Quality

Merriam-Webster defines quality as "a high level of value or excellence." The Institute of Medicine has defined quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." As it relates to diagnostic imaging and image-guided treatment, quality can be considered to be "the extent to which the right procedure is done in the right way, at the right time, and the correct interpretation is accurately and quickly communicated to the patient and referring physician. The goals are to maximize the likelihood of desired health outcomes and to satisfy the patient."

Several important concepts are connected to these statements.

First, quality has two important dimensions: excellence and consistency. It is not enough to provide excellent care; it must be done on a consistent basis. Lack of consistency is a marker of poor quality.

Second, performance must be monitored to ensure consistent quality. It is unlikely for an organization to achieve consistent excellent performance in the absence of performance standards or measurements.

Third, the goals are twofold: 1) maximize the likelihood of health outcomes desired by the patient and 2) satisfy the patient. In other words, optimizing health outcomes and patient experience are both important goals of healthcare. Furthermore, while excellence may be a subjective term, the ultimate arbiter of "quality" is the patient. Those who wish to provide quality care must understand and seek to achieve consistent excellence from the perspective of the patient—which may differ from that of the provider.

Fourth, the goal is to consistently achieve desired health outcomes using methods that are consistent with current professional knowledge. Achieving excellent outcomes on a consistent basis depends on consistency in the methods, or processes, that are used to achieve those outcomes. Therefore, a major goal of quality is that of decreasing unnecessary variation, both in processes and outcomes. In a practice with multiple professionals, this generally requires those professionals to collaborate in developing and adhering to practice standards based on the evidence.

2.1.2 Quality as a Discipline

Achieving consistent excellence in processes and outcomes is challenging in healthcare, including in radiology. However, healthcare is by no means the only field in which consistent excellence is desired. Over the past century, "quality" has emerged as its own discipline of study and practice, with a set of broadly applicable definitions, principles, and tools.

Quality control (QC) refers to measuring and testing elements of performance to ensure that standards are met and correcting instances of poor quality. An example of a QC activity is when a radiologist reviews and corrects errors in a radiology report before finalizing it.

Quality assurance (QA) refers to a process for monitoring and ensuring performance quality in an organization. This includes QC activities, but also refers to strategies designed to prevent instances of poor quality. An example of a QA activity is the use of standardized report templates to minimize errors in reporting accompanied by verification of appropriate use with audit-based performance metrics.

Quality improvement (QI) refers to activities designed to improve performance quality in an organization in a systematic and sustainable way. This requires a deliberate effort within an organization to agree on a measurable performance objective, measure the relevant performance, understand the causes of poor performance, develop and implement strategies to improve performance, and ensure that those strategies are embedded in the organization such that performance will not relapse. An example of QI

is a project whereby radiologists agree to improve consistency in reporting using standardized radiology report templates, implement those templates, monitor radiology reports and make necessary adjustments, and ensure that consistency is maintained through feedback and accountability.

QC is generally considered to be the most basic level of quality-related activities in an organization. QA is more comprehensive than QC and is required to maintain consistently high performance levels in an organization. However, QA typically is designed to maintain rather than improve performance, implying that quality was presumed to be adequate in the first place. QI, on the other hand, assumes that quality is not as good as it could be and employs strategies to successfully improve quality through a variety of means, including changes in processes, systems, and even organizational structure. As organizations' focus has transitioned in recent decades from seeking to maintain the status quo to seeking to constantly improve performance, the field of quality has transitioned from relying solely on a QA approach to one of *continuous quality improvement* (CQI).

Quality methods and philosophies have evolved in several other important ways in the past several decades:

- Rather than being solely the purview of a "quality department," quality has come to be recognized as the responsibility of everyone in the organization—especially organizational leaders.
- The focus has shifted from detecting and correcting errors that have already occurred to improving processes and systems to prevent errors from happening or from causing harm.
- Frontline staff are increasingly engaged to help improve processes.
- The value of making errors visible rather than quietly fixing them without sharing them with the staff is increasingly recognized. Exposing errors allows them to be more easily detected so they can be corrected and their causes addressed.

2.1.3 2001 Institute of Medicine Report, *Crossing the Quality Chasm*

In 2001, the Institute of Medicine (IOM) published a report entitled, "Crossing the Quality Chasm: A New Health System for the 21st Century." In this report, the IOM committee members maintained that all healthcare constituencies, including policymakers, purchasers, regulators, health professionals, health-care trustees and management, and consumers, should commit to a shared explicit purpose to continually reduce the burden of illness, injury, and disability, and improve the health and functioning of the people of the United States.

The committee asserted that healthcare should be:

- *Safe*—avoiding injuries to patients from the care that is intended to help them.
- *Effective*—providing services based on scientific knowledge to all who can benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse).
- *Patient-centered*—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- *Timely*—reducing waits and potentially harmful delays for both those who receive and those who give care.
- *Efficient*—avoiding waste, in particular waste of equipment, supplies, ideas, and energy.
- *Equitable*—providing care that does not vary in quality because of personal characteristics.

Since its publication, the IOM "Chasm" report, which was itself a follow-up to a 2000 IOM report on medical error, has provided a road map for individuals and organizations in healthcare to focus their improvement efforts.

2.1.4 Core Competencies of the ABMS and ACGME

To encourage active physician participation in advancing the goals of continuous improvement, in 1999 the Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS), which is composed of subspecialty boards including the American Board of Radiology, described six core competencies that all physicians should attain.

- *Practice-based Learning and Improvement:* Show an ability to investigate and evaluate patient care practices, appraise and assimilate scientific evidence, and improve the practice of medicine.
- *Patient Care and Procedural Skills:* Provide care that is compassionate, appropriate, and effective treatment for health problems and promote health.
- *Systems-based Practice:* Demonstrate awareness of and responsibility to the larger context and systems of healthcare. Be able to call on system resources to provide optimal care (e.g., coordinating care across sites or serving as the primary case manager when care involves multiple specialties, professions, or sites).
- *Medical Knowledge:* Demonstrate knowledge about established and evolving biomedical, clinical, and cognitive sciences and their application in patient care.
- *Interpersonal and Communication Skills:* Demonstrate skills that result in effective information exchange and teaming with patients, their families, and professional associates (e.g., fostering a therapeutic relationship that is ethically sound; using effective listening skills with nonverbal and verbal communication; and working both as a team member and, at times, as a leader).
- *Professionalism:* Demonstrate a commitment to carrying out professional responsibilities, adhering to ethical principles, and being sensitive to diverse patient populations.

By establishing this set of competencies, the ACGME and ABMS assert that the skills necessary to effectively practice medicine in a modern complex healthcare environment extend beyond the traditional domains of medical knowledge and individual practice. It is not enough for professionals to gain adequate knowledge; they must also continuously improve their knowledge and practice for the duration of their careers. They must be not only technically competent, but also compassionate and ethical. They must practice effectively not only as individuals, but also as members of teams, organizations, and systems of care. Organizations and leaders who are responsible for certifying competence of practitioners must demonstrate adequacy of the professional's competence in all domains.

2.2 Core Concepts of Safety

2.2.1 2000 Institute of Medicine Report, *To Err is Human*

In 1998, the National Academy of Sciences' Institute of Medicine (IOM) initiated the Quality of Health Care in America project to develop a strategy that would result in improved quality of care in the United States. To Err is Human: Building a Safer Health System, published in 2000, was the first in a series of reports arising from this project. The report's findings that between 44,000 and 98,000 in-hospital deaths per year were attributable to medical errors made national headlines, including a suggestion that an epidemic of death from medical errors exceeded that from motor vehicle accidents, breast cancer, or AIDS. The report projected total societal costs of medical errors to be between $17 billion and $29 billion.

The report defined medical error as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim, with the highest risk for errors occurring in high-acuity environments such as the intensive care unit, operating room, and emergency department. The report identified several fundamental factors contributing to the errors, including the following: 1) the decentralized nature of the healthcare delivery system (or "nonsystem," as the report calls it); 2) the failure of licensing systems to focus on errors; 3) the impediment of the liability system to identify errors; and 4) the failure of third-party providers to provide financial incentive to improve safety.

The report authors emphasized that most errors are multifactorial; most errors can be attributed to unsafe systems and processes of care as well as to human error. Therefore, the only strategy to decrease medical errors that is likely to be both successful and sustainable in the long run is to design safety into systems and processes of care. Blaming and "rooting out the bad apples," the authors contended, is not a viable strategy to decrease error.

2.2.2 2015 Institute of Medicine Report, *Improving Diagnosis in Health Care*

In 2015, the IOM issued what it considered to be a follow-up report to its 2000 report on medical error, this time focusing on diagnostic error. In this report, Improving Diagnosis in Health Care, the IOM committee defined diagnostic error as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient." The definition is purposely patient-focused because, according to the report, patients are considered to be key team members in the collaborative efforts required to prevent diagnostic error.

Quickly establishing a correct diagnosis is critical to the provision of safe and effective patient care. The problem of diagnostic error tends to be underappreciated, for several reasons. Data on diagnostic error are sparse, few reliable measures exist, and often the error is identified only in retrospect. The best estimates indicate that nearly all Americans will likely experience a meaningful diagnostic error in their lifetimes. A poll commissioned by the National Patient Safety Foundation in 1997 found that approximately one in six of those surveyed had experience with diagnostic error, either personally or through a close friend or relative. On average, 10% of postmortem exams were associated with diagnostic errors that might have affected patient outcomes. The report authors maintained that reducing diagnostic error should be a key component of quality improvement efforts by healthcare organizations.

Similar to the 2000 IOM report, this report called for objective, nonpunitive efforts to understand error and to improve systems and processes accordingly. This includes learning from both errors and near misses on one end of the spectrum and from exemplary accurate and timely diagnoses on the other end. The report authors viewed the diagnostic process as a collaborative activity, often between numerous professionals and professional groups. Therefore, improving diagnosis often requires collaborative efforts between professionals to understand error and improve performance.

The report authors made eight specific recommendations for improvement in the diagnostic processes:

1. Facilitate more effective teamwork among healthcare professionals, patients, and their families. Radiologists and pathologists are an integral part of the diagnostic team.
2. Enhance healthcare professional education and training in the diagnostic process.
3. Ensure that health information technologies support patients and healthcare professionals.
4. Develop and deploy organizational approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice.
5. Establish a work system and culture that supports the diagnostic process and improvements in performance. This may include redesigning payment structures since fee for service (FFS) payments lack incentives to coordinate care among team members, such as communication among treating clinicians, pathologists, and radiologists about diagnostic test ordering, interpretation, and subsequent decision making.
6. Develop a reporting environment and medical liability system that facilitates improvement.
7. Design a payment and care delivery environment that supports the diagnostic process. Specifically, oversight bodies should require that healthcare organizations have programs in place to monitor the diagnostic process and identify, learn from, and reduce diagnostic errors and near misses in a timely fashion.
8. Provide dedicated funding for research on the diagnostic process and diagnostic errors.

With respect to radiology, the 2015 IOM report identified failures in communication as being a significant contributor to diagnostic error. The report authors made several recommendations for IT professionals and organizational leaders to improve communication, including the following:

- Standardize communication policies and definitions across networked organizations
- Ensure clear identification of the patient's care team to facilitate contact by the radiology team
- Implement effective results management and tracking processes
- Develop shared quality and reporting metrics

2.2.3 Human Factors

Background

An obstetric nurse connects a bag of pain medication intended for an epidural catheter to the mother's intravenous (IV) line, resulting in a fatal cardiac arrest. Newborns in a neonatal intensive care unit are given full-dose heparin instead of low-dose flushes, leading to three deaths from intracranial bleeding. An elderly man experiences cardiac arrest while hospitalized, but when the code blue team arrives, the team is unable to administer a potentially life-saving shock because the defibrillator pads cannot be connected to the defibrillator itself.

Busy healthcare workers rely on equipment to carry out life-saving interventions with the underlying assumption that technology will improve outcomes. But as these examples illustrate, the interaction between workers, equipment, and the environment can actually increase the risk of consequential errors. Each of these safety hazards ultimately was attributed to a relatively simple, yet overlooked, problem with system design. The bag of epidural anesthetic was similar in size and shape to IV medication bags, and, crucially, the same catheter could access both types of bags. Full-dose and prophylactic-dose heparin vials appeared virtually identical, and both concentrations were routinely stocked in automated dispensers at the point of care. Multiple brands of defibrillators exist that differ in physical appearance as well as functionality; a typical hospital may have many different models scattered around the building, sometimes even on the same unit.

Human Factors Engineering

Human factors engineering as a discipline attempts to identify and address such problems in a systematic way. It takes into account human strengths and limitations in the design of interactive systems that involve people, equipment, technology, and work environments to ensure safety, effectiveness, and ease of use. A human factors engineer examines a particular activity in terms of its component tasks and then assesses the human physical, mental and skill demands in the context of team dynamics, work environment (e.g., adequate lighting, limited noise, or other distractions), and device design required to optimally perform a task. In essence, human factors engineering focuses on how systems work in actual practice, with real—and fallible—human beings at the controls. It attempts to design systems that optimize safety and minimize the risk of error in complex environments.

Human factors engineering has long been used to improve safety in many industries, including aviation and nuclear power. Its application to healthcare is relatively recent; pioneering studies of human factors in anesthesia were integral to the redesign of anesthesia equipment, significantly reducing the risk of injury or death in the operating room.

Standardization

Human factors engineering asserts that equipment and processes should be standardized whenever possible to increase reliability, improve information flow, and minimize cross-training needs. Standardizing equipment across clinical settings is one basic example, but standardized processes are increasingly recognized as a requirement for safety. The use of checklists as a means of ensuring that safety steps are performed, and performed in the correct order, has its roots in human factors engineering principles. Establishing an agreed-upon, standardized approach for the basic elements of a procedure allows team members to identify when unintended variances from that approach occur (which may represent errors) and frees the team members to better focus on the unique aspects of the case.

Communication

Effective communication is a critical aspect of quality and safety in any complex environment. Communication can be defined as the meaningful exchange of information between individuals or groups of individuals; it is often bidirectional or multidirectional and is successful when it results in shared understanding of meaning. Communication consists of two major parts: 1) *conveyance*—transmission of information from a sender to a receiver, and 2) *convergence*—verification, discussion, and clarification until both parties recognize that they mutually agree (or fail to agree) on the meaning of the information. Convergence activities are especially critical when information is ambiguous or when the negative impact of a miscommunication would be severe.

