NONINTERPRETIVE SKILLS DOMAIN SPECIFICATION & RESOURCE GUIDE

December 2012
Revised January 2013

ACKNOWLEDGEMENTS

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NONINTERPRETIVE SKILLS DOMAIN SPECIFICATION & RESOURCE GUIDE

I.   General Quality Improvement

A. Quality Improvement Definition

1. Traditional definition of quality in healthcare
    a. Quality improvement (QI) is a more recent phenomenon in health care, 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 *(Roper, IOM 2006).*

2. Limitations of traditional QI techniques in healthcare
    a. The classic definition of quality is too narrow and doesn't encompass the complex healthcare system of today. Traditional quality assurance features a static approach to quality in which the goal is conformance to standards.
    b. The traditional approach tends to focus on physician performance and to underemphasize the contributions of non-MDs and organizational processes and as such, focuses on physicians and changing physician behavior and emphasizes the technical performance of physicians and interpersonal relations. While these are important, they do not address the ability to mobilize an organization's resources to meet patient needs and organization goals.

3. Application of industrial quality management science to healthcare
    a. Traditional older theory and practice of QA in medicine are felt to be inadequate for the complex, modern healthcare organization. High quality care is traditionally felt to consist of scientific/technical components and an interpersonal component. QA programs historically had three major focuses: measuring performance, comparing performance to standards, and improving performance when standards are not met.
    b. Modern quality science is a discipline whereby statistical techniques are used to assist decision-making regarding product quality and production pathways. It has seen significant improvements in the quality of products and services,

improved productivity and efficiency, and improved profitability, in many instances

(The Case for Using Industrial Quality Management Science in Health Care Organizations, Laffel and Blumenthal, JAMA, 262, 20, 1989).

4. 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. Six IOM quality aims.

   Care that is:

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

C. Six core competencies of MOC

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

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

   3. Interpersonal and Communication Skills—Demonstrate skills that result in effective information exchange and teaming with patients, their families, and professional associates (e.g., fostering a therapeutic relationship that is ethically sound and uses effective listening skills with nonverbal and verbal communication; working as both a team member and at times as a leader).

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

   5. 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).

   6. 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.

   1. Dashboards: According to Stephen Few, "A dashboard is a visual display of the most important information needed to achieve one or more objectives; consolidated and arranged on a single screen so the information can be monitored at a glance."

      http://www.perceptualedge.com/articles/ie/dashboard_confusion.pdf

   2. 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."

      http://www.businessdictionary.com/definition/benchmarking.html

E. Methodologies

   1. 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.

PDSA Cycle

      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:

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

- 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.

SELF-REFLECTION NARRATIVE: When the project is completed, write a short paragraph of self-reflection, stating the way(s) in which the project positively impacted your practice and/or your patients.

2. Lean

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.

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.

Tool set:
- Value Stream Mapping
- Five S
- Pull Systems "Just-in-Time"
- Error-proofing

Value Stream Mapping is a tool to help understand and improve the material and information flow within a process. The end product is a visual flow map, in a simple graphical format, of the whole process from end to end in a method that is easy to understand by those working through the process. The graphic format encourages

and supports a team approach and provides a mechanism to constructively critique activity. Very specific data can be collected and displayed for process steps, wait steps, and information flow. In process improvement projects, one can display the existing flows, or the Current State Map, and explore and define the improved or altered process, or the Future State Map.

The Five S tool is focused on standardization of work areas. Goals are to eliminate clutter, establish "a place for everything and everything in its place," standardize the manner in which work flows across the station, and maintain the new simplified state. The Five S process is necessary, but not sufficient, in Lean improvement processes.

Five S: (translated from the Japanese *seiri, seiton, seiso, seiketsu*, and *shitsuke)*

- Sorting
- Straightening
- Systematic cleaning
- Standardizing
- Sustaining

Pull systems, just-in-time, or *kanban*, are system fundamentals that differentiate Lean and TPS from more common assembly line practices of overproducing at individual work steps, thus creating large piles of inventory that must be stored or inventoried until actually needed by the next process step. Inventory or work accumulating in queue is a fundamental source of waste. In theory, pull systems work to emulate one-piece flow where the next step of work on an item occurs immediately at the completion of the prior step, the prior step is not creating any more than the next step can handle, and the next step is not idly waiting on the prior step for work. In practice, this is managed by producing a small buffer of inventory and implementing alert systems (kanbans) that signal readiness for additional parts or work. Pull-systems and kanbans are practical solutions to the unreality of true, consistent one-piece flow. The small inventories and need for signaling is viewed as "necessary waste"—useful, but to be minimized.

Error-proofing is a concept of defining and standardizing process steps and quickly addressing new sources of error with further refinement of the steps. Recognition of error or defect obligates a team member to "stop the line," or draw immediate attention to the defect so that supervisors and problem-solving teams can address the defect and the variation in process that caused it. It is systems-focused inquiry, rather than individually focused, thus maintaining the goodwill of the team members.

Smoothness of workflow from end to end is the ultimate goal of Lean systems. Poor flow results from two primary issues: 1) unreasonable work due to poor organization and 2) pushing beyond natural limits. Poor organization induces moving things around, awkward transitions, potentially dangerous tasks, and uneven tempo of work. Pushing beyond natural limits leads to shortcuts, idiosyncratic decision making, and multiple variations in process. It is important to note once again that this view focuses on system impositions on workers rather than flawed employees.

> Primary reference: The Toyota Way, 14 Management Principles from the World's Greatest Manufacturer; Liker, Jeffery K.; McGraw-Hill 2004.

3. Design-Measure-Analyze-Improve-Control
The Six Sigma version of this process is DMAIC: Design-Measure-Analyze-Improve-Control. This refers loosely to striving for near perfection in the performance of a process or production of a product. The name derives from the Greek letter sigma, often used to refer to the standard deviation of a normal distribution. By definition, 95 percent of a normally distributed population falls within two standard deviations of the average (or "2 sigma"). This leaves 5 percent of observations as "abnormal" or "unacceptable." Six Sigma targets a defect rate of 3.4 per million opportunities—six standard deviations from the population average.

When it comes to industrial performance, having 5 percent of a product fall outside the desired specifications would represent an unacceptably high defect rate. What company could stay in business if 5 percent of its product did not perform well? For example, would we tolerate a pharmaceutical company that produced pills containing incorrect dosages 5 percent of the time? Certainly not. But when it comes to clinical performance—the number of patients who receive a proven medication or the number of patients who develop complications from a procedure—we routinely accept failure or defect rates in the 2 percent to 5 percent range, orders of magnitude below Six Sigma performance.

Not every process in healthcare requires such near-perfect performance. In fact, one of the lessons of Reason's Swiss cheese model is the extent to which low overall error rates are possible even when individual components have many "holes." However, many high-stakes processes are far less forgiving since a single "defect" can lead to catastrophe (e.g., wrong-site surgery, accidental administration of concentrated potassium).

F. Target identification
The process of QI requires choosing a part of the radiologist's practice to examine or focus upon. The proposed target should be important, visible, and recognizable by patients; have a high probability of being successful and making a real difference; allow for improvement; be measured without significant disruption of day-to-day activities; and be controllable by the radiology organization doing the project. It is also imperative that all members of the QI team participate in choosing the target. Target identification involves two steps:

1. Focus on processes as objects of improvement (85 percent of worker effectiveness is due to the system within which he/she works, not the individual's skill).

2. Eliminate unnecessary variation (focus on key inputs to processes, analyze quantitatively, and use valid measures for breakthrough improvements).

G. QI tools (http://www.rsna.org/QI_Tools.aspx)

1. Brainstorming (http://www.rsna.org/Brainstorming.aspx)
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
- Determine data collection issues

The major steps in effective brainstorming sessions are:

a. Explain the subject of the brainstorming session to the team. The topic can be distributed before the meeting to get thinking started. If shared for the first time at the beginning of the meeting, let participants have two to three minutes to think the topic.
b. Set a time limit. Depending on the complexity of the issue, the brainstorming session may take one to four hours; however, it is not unusual to have several consecutive brainstorming topics/exercises during a quality improvement project.
c. Identify a note taker to list the ideas on a flip chart, or have people write their ideas on index cards or Post-It notes.
d. Ask participants to call out one idea at a time. This can be done by going around the table, which structures participation, or at random, which favors greater creativity. Another option is to go around the table once and then open discussion up to all to call out ideas. Keeps the team going when ideas slow down; however, it is okay to let a participant pass if an idea does not come quickly. There should be no discussion or criticism during this session; the goal is to identify all the ideas and issues. The evaluation of the ideas, issues, and plans comes later.
e. Build and expand on ideas; think freshly and encourage creativity. Use the rule that there are no bad ideas. Refrain from historical reminiscences about what may have been tried in the past. After all the ideas have been shared, eliminate duplicates. If a large number of ideas have been generated, have the team organize them into thematic clusters.

