Diagnostic Radiology
Core Quality and Safety Study Guide
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Preamble

The Quality & Safety portion of the ABR Core Exam is intended to focus on established knowledge in the area of Radiology Quality and Safety. Since the range of content relevant to the topic of Radiology Quality & Safety is broad, this study guide serves as a syllabus of the “core” knowledge that residents eligible to take the Core Exam are expected to know. This should be considered to be 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 an actual textbook, other definitive source material or education you should be receiving during your residency training program.

We would also draw your attention to the list of references at the end of this document and to web links to key public documents in Radiology Quality & Safety which are available on the websites of the major voluntary organizations in Radiology, such as ACR, ARRS, and RSNA, among others. These “deeper” resources are highly recommended to provide perspective and depth of understanding to the concepts which are only superficially outlined here.

Part I is an overview of concepts and serves as a framework and Part II contains more detailed and practical material.

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.

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PART 1: Toward a Conceptual Framework of Quality & Safety in Radiology

I. General Quality Improvement
   A. Quality improvement definitions
      i. Traditional definition of quality in healthcare
         a. 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.

         b. 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.

         c. QI involves both prospective and retrospective reviews. It is aimed at improvement—measuring where you are and figuring out ways 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 the QA entity, 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.”

         d. The process of improving the lives of patients, the health of communities, and the joy 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.

      ii. The new paradigmatic approach to quality science
         a. 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.

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

d. Personnel management: centered on the treatment of employees and professional as valuable resources.

B. The Institute of Medicine’s (IOM) six quality aims

*We strive to provide healthcare that is:*

1. Safe
2. Timely
3. Effective
4. Efficient
5. Equitable
6. Patient-centered

C. Six core competencies of MOC

i. **Patient Care**—Provide care that is compassionate, appropriate, and effective treatment for health problems and to promote health.

ii. **Medical Knowledge**—Demonstrate knowledge about established and evolving biomedical, clinical, and cognate sciences and their application in patient care.

iii. **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).

iv. **Professionalism**—Demonstrate a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to diverse patient populations.

v. **Systems-Based Practice**—Demonstrate awareness of and responsibility to 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).

vi. **Practice-Based Learning and Improvement**—Able to investigate and evaluate patient care practices, appraise and assimilate scientific evidence, and improve the practice of medicine.
D. Best practices
Since unnecessary variation causes poor quality, we have justification for developing consensus about best practices. They should be updated regularly, and they should be distinguished from mandatory adherence to static guidelines/standards.

i. **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.”

ii. **Benchmarking**: “A measurement of the quality of an organization's policies, products, programs, strategies, etc., and their comparison with standard measurements or similar measurements of its peers.

The objectives of benchmarking are (1) to determine what and where improvements are called for, (2) to analyze how other organizations achieve their high performance levels, and (3) to use this information to improve performance.”

E. Methodologies
i. The **PDSA (Plan-Do-Study-Act) cycle** is a four-step process commonly used for continuous quality improvement. This simple but powerful tool may serve as the basis for an action-oriented iterative process by linking multiple PDSA cycles repeated in sequence. An initial cycle is performed to obtain baseline data, followed by subsequent cycles applied to assess the effects of quality improvement initiatives.

![The “PDSA Cycle”](Image Source: Wikicommons)
**PLAN.** Identify an area of your practice judged to be in need of improvement and devise a measure to assess the degree of need. Develop a plan to implement the measure and obtain the required data. Finally, set a target or goal for the measure to reach.

This step involves first selecting a project area of interest (topic) that is relevant to your practice, that you would like to improve, and that is amenable to repeated measurement. In doing so, it is often helpful to evaluate your practice in light of the six Institute of Medicine Quality Aims: What about your practice could be made safer, timelier, more efficient, more effective, more patient centered, or more equitable? You should choose a topic that has the potential to make an improvement. Because the purpose of PQI is to address and improve real issues in your practice, performance topics that do not present challenges or perceived gaps in practice are not appropriate as subjects for PQI projects.

Your next task is to devise an appropriate measure to gauge the issue you have selected. This often may be articulated initially as a quality question, from which a metric can be derived. After you adopt a measurement to be taken, set a target level of performance desired in your practice. It is also helpful to predict what you believe your measure will show when applied to your practice. If you predict that the goal will be met on initial measurement, then this is likely not a suitable topic, and another should be chosen.

**Example:**

**Area of Interest (Topic):** “Time out” at interventional radiology procedures

**Quality Question:** In my practice, in what percentage of interventional radiology procedures was a “time out” performed?

**Measurement to be Taken:** Number of procedures in which a “time out” occurred/total number of interventional radiology procedures x 100%.

**Desired Target Level (Goal) of Performance:** “Time out” before beginning a procedure in 100 percent of cases.

**Baseline Measurement Prediction:** Upon initial measurement, I believe that the measure will show a “time out” before beginning of procedure in 70 percent of cases.

Devise a plan or process for collecting the data.

**DO.** In this step, put the plan in action and take baseline measurements in an unbiased manner for an appropriate number of cases/data points. Then collect the data.
**STUDY.** Determine how well your measure compared to the desired goal and explore root causes for lacking goal achievement. Analyze baseline data and compare with both the predicted result and the desired performance target. Then summarize conclusions and what you have learned. One of two results will then be pertinent:

a. If the results **did not** meet the performance target, determine the factors to which you attribute the results and examine all potential root causes.

b. If, unexpectedly, the results **did** meet the performance target, institute a plan to sustain the gain and to re-measure at appropriate intervals.

**ACT.** Devise and implement a plan for performance improvement that addresses the perceived root causes for not achieving the performance target. Implement an improvement plan that you have developed before re-measurement.

After your improvement plan implementation, begin another PDSA cycle to assess the degree of any gain achieved. The cycle can be used continuously until you reach your goal, or employed intermittently to document the stability of any gain achieved.

ii. Lean and Six Sigma

**Lean Process Improvement** (Lean) is an organizational style of continuous improvement workflow management that emerged from postwar Japan as a significant evolutionary step beyond the assembly line of Henry Ford in the early 1900s. Lean is a common term for the continuous improvement practice of Toyota Motors and is also known as the Toyota Production System (TPS). Fundamental to TPS is an emphasis on smoothness of workflow from end to end. Lean is distinct from the **Six Sigma** method in that the latter is best used for closing performance gaps or inducing breakthrough improvement in a segment of the overall process. Lean and Six Sigma can be complementary.

The two core management principles of Lean are:

- relentless elimination of waste and
- respect for people with long-term relationships among employer, employee, suppliers, and customers, based on continuous improvement and mutual trust.

It is important to note that this methodology, in its original “pure” form, has a fundamental reliance on company culture. Application of Lean principles in the U.S. tends to emphasize the Lean tool set over culture.

Waste is considered to be any element of the workflow that does not add value...
in the eyes of the end-consumer. Principal forms of waste include transportation, inventory, motion, waiting, overproduction, overprocessing, and defective steps or products. Lean places a big emphasis on standardized work in order to reduce unnecessary variation and eliminate non value-added work, fluctuations in quality and volume, and idiosyncratic behaviors. The focus on unnecessary variation is one reason Lean has become popular in healthcare quality improvement.

Organizational culture can be a significant stumbling block in the implementation of Lean because Lean relies heavily on employee engagement at a community level. Explicit in its origins is a long-term relationship with the team. In the U.S., application of Lean principles is typically admixed with an intent to quickly reduce costs, frequently acquiring the feel or intent of downsizing the workforce. People are not considered part of process waste in TPS, but rather, employees are the key to recognizing and improving the workplace.

F. QI tools

i. **Brainstorming** is an organized process for generating a list of ideas about an issue or process. Brainstorming sessions may take several hours. These sessions are used to:

   - Identify all issues
   - Understand and clarify the process
   - Generate potential solutions or action plans

ii. **Cause-and-effect diagrams (Fishbone diagram)** are used to categorize and organize ideas about contributing factors and their relationships within a process. Use a cause-and-effect diagram to:

   a. Define and understand the causes of an outcome.

   b. Graphically display the relationship of causes to the outcome.

   c. Help identify improvement opportunities by drawing a central horizontal line with a box at one end. Write the specific process or outcome being studied in the box. Next, draw four to six vertical lines from the horizontal line; these will identify classes of contributors (sources) to the central issue. Frequent classes include people, equipment, environment, methods, and materials. These may be supplemented by other sources identified by the team.

   d. Generate a list of factors or situations that “cause” a problem and assign them to one of the identified sources. The cause-and-effect diagram can be completed by either working entirely through all of the causes in one
source before moving on to the next, or by moving randomly from source to source as items are identified.

e. Look for multiple causes within a single source. Ask questions such as:

- What is being done?
- Why (cause) is it done at all?
- What else could be done in its place to accomplish the same result?
- When is it done?
- Why (cause) is it done at that time?
- Is there another time it could be done?
- Who does it?
- Why (cause) are these specific individuals doing it?
- Could someone else do it?
- Where is it done?
- Why (cause) is it done there?
- Where else could it be done?
- How is it done?
- Why (cause) is it done that way?
- Are there other ways it could be accomplished?

f. Continue to analyze the situation until the causes of the problem are specific enough to identify a potential change. Then seek consensus on the likely few causes that, if “fixed,” would improve the process.

iii. **Flowcharts** are graphic diagrams or maps that illustrate the steps and decision points that make up a work process. They represent a common understanding of the process and enable the team to examine individual steps in order to identify problems and improvement opportunities.

a. Use a flowchart to:

- Clarify the steps and decision points in the process;
- Identify the complexity or variability of the process, as well as its management;
- Clarify outcome vs. process steps;
- Establish measures for procedures within a process;

Flowcharts can depict a process at two or more levels: the first is a high-level diagram that describes the overall process from the beginning to the ending point. The actual diagram for a high-level flowchart can be a series of phrases in sequential boxes. The second is a low-level flow diagram that contains more detail about the major steps in a process and can be constructed once the specific start and end points are defined. For lengthy, time-dependent processes, it may be helpful to create a mid-level flowchart or process map.
iv. **Pareto Charts** are used to determine the most important quality issues, in which factors that contribute to the overall effect are arranged from left to right in decreasing order of importance or frequency. A Pareto chart contains both bars and a line graph, with the bars depicting individual values or variables, and the line graph illustrating the cumulative total. Proper ordering is a vital step because it guides the team to concentrate its efforts on factors with the greatest impact (25). The Pareto principle (PP) states that when multiple variables affect a situation, a few of them are actually responsible for most of the impact. The PP explains a phenomenon in which 80 percent of variation seen in everyday processes can be explained by simply 20 percent of the causes of that variation.

v. **Control Charts** (also known as Shewart charts) aim to analyze the performance of a process in a common language. By analyzing the performance a control chart (CC) is used to control, monitor, and enhance process performance over time by recognizing changes and its source. A CC uses samples of success as the numerator, total opportunities as the denominator, and the events are graphed to evaluate how a process changes over time. A line can be used to illustrate deviations of the data from the average, and upper and lower control limits can be used to represent the acceptable range. These lines can help determine whether the process change over time is stable (consistent) or is unstable (unpredictable). This helps determine whether process variations are in or out of control.

II. **Patient Safety**

A. **National Patient Safety Goals**

In 2002, The Joint Commission established its National Patient Safety Goals (NPSGs) program. The NPSGs were established to help organizations address specific areas of concern for patient safety. The goals highlight problem areas in healthcare and describe evidence-based solutions. Examples include prevention of falls, patient identification, reducing hospital infections and pressure ulcers, and improving hospital staff communication. The first set of NPSGs was effective January 1, 2003. The Joint Commission also created a “do not use” list of abbreviations in 2004 to avoid acronyms and symbols that lead to misinterpretation.

The National Patient Safety Goals are developed by the Patient Safety Advisory Group, composed of widely recognized expert physicians, nurses, pharmacists, engineers, risk managers, and others with real-world patient safety experience across the many healthcare settings. The Joint Commission then determines the highest priority patient safety issues and how best to address them.

There were no new NPSGs in 2011 and only one in 2012, related to urinary-catheter-acquired, healthcare-associated infections for hospitals. The National Patient Safety
Goals for each program and more information are available on The Joint Commission website.

Key NPSGs involving radiology practices (hospital and ambulatory) include:

- Use at least two patient identifiers when providing care, treatment, and services (NPSG.01.01.01).
- Report critical results of tests and diagnostic procedures on a timely basis (NPSG.02.03.01).
- Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings (NPSG.03.04.01).
- Maintain and communicate accurate patient medication information (NPSG.03.06.01).
- Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines (NPSG.07.01.01).
- Implement evidence-based practices to prevent healthcare–associated infections due to multidrug-resistant organisms in acute care hospitals (NPSG.07.03.01).
- Implement evidence-based practices to prevent central line–associated bloodstream infections (NPSG.07.04.01).
- Conduct a pre-procedure verification process (UP.01.01.01).
- Mark the procedure site (UP.01.02.01).
- Perform a time-out before the procedure (UP.01.03.01).

B. Epidemiology of error

Issues that have created a national focus have originated from the most common types of adverse events, such as inadequate information flow, human/performance problems, patient-related issues, poor organizational transfer of knowledge, insufficient staffing patterns/workflow, technical failures, inadequate policy/procedure, and defective systems for classifying errors by severity and frequency.

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 ten 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.

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 five years, consisting of four main foci:

1. Establishing a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety.
2. Identifying and learning from errors by developing a nationwide, public, mandatory reporting system and by encouraging healthcare organizations and practitioners to develop and participate in voluntary reporting systems.
3. Raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of healthcare.
4. 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. They 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 easily preventable events are of sufficient importance that they should never occur in a properly functioning healthcare environment. The Leapfrog Group, an association of private and public-sector group purchasers, has also initiated a market-based strategy to improve safety.

### C. Types of Errors

A model classification system:

1. **Diagnostic errors**
   a. Error or delay in diagnosis
   b. Failure to employ indicated test
   c. Use of outmoded tests or therapy
   d. Failure to act on results of monitoring or testing

2. **Treatment errors**
   a. Error in the performance of an operation, procedure, or test
   b. Error in administering the treatment
   c. Error in the dose or method of using a drug
   d. Avoidable delay in treatment or in responding to an abnormal test
   e. Inappropriate (not indicated) care

3. **Preventive errors**
   a. Failure to provide prophylactic treatment
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b. Inadequate monitoring or follow-up of treatment

iv. **Other errors**
   a. Failure of communication
   b. Equipment failure
   c. Other system failure

D. **Human factors**

Human factors engineering is the discipline that attempts to identify and address these issues. It is the discipline that 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 attempts to design systems that optimize safety and minimize the risk of error in complex environments.

E. **Communication**

Communication plays a role in achieving patient safety, removing barriers that affect patient-practitioner interactions, and disclosure of adverse events, including: (1) telling the patient and family what happened in terms they can understand; (2) taking responsibility; (3) apologizing; and (4) explaining what will be done to prevent similar errors, improved transitions of care—specific strategies.

For additional information refer to: **ACR Practice Guideline for Communication of Diagnostic Imaging Findings**

F. **Culture of safety**

- Beliefs, attitudes, and values about work, risk, and safety
- The value of learning
- Distinction between errors resulting from deliberate unsafe acts
- Errors that are a result of system failures

i. **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.

ii. Measuring and Achieving a Culture of Safety

**Safety culture** is generally measured by surveys of providers at all levels. Available validated surveys include Agency for Healthcare Research and Quality’s (AHRQ) 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 training, executive walk rounds, and establishing unit-based safety teams, have been associated with improvements in safety culture measurements but have not yet been convincingly linked to lower error rates. Other methods, such as rapid response teams and structured communication methods like SBAR, are being widely implemented to help address cultural issues such as rigid hierarchies and communication problems, but their effect on overall safety culture and error rates remains unproven.

The culture of individual blame, which is still dominant and traditional 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” is being introduced. A just culture focuses 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, and not the severity of the event. For example, reckless behavior such as refusing to perform a “time-out” prior to surgery would merit punitive action, even if patients were not harmed.
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#### THREE BEHAVIORS

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<tr>
<th>human errors</th>
<th>at-risk behavior</th>
<th>reckless behavior</th>
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<tr>
<td>a product of our current system design and our behavioral choices</td>
<td>a choice where the risk is believed to be insignificant or justified</td>
<td>a conscious disregard for a substantial and unjustifiable risk</td>
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<td>manage through changes in:</td>
<td>manage through:</td>
<td>manage through:</td>
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<td>☐ choices</td>
<td>☐ removing incentives for the behavior</td>
<td>☐ remedial action</td>
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<td>☐ processes</td>
<td>☐ creating incentives for better choices</td>
<td>☐ punitive action</td>
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<td>☐ procedures</td>
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Factors affecting human performance

![Graph showing Human Reliability and Human Error](image)
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 of the determinants of safety culture are dependent on inter-professional 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.”

G. Definitions of Error Types
   i. Active Error (or Active Failure) vs. Latent Errors

   The terms active and latent as applied to errors, according to James Reason, includes errors that are considered “active” and “latent.” Active errors occur at the point of contact between a human and some aspect of a larger system (e.g., a human-machine interface). They are generally readily apparent (e.g., pushing an incorrect button, ignoring a warning light) and almost always involve someone at the front line.

   Latent errors (or latent conditions), in contrast, refer to less apparent failures of organization or design that contribute to the occurrence of errors or allow them to cause harm to patients. To complete the metaphor, latent errors are those at the other end of the scalpel—the blunt end—referring to the many layers of the healthcare system that affect the person “holding” the scalpel.

   ii. Adverse Event: Any injury caused by medical care.

   Examples:

   - pneumothorax from central venous catheter placement
   - anaphylaxis to penicillin
   - postoperative wound infection
   - hospital-acquired delirium (or “sundowning”) in elderly patients

   Identifying something as an adverse event does not imply “error,” “negligence,” or poor quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not from an underlying disease process. Thus, pneumothorax from central venous catheter placement counts as an adverse event regardless of insertion technique. Similarly, postoperative wound infections count as adverse events even if the operation proceeded with optimal adherence to sterile procedures, the patient received
appropriate antibiotic prophylaxis in the perioperative setting, etc. (see also
iatrogenic).

iii. **Authority Gradient** refers to the balance of decision-making power or the
steepness of command hierarchy in a given situation. Members of a crew or
organization with a domineering, overbearing, or dictatorial team leader
experience a steep authority gradient. Expressing concerns, questioning, or even
simply clarifying instructions would require considerable determination on the
part of team members who perceive their input as devalued or frankly
unwelcome. Most teams require some degree of authority gradient; otherwise,
roles are blurred and decisions cannot be made in a timely fashion. However,
effective team leaders consciously establish a command hierarchy appropriate
to the training and experience of team members. Authority gradients may occur
even when the notion of a team is less well defined. For instance, a pharmacist
calling a physician to clarify an order may encounter a steep authority gradient,
based on the tone of the physician’s voice or a lack of openness to input from
the pharmacist. A confident, experienced pharmacist may nonetheless continue
to raise legitimate concerns about an order, but other pharmacists might not.

iv. **Errors on the “Blunt End”**

The “blunt end” refers to the many layers of the healthcare system not in direct
contact with patients, but which influence the personnel and equipment at the
sharp end who do contact patients. In many ways, this overlaps the “latent”
error concept. The blunt end thus consists of those who set policy, manage
healthcare institutions, and design medical devices, and other people and forces,
which, though removed in time and space from direct patient care, nonetheless
affect how care is delivered. Thus, an error programming an intravenous pump
would represent a problem at the sharp end, while the institution’s decision to
use multiple different types of infusion pumps, making programming errors
more likely, would represent a problem at the blunt end. The terminology of
“sharp” and “blunt” ends corresponds roughly to active failures and latent
conditions.

v. **Close Call (Near Miss)** is an event or situation that did not produce patient
injury, but only because of chance. This good fortune might reflect robustness of
the patient (e.g., a patient with penicillin allergy receives penicillin, but has no
reaction) or a fortuitous, timely intervention (e.g., a nurse happens to realize
that a physician wrote an order in the wrong chart). Such events have also been
termed near miss incidents. It is generally held that careful analysis of “near
miss” events can lead to process improvement and improved safety.

vi. **Latent Error (or Latent Condition)**

As noted above, this term was perhaps first coined by James Reason. Latent
errors (or latent conditions) refer to less apparent failures of organization or
design that contributed to the occurrence of errors or allowed them to cause harm to patients. For instance, whereas the active failure in a particular adverse event may have been a mistake in programming an intravenous pump, a latent error might be that the institution uses multiple different types of infusion pumps, making programming errors more likely. Thus, latent errors are quite literally “accidents waiting to happen.”

vii. **Mistakes**

In some contexts, errors are dichotomized as slips or mistakes, based on the cognitive psychology of task-oriented behavior. Mistakes reflect failures during attentional behaviors—behaviors that requires conscious thought, analysis, and planning, as in active problem solving. Rather than lapses in concentration (as with slips), mistakes typically involve insufficient knowledge, failure to correctly interpret available information, or application of the wrong cognitive heuristic or rule. Thus, choosing the wrong diagnostic test or ordering a suboptimal medication for a given condition represents a mistake.

Unfortunately, healthcare has typically responded to all errors as if they were mistakes, with remedial education and/or added layers of supervision. In point of fact, most errors are not “mistakes” of this type, and are perhaps prevented through sharply different mechanisms after careful analysis.

viii. **Sharp End** refers to the personnel or parts of the healthcare system in direct contact with patients. Personnel operating at the sharp end may literally be holding a scalpel (e.g., an orthopedist who operates on the wrong leg) or figuratively be administering any kind of therapy (e.g., a nurse programming an intravenous pump) or performing any aspect of care. To complete the metaphor, the blunt end refers to the many layers of the healthcare system that affect the scalps, pills, and medical devices, or the personnel wielding, administering, and operating them. Thus, an error in programming an intravenous pump would represent a problem at the sharp end, while the institution’s decision to use multiple types of infusion pumps (making programming errors more likely) would represent a problem at the blunt end.

ix. **Sentinel event**

According to the Joint Commission, “a sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.” Serious injury specifically includes loss of limb or function. The phrase, “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called “sentinel” because they signal the need for immediate investigation and response.

H. **Tools for evaluating risk and adverse events**

i. **Failure Mode and Effects Analysis (FMEA)**
FMEA is a common process used to prospectively identify error risk within a particular process. It begins with a complete process mapping that identifies all the steps that must take place for a given process to occur (e.g., programming an infusion pump or preparing an intravenous medication in the pharmacy). With the process mapped out, the FMEA then continues by identifying the ways in which each step can go wrong (i.e., the failure modes for each step), the probability that each error will be detected (i.e., so that it can be corrected before causing harm), and the consequences or impact of the error not being detected. The estimates of the likelihood of a particular process failure, the chance of detecting such failure, and its impact are combined numerically to produce a criticality index.

This criticality index provides a rough quantitative estimate of the magnitude of hazard posed by each step in a high-risk process. Assigning a criticality index to each step allows prioritization of targets for improvement. For instance, an FMEA analysis of the medication-dispensing process on a general hospital ward might break down all steps from receipt of orders in the central pharmacy to the filling of automated dispensing machines by pharmacy technicians. Each step in this process would be assigned a probability of failure and an impact score, so that all steps could be ranked according to the product of these two numbers. Steps ranked at the top (i.e., those with the highest criticality indices) would be prioritized for error proofing.

FMEA makes sense as a general approach and it (or similar prospective error-proofing techniques) has been used in other high-risk industries. However, the reliability of the technique is not clear. Different teams charged with analyzing the same process may identify different steps in the process, assign different risks to the steps, and consequently prioritize different targets for improvement.

ii. Root Cause Analysis
   a. Background

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 described 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 who suspected the mistake 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 many find it misleading. As illustrated by the Swiss cheese model, 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 “holes in the cheese” and obscure the overall relationships between different layers and other aspects of system design. Accordingly, some have suggested replacing the term “root cause analysis” with “systems analysis.”
**Factors That May Lead to Latent Errors**

<table>
<thead>
<tr>
<th>Type of Factor</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional/regulatory</td>
<td>A patient on anticoagulants received an intramuscular pneumococcal vaccination, resulting in a hematoma and prolonged hospitalization. The hospital was under regulatory pressure to improve its pneumococcal vaccination rates.</td>
</tr>
<tr>
<td>Organizational/management</td>
<td>A nurse detected a medication error, but the physician discouraged her from reporting it.</td>
</tr>
<tr>
<td>Work environment</td>
<td>Lacking the appropriate equipment to perform hysteroscopy, operating room staff improvised using equipment from other sets. During the procedure, the patient suffered an air embolism.</td>
</tr>
<tr>
<td>Team environment</td>
<td>A surgeon completed an operation despite being informed by a nurse and the anesthesiologist that the suction catheter tip was missing. The tip was subsequently found inside the patient, requiring reoperation.</td>
</tr>
<tr>
<td>Staffing</td>
<td>An overworked nurse mistakenly administered insulin instead of an anti-nausea medication, resulting in hypoglycemic coma.</td>
</tr>
<tr>
<td>Task-related</td>
<td>An intern incorrectly calculated the equivalent dose of long-acting MS Contin for a patient who had been receiving Vicodin. The patient experienced an opiate overdose and aspiration pneumonia, resulting in a prolonged ICU course.</td>
</tr>
<tr>
<td>Patient characteristics</td>
<td>The parents of a young boy misread the instructions on a bottle of acetaminophen, causing their child to experience liver damage.</td>
</tr>
</tbody>
</table>
PART II: Practical Applications in Patient Safety

I. Periprocedural care

A. Patient Identification

Patient identification is critical to ensure that the right patient receives the right treatment, medication, invasive/non-invasive procedure, blood products, and to reduce the chance of unnecessary radiation exposure, etc. Two patient identifiers should be used prior to 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, relative, guardian, 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 prior to the procedure. Such assessment may be performed 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. That assessment may include a focused history and physical examination, including 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 institution 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 Guideline 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 or recorded on videotape or another similar permanent modality.
Consent should be obtained from the patient or the patient’s legal representative by the physician or other healthcare provider performing the procedure, or by other qualified personnel assisting that person. 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 need 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 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.

E. Time-out

Required for many image-guided interventional procedures and invasive diagnostic imaging procedures in adherence with The Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™. This protocol includes the concept of a “time-out”, which includes verification of the correct patient
identity, the correct site of the procedure, and the procedure to be performed. Conduct a time-out immediately before starting the invasive procedure or making the incision. Marking the incision or insertion site on the patient’s skin is required “when there is more than one possible location for the procedure and when performing the procedure in a different location would negatively affect quality or safety.” When possible, the patient should be involved in the site marking process. The procedure site is marked by a licensed independent practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed.

F. Handwashing

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.

G. Simulation

Although the apprenticeship model of medical training has been in use for centuries, there are several problems with its use. The fundamental ethical principle of non-maleficence requires that no preventable harm come to patients involved in the training process. In addition, changing medical practice patterns with shorter hospital stays and duty-hour restrictions are making it difficult for trainees to be exposed to enough patients to prepare them to deal with the many possible scenarios they may face in practice. Despite these limitations, the apprenticeship model cannot be completely rejected because it is essential for trainees to perfect their technique by caring for real patients with the guidance of experienced practitioners. Simulation-based training can allow novices to learn from their mistakes in a safe environment and in accordance with the principles of deliberate practice, thus allowing simulation to be a bridge to help get trainees from the novice state, in which they have a higher risk of causing harm, to a more experienced state in which they are more likely to do what is needed for patients.

II. 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, nurses, and 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 be immediately 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.

Issues related to MR contrast agents are discussed elsewhere in this study guide. For additional information refer to: ACR Guidance Document for Safe MR Practices

III. Contrast Safety – 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. With use of low osmolality contrast media, large studies have shown an overall incidence of reactions of 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 Contrast Manual 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. Pre-screening for IV contrast safety

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 2-3 times increased risk of contrast reaction. Asthma may also increase the risk of 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 one hour with maximum effect reached by four hours. Histamine in sedimented leukocytes is reduced by four hours with maximal effect by eight hours. However, reactions may also occur related to administration of corticosteroids, especially when given intravenously. Thus, the preferred premedication regimens utilize oral medications with at least six 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. Many facilities now use low osmolality contrast media, which also reduce non-idsosyncratic physiologic reactions such as heat sensation.

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

b. Methylprednisolone (Medrol®): 32 mg by mouth 12 hours and 2 hours before contrast media injection. An antihistamine (as in option 1) can also be added to this regimen injection. If the patient is unable to take oral medication, 200 mg of hydrocortisone intravenously may be substituted for oral prednisone in the Greenberger protocol.

When contrast administration is required in a shorter timeframe, 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 4-6 hours prior to contrast injection. The ACR Contrast Manual lists the following options, in decreasing order of desirability:

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

b. Dexamethasone sodium sulfate (Decadron®) 7.5 mg or betamethasone 6.0 mg intravenously q4h until contrast study must be done in patient 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

c. 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 benefits of such regimens are 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.

For additional information refer to: ACR Practice Guideline for use of Intravascular Contrast Media

iii. Treatment
When a reaction does occur, rapid recognition, assessment, and diagnosis are important to allow effective treatment. The ACR Contrast Manual lists the following table for management of contrast reactions in adults and has a separate table for children:

a. Urticaria
   1. Discontinue injection if not completed.
   2. No treatment needed in most cases.
   3. Give H1-receptor blocker: diphenhydramine (Benadryl®)
      PO/IM/IV 25 to 50 mg.

   If severe or widely disseminated: give alpha agonist (arteriolar and venous constriction): epinephrine SC (1:1,000) 0.1 to 0.3 ml (=0.1 to 0.3 mg) (if no cardiac contraindications).

b. Facial or Laryngeal Edema
   1. Give O2 6 to 10 liters/min (via mask).
   2. Give alpha agonist (arteriolar and venous constriction):
      epinephrine SC or IM (1:1,000) 0.1 to 0.3 ml (=0.1 to 0.3 mg) or, especially if hypotension evident, epinephrine (1:10,000) slowly IV 1 to 3 ml (=0.1 to 0.3 mg).

      Repeat as needed up to a maximum of 1 mg.

   If not responsive to therapy or if there is obvious acute laryngeal edema, seek appropriate assistance (e.g., cardiopulmonary arrest response team).

c. Bronchospasm
   1. Give O2 6 to 10 liters/min (via mask).

      Monitor: electrocardiogram, O2 saturation (pulse oximeter), and blood pressure.
   2. Give beta-agonist inhalers (bronchiolar dilators, such as metaproterenol [Alupent®], terbutaline [Brethaire®], or albuterol [Proventil® or Ventolin®]) 2 to 3 puffs; repeat as necessary. If unresponsive to inhalers, use SC, IM, or IV epinephrine.
   3. Give epinephrine SC or IM (1:1,000) 0.1 to 0.3 ml (=0.1 to 0.3 mg) or, especially if hypotension evident, epinephrine (1:10,000) slowly IV 1 to 3 ml (=0.1 to 0.3 mg).

      Repeat as needed up to a maximum of 1 mg.

   Call for assistance (e.g., cardiopulmonary arrest response team) for severe bronchospasm or if O2 saturation <88 percent persists.
d. Hypotension with Tachycardia
   1. Legs elevated 60 degrees or more (preferred) or Trendelenburg position.

   Monitor: electrocardiogram, pulse oximeter, blood pressure.
   2. Give O2 6 to 10 liters/min (via mask).
   3. Rapid intravenous administration of large volumes of Ringer’s lactate or normal saline.

   If poorly responsive: epinephrine (1:10,000) slowly IV 1 ml (=0.1 mg). Repeat as needed up to a maximum of 1 mg.

   If still poorly responsive seek appropriate assistance (e.g., cardiopulmonary arrest response team).

e. Hypotension with Bradycardia (Vagal Reaction)
   1. Secure airway: give O2 6 to 10 liters/min (via mask).

   Monitor vital signs.
   2. Legs elevated 60 degrees or more (preferred) or Trendelenburg position.
   3. Secure IV access: rapid administration of Ringer’s lactate or normal saline.
   4. Give atropine 0.6 to 1 mg IV slowly if patient does not respond quickly to steps 2 to 4.
   5. Repeat atropine up to a total dose of 0.04 mg/kg (2 to 3 mg) in adult.
   6. Ensure complete resolution of hypotension and bradycardia prior to discharge.

f. Hypertension, Severe
   1. Give O2 6 to 10 liters/min (via mask).

   Monitor electrocardiogram, pulse oximeter, blood pressure.
   2. Give nitroglycerine 0.4 mg tablet, sublingual (may repeat x 3); or, topical 2 percent ointment, apply 1-inch strip.
   3. If no response, consider labetalol 20 mg IV, then 20 to 80 mg IV every 10 minutes up to 300 mg.
   4. Transfer to intensive care unit or emergency department.
   5. For pheochromocytoma: phentolamine 5 mg IV (may use labetalol if phentolamine is not available).

g. Seizures or Convulsions
   1. Give O2 6 to 10 liters/min (via mask).
   2. Consider diazepam (Valium®) 5 mg IV (or more, as appropriate) or midazolam (Versed®) 0.5 to 1 mg IV.
   3. If longer effect needed, obtain consultation; consider phenytoin (Dilantin®) infusion – 15 to 18 mg/kg at 50 mg/min.
4. Careful monitoring of vital signs required, particularly of pO2 because of risk to respiratory depression with benzodiazepine administration.
5. Consider using cardiopulmonary arrest response team for intubation if needed.

h. Pulmonary Edema
1. Give O2 6 to 10 liters/min (via mask).
2. Elevate torso.
3. Give diuretics: furosemide (Lasix®) 20 to 40 mg IV, slow push.
4. Consider giving morphine (1 to 3 mg IV).
5. Transfer to intensive care unit or emergency department.

Abbreviations:
IM = intramuscular
IO = intraosseous
IV = intravenous
PO = orally
MR contrast agents NSF
Extravasation risk factors, prevention, treatment

iv. Contrast induced nephropathy (CIN) is broadly defined as “a sudden deterioration in renal function following the recent intravascular administration of iodinated contrast medium in the absence of another nephrotoxic event.” However, 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 change in the baseline serum creatinine, generally defined as a 25 to 50 percent increase. The usual clinical course of CIN is a rise in serum creatinine within 24 hours of contrast administration, which peaks at about four days and returns to baseline within seven 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 angiography, there is 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 of 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 8 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.

Risk factors for CIN are also controversial, although there is consensus that pre-existing 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 a serum creatinine of 2.0 gm/dL in patients with chronic, stable renal insufficiency. Acute kidney injury is also considered a risk factor, and in that situation, the serum creatinine is not 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 with end-stage oliguric renal stage on dialysis may be at risk of conversion to anuria. However, 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.

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; 2) history of renal disease (including dialysis, kidney transplant, single kidney, renal cancer, or renal surgery); 3) hypertension requiring medical therapy; 4) diabetes mellitus; and 5) 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 non-contrast 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% saline or Lactated Ringer’s. A suggested protocol per the ACR Contrast Manual is infusion at 100 ml/hr for 6-12 hours before contrast administration and 4-12 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 Contrast Manual 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 Contrast Manual states, “Use of these agents to reduce the risk of CIN is not recommended.”

B. 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 Contrast Manual (version 7, 2010) states, “The frequency of all acute adverse events after an injection of 0.1 or 0.2 mmol/kg of gadolinium chelate ranges from 0.07 percent to 2.4 percent. 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. A 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.”

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.

An additional consideration with use of GBCM is the risk of Nephrogenic Systemic Fibrosis (NSF). The ACR Contrast Manual 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. Death may result in some patients, presumably as a result of visceral organ involvement.”

There are many continuing controversies and uncertainties regarding NSF and its relationship to the administration of GBCM. However, the combination of severe chronic
kidney disease (Stage 4 [eGFR 15-29 ml/min/1.73 m²], Stage 5 [eGFR <15 ml/min/1.73 m²], and patients on dialysis) or acute kidney injury and a history of GBCM administration is found in most patients who develop NSF. 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. There is also controversy regarding the relative risk of the various available GCMs. 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 through a process known as transmetallation. 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.

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 GBCA to patients with an eGFR <30 ml/min/1.73 m² or with acute kidney injury. This requires screening of patients. The ACR Contrast Manual recommends obtaining an eGFR within six weeks of anticipated GBCM injection in patients with a history of renal disease (including a solitary kidney, kidney transplant, or renal neoplasm), over age 60, or with a history of hypertension or diabetes mellitus. 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.

C. 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 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 hyperosmolarity 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. Wang et al., in a series of 442 extravasations of low osmolality contrast media in adults, 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 they develop 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.

IV. Radiation safety dose optimization

The potential dangers of medical radiation exposure have been recognized since the early days of its use following Roentgen’s discovery of x-rays in 1895. In fact, many of the earliest radiologists suffered disability and death from radiation-induced effects, including cancers. However, over time, improvements in equipment and the use of basic radiation safety principles greatly reduced the risk to patients and operators in routine use.

Recognizing the increasing radiation exposure from medical imaging and the associated risks, organized radiology has put forth multiple initiatives to measure and reduce medical radiation exposure. Several of these are discussed below.

A. Image Gently

In recognition of the potential risks of radiation from diagnostic imaging procedures, particularly in the pediatric population, the Society for Pediatric Radiology formed a committee in late 2006. In 2007 this committee reached out to other major
organizations and formed the Alliance for Radiation Safety in Pediatric Imaging. The founding organizations of the Alliance were the Society of Pediatric Radiology, the American College of Radiology, the American Society for Radiologic Technologists, and the American Association of Physicists in Medicine. The Alliance expressed a primary objective: to raise awareness in the imaging community of the need to adjust radiation dose when imaging children, with the ultimate goal of changing practice. To support its objective and goal, the founding organizations invited other national and international organizations to become Alliance Organizations. As of November 2011, the Image Gently website listed 61 such organizations.

The initial focus of Image Gently was on CT scanning due to the rapid increase of CT scan usage in the pediatric population and the large contribution of CT scans to the overall medical radiation dose to the pediatric population. In addition, many facilities, especially those that were not primarily focused on pediatric patients, may not have sufficiently adjusted their imaging protocols from their usual adult population. In August 2009, the campaign expanded to a second focus, safety in pediatric interventional radiology (see section on Step Lightly below).

An early and ongoing focus of the campaign was to encourage imaging professionals to take a pledge to “image gently.” They pledged:

- to make the image gently message a priority in staff communications this year;
- to review the protocol recommendations and, where necessary, implement adjustments to our processes;
- to respect and listen to suggestions from every member of the imaging team on ways to ensure changes are made; and
- to communicate openly with parents

Image Gently has emphasized the use of social marketing to disseminate its message. The first phase of the campaign targeted imaging professionals (radiologists, radiology technologists, and medical physicists). The second phase targeted referring physicians (especially pediatricians, emergency medicine physicians, surgeons, and oncologists). The third phase targeted parents and the public. Examples of communication methods used by Image Gently include a website, scientific articles and articles in the trade press, public service announcements in radiology trade news outlets, posters, blast e-mails, and healthcare blogs. The Image Gently website has resources for the radiologist, radiologic technologist, medical physicist, referring physician, and parent. The website includes specific advice to reduce radiation dose in clinical practice.

B. **Image Wisely**

Responding to the same concerns that led to the Image Gently campaign for the pediatric population, in June 2009 the American College of Radiology and the Radiological Society of North America established the Joint Task Force on Adult Radiation Protection to address issues of radiation dose optimization in the adult population.

As described by the co-chairs of the Task Force, its mission was "to raise awareness of opportunities to eliminate unnecessary imaging examinations and to lower the amount
of radiation used in necessary imaging examinations to only that needed to acquire appropriate medical images.” The group’s charge was “to make recommendations for a campaign to develop educational resources for radiologists, medical physicists, and technologists who provide medical imaging care within the United States and for consumers of medical imaging care, including referring physicians, patients, and the public.” Similar to the Image Gently campaign, the adult initiative was “charged to broadcast the availability of these educational resources by using a wide variety of electronic and print media, to institute initiatives that ensure adoption of best practices in optimization of radiation dose by imaging groups, and, through networking, to solicit the involvement and participation of affiliated healthcare organizations, educational institutions, government agencies, and vendors of imaging equipment.”

The name “Image Wisely” was chosen for the campaign for adult radiation protection. The task force chose to broaden its membership to include the American Association of Physicists in Medicine and the American Society of Radiologic Technologists. However, in contrast in Image Gently, the Image Wisely campaign has not sought to add other organizations into a broader alliance.

Image Wisely has created a website with resources for imaging professionals (imaging physicians, medical physicists, and radiological technologists), referring physicians, and patients. The primary focus of the Image Wisely campaign is CT scanning. The website includes links to CT dose optimization resources from five major CT vendors in the U.S. In conjunction with the U.S. Food and Drug Administration (FDA), Image Wisely has also developed a “Patient Medical Imaging Record” that “allows patients to easily track the date, type, and location of their radiology exams.”

A focus of Image Wisely is a voluntary “pledge to image wisely by optimizing the use of radiation when imaging patients.” The number of pledges passed the 10,000 level in November 2011. The Image Wisely pledge is:

- to put my patient’s safety, health, and welfare first by optimizing imaging examinations to use only the radiation necessary to produce diagnostic quality images;

- to convey the principles of the Image Wisely program to the imaging team in order to ensure that my facility optimizes its use of radiation when imaging patients;

- to communicate optimal patient imaging strategies to referring physicians, and to be available for consultation;

- to routinely review imaging protocols to ensure that the least radiation necessary to acquire a diagnostic quality image is used for each examination

C. CT Dose Index (and CT Dose Index Registry)

The precise radiation dose received by a patient during a CT examination cannot be readily determined and depends on many factors including the CT scanner itself, the technical parameters used for the specific examination, the scan protocol (including the
The number of phases scanned and scan pitch, the body part scanned, and patient factors such as overall size and tissue composition and distribution. Therefore, relative dose is assessed based on dose index parameters that can be calculated from phantom measurements. When an estimate of patient dose from a specific exam is needed, a medical physicist can calculate an estimated dose based on the parameters of the study and specific patient factors.

Two dose index parameters are generally calculated and reported by CT scanners, the CTDIvol (CT Dose Index Volume) and the DLP (Dose Length Product). The definition and calculation CTDIvol are beyond the scope of this discussion. For helical CT scanning, the DLP equals the product of the CTDIvol and the scanning length. The unit of measurement for CTDIvol is the mGy (milliGray) and for DLP, mGycm.

The American College of Radiology (ACR) has developed a Dose Index Registry (DIR). Data from CT scanners at participating facilities including CTDIvol and DLP are sent to the DIR, and summary data are reported back to the facilities with comparison to similar facilities that also participate in the registry. Facilities can use this data to track their performance and adjust their scanning parameters and/or protocols as appropriate.

The ACR has also established three diagnostic CT reference values based on data from its CT Accreditation Program. The CTDIvol values are 75 mGy for CT of the head, 25 mGy for CT of the adult abdomen, and 20 mGy for CT of the pediatric (5 year old) abdomen. Facilities can compare their calculated values against these reference values and modify their scanning parameters as needed.
D. Principles of Dose Management and ALARA

Radiologists have long recognized the principle of **ALARA. As low as reasonably achievable**, to minimize radiation dose delivered to patients, staff, and society as a whole. This is summarized in an American College of Radiology (ACR) resolution first passed in 2006 and modified in 2009 as follows:

“Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not, manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard.”

Although the ALARA principle addresses the actual performance of an examination, the first steps in reducing radiation exposure are to perform only indicated examinations, to perform the most appropriate examination, and to consider alternative examinations that do not use ionizing radiation, such as ultrasound and MRI, when appropriate, especially in populations where radiation exposure is more significant, such as children and young adults with expected benign disease.

CT is appropriately a major focus of radiation reduction methods as it accounts for the largest overall population exposure from medical imaging. CT techniques should be modified based on the size of the patient, as advocated by the Image Gently and Image Wisely campaigns, which are discussed elsewhere in this study guide. When a reduced kVp can be used, this may have a collateral benefit of improved detection of iodinated contrast CT by better matching the k-edge of iodine. Equipment manufacturers continue to develop hardware and software improvements that can significantly reduce radiation dose through modulation of the tube current and improved reconstruction methods, such as iterative reconstruction. Radiologists should also review imaging protocols and eliminate series of images such as combined pre-contrast and post-contrast studies or multiple post-contrast phases of images if some of the series are not needed for diagnosis. Radiologists and technologists should also limit the length of long-axis scanning to the minimum area indicated.

There is increasing emphasis on dose monitoring and recording of dose parameters in the medical record. Radiologists should be aware of any local requirements, but voluntary dose monitoring can be an important step in reducing patient radiation exposure.
V. ACR Appropriateness Criteria and decision support

The American College of Radiology (ACR) has developed a group of documents known as the ACR Appropriateness Criteria®. Their primary purpose is to “assist referring physicians in making appropriate imaging decisions for given patient clinical conditions.” Their initial development began in 1993, and they have been constantly updated and expanded since that time. As of October 2011, there are over 175 Clinical Conditions and 850 Variants covered by the Appropriateness Criteria®, including topics in Diagnostic Radiology, Interventional Radiology, and Radiation Oncology.

The ACR describes the development, purpose and methodology of the Appropriateness Criteria® as follows:

The ACR Task Force on Appropriateness Criteria (ACR AC) was created and panel chairs were appointed in late 1993. In 1994, deliberations had begun to develop nationally accepted, scientifically-based guidelines to assist referring physicians in making appropriate imaging decisions for given patient clinical conditions in order to provide the College’s perspective on how to best use limited healthcare resources.

In creating the ACR AC, the Task Force incorporated attributes for developing acceptable medical practice guidelines used by the Agency for Healthcare Research and Quality (AHRQ) as designed by the Institute of Medicine. From the beginning, the methodology relied on a combination of evidence and, when the data from scientific outcome and technology assessment studies are insufficient, expert consensus. Additionally, the methodology employs the input of physicians from other medical specialties to provide important clinical perspectives.

The AHRQ is explicit in stating its intent that scientific evidence should be used as much as possible, but that judgment and group consensus will be necessary in the development of medical guidelines. The National Guidelines Clearinghouse (NGC), one of the initiatives of AHRQ, is a public resource for evidence-based clinical practice guidelines. The ACR AC topics are posted on the NGC site.

Currently, the ACR ACs are the most comprehensive evidence-based guidelines for diagnostic imaging selection, radiotherapy protocols, and image-guided interventional procedures. They embody the best current evidence for selecting appropriate diagnostic imaging and interventional procedures for numerous clinical conditions.

The Appropriateness Criteria® for Diagnostic Radiology are divided into ten clinical imaging topics: Breast, Cardiac, Gastrointestinal, Musculoskeletal, Neurologic, Pediatric, Thoracic, Urologic, Vascular, and Women’s. Each topic is managed by an expert panel which includes radiologists and clinical specialists from outside radiology. Each topic contains a variable number
of clinical conditions, which are then subdivided into a variable number of variants. For example, Thoracic Imaging includes 11 clinical conditions, one of which is “Hemoptysis.” “Hemoptysis” includes three variants based on patient factors and symptoms. For each variant, each possible imaging modality is rated on a 1 (low) to 9 (high) scale based on the appropriateness of the modality for the variant under discussion.

These ratings are determined by the expert panel using a process known as the Modified Delphi Technique, which attempts to reach consensus of the panel members through serial rounds of anonymous voting. Ratings of 1-3 are defined as “usually not appropriate”, 4-6 as “may be appropriate”, and 7-9 as “usually appropriate.” The panel may also indicate, if needed, that there was “No Consensus.” It is important to remember that the ratings refer to the appropriateness of an imaging modality for the initial imaging examination based on the variant. Thus, in some cases, additional studies may become appropriate following the initial study, even though those additional studies had a low rating as the initial study. The ratings are reported in a “variant table” and are accompanied by a narrative document and references. Each imaging modality is also assigned a “relative radiation level” on a six-point scale based on an adult effective dose estimate range and a pediatric effective dose estimate range.

The ACR Appropriateness Criteria® could be adapted for use in decision support software and computerized order entry programs. This has been done commercially under licensure from the ACR, and additional applications are under development by the ACR.

For additional information refer to: ACR Appropriateness Criteria

VI. ACR Practice Guidelines and Technical Standards

The American College of Radiology (ACR) has developed a group of documents known as the Practice Guidelines and Technical Standards. They were first developed beginning in 1990 and were known as ACR Standards. In 2003, the name was changed to ACR Practice Guidelines and Technical Standards and each existing standard was reclassified as either a Practice Guideline or a Technical Standard.

The ACR describes their purpose and intended use as follows:

ACR Practice Guidelines and Technical Standards define principles and technical parameters of radiologic and radiation oncology practice, which should generally produce desired healthcare outcomes. They describe a range of acceptable approaches for the diagnosis and/or treatment of disease for most patients in most circumstances. Given differences in training, experience, and local conditions, the ACR Practice Guidelines and Technical Standards acknowledge the need for healthcare providers to exercise their independent medical judgment in making decisions regarding the use and specific details of any procedure.

ACR Practice Guidelines and Technical Standards are educational tools designed to provide consensus-based, scientifically valid and medically credible information to assist healthcare providers in delivering effective, efficient, consistent and safe medical care. They may be developed jointly with other professional organizations.
Used in conjunction with the ACR Appropriateness Criteria®, it is expected that the ACR Practice Guidelines and Technical Standards will increase the likelihood that appropriate procedures will be performed in a safe and acceptable manner and will help to reduce unnecessary ones.

ACR Practice Guidelines and Technical Standards are intended to be living documents that are regularly reviewed and revised to reflect changes in radiologic and radiation oncology practice.

PRACTICE GUIDELINES describe recommended conduct in specific areas of clinical practice. They are based on analysis of current literature, expert opinion, open forum commentary, and informal consensus. Guidelines are not intended to be legal standards of care or conduct and may be modified as determined by individual circumstances and available resources.

TECHNICAL STANDARDS describe technical parameters that are quantitative or measurable. They often include specific recommendations for patient management or equipment specifications or settings. Technical Standards are based on analysis of current literature, expert opinion, open forum commentary, and informal consensus. Technical Standards are intended to set a minimum level of acceptable technical parameters and equipment performance and may be modified as determined by individual circumstances and available resources.

As of October 2011, there are 170 ACR Practice Guidelines and Technical Standards. This number changes yearly as new documents are added and, less frequently, old documents are retired or merged into new ones. While the focus of this study guide is on Diagnostic Radiology, the Practice Guidelines and Technical Standards also cover topics in Radiation Oncology and Medical Physics. However, most of the Practice Guidelines address common diagnostic radiology examinations. The documents are reviewed, and revised as necessary, on a five-year cycle or sooner if needed. All Diagnostic Radiology Practice Guidelines and Technical Standards are approved by the ACR Council at the ACR Annual Meeting and Chapter Leadership Conference, and collaborative documents are approved by the collaborating organizations using their own methods.

Practice Guidelines that discuss diagnostic radiology examinations are usually titled, “ACR [collaborative societies, if any] Practice Guideline for the Performance of [name of examination].” Their overall purpose is to promote proper performance of the examination in question. A common format includes an Introduction, Goal, Indications and Contraindications, Qualifications and Responsibilities of Personnel, Specifications of the Examination, Documentation and Reporting, Equipment Specifications, Radiation Safety in Imaging, and Quality Control and Improvement, Safety, Infection Control, and Patient Education. However, other general topics are also covered by Practice Guidelines, including Communication of Diagnostic Imaging Findings, Continuing Medical Education, Expert Witness, Use of Intravascular Contrast Media, and Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation.

While the ACR Practice Guidelines and Technical Standards are the major documents of this sort relevant to Diagnostic Radiology in the United States, other organizations in other disciplines and imaging organizations in other countries have similar documents which may have different names. International examples in diagnostic imaging include the Royal College of Radiologists (United Kingdom) Standards, the Canadian Association of Radiologists Standards, and the Royal Australian and New Zealand College of Radiologists (RANZCR) Standards of Practice.
VII. Peer Review

Peer review is an essential process in Radiology Quality and Safety, in which a random sample, often 5-10%, of clinical work done by each radiologist in the group is evaluated by a peer or peers with comparable clinical credentialing. Feedback is typically provided to the original radiologist and peer review data are also collected confidentially by a central authority, such as the departmental quality committee. Such peer review data are immune to legal action or discovery. Peer review thus constitutes a “safe” form of self-regulation between qualified radiologists. It is typical in subspecialized practices for peer review to be divided by subspecialty (e.g., neuroradiologists review the work of other neuroradiologists, but not the work of the nuclear medicine practitioners, etc.) but in non-specialized practice all types of radiologist work are evaluated equally. Peer review data are often required by accreditation bodies or regulatory bodies to assure that ongoing quality assurance processes are in place. In general, peer review programs are generally designed toward maintenance of standards of quality, to improve radiologists’ performance, and provide credibility to oversight organizations, such as The Joint Commission. The American Board of Radiology has created a simplified system for Peer review, the RadPeer™ system, which is used by many radiology groups. RadPeer™ has now accumulated over a decade of experience nationwide.
References & Additional Reading

1. ACR Practice Guidelines and Technical Standards. Available online at:
8. Linda Kohn, Janet Corrigan, and Molla Donaldson, Editors, “To Err is Human: Building a Safer Health System”, Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington, D.C., 2000
9. (http://www.jointcommission.org/sentinel_event.aspx
11. ACR-SIR Practice Guideline on Informed Consent for Image-Guided Procedures
13. Program. Available at:
14. Agency for Healthcare Research and Quality (AHRQ). National Quality Measures Clearinghouse. Anesthesiology and critical care: percentage of patients who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique followed. Available at:
17. ACR Manual on Contrast Media v7. Available online at:
18. ACR Manual on Contrast Media v7. Available online at:
20. JACR Vol 5, No 1, January 2008 – Symposium on Nephrogenic Systemic Fibrosis
21. ACR Manual on Contrast Media v7. Available online at:
27. ACR Dose Index Registry. Available at: https://nrdr.acr.org/Portal/DIR/Main/page.aspx.