High Reliability Organization (HRO)

In modern medicine, care delivery is frequently performed in a high complexity setting. A so-called "high reliability organization (HRO)" is an organization that, despite operating in a high-stress, high-risk, complex environment, continually manages its environment mindfully, adopting a constant state of vigilance that results in the fewest number of errors. Many healthcare organizations are attempting to adopt high-reliability behaviors and organizational strategies to reduce medical errors for their patients.

According to the authors of the concept, HROs maintain resilience through stressful situations by both *anticipating* unexpected events and containing their impact when they occur. Anticipation has three elements: *preoccupation with failure, reluctance to simplify,* and *sensitivity to operations.* Containment has two elements: *commitment to resilience* and *deference to expertise*. These can be described as follows:

Anticipation

1. **Preoccupation with failure.** Members of the organization recognize that even minor lapses can have severe consequences and tend to be deliberately watchful for clues that indicate trouble. The organizations have processes in place to enable individuals, teams, and systems to quickly detect and respond to potential threats before they result in harm.

2. **Reluctance to simplify.** When problems arise, rather than accept simple explanations, individuals are expected to dig deeper to understand the source of the problem.

3. **Sensitivity to operations.** Members of the organization—especially the leaders—continuously understand the messy reality of the details of what is *actually happening* in the place of work rather than what is *supposed to be happening* and respond accordingly.

Containment

4. **Commitment to resilience.** It is assumed that unexpected trouble is both ubiquitous and unpredictable. HROs recognize that they can never fully anticipate each unexpected event, so they empower individuals to adjust and innovate as necessary and then seek to learn from those situations.

5. **Deference to expertise.** No one individual ever knows everything about any situation. People with greater authority often have less useful knowledge about a situation than those with lesser authority. HROs overcome the dangers of hierarchy by enabling leaders to defer to the relevant expertise, regardless of its source, while preserving the organizational structure.

2.2.4 Human Error

People are prone to error, but not all errors are identical. A commonly used human error classification scheme is the "skill-rule-knowledge" (SRK) model. This model refers to the cognitive mode in which the individual is operating when he or she commits an error. Actions that are largely performed automatically, requiring little conscious attention, are considered *skill-based actions*, such as tying one's shoes or driving on the open freeway. Actions that require an intermediate level of attention are considered *rules-based actions*, such as deciding which clothes to wear or when to proceed at a four-way stop. Actions that require a high level of concentration, usually in the setting of situations that are new to the individual, are knowledge-based actions, such as playing a sport for the first time or driving in poor visibility conditions in an unfamiliar city.

Appropriate strategies for ensuring safety in the face of human error depend on the type of error committed. Skill-based errors tend to be amenable to behavior-shaping constraints that make it hard to perform the wrong action (i.e., forcing functions, such as a microwave that cannot be operated with the door open) and enablers that make it easy to perform the right action (i.e., affordances, such as installing a door handle for pulling and a plate for pushing). Rules- and knowledge-based errors tend to be amenable to increased supervision, additional training and coaching, deliberate practice, and intelligent decision support.

Note that additional training is generally less effective for skill-based errors, and behavior shaping constraints are less effective for rules- or knowledge-based mistakes. For example, a radiologist who accidentally dictates "100 mg" instead of "100 μg" is unlikely to benefit from an educational course on units of measure in the metric system. Conversely, a simple clinical decision-support rule that forces a physician to order ultrasonography when he or she thinks that magnetic resonance imaging is warranted is more likely to be ignored and thus less likely to be successful than education and consensus-building efforts. Thus, in learning from an error, it is important to determine the cognitive mode in which the individual was operating at the time.

2.2.5 Culture of Safety

Background

The concept of *safety culture* originated in studies of high reliability organizations. High reliability organizations maintain a commitment to safety at all levels, from frontline providers to managers and executives. According to the Agency for Healthcare Research and Quality (AHRQ), this commitment establishes a "culture of safety" that encompasses the following key features:

- Acknowledgment of the high-risk nature of an organization's activities and the determination to achieve consistently safe operations
- A blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment
- Encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems
- Organizational commitment of resources to address safety concerns

Studies have documented considerable variation in perceptions of safety culture across organizations and job descriptions. Historically, nurses have often complained of the lack of a blame-free environment and providers at all levels have noted problems with organizational commitment to establishing a culture of safety. The underlying reasons for the underdeveloped healthcare safety culture include poor teamwork and communication, a "culture of low expectations," and the presence of steep authority gradients.

Authority Gradient

In an organization with steep authority gradients, especially where there is fear of punishment for errors, quality and safety problems are rarely reported to senior leadership. In this way, such authority gradients not only undermine the safety culture, but increase the difficulty of accurately measuring error rates.

Measuring and Achieving a Culture of Safety

Perceptions by the staff of poor safety culture have been linked to increased error rates. Safety culture can be measured by surveys of providers at all levels. Available validated surveys include the AHRQ's Patient Safety Culture Surveys and the Safety Attitudes Questionnaire.

Just Culture

The traditional culture of individual blame, which still dominates some healthcare organizations, impairs the advancement of a safety culture. However, while blame is generally an undesirable approach to safety, individuals need to be held accountable for their actions to a certain degree. In an effort to reconcile the need for reducing a focus on blame and maintaining individual accountability, the concept of "just culture" was proposed by David Marx. The just culture model distinguishes between human error (e.g., slips), at-risk behavior (e.g., taking shortcuts), and reckless behavior (e.g., flaunting firmly established safety rules). In this model, the response to an error or near miss is predicated on the type of behavior associated with the error, not the outcome or severity of the event.

For example, reckless behavior, in which firmly established safety norms are willfully ignored, such as a physician who refuses to perform a time out before surgery, may merit firm—possibly punitive—action, even if no patients were harmed. In contrast, a person who makes an innocent human error, even if this error resulted in significant patient harm, would be consoled since human errors are considered to be inevitable and not necessarily the result of negligence. In the middle ground, those persons who engage in at-risk behavior—e.g., workarounds of convenience, such as failing to communicate critical results, that could subvert established safety precautions—probably underestimate the risks of their actions. These persons are counseled or coached in the Just Culture Model (**Table 2.1**).

A safety coach or champion is a person in the organization who takes ownership of the processes and fosters the creation and maintenance of the safety culture, including oversight of safety-reporting systems whereby safety incidents and near-miss events are reported and archived. In a safety-reporting system, the primary focus is on the patient, the event, and the processes and systems to identify opportunities for sustainable improvement. The individual who made the error should not be the focus of the investigation, as long as the individual was not acting recklessly. In other words, the reporting system should not be used as a means of instigating punitive action.

The term "second victim" has been coined for a healthcare worker who is traumatized by an error or adverse patient event in which they were involved.

Three Manageable Behaviors of the Just Culture Model

Behavior or event	*Human Error*	*At-risk Behavior*	*Reckless Behavior*
Definition	A product of our current system design and our behavioral choices	A choice where the risk is believed to be insignificant or justified	A conscious disregard for a substantial and unjustifiable risk
Management Strategies	• Modify available choices • Change processes/ workflows • Improve training programs • Redesign system or facility	• Counsel individual • Better incentivize correct behavior • Modify processes, training, etc. as needed	• Remediate • Take punitive action as warranted
Recommended approach to the individual	Console	Coach	Counsel

Table 2.1 Outline of the Just Culture Model. Adapted from Marx 2009.

These individuals often feel an intense sense of guilt, sorrow, and anxiety, and may even exhibit signs similar to post-traumatic stress disorder. Many hospitals have begun to develop internal programs to identify, console, and advocate on behalf of such individuals.

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3 Practical Quality and Safety Applications in Healthcare

3.1 Practical Quality Applications in Healthcare

Quality improvement activities can be divided into two aspects: 1) frequent small improvement efforts conducted in close association with the management of the day-to-day clinical operations and 2) dedicated improvement projects to address areas of performance that generally require more focused improvement efforts.

3.1.1 Daily Management Systems

A daily management system (DMS) provides a day-to-day operating framework for leaders to engage with staff to solve problems on a continuous basis. The objective of the DMS is to facilitate communication and coordination within and across organizational units and roles in the organization. For example, in a radiology department, a DMS allows for coordination and communication between 1) radiologists, technologists, nurses, medical assistants, IT professionals, administrators, etc.; 2) front line staff, managers, and leaders; and 3) the radiology department and other units such as the emergency department, inpatient units, medical and surgical specialties, etc.

A DMS can be implemented in a variety of ways to meet local organizational needs. However, DMS programs tend to have a few core elements that help them achieve the programs' objectives.

Tiered Huddles
A huddle is a brief structured meeting occurring in an organizational unit in which participants review what has recently occurred, the current status of the unit, and what is anticipated in the near future. First-tier huddles are held within local units and involve all frontline staff on service for the day. Unit leaders then attend huddles at a higher tier, whose leaders in turn attend huddles at a higher tier, up to the executive team. Huddles generally take place at a *visibility board* (often simply an organized white board), which tracks important elements of the daily management huddles for all staff members to see.

Goal and Metrics Review
Organizational goals help focus the members on making tangible progress toward better fulfillment of the organization's missions. Performance metrics enable members of the organization to objectively determine how well those goals are being met. Ideally such goals and metrics should be aligned with the stated values of the organization, including excellence in care, patient safety, patient and family experience, efficiency, etc. A brief review of quantitative metrics at the huddle on a regular basis helps the organization make iterative improvements to facilitate continued progress toward the goals.

Daily Readiness Assessment
A daily readiness assessment reviewed at the huddle helps the staff be aware of the number and types of patients to be seen that day and to determine whether they are prepared to accommodate their needs. Topics that are typically reviewed include 1) methods: ensuring that the proper protocols and plans are in place to accommodate patients, especially those with special needs, 2) equipment: reviewing whether all of the equipment is operational and staff have appropriate training, 3) supplies: ensuring that all needed supplies are available for use, and 4) associates: ensuring that appropriate staff are in place to meet patient needs and that any staff shortages have been accommodated.

Problem Management and Accountability Cycle
Continuous problem solving is a critical element of the DMS. Staff are encouraged to identify problems at the daily huddle. Problems are documented on the visibility board, along with an "owner" of the problem and an expected resolution date. Problems that are more complex often are listed on a separate board along with the owner of the problem, the date the issue was first identified, and a date on which the owner is expected to make a progress report.

Regular Follow-up
The regular cadence of the daily huddles, along with the tracking of assignments on the visibility board, provides a mechanism to routinely follow up on assignments. This follow-up greatly increases the likelihood that assignments will be completed or revised as needed.

Frequent Visits to the Workplace
A core tenet of effective management is that one must see what is happening in the workplace to truly understand it. Managers and leaders are encouraged to minimize the time spent in closed-door meetings in favor of spending time where the work is done. When individuals visit the workplace, they are expected to respectfully observe and ask questions to learn about the work; they should not give direction, solve problems, or otherwise interfere with the work during this time.

3.1.2 Project-based Improvement Methods

Problems that are too difficult to solve using routine daily problem-solving methods may be more amenable to dedicated improvement projects. Several well-known improvement models exist, including Lean, Six Sigma, and the Model for Improvement. Each of these models uses a similar approach to structuring improvement projects, though framed in different ways. The following sections summarize the major steps that the models share.

Identifying a Problem
As it relates to improvement, the term "problem" can be interpreted two ways: 1) something that is difficult to deal with, a source of trouble, worry, etc. and 2) something to be worked out or solved, such as an arithmetic problem.

The fact that the problem is a source of trouble is what drives the organization to decide to focus improvement in a specific area. Before beginning the project, leaders should make sure that it addresses a problem that is of high importance to the organization, so that it will receive needed support when challenges arise.

Framing the problem as a challenge to be solved helps depersonalize the issue and turn it into an opportunity for improvement. Clearly defining the problem is the first step in solving the problem, helping to ensure that the project team remains focused and aligned as team members evaluate causes and consider possible solutions.

Forming a Team
To effectively carry out the project, a dedicated team is organized for a limited period of time and given the guidance, resources, instruction, and authority needed to make process and other organizational changes to improve performance in a sustainable way. Project roles typically include the following:

- *Project Sponsor*: This individual provides organizational oversight and support, removing barriers as they arise. The sponsor should have the organizational authority to provide resources and resolve interpersonal conflicts. Projects may have more than one sponsor. While sponsors may provide general guidance and suggestions, they should be careful to avoid overstepping their bounds and assuming the project leader's role.
- *Project Leader:* The project leader's role is to direct and coordinate activities of the project to ensure its success. The leader helps assemble the team, manage the project, delegate and follow up on assignments, report on progress, alert the project sponsor when more help is needed, and ensure the timely completion of the project. Project leaders should have strong organizational and leadership skills.
- *Project Participants:* Participants should be selected from the areas targeted for improvement; each organizational unit included in the process targeted for improvement must be represented on the team. It is generally more effective to select "front-line" staff who perform the work on a daily basis rather than supervisors, managers, or other organizational leaders. Participation should be voluntary.
- *Project Coach:* The project coach is an expert in improvement methods who advises and supports the team. The coach helps guide the project leader and team, facilitates communication with the sponsor, and alerts organizational leaders when the project appears to be veering off track. However, the coach should avoid encroaching on the role of project leader or performing tasks of the project participants.

Assessing Current Performance
Improvement project team members are expected to visit the workplace and spend at least several hours quietly observing and taking notes. Team members should respectfully ask questions to deeply understand the process: what is done and why it is done that way. They should convene and discuss their observations, mapping out the process, and then revisit the workplace to validate their observations. They should, to the extent possible, observe all steps in the process at different times of day and days of the week.

Measuring Performance
To be able to assess performance in an objective and repeatable fashion, team members should develop performance measures. These may include *outcome measures,* including those of *end outcomes* such as morbidity, patient satisfaction, and costs, as well as those of *intermediate outcomes*, such as service times, error rates, and supply utilization. In addition to outcomes measures, *process measures* can be used such as adherence to standard work, equipment utilization rates, and times for each process step.

After one or more quantitative measures are established, performance should be tracked and monitored. Performance can be monitored with a *run chart*, which displays data over time. The run chart should display the mean before the beginning of the project and at the end of the project, as well as the performance goal. An *annotated run chart* is a run chart that also indicates the dates and the nature of interventions implemented during the project **(Fig. 3.1 below**.)

Establishing a Specific Goal
The project team should establish a performance goal (often referred to as an aim statement). A commonly used acronym to describe the attributes of the goal is "SMART," meaning that the goal should be specific, measurable, achievable, relevant, and time-bound. The goal should state the beginning performance, the end performance, and the date (i.e., "from what, to what, by when"). For example, the goal might state, "Our goal is to decrease mean daily examination completion time from 120 minutes to 30 minutes by July 1, 2018."

Identifying Causes of Problems
After establishing a measure and a goal and observing the process in detail, the project team should seek to discover and document the causes of problems that negatively impact performance. A tool for documenting these causes is a *cause-and-effect diagram*, also known as a *fishbone diagram* **(Fig. 3.2 on next page)**.

Prioritizing Problem-solving Efforts
After possible causes of problems are documented, the frequency of those causes should be measured in some way. Often this is accomplished with a simple tally sheet, in which staff members document every time the problem occurs over a period of time along with the cause for the occurrence. These can then be plotted in a Pareto chart **(Fig. 3.3 on next page)**, which illustrates which causes occur most frequently. The Pareto principle, also known as the "80/20 rule," states that a few causes are usually responsible for the majority of the problems. Problem-solving efforts can then be prioritized accordingly.

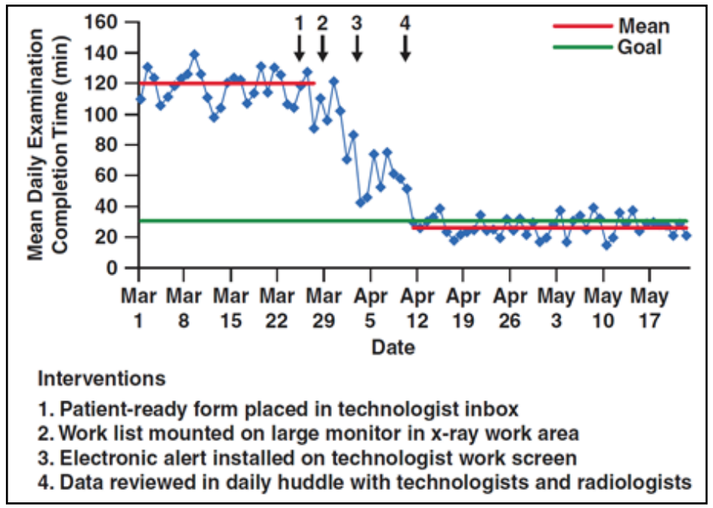

Figure 3.1 Example of an annotated run chart. Each point represents the mean daily examination completion time. Dates that interventions were implemented are plotted on the chart and described in the key. The goal for this hypothetical project was to decrease mean daily examination completion time from 120 minutes to 30 minutes. Source: Larson and Mickelsen. *AJR Am J Roentgenol* 2015.

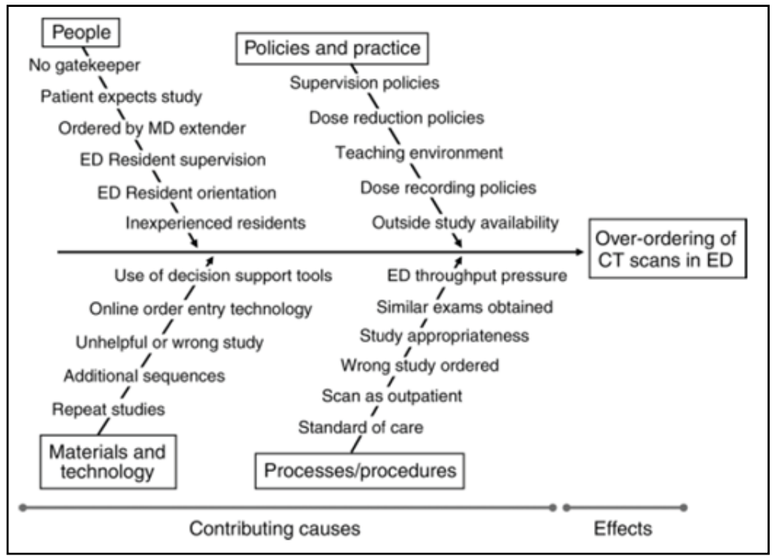

Figure 3.2. Cause-and-effect diagram or fishbone diagram. This diagram lists and categorizes possible contributing causes to the problem of over-ordering of CT scans in the emergency department (ED). Source: Kruskal et al. *Radiographics* 2011.

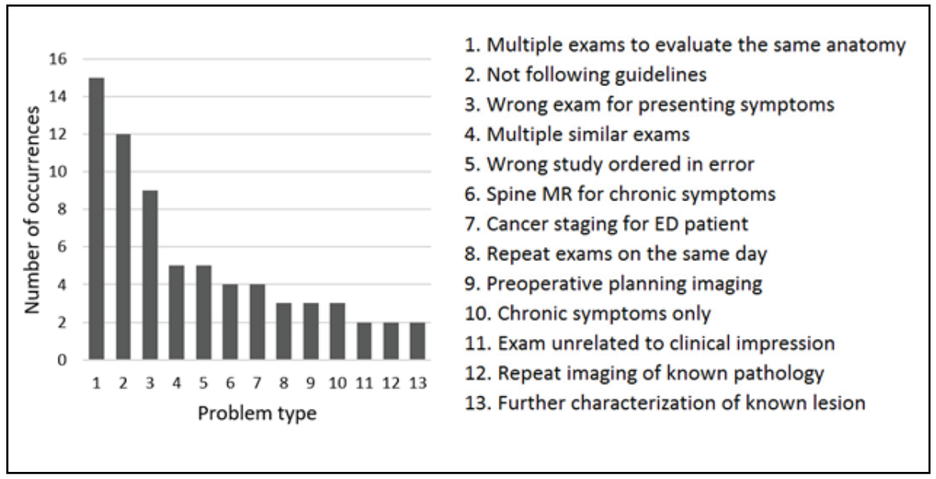

Figure 3.3. Pareto chart. This chart illustrates which causes are most commonly responsible for the problem. In this case, the team was seeking to identify the most common types of unhelpful emergency department (ED) exams. Source: Kruskal et al. *Radiographics* 2011.

Developing Solutions through Iterative Testing
After the problem has been thoroughly investigated, including likely causes, it is the project team's task to develop strategies to solve the problem by making process changes. However, such changes are rarely successful in the form in which they are originally conceived and typically require multiple revisions before they can be fully implemented. The process of iteratively testing, refining, and validating process changes is known as the Plan-Do-Study-Act (PDSA) cycle.

The PDSA cycle is essentially a restatement of the scientific method. A synonym for a PDSA cycle is a planned test of change. A cycle starts with a hypothesis of how a process change will lead to a desired outcome. The steps include developing a plan to test that hypothesis (planning the test), testing the hypothesis (doing the test), analyzing the data (studying the results), and drawing actionable conclusions and determining next steps (acting accordingly).

Because the effects of process changes are not known in advance, initial changes are typically tested on as small a scale as possible and in a relatively protected environment. It is expected that many of these proposed changes will be unsuccessful. For this reason, the team is wise to generate a number of potential changes through brainstorming. When a test of change does not result in the desired outcome, the project team may wish to modify the approach and test it again or abandon it altogether and try a different approach. Changes are tested on a larger scale only after they have been proven successful on a smaller scale. The final determination of whether the changes are effective in practice is if they result in improved performance. Hence, it is critical to continuously monitor performance throughout the life of an improvement project.

Improvement is generally most effective when multiple PDSA cycles are run in parallel or in rapid succession. With each test, the improvement team gains greater insight and knowledge of how specific changes impact outcomes—for better and for worse. Only after the problems have been worked out and the team is confident that the changes will result in the desired improved outcomes are the changes fully implemented. Despite the fact that multiple PDSA cycles are needed for most successful improvement projects, if they are executed well and kept as small and brief as possible, the process of testing, refining, and validating changes need not be protracted.

Sustaining the Improvement
Without deliberate mechanisms to sustain improvements, performance usually reverts to the initial state. Strategies to increase the likelihood that results will be sustained include 1) establishing regular measurement and feedback, 2) using handoffs to enforce standards by ensuring that all staff expect the same standard, 3) establishing the practice of stopping the process and summoning immediate supervisors whenever a problem is encountered, 4) embedding checks into the process, and 5) using high-reliability solutions.

High-reliability Solutions: Process changes may take many forms, including education and feedback, standardization of procedures, and infrastructure and system changes. In general, processes that rely on education and feedback tend to result in lower consistency in outcome, or reliability, than those that rely on standardization of procedures, which in turn tend to result in lower consistency of outcome than those that rely on changes to infrastructure and organizational culture. As a general rule, high-reliability process changes are more effective and require less effort by the process owner to sustain than low-reliability solutions.

QI Project Management
A project is defined as "a temporary group activity, designed to produce a unique product, service, or result." Project management is the "application of knowledge, skills, and techniques to execute projects effectively and efficiently." Effective project management techniques bring order to what can otherwise be a chaotic process, to help ensure that projects meet their objectives. Examples include 1) task management: defining each task, clearly setting expectations of what is to be done by whom and by when, and following up on each task; 2) progress tracking: keeping people apprised of project progress, reminding individuals as deadlines approach, and alerting appropriate individuals when milestones are missed; 3) conducting effective meetings; and 4) avoiding mistakes common to quality improvement.

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3.2 Practical Safety Applications in Healthcare

3.2.1 Periprocedural Care

Patient Identifiers
Patient identification is critical to ensure that the right patient receives the right treatment, medication, invasive or noninvasive procedure, and blood products, as well as to reduce the chance of unnecessary radiation exposure. At least two patient identifiers should be used before every procedure. Identifiers can include patient name, assigned identification number, telephone number, or other person-specific identifier (e.g., date of birth, government-issued photo identification, and last four digits of the social security number). Transient factors such as patient's location or room number cannot be used. Sources of identifiers may include the patient, a relative, a guardian, a domestic partner, or a healthcare provider who has previously identified the patient. In the case of a discrepancy between identifiers, the practitioner should stop and seek additional information to confirm the identity before proceeding.

Patient Assessment
Before sedation is initiated, a patient must be assessed and approved for sedation. Recent oral intake, recent illness, pulmonary status (including upper airway), cardiac status, baseline vital signs, level of consciousness, pulse oximetry, capnography (if available), and electrocardiography (when applicable) should be obtained and documented.

Sedation
The Joint Commission and the American Society of Anesthesiologists have defined four levels of sedation, analgesia, and anesthesia:

1. **Minimal Sedation or Anxiolysis**. A drug-induced state, created by the administration of medications to reduce anxiety, during which the patient responds to verbal commands. In this state, cognitive function and coordination may be impaired, but ventilatory and cardiovascular functions are unaffected.

2. **Moderate Sedation/Analgesia.** A minimally depressed level of consciousness, induced by the administration of pharmacologic agents, in which the patient retains a continuous and independent ability to maintain protective reflexes and a patent airway and to be aroused by physical or verbal stimulation.

3. **Deep Sedation/Analgesia.** A drug-induced depression of consciousness during which the patient cannot be easily aroused but responds purposefully after repeated or painful stimulation. Independent ventilatory function may be impaired. The patient may require assistance in maintaining a patent airway. Cardiovascular function is usually maintained.

4. **General Anesthesia.** A controlled state of unconsciousness in which there is a complete loss of protective reflexes, including the ability to maintain a patent airway independently and to respond appropriately to painful stimulation.

It is important to recognize that these "levels" are actually a continuum. Patients may rapidly move between the levels and may reach a deeper level of sedation than desired. Sedation may result in the loss of protective reflexes. Thus, all sedated patients require monitoring regardless of the intended level of sedation.

Patients who are candidates for sedation by a nonanesthesia provider such as a radiologist must be screened to determine if they have risk factors that may increase the likelihood of an adverse outcome. Such risk factors include, but are not limited to, congenital or acquired abnormalities of the airway, liver failure, lung disease, congestive heart failure, symptomatic brain stem dysfunction, apnea or hypotonia, a history of adverse reaction to sedating medications, morbid obesity, and severe gastroesophageal reflux.

The patient's American Society of Anesthesiologists (ASA) Physical Status Classification should also be assessed. This is a six-level classification as follows:

- Class I - A normal healthy patient
- Class II - A patient with mild systemic disease
- Class III - A patient with severe systemic disease
- Class IV - A patient with severe systemic disease that is a constant threat to life
- Class V - A moribund patient who is not expected to survive without the operation
- Class VI - A declared brain-dead patient whose organs are being removed for donor purposes

Patients in Classes III and IV or with other significant risk factors may require a consultation with anesthesiology or the performance of sedation by an anesthesiologist or anesthetist. Patients in Class V should not be sedated by nonanesthesiologists.

When sedation is performed under the supervision of a radiologist, there must be a separate qualified healthcare professional whose primary focus is the monitoring, medicating, and care of the patient. The patient must have intravenous access. Continuous monitoring should include, at a minimum, level of consciousness, respiratory rate, pulse oximetry, blood pressure (as indicated), heart rate, and cardiac rhythm. Similar monitoring is needed in the recovery period from sedation. The supervising physician should have sufficient knowledge of the pharmacology, indications, and contraindications for the use of sedative agents, including the use of reversal agents. A key point related to reversal agents is that their duration of effect may be shorter than that of the sedating agent, leading to a risk of relapse into a deeper level of sedation. It is recommended that consciousness and vital signs return to acceptable levels and remain at those levels for a period of two hours from the time the reversal agent was administered before monitoring ends and the patient is discharged.

Informed Consent
Informed consent is required for invasive image-guided procedures. Apart from legal or regulatory requirements, patients have the right to be informed about the procedures they undergo and may request to speak with a radiologist even when local policy does not require the radiologist to initiate an informed consent process.

Despite the fact that a consent form is often used to document the discussion, the *ACR-SIR Practice Parameter on Informed Consent for Image-Guided Procedures* states that "informed consent is a process and not the simple act of signing a formal document." Consent can also be documented by a note in the patient's medical record, by a recording on videotape, or by another similar permanent modality. Consent should be obtained from the patient or the patient's legal representative by a physician or other healthcare provider performing the procedure. The final responsibility for answering the patient's questions and addressing any patient concerns rests with the physician performing or supervising the procedure.

Elements of informed consent include 1) the purpose and nature of the intended procedure, 2) the method by which the procedure will be performed, 3) likely risks, complications, and expected benefits, 4) risks of not proceeding, 5) any reasonable alternatives to the proposed procedure, and 6) the right to decline the proposed procedure. An exception to these steps exists when a delay in treatment would jeopardize the health of a patient who is unable to provide informed consent (e.g., an unconscious trauma patient for whom family has not yet been identified). Since the patient must be able to understand the consent process for it to be valid, consent must be obtained before procedure-related sedation is administered.

When the patient is not able to give valid consent because of short-term or long-term mental incapacity, whether from pain medications or otherwise, or when the patient has not achieved the locally recognized age of majority, consent should be obtained from the patient's appointed healthcare representative, legal guardian, or appropriate family member. In emergency situations when the patient needs immediate care, the patient's predetermined wishes are not known or appropriately documented, and consent cannot be obtained from the patient's representative, the physician may provide treatment or perform a procedure "to prevent serious disability or death or to alleviate great pain or suffering."

Minors' Rights in Medical Decision Making
Courts in the United States have recognized that children younger than 18 years deserve a voice in determining their course of medical treatment if they show maturity and competence. However, rules that govern the issue of parental rights versus minors' rights vary from state to state. States and courts have never allowed children younger than 12 years to make medical decisions and exercise self-determination, whereas adolescents between ages 12 and 18 (or 19 in some states) experience a gradual transition to self-determination. Factors that impact the determination of adolecents' rights include the following:

1. **Legal determination of maturity,** such as married status, parenthood, self-sufficiency, or active duty in the armed services.

2. **Evidence that the child is sufficiently mature to make his or her own decisions,** such as age greater than 14 years; evidence that the minor has the ability to understand the implications of treatment, including risks, benefits, likely short- and long-term consequences, and alternatives; and evidence that the minor can make an informed decision without coercion.

3. **Conditions exempting parental consent**, such as seeking testing or treatment for sexually transmitted diseases, included HIV; seeking contraception, prenatal care, or abortion; or seeking mental health treatment, emergency care, or treatment of alcohol or drug abuse after the age of 12 years.

Universal Protocol
Universal protocol refers to the three-part process of *conducting a preprocedure verification, marking the procedure site,* and *performing a preprocedure time out*. Note that site marking may be performed before completing the preprocedure verification.

1. **Preprocedure verification**. This is an ongoing process of information gathering and confirmation before the procedure. The purpose is to ensure that all relevant information and equipment are 1) available before the start of the procedure, 2) correctly labeled, identified, and matched to the patient's identifiers, and 3) reviewed and are consistent with the expectations of the procedure to be performed. Preprocedural verification may occur at more than one time and place before the procedure.

2. **Marking of the procedure site.** At a minimum, a procedure site should be marked when there is more than one possible location for the procedure and when performing the procedure in a different location could harm the patient. If possible, the patient should be involved in the site marking. The site must be marked by a licensed independent practitioner who will be present when the procedure is performed. In limited circumstances, site marking may be delegated to medical residents, physician assistants (PAs), or advanced practice registered nurses (APRNs), but ultimately the licensed independent practitioner is accountable for the procedure, even when delegating site marking. The mark should be made at or near the procedure site, and should be sufficiently permanent to be visible after skin preparation and draping. It should also be unambiguous and used consistently throughout the organization. An organization should have written alternative processes for situations such as procedures on mucosal surfaces or perineum, minimal access procedures treating a lateralized internal organ, interventional procedure cases for which the catheter or instrument insertion site is not predetermined (such as cardiac catheterization), procedures on teeth, and procedures on premature infants, for whom the mark may cause a permanent tattoo.

3. **Preprocedure time out**. A standardized time out should be conducted immediately before an invasive procedure is started or an incision is made. The designated member of the team starts the time out. The time out should involve the immediate members of the team, including the individual performing the procedure, anesthesia providers, the circulating nurse, the operating room technician, and other active participants who will be present throughout the case. During the time out, all relevant members of the team actively communicate and at a minimum agree on the following: correct patient identity, correct site, and procedure to be done. Documentation of the time out should be performed according to the organization's policy.

3.2.2 Hand Hygiene

Hand hygiene refers to cleaning one's hands by using either handwashing (washing hands with soap and water), antiseptic hand wash, antiseptic hand rub (i.e., alcohol-based hand sanitizer including foam or gel), or surgical hand antisepsis.

Alcohol-based hand sanitizers are the most effective products for reducing the number of bacteria on the hands. When hands are not visibly dirty, alcohol-based hand sanitizers are the preferred method for cleaning one's hands in the healthcare setting. Soap and water are recommended when hands are visibly dirty, before eating, after using a restroom, or after known or suspected exposure to *Clostridium difficile*, norovirus, or *Bacillus anthracis*.

Hand hygiene should be performed 1) before eating, 2) before and after having direct contact with a patient's skin, 3) after contact with blood, body fluids or excretions, mucous membranes, nonintact skin, or wound dressings, 4) after contact with inanimate objects in the immediate vicinity of the patient, 5) if hands will be moving from a contaminated-body site to a clean-body site during patient care, 6) after glove removal, and 7) after using a restroom. When hands are cleaned with soap and water, they should be rubbed together vigorously for at least 15 seconds, and the soap and water should cover all surfaces of the hands and fingers. When alcohol-based hand sanitizer is used, the product should cover all surfaces as hands are rubbed together. This should take about 20 seconds.

3.2.3 Root Cause Analysis

Root cause analysis (RCA) is a structured method used to analyze serious adverse events to decrease the likelihood of recurrence. The goal of RCA is to identify both active errors (errors occurring at the point of interface between humans and a complex system) and latent conditions (the hidden problems within healthcare systems that increase the likelihood of an adverse event). For example, an active error occurs when a nurse accidentally administers a full dose of heparin rather than a heparin flush; an associated latent condition might be the fact that the two vials appear virtually identical and both are routinely stocked near each other in the same cabinet at the point of care.

RCAs should generally begin with data collection to create an objective narrative of the event based on a review of the medical record and interviews with people involved. A multidisciplinary team should then analyze the sequence of events leading to the error, with the goals of identifying how the event occurred (active errors) and underlying conditions that contributed to the event (latent conditions). It should be recognized that serious adverse events are almost never the result of a single cause, and often are associated with numerous contributing factors. The RCA should culminate in an analysis of issues that should be addressed to decrease the likelihood of recurrence and a plan for addressing those issues, including a timeline and individual responsibility.

In the setting of a serious adverse event, immediate interventions may be implemented to quickly reduce the risk of recurrence of a similar error. However, such quickly generated solutions typically do not address the root cause and should only serve as a placeholder until more reliable and sustainable solutions can be developed, tested, and implemented.

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4 Practical Safety Applications in Radiology

4.1 MR Safety

The strong magnetic field of MR scanners produces unique safety issues in the imaging environment. The magnetic field is always on. While the patient is a major focus of safety efforts, the same issues apply to technologists, nurses, and physicians working regularly in the MR environment. However, greater risk may exist related to other personnel who do not regularly work in the MR environment, including physicians and nurses; nonimaging technologists, who rarely enter the MR suite and may do so in urgent situations related to acute patient decompensation; security and cleaning personnel, who may be more likely to unknowingly bring ferromagnetic materials into the MR environment; and patients' family members, who may be overlooked in screening programs. To address these and other issues, the American College of Radiology (ACR) established a Blue Ribbon Panel on MR Safety, which developed and continues to update the ACR Guidance Document on MR Safe Practices.

4.1.1 Zoning and Screening

A key concept in MR safety is the conceptual division of the MR site into four zones, with progressive monitoring and restriction of entry into the higher numbered, more controlled zones. These zones are defined as follows:

1. **Zone I**: Access is unrestricted. This zone includes all areas that are freely accessible to the general public. This is the area through which patients and others access the controlled MR environment.

2. **Zone II**: This is the interface between the uncontrolled Zone I and the strictly controlled Zones III and IV. Zone II may be used to greet patients, obtain patient histories, and screen patients for MR safety issues. Patients in Zone II should be under the supervision of MR personnel.

3. **Zone III**: This is the area where there is potential danger of serious injury or death from interaction between unscreened people or ferromagnetic objects and the magnetic field of the scanner. The scanner control room is typically in Zone III. Access to Zone III must be strictly restricted and under the supervision of MR personnel, with physical restriction such as locks or passkey systems.

4. **Zone IV**: This is the MR scanner magnet room and therefore is the highest risk area. This zone should be clearly demarcated and marked as potentially hazardous because of the strong magnetic field. Access to Zone IV should be under the direct observation of MR personnel. When a medical emergency occurs, MR trained and certified personnel should begin basic life support or CPR if required, while emergently moving the patient from Zone IV to a magnetically safe location.

The major transition happens from Zone II to Zone III. Personnel working within Zone III should have specific education on MR safety and pass an MR safety screening process. All other individuals entering Zone III should be appropriately screened as they enter. When possible, MR screening begins with a focused history to identify potential metallic foreign objects and medical implants. This may be supplemented as needed by radiographs or by review of previous imaging studies such as CT or MRI of the questioned area, if available. When an object or implant is identified, its MR compatibility or safety should be assessed specific to the strength of the magnet. Objects that are nonhazardous in all MR environments are deemed "MR Safe," whereas those contraindicated in any MR environment are labeled "MR Unsafe." "MR Conditional" devices are MRI compatible in specific conditions. Published information is available regarding the MR safety of most medical implants.

Ferromagnetic objects should be restricted from entering Zone III whenever practical. All MR sites should have a handheld magnet (≥ 1000 Gauss) or handheld ferromagnetic detection device, which allows for testing of external objects and some superficial internal implants. Occasionally, devices

that are determined to be ferromagnetic and MR Unsafe may be permitted into Zone III. The device must be appropriately secured at all times and under the supervision of trained MR personnel to ensure that it does not become exposed to magnetic fields or gradients from the MR scanner. The strong magnetic field strength inherent to a MR scanner can pose a risk for projectile injury if a ferromagnetic object is brought too close in proximity. There have been reports of projectile injuries from anesthetic gas or oxygen cylinders, including patient deaths. In addition to patient injury, projectiles may also result in extensive damage to the MR unit.

Screening is more difficult when the patient is unconscious or otherwise unable to provide a reliable history. In such cases, screening should be performed as effectively as possible from other sources, such as family members and the medical record, and the urgency of the examination should be balanced with the level of uncertainty of the screening process. An examination by trained MR personnel should be performed to assess for surgical scars that may warrant additional evaluation. The 5 Gauss line is the point at which the magnetic field begins to affect electromagnetic devices such as pacemakers. This line should be marked on the floors or walls for safety, particularly when it extends beyond the walls of the MR scanner room. It is important to remember that the magnetic field is three-dimensional. Thus, the restricted area may extend through the floor and/or ceiling to adjacent floors.

4.1.2 Intracranial Aneurysm Clips and Pacemakers

Medical devices contain varying amounts of ferromagnetic material and can be subject to translational and rotational forces when interacting with the magnetic field of a MR unit. While many devices are composed of nonferromagnetic materials and do not pose a risk, some, such as aneurysm clips and cardiac implantable electronic devices, require caution. Aneurysm clips are attached to soft-tissue structures. There has been at least one documented case of a fatality due to rotation of an aneurysm clip while the patient was in the MR scanner. If a patient is identified to have an intracranial aneurysm clip, MRI should not be performed unless it is documented that the specific manufacturer, model, and type of aneurysm clip is MR Safe or MR Conditional. While a patient previously may have safely undergone an MR examination with an aneurysm clip, that fact alone is not sufficient to determine that the implant is MR Safe or Conditional because variations exist between MR scanners.

Cardiac implantable electronic devices similarly can be adversely affected if scanned in an MR unit, which can lead to complications, including failure to pace, induction of ventricular fibrillation, and heating of cardiac tissue adjacent to the leads; these complications can potentially be fatal. FDA labeled MR Conditional pacemakers became available in February 2011. If MRI is performed on a patient with a pacemaker or implantable cardioverter-defibrillator (ICD), radiology and cardiology personnel as well as a crash cart should be available throughout the procedure in case a significant arrhythmia develops during the examination.

4.1.3 MR and Pregnancy

MRI exposure has not been shown to have a detrimental effect on the developing fetus. For this reason, no special consideration regarding exposure to MRI is recommended during pregnancy. However, since it is impossible to completely exclude the possibility of any risk whatsoever, patients and clinicians should consider whether it is safe to delay an MR examination until the end of pregnancy. Pregnant healthcare workers may work in an MRI environment during all stages of pregnancy, though they should not remain within Zone IV during data acquisition or scanning.

4.1.4 MR-induced Burns

Loops of metallic wire, patches of metal, and other electrical conduction circuits may be rapidly heated by radiofrequency pulses during normal operation of an MRI system. Because of the risk of burns, care must be taken to prevent such loops or metallic patches from touching patients' skin during routine scanning. Certain transdermal patches may contain aluminum and other metals that may cause burns. Occasionally, large tattoos may undergo heating and cause burns; application of an ice pack may be necessary to reduce the risk of skin burning.

4.1.5 Quenching

MRI "quenching" occurs when there is heating of the magnetic coils, which leads to a chain reaction with rapid liquid helium evaporation and further—often rapid—resistive heating of the magnetic coils because superconductivity is lost. The electromagnet is usually destroyed by this process, which also floods the room with helium gas, displacing the normal room air and creating a risk for asphyxiation. Emergency venting systems are required to protect patients and operators from asphyxiation; however, all personnel must evacuate immediately in the event of a quench.

4.2 Management of Intravascular Contrast Media

4.2.1 Iodinated Contrast Media

Types of Iodinated Contrast Media
All iodinated contrast media used for intravascular administration are classified as low-osmolality contrast media (which also encompasses iso-osmolar agents). At the concentrations used for CT and angiography, low-osmolality contrast media have approximately twice the osmolality as that of human serum. Iso-osmolality media, which are sometimes used for intra-arterial injection (and rarely for intravenous injection), are nonionic dimers and, as the name implies, have an osmolality approximately equal to human serum. Many low-osmolality nonionic contrast agents are approved for use in the United States (including iohexol (Omnipaque®), iopamidol (Isovue ®), iopromide (Ultravist ®), ioversol (Optiray®), and ioxilan (Oxilan®), but only one nonionic iso-osmolality contrast agent (iodixanol [Visipaque®]).

Adverse Reactions to Iodinated Contrast Material
Most patients who receive iodinated contrast media will have no adverse effects. Adverse contrast reactions of any type have been reported in up to 3% of patients injected with nonionic contrast material, though some series have reported a much lower frequency.

Acute adverse reactions can be categorized as either physiologic or allergic-like. Physiologic reactions are dose related. These reactions are less likely to occur and, when they occur, are less likely to be severe when lower doses of contrast material are administered. They are believed to represent direct toxic effects of injection.

The mechanism of allergic-like reactions is not understood in most patients. However, it is known that in most patients these reactions do not consist of the characteristic antigen-IgE antibody response. Therefore, sensitization due to prior exposure is not required for an allergic-like reaction to contrast material to occur. Thus, these reactions are generally considered to be "allergic-like" rather than "allergic." Nonetheless, allergic-like reactions present with symptoms similar to those of true allergic reactions. These reactions are idiosyncratic and not dose related. For example, a severe allergic-like reaction is believed to be just as likely to result from injection of a small volume as from a large volume of contrast material.

Acute adverse reactions are categorized as being mild, moderate, or severe. Examples of some reactions of different types and severity as summarized in the *ACR Manual on Contrast Media* are as follows:

Mild Reactions: Signs and symptoms are self-limited and without progression.

1. **Mild Physiologic Reactions**: Nausea, vomiting, flushing, warmth, chills, headache, anxiety, altered taste, mild hypertension, and spontaneously resolving vasovagal reaction
2. **Mild Allergic-like Reactions**: Few hives, pruritus, limited cutaneous edema, itchy/scratchy throat, nasal congestion, sneezing, stuffy nose

Moderate Reactions: Signs and symptoms are more pronounced and commonly require medical management.

1. **Moderate Physiologic Reactions**: protracted nausea, chest pain, vasovagal reaction that requires and is responsive to treatment
2. **Moderate Allergic-like Reactions**: Diffuse hives, diffuse erythema (with stable vital signs), facial edema without dyspnea, wheezing with mild or no hypoxia

Severe Reactions: Signs and symptoms are potentially life threatening and can result in permanent morbidity or death if not managed appropriately.

1. **Severe Physiologic Reactions**: Vasovagal reaction resistant to treatment, arrhythmia, seizures, hypertensive crisis, pulmonary edema, cardiopulmonary arrest
2. **Severe Allergic-like Reactions**: Diffuse edema or facial edema with dyspnea, erythema with hypotension, laryngeal edema with stridor and/or hypoxia, wheezing with hypoxia, severe hypotension and tachycardia, pulmonary edema, cardiopulmonary arrest

As noted above, pulmonary edema and cardiopulmonary arrest can be symptoms of either severe physiologic or severe allergic-like reactions.

Fortunately, the vast majority of acute adverse reactions to contrast media are physiologic, mild, and self-limiting, often consisting of warmth, metallic taste, and nausea. Allergic-like reactions are much less common, encountered in <1% of injected patients. In one recent series, 0.6% of patients injected with nonionic contrast media had allergic-like reactions, most of which were mild. Severe life-threatening allergic-like reactions are

extremely rare, with the incidence of such reactions estimated to be 0.01-0.04% of injected patients.

Risk Factors for Adverse Reactions
Several factors increase the likelihood of an adverse reaction to contrast material. Patients with a history of a prior allergic-like reaction to the same class of contrast material (iodinated or gadolinium-based) are believed to have five times the risk of the general population for having another allergic-like reaction. Patients with other allergies and asthma are about two to three times as likely to have an allergic-like reaction. Allergies to shellfish or other iodine-containing products (such as povidone-iodine [Betadine®]) are not believed to increase the risk for an allergic-like contrast reaction beyond that of other allergies. Also, a history of a prior allergic-like reaction to gadolinium-based contrast material (GBCM) is not believed to increase the risk of an allergic-like reaction to iodinated contrast agents above that of other allergies and vice versa.

Some patients' underlying diseases may be exacerbated by administration of contrast material. Such disease exacerbations are considered to be non-allergic-like reactions. These can occur in patients with severe chronic kidney disease (CKD) and acute kidney injury (AKI) (see section on postcontrast AKI), cardiac arrhythmias, congestive heart failure, myasthenia gravis, and severe hyperthyroidism.

Additional attention should be paid to the use of intravascular iodinated contrast media in patients with thyroid cancer or hyperthyroidism who are anticipating treatment with radioactive iodine (^{131}I). Such patients should not receive iodinated contrast in the 4 to 6 weeks before anticipated radioiodine treatment, as the nonradioactive iodine load delivered by the contrast material will saturate the thyroid gland and could render treatment ineffective.

Screening of Patients before Contrast Material Administration
Safe administration of contrast material begins with a focused patient history to identify the factors that may increase the likelihood of an adverse reaction to contrast material. The likelihood of an allergic-like contrast reaction may be reduced by institution of a premedication regimen.

Premedication
Premedication may be considered for any patient who is at increased risk of an acute allergic-like reaction to contrast. Policies vary by site, but it is generally agreed in the United States that premedication is indicated at least in patients who have had a previous moderately severe or severe allergic-like reaction to the same class of contrast material. Premedication likely reduces the risk of future contrast reaction in high-risk patients, but it does not eliminate it. A contrast reaction that occurs despite premedication is called a "breakthrough reaction."

The most widely accepted premedication regimens, or "preps," involve the use of corticosteroids, with the first dose administered 12 to 13 hours before contrast material injection. One common regimen, advocated by Greenberger and colleagues, involves oral administration of 50 mg of prednisone 13, 7, and 1 hour(s) before contrast material injection, and oral administration of 50 mg of diphenhydramine (Benadryl®) 1 hour before injection. Another common regimen, advocated by Lasser and colleagues, involves oral administration of 32 mg of methylprednisolone 12 and 2 hours before contrast material injection. While a 12- or 13-hour oral regimen has been proven effective, and a 1- or 2-hour oral regimen has not been proven effective, the precise minimum effective time for premedication is not known.

In some situations, patient health can be jeopardized seriously by having the patient wait 12 or more hours before a contrast-enhanced study. In these situations, "rapid" corticosteroid regimens may be utilized, with the understanding that the evidence of the effectiveness of this approach is not solid. One of the more commonly used rapid preps consists of intravenous (IV) administration of 200 mg of hydrocortisone every 4 hours until the study is performed, preferably deferring imaging until at least two doses have been administered. In this rapid prep, 50 mg of diphenhydramine is also administered 1 hour before contrast material injection.

The proven benefit of corticosteroid premedication regimens is a reduction in the number of mild reactions in average-risk patients. There is no definite evidence that premedication protects against moderate, severe, or life-threatening reactions. The rarity of severe reactions makes it difficult to prove a benefit of premedication in this setting.

Even with appropriate use of an accepted premedication regimen, breakthrough reactions occur in a small number of high-risk patients. When they do occur, they are of similar severity to the initial reaction about 80% of the time, less severe 10% of the time, and more severe 10% of the time.

A patient who has had an allergic-like reaction to contrast media despite steroid premedication can be reinjected in the future after being premedicated again, provided that the previous breakthrough reaction was mild. Many such patients will not have a repeat reaction, and if a repeat reaction occurs, it will most likely be of the same severity as the previous breakthrough reaction (e.g., mild subsequent breakthrough reaction if the previous breakthrough reaction was mild).

The greatest risk of corticosteroid premedication to patient health is probably the delay that it causes in the performance of an imaging study (which can delay disease diagnosis, increase cost, and, in inpatients, expose patients for longer periods of time to additional risk of hospital-acquired conditions). While transient hyperglycemia can occur from three doses of corticosteroids, it is usually mild and is rarely clinically significant. Other complications from a short burst of corticosteroids, such as exacerbation of infection and peptic ulcer disease, steroid psychosis, and tumor lysis syndromes, have been reported, but are very rare. These associations are anecdotal.

Postcontrast Acute Kidney Injury and Contrast-induced Nephropathy
Postcontrast acute kidney injury (PC-AKI) is a general term used to describe a sudden deterioration in renal function that occurs after the intravascular administration of iodinated contrast media (with an onset within 24 to 48 hours). Such injury may occur whether or not the contrast medium is actually determined to have caused the deterioration in renal function. PC-AKI is a correlative diagnosis, meaning that AKI can be correlated to, but not proven to be caused by, the administration of IV contrast.

Contrast-induced nephropathy (CIN) is defined as a sudden deterioration in renal function caused by intravascular administration of iodinated contrast media. CIN is a subset of PC-AKI. CIN is a causative diagnosis.

Most recent papers published on CIN today, and nearly all papers published on CIN before 2006, consider(ed) all PC-AKI to be CIN. This error led to substantially overinflated estimates of the rate of CIN. It is now known that most PC-AKI is not due to CIN.
CIN was previously believed to be common, because the vast majority of published studies that came to this conclusion did not include control groups of patients who did not receive contrast material. For this reason, distinction between CIN and PC-AKI was not possible in these studies. Additionally, many previous publications studied patients who had undergone arteriography rather than IV contrast material injections. Catheter angiography may be associated with additional risks to the patient, which could also affect renal function, including catheter manipulation in the abdominal aorta (i.e., atheroemboli) and exposure of the kidneys to more concentrated contrast media.

With the recent performance of several large propensity-adjusted controlled retrospective studies, it is now understood that if CIN occurs at all, it is most likely to develop in patients who have severe CKD (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73 m^2) or AKI. Its existence in patients with an eGFR of 45 mL/min/1.73 m2 or higher is very unlikely, and in patients with an eGFR between 30 and 45 mL/min/1.73 m2, it is questionable. As a result, at the present time, special precautions for administering intravascular iodinated contrast material are advised only for patients with severe CKD (eGFR < 30 mL/min/1.73 m2) or AKI. Administration of multiple doses of contrast material within 24 to 48 hours (and/or cumulative doses above some threshold—for example, 280 mL) may also be a risk factor for AKI. This dose-toxicity relationship has been consistently shown after coronary arteriography, but has not been conclusively shown for IV administrations.

The historical definition of PC-AKI refers to an absolute increase in serum creatinine from baseline of at least 0.5 mg/dL, or a 25-50% increase in the baseline serum creatinine level. The Acute Kidney Injury Network (AKIN) has suggested that, regardless of the cause, AKI should be diagnosed whenever there is 1) an absolute serum creatinine increase of at least 0.3 mg/dL, or 2) a percentage increase in serum creatinine of at least 50% (1.5-fold above baseline), or 3) a reduction in urine output to 0.5 mL/kg/hour for at least 6 hours.

The usual clinical course of PC-AKI (including CIN) is a rise in serum creatinine beginning within 24 hours of contrast material administration, peaking at about 4 days and then usually returning to baseline by 7 to 10 days. Most affected patients are non-oliguric. Permanent renal dysfunction is unusual.

Other previously identified diseases or conditions may predispose patients to develop AKI but most likely, in and of themselves, do not specifically predispose patients to develop CIN. These include diabetes mellitus, dehydration, cardiovascular disease, diuretic use, advanced age, multiple myeloma, hypertension, and hyperuricemia.
Although patients with end-stage renal disease who are

on chronic hemodialysis could experience additional renal function compromise (resulting in a further decrease in any remaining urine output that might be helpful for managing electrolyte balance), such a risk is theoretical. Many nephrologists agree to inject these patients with intravascular contrast material if a contrast-enhanced study is necessary. There is also a possibility that such patients, if their fluid status is brittle, could develop fluid overload as a result of the administration of even a relatively small volume of hyperosmolality contrast media. Because iodinated contrast media have no significant toxicity if retained in the body after injection, there is no requirement that chronic dialysis be timed to occur either immediately before or immediately after contrast media administration.

There is some controversy concerning screening of patients' renal function before contrast material administration if no recent serum creatinine level/eGFR level is available. Suggested indications for obtaining a blood test, from which an eGFR can be determined, include age > 60 years, history of renal disease (including dialysis, renal transplant, solitary kidney, renal cancer, or renal surgery), hypertension, diabetes mellitus, and metformin use. If a potentially at-risk patient's condition is stable, a creatinine value within 30 days of contrast administration is generally considered sufficient.

In patients with severe CKD or AKI who are considered at increased risk of developing CIN, several prophylactic strategies should be considered. Since most iodinated contrast media are currently administered for CT scans, alternatives include performing only noncontrast scans or using other modalities such as ultrasound or MR (note that contrast-enhanced MRI performed with certain MR contrast media is associated with a risk of nephrogenic systemic fibrosis [NSF] – see separate section on NSF). When iodinated contrast media administration is deemed necessary in high-risk patients, the lowest possible dose needed to perform a diagnostic study should be used.

The most proven strategy for minimizing the risk of PC-AKI is IV volume expansion with isotonic fluids, such as 0.9% saline or Lactated Ringers. Some suggested volume expansion protocols have included administration of volumes of 100 mL/hr for 6 to 12 hours before contrast administration and continued for 4 to 12 hours after contrast administration.

A number of other prophylactic agents have been suggested, but there is no consistent proof that any of these are effective in preventing PC-AKI or CIN. These include volume expansion with sodium bicarbonate, and use of N-acetylcysteine. A number of other agents, such as mannitol, furosemide, theophylline, etc., have been discredited.

It has recently been shown that high-dose statins appear to be effective in reducing the risk of PC-AKI before cardiac catheterization.

Metformin
Metformin-containing drugs are prescribed as oral agents of choice for treating many patients with diabetes mellitus. Metformin is contraindicated in patients with severe renal dysfunction, however, because a very small percentage develop lactic acidosis, leading to a reported 50% mortality rate. There is no direct interaction between iodinated contrast material and metformin; however, if a patient receiving metformin develops AKI, the possibility of lactic acidosis exists. The American College of Radiology Committee on Drugs and Contrast Media currently recommends that no precautions are necessary in diabetic patients taking metformin, unless the eGFR is < 30 mL/min/1.73 m^2 or the patient is undergoing arterial catheterization with the risk of emboli to the renal arteries. In these instances, the drug should be withheld for 48 hours after contrast material administration and only reinstituted if the renal function is reassessed and found to be normal.

Thus, metformin itself is not a risk factor for the development of CIN, but patients who develop renal failure while taking metformin are at risk of developing lactic acidosis.

Iodinated Contrast Material in Pregnancy
There is no evidence that maternal exposure to intravascular iodinated contrast material is harmful to the fetus. Specifically, there is no evidence that fetal exposure to iodinated contrast material, which crosses the placenta, increases mutagenesis or cancer risk or affects renal function.

Iodinated Contrast Material in Women Who Are Breastfeeding
Only 1% of maternally administered contrast material enters the milk of breast-feeding mothers and, of this, only 1% of the contrast material in breast milk is absorbed through an infant's gastrointestinal tract. This represents less than 1% of the recommended infant dose of iodinated contrast material that could be used for a contrast-enhanced imaging study on that infant. Nonetheless, even this small amount of contrast material can alter the breast milk taste.

There is no evidence that this tiny amount of absorbed iodinated contrast material has any adverse effect on the infant. Although it is generally accepted that no precautions need to be taken, it is generally recommended that a lactating mother be informed that studies assessing the risks to an infant are limited. If concerned, the mother can abstain from breastfeeding for 12 to 24 hours after a contrast-enhanced study is performed. A concerned mother may pump and discard breast milk that is produced during this time period.

Extravasation
Extravasation of IV-administered iodinated contrast media is an occasionally-encountered complication of intravascular contrast material administration, usually occurring during CT. The reported overall rate of extravasation with power injection for CT scanning ranges from 0.1% to 0.9%. While extravasations are more likely to occur when poor catheter insertion technique is utilized, they can be encountered even when proper technique is employed.

Patients are believed to be at increased risk for extravasation when distal access sites are used (such as the hand, wrist, foot, and ankle) rather than the antecubital fossa, when utilized indwelling lines have been in place for more than 24 hours (in which case some degree of phlebitis may be present), and when there are multiple punctures into the same vein. Certain risk factors are believed to be associated with an increased volume of extravasated contrast, including inability of the patient to communicate (such as infants and children, the elderly, and patients with altered consciousness), severe illness, and debilitation.

Immediately after extravasation of contrast material occurs, most patients complain of swelling or tightness and/or stinging or burning pain at the site of extravasation. Edema, erythema, and tenderness may be found on physical examination. Ninety-eight percent of extravasation injuries resolve with no adverse sequelae. In the remaining 2% of injuries, there is some patient morbidity that develops because contrast material can damage adjacent tissue, likely due to a combination of direct toxic effect and its hyperosmolality. Adverse effects are usually self-limited, most commonly consisting of prolonged pain or swelling.

Severe extravasation injuries occur in <1% of patients with extravasations. The most common and most potentially devastating severe injuries after extravasation of nonionic contrast media are compartment syndromes, which result from mechanical compression. Skin ulceration and tissue necrosis are less commonly encountered. Other complications, including lymphedema and reflex sympathetic dystrophy, are extremely rare and, in most cases, likely are not directly related to the extravasation itself.

Compartment syndromes are more likely to develop when large volume extravasations occur, especially into smaller compartments such as the hand, wrist, or foot, though even most large volume extravasations resolve without any adverse effects. The risk of a severe extravasation injury may also be increased in patients with arterial insufficiency or compromised venous or lymphatic drainage.

Severe symptoms may not be evident immediately after the extravasation occurs. They may develop gradually over time. For this reason, patients should be followed until their symptoms resolve, improve, or, at least, remain minor. After monitoring, if a symptomatically improving or stable patient is discharged from the radiology department, he or she must be given clear instructions concerning what symptoms may indicate a severe injury and where and how to seek prompt additional treatment if necessary. Symptoms concerning for severe extravasation injury include worsening pain or failure of existing pain to improve; decreasing arm, wrist or finger motion; loss of sensation or paresthesias in the affected extremity; and any evidence of skin breakdown.

There is little that can be done to mitigate the effects of contrast extravasations once they occur. Elevation of the affected extremity above the level of the heart is recommended to decrease capillary hydrostatic pressure. This may promote resorption of the extravasated contrast material. Cold compresses can be applied to the site of extravasation. Attempted aspiration of the extravasated contrast media and injection of medications into the extravasation site (such as corticosteroids or hyaluronidase) are both ineffective.

Surgical consultation should be obtained after an extravasation whenever there is concern for a developing compartment syndrome or for tissue necrosis. Ominous symptoms that indicate the need for prompt surgical consultation include progressive swelling or pain, decreased finger mobility, altered tissue perfusion (manifested by decreased capillary refill), change in sensation, or skin ulceration or blistering. In some instances it may be difficult to recognize the early signs

of a compartment syndrome. In general, however, the earliest and most reliable sign of a severe injury is severe or progressive pain. It should be noted that there is no extravasation volume threshold above which surgical consultation is considered mandatory.

4.2.2 Gadolinium-based Contrast Media (GBCM)

Classification of GBCM
Most contrast agents used for MRI contain gadolinium. Gadolinium-based contrast media (GBCM) are classified as linear or macrocyclic, and ionic or nonionic. In general, macrocyclic GBCM are more stable than linear agents. Among the linear agents, the nonionic agents are less stable than the ionic agents. At the present time, eight gadolinium-containing contrast agents are available for use in the United States, as summarized in **Table 4.1**.

Agent	Ionicity	Linear or macrocyclic
Gadopentetate dimeglumine (Magnevist®)[1]	Ionic	Linear
Gadobenate (MultiHance®)[2]	Ionic	Linear
Gadoxetate (Eovist®)[3]	Ionic	Linear
Gadodiamide (Omniscan®)[1]	Nonionic	Linear
Gadoversetamide (Optimark®)1	Nonionic	Linear
Gadoteridol (ProHance®)[2]	Nonionic	Macrocyclic
Gadobutrol (Gadavist®)[2]	Nonionic	Macrocyclic
Gadoterate (Dotarem®)[2]	Ionic	Macrocyclic

Table 4.1. Characteristics of approved gadolinium-containing contrast agents.

[1]Indicates agents that have a higher risk for nephrogenic systemic fibrosis (NSF) (ACR 2015).
[2]Indicates agents that have a lower risk for nephrogenic systemic fibrosis (NSF) (ACR 2015).
[3]Indicates agent with limited evidence regarding association with nephrogenic systemic fibrosis (NSF) (ACR 2015).

Of the available agents, two have hepatobiliary excretion and may be used for hepatobiliary imaging: gadoxetate disodium (Eovist®—50% hepatic excretion at 20 minutes) and gadobenate dimeglumine (MultiHance®—5 % hepatic excretion at 2 to 3 hours). Gadofosveset (Ablavar®), a blood pool agent, was removed voluntarily from the market by the manufacturer in 2016. All of the macrocyclic agents are extracellular agents and function similarly to iodinated contrast material in that regard.

Acute Adverse Reactions to GBCM
Acute adverse reactions to GBCM occur approximately two to four times less frequently than reactions to iodinated contrast media. In general, the physiologic and allergic-like reactions that occur after GBCM administration are similar to those that occur after injection of iodinated contrast agents. For this reason, treatment of contrast reactions to GBCM is similar to that of contrast reactions to iodinated contrast media (see separate section on treatment, to follow).

The vast majority of GBCM reactions are mild and non-allergic-like (i.e., physiologic), including coldness at the injection site, nausea with or without vomiting, headache, warmth or pain at the injection site, paresthesias, and dizziness. Rash, hives, and urticaria are the most frequent allergic-like symptoms; however, respiratory and cardiovascular reactions can occur. Even fatal contrast reactions have been reported

A unique physiologic side effect of gadoxetate disodium (Eovist®) is transient tachypnea, which can cause motion artifact on arterial-phase MRI. It is more common with high volume, off-label administrations (e.g., fixed volumes of 10 to 20 mL).

Patients at highest risk for adverse reactions to GBCM are those who have had previous reactions to these agents (even to a different GBCM). Lesser risk factors include other allergies (including previous allergic-like reactions to iodinated contrast media) and asthma.

Some suggested preventive measures to be considered in patients who have experienced previous adverse reactions to GBCM include using a different gadolinium compound for reinjection, and, when the previous reaction was allergic-like, premedicating patients with corticosteroids and antihistamines (using a regimen identical to that used for prophylaxis of adverse reactions to iodinated contrast material). At the present time, there is no evidence that premedication before GBCM in at-risk patients is effective, but it is still often performed, based on evidence extrapolated from experience with iodinated contrast material.

GBCM have been classified by the Food and Drug Administration as pregnancy class C drugs (no adequate and well-controlled studies in humans have been performed, although animal reproduction studies have shown an adverse effect on the fetus) and are therefore relatively contraindicated in pregnant patients. These agents pass through the placental barrier and enter the fetal circulation. They are then filtered by the fetal kidneys and excreted into the amniotic fluid, where they may remain for a prolonged period of time. With prolonged presence of the chelate in the amniotic fluid, there is a theoretical increased potential of dissociation of the potentially toxic gadolinium ion (see separate section on nephrogenic systemic fibrosis, to follow). For this reason, GBCM should only be administered to pregnant patients in carefully selected situations in which the benefit is thought to overwhelmingly outweigh the potential risk.

GBCM in Women Who Are Breastfeeding
Only tiny amounts (0.04%) of administered GBCM are excreted into the milk of breastfeeding mothers, and only a tiny percentage of this (1%) GBCM is absorbed by an infant. This is much less than the allowed infant GBCM dose, when a contrast-enhanced imaging study is needed in an infant. There is no evidence that the tiny amount of absorbed GBCM has any adverse effect on a breastfed infant. Therefore, there is no need for a mother to stop breastfeeding after a GBCM-enhanced study. However, as with the administration of iodinated contrast material, if the mother is concerned, she can stop breastfeeding for 12 to 24 hours after the study, and pump and discard any milk produced during this time.

Nephrogenic Systemic Fibrosis (NSF)
Nephrogenic systemic fibrosis (NSF) is a fibrosing disease most evident in the skin and subcutaneous tissues, but also may involve other organs, such as the lungs, esophagus, heart, and skeletal muscles. Initial symptoms typically include skin thickening with plaque formation. Symptoms and signs may progress rapidly, with some affected patients developing contractures and joint immobility. Occasionally, the disease may be fatal. There is no known effective treatment.

NSF occurs nearly exclusively in patients with severe CKD (stage 4, eGFR = 15 to 29 mL/min/1.73 m2; stage 5, eGFR < 15 mL/min/1.73 m2) or in patients with AKI who have been exposed to GBCM. Symptom onset can occur from days to years after GBCM administration. Identification of the GBCM responsible for the precipitation of this disease is sometimes difficult, as many patients have received multiple different MR contrast agents. GBCM agent exposure is considered to be "confounded" in patients with NSF who have been exposed to multiple GBCM; the exposure is considered

to be "unconfounded" when a patient with NSF has only been exposed to one agent.

NSF has been encountered almost exclusively after patient exposure to several specific linear GBCM, with the high-risk agents being gadodiamide (Omniscan®), gadoversetamide (OptiMark®), and gadopentetate dimeglumine (Magnevist®). In addition, higher doses and multiple doses of the higher risk GBCM are believed to increase the likelihood of NSF, although cases have occurred after only a single administration of a standard dose of GBCM.

Few, if any, cases of unconfounded NSF have been reported with the lower-risk agents, which include gadobenate dimeglumine (MultiHance®), gadobutrol (Gadavist®), gadoterate meglumine (Dotarem®), and gadoteridol (ProHance®). Gadoxetate disodium (Eovist®) is a newer agent with more limited evidence regarding its association with NSF.

Because many patients with severe CKD who are exposed to GBCM do not develop NSF, there are believed to be other factors required for disease development. Several possible other risk factors have been suggested, including metabolic acidosis or medications that predispose patients to acidosis; increased iron, calcium, and/or phosphate levels; high-dose erythropoietin therapy; immunosuppression; vasculopathy; an acute pro-inflammatory event; and infection. Unfortunately, no consistent relationship between these factors and NSF has been identified.

The mechanism of NSF is unknown, although many experts have speculated that it may result from dissociation of the gadolinium ion from its chelate in vivo, with subsequent precipitation of gadolinium in tissue. This is because the most commonly implicated GBCM have lower stability than do most of the nonimplicated GBCM.

As a response to the emergence of NSF, radiologists have instituted a number of precautions, which have been effective in nearly eliminating this disease. These precautions include 1) screening patients referred for contrast-enhanced MRI for renal disease (which may include obtaining eGFR levels in any patient with a history of a solitary kidney, kidney transplant, or renal neoplasm; age > 60 years; or hypertension or diabetes mellitus), 2) avoiding GBCM administration in patients with Stage 4 or 5 CKD and patients with AKI, 3) injecting the smallest volumes of contrast material required to obtain a diagnostic study, and 4) avoiding high-risk agents if GBCM administration is deemed necessary in these patients. In fact, the three

agents at highest risk for causing NSF (gadodiamide [Omniscan®], gadoversetamide [OptiMark®], and gadopentetate dimeglumine [Magnevist®]) are absolutely contraindicated when the eGFR is less than 30; they should never be administered in this setting.

It has been suggested that patients with an eGFR < 40 mL/min/1.73 m2 be considered at high risk, because renal function can fluctuate. For example, a patient may have an eGFR between 30 and 40 mL/min/1.73 m2 on one day and an eGFR of < 30 mL/min/1.73 m2 on another day. However, a threshold of < 30 may make more sense, because there are only anecdotal reports of patients with an eGFR of 30 to 40 mL/min/1.73m2 developing NSF.

If GBCM-enhanced MRI is to be obtained in patients with severe chronic kidney disease or AKI, informed consent should be considered for the higher-risk agents.

There is no proof that immediate post-MRI dialysis reduces the risk of NSF in GBCM-exposed patients.

Gadolinium Retention
Some administered gadolinium remains in the body after GBCM administration. It has long been known that this retention occurs in the skeleton and is greater with nonionic linear than macrocyclic agents.

More recently, investigators have found that gadolinium is also retained within the brain (particularly the globus pallidus and dentate nucleus). This occurs even in patients with normal renal function. The amount of gadolinium accumulation has also been found to be proportional to the amount of GBCM that a patient has received, at least with respect to linear nonionic agents. It is not clear in what state the gadolinium is retained. As with retention in the bones, retention in the brain is much greater with linear than with macrocyclic agents. There is no evidence of any adverse neurologic effect of this accumulation (even after millions of GBCM administrations throughout the world); however, further study is necessary to determine the effect, if any, that gadolinium deposition in the brain may have.

4.2.3 Treatment of Acute Contrast Reactions
When an allergic-like reaction occurs, rapid recognition, patient assessment, and diagnosis are important so that appropriate treatment can be instituted rapidly.
A responding radiologist should assess the patient quickly. A brief discussion with the patient and any present healthcare providers, when possible, should provide the following information: the reason for the imaging study, a description of the patient's current symptoms, and a brief summary of the patient's health problems and medications. Vital signs should be obtained promptly. IV access should be secured. A pulse oximeter should be available. Oxygen should also be available and, if administered, should be given at high doses.

The examining radiologist should quickly determine the level of patient consciousness, the appearance of the skin, the quality of phonation, and the presence or absence of respiratory and cardiovascular symptoms. Mild reactions usually resolve within 20 to 30 minutes and do not require medical treatment; however, some patients with moderate and severe reactions may initially develop only mild symptoms. For this reason, all patients should be monitored until their symptoms resolve.

The management of a contrast reaction depends on the nature of the reaction and its severity. Treatments recommended in the ACR Manual on Contrast Media for different types of reactions in adults are summarized below.

Hives (Urticaria)
- No treatment is needed in most cases.
- If symptomatic, administer diphenhydramine (Benadryl®) 25 to 50 mg orally (PO), intramuscularly (IM), or intravenously (IV). Alternatively, use fexofenadine (Allegra) 180 mg PO.
- If severe, administer epinephrine IM (1:1000) 0.3 mL (0.3 mg), or IM EpiPen or equivalent (0.3 mL 1:1000 dilution fixed), or epinephrine IV 1 mL (0.1 mg) of 1:10,000 dilution slowly into a running IV infusion of saline.

Diffuse Erythema
- Preserve IV access, monitor vitals, and use a pulse oximeter.
- Give O_2 6 to 10 L/min (via mask).
- If the patient is normotensive, no further treatment is usually needed.
- If the patient is hypotensive, give 1 L of IV fluids rapidly, either 0.9% normal saline or Lactated Ringer's solution.
- If hypotension is profound or does not respond to IV fluids, consider epinephrine IV (1:10,000) 1 mL (0.1 mg) slowly into a running infusion of IV saline. Repeat as needed at 5- to 10-minute intervals up to 10 mL total. In the absence of IV access, consider epinephrine IM (1:1000) 0.3 mL (0.3 mg), or IM EpiPen or equivalent (0.3 mL 1:1000 dilution fixed). IM epinephrine may be repeated up to 1 mg total.
- Consider calling an emergency response team or 911 based on the severity of the reaction and the completeness of patient response to treatment.

Laryngeal Edema
- Preserve IV access, monitor vitals, and use a pulse oximeter.
- Give O_2 6 to 10 L/min (via mask).
- Give epinephrine IM (1:1000) 0.3 mL (0.3 mg), or IM EpiPen or equivalent (0.3 mL 1:1000 dilution fixed), or, especially if hypotensive, epinephrine IV (1:10,000) 1 mL (0.1 mg) slowly into a running infusion of IV saline.
- Repeat epinephrine as needed up to a maximum of 1 mg.
- Consider calling an emergency response team or 911 based on the severity of the reaction and the completeness of patient response to treatment.

Bronchospasm
- Preserve IV access, monitor vitals, and use a pulse oximeter.
- Give O_2 6 to 10 L/min (via mask).
- Give beta-agonist inhaler albuterol, 2 puffs (90 mcg per puff); can repeat as necessary. In moderate cases, consider adding epinephrine IM (1:1000) 0.3 mL (0.3 mg), or IM EpiPen or equivalent (0.3 mL 1:1000 dilution fixed), or epinephrine IV (1:10,000) 1 mL (0.1 mg) slowly into a running infusion of IV saline.
- Repeat epinephrine as needed up to a maximum of 1 mg.
- Consider calling an emergency response team or 911 based on the completeness of patient response to treatment.

Hypotension, Any Cause (systolic blood pressure < 90 mm Hg)
- Preserve IV access, monitor vitals, and use a pulse oximeter.
- Elevate legs at least 60 degrees (Trendelenburg position).
- Give O_2 6 to 10 L/min (via mask).
- Consider rapid IV administration of 1 L IV fluids, 0.9% normal saline or Lactated Ringer's solution.

Hypotension with Bradycardia (pulse < 60 bpm) (Vagal Reaction)
- If mild, no additional treatment is usually needed beyond that listed above for any cause of hypotension.
- If severe (patient remains unresponsive to above measures), give atropine 0.6 to 1.0 mg IV, followed by a saline flush. (Note: lower doses of atropine may exacerbate bradycardia.)
- May repeat atropine up to a total dose of 3 mg.
- Consider calling an emergency response team or 911.

Hypotension with Tachycardia (pulse > 100 bpm) (Allergic-like Reaction)
- If hypotension persists after basic treatment listed above, for any cause of hypotension, give epinephrine IV (1:10,000) 1 mL (0.1 mg) slowly into a running infusion of IV saline. Can repeat as needed up to 10 mL (1 mg) total. Alternately, IM epinephrine could be given, (1:1000) 0.3 mL (0.3 mg), or IM EpiPen or equivalent (0.3 mL 1:1000 dilution fixed). IM epinephrine may be repeated up to 1 mg total.
- Consider calling an emergency response team or 911 based on the severity of the reaction and the completeness of patient response to treatment.

Hypertensive Crisis (diastolic bp > 120 mm Hg; systolic bp > 200 mm Hg; symptoms of end organ compromise)
- Preserve IV access, monitor vitals, and use a pulse oximeter.
- Give O_2 6 to 10 L/min (via mask).
- Administer labetalol 20 mg IV slowly over 2 minutes; can double dose every 10 minutes (e.g., 40 mg 10 minutes later, then 80 mg 10 minutes after that).
- If labetalol is not available, give nitroglycerine 0.4 mg tablet, sublingual (may repeat every 5 to 10 minutes).
- Administer furosemide (Lasix®) 20 to 40 mg IV slowly over 2 minutes.
- Call emergency response team or 911.

Pulmonary Edema
- Preserve IV access, monitor vitals, and use a pulse oximeter.
- Give O_2 6 to 10 L/min (via mask).
- Elevate head of bed, if possible.
- Give furosemide (Lasix®) 20 to 40 mg IV, slowly over 2 minutes.
- Consider giving morphine 1 to 3 mg IV, may repeat every 5 to 10 minutes as needed.
- Call emergency response team or 911.

Seizures or Convulsions

- Observe and protect the patient. Turn the patient on his or her side to avoid aspiration. Suction airway as needed.
- Preserve IV access, monitor vitals, and use a pulse oximeter.
- Give O_2 6 to 10 L/min (via mask).
- If unremitting, administer lorazepam (Ativan®) 2 to 4 mg and call emergency response team. IV slowly to maximum dose of 4 mg.

Hypoglycemia

- Preserve IV access.
- Give O_2 6 to 10 L/min (via mask).
- If the patient is able to swallow, give oral glucose, such as two sugar packets, or 15 g of glucose tablet or gel, or 4 ounces of fruit juice.
- If the patient is unable to swallow and IV access is available, give D50W 1 ampule (25 gm) IV over 2 minutes. As adjunctive therapy, may also give D5W or D5NS at 100 mL/hr.
- If the patient is unable to swallow and IV access is not available, give glucagon 1 mg IM.

Anxiety (panic attack)

- This is a diagnosis of exclusion. The patient must be assessed for developing signs and symptoms of another more severe reaction or condition, such as those listed above.
- Preserve IV access, monitor vitals, and use a pulse oximeter.
- If there are no identifiable manifestations of another diagnosis and there is normal oxygenation, consider this diagnosis.
- Reassure the patient.

Unresponsive and Pulseless

- Check for responsiveness.
- Activate emergency response team or call 911.
- Perform CPR per American Heart Association protocols.
- Defibrillate as indicated if equipment is available.
- May administer epinephrine IV (1:10,000) 10 mL (1 mg) between 2-minute cycles of CPR.

Reaction Rebound Prevention

- IV corticosteroids are not useful in acute treatment of any reaction.
- However, IV corticosteroids help prevent a short-term recurrence of an allergic-like reaction and may be considered for a patient having a severe allergic-like reaction before transportation to the emergency department.
- Give hydrocortisone 5 mg/kg IV over 1 to 2 minutes, or methylprednisolone 1 mg/kg IV over 1 to 2 minutes.

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5 Reimbursement, Regulatory Compliance, and Legal Considerations in Radiology

5.1 Reimbursement and Regulatory Compliance

5.1.1 Coding, Billing, and Reimbursement

Appropriate reimbursement for healthcare services involves a series of complex and interconnected steps that often vary depending on the payer. A number of generalizable principles based on Medicare rules should guide best practice efforts to optimize revenue and compliance activities.

Currently, nearly all physician services are reimbursed on a transactional volume-based fee-for-service basis. To be eligible for reimbursement, each physician service needs to be identifiable with a unique code that acts as the basis for payment. Current Procedural Terminology (CPT) is the most prevalent platform for these codes. Although many radiology professional societies participate in the CPT process, the CPT Editorial Panel, appointed by the American Medical Association (AMA) Board of Trustees, maintains full editorial control over code set development and maintenance.

After they are approved, CPT codes are evaluated using Resource Based Relative Value Scale (RBRVS) methodology by the AMA's RBRVS Update Committee (RUC), which makes recommendations to CMS on Relative Value Unit (RVU) assignments. Each service's total RVUs reflect 1) encounter time, intensity, effort, and skill (the work RVU); 2) costs of maintaining a practice, such as equipment, supplies, and nonphysician staff (the practice expense RVU); and 3) professional liability expenses (the malpractice RVU). The work RVU is used by many practices to track physician productivity. Although the Centers for Medicare and Medicaid Services (CMS) formally assigns RVUs to services independently, it has historically accepted the AMA RUC recommendations in more than 90% of cases. With minor geographic cost adjustments, those RVUs are multiplied by an annual Conversion Factor to determine CMS payments under the Medicare Physician Fee Schedule.

CMS and private insurers generally pay only for services deemed medically necessary. CMS defines medical necessity as "healthcare services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." In practicality, the determination of medical necessity is usually a rules-based administrative exercise performed at the time a claim is submitted to a payer, wherein a CPT service code must match a pre-approved diagnosis code list. Those diagnosis codes must be in the form of the *International Classification of Diseases* (ICD) system, established by the World Health Organization, currently in its 10th revision (ICD-10). ICD-10 codes describe the signs, symptoms, or specific diagnosis of a patient that form the indication for a healthcare service. Terms such as "rule out" or "consistent with" are not capable of being coded by ICD-10, and therefore do not meet medical necessity criteria.

Reimbursement for radiology services is largely predicated on the adequacy of documentation within the physician report. Professional coders, assisted by software tools, extract information from radiology reports to assign both ICD-10 and CPT codes. The Radiology Coding Certification Board is the primary organization that credentials professional medical imaging coders. These individuals extract ICD-10 information from radiology reports using any statements 1) about examination indication and clinical history provided by the referring physician or patient and 2) from any specific diagnostic information located in the findings section or (preferably) in the impression section of the radiologist's report. CPT codes are assigned based on the specific details of the described service. For radiography, more views generally translate to higher complexity codes. For ultrasound, organ inventory "checklists" apply to abdominal, pelvic, obstetrical, and extremity imaging. For CT and MRI, details of contrast administration (i.e., without, with, or without and with contrast) determine the CPT code level for a specific body part. Structured template reporting helps radiologists comply with many of these reporting requirements, facilitating appropriate reimbursement and regulatory compliance.

Many private payers, Medicaid plans, and Medicare Advantage (i.e., not traditional Medicare indemnity)

payers contract with radiology benefit management (RBM) companies, and require preauthorization (also known as precertification) as a condition for reimbursement for any elective outpatient advanced imaging service. Before performing advanced imaging services such as CT, MRI, and PET/CT, radiology facilities should determine whether preauthorization is required for a particular service for a particular patient and, if so, whether such preauthorization has been obtained. Although a necessary condition for payment, preauthorization by an outsourced RBM does not always guarantee a subsequent favorable medical necessity determination by the insurer itself when a claim is filed. As a general rule, preauthorization requirements do not apply to emergency department and inpatient services.

The False Claims Act (FCA) protects the government from being overcharged or sold substandard goods or services. A false claim is generally defined as a request for payment for services that a provider knew or should have known was false or fraudulent. While the U.S. Department of Justice does not expect physicians to be experts in all of these nuanced matters, it has set an expectation that radiology practice processes, structures, and cultures be oriented toward optimizing the integrity of revenue cycle operations. Best practice techniques call for formal compliance plans, with a formally designated compliance officer and compliance committee appropriately empowered to oversee these activities. A false claim ruling can result in fines of up to three times the billed amount plus $11,000 *per claim filed*, because each single exam or service billed to Medicare or Medicaid counts as a claim. To date, the largest radiology practice government settlement agreement for allegations of fraud is $7 million.

5.1.2 Patient Privacy and HIPAA

Respect for patient privacy is a core responsibility of a medical professional. The Privacy and the Security rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) represent a codification of this principle in the law. They provide a set of national privacy standards and bring with them the power of law. As such, compliance activities must prioritize patient privacy. HIPAA rules apply to healthcare providers, plans, and clearinghouses alike.

The Privacy Rule establishes national standards for the protection of individually identifiable health information, referred to as protected health information (PHI). The Security Rule establishes a national set of security standards for securing PHI when held or transferred in electronic form. It operationalizes the protections contained in the Privacy Rule by addressing both technical and nontechnical safeguards that organizations must put in place to secure individuals' electronic PHI (e-PHI). Within the U.S. Department of Health and Human Services, the Office for Civil Rights (OCR) has responsibility for enforcing these rules with civil money penalties.

The major goals of the HIPAA rules are to assure appropriate protection of each individual's PHI while still permitting the flow of information necessary to provide and promote quality healthcare. The following identifiers are included in the definition of PHI: 1) names; 2) geographic subdivisions smaller than a state (except for the first three digits of a ZIP code representing a population greater than 20,000); 3) all elements of dates (except year) related to an individual, such as birthdate, admission date, discharge date, and date of death; 4) phone numbers; 5) fax numbers; 6) email addresses; 7) Social Security numbers; 8) medical record numbers; 9) health plan beneficiary numbers; 10) account numbers; 11) certificate and license numbers; 12) vehicle identification and license plate numbers; 13) device identifiers and serial numbers; 14) webpage universal resource locators (URLs); 15) Internet Protocol (IP) addresses; 16) biometric identifiers such as finger- and voice-prints; 17) full face or similar photographs; and 18) any other unique identifier, characteristic, or code.

As a general rule, an individual's PHI cannot be disclosed or transmitted to anyone other than the individual without that individual's authorization. Exceptions include information disclosed or transmitted when necessary for 1) the delivery of care or treatment, 2) payment activities, and 3) healthcare operations involving quality or competency assurance, fraud or abuse detection, or compliance. In addition, when required by law, information can be released 1) to public health authorities, 2) during investigation of abuse, neglect, or domestic violence, 3) to oversight agencies, 4) for judicial and administrative proceeding, 5) for law enforcement purposes, and 6) for worker's compensation.

5.1.3 Human Subjects Research

Properly controlled biomedical research involving human subjects is essential to advancing medical knowledge and care. Unfortunately, human cruelty has occasionally been perpetrated in the name of research, and not all human studies have been either justifiable or useful. The discoveries of such abuses during Nazi Germany were the basis for the development of the Nuremberg Code, which represented the first international codification of minimal expectations for the conduct of ethical research involving human subjects. The Code's most important principles were that experiments involving human subjects should occur only with subjects who have freely chosen to participate, and in the context of a clear scientific rationale. The subsequent Declaration of Helsinki, now widely regarded as the cornerstone of human research ethics, has recommended that all research protocols be reviewed by an independent committee prior to initiation.

That recommendation led to the development of the Institutional Review Board (IRB) system currently in place in the United States, wherein appropriately constituted groups, usually at the university or health system level, are formally designated to review and monitor biomedical research involving human subjects. In accordance with Food and Drug Administration (FDA) regulations, an IRB has the authority to approve, require modifications in order to secure approval, or deny approval for proposed research protocols. These review groups serve important roles in the protection of the rights and welfare of human research subjects.

IRBs are required to ensure a "diversity of members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes" and to register with the Department of Health and Human Services (HHS). Institutions engaged in research involving human subjects usually have their own IRBs to oversee research conducted within the institution or by its staff. However, institutions without an IRB are permitted to arrange for an outside IRB to assume oversight responsibilities.

Because the free choice of research subject participation is a fundamental prerequisite to ethical research, an IRB carefully scrutinizes all aspects of consent. The research informed consent process involves 1) providing adequate information about a study to potential subjects, 2) providing an adequate opportunity for subjects to consider all options, 3) responding adequately to all subject questions, 4) ensuring that the subject comprehends all necessary information, 5) obtaining the subject's voluntary agreement to participate, and 6) providing ongoing information as the subject or situation so requires. In some situations (such as many studies involving the retrospective review of imaging), an IRB may waive the requirement for informed consent when the research involves no more than minimal risks to participants, and cannot be practically carried out without such a waiver. IRBs typically provide an exemption from formal protocol review when a project constitutes a quality improvement activity, as long as the primary objective is to improve local practice rather than to create generalizable knowledge. IRB approval is not required for studies that do not meet federal definitions of human subjects research (e.g., studies that utilize open source public datasets).

5.2 Malpractice and Risk Management

5.2.1 General Principles of Malpractice

Malpractice fears have been cited as a cause of physician burnout and distress, including in radiology. Approximately 7% of all radiologists are named in a medical malpractice lawsuit each year; radiology indemnity payments in malpractice cases average approximately $480,000. The average radiologist spends approximately 19 months of his or her career with an unresolved open malpractice claim. Malpractice concerns have also been identified as a cause of overutilization of services; more than 90% of physicians report that they at least sometimes engage in the practice of defensive medicine.

Malpractice insurance coverage is usually mandated as a condition of state licensure and hospital credentialing. "Claims-made" policies are the most common types of policies and protect physicians from personal financial liability, up to a predetermined policy cap, but only while the policy is in effect. Physicians with claims-made policies thus usually need to arrange for tail insurance when changing jobs or retiring to ensure continued financial protection. "Occurrence" policies cover any claim for an event that took place during the period of coverage, even if a claim is filed after the policy lapses.

Medical malpractice lawsuits are based on the tort of negligence, and require four elements: 1) The physician must have an *established duty* to a patient. For example, duty would exist for a radiologist to provide treatment for a patient undergoing a contrast reaction in the radiology department but not for interpreting the contents of a CT scan on a CD in a patient's purse in her ICU room unless those images were submitted for formal review under established hospital policy.

2) There must have been a *breach of duty*, which usually involves a failure to meet the standard of care. The definition of standard of care varies by jurisdiction, but is generally how a reasonable, prudent, or ordinary physician of a similar specialty would have acted in similar circumstances. 3) *Causation* must exist, in that the breach must have been the proximate cause of injuries. A radiologist, for example, may have negligently missed a lung mass on a chest radiograph, but establishing that as the proximate cause of a hemorrhagic stroke the next day would be difficult. 4) The negligence must result in *damages*. In many jurisdictions, emotional distress, pain, and suffering are frequently considered remunerative damages.

Claims of negligence against radiologists generally fall into 3 categories: 1) diagnostic errors, 2) procedural complications, and 3) communication deficiencies.

5.2.2 Malpractice Related to Diagnostic Errors

The most common cause of malpractice lawsuits against radiologists is for alleged errors in diagnosis. Depending on the clinical indication and modality, the sensitivity of imaging in detecting disease is highly variable, and plaintiff lawyers frequently contend that any false negative interpretation represents medical negligence. In the setting of chest radiography in lung cancer screening, for example, as many as 90% of cancers are identifiable in retrospect, and so a radiologist's potential legal exposure is not insignificant. Hindsight bias represents the tendency for people with a knowledge of the actual outcome of a case to believe falsely that they would have predicted its outcome. This jury bias makes defending such cases difficult.

Negligent diagnosis claims can be categorized as related to 1) failures of perception (i.e., not identifying a finding), 2) failures of interpretation (i.e., identifying a finding but not appropriately appreciating or adequately communicating its significance), or 3) combinations of both. Diagnostic errors can also be categorized as 1) cognitive errors (e.g., not identifying a lung nodule when interpreting a chest radiograph), which are usually errors of visual perception (scanning, recognition, and interpretation), or 2) system errors (e.g., failure to adequately communicate the presence of that nodule), which are usually attributed to health system issues or context of care delivery problems. As in other medical disciplines, errors in diagnosis in radiology often result from a combination or interaction between cognitive and system errors, such as preliminary reports by residents that are revised in a final report but not fully communicated to care teams. Certain system factors, such as lighting conditions, shift length, or pace of interpretation, have been shown to increase the likelihood of diagnostic errors. Enhanced awareness of these types of errors helps radiologists identify areas of diagnostic vulnerability and institute interventions to improve patient care and mitigate their own potential risks.

5.2.3 Malpractice Related to Procedural Complications

Any invasive procedure has a risk of complication. Such complications vary in type and severity based on the procedure, and can similarly serve as the grounds for medical negligence claims. Despite what some plaintiff lawyers might contend, complications by themselves do not indicate negligence. Lawsuits based on procedural complications, however, are more successfully argued in scenarios in which a radiologist did not exercise appropriate care in 1) minimizing the risk of the complication, 2) identifying complication once it occurred, or 3) treating the complication. In the instance of the very common complication of pneumothorax after a lung biopsy, for example, a radiologist's malpractice risk would increase if he or she 1) used an overly large needle or chose a trajectory unnecessarily crossing an aerated lung, 2) did not obtain a postprocedural chest radiograph, or 3) discharged the patient to home in the setting of an enlarging pneumothorax.

Patients and their families are more likely to sue physicians for damages related to complications if they believe that details of their care were withheld. As a result, most risk managers advocate full and prompt disclosure of any untoward events, and ongoing communication about decision-making and treatment. Detailed and contemporaneous documentation of events, discussions, and rationale for decisions in the radiology report and/or elsewhere in the medical record may prove helpful in court.

Engaging patients (and their families, when appropriate) in decision-making before a procedure also helps set realistic expectations. The doctrine of informed consent has been codified in the U.S. courts as a basic right of self-determination: "Any human being of adult years and sound mind has a right to determine what shall be done with his body; and a surgeon who performs an operation without his patient's consent commits an assault." Courts have subsequently expanded that decision to apply to procedures other than open operations and those performed by nonsurgeon physicians. Necessary elements of informed consent are described in Section 3.2.1 of this study guide. Although most hospitals have standard consent forms in place, additional detailed documentation in procedure reports may prove helpful in a claim of negligence.

5.2.4 Malpractice Related to Communications Deficiencies

Appropriate communication of actionable information from radiologists to clinical caregivers is a critical component of patient care. Both courts and regulatory agencies are increasingly holding radiologists to higher standards of ensuring prompt communication of diagnostic information. In fact, a number of court decisions have focused not only on a radiologist's duty to communicate important or critical findings with referring physicians, but also on communications with patients themselves when their treating physicians may not be available.

Routine Communication
In radiology, routine communication refers to the creation and delivery of written reports. The ACR Practice Parameter for Communication of Diagnostic Imaging Findings outlines suggested formatting for reports, which includes relevant demographic information (e.g., patient name and identifying information, referring physician, facility information), examination details (e.g., type and time of examination including contrast administration information, time of dictation), and report content recommendations (e.g., findings, impressions, limitations, complications). It is acceptable for demographic information and examination details to be contained in the metadata associated with the report (rather than in the dictated report body itself). Radiology reports are now typically generated and transmitted electronically.

The final report represents the definitive documentation of the results of an imaging examination or procedure. It should be proofread to minimize typographical errors and confusing or conflicting statements. The use of abbreviations or acronyms should be limited to avoid ambiguity. The final report should be completed in accordance with all appropriate state and federal requirements (e.g., Mammography Quality Standards Act). A copy of the final report should be archived by the imaging facility as part of the patient's medical record and be retrievable for future reference. Retention and distribution must be in accordance with all state and federal regulations and facility policies.

Nonroutine Communication
While routine communication is typically carried out through institutionally established final reporting mechanisms, certain circumstances dictate alternative communication mechanisms to ensure timely receipt of important diagnostic information. These include situations warranting preliminary reports and results of an urgent or other significantly important nature.

Occasionally, a preliminary report is issued before the final report, and may be rendered for the purpose of directing immediate patient management (e.g., when old comparison images are not yet available but reporting cannot wait) or to meet the needs of a particular practice environment (e.g., by a trainee in a teaching institution or by a general practice radiologist when a subspecialist radiologist is not immediately available). Such preliminary communications should be archived, since they may have served as the basis of immediate clinical decisions. Institutions are expected to maintain policies for reconciling discrepanicies between preliminary and final reports and for discrepancies encountered upon subsequent review of a final report. Any clinically significant variation in findings or impression between a preliminary and final interpretation should be clearly documented and reported as soon as possible and in a manner that ensures receipt by the ordering or treating physician.

Clinical situations that may warrant nonroutine communication include the following:

1. **Findings that warrant immediate or urgent intervention**. These are generally new or unexpected findings on an imaging study that suggest life-threatening conditions or those that may require an immediate change in patient management. Aside from risk management imperatives, The Joint Commission (TJC) requires that professionals "report critical results of tests and diagnostic procedures on a timely basis." TJC-accredited facilities are required to define critical tests and critical results and monitor performance in reporting those results. A critical result is defined as "any result or finding that may be considered life threatening or that could result in severe morbidity and require urgent or emergent clinical attention." Examples include tension pneumothorax, ruptured aortic aneurysm, acute intracerebral hemorrhage, and

pneumoperitoneum. Each facility has leeway in defining its own critical tests and critical results; there is no standard list for either category. For all critical results, communication requires direct contact between the radiologist and the requesting or responding clinician or another licensed healthcare provider responsible for that patient's care. In addition, communication is generally expected to occur within 60 minutes of the time that the observation is made, and it must be documented. When the ordering physician or healthcare provider cannot be contacted expeditiously, it may be appropriate to convey results directly to the patient, depending on the nature of the findings. At some institutions, these critical results are deemed "Level 1 results."

2. **Findings that may not require immediate attention but nonetheless may seriously impact a patient's health, worsen over time, or result in an adverse outcome.** These include the following: 1) New or unexpected findings that could result in mortality or significant morbidity if not treated in a timely manner. Referred to as "Level 2 results" by some institutions, these are less dire than critical results and generally warrant communication within 12 hours. For such findings, the radiologist might call the care team directly, or might request a call service or assistant to call on his or her behalf. Examples include intra-abdominal abscess or impending pathological hip fracture. 2) New or unexpected findings on an imaging study that could result in significant but not immediate morbidity if not appropriately treated. Deemed "Level 3 results" by some institutions, communication is not particularly time sensitive but mechanisms must be in place to ensure that these important or potentially important findings are not overlooked. Examples include a newly identified lung nodule or solid renal mass. These findings may be reported electronically when electronic messaging tracking mechanisms are in place to make sure that information was successfully received and, when necessary, supplemented by telephone confirmation.

Documentation of all nonroutine communication should include the date and time of the communication, the person reporting the information, the person receiving the information, and a summary of or reference to the information that was conveyed.

Informal Communication

Radiologists may occasionally be asked to provide interpretations that do not result in a formal report but are nonetheless used to make treatment decisions. Such communications may take the form of a "curbside consult" that may occur informally in the reading room or during a clinical conference. These circumstances often preclude immediate documentation and may also occur in suboptimal viewing conditions (e.g., no comparison studies, no original reports, or inadequate incomplete history). Informal communications carry additional inherent risk since the documentation of the clinician initiating the informal consultation may constitute the only written record of that communication. For these reasons, informal communications are largely discouraged; when such communications do occur, radiologists should document them independently from the referring clinician's documentation.

Radiology departments are encouraged to establish processes and policies for reporting studies performed at outside institutions. Radiologists who provide consultations of this nature are encouraged to document any information conveyed, including formal interpretations. Although formal second opinion interpretations are historically nonpayable, Medicare and private payers are increasingly reimbursing radiologists for them when they are medically necessary and are billed in accordance with payer rules.

5.2.5 Discoverability of Communications

In malpractice lawsuits, most communication related to any part of the case—whether written or oral—is considered discoverable and can be used as evidence at trial. However, certain important exceptions apply. The attorney–client privilege is one of the oldest recognized privileges for confidential communications. It encourages clients in all legal matters (not just malpractice cases) to make full and frank disclosures to their attorneys, who should then be better able to provide candid advice and effective representation. Nearly all communication between a client and his or her attorney is protected from discovery. For this reason, physicians involved in lawsuits are strongly discouraged from speaking with any parties other than their attorneys about any elements of their cases.

Most jurisdictions also protect certain peer review activities from legal discovery. Peer review protection laws are designed to provide an incentive for healthcare providers to perform ongoing quality improvement activities without fear of increased tort risk. As a general rule, no person who participates in any approved peer review process shall be permitted or required to testify in any civil action as to the findings, recommendations, evaluations, opinions, or other actions of the peer review process. However, communications are only protected if they occur within established peer review processes; informal conversations with colleagues outside established peer review processes, for example, are typically not protected from legal discovery.

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