2. Cause-and-effect diagram (Fishbone diagram)
A cause-and-effect diagram is 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?

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.

3. Flowcharts (http://www.rsna.org/flowchart.aspx)
A flowchart is a graphic diagram or map that illustrates the steps and decision points that make up a work process. It represents a common understanding of the process and enables 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.

b. How to create a flowchart
i. Define start and end points to the selected process, as well as where it interfaces with a larger process and/or support processes.
ii. Identify the individual steps within the current process, not how the team thinks it should happen. Identify the decision points in the process, as these may highlight the potential for roadblocks, errors, or miscommunication in the systems. Questions that may help in flowcharting a process are:
- What is being done?
- When is it done?
- Who does it?
- Where is it done?
- How it is done?
c. Create the initial flowchart using Post-It notes. Place the notes on a flip chart pad or blank wall. Keep the flowchart simple and use arrows to show

the direction of all the steps in the process. Make sure each step is placed in the order that it occurs in the current process.

d. Allow time for the team to study the flowchart; it may need to be left up for several days. This will allow the team time to observe the current process and make adjustments and additions to the flowchart as needed. Finalize the flowchart at a second meeting.

e. Keep the flowchart. The team will need to refer to it several times throughout the course of the project.

f. Formal flowcharts use special shapes to represent different types of actions or steps in a process. Lines and arrows show the sequence of the steps and the relationships among them.
The vast majority of flowcharts rely on just four symbols: oval (endpoint), rectangle (process), diamond (decision), and circle (connector). In fact, if you use other flowcharting shapes, many people will not know what they represent, so add a shape symbol key to your flowchart.

At decision points (diamonds), use a down arrow to show a positive workflow and an arrow, typically going right from the shape, for an alternative workflow or stop.

Only one arrow for "Yes" and one arrow for "No" should flow from each decision. If more than one arrow is needed for multiple yes and no responses, this usually suggests that the decision question is unclear, or that two decisions are stacked and require separation.

Draw lines after all the steps and decisions are identified.

At any time during the creation of the flowchart, it may become evident that the starting and ending points are farther apart than initially thought. It is acceptable to adjust the starting and ending points to make the quality improvement project more manageable.

Use the flowchart during a cause-and-effect analysis to facilitate identification of process factors or issues.

4. Multivoting (http://www.rsna.org/multivoting.aspx)
Multivoting is a simple, structured approach used by teams to select the most significant or highest priority item from a list. This process relies on popular opinion and is a method of prioritizing projects or elements of projects. It usually follows a brainstorming session that has generated many ideas.

How to Conduct a Multivoting Activity
a. List the ideas generated during a brainstorming session. If there is a large number, place the ideas into thematic groups.
b. Agree upon one or more criteria for voting.
c. Based on the identified criteria, ask each team member to select (vote for) one-third of the ideas and to mark his or her vote next to the idea on the flipchart.
d. Tally the votes for each idea.
e. Eliminate the ideas with the fewest votes. When deciding on ideas to eliminate during a round of voting, general parameters are:

Team Size (# of people)	Eliminate ideas with fewer than "x" votes
4 to 5	2
6 to 9	3
10 to 15 or more	5

    f.   Repeat the voting and elimination process until a workable list of ideas remains.

    g.   Rank order the ideas from the final list.
If a number of ideas receive the same low number of votes, another vote may be necessary on those ideas alone.

5. Nominal Group Technique (NGT)
This is a more formal and structured approach to generating a list of ideas or merging them into a more sustainable number. The term "nominal" is used to denote the minimal conversations or interactions among the team. This approach can be quite effective for discussing controversial concepts. It also allows for defusing a domineering staff member or influential employee who tends to control the discussion and be the prevailing voice. NGT promotes team ownership of decision-making. There are two stages of NGT:

    a.   Formalized brainstorming: similar to general brainstorming, except everything discussed is written down. A question is posed before beginning the session. At the start of the meeting:
- Introduce and clarify the question;
- Ask the group to explain its understanding of the question;
- Generate ideas—write down thoughts;
- Ask each member to read one idea and write it down on a flip chart; no discussion or questions;
- Post all ideas from the flip chart on a wall or board;
- When all questions are done, condense to a more feasible size (< 10). No one may remove another member's ideas;
- Number the final ideas.

    b.   Decision-making: Have members of the team make a list of selected ideas from the list, place one idea per index card, and prioritize the individually chosen list, with the highest value going to the first card on the list. Collect the cards and tally the votes. The highest total point value garners the most important spot. Review the results as a group and discuss the need for hearing objections or future voting. If one or more members disagree, the team may consider the top two or three choices.

6. Prioritization matrix
This useful tool is used by teams to achieve consensus regarding an issue. It can rank problems or concepts by specific criteria important to the organization. After a matrix is completed, the team will visualize which problems are most important and can prioritize them for improvement.

How to create a prioritization matrix: through a brainstorming session, create a table by answering the following questions:

    a.   What are the issues/concerns? (problem)
    b.   How often does each issue occur? Hourly? Monthly? (frequency)
    c.   How serious is each issue? (importance)

d. How solvable is each problem? (feasibility)

Problem	Frequency	Importance	Feasibility	Total Points

Each team member ranks each issue, the ratings of all members are totaled, and then the issues are prioritized. Sometimes multiple votes are necessary for a clear, most important choice to emerge.

7. Walk-through
This simulates the processes a patient encounters during his or her interaction with a clinical micro-system, in this case, the radiology department. The process can substantiate or validate survey findings and identify bottlenecks or roadblocks in the system. It provides direct knowledge of what it is like to be a patient in the organization. To perform a walk-through:

  o Select one clinical procedure;
  o Alert staff that one team member will be acting as a surrogate patient;
  o Experience the process exactly as a patient would;
  o Call for an appointment;
  o Drive to the appointment;
  o Park in general parking;
  o Follow directional signs;
  o Arrive at radiology department;
  o Fill out paper forms;
  o Sit in waiting area and note length of wait, cleanliness, etc.;
  o Do the same in the changing area;
  o Keep a log of experiences and feelings during process; ask staff for their experiences;
  o When the walk-through is complete, have the entire team congregate to share ideas.

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.

Goals are also revised through the Patient Safety Advisory Group. An example is the history of NPSG 03.06.01 on Medication Reconciliation. The goal was revised based on input from the field that the goal, as written, was too prescriptive and detailed. The Joint Commission determined at the time that survey medication reconciliation findings would not be included in the organization's accreditation decision until a revised NPSG was developed. The revised NPSG underwent review in the second quarter of 2010, and medication reconciliation was reaffirmed as an important patient safety issue that should continue as an NPSG.

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.

(http://www.jointcommission.org/standards_information/npsgs.aspx)

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.

Those numbers were based on extrapolation nationally of two large studies from Colorado/Utah and New York "which found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively. In Colorado and Utah hospitals, 6.6 percent of adverse events led to death, as compared with 13.6 percent in New York hospitals. In both of these studies, over half of these adverse events resulted from medical errors and could have been prevented"(3). Aside from medical-error-related deaths, the report projected total societal financial costs to be between $17 and 29 billion.

Medical errors were defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim, with the highest risk for errors occurring in the ICU, OR, and ED. The report identified several fundamental factors contributing to the errors, including: 1) the decentralized nature of the healthcare delivery "nonsystem"; 2) the failure of the licensing systems to focus on errors; 3) the impediment of the liability system to identify errors; and 4) the failure of third-party providers to provide financial incentive to improve safety. Most errors were felt to be **system errors** rather than individual problems.

The report laid out a comprehensive strategy to reduce preventable medical errors with the goal of a 50 percent reduction in errors over the next 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.

    a. Recommending that Congress create a Center for Patient Safety, funded with $100M annually.

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.

    a. Recommending that Congress enact laws to protect confidentiality of information from litigation.

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.

5. 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 that 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

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

2. Treatment
    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
    a. Failure to provide prophylactic treatment
    b. Inadequate monitoring or follow-up of treatment

4. Other
    a. Failure of communication
    b. Equipment failure
    c. Other system failure

    http://www.iom.edu/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx

    Leape, Lucian, et al., Preventing Medical Injury. Qual Rev Bull. 19(5):144-149, 1993

    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

D. **Ten Rules for Redesign**
To help in achieving these improvement aims, the committee deemed that it would be neither useful nor possible to specify a blueprint for 21st-century healthcare delivery systems. Imagination abounds at all levels, and all promising routes for innovation should be encouraged. At the same time, the committee formulated a set of ten simple rules, or general principles, to inform efforts to redesign the healthcare system. These rules are:

1. ***Care is based on continuous healing relationships****.* Patients should receive care whenever they need it, and in many forms, not just face-to-face visits. This implies that the healthcare system must be responsive at all times, and access to care should be provided over the Internet, by telephone, and by other means in addition to in-person visits.

2. ***Care is customized according to patient needs and values.*** The system should be designed to meet the most common types of needs, but it also should have the capability to respond to individual patient choices and preferences.

3. ***The patient is the source of control.*** Patients should be given the necessary information and opportunity to exercise the degree of control they choose over healthcare decisions that affect them. The system should be able to accommodate differences in patient preferences and encourage shared decision making.

4. ***Knowledge is shared and information flows freely****.* Patients should have unfettered access to their own medical information and to clinical knowledge. Clinicians and patients should communicate effectively and share information.

5. ***Decision making is evidence based.*** Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.

6. ***Safety is a system property****.* Patients should be safe from injury caused by the care system. Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.

7. ***Transparency is necessary.*** The system should make available to patients and their families information that enables them to make informed decisions when selecting a health plan, hospital, or clinical practice, or when choosing among alternative treatments. This should include information describing the system's performance on safety, evidence-based practice, and patient satisfaction.

8. ***Needs are anticipated.*** The system should anticipate patient needs, rather than simply react to events.

9. ***Waste is continuously decreased.*** The system should not waste resources or patient time.

10. ***Cooperation among clinicians is a priority***. Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

E. Systems thinking

1. Definition of systems
   - Providers, patients, support staff, clinical processes, administrative processes, technology, and information that all come together to produce care

2. The multiple layers of the system that affect safety
   - Nation, state, hospital, caregiving unit

3. Error mitigation versus recovery

F. Human factors

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

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

   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.

Human factors engineering has long been used to improve safety in many industries outside of healthcare—it has been employed to analyze errors in aviation, automobiles, and the Three Mile Island nuclear power plant accident. Its application to healthcare is relatively recent; pioneering studies of human factors in anesthesia were integral to the redesign of anesthesia equipment, significantly reducing the risk of injury or death in the operating room.

2. Applications of Human Factors Engineering to Improving Safety
The very nature of human factors engineering precludes "one size fits all" solutions, but several tools and techniques are commonly used as human factors approaches to addressing safety issues.

    a. *Usability testing*—Human factors engineers test new systems and equipment under real-world conditions as much as possible, in order to identify unintended consequences of new technology. One prominent example of the clinical applicability of usability testing involves electronic medical records and computerized provider order entry (CPOE). A seminal study found increased mortality in a pediatric intensive care unit after implementation of a commercial CPOE system, attributable in part to an unnecessarily cumbersome order entry process that reduced clinicians' availability at the bedside. Usability testing might have identified this issue and prompted earlier implementation of solutions—such as standardized order sets and the ability to obtain emergency medications outside of the CPOE system—that subsequently allowed for successful implementation of the system elsewhere. Simulated clinical scenarios may be used to conduct usability testing, as was performed in another study that identified significant limitations of existing CPOE systems. Simulated resuscitation scenarios have also helped identify usability problems with defibrillators.

    b. Usability testing is also essential for identifying *workarounds*—the consistent bypassing of policies or safety procedures by frontline workers. Workarounds frequently arise because of flawed or poorly designed systems that actually increase the time necessary for workers to complete a task. As a result, frontline personnel work around the system in order to get work done efficiently. In the obstetric example above, the hospital had implemented a bar-code system designed to prevent medication administration errors. However, the system did not reliably scan IV bags. Nurses therefore developed a workaround for urgent situations, whereby they would administer the IV medication without scanning the bar code, and only later manually document its administration. This workaround was deemed to be a substantial contributor to the ultimately fatal error.

    c. *Forcing functions*—A forcing function is an aspect of a design that prevents an unintended or undesirable action from being performed or allows its performance only if another specific action is performed first. For example,

automobiles are now designed so that the driver cannot shift into reverse without first putting his or her foot on the brake pedal. Forcing functions need not involve device design. One of the first forcing functions identified in healthcare was the removal of concentrated potassium from general hospital wards. This action helps prevent the inadvertent addition of concentrated potassium to intravenous solutions prepared by nurses on the wards, an error that has produced small but consistent numbers of deaths for many years.

d. *Standardization*—An axiom of human factors engineering is that equipment and processes should be standardized whenever possible in order to increase reliability, improve information flow, and minimize cross-training needs. Standardizing equipment across clinical settings (as in the defibrillator example above) is one basic example, but standardized processes are increasingly being implemented as safety measures. The widening use of checklists as a means of ensuring that safety steps are performed in the correct order has its roots in human factors engineering principles.

> *Example*: The World Health Organization (WHO) has a "Safe Surgery Checklist"—a list of 19 measures that should be performed before an invasive procedure to improve the safety of that procedure. The steps are divided into those that should occur before anesthesia induction, before skin incision, and before the patient leaves the operating room. Although devised for actual surgical procedures, the concepts can be modified to fit any invasive procedure, including those that occur in the interventional radiology suite, with moderate sedation. The 19 steps are:

> Before induction of anesthesia
> > i.   Confirm patient identity, site, procedure and consent
> > ii. Site marking
> > iii. Check of anesthesia machine and medication
> > iv. Pulseoximeter in place and functioning
> > v.   Allergies?
> > vi. Difficult airway or aspiration risk?
> > vii. Risk of significant blood loss?

> Before skin incision
> > viii. Confirm all team members have introduced themselves by name and role
> > ix.   Confirm patient name, procedure, and site of incision
> > x.   Antibiotic prophylaxis?
> > xi.   Review anticipated critical events
> > xii. Review patient-specific concerns related to anesthesia
> > xiii. Confirm sterility of equipment/equipment concerns
> > xiv. Is essential imaging available?

> Before patient leaves operating room
> > xv.   Nurse confirms name of procedure.
> > xvi.   Nurse confirms instrument, sponge, and needle counts.
> > xvii. Nurse confirms specimen labeling.
> > xviii. Any equipment problems to be addressed?
> > xix.   Concerns for recovery or management
> > http://whqlibdoc.who.int/publications/2009/9789241598590_eng_Checklist.pdf

e. *Resiliency efforts*—Given that unexpected events are likely to occur, attention needs to be given to their detection and mitigation before they worsen. Rather

than focusing on error and designing efforts to preclude it, resiliency approaches tap into the dynamic aspects of risk management, exploring how organizations anticipate and adapt to changing conditions and recover from system anomalies. Building on insights from high-reliability organizations, complex adaptive systems, and resourceful providers at the point of care, resilience is viewed as a critical system property, reflecting the organization's capacity to bounce back in the face of continuing pressures and challenges when the margins of safety have become thin.

Despite the above examples, it is generally agreed that human factors principles are underutilized in examination of safety problems and in designing potential solutions. The ever-lengthening list of unintended consequences of CPOE can, in part, be viewed as a failure to appropriately design such systems with human factors in mind.

G. 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.

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

1. Background
The concept of safety culture originated outside healthcare in studies of high reliability organizations—organizations that consistently minimize adverse events despite carrying out intrinsically complex and hazardous work. High reliability organizations maintain a commitment to safety at all levels, from frontline providers to managers and executives. This commitment establishes a "culture of safety" that encompasses these key features:
- acknowledgment of the high-risk nature of an organization's activities and the determination to achieve consistently safe operations;
- a blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment;
- encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems; and
- 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.

2. 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.

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."

3. Current Context

The National Quality Forum's Safe Practices for Healthcare and the Leapfrog Group both mandate safety culture assessment. The Agency for Healthcare Research and Quality also recommends yearly measurement of safety culture as one of its "10 patient safety tips for hospitals." Baseline data on safety culture in a variety of hospital settings, derived from the Hospital Survey on Patient Safety Culture, are available from AHRQ.

I. Definitions

1. Active Error (or Active Failure)
The terms active and latent as applied to errors were coined by Reason. 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. Active failures are sometimes referred to as errors at the sharp end, figuratively referring to a scalpel. In other words, errors at the sharp end are noticed first because the person closest to the patient commits them. This person may literally be holding a scalpel (e.g., an orthopedist operating on the wrong leg), may figuratively be administering any kind of therapy (e.g., a nurse programming an intravenous pump), or may be performing any aspect of care. 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.

2. Adverse Drug Event (ADE)

An adverse event (i.e., injury resulting from medical care) involving medication use.

Examples:
- anaphylaxis to penicillin
- major hemorrhage from heparin
- aminoglycoside-induced renal failure
- agranulocytosis from chloramphenicol

As with the more general term "adverse event," the occurrence of an ADE does not necessarily indicate an error or poor quality of care. ADEs that involve an element of error (either of omission or commission) are often referred to as preventable ADEs. Medication errors that reached the patient but by good fortune did not cause any harm are often called potential ADEs. For instance, a serious allergic reaction to penicillin in a patient with no prior such history is an ADE, but so is the same reaction in a patient who has a known allergy history but receives penicillin due to a prescribing oversight. The former occurrence would count as an adverse drug reaction or non-preventable ADE, while the latter would represent a preventable ADE. If a patient with a documented serious penicillin allergy received a penicillin-

like antibiotic but happened not to react to it, this event would be characterized as a potential ADE.

An ameliorable ADE is one in which the patient experienced harm from a medication that, while not completely preventable, could have been mitigated. For instance, a patient taking a cholesterol-lowering agent (statin) may develop muscle pains and eventually progress to a more serious condition called rhabdomyolysis. Failure to periodically check a blood test that assesses muscle damage or failure to recognize this possible diagnosis in a patient taking statins who subsequently develops rhabdomyolysis would make this event an ameliorable ADE: harm from medical care that could have been lessened with earlier, appropriate management. Again, the initial development of some problem was not preventable, but the eventual harm that occurred need not have been so severe, hence the term ameliorable ADE.

3. Adverse Drug Reaction
   Adverse effect produced by the use of a medication in the recommended manner, i.e., a drug side effect. These effects range from nuisance effects (e.g., dry mouth with anticholinergic medications) to severe reactions, such as anaphylaxis to penicillin. Adverse drug reactions represent a subset of the broad category of adverse drug events—specifically, they are non-preventable ADEs.

4. 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).

5. Authority Gradient
   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.

6. 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. 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.

7. Close Call (Near Miss)

   This 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.

8. Latent Error (or Latent Condition)

   The terms active and latent as applied to errors were coined by 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." Latent errors are sometimes referred to as errors at the blunt end, referring to the many layers of the healthcare system that affect the person "holding" the scalpel. Active failures, in contrast, are sometimes referred to as errors at the sharp end, or the personnel and parts of the healthcare system in direct contact with patients.

9. 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. Mistakes often reflect lack of experience or insufficient training. Reducing the likelihood of mistakes typically requires more training, supervision, or occasionally disciplinary action (in the case of negligence).

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 actually slips, which are failures of schematic behavior that occur due to fatigue, stress, or emotional distractions, and are prevented through sharply different mechanisms.

10. Potential ADE
A potential adverse drug event is a medication error or other drug-related mishap that reached the patient but happened not to produce harm (e.g., a penicillin-allergic patient receives penicillin but happens not to have an adverse reaction). In some studies, potential ADEs refer to errors or other problems that, if not intercepted, would be expected to cause harm. Thus, in some studies, if a physician ordered penicillin for a patient with a documented serious penicillin allergy, the order would be characterized as a potential ADE, on the grounds that administration of the drug would carry a substantial risk of harm to the patient.

11. Sharp End
The 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 scalpels, 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. The terminology of "sharp" and "blunt" ends corresponds roughly to active failures and latent conditions.

12. Sentinel event (http://www.jointcommission.org/sentinel_event.aspx)
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.

J. Tools for evaluating risk and adverse events

1. 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.

2. 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."

Table. Factors That May Lead to Latent Errors

Type of Factor	Example
Institutional/regulatory	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.
Organizational/management	A nurse detected a medication error, but the physician discouraged her from reporting it.
Work environment	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.
Team environment	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.
Staffing	An overworked nurse mistakenly administered insulin instead of an anti nausea medication, resulting in hypoglycemic coma.
Task-related	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.
Patient characteristics	The parents of a young boy misread the instructions on a bottle of acetaminophen, causing their child to experience liver damage.

b. Effectiveness of Root Cause Analysis

RCA is one of the most widely used approaches to improving patient safety, but perhaps surprisingly, few data exist to support its effectiveness. As noted in a recent commentary, much of the problem lies in how RCAs are interpreted rather than in how they are performed, since there is no consensus on how hospitals should follow up or analyze RCA data. This limits the utility of RCA as a quality improvement tool. Another issue is that few formal mechanisms exist for analysis of multiple RCAs across institutions. As an individual RCA is essentially a case study of a specific error, analysis of multiple RCAs performed at different institutions may help identify patterns of error and point the way toward solutions. Some states mandate performance of an RCA for certain types of errors (including never events) and report the findings of these RCAs in aggregate. Ultimately, Patient Safety Organizations listed by AHRQ will also serve this function.

c. Current Context

The Joint Commission has mandated use of RCA to analyze sentinel events (such as wrong-site surgery) since 1997. As of April 2007, 26 states have mandated reporting of serious adverse events (increasingly using the National Quality Forum's list of "Never Events"), and many states also require that RCA be

performed and reported after any serious event. Although no data are yet available on this subject, RCA use has likely increased with the growth in mandatory reporting systems.

3. Medication Reconciliation
   a. Background
   Patients admitted to a hospital 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. Though most often discussed in the hospital context, medication reconciliation can be equally important in ambulatory care, as many patients receive prescriptions from more than one outpatient provider.
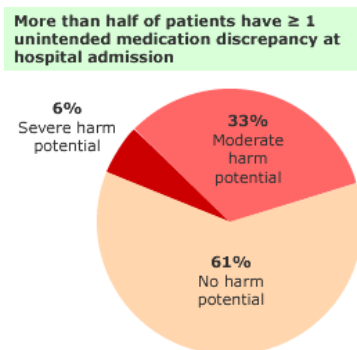
Source: Cornish PL, Knowles SR, Marchesano R, et al. Unintended medication discrepancies at the time of hospital admission. Arch Intern Med. 2005;165:424-429.

   b. Accomplishing Medication Reconciliation
   While the importance of medication reconciliation is universally recognized, the optimal method for reconciling medications has yet to be determined. A variety of methods have been studied, including having pharmacists perform the entire process, linking medication reconciliation to existing computerized provider order entry systems, and integrating medication reconciliation within the electronic medical record system. Patients are also increasingly being involved in the medication reconciliation process, especially in the ambulatory setting.

   The evidence supporting patient benefits from reconciling medications is relatively scanty. Interventions led by pharmacists may be the most promising, as at least one study utilizing a pharmacist-led medication reconciliation process at discharge did improve clinical outcomes, and other studies have shown reductions in actual and potential medication errors. While information

technology solutions are being widely studied, and do appear to significantly reduce medication discrepancies, their effect on clinical outcomes remains unclear.

c. Current Context
Medication reconciliation was named as 2005 National Patient Safety Goal #8 by the Joint Commission. The Joint Commission's announcement called on organizations to "accurately and completely reconcile medications across the continuum of care." In 2006, accredited organizations were required to "implement a process for obtaining and documenting a complete list of the patient's current medications upon the patient's admission to the organization and with the involvement of the patient" and to communicate "a complete list of the patient's medications…to the next provider of service when a patient is referred or transferred to another setting, service, practitioner or level of care within or outside the organization."

However, in 2009, the Joint Commission announced that they would no longer formally score medication reconciliation during on-site accreditation surveys. This policy change was made in recognition of the lack of proven strategies for accomplishing medication reconciliation.

K. Periprocedural care: patient identifiers, informed consent, time-out

1. 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.

2. 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.

3. 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."

4. Time-out
Many image-guided interventional procedures and invasive diagnostic imaging procedures require adherence to The Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery [TM]. 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.

5. Hand washing
Many procedures require some level of cleanliness or sterility. This may be as simple as hand washing by the physician and other personnel involved in the procedure or more advanced, including sterile cleansing and draping of the procedural site and use of protective garb such as sterile gloves and face masks.

For more invasive procedures such as central venous catheter insertion, "maximum sterile barrier technique" should be used. As defined by the National Quality Measures Clearinghouse, this requires cap, mask, sterile gown, sterile gloves, a large sterile sheet, hand hygiene, and cutaneous antisepsis.

ACR-SIR Practice Guideline on Informed Consent for Image-Guided Procedures

ACR-SIR Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures

The Joint Commission. National Patient Safety Goals Effective July 1, 2011 – Hospital Accreditation Program. Available at: http://www.jointcommission.org/assets/1/6/NPSG_EPs_Scoring_HAP_20110706.pdf. Accessed 12-3-11.

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: http://www.qualitymeasures.ahrq.gov/content.aspx?id=28003. Accessed 12-3-11.

Agency for Healthcare Research and Quality (AHRQ). Patient Safety Primers – Medication Reconciliation. Available at: http://psnet.ahrq.gov/primer.aspx?primerID=1. Accessed 12-3-11.

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

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

    The Joint Commission and the American Society of Anesthesiologists have defined various levels of sedation, analgesia, and anesthesia, which are listed below. However, a key point to recognize is that these "levels" are truly a continuum. Patients may rapidly move between the levels and may reach a deeper level of sedation than desired. Sedation may result in the loss of protective reflexes. Thus, all sedated patients require monitoring regardless of the intended level of sedation.

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

    1. **Minimal sedation or anxiolysis:** The administration of medications for the reduction of anxiety and a drug-induced state during which the patient responds to verbal commands. In this state, cognitive function and coordination may be impaired, but ventilatory and cardiovascular functions are unaffected.

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

    3. **Deep sedation/analgesia**: A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following

repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

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

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

When a patient is considered for sedation by a non-anesthesia provider such as a radiologist, the patient must be screened by that provider or another qualified provider to determine if the patient has risk factors that may increase the likelihood of an adverse outcome. Such risk factors include, but are not limited to, congenital or acquired abnormalities of the airway, liver failure, lung disease, congestive heart failure, symptomatic brain stem dysfunction, apnea or hypotonia, history of adverse reaction to sedating medications, morbid obesity, and severe gastroesophageal reflux. The patient's American Society of Anesthesiologists (ASA) Physical Status Classification should also be assessed. This is a six-level classification as follows:

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

Patients who are ASA Class I and II would generally qualify for moderate sedation. Those in Class III and IV or with other significant risk factors may require additional consideration, including possibly consultation with anesthesiology or performance of sedation by an anesthesiologist or anesthetist. Patients in Class V should not be sedated by non-anesthesiologists.

When sedation is performed under the supervision of a radiologist, there must be a separate qualified healthcare professional whose primary focus is the monitoring, medicating, and care of the patient. The patient must have intravenous access. Continuous monitoring should include at minimum level of consciousness, respiratory rate, pulseoximetry, blood pressure (as indicated), heart rate, and cardiac rhythm. Similar monitoring is needed in the recovery period from sedation. The supervising physician should have sufficient knowledge of the pharmacology, indications, and contraindications for the use of sedative agents to enable safe

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

Commonly used drugs and reversal agents

> *ACR-SIR Practice Guideline for Sedation/Analgesia. Available at:* *http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/iv/adult_sedation.aspx.*

> *Practice guidelines for sedation and analgesia by non-anesthesiologists. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Anesthesiology 2002; 96:1004-1017.*

> *Practice advisory on anesthetic care for magnetic resonance imaging: a report by the Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging. Anesthesiology 2009; 110:459-479.*

> *Cote C., Wilson, S., Work Group on Sedation. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: an update. American Academy of Pediatrics 2006; 118:2587-2601.*

M. 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.

> *Kanal E, Barkovich AJ, Bell C, et al. ACR Guidance Document for Safe MR Practices: 2007. AJR 2007; 188:1-27.*

N. Contrast reactions and management

1. 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."

    a. Screening
        Safe administration of contrast begins with a focused patient history to identify factors that may increase the likelihood of a reaction or may contraindicate the administration of contrast. The greatest risk factor for an allergic-like reaction to contrast is a history of a prior reaction to contrast, which is associated with a five times increased risk of subsequent reaction. Any other allergic history, but particularly a history of major anaphylactic reaction, may increase the patient's risk, but some specific allergies such as to shellfish are no longer considered to be highly significant. However, atopy results in a 2-3 times increased risk of contrast reaction. Asthma may also increase the risk of contrast reaction.

Significant cardiac disease also imparts an increased risk. There is controversy as to whether patient anxiety increases the risk of a contrast reaction.

b. 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-idiosyncratic physiologic reactions such as heat sensation.

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

i. 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

ii. Methylprednisolone (Medrol®): 32 mg by mouth 12 hours and 2 hours before contrast media injection. An anti-histamine (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 time-frame, there is less evidence of efficacy of premedication and less agreement on the optimal regimen since IV steroids have not been shown to be effective when administered fewer than 4-6 hours prior to contrast injection. The ACR Contrast Manual lists the following options, in decreasing order of desirability:

i. 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

ii. Dexamethasone sodium sulfate (Decadron®) 7.5 mg or betamethasone 6.0 mg intravenously q4h until contrast study must

be done in patent with known allergy to methylprednisolone, aspirin, or non-steroidal anti-inflammatory drugs, especially if asthmatic. Also diphenhydramine 50 mg IV 1 hour prior to contrast injection; or

 iii. 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.

c. 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:

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).

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).

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

Monitor: electrocardiogram, O2 saturation (pulseoximeter), 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.

Hypotension with Tachycardia
1. Legs elevated 60 degrees or more (preferred) or Trendelenburg position.
2. Monitor: electrocardiogram, pulseoximeter, blood pressure.
3. Give O2 6 to 10 liters/min (via mask).
4. 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).

Hypotension with Bradycardia (Vagal Reaction)
1. Secure airway: give O2 6 to 10 liters/min (via mask).
2. Monitor vital signs.
3. Legs elevated 60 degrees or more (preferred) or Trendelenburg position.
4. Secure IV access: rapid administration of Ringer's lactate or normal saline.
5. Give atropine 0.6 to 1 mg IV slowly if patient does not respond quickly to steps 2 to 4.
6. Repeat atropine up to a total dose of 0.04 mg/kg (2 to 3 mg) in adult.
7. Ensure complete resolution of hypotension and bradycardia prior to discharge.

Hypertension, Severe
1. Give O2 6 to 10 liters/min (via mask).
2. Monitor electrocardiogram, pulseoximeter, blood pressure.
3. Give nitroglycerine 0.4 mg tablet, sublingual (may repeat x 3); or, topical 2 percent ointment, apply 1-inch strip.
4. If no response, consider labetalol 20 mg IV, then 20 to 80 mg IV every 10 minutes up to 300 mg.
5. Transfer to intensive care unit or emergency department.
6. For pheochromocytoma: phentolamine 5 mg IV (may use labetalol if phentolamine is not available).

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.

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

ACR Manual on Contrast Media v7. Available online at:
http://www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual.aspx.

d. Contrast induced nephropathy

Contrast induced nephrotoxicity (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 of 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 angiocardiography, 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."

2. 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."

Patients with a prior reaction to GBCM have an eight-times increased risk of a subsequent reaction, which may be more severe than the first reaction. Other risk factors include asthma and other allergies, including to iodinated contrast media. Patients with these risk factors may have a risk of reaction of up to 3.7 percent. While there is limited information about the efficacy of preventive measures, suggested measures include using a different gadolinium compound and premedicating the patient with corticosteroids and antihistamines. Treatment of contrast reactions is similar to that for iodinated contrast media.

GBCM are relatively contraindicated in pregnant patients. These agents pass through the placental barrier and enter the fetal circulation. They are then filtered by the fetal kidneys and excreted into the amniotic fluid where they may remain for a prolonged period to time. With prolonged presence of the chelate in the amniotic fluid, there is an increased potential of dissociation of the potentially toxic gadolinium ion. Although the risk to the fetus is unknown, due to the potential risk, GBCM should only be administered to pregnant patients in carefully selected situations when there is felt to be overwhelming benefit to their use.

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 pruritis. 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 GBCMs. 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. Consultation with the referring physician and informed consent from the patient are also recommended. In patients with less severe Stage 3 chronic kidney disease, use of the lowest possible dose of contrast and avoidance of the higher risk agents is recommended. In patients in Stage 3a (eGFR of 45–59 ml/min/1.73 m2), no further precautions are recommended. For patients in Stage 3B (eGFR of 30–44 ml/min/1.73 m2), greater precautions such as those for patients with Stage 4 chronic kidney disease should be considered, especially for those with an eGFR close to 30 since the eGFR measurement may vary over time.

> *ACR Manual on Contrast Media v7. Available online at:*
> http://www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual.aspx.
>
> *JACR Vol 5, No 1, January 2008 – Symposium on Nephrogenic Systemic Fibrosis*

3. 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 hyperosmolality of the contrast. An acute local inflammatory response is initiated, which may peak in 24 to 48 hours.

Two severe complications may occur. The most common is a compartment syndrome related to mechanical compression. The major risk factors for compartment syndrome are the volume of extravasated contrast and the capacity of the site of extravasation. The second severe complication is skin ulceration and tissue necrosis. The risk of a severe extravasation injury is increased in patients with arterial insufficiency or compromised venous or lymphatic drainage in the affected extremity. Severe injury is also more likely with larger volumes of contrast and extravasation into smaller anatomic compartments such as the dorsum of the hand, foot, or ankle. However, such injuries are rare. 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.

> *ACR Manual on Contrast Media v7. Available on line at:*
> http://www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual.aspx.
>
> *Wang CL, Cohan RH, Ellis JH, Adusumilli S, Dunnick NR. Frequency, management, and outcome of extravasation of nonionic iodinated contrast medium in 69,657 intravenous injections. Radiology 2007; 243:80–87.*

O. 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.

Increased awareness of the risks of medical radiation in modern imaging was raised in 2005 with a report from the Biological Effects of Ionizing Radiation (BEIR) Committee of the National Academy of Sciences (commonly known as the *BEIR VII Report*). The committee was primarily tasked "to develop the best possible risk estimate for human exposure to low-dose, low-LET (linear energy transfer) ionizing radiation." The definition of "low dose" was 0-100 mSv, which encompasses the range of diagnostic imaging procedures. A major focus was to assess the shape of the response curve to low-dose radiation, particularly among the linear no threshold (LNT), linear-quadratic, and threshold models. The BEIR VII committee concluded that "the current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans." This would translate into a small increased risk of cancer from clinical CT doses. Douple and Jostes noted: "On average, assuming a sex and age distribution similar to that of the entire U.S. population, the BEIR VII lifetime risk model predicts that approximately one person in 100 would be expected to develop cancer (solid cancer or leukemia) from a dose of 100 mSv above background, while approximately 42 of the 100 individuals would be expected to develop solid cancer or leukemia from other causes." However, not all experts agree that the LNT model is correct.

Subsequently, in 2007 Brenner and Hall published a widely discussed and cited article in the *New England Journal of Medicine*, which estimated the number of cancers that might be attributed to CT scanning. They concluded that based on data from 1991-1996, "about 0.4% of all cancers in the United States may be attributable to the radiation from CT studies." Further, based on subsequent increases in CT usage, "this estimate might now be in the range of 1.5-2.0%." This estimated risk is heavily dependent on age at time of exposure, being much higher in younger patients, especially children. This reflects both a greater sensitivity to radiation effects in younger patients and a longer expected lifespan during which cancer can develop.

The National Council on Radiation Protection and Measurements (NCRP) compared the ionizing radiation exposure to the US population and its relative sources in the early 1980s (during the early years of CT scanning) and in 2006. They showed a six-fold increase in total medical radiation exposure during that time. In the early 1980s, background radiation represented 83 percent of the total population exposure, with 15 percent from medical imaging. By 2006, the contribution from background had fallen to only 50 percent of the total, with no significant overall change in the amount of background radiation. Medical imaging rose to 48 percent of the total, and the number of CT scans performed rose from an estimated 3 million to 67 million. While CT scans accounted for 17 percent of all radiological and nuclear medicine imaging procedures in 2006, they contributed 49 percent of the total estimated medical dose. Radiographic and fluoroscopic studies, while accounting for 74 percent of all procedures, contributed only 11 percent of the total estimated medical dose. Nuclear medicine represented only 5 percent of total procedures but 26 percent of estimated medical dose. The remaining 14 percent of dose came from interventional procedures, which accounted for 4 percent of total procedures.

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.

1. 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 web site 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 web site includes specific advice to reduce radiation dose in clinical practice.

Goske et al. provided the following summary of the Image Gently campaign:

The message of the Image Gently campaign is simple: Reduce or "child-size" the amount of radiation used when obtaining a CT scan in children. This message is targeted to the radiologists who perform relatively few CT examinations of pediatric patients in their hospital or outpatient practice but who, in aggregate, perform many pediatric CT examinations throughout the United States. We know radiologists and radiology technologists want to do the best for their pediatric patients but may be hampered by a lack of familiarity with pediatric protocols.

The Image Gently campaign wishes to provide those radiologists and technologists who work in predominantly "adult" hospital settings with the tools to decrease radiation by doing four simple things.

- First, **reduce or "child-size" the amount of radiation used**. Radiation dose in CT is linearly related to mA. Dose reduction can be accomplished simply by contacting your medical physicist and asking him or her to determine the baseline radiation dose for an adult for your equipment and compare that dose with the ACR Standards. If the doses are higher than those suggested, reduce your technique for adult patients. Next, access the Image Gently Website (www.imagegently.org) and view the protocols provided for children. The beauty of these protocols is that they are independent of equipment manufacturer, age of machine, or number of detectors. Although your institution or site may wish to lower scan technique even more, these protocols provide a starting point for making this important change at your site. Work with radiology technologists to implement the protocols. These professionals control the critical "last step" before a scan is obtained.
- Second, **scan only when necessary**. An increased awareness about the need to discuss the risk–benefit ratio for performance of a CT examination enhances the role of the radiologist consultant and provides an opportunity for educational interaction with the child's pediatrician, who has unique medical knowledge critical to the care of the patient. As noted by the National Council on Radiation Protection & Measurements, "any decision by a medical provider to expose a patient to ionizing radiation shall be justified." This means that the expected benefits to the patient must exceed the overall risk.
- Third, **scan only the indicated region**. Protocols in children should be individualized. A follow-up CT scan in an asymptomatic child with an incidental lung nodule is unlikely to require that the entire chest be rescanned.
- Fourth, **scan once**; multiphase scanning is usually not necessary in children. CT with and without contrast material is rarely needed in children. Multiphase imaging often will double or triple the dose to the child and rarely adds to the diagnostic information of the study.

  Goske MJ, Applegate KE, Boylan J, et al. The Image Gently Campaign: Working Together to Change Practice. AJR 2008; 190:273-274.

  Goske MJ, Applegate KE, Boylan J, et al. Image Gently^{SM}: A National Education and Communication Campaign in Radiology Using the Science of Social Marketing. J Am Coll Radiol 2008; 5:1200-1205.

  Image Gently web site: http://spr.affiniscape.com/associations/5364/ig/.

2. 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.

Looking forward, Image Wisely "plans to go beyond education by developing a stronger link between optimizing radiation dose and accreditation." This initiative would allow imaging professionals to demonstrate that they are living out their Image Wisely Pledge. Additionally, "a third level of commitment will include participation in a national dose registry, allowing comparison of an individual provider's radiation doses to national benchmarks."

> *Brink JA, Amis ES. Image Wisely: A Campaign to Increase Awareness about Adult Radiation Protection. Radiology 2010; 257:601-602.*
>
> *Image Wisely web site:* http://www.imagewisely.org/

3. Step Lightly

Sidhu et al. describe Step Lightly as follows: "The main goal of the Step Lightly campaign is to educate the healthcare team and the public on the desirability of reducing radiation dose as much as possible in pediatric interventional radiology while continuing to benefit as a society from the innovative and at times life-saving techniques of the specialty. Ancillary goals include providing education on the effects of medical radiation in children, encouraging a team effort in improving radiation safety in pediatric interventional radiology, and providing easily accessible and usable information for health professionals and patients. Therefore, relevant information on radiation safety for pediatric interventional practice has been gathered and posted on the Image Gently website, along with key references and helpful links. There are separate sections for the various audiences: patients, radiologists, technologists, pediatricians, physicists, and the media, with more user-specific information on each page. Last, a variety of downloadable tools for patients and practitioners are available on the site, which are detailed in the subsequent sections."

The key messages of Step Lightly are:

- *Step lightly o*n the fluoroscopy pedal;
- Stop and child-size the technique;
- Consider ultrasound or, when applicable, MRI guidance.

The campaign provides a sticker to place on the fluoroscopy pedal or monitor to serve as a reminder to those performing interventional procedures to use the minimal radiation dose possible. The campaign seeks to "remind practitioners to "step lightly" on the fluoroscopic pedal during pediatric interventions, and to "leave a small footprint," so to speak, on this sensitive population."

Sidhu MK, Goske MJ, Cloey BJ, et al. Image Gently, Step Lightly: Increasing Radiation Dose Awareness in Pediatric Interventions through an International Social Marketing Campaign. JVIR 2009; 20:1115-1119.

4. 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 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 $CTDI_{vol}$ (CT Dose Index Volume) and the DLP (Dose Length Product). The definition and calculation $CTDI_{vol}$ are beyond the scope of this discussion. For helical CT scanning, the DLP equals the product of the $CTDI_{vol}$ and the scanning length. The unit of measurement for $CTDI_{vol}$ 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 $CTDI_{vol}$ 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 $CTDI_{vol}$ 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.

ACR Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/med_phys/reference_levels.aspx*.*

ACR Dose Index Registry. Available at: https://nrdr.acr.org/Portal/DIR/Main/page.aspx*.*

Morin RL, Coombs LP, Chatfield MB. ACR Dose Index Registry. J Am Coll Radiol 2011; 8:288-291.

5. Principles of Dose Management/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.

Nuclear medicine is also a significant source of medical radiation exposure. Since the amount of radiation delivered is based on the administered activity of the radiopharmaceutical, the administered activity should be adjusted when appropriate, based on patient size and the requirement of the examination. This is particularly important in children. The Society of Nuclear Medicine (SNM), through the Pediatric Imaging Council in conjunction with the Society of Pediatric Radiology and the American College of Radiology, have developed the North American Guidelines for Pediatric Nuclear Medicine, which are intended to assist practitioners in obtaining "high quality images at low radiation dose." These guidelines provide recommended weight-based administered activities for various radiopharmaceuticals in common use with minimum and maximum administered activity levels.

Although the dose from individual radiographic examination is relatively low compared to most CT and nuclear medicine procedures, the large number of such examinations makes them a significant source of medical radiation exposure. With the increased use of digital imaging, overexposure is less evident to technologists and radiologists than with conventional film-screen technology. This phenomenon is known as "dose creep." To prevent dose creep, technologists can refer to validated radiographic technique charts, and technologists and departments should monitor "exposure indicators." Such indicators may vary among manufacturers, but they allow consistent use of proper technique and radiation dose.

Fluoroscopy, whether used in diagnostic or interventional procedures, can be a significant source of radiation exposure. As with other modalities, technical parameters should be adjusted based on patient size and the requirements of the examination or procedure. Collimation should be used when possible. Significant dose reduction can be achieved through use of pulsed fluoroscopy when appropriate. Last image hold can allow the radiologist to evaluate a fluoroscopic finding without continued radiation exposure. In angiographic procedures, "road mapping" can facilitate catheter manipulation and limit fluoroscopy time. In some examinations, fluoroscopic image capture can replace some or all radiographic exposures and significantly reduce dose, although generally with some loss of detail. Magnification modes and high dose fluoroscopy modes should be used only when necessary.

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.

Revised Radiation Safety Language in Imaging Practice Guidelines. ACR Digest of Council Actions 2011-2012, page 80. Available online at: http://www.acr.org/SecondaryMainMenuCategories/mbr_chapter/FeaturedCategories/CouncilResources/DigestofCouncilAction/DigestCouncilActions.aspx. Accessed 12-17-11.

Guite KM, Hinshaw JL, Ranallo FN, et al. Ionizing Radiation in Abdominal CT: Unindicated Multiphase Scans Are an Important Source of Medically Unnecessary Exposure. J Am Coll Radiol 2011; 8:756-761.

Gelfand MJ, Parisi MT, Treves ST. Pediatric Radiopharmaceutical Administered Doses: 2010 North American Consensus Guidelines. J Nucl Med 2011; 2:318-322.

North American Consensus Guidelines for Administered Radiopharmaceutical Activities in Children and Adolescents also available at: http://www.pedrad.org/associations/5364/files/ImGen11_Nu_Med_Poster.pdf. Accessed 12-17-11.

ACR-AAPM-SIIM Practice Guideline for Digital Radiography. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/dx/digital_radiography.aspx. Accessed 12-17-11. (Note: This Guideline will be revised in 2012.)

ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures. Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/med_phys/management_fluoro_procedures.aspx. Accessed 12-17-11.

P.   Life support: Fundamental BLS principles
(BLS for Healthcare Providers, American Heart Association, Student Manual Professional, 2011)

Four Basic activities:
- Chest compressions
- Airway
- Breathing
- Defibrillation

Change in <u>sequence</u>**:**
1) Chest compression; 2) airway; 3) breathing

Despite significant advances in prevention, cardiac arrest remains a very important public health problem and is the leading cause of death in the U.S. and other countries. In the U.S. and Canada, approx 350,000 people (1/2 in hospital) have cardiac arrest and receive CPR. Countless others have arrest without attempted resuscitation. High quality CPR improves a victim's chances of surviving an arrest.

Critical components of high-quality CPR:
- Start compressions within 10 seconds of recognized cardiac arrest;
- Push hard, fast. Compress at least 100/minute, depth of 2 inches adults and children, 1.5 inches for infants (< 1 year of age);
- Allow complete chest recoil after compression;
- Minimize interruptions in compressions to less than 10 seconds;
- Effective breaths that make chest rise; and
- Avoid extreme ventilation.

Adult Chain of Survival:
- Immediate recognition of cardiac arrest and activation of emergency response system;
- Early CPR with chest compressions;
- Rapid defibrillation;
- Effective advance life support; and
- Integrated post-cardiac arrest care.

Pediatric Chain of Survival
- Prevention of arrest;
- Early high-quality bystander CPR;
- Rapid activation of EMS;
- Effective advanced life support; and
- Integrated post-cardiac arrest care.

There is an increased emphasis on providing CPR as part of a team, with rescuers performing several actions simultaneously. For instance, first, the rescuer activates the emergency response system; second, he or she begins

chest compressions; third, the rescuer provides ventilations; and fourth, her or she retrieves and prepares the defibrillator.

The step of "look, listen and feel for breathing" has been removed. This was terminated due to bystanders often failing to start CPR when observing agonal breathing (a slow rate, forceful or weak, snorting, snoring, or groaning). The rescuer should check for two things: response and breathing.

1. Single-rescuer CPR:
A single rescuer should 1) activate ERS and begin compressions (100/min), followed by 2) opening the airway and then giving two breaths, and then 3) repeating the cycle after checking for peripheral pulse (carotid or radial). The carotid pulse should be assessed first, for between 5 and 10 seconds. The compression: ventilation ratio is 30:2. The rescuer should be sure the patient is on a firm surface to ensure circulation of blood flow from the heart.

   a. Airway
   There are two methods for opening the patient's airway:

   - Head tilt-chin lift
     Head tilt method: place one hand on victim's forehead, push back with palm. Place fingers of other hand under bony part of lower jaw near chin. Lift jaw to bring chin forward.

   - Jaw thrust
     Use the jaw thrust if any concern over a head or neck injury. The jaw is lifted, fingers placed under angle of jaw, lifting with both hands, without tilting the head.

     Use a barrier device, such as facemask or bag-mask device, if available. These masks have a one-way valve to divert exhaled air, blood, or body fluids away from rescuer.

   b. Breathing:
   One-rescuer CPR: position yourself at victim's side, place mask on victim's face, seal mask with both hands, perform a head tilt-chin lift to open airway, press firmly on mask to seal, and deliver air over one second, watching victim's chest rise. Bag-mask devices are not recommended for single rescuer situation, but are useful in two-rescuer CPR. Even if you are supplying supplemental oxygen, still use one- second per breath for any method of delivery.

2. Two-rescuer CPR:
   - Rescuer #1 is at the victim's side. He or she should conduct chest compressions, (two-inch compression, 100/minute), allow the chest to recoil after compression, and limit interruptions to < 10 seconds (compressions-to-breaths ratio of 30:2, count compressions aloud). Switch places every five cycles or two minutes, taking less than five seconds to switch places.
   - Rescuer #2 is at the victim's head. He or she should maintain an open airway using head tilt-chin lift or jaw thrust. The rescuer should then give breaths, watching for chest rise and avoiding excessive ventilation. Observe performance of chest compressions,

offering suggestions for correct form. Switch duties every five cycles or two minutes.

3. Defibrillation
These devices—automatic external defibrillators (AED)—are essentially laptop computers that analyze a collapsed victim's heart rhythm and determine if an electrical shock is needed, and then deliver one, such that both laypersons and healthcare providers can use these in the field. The time from collapse to defibrillation is one of the most important factors in survival from sudden cardiac arrest with ventricular fibrillation.

    a. Set-up
    Position the device at victim's side, next to rescuer who will be using it. This allows the second rescuer to perform chest compressions while first rescuer attaches the pads and uses the AED controls.

        • Power on the AED;
        • Attach pads to chest-right upper chest and lower left chest below and lateral to heart (if chest is very hairy, may need to shave the chest for pad attachment);
        • Older than eight years, use adult pads. If less than eight and pediatric pads available, use them;
        • "Clear" the victim and analyze the rhythm;
        • If AED states a shock is needed, make sure the victim is "cleared" of contact from others;
        • Press SHOCK button (< 10 seconds from last compression much better prognosis for survival);
        • If no shock needed, continue chest compressions and CPR;
        • After five cycles or approximately two minutes, the AED will prompt you to re-analyze the rhythm and possibly re-shock the victim.

4. Pediatric CPR
Differs from adult CPR.* If solo rescuer, deliver five cycles of CPR before activating EMR (emergency medical response) system. Check victim's carotid or femoral pulse to assess circulation. If heart rate is < 60/min. with signs or poor perfusion, start chest compressions and breaths at 30:2 ratio (like adults). If a second rescuer appears, go to compression: ventilation ratio of 15:2. One may use one or two hands for chest compression on very small children.

    *In **adults**, sudden cardiac arrest occurs with oxygen content normal for the first few minutes, so compressions alone may be sufficient. In children, cardiac arrest often accompanies respiratory failure, so the oxygen level may be low to start. Therefore, a combination of compressions and breaths is important.

5. Rescue Breathing
When pulse present, but victim is not breathing, employ rescue breathing.

        • Adults: one breath every five seconds;
        • Infants/Children: one breath every three to five seconds;
        • Both scenarios: give breath over one second; chest should visibly rise; check pulse every two minutes

6. Relief of Choking
It is most important to distinguish mild from severe airway obstruction.

- If the victim has good air exchange, can cough forcefully, is wheezing between coughs, or can talk, it is a mild airway obstruction; encourage victim to cough and breathe on own. If mild airway obstruction persists, active the EMR;
- If the victim has no or poor air exchange, a weak or ineffective cough, makes a high-pitched noise while inhaling, become cyanotic/blue, is unable to speak, or clutches the neck with thumb and fingers, one must try to relieve the obstruction;
- Use the Heimlich maneuver in adults and children one year or older;
- In infants, use a combination of back slaps and chest thrusts alternating every five attempts.

III. Professionalism & Ethics

A. Attributes of professionals
Professionalism is the skill, competence, and character expected of members of highly trained occupations, including physicians.

The public assumes its physicians are highly professional. However, as healthcare technology expands and healthcare consumes larger and larger percentages of our gross domestic product, governmental agencies, many medical specialty societies and specialty boards (including the ABR), have expressed concerns that the basic concepts of professionalism are threatened. We should all be mindful of these concerns. It is suggested that all physicians reflect on their professionalism and whether they measure up to public expectations. The topic is certainly germane to many of the American College of Radiology discussions on governmental relations and socioeconomic issues.

Professionalism requires skills, competence, and character. Physicians' skills are honed in medical school and postgraduate residency training. Physicians' competence is verified by ABR certification and, in the future, can be confirmed through Maintenance of Certification (MOC). These components of professionalism are objective and demonstrable. Character is more multifarious, but perhaps it is the most important of all the components. It requires recognition of the preeminence of the patient, a commitment to a global view of healthcare, and an allegiance to an appropriate use of our healthcare resources.

Preeminence of the patient demands that radiologists place their patients' interests first in all healthcare decisions. This preeminence may seem obvious, but many factors including economics, overzealousness in implementing new procedures and overconfidence in our abilities and knowledge may cause us to deviate from this concept. Financially motivated self-referral by radiologists' clinical colleagues also threatens patient preeminence.

Radiologists should remember this threat as they enter into financial arrangements with other individuals and corporations. It is this belief in the inherent conflict between patient interest and a physician's financial interest, when a clinician owns imaging equipment to which he or she then refers patients, that has led to the ACR's efforts to eliminate economically-motivated self-referral. While governmental agencies may have had other motives in passage of "Stark" laws, this legislation clearly speaks to the same potential for conflict of interest addressed by the ACR and the need to keep the patient preeminent in all

interactions. Patient privacy is also an important part of patient preeminence and professionalism. Again, the federal government has addressed this issue in HIPPA legislation. While radiologists complain about the increased bureaucracy that this legislation has spawned, the concept of patient confidentiality is valid.

Professionalism demands that radiologists take a global view of healthcare. The ACR has encouraged a broader view of healthcare. The ACR initiated an international service program to promote international and community service participation and to improve radiology in developing nations.

Finally, professionalism also requires a wise use of resources. With imaging costs increasing at a rate nearly three times that of general medical expenditures, payers, employers, and patients are all demanding fiscal responsibility of professionals. Radiology leaders have frequently been asked by carriers whether radiologists are merely interpreters of examinations, or whether radiologists are consultants. The clear intent of these comments is that those controlling the purse strings believe that professionalism requires fiduciary responsibility. They believe radiologists should be more than interpreters and should also use their skills to assist in defining appropriate imaging examinations and to help control waste.

The patient is not the only beneficiary in this relationship. The benefit for the radiologist is patient confidence and respect for radiologists as professionals. Ultimately, what is best for patients is best for radiologists. The public expects professionalism from all physicians. It currently requires such professional behavior of other professions such as airline pilots, and it deserves as much from its radiologists. Moreover, in the future, the public will demand such professionalism.

External threats to professionalism from economically-motivated self-referral are discussed above; however, there are internal threats as well, including teleradiology and after-hours services. While these two dimensions have great potential for good, they also have the potential to subvert the specialty of radiology by removing radiologists' contact with their patients and local colleagues. Radiologists risk becoming a commodity to be bought, sold, and traded. As a commodity, professionalism would be non-existent. There are also internal threats to professionalism from "boundary" violations, which are actions that push or cross the border of legal and ethical behavior. They include radiologists' participation in self-referral schemes including per-click interpretations. While all of these schemes are not illegal, they certainly push the envelope of what might be considered professional behavior. Some boundary issues, such as sexual contact, lending money to patients, and inappropriate work-payment relationships with patients clearly cross the line of acceptable professional action. Such actions not only threaten the patient and radiologist involved, they also sully the entire specialty.

Threats to professionalism exist. Fortunately, current efforts by both the ACR and the ABR continue to promote professionalism. The ACR promotes professionalism by its opposition to economically-motivated self-referral. Explaining this behavior as a violation of the doctor-patient relationship defines it in terms of a violation of professionalism. The College also has many other programs promoting professionalism including its Appropriateness Criteria, accreditation programs, practice guidelines and technical standards, and peer review through RADPEER. The American Board of Radiology promotes professionalism through initial examinations affirming radiologists' competence and skill. The ABR Maintenance of Certification program, which evaluates professional status, commitment to learning, cognitive skills, and performance in practice also affirms to the public that radiologists

holding lifetime ABR certificates have current skills, competence, and character to practice with skill and safety.

Professionalism dates from the time of Hippocrates. It dictates radiologists' conduct and how most radiologists have performed throughout their careers; however, some of its precepts are threatened. Radiologists must rise to meet challenges to our professionalism. It is more than an educational and training achievement; it is an ongoing action. Professionalism is a commitment to humanity and to the individual dignity of radiologists' patients. Through this commitment and with the cooperation of other radiologists, the specialty of radiology will achieve not only the individual and corporate rewards that professionalism offers, but most importantly, radiologists' patients will benefit through an improvement in the quality of their healthcare.

Medical Professionalism in the New Millennium: A Physician Charter

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

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

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

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

A Set of Professional Responsibilities

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

Commitment to honesty with patients. Physicians must ensure that patients are completely and honestly informed before the patient has consented to treatment and after treatment has occurred. This expectation does not mean that patients should be involved in every minute decision about medical care; rather, they must be empowered to decide on the course of therapy.

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

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

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

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

Physicians, both individually and through their professional associations, must take responsibility for assisting in the creation and implementation of mechanisms designed to encourage continuous improvement in the quality of care.

Commitment to improving access to care. Medical professionalism demands that the objective of all healthcare systems be the availability of a uniform and adequate standard of care. Physicians must individually and collectively strive to reduce barriers to equitable healthcare. Within each system, the physician should work to eliminate barriers to access based on education, laws, finances, geography, and social discrimination. A commitment to

equity entails the promotion of public health and preventive medicine, as well as public advocacy on the part of each physician, without concern for the self-interest of the physician or the profession.

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

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

Commitment to maintaining trust by managing conflicts of interest. Medical professionals and their organizations have many opportunities to compromise their professional responsibilities by pursuing private gain or personal advantage. Such compromises are especially threatening in the pursuit of personal or organizational interactions with for-profit industries, including medical equipment manufacturers, insurance companies, and pharmaceutical firms. Physicians have an obligation to recognize, disclose to the general public, and deal with conflicts of interest that arise in the course of their professional duties and activities. Relationships between industry and opinion leaders should be disclosed, especially when the latter determine the criteria for conducting and reporting clinical trials, writing editorials or therapeutic guidelines, or serving as editors of scientific journals.

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

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

B. Physician-physician and physician-patient interactions/relationships, consultation, and communication
    1. HIPAA privacy rule, confidentiality, archive integrity/security
        a. Set of national standards
        b. Major goal is to assure proper protection of individual's health information while still allowing the flow of information necessary to provide and promote quality health care.
        c. Addresses use and disclosure of individually identifiable health information (protected health information)
        d. Applies to health plans, health care clearinghouses and health care providers that transmit health information in electronic format.
        e. Situations in which identifiable data can be transmitted without individual authorization include but are not limited to: to the individual at his or her request, in the course of treatment, for payment activities and to health care operations involving quality or competency assurance, fraud or abuse detection or compliance activities. In addition, when required by law, information can be released to public health authorities, during investigation of abuse, neglect or domestic violence, to oversight agencies, for judicial and administrative proceedings, for law enforcement purposes and for worker's compensation.
            (http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf)

IV.   Compliance, Regulatory and Legal Issues

A. Risk management/legal issues
    *   Malpractice, preservation of medical records, and communication
    *   Chaperones: According to the AMA, "From the standpoint of ethics and prudence, the protocol of having chaperones available on a consistent basis for patient examinations is recommended. Physicians aim to respect the patient's dignity and to make a positive effort to secure a comfortable and considerate atmosphere for the patient; such actions include the provision of appropriate gowns, private facilities for undressing, sensitive use of draping, and clear explanations on various components of the physical examination. A policy that patients are free to make a request for a chaperone should be established in each health care setting. This policy should be communicated to patients, either by means of a well-displayed notice or preferably through a conversation initiated by the intake nurse or the physician. The request by a patient to have a chaperone should be honored.

        An authorized health professional should serve as a chaperone whenever possible. In their practices, physicians should establish clear expectations about respecting patient privacy and confidentiality to which chaperones must adhere. If a chaperone is to be provided, a separate opