This study guide is to be used in preparation for all Core, Certifying, and Maintenance of Certification examinations administered during the calendar year 2017.
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Introduction

The Noninterpretive Skills portion of the ABR examinations is intended to focus on established knowledge in the areas of radiology quality and safety, professionalism and ethics, compliance, and regulatory and legal issues, as well as basic research and screening concepts. Since the range of content relevant to these topics is broad, this study guide serves as a syllabus of the fundamental knowledge that radiologists eligible to take the Core, Certifying, and Maintenance of Certification (MOC) examinations are expected to know. This study guide should be considered a major resource to identify topics and content for the examination, but it is not the “last word” on these topics, nor does it take the place of textbooks, other definitive source material, education you should have received during your residency or fellowship training, or continuing education. We also draw your attention to the Bibliography and Suggested Reading List at the end of this document and to web links to key public documents, which are available on the websites of the major voluntary organizations in radiology, such as ACR, ARRS, and RSNA. We highly recommend these “deeper” resources to provide perspective and depth of understanding of the concepts that are only superficially outlined here.

If you are reviewing this in printed format, please be sure to check the ABR website (www.theabr.org) for updated study guide materials and questions.
Part I: General Quality Improvement

A. Traditional Definition of Quality in Healthcare

Quality improvement (QI) is a more recent phenomenon in healthcare, but many are familiar with the term quality assurance (QA) as it was a common term for a number of years. Quality Control (QC) is a process by which we review the quality of all factors involved in producing an item.

1. Quality Assurance (QA) can be considered reactive, generally retrospective, occasionally involving policing, and in many ways punitive or finger pointing. It often involves determining who was at fault after a medical error. The term QA is older and not often used today.

2. Quality Improvement (QI) involves both prospective and retrospective reviews. It is aimed at improvement—measuring where you are and determining how to make things better. It specifically attempts to avoid attributing blame and to create systems that prevent errors from happening. It is a continuous process (also known as continuous quality improvement or CQI) that must occur consistently in an ongoing fashion, unlike QA, which is static. QI activities can be very helpful in improving how things work. Trying to locate the “defect” in the system and determining new ways to do things can be challenging and fun. It’s a great opportunity to “think outside the box.”

3. Quality Control (QC) has been defined as a system for verifying and maintaining a predetermined level of quality in a product or service. This is accomplished through planning carefully, using proper equipment, inspecting on an ongoing basis, and taking corrective action if required. Quality control involves measurements of accuracy, precision, and reliability. For example, a radiologist would request a repeat chest radiograph if the apices are excluded.

The process of improving the lives of patients, the health of communities, and the satisfaction of the healthcare workforce involves focusing on an ambitious set of goals adapted from the Institute of Medicine’s six improvement aims for the healthcare system: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. Quality care is also coordinated, compassionate, and innovative.

B. The New Paradigmatic Approach to Quality Science

1. Redefined quality in healthcare: continuous effort by all members of an organization to meet the needs and expectations of patients and other customers, insurance companies, families, providers, and employees.

2. Measuring quality: recognition and analysis of variation is fundamental to thinking of quality measurement.

3. Improving quality: includes reducing unnecessary variation, focusing on processes as the objects of improvement, and having leadership that is proactive and supportive of continuous quality improvement.

4. Personnel management: centered on the treatment of employees and professionals as valuable resources.
C. Six Core Competencies of MOC

1. Patient Care—Provide care that is compassionate, appropriate, and effective treatment for health problems and that promotes health.
2. Medical Knowledge—Demonstrate knowledge about established and evolving biomedical, clinical, and cognate sciences and their application in patient care.
3. 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 and uses effective listening skills with nonverbal and verbal communication; working as both a team member and at times as a leader).
4. Professionalism—Demonstrate a commitment to carrying out professional responsibilities, an adherence to ethical principles, and a sensitivity to diverse patient populations.
5. Systems-based Practice—Demonstrate awareness of and responsibility to a 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).
6. Practice-based Learning and Improvement—Demonstrate the ability to investigate and evaluate patient care practices, appraise and assimilate scientific evidence, and improve the practice of medicine.

D. Best Practices

1. Dashboards—According to Stephen Few, “A dashboard is a visual display of the most important information needed to achieve one or more objectives, consolidated and arranged on a single screen so the information can be monitored at a glance.”
2. Benchmarking has been defined as a measurement of the quality of an organization’s policies, products, programs, and strategies, especially in comparison to those measurements of the organization’s peers. Benchmarking helps determine what and where improvements are called for; it analyzes how other organizations achieve their high performance levels; and it uses this information to improve performance.

E. Methodologies

1. The PDSA Cycle

Virtually all improvement models reflect a common theme of setting a goal, acquiring and analyzing data, and implementing needed process changes. The key to sustainable improved performance is to ensure that the implemented changes are effective in creating desired performance outcomes. However, a core tenet of modern quality improvement theory is the assumption that proposed changes will almost never be immediately successful, at least as they are originally conceived, and will 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 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. In such a case, 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 and beyond.

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 well executed and kept as small and brief as possible, changes can be tested, refined, and validated quickly. This process of rapid, short-cycle iteration allows improvement projects to be accomplished successfully and in a timely manner.

2. Other Methodologies

There are many other methodologies for process improvement, including Lean Process Improvement (Lean) and the Six Sigma method.
Part II: Patient Safety

A. Findings of IOM Report: “To Err is Human: Building a Safer Health System”

In 1998 the National Academy of Sciences’ Institute of Medicine initiated the Quality of Health Care in America project to develop a strategy that would result in a threshold improvement in quality over the next 10 years. “To Err is Human,” published in 1999, was the first in a series of reports arising from that project. Its contention that between 44,000 and 98,000 deaths per year could be attributable to medical errors made national headlines, suggesting a national epidemic of medical errors. The projected deaths exceeded those from motor vehicle accidents, breast cancer, or AIDS.

Those numbers were based on extrapolation nationally of two large studies from Colorado/Utah and New York, “which found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively. In Colorado and Utah hospitals, 6.6 percent of adverse events led to death, as compared with 13.6 percent in New York hospitals. In both of these studies, over half of these adverse events resulted from medical errors and could have been prevented.” Aside from medical-error-related deaths, the report projected total societal financial costs to be between $17 billion and $29 billion.

Medical errors were defined 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 the ICU, OR, and ED. The report identified several fundamental factors contributing to the errors, including: 1) the decentralized nature of the healthcare delivery “nonsystem”; 2) the failure of the 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. Most errors were felt to be system errors rather than individual problems.

The report laid out a comprehensive strategy to reduce preventable medical errors with the goal of a 50 percent reduction in errors over the next 5 years, consisting of four main foci:

- Establishing a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety; recommending that Congress create a Center for Patient Safety, funded with $100 million annually.
- Identifying and learning from errors by developing a mandatory nationwide public-reporting system and by encouraging healthcare organizations and practitioners to develop and participate in voluntary reporting systems; recommending that Congress enact laws to protect confidentiality of information from litigation.
- Raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of healthcare.
- Implementing safety systems in healthcare organizations to ensure safe practices at the delivery level.

The report resulted in Congressional hearings and appropriation in 2000 of $50 million to fund the Agency for Healthcare Research and Quality (AHRQ). The AHRQ contracted with the National Quality Forum to create a list of “never events” for states to use as a basis of a mandatory reporting system. These are easily preventable events that are of sufficient importance that they should never occur in a properly functioning healthcare environment.
Six IOM Quality Aims: The IOM has determined that medical care for patients should incorporate the following elements:

- Safe
- Timely
- Effective
- Efficient
- Equitable
- Patient-centered

B. Human Factors

1. 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, they are unable to administer a potentially life-saving shock because the defibrillator pads and the defibrillator itself cannot be physically connected.

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 among workers, the equipment, and the environment can actually increase the risk of disastrous errors. Each of these safety hazards ultimately was attributed to a relatively simple, yet overlooked, problem with equipment 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 appear virtually identical, and both concentrations are 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.

2. Human Factors Engineering

Human factors engineering is the discipline that attempts to identify and address these issues. It takes into account human strengths and limitations in the design of interactive systems that involve people, tools and 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 physical demands, skill demands, mental workload, team dynamics, aspects of the work environment (e.g., adequate lighting, limited noise, or other distractions), and device design required to complete the task optimally. In essence, human factors engineering focuses on how systems work in actual practice, with real—and fallible—human beings at the controls, and 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 outside healthcare. 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.

3. Standardization

An axiom of human factors engineering is 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 being implemented as safety measures. The widening use of checklists as a means of ensuring that safety steps are performed in the correct order has its roots in human factors engineering principles.

C. High Reliability Organization (HRO)

An HRO is an organization that, despite operating in a high-stress, high-risk environment, continually manages its environment mindfully, adopting a constant state of vigilance resulting in the fewest number of errors. Many healthcare organizations have adopted, or are in the process of adopting, high-reliability behaviors and business strategies, resulting in fewer medical errors for their patients. HROs have five characteristics:

- Fixation on failure
- Avoidance of oversimplification
- Sensitivity to operations
- Respect of expertise
- Dedication to resilience

D. Culture of Safety

1. Background

The concept of safety culture originated outside healthcare in studies of high reliability organizations—organizations that consistently minimize adverse events despite carrying out intrinsically complex and hazardous work. High reliability organizations maintain a commitment to safety at all levels, from frontline providers to managers and executives. This commitment establishes a "culture of safety" that encompasses these 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
Improving the culture of safety within healthcare is an essential component of preventing or reducing errors and improving overall healthcare quality. Studies have documented considerable variation in perceptions of safety culture across organizations and job descriptions. In prior surveys, nurses have consistently 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 are complex, with poor teamwork and communication, a “culture of low expectations,” and authority gradients all playing a role.

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 undermine the safety culture.

2. Measuring and Achieving a Culture of Safety

Safety culture is generally measured by surveys of providers at all levels. Available validated surveys include the Agency for Healthcare Research and Quality’s (AHRQ’s) Patient Safety Culture Surveys and the Safety Attitudes Questionnaire. These surveys ask providers to rate the safety culture in their unit and in the organization as a whole, specifically with regard to the key features listed above. Versions of the AHRQ Patient Safety Culture Survey are available for hospitals and nursing homes, and AHRQ provides yearly updated benchmarking data from the hospital survey.

Safety culture has been defined and can be measured, and perceived poor safety culture has been linked to increased error rates. However, achieving sustained improvements in safety culture can be difficult. Specific measures, such as teamwork systems, administrative walk-arounds, and establishing unit-based safety teams have been associated with improvements in safety culture measurements.

The older culture of individual blame, which is traditional and in some organizations still dominant in healthcare, undoubtedly impairs the advancement of a safety culture. One issue is that, while “no blame” is the appropriate stance for many errors, certain errors do seem blameworthy and demand accountability. In an effort to reconcile the twin needs for no-blame and appropriate accountability, the concept of “just culture” was proposed by David Marx. In the just culture model, the focus is on identifying and addressing systems issues that lead individuals to engage in unsafe behaviors, while maintaining individual accountability by establishing zero tolerance for reckless behavior. It distinguishes between human error (e.g., slips), at-risk behavior (e.g., taking shortcuts), and reckless behavior (e.g., ignoring required safety steps), in contrast to an overarching “no-blame” approach still favored by some. In a just culture, the response to an error or near miss is predicated on the type of behavior associated with the error, not the severity of the event.

For example, reckless behavior in which safety norms are willfully ignored, such as someone refusing to perform a “time-out” prior to surgery, would merit tough, punitive action, even if no patients were harmed. In contrast, a person who made a good-faith 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 that subvert
established safety precautions, probably underestimate the risks of their actions. These persons are counseled or coached in the Just Culture Model (see below).

<table>
<thead>
<tr>
<th>Three Manageable Behaviors of the Just Culture Model</th>
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<tbody>
<tr>
<td>Human Errors</td>
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<tr>
<td>A product of our current system design and our behavioral choices</td>
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<tr>
<td>Manage through changes in:</td>
</tr>
<tr>
<td>• Choices</td>
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<td>• Processes</td>
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<td>• Procedures</td>
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<td>• Training</td>
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<td>• Design</td>
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<td>• Environment</td>
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<td>Console</td>
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3. Human Reliability Curve

The graphic below relates human reliability to human performance. Note that human performance never reaches 100 percent reliability:
Fundamentally, in order to improve safety culture, the underlying problem areas must be identified and solutions constructed to target each specific problem. Although many organizations measure safety culture at the institutional level, significant variations in safety culture may exist within an organization. For example, the perception of safety culture may be high in one unit within a hospital and low in another unit, or high among management and low among frontline workers. These variations likely contribute to the mixed record of interventions intended to improve safety climate and reduce errors.

Many determinants of safety culture depend on interprofessional relationships and other local circumstances, and thus change in safety culture occurs at a micro-system level. Some organizational behavior experts therefore believe that safety culture improvement needs to emphasize incremental changes to providers’ everyday behaviors, “growing new [safety] culture that can be layered onto the old.”

A safety coach/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 any safety-reporting system whereby safety incidents and near-miss events are reported and archived. In a safety-reporting system, the primary focus is on the patient, the system, and the event, in order to identify flawed systems and processes, and not on the individual (i.e., to assign blame and provide documentation for punitive action).

Healthcare practitioners are exposed to emotional turmoil caused by patient tragedies, such as a loss-of-life event, whether it is clinically anticipated or an error has occurred. A healthcare worker who is traumatized by, or unduly punished for, an error or adverse patient event is deemed to be a “second victim.” Such “second” victimization was extremely common in the traditional “blame-full” culture of American medicine that prevailed until the early part of the current century, wherein all errors and adverse events were blamed on one individual whenever possible, and such errors were viewed to have occurred as the result of that individual’s personal or characteristic weakness, ineptitude, or carelessness (and sometimes moral failure as well!). Second victims may exhibit signs similar to post-traumatic stress disorder. Many hospitals have developed internal programs to identify, console, and advocate on behalf of such “second victims.”

4. Understanding the Unique Aspects of Radiological Error

Two broad categories of radiologists’ errors have been identified:

- perceptual errors and
- cognitive (interpretive) errors.

Perceptual errors are far more common, accounting for between 60 and 80 percent of radiologists’ errors. These errors occur during the initial detection phase of image interpretation. A perceptual error is deemed to have occurred when an abnormality is determined to have been present in retrospect on a diagnostic image but was not seen by the interpreting radiologist at the time of the primary interpretation. The underlying causes for this type of error remain poorly understood; however, an increased incidence of perception error may be attributable to specific risk factors, such as poor conspicuity of the target lesion on the image, reader fatigue, an overly rapid pace of performing interpretations, distractions such as phone calls or other interruptions, and a phenomenon known as “satisfaction of search.” This
occurs when the finding of an abnormality on a study results in a second abnormality being overlooked, ostensibly because the radiologist is “satisfied” with the results of his or her image search. Most perceptual errors, however, are without any obvious cause. All too often a finding that is readily apparent in retrospect is inexplicably missed.

The consistency of experimental results on perceptual errors, reported worldwide by radiologists at all levels of training and experience working in a wide variety of clinical settings and across all imaging modalities, argues strongly against the idea that the radiologists who make such errors are to blame for being careless, sloppy, negligent, or underperforming in some key way; rather, the phenomenon of radiologists’ underperception and misperception appears to be a feature of the extremely complex “system” in which radiologists operate.

5. Tools for Evaluating Risk and Adverse Events

   a. Root cause analysis. Root cause analysis (RCA) is a structured method used to analyze serious adverse events. Initially developed to analyze industrial accidents, RCA is now widely deployed as an error analysis tool in healthcare. A central tenet of RCA is identifying underlying problems that increase the likelihood of errors while avoiding the trap of focusing on mistakes by individuals. The goal of RCA is thus to identify both active errors (errors occurring at the point of interface between humans and a complex system) and latent errors (the hidden problems within healthcare systems that contribute to adverse events).

   RCAs should generally follow a pre-specified protocol that begins with data collection and reconstruction of the event in question through record review and participant interviews. A multidisciplinary team should then analyze the sequence of events leading to the error, with the goals of identifying how the event occurred (through identification of active errors) and why the event occurred (through systematic identification and analysis of latent errors). The ultimate goal of RCA, of course, is to prevent future harm by eliminating the latent errors that so often underlie adverse events.

   As an example, a classic paper describes a patient who underwent a cardiac procedure intended for another, similarly named, patient. A traditional analysis might have focused on assigning individual blame, perhaps to the nurse who sent the patient for the procedure despite the lack of a consent form. However, the subsequent RCA revealed 17 distinct errors, ranging from organizational factors (the cardiology department used a homegrown, error-prone scheduling system that identified patients by name rather than by medical record number) to work environment factors (a neurosurgery resident suspected the mistake but did not challenge the cardiologists because the procedure was at a technically delicate juncture). This led the hospital to implement a series of systematic changes to reduce the likelihood of a similar error in the future.

   RCA is a widely used term, but it can be misleading since many adverse events actually have more than one “root cause.” Multiple errors and system flaws often must intersect for a critical incident to reach the patient. Labeling one or even several of these factors as “causes” may place undue emphasis on specific components and obscure the overall relationships among different aspects of the system.
In root cause analysis, a “quick fix” may be implemented early in the process to rapidly reduce the risk of another similar error. The quick fix is done even though it may not be a definitive solution to a root cause. In fact, the quick fix can be based on the proximate cause (an obvious or “close” cause of an event) of the accident in question. In the example above, the proximate cause of the error was the nurse sending the unintended, though similarly named, patient to undergo a procedure; the root causes were the underlying organizational factors. An example of a “quick fix” in this situation might be to immediately implement a requirement for a second means of identifying patients prior to procedures, such as requiring a DOB in addition to a full name. While this will prevent an identical error from occurring and can be implemented quickly, this intervention does not address the root cause(s).

<table>
<thead>
<tr>
<th>Factors that may lead to errors</th>
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<tbody>
<tr>
<td>Type of Factor</td>
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<tr>
<td>Institutional/regulatory</td>
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<tr>
<td>Organizational/management</td>
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<td>Work environment</td>
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<td>Team environment</td>
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<tr>
<td>Staffing</td>
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<tr>
<td>Task related</td>
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<tr>
<td>Patient characteristics</td>
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b. Basic Concepts of Evaluation: Precision vs. Accuracy

- Precision – How variable is the test result in ANY given situation?
- Accuracy – How variably does the result reflect the desired diagnosis?
These concepts can be illustrated by the following figures. In considering a process improvement, it must be borne in mind that interventions to improve precision may not improve accuracy, and vice-versa.

6. Periprocedural Care

a. Patient Identifiers. Patient identification is critical to ensure that the right patient receives the right treatment, medication, invasive/non-invasive procedure, and blood products, as well as to reduce the chance of unnecessary radiation exposure, etc. Two patient identifiers should be used before a procedure. Identifiers can include patient name, assigned identification number, telephone number, or other person-specific identifier (date of birth, government-issued photo identification, and last four digits of the social security number). The patient’s location or room number cannot be used. Sources of patient identifiers may include the patient, a relative, a guardian, a domestic partner, or a healthcare provider who has previously identified the patient.

b. Patient assessment. Interventional image-guided procedures and some less invasive diagnostic imaging procedures may require specific patient assessment before the procedure. Such assessment may be done by the radiologist performing the procedure, a qualified assistant working with that radiologist (such as a nurse practitioner or physician’s assistant), or the referring provider. The assessment may include a focused history and physical examination, with an assessment of risk factors for sedation if needed, and the performance of relevant pre-procedural laboratory tests or other diagnostic tests.

c. Informed Consent. Informed consent is required for invasive image-guided procedures and may be required or at least advisable for some diagnostic imaging procedures. Specific procedures for which informed consent is required may be determined at a national level, such as by The Joint Commission, or locally, such as by state law or local institutional policy. Furthermore, apart from any 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.

The ACR-SIR Practice Parameter on Informed Consent for Image-Guided Procedures notes that “informed consent is a process and not the simple act of signing a formal document.”
However, a consent form is commonly used to document the physician’s discussion with the patient. Consent can also be documented by a note in the patient’s medical record, recorded on videotape, or by another similar permanent modality. The physician or other healthcare provider performing the procedure, or other qualified personnel assisting that person, should obtain consent from the patient or the patient’s legal representative. However, the final responsibility for answering the patient’s questions and addressing any patient concerns rests with the physician or other provider performing or supervising the procedure.

Elements of informed consent include a discussion of the proposed procedure, including its benefits, potential risks (every conceivable risk does not need to be relayed to the patient), and reasonable alternatives to the procedure. The patient should also be informed of the risks of refusing the procedure. Consent should not be obtained in a coercive manner, and many institutions require that consent be obtained before the patient enters the procedure room. 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.

The necessity for acute pain relief may need to be balanced against the requirements of the consent process. When the patient is not able to give valid consent due to short-term or long-term mental incapacity, 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 and consent cannot be obtained from the patient or a representative, the physician may provide treatment or perform a procedure “to prevent serious disability or death or to alleviate great pain or suffering.”

d. Medication Reconciliation. Medication reconciliation is required for patients admitted to a hospital who commonly receive new medications or have changes made to their existing medications. Hospital-based clinicians also may not be able to easily access patients’ complete medication lists, or may be unaware of recent medication changes. As a result, the new medication regimen prescribed at the time of discharge may inadvertently omit needed medications, unnecessarily duplicate existing therapies, or contain incorrect dosages.

Such unintended inconsistencies in medication regimens may occur at any point of transition in care (e.g., transfer from an intensive care unit to a general ward), as well as at hospital admission or discharge. Studies have shown that unintended medication discrepancies occur in nearly one-third of patients at admission, a similar proportion at the time of transfer from one site of care to another within a hospital, and in 14 percent of patients at hospital discharge. Medication reconciliation refers to the process of avoiding such inadvertent inconsistencies across transitions in care by reviewing the patient’s complete medication regimen at the time of admission, transfer, and discharge and comparing it with the regimen being considered for the new setting of care.

The six rights of medication administrations are right patient, right medication, right route, right dose, right time, and right documentation.

   a. *Conduct a pre-procedure verification process. Address missing information or discrepancies before starting the procedure.*

      i. Verify the correct procedure, for the correct patient, at the correct site.
      ii. When possible, involve the patient in the verification process.
      iii. Identify the items that must be available for the procedure.
      iv. Use a standardized list to verify the availability of items for the procedure. (It is not necessary to document that the list was used for each patient.) At a minimum, these items should include:
         - Relevant documentation
           Examples: history and physical, signed consent form, and pre-anesthesia assessment
         - Labeled diagnostic and radiology test results that are properly displayed
           Examples: radiology images and scans, pathology reports, and biopsy reports
         - Any required blood products, implants, devices, and special equipment
      v. Match the items that are to be available to the patient in the procedure area.

   b. *Mark the procedure site.* At a minimum, mark the site when there is more than one possible location for the procedure, and when performing the procedure in a different location could harm the patient.

      i. For spinal procedures, mark the general spinal region on the skin. Special intraoperative imaging techniques may be used to locate and mark the exact vertebral level.
      ii. Mark the site before the procedure is performed.
      iii. If possible, involve the patient in the site-marking process.
      iv. A licensed independent practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed should mark the site. In limited circumstances, site marking may be delegated to some medical residents, physician assistants (PAs), or advanced practice registered nurses (APRNs).
      v. Ultimately, the licensed independent practitioner is accountable for the procedure, even when delegating site marking.
      vi. The mark is unambiguous and is used consistently throughout the organization.
      vii. The mark is made at or near the procedure site.
      viii. The mark is sufficiently permanent to be visible after skin preparation and draping.
      ix. Adhesive markers are not the sole means of marking the site.
      x. For patients who refuse site marking or when it is technically or anatomically impossible or impractical to mark the site (see examples below), use your organization’s written alternative process to ensure that the correct site is operated on. Examples of situations that involve alternative processes:
         - Mucosal surfaces or perineum
         - Minimal-access procedures treating a lateralized internal organ, whether percutaneous or through a natural orifice
         - Interventional procedure cases for which the catheter or instrument insertion site is not predetermined. Examples include cardiac catheterization and pacemaker insertion.
• Teeth
• Premature infants, for whom the mark may cause a permanent tattoo

c. **Perform a time-out.** The procedure should not start until all questions or concerns are resolved.
   i. Conduct a time-out immediately before starting the invasive procedure or making the incision.
   ii. A designated member of the team starts the time-out.
   iii. The time-out is standardized.
   iv. The time-out involves the immediate members of the procedure team: the individual performing the procedure, anesthesia providers, circulating nurse, operating room technician, and others who will be actively participating in the procedure from the beginning.
   v. All relevant members of the procedure team actively communicate during the time-out.
   vi. During the time-out, the team members agree, at a minimum, on the following:
      • Correct patient identity
      • Correct site
      • Procedure to be done
   vii. When the same patient has two or more procedures, if the person performing the procedure changes, another time-out needs to be performed before starting each procedure.
   viii. Document the completion of the time-out. The organization determines the amount and type of documentation.

8. **Hand Washing**

Many procedures require some level of cleanliness or sterility. This may be as simple as hand washing by the physician and other personnel involved in the procedure or more advanced, including sterile cleansing and draping of the procedural site and use of protective garb such as sterile gloves and face masks. For more invasive procedures such as central venous catheter insertion, “maximum sterile barrier technique” should be used. As defined by the National Quality Measures Clearinghouse, this requires cap, mask, sterile gown, sterile gloves, a large sterile sheet, hand hygiene, and cutaneous antisepsis.

9. **Sedation**

**Continuum of Sedation:** Various levels of sedation and/or analgesia may be needed for some diagnostic imaging procedures (particularly MRI) and especially image-guided interventional procedures. However, specific risks associated with altering the consciousness and protective reflexes of a patient must be considered to safely sedate a patient. In addition, particularly in diagnostic imaging procedures, the patients who are in greatest need of sedation may be those who are at greatest risk from it, including children, elderly patients, and patients with co-morbidities.

The American College of Radiology and the Society of Interventional Radiology have collaborated on the ACR-SIR Practice Parameter for Sedation/Analgesia, which addresses these issues. This
Practice Parameter also draws on publications of the American Society of Anesthesiologists and the American Academy of Pediatrics.

The Joint Commission and the American Society of Anesthesiologists have defined various levels of sedation, analgesia, and anesthesia, which are listed below. However, a key point to recognize is that these “levels” are truly 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.

Levels of sedation/analgesia/anesthesia are defined by The Joint Commission and the American Society of Anesthesiologists as follows:

a. **Minimal Sedation or Anxiolysis.** The administration of medications for the reduction of anxiety and creation of a drug-induced state 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.

b. **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.

c. **Deep Sedation/Analgesia.** A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

d. **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.

Minimal sedation or anxiolysis is usually achieved with oral medications, whereas the deeper levels are usually achieved with intravenous or inhaled medications. Administration of anesthesia is generally limited to anesthesiologists and nurse anesthetists. Some interventional radiologists may be trained to provide deep sedation, but that is also more commonly administered by anesthesiologists and nurse anesthetists. Moderate sedation is potentially within the scope of practice of radiologists, particularly those who perform interventional procedures, but most hospitals have specific training and experience requirements and require specific privileges in sedation.

When a patient is considered for sedation by a non-anesthesia provider such as a radiologist, the patient must be screened by that provider or another qualified provider to determine if the patient has 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, 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 who are ASA Class I and II would generally qualify for moderate sedation. Those in Class III and IV or with other significant risk factors may require additional consideration, including possibly consultation with anesthesiology or performance of sedation by an anesthesiologist or anesthetist. Patients in Class V should not be sedated by non-anesthesiologists.

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 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 to enable safe administration and have the ability to recognize and initiate treatment for adverse reactions, including the use of reversal agents. A key point related to reversal agents is that their duration of effect may be shorter than the sedating agent. Therefore, there is a risk of relapse into a deeper level of sedation. Recommended discharge criteria suggest that the level of consciousness and vital signs should return to acceptable levels for a period of two hours from the time of administration of the reversal agent before monitoring ends.

10. 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; non-imaging 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 for Safe MR Practices.

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:
- Zone I: Access is unrestricted, but this is the area through which patients and others access the controlled MR environment.

- Zone II: This is the interface between the uncontrolled, publicly accessible 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.

- 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. It is important to remember that the magnetic field is three-dimensional. Thus, the restricted area may extend not only in all directions on the same floor of the facility but also potentially through the floor and/or ceiling to adjacent floors.

- 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 due to the strong magnetic field. Access to Zone IV should be under direct observation of MR personnel. When a medical emergency occurs, the patient should immediately be removed to a magnetically safe location while resuscitation or stabilization is begun.

Personnel working within Zone III should have specific education on MR safety and pass an MR safety screening process. Any other people entering Zone III also should be appropriately screened. 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 prior imaging studies such as CT or MR 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. Published information is available regarding the MR safety of most medical implants. Screening is more difficult when the patient is unconscious, unresponsive, 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. Patients should remove all metallic belongings and devices and ideally should wear a site-supplied gown free of metallic fasteners. Other MRI-related quality and safety concerns include the following:

a. **Quench events and other unique risks posed by the magnetic field and MRI operation.** 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. Emergency venting systems are required to protect patients and operators from asphyxiation; however, all personnel must evacuate immediately in the event of a quench. Since it is the displacement of oxygen in a quench event that can lead to asphyxiation, oxygen levels are monitored in the MRI scanner at all times. In the event of a tank burst or
helium leak, again, the liquid helium cryogen will expand as a gas, which will flood the scanner room; under such circumstances, the room must also be evacuated.

b. **CPR.** Because of the strong magnetic field, it is generally not advisable to perform CPR in proximity to the magnetic core. If a patient needs CPR, the patient must first be taken out of the MRI scanner room.

c. **Heated metal loops of wire or patches of metal** may be rapidly heated by radio frequency pulses during normal operation of an MRI system. Due to 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 metal that may cause burns. Occasionally, large tattoos may similarly undergo heating from a similar mechanism, and application of an ice pack may be necessary to reduce the risk of skin burning.

11. Contrast Reactions and Management

a. **Iodinated Contrast Media.** Most patients who receive iodinated contrast media will have no ill effects. When a reaction does occur, it is usually mild and self-limited. The term “low osmolality” includes contrast media with osmolality approximately twice that of human serum and iso-osmolality media, which have osmolality approximately equal to human serum. Large studies have shown that with use of low osmolality contrast media, the overall incidence of reactions is 0.2-0.7 percent. However, rarely severe and even life-threatening reactions may occur. The incidence of such reactions with intravenous injection of low osmolality contrast media is 0.01-0.02 percent. The ACR Manual on Contrast Media lists three goals for contrast administration: “1) to assure that the administration of contrast is appropriate for the patient and the indication; 2) to minimize the likelihood of a contrast reaction; and 3) to be fully prepared to treat a reaction should one occur.”

i. **Screening.** Safe administration of contrast begins with a focused patient history to identify factors that may increase the likelihood of a reaction or may contraindicate the administration of contrast. The greatest risk factor for an allergic-like reaction to contrast is a history of a prior reaction to contrast, which is associated with a five times increased risk of subsequent reaction. Any other allergic history, but particularly a history of major anaphylactic reaction, may increase the patient’s risk, but some specific allergies, such as to shellfish, are no longer considered to be highly significant. However, atopy results in a two- to three-times increased risk of contrast reaction. Asthma may also increase the risk of contrast reaction. Significant cardiac disease also imparts an increased risk. There is controversy as to whether patient anxiety increases the risk of a contrast reaction.

ii. **Premedication.** Premedication may be considered for patients who are considered at increased risk of an acute allergic-like reaction to contrast. Neither the mechanism of anaphylactoid reactions nor the mechanism of action of commonly used corticosteroid medications is fully understood. However, most reactions (about 90 percent) are associated with release of histamine and other mediators from circulating basophils and eosinophils. A minority of reactions (about 4 percent) may be IgE mediated and thus truly allergic. Intravenous methylprednisolone can reduce the number of circulating basophils and eosinophils within 1 hour, with maximum effect reached by 4 hours.
Histamine in sedimented leukocytes is reduced by 4 hours, with maximal effect by 8 hours. However, reactions may also occur related to administration of corticosteroids, especially when given intravenously. Thus, the preferred premedication regimens use oral medications with at least 6 hours from initial administration to contrast media injection. Supplemental administration of an H-1 antihistamine, such as diphenhydramine (Benadryl®), may reduce the frequency of urticaria, angioedema, and respiratory symptoms. The osmolality of the contrast media also affects the likelihood of a reaction. Hyperosmolality stimulates release of histamine from basophils and mast cells. Increased size and complexity of the contrast molecule may also potentiate the release of histamine. Most facilities now use low osmolality contrast media, which also reduce non-idiiosyncratic physiologic reactions such as heat sensation.

The two most frequently used elective premedication regimens as listed in the ACR Manual on Contrast Media are:

- **Prednisone:** 50 mg by mouth at 13 hours, 7 hours, and 1 hour before contrast media injection, plus Diphenhydramine (Benadryl®): 50 mg intravenously, intramuscularly, or by mouth 1 hour before contrast medium; or

- **Methylprednisolone (Medrol®):** 32 mg by mouth 12 hours and 2 hours before contrast media injection. An antihistamine (as above) can also be added to this regimen. If the patient is unable to take oral medication, 200 mg of hydrocortisone intravenously may be substituted for oral prednisone.

When contrast administration is required in a shorter time frame, there is less evidence of efficacy of premedication and less agreement on the optimal regimen since IV steroids have not been shown to be effective when administered fewer than 4 to 6 hours prior to contrast injection. The ACR Manual on Contrast Media lists the following options, in decreasing order of desirability:

- **Methylprednisolone sodium succinate (Solu-Medrol®):** 40 mg, or hydrocortisone sodium succinate (Solu-Cortef®) 200 mg, intravenously every 4 hours (q4h) until contrast study is required, plus diphenhydramine 50 mg IV 1 hour prior to contrast injection; or

- **Dexamethasone sodium sulfate (Decadron®):** 7.5 mg or betamethasone 6.0 mg intravenously q4h until contrast study must be done in patent with known allergy to methylprednisolone, aspirin, or non-steroidal anti-inflammatory drugs, especially if asthmatic. Also, diphenhydramine 50 mg IV 1 hour prior to contrast injection; or

- **Omit steroids entirely and give diphenhydramine 50 mg IV.** Corticosteroids should be used with caution in some groups of patients, including those with diabetes, uncontrolled hypertension, tuberculosis, systemic fungal infections, peptic ulcer disease, and diverticulitis.
It is important to note that the proven benefit of such regimens is reduction in minor reactions. There is no proof that premedication protects against severe life-threatening reactions, but the rarity of such reactions would make it difficult to prove a benefit. However, even with appropriate use of an accepted premedication regimen, reactions may occur in at-risk patients. Additionally, many reactions occur in patients with no demonstrable risk factors. Thus, physicians administering contrast media must be able to treat a reaction should one occur.

Special consideration should be given for the use of IV contrast 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 prior to anticipated radioiodine treatment, as the iodine load in the contrast bolus will effectively “block” the thyroid gland and render the treatment ineffective.

iii. Treatment. When a reaction does occur, rapid recognition, patient assessment, and diagnosis are important to allow effective treatment. The level of consciousness, the appearance of the skin, quality of phonation, lung auscultation, blood pressure, and heart rate assessment will allow the responding physician to quickly determine the severity of a reaction. These findings also allow for the proper diagnosis of the reaction, including urticaria, facial or laryngeal edema, bronchospasm, hemodynamic instability, vagal reaction, seizures, and pulmonary edema. Mild reactions usually do not require medical treatment but may progress to a more severe reaction. Most moderate and all severe reactions require prompt and aggressive treatment. Some reactions are allergic-like, while others are physiologic.

The ACR Manual on Contrast Media classifies acute contrast reactions as follows:

Mild – Signs and symptoms are self-limited without evidence of progression. Examples of mild allergic-like reactions include limited urticaria or pruritus, limited cutaneous edema, limited “itchy” or “scratchy” throat, nasal congestion, and sneezing, conjunctivitis, or rhinorrhea. Examples of mild physiologic reactions include limited nausea and vomiting, transient flushing, warmth or chills, headache, dizziness, anxiety, altered taste, mild hypertension, and vasovagal reaction that resolves spontaneously.

Moderate – Signs and symptoms are more pronounced and commonly require medical management. Examples of moderate allergic-like reactions include diffuse urticaria or pruritus, diffuse erythema with stable vital signs, facial edema without dyspnea, throat tightness of hoarseness without dyspnea, and wheezing or bronchospasm with mild or no hypoxia. Examples of moderate physiologic reactions include protracted nausea and vomiting, hypertensive urgency, isolated chest pain, and vasovagal reactions that require and are responsive to treatment.

Severe – Signs and symptoms are often life-threatening and can result in permanent morbidity or death if not managed appropriately. Note that cardiopulmonary arrest is a nonspecific end-stage result of many types of severe reactions. Pulmonary edema is a rare severe reaction. Cardiogenic pulmonary edema can occur in patients with tenuous cardiac reserve. Non-cardiogenic pulmonary edema can occur in patients with normal cardiac function and can be allergic-like or physiologic.
Examples of severe allergic-like reactions include diffuse edema or facial edema with dyspnea, diffuse erythema with hypotension, laryngeal edema with stridor and/or hypoxia, wheezing or bronchospasm with significant hypoxia, and anaphylactic shock (hypotension and tachycardia). Examples of severe physiologic reactions include vasovagal reaction unresponsive to treatment, arrhythmia, convulsions or seizures, and hypertensive emergency.

Management of contrast reactions depends on the nature of the reaction and its severity, as discussed above. The ACR Manual on Contrast Media lists the recommendations below for management of contrast reactions and other emergencies in adults. There are separate recommendations for management of these conditions in children.

Hives (Urticaria)
- No treatment is needed in most cases.
- If symptomatic, consider diphenhydramine (Benadryl®) 25 to 50 mg PO for mild reaction, or give by IM or IV route if moderate or severe. Alternatively, for mild or moderate reactions, may use fexofenadine (Allegra) 180 mg PO.
- If severe, give 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 to 3 mL of 1:10,000 dilution slowly into a running IV infusion of saline.
- Monitor vital signs and maintain IV access in moderate and severe cases.

Diffuse Erythema
- Preserve IV access, monitor vitals, and use pulse oximeter.
- Give O₂ 6 to 10 liters/min (via mask).
- If the patient is normotensive, no further treatment is usually needed.
- If the patient is hypotensive, give 1000 mL of IV fluids rapidly, either 0.9% normal saline or Lactated Ringers.
- If hypotension is profound or does not respond to IV fluids, consider epinephrine IV (1:10,000) 1 to 3 mL slowly into a running infusion of IV saline. Repeat as needed at 5- to 10-minute intervals up to 10 mL (1 mg) total. Only 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 emergency response team or 911 based on the severity of the reaction and the completeness of response.

Laryngeal Edema
- Preserve IV access, monitor vitals, and use pulse oximeter.
- Give O₂ 6 to 10 liters/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 to 3 mL (= 0.1 to 0.3 mg) slowly into a running infusion of IV saline.
- Repeat epinephrine as needed up to a maximum of 1 mg.
- Consider calling emergency response team or 911 based on the severity of the reaction and the completeness of response.
**Bronchospasm**
- Preserve IV access, monitor vitals, and use pulse oximeter.
- Give O₂ 6 to 10 liters/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 to 3 mL (= 0.1 to 0.3 mg) slowly into a running infusion of IV saline.
- Repeat epinephrine as needed up to a maximum of 1 mg.
- In severe cases, IV route of epinephrine administration is preferred.
- Consider calling emergency response team or 911 based on the completeness of response.

**Hypotension, any cause (systolic blood pressure < 90 mm Hg)**
- Preserve IV access, monitor vitals, and use pulse oximeter.
- Elevate legs at least 60 degrees (Trendelenburg position).
- Give O₂ 6 to 10 liters/min (via mask).
- Consider rapid IV administration of 1000 mL of IV fluids, 0.9% normal saline or Lactated Ringers.

**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 slowly, followed by saline flush.
- May repeat atropine up to a total dose of 3 mg.
- Consider calling the emergency response team or 911.

**Hypotension with Tachycardia (pulse > 100 bpm) (Anaphylactoid Reaction)**
- If hypotension persists after basic treatment listed above, for any cause of hypotension, give epinephrine IV (1:10,000) 1 to 3 mL slowly into a running infusion of IV saline. Can repeat as needed up to 10 mL (1 mg) total. Alternately, epinephrine could be given, 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 the emergency response team or 911 based on the severity of the reaction and the completeness of the response.

**Hypertensive Crisis (diastolic bp > 120 mm Hg; systolic bp > 200 mm Hg; symptoms of end organ compromise)**
- Preserve IV access, monitor vitals, and use pulse oximeter.
- Give O₂ 6 to 10 liters/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 pulse oximeter.
• Give O₂ 6 to 10 liters/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 patient on side to avoid aspiration.
  Suction airway as needed.
• Preserve IV access, monitor vitals, and use pulse oximeter.
• Give O₂ 6 to 10 liters/min (via mask).
• If unremitting, call emergency response team. Administer lorazepam 2 to 4 mg IV slowly to maximum dose of 4 mg.

**Hypoglycemia**
• Preserve IV access.
• Give O₂ 6 to 10 liters/min (via mask).
• If 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 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 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 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 as per American Heart Association protocols.
• Defibrillate if available as indicated.
• May administer epinephrine IV (1:10,000) 10 mL between 2-minute cycles.
Reaction rebound prevention
- IV corticosteroids are not useful in acute treatment of any reaction.
- May help prevent a short-term recurrence of an allergic-like reaction and may be considered prior to transportation of a patient having a severe allergic-like reaction 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.

**Abbreviations**
- IM = intramuscular
- IV = intravenous
- PO = orally

b. Post-contrast Acute Kidney Injury and Contrast-induced Nephropathy. Post-contrast acute kidney injury (PC-AKI) is “a general term used to describe a sudden deterioration in renal function that occurs within 48 hours following the intravascular administration of iodinated contrast medium,” which may occur whether or not the contrast is actually determined to have caused the deterioration in renal function. PC-AKI is a correlative diagnosis. Contrast-induced nephropathy (CIN) is defined as “a sudden deterioration in renal function that is caused by intravascular administration of iodinated contrast medium” and is a subset of PC-AKI. CIN is a causative diagnosis.

“At the current time, it is the position of ACR Committee on Drugs and Contrast Media that CIN is a real, albeit rare, entity.” Very few published studies have adequately isolated patients in whom administration of iodinated contrast media is the only potentially nephrotoxic event. Also, many older studies did not include a control group of patients who did not receive contrast media. Finally, the route of contrast administration is important, with arterial administration representing a greater risk than intravenous administration. Despite the controversies and uncertainties, caution is still advised in administering contrast to some patients, especially those with preexisting renal disease.

There is no single accepted criterion to diagnose CIN. A common historical criterion is an absolute increase in the serum creatinine from baseline of at least 0.5 mg/dL, but other definitions require an absolute increase of up to 2.0 mg/dL. Another approach is to assess the percentage of change in the baseline serum creatinine, generally defined as a 25 to 50 percent increase. A more recent definition of acute kidney injury comes from the Acute Kidney Injury Network (AKIN). By AKIN criteria, acute kidney injury is diagnosed if any one of the following occurs within 48 hours after any nephrotoxic event: 1) absolute serum creatinine increase of at least 0.3 mg/dL, or 2) percentage increase in serum creatinine of at least 50 percent (1.5 fold above baseline), or 3) urine output decreased to 0.5 mL/kg/hour for at least 6 hours. Note that this system has not been directly studied with respect to CIN.

The usual clinical course of CIN is a rise in serum creatinine within 24 hours of contrast administration, which peaks at about 4 days and returns to baseline within 7 to 10 days. Development of permanent renal dysfunction is unusual.
Just as there is no single accepted definition of CIN, there is also no agreement on the pathogenesis of CIN. Suggested etiologies include renal hemodynamic changes (vasoconstriction) and direct tubular toxicity, either by an osmotic or chemotoxic mechanism. While there is evidence of a dose-related risk of CIN in arterial administration for angiocardiography, there are conflicting data as to whether dose is a risk factor with intravenous administration.

The frequency of CIN is also difficult to determine, partly related to the lack of agreement on a single clinical definition. However, most studies have shown a risk of CIN of less than 10 percent, even in patients with moderate chronic kidney disease. In addition, recent studies have suggested that many cases of deterioration of renal function historically classified as CIN may be due to other coexistent and confounding factors. Newhouse et al. studied more than 30,000 patients in a single institution who did not receive iodinated contrast and found an increase in serum creatinine of at least 25 percent in more than half the patients, and of at least 0.4 gm/dL in more than 40 percent. Had those patients received contrast, the changes might have been attributed to the contrast.

Very few studies of CIN included a control group of patients who did not receive contrast. The authors of Version 10.1 of the ACR Manual on Contrast Media found only eight such studies, and only one of those (Bruce et. al) showed a greater risk of post-contrast serum creatinine elevation compared to the control group—and in that study, only in patients with a baseline creatinine value of 1.8 mg/dL or more. In a more recent study, McDonald et al. studied more than 50,000 patients undergoing enhanced or unenhanced body CT scans over 11 years. Although the percentage of patients defined as having acute kidney injury after a CT scan increased with their baseline serum creatinine from less than 3 percent in those with baseline creatinine of < 1.5 mg/dL to more than 11 percent in those with baseline creatinine > 2.0 mg/dL, the odds ratio of developing acute kidney injury was lower in the group who received contrast; however, the difference was statistically significant only for the entire group of patients and not significant with various score adjustments. Four studies with greater than 10,000 patients, each trying to address selection bias by propensity score adjustment and matching, have found much lower incidences of CIN than was commonly believed.

Risk factors for CIN are also controversial, although there is consensus that preexisting renal insufficiency does confer an increased risk. However, the level at which the risk is significant is also controversial. The ACR Manual on Contrast Media suggests eGFR of < 30 mL/min/1.73 m² in patients with chronic, stable renal insufficiency. Acute kidney injury is also considered a risk factor, and in that situation, neither eGFR nor serum creatinine is an accurate measure of actual renal function. Other proposed but less certain risk factors include diabetes mellitus, dehydration, cardiovascular disease, diuretic use, advanced age, multiple myeloma, hypertension, hyperuricemia, and multiple administrations of iodinated contrast media within 24 hours. Patients who have progressed to end-stage anuric renal disease are not at risk of CIN, although the osmotic load can present its own problems related to increased intravascular volume. “Unless an unusually large volume of contrast medium is administered, or there is substantial underlying cardiac dysfunction, there is no need for urgent dialysis after intravascular iodinated contrast medium administration.”
Given these various controversies about CIN, it is difficult to define which patients should be screened prior to contrast administration and which patients would benefit from pretreatment. The *ACR Manual on Contrast Media* suggests obtaining a serum creatinine measurement in patients with one or more of the following criteria: 1) age > 60 years; 2) history of renal disease, including dialysis, kidney transplant, single kidney, renal cancer, or renal surgery; 3) hypertension requiring medical therapy; 4) diabetes mellitus; or 5) use of metformin or metformin-containing drugs. (Note that metformin is not a risk factor for development of CIN, but patients who develop renal failure while taking metformin are at risk of developing lactic acidosis.) If the patient’s condition is stable, a creatinine value within 30 days of contrast administration is generally considered sufficient.

In patients considered at increased risk of CIN, several strategies should be considered. Since most iodinated contrast is currently administered for CT scans, alternatives include performing only noncontrast scans or using other modalities such as ultrasound or MRI (usually without contrast due to risk of NSF). When contrast is deemed necessary and appropriate, use of the lowest dose possible may be helpful, although there is no clear proof of dose-related risk with IV administration of iodinated contrast. In patients with renal insufficiency, there is evidence that low-osmolality contrast media (LOCM) are less nephrotoxic than high-osmolality contrast media (HOCM), but HOCM are seldom used in current clinical practice in the United States.

Various pretreatment strategies have been investigated for patients felt to be at risk of CIN. Of these, the most proven is intravenous hydration, preferably with isotonic fluids such as 0.9 percent saline or Lactated Ringer’s. A suggested protocol per the *ACR Manual on Contrast Media* is infusion at 100 mL/hr for 6 to 12 hours before contrast administration and 4 to 12 hours after contrast administration. However, as with other studies related to CIN, most of the data relate to cardiac angiography.

Data are mixed regarding the use of IV sodium bicarbonate and N-acetylcysteine, but the *ACR Manual on Contrast Media* does not believe that these strategies are superior to IV hydration. Other strategies that have been investigated but have even less proven efficacy include mannitol (an osmotic diuretic), furosemide (a loop diuretic), theophylline, endothelin-1, and fenoldopam. In regard to these latter agents, the *ACR Manual on Contrast Media* states: “Neither mannitol nor furosemide is recommended for CIN risk reduction.”

c. **MR Contrast Agents.** Acute adverse reactions to gadolinium-based contrast media (GBCM) used in MRI are less frequent than reactions to iodinated contrast media. The *ACR Manual on Contrast Media* states: “The adverse event rate for GBCM administered at clinical doses (0.1–0.2 mmol/kg for most GBCM) ranges from 0.07% to 2.4%.” The vast majority of these reactions are mild, including coldness at the injection site, nausea with or without vomiting, headache, warmth or pain at the injection site, paresthesias, dizziness, and itching. Reactions resembling an ‘allergic’ response are very unusual and vary in frequency from 0.004 percent to 0.7 percent. Rash, hives, or urticaria are the most frequent of this group, and, very rarely, there may be bronchospasm. Severe, life-threatening anaphylactoid or nonallergic anaphylactic reactions are exceedingly rare (0.001 to 0.01 percent). In an accumulated series of 687,000 doses, there were only five severe reactions. In another survey based on 20 million administered doses, there were 55 cases of severe reactions. Fatal reactions to gadolinium chelate agents occur but are extremely rare.”
Patients with a prior reaction to GBCM have an eight-time increased risk of a subsequent reaction, which may be more severe than the first reaction. Other risk factors include asthma and other allergies, including allergy to iodinated contrast media. Patients with these risk factors may have a risk of reaction of up to 3.7 percent. While information about the efficacy of preventive measures is limited, suggested measures include using a different gadolinium compound and premedicating the patient with corticosteroids and antihistamines. Treatment of contrast reactions is similar to that for iodinated contrast media.

GBCM are 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 to time. With prolonged presence of the chelate in the amniotic fluid, there is an increased potential of dissociation of the potentially toxic gadolinium ion. Although the risk to the fetus is unknown, due to the potential risk, GBCM should only be administered to pregnant patients in carefully selected situations when there is felt to be overwhelming benefit to their use.

d. *Nephrogenic Systemic Fibrosis (NSF).* An additional consideration with use of GBCM is the risk of Nephrogenic Systemic Fibrosis (NSF). The ACR Manual on Contrast Media defines NSF as “a fibrosing disease, primarily identified in the skin and subcutaneous tissues but also known to involve other organs, such as the lungs, esophagus, heart, and skeletal muscles. Initial symptoms typically include skin thickening and/or pruritus. Symptoms and signs may develop and progress rapidly, with some affected patients developing contractures and joint immobility. In some patients, the disease may be fatal.”

Although there are continuing controversies and uncertainties regarding NSF, it is now generally accepted that exposure to GBCM in the setting of acute kidney injury or severe chronic kidney disease is needed for development of NSF. In patients with severe chronic kidney disease (Stage 4, eGFR 15-29 mL/min/1.73 m²) or end-stage chronic kidney disease (Stage 5 eGFR < 15 mL/min/1.73 m²), there is an estimated 1 to 7 percent risk of developing NSF after one or more exposures to at least some GBCM. However, most patients who developed NSF had end-stage chronic kidney disease and were on dialysis. There is only one published case report of NSF in a patient with eGFR above 30 mL/min/1.73 m² in absence of acute kidney injury. Between 12 and 20 percent of cases of NSF occurred in patients with acute kidney injury, often, but not always, superimposed upon chronic kidney disease. Higher doses and multiple doses of GBCM are believed to increase the risk of NSF, but cases have occurred with single administration of a standard dose of GBCM.

Other postulated risk factors for NSF include 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, but none of these have been confirmed as true co-factors.

Particularly, there is controversy regarding the relative risk of the various available GBCM. While there are confounding factors, such as the relative market share of the agents and their use in higher doses, some agents do appear to have a higher risk of NSF, perhaps related to the likelihood of dissociation of the gadolinium ion from its chelate. The free
gadolinium may then bind with an anion such as phosphate, with deposition of the resulting insoluble precipitate in various tissues where a fibrotic reaction occurs.

Since the recognition of NSF and its relationship to GBCM administration, the incidence of GSF has fallen to close to zero, primarily by avoiding or severely limiting administration of GBCM to patients on dialysis, with an eGFR < 30 mL/min/1.73 m², or with acute kidney injury. This requires screening of patients. This GFR is lower than the usual threshold levels that trigger concern for CIN, discussed above. The ACR Manual on Contrast Media recommends obtaining an eGFR in patients who would be considered for GBCM administration with a history of renal disease (including a solitary kidney, kidney transplant, or renal neoplasm), are over age 60, or have a history of hypertension or diabetes mellitus. The time frame for testing may vary with any known prior testing and the known degree of renal disease, if any. For most patients, testing within 6 weeks is sufficient, although with known renal disease, retesting within 1 to 2 weeks is advisable.

In patients at risk for NSF, an alternative exam without gadolinium administration should be used if possible. If a GBCM must be administered, the lowest possible dose should be used, and the agents with the highest association with NSF should be avoided. Consultation with the referring physician and informed consent from the patient may be appropriate. In patients with eGFR < 40 mL/min/1.73 m², especially inpatients, precautions similar to those for patients with stage 4 chronic kidney disease are recommended since the eGFR measurement may vary over time. No special precautions are required in patients with eGFR > 40 mL/min/1.73 m².

e. Extravasation. Extravasation of intravenously administered iodinated contrast media can cause significant patient morbidity, although most patients have no significant sequelae. While extravasation can occur with hand injection or power injection, and the frequency of extravasation is not thought to be related to the injection flow rate, the severity of extravasation is likely to be greater with power injection since a larger volume of contrast media is injected in a shorter period of time, and observation of the injection site may be more difficult. The reported rate of extravasation with power injection for CT scanning ranges from 0.1 percent to 0.9 percent.

Patient risk factors for the development of extravasation include inadequate ability to communicate (such as infants and children, the elderly, and patients with altered consciousness), severe illness and debilitation, and abnormal circulation in the limb to be injected. Risk factors related to the venous access include distal access sites (such as the hand, wrist, foot, and ankle), use of indwelling lines in place for more than 24 hours, and multiple punctures into the same vein.

Immediately after extravasation of contrast, most patients will 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. Extravasated contrast is toxic to the skin and surrounding soft tissues, possibly related to the hyperosmolality of the contrast. An acute local inflammatory response is initiated, which may peak in 24 to 48 hours.

Two severe complications may occur. The most common is a compartment syndrome related to mechanical compression. The major risk factors for compartment syndrome are
the volume of extravasated contrast and the capacity of the site of extravasation. The second severe complication is skin ulceration and tissue necrosis. The risk of a severe extravasation injury is increased in patients with arterial insufficiency or compromised venous or lymphatic drainage in the affected extremity. Severe injury is also more likely with larger volumes of contrast and extravasation into smaller anatomic compartments, such as the dorsum of the hand, foot, or ankle. However, such injuries are rare. In a series of 442 extravasations of low osmolality contrast media in adults, Wang et al. reported only one case of compartment syndrome and three cases of skin blisters or ulcerations.

There is no consensus on the most effective treatment for extravasation. Elevation of the affected extremity above the level of the heart to decrease capillary hydrostatic pressure may promote resorption of the extravasated contrast. Warm and cold compresses to the site of extravasation are both advocated by some radiologists, with no clear evidence to favor the superiority of either approach. Some departments may use these approaches sequentially. Heat may help promote resorption of the extravasated contrast and improve distal blood flow. Cold may help relieve pain at the injection site. There is also no clear evidence to support attempted aspiration of the extravasated contrast media or the injection of other agents at the site of extravasation.

The potential severity and prognosis of contrast extravasation cannot be immediately determined. Therefore, clinical follow-up is needed for at least several hours after the event. This may require holding outpatients until initial symptoms are improved and the radiologist is assured that no new symptoms have developed. Patients or their caretakers should be instructed to seek additional care if the patient develops new or worsening symptoms such as skin ulceration or neurologic or circulatory symptoms. Surgical consultation should be obtained for patients who develop progressive swelling or pain, altered tissue perfusion (manifested by decreased capillary refill), change in sensation, or skin ulceration or blistering.
Part III: Professionalism and Ethics


The Physician Charter is the product of an international effort of the American Board of Internal Medicine (ABIM) Foundation, the American College of Physicians-American Society of Internal Medicine (ACP-ASIM) Foundation, and the European Federation of Internal Medicine. The charter was initiated by the following premise: Changes in the healthcare delivery systems in countries throughout the industrialized world threaten the values of professionalism. Unique in its timeliness, scope, and broad appeal, the document is a restatement of our obligations as practicing physicians to the patients whom we serve. It has been endorsed by virtually all major medical organizations in the United States and many throughout the world.

Preamble

Professionalism is the basis of medicine’s contract with society. It demands placing the interests of patients above those of the physician, setting and maintaining standards of competence and integrity, and providing expert advice to society on matters of health. The principles and responsibilities of medical professionalism must be clearly understood by both the profession and society. Essential to this contract is public trust in physicians, which depends on the integrity of both individual physicians and the whole profession. At present, the medical profession is confronted by an explosion of technology, changing market forces, problems in healthcare delivery, bioterrorism, and globalization. As a result, physicians find it increasingly difficult to meet their responsibilities to patients and society. In these circumstances, reaffirming the fundamental and universal principles and values of medical professionalism, which remain ideals to be pursued by all physicians, becomes all the more important. The medical profession everywhere is embedded in diverse cultures and national traditions, but its members share the role of the healer, which has roots extending back to Hippocrates. Indeed, the medical profession must contend with complicated political, legal, and market forces. Moreover, there are wide variations in medical delivery and practice through which any general principles may be expressed in both complex and subtle ways. Despite these differences, common themes emerge and form the basis of this charter in the form of three fundamental principles and as a set of definitive professional responsibilities.

Fundamental Principles

Principle of primacy of patient welfare. This principle is based on a dedication to serving the interest of the patient. Altruism contributes to the trust that is central to the physician-patient relationship. Market forces, societal pressures, and administrative exigencies must not compromise this principle.

Principle of patient autonomy. Physicians must have respect for 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 those decisions are in keeping with ethical practice and do not lead to demands for inappropriate care.

Principle of social justice. The medical profession must promote justice in the healthcare system, including the fair distribution of healthcare resources. Physicians should work actively to eliminate
discrimination in healthcare, whether based on race, gender, socioeconomic status, ethnicity, religion, or any other social category.

**A Set of Professional Responsibilities**

**Commitment to professional competence.** Physicians must be committed to lifelong learning and be responsible for maintaining the medical knowledge and the clinical 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.

**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. This expectation does not mean that patients should be involved in every minute decision about medical care; rather, they must be empowered to decide on the course of therapy.

Physicians should also acknowledge that in healthcare, medical errors that injure patients do sometimes occur. Whenever patients are injured as a consequence of medical care, they should be informed promptly because failure to do so seriously compromises patient and societal trust. Reporting and analyzing medical mistakes provide the basis for appropriate prevention and improvement strategies and for appropriate compensation to injured parties.

**Commitment to patient confidentiality.** Earning the trust and confidence of patients requires that appropriate confidentiality safeguards be applied to disclosure of patient information. This commitment extends to discussions with persons acting on a patient’s behalf when obtaining the patient’s own consent is not feasible. Fulfilling the commitment to confidentiality is more pressing now than ever before, given the widespread use of electronic information systems for compiling patient data and an increasing availability of genetic information. Physicians recognize, however, that their commitment to patient confidentiality must occasionally yield to overriding considerations in the public interest (for example, when patients endanger others).

**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.

**Commitment to improving quality of care.** Physicians must be dedicated to continuous improvement in the quality of healthcare. This commitment entails not only maintaining clinical competence but also working collaboratively with other professionals to reduce medical error, increase patient safety, minimize overuse of healthcare resources, and optimize the outcomes of care. Physicians must actively participate in the development of better measures of quality of care and the application of quality measures to assess routinely the performance of all individuals, institutions, and systems responsible for healthcare delivery.

Physicians, both individually and through their professional associations, must take responsibility for assisting in the creation and implementation of mechanisms designed to encourage continuous improvement in the quality of care.
Commitment to improving access to care. Medical professionalism demands that the objective of all healthcare systems be the availability of a uniform and adequate standard of care. Physicians must individually and collectively strive to reduce barriers to equitable healthcare. Within each system, the physician should work to eliminate barriers to access based on education, laws, finances, geography, and social discrimination. A commitment to equity entails the promotion of public health and preventive medicine, as well as public advocacy on the part of each physician, without concern for the self-interest of the physician or the profession.

Commitment to a just distribution of finite resources. While meeting the needs of individual patients, physicians are required to provide healthcare that is based on the wise and cost-effective management of limited clinical resources. They should be committed to working with other physicians, hospitals, and payers to develop guidelines for cost-effective care. The physician’s professional responsibility for appropriate allocation of resources requires scrupulous avoidance of superfluous tests and procedures. The provision of unnecessary services not only exposes one’s patients to avoidable harm and expense but also diminishes the resources available for others.

Commitment to scientific knowledge. Much of medicine’s contract with society is based on the integrity and appropriate use of scientific knowledge and technology. Physicians have a duty to uphold scientific standards, to promote research, and to create new knowledge and ensure its appropriate use. The profession is responsible for the integrity of this knowledge, which is based on scientific evidence and physician experience.

Commitment to maintaining trust by managing conflicts of interest. Medical professionals and their organizations have many opportunities to compromise their professional responsibilities by pursuing private gain or personal advantage. Such compromises are especially threatening in the pursuit of personal or organizational interactions with for-profit industries, including medical equipment manufacturers, insurance companies, and pharmaceutical firms. 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 the latter determine the criteria for conducting and reporting clinical trials, writing editorials or therapeutic guidelines, or serving as editors of scientific journals.

Commitment to professional responsibilities. As members of a profession, physicians are expected 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. Physicians have both individual and collective obligations to participate in these processes. These obligations include engaging in internal assessment and accepting external scrutiny of all aspects of their professional performance.

Summary

The practice of medicine in the modern era is beset with unprecedented challenges in virtually all cultures and societies. These challenges center on increasing disparities among the legitimate needs of patients, the available resources to meet those needs, the increasing dependence on market forces to transform healthcare systems, and the temptation for physicians to forsake their traditional commitment to the primacy of patients’ interests. To maintain the fidelity of medicine’s social contract
during this turbulent time, we believe that physicians must reaffirm their active dedication to the principles of professionalism, which entails not only their personal commitment to the welfare of their patients but also collective efforts to improve the healthcare system for the welfare of society. This Charter on Medical Professionalism is intended to encourage such dedication and to promote an action agenda for the profession of medicine that is universal in scope and purpose.
Part IV: Compliance, Regulatory, and Legal Issues

Confidentiality: HIPAA Privacy Rule

- Provides a set of national standards.
- The major goal is to assure proper protection of each individual’s health information while still allowing the flow of information necessary to provide and promote quality healthcare.
- Addresses the use and disclosure of individually identifiable health information (protected health information, or PHI). Information that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual is protected. Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, and Social Security number).
- Applies to health plans, healthcare clearinghouses, and healthcare providers that transmit health information in electronic format.
- Situations in which identifiable data can be transmitted without individual authorization include, but are not limited to, the following: 1) to the individual at his or her request, 2) in the course of treatment, 3) for payment activities, and 4) to healthcare operations involving quality or competency assurance, fraud or abuse detection, or compliance activities. In addition, when required by law, information can be released to public health authorities; during investigation of abuse, neglect, or domestic violence; to oversight agencies; for judicial and administrative proceedings; for law enforcement purposes; and for worker’s compensation.

Risk Management and Legal Issues

Communications and Quality Care

Quality patient care is strongly promoted when study results are conveyed in a rapid fashion to those in charge of treatment decisions. An efficient and effective method of communication should 1) be created to meet the need for adequate response, 2) promote the interpreting physician as a consultant by supporting physician-to-physician or physician-to-allied healthcare worker communication, and 3) diminish the likelihood of communication errors. Factors and circumstances pertaining to a particular clinical issue influence the method and timing of communication between interpreting radiologists and referring physicians. In some situations, the timing of communication is a matter of convenience or necessitated by scheduling requirements. In some cases, it is probably more valuable to ensure the receipt of information by the appropriate clinician. In general, timely receipt of the report outweighs the method of delivery.

Standard Communications

In radiology, standard communication refers to the creation and delivery of written reports. Most physicians receive their reports in electronic form, by viewing them on the written or electronic medical record, and, less frequently, on printouts from the radiology department or other systems. Some departments have residents or physician extenders perform preliminary reports that are not permanent. In this case, departments require that medically significant changes to the preliminary report be communicated directly to the requesting physician or his/her designee. Minor changes (e.g., spelling, grammatical, syntax) do not require such notification. Once issued, final reports are part of the medical...
record and cannot be edited. Changes can only be made by creating an addendum to the report. When viewed in an electronic system, the addendum (if present) appears before the original report.

The final report is the definitive documentation of the results of an imaging examination or procedure. It should be proofread to minimize typographical errors, accidentally deleted words, and confusing or conflicting statements. Use of abbreviations or acronyms should be limited to avoid ambiguity. The final report also should be completed in accordance with appropriate state and federal requirements (for example, the Final Regulations, Mammography Quality Standards Act for Mammography Reporting). Electronic or rubber-stamp signature devices, instead of a written signature, are acceptable unless contrary to state law, and as long as access to such devices is secure. The final report should be transmitted to the healthcare provider or referring physician who provides the clinical follow-up in accordance with appropriate state and federal requirements. The referring physician or other relevant healthcare provider also shares in the responsibility of obtaining results of imaging studies he or she has ordered.

If feasible, a copy of the final report should accompany the transmittal of relevant images to other health care professionals, when such images are requested. 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 of these records must be in accordance with state and federal regulations and facility policies.

**Non-standard Communications**

There are three levels of results based on the urgency with which non-standard findings must be communicated:

- **Level 1**: New or unexpected findings on an imaging study that suggest conditions that are life threatening or would require an immediate change in patient management.

  The ACR’s goals are identical to The Joint Commission’s National Patient Safety Goal NPSG.02.03.01: “Report critical results of tests and diagnostic procedures on a timely basis.” Accredited facilities are required by The Joint Commission (TJC) to define critical tests and critical results, and to monitor performance in reporting those results. Although initially developed for laboratory medicine, these concepts have been extended to imaging examinations. A critical result has been 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, a leaking or ruptured aortic aneurysm, acute intracerebral hemorrhage, significant pulmonary embolus, acute DVT, and unexpected free air in the abdomen. Critical tests are those that "require rapid communication of results, whether normal, abnormal, or critical." Examples include PE protocol CTs and Doppler US to exclude DVT.

  The Joint Commission requires that radiologists identify certain imaging results as critical. Each facility has leeway to define its own critical tests and critical results; there is no standard list for either category. For all critical results, Level 1 communication is mandated and audited. Such communication requires direct contact between the radiologist and the requesting or responding clinician or another licensed healthcare provider responsible for that patient’s care.
This communication must occur within 30 to 60 minutes of the time that the observation is made and 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 imaging findings.

Note that while all critical results require Level 1 communication, not all Level 1 communication will meet the definition of a critical result (for example, reporting a negative PE protocol).

- **Level 2:** New or unexpected findings on an imaging study that could result in mortality or significant morbidity if not appropriately treated urgently (within 2 to 3 days).

Level 2 results are less dire and require communication within 6 to 12 hours. For results in this category, the radiologist might call directly, or might request a call service or associate to call on his or her behalf. Examples include an intra-abdominal abscess or an impending pathological hip fracture.

- **Level 3:** New or unexpected findings on an imaging study that could result in significant morbidity if not appropriately treated, but are not immediately life-threatening.

Level 3 communications are not particularly time sensitive but report an important or potentially important finding that should not be overlooked. A newly observed lung nodule or solid renal mass fall into this category. Many of these findings are reported electronically. Most centers track these emails to make sure that they are successfully sent and, when necessary, supplement them by phone or fax.

The documentation of these communications should include the date and time of the communication, the person reporting the findings, and the person receiving the findings. Level 1 communication may also require reporting the time the finding was observed to document compliance with the 30- to 60-minute window for communication.

**Informal Communications**

Radiologists may be asked to provide interpretations that do not result in a formal report but are used to make treatment decisions. Such communications may take the form of a “curbside consult” or a “wet reading” that may occur during clinical conferences, interpretations while involved in other activities, or review of an outside study. These circumstances may preclude immediate documentation and may occur in suboptimal viewing conditions without comparison studies and their accompanying reports or adequate patient history. Informal communications carry inherent risk, and frequently the ordering physician’s or healthcare provider’s documentation of the informal consultation may be the only written record of the communication. Interpreting physicians who provide consultations of this nature are encouraged to document those interpretations. A system for reporting outside studies is also encouraged.

**Malpractice**

An estimated 30 percent of abnormal radiographic findings are missed, and about 5 percent of radiologic interpretations rendered by radiologists in daily practice contain errors. In 1999, it was
reported that nearly 20 percent of lung cancers presenting as a nodule on chest radiographs, with a median diameter of 16 mm, were missed on initial reading. As a radiologist, this is hard to believe, yet the data are found in widely accepted pulmonary medicine literature. The most common cause of malpractice suits against radiologists is errors in diagnosis. Radiologists’ diagnostic errors are sorted into those related to failures in detection, interpretation, communication of results, or suggesting an appropriate follow-up test.

*Cognitive errors* (e.g., a missed lung nodule when interpreting a chest radiograph) are usually errors of visual perception (scanning, recognition, and interpretation).

*System errors* (e.g., failure to communicate the presence of a pulmonary nodule to the ordering physician) are usually attributed to health system issues or context of care delivery problems.

*Radiologic errors*, as in general medical diagnosis faults, often result from a combination or interaction between cognitive and system errors (for example, preliminary reports by residents that are revised in a final report but not fully communicated to caregivers). Certain system factors (e.g., lighting conditions, shift length, or pace of interpretation required) can increase cognitive diagnostic errors.

Potential strategies to reduce the errors include making physicians aware of the thought processes and biases and being systematic in asking questions prior to finishing a case: Are all the findings accounted for by my diagnosis? Does my diagnosis fit the symptoms? Are there consequences of this diagnosis? What diagnosis should I not miss? What is the true differential? What else could it be? Checklists can be helpful with this process but have not been extensively studied.

**Institutional Review Board (IRB)**

Under FDA regulations, an Institutional Review Board (IRB) is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

The fundamental purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

By federal regulation, IRBs are required to register with the Department of Health and Human Services (HHS). Institutions engaged in research involving human subjects will usually have their own IRBs to oversee research conducted within the institution or by the staff of the institution. However, FDA regulations permit an institution without an IRB to arrange for an outside IRB to be responsible for initial and continuing review of studies conducted at the non-IRB institution. Most institutional IRBs have jurisdiction over all studies conducted within that institution.

A clinical investigator may be a member of an IRB. However, IRB regulations prohibit any member from participating in the IRB’s initial or continuing review of any study in which the member has a conflicting
interest, except to provide information requested by the IRB. IRBs should strive for a membership that has a diversity of representative capacities and disciplines. FDA regulations require that an IRB must have "diversity of members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes."

FDA regulations allow for one emergency use of a test article in an institution without prospective IRB review, provided that such emergency use is reported to the IRB within 5 working days after such use. In its review of the emergency use, if it is anticipated that the test article may be used again, the IRB should request that a protocol and consent document(s) be developed so an approved protocol would be in place when the next need arises. Investigators must ensure prompt reporting of any changes in a research activity to the IRB, including completion of the study.

Informed consent is important to patient rights and welfare. The consent document is a written summary of the information that should be provided to the subject. Many clinical investigators use the consent document as a guide for the verbal explanation of the study. The subject's signature provides documentation of agreement to participate in the study but is only one part of the consent process. The entire informed consent process involves giving a subject adequate information concerning the study, providing adequate opportunity for the subject to consider all options, responding to the subject's questions, ensuring that the subject has comprehended the information, obtaining the subject's voluntary agreement to participate, and continuing to provide information as the subject or situation requires. To be effective, the process should provide ample opportunity for the investigator and the subject to exchange information and ask questions.

Centers for Medicare and Medicaid Services (CMS) Definitions

**CPT codes:** Current procedural terminology (CPT) codes are maintained by the American Medical Association through an editorial panel. They are designed to give information about medical services and procedures and to provide uniformity across physicians, coders, patients, payers, and accreditation organizations.

**ICD:** International Classification of Diseases (ICD) is a medical classification list formulated during an international conference sponsored by the World Health Organization (WHO). Medical necessity is often defined as concordance between ICD and CPT codes.

**Bundling** refers to a process by which individual components of a complicated procedure are combined into one code for the purposes of billing.

**Meaningful use** is a government initiative whereby certified electronic health record (EHR) technology will be used to improve quality, safety, and efficiency and reduce health disparities; engage patients and their families; improve patient care coordination and population and public health; and maintain privacy and security of patient health information. Ultimately, it is hoped that meaningful use compliance will lead to better clinical outcomes, improved population health outcomes, increased transparency and efficiency, empowered individuals, and more robust research on health systems. **RVU** refers to relative value unit.
Part V: Research and Screening

Basic Statistics for Literature Interpretation in Imaging

Types of Data

It is important to correctly identify the type of data to determine the most appropriate statistical test.

- **Nominal**: Data values fall into categories or classes without any inherent order. Classify objects according to type or characteristic (examples: gender, race, and subspecialty).
- **Ordinal**: Data possess some inherent ordering or rank, but the size of the interval between categories is not uniform or quantifiable. Classify objects according to type or characteristic. These data cannot be averaged (examples: BI-RADS classification; assigning excellent, very good, good, or fair ratings to image quality).
- **Interval**: Data possess inherent order, and the interval between successive values is equal. These data can be averaged. Interval data may be continuous (can take on any value in a continuum; example: temperature in Celsius) or discrete (can take on only specific values and are expressed as counts; example: number of seizures per month).
- **Ratio**: Data are similar to interval data in possessing inherent order and uniform size intervals, but measures reflect a ratio between a continuous quantity and a unit magnitude of the same kind. The distinguishing feature is that ratio data can have a natural zero value (examples: birth weight in kg, percent vessel stenosis).

Types of Variables

- **Categorical**: Basic units are not quantifiable (examples: race, gender). These can be nominal (lower information content) or ordinal (intermediate information content).
- **Continuous or ordered discrete**: Can take values within a given interval and generally have higher information content (examples: time, age, blood pressure).

Types of Results

- **True positive**: when a person with a positive test result does have the disease in question.
- **True negative**: when a person with a negative test result does not have the disease in question.
- **False positive**: when a person has a positive test result but does not have the disease in question.
- **False negative**: when a person has a negative test result but does have the disease in question.

Central Tendency (Mean, Median, Mode, and Range)

The mean, or average, is calculated by summing all the observed values in the data set and then dividing that number by the total number of observations. The median is defined as the 50th percentile of the observed set of values; that is, if the observed values are listed from smallest to greatest value, the median is the midpoint of the values. (If there is an even number of observations, then the median is a point halfway between the middle pair of values.) Compared with the mean, the median is less influenced by unusual data points (i.e., outliers). The mode is defined as the observed value that occurs
most frequently in the data set. Mode is most often used when variables of interest are categorical or nominal (e.g., race, sex). The range is the difference between the largest and smallest value in a data set.

**Measuring Variability in Data**

Variability in a data set can be described by multiple methods. Range is defined as the difference between the largest observed value and the smallest observed value. Percentiles describe the shape of a distribution of values; the 25\textsuperscript{th} percentile is the value at which 25 percent of the data lie below that observed value, and the rest lie above it. Variance describes the amount of spread around the mean of a data set.

The standard deviation is defined as the square root of the variance. Standard deviation can be thought of as the average distance of observations from the mean.

**p Values**

In testing a hypothesis, α is the predetermined level of statistical significance that the investigator sets as the maximum acceptable chance of committing a Type I error (defined as rejecting the null hypothesis when it is actually true). The \( p \) value is the observed significance level of a statistical test, as determined by analyzing the data. The \( p \) value is the probability of seeing an effect as big as or bigger than the one observed in the study by chance (i.e., if the null hypothesis were true). The \( p \) value measures the strength of evidence against the null hypothesis. A non-significant result (\( p \) value greater than \( \alpha \)) does not prove the null hypothesis; it means that there is insufficient evidence to doubt the validity of the null hypothesis. Note that statistics are used to explore connections between variables, not to prove causation. Features that support causality include consistent results across different study designs, strong associations (more significant \( p \) values), a dose-response relationship between the risk and the outcome, and biologic plausibility.

**Confidence Limits**

A confidence interval (CI) is a range of reasonable values that are intended to contain the parameter of interest (e.g., the mean) with a certain degree of confidence. CIs are used to estimate population values without having data from all members of the population. CIs for population estimates provide information about how precise the estimate is (wider CIs indicate less precision). The desired degree of confidence is most often chosen at 95 percent. Confidence intervals can be calculated for estimates of population characteristics, point estimates (e.g., odds ratios), or proportions (e.g., sensitivity and specificity). Whereas \( p \) values indicate a statistically significant result, CIs provide a range of values, which help the reader interpret implications of the results at either end of the range.

**Sensitivity**

The sensitivity of a test is the proportion of people who have the disease and test positive for it. Sensitivity (and specificity) are intrinsic properties of a test and do not depend on the population being tested. Use of the 2 x 2 table below can be helpful in understanding this definition, as well as other commonly used statistical measures.
### Sensitivity

Sensitivity is the number of TP divided by the sum of TP plus FN (this sum being the total number of disease positives). A test with high sensitivity is most useful for ruling out the disease (“SNOUT” SeNsitivity to rule OUT); that is, a negative result suggests a low chance of having the disease. Good screening tests have high sensitivity. Tests with high sensitivity have low Type II error rates.

### Specificity

The specificity of a test is the proportion of people who do not have the disease who test negative for it. Specificity is the number of TN divided by the sum of FP plus TN (the sum being the total number of disease negatives). A test with high specificity is most useful for ruling in the disease (“SPIN” SPecificity to rule IN), that is, a positive result means a good chance of having the disease. Good confirmatory tests have high specificity. Tests with high specificity have low Type I error rates.

### Accuracy

Accuracy is assessed by comparing a measurement to a reference standard (i.e., “gold standard”), a standard technique that is considered closest to the truth. Accuracy is defined as the degree to which a variable represents what it is intended to represent (as opposed to precision, which is defined as the degree to which a measurement has the same value when measured several times). Strategies for enhancing accuracy include standardizing measurement methods, training observers, refining/automating instruments, and blinding. Accuracy is the sum of TP and TN divided by the total number of subjects studied: (TP + TN) / (TP + TN + FP + FN). Accuracy as defined here depends on disease prevalence. For conditions with extremely low disease prevalence, accuracy has little role in defining how “good” a method is for condition detection, as accuracy will remain high despite missing all positive cases (for example, if 5 in 100 c-spine plain film series done for trauma are positive, calling all series normal retains an accuracy of 95 percent but has a sensitivity of 0 percent).

### Positive Predictive Value

The positive predictive value (PPV) is the proportion of people with positive test results who actually have the disease (i.e., are correctly diagnosed by the test). PPV is the number of TP divided by the sum of TP and FP (the sum being the total number of those who test positive). PPV depends on the prevalence of the disease. Studies used to estimate PPV and NPV should include a prevalence of the disease in subject groups that is similar to the prevalence of disease in the population. If these prevalences are not similar, then likelihood ratios should be used instead of PPV and NPV. Case control studies, which do not yield prevalence, cannot be used to estimate PPV (or NPV).
**Negative Predictive Value**

The negative predictive value (NPV) is the proportion of people with negative test results who do not have the disease (i.e., are correctly diagnosed by the test). NPV is the number of TN divided by the sum of TN and FN (the sum being the total number of those who test negative). NPV depends on the prevalence of the disease.

**ROC Analysis**

A receiver operating characteristic (ROC) curve is a plot of test sensitivity (y axis) versus false positive rate (x axis). False positive rate is equal to (1 – specificity). ROC curves can be constructed for any measurements that can be meaningfully ranked in magnitude. Defining test results as positive or negative requires a choice of appropriate cut point, which is often determined by the clinical setting in which the test is used. For example, in mammography, radiologists may interpret mammograms as normal, benign, probably benign, suspicious, or malignant. A positive test result could be defined as any interpretation of suspicious or malignant; that is, the cut point between positive and negative results is chosen at between probably benign and suspicious. Alternatively, a positive result could be defined as any interpretation other than normal, with cut point between normal and benign. The more appropriate cut point depends on how the test will be used. For accuracy as defined above, only a single cut point can be used. The ROC curve is generated using the sensitivity and specificity values calculated at each possible cut point, so that the ROC curve displays all possible cut points. The ROC curve is a good summary measure of test accuracy because it does not depend on disease prevalence or which cut point is chosen.

**Biases**

**Research Biases**

- **Selection bias** occurs when comparisons are made between groups of subjects that differ in ways other than factors under study, affecting outcomes. Selection bias includes the following:
  - **Spectrum bias** occurs when the sample is missing important subgroups.
  - **Verification bias** occurs when patients with positive or negative test results are preferentially referred for the reference standard test, and then sensitivity and specificity are based only on those patients who underwent the reference test.
  - **Sampling bias** occurs if some members of a population are more or less likely to be included than others. All types of selection bias may reduce the ability to generalize results to the rest of the population (i.e., external validity is compromised).

- **Measurement bias** occurs when methods of measurement are dissimilar between groups of patients. **Review bias** is a type of measurement bias; it occurs when tests are performed or interpreted without proper blinding.

- **Confounding bias** occurs when two factors are associated, and the effect of one is distorted or confused by the effect of the other.
Screening Biases

- **Screening bias/compliance bias:** Patients who volunteer for screening studies tend to be healthier and have better outcomes than those who do not volunteer, regardless of screening.

- **Lead-time bias:** The period of time between the detection of a disease by screening and when it would be diagnosed because symptoms had developed. When lead time is short, treatment of disease found by screening is likely to be no more effective than treatment after symptoms appear. If early treatment is no more effective than treatment at clinical presentation, lead-time bias can be seen: time from diagnosis to death is longer for those screened, but survival is not improved (diagnosed time is longer, but death occurs at the same time as if unscreened). An appropriate way to avoid lead-time bias is to compare age-specific mortality rates, rather than survival rates from the time of diagnosis.

- **Length-time bias:** Cancers demonstrate a wide range of growth rates. Screening tests are likely to find more slow-growing tumors since they are present for a longer period of time before they cause symptoms. Since slow-growing tumors tend to be associated with better prognosis, screening tests tend to find tumors with inherently better prognosis. Usual medical care (as opposed to screening) tends to find more fast-growing tumors, since these are more likely to cause symptoms. As a result, the mortality rates of tumors found on screening may be better than those found in usual care, but this difference is not because of the screening itself.

- **Overdiagnosis:** Screening may detect disease that will never become clinically important in a patient’s lifetime. This can lead to unnecessary treatment but also to apparent improvement in mortality rates of tumors (analogous to length time bias above) that is not due to the screening itself.
Bibliography and Suggested Reading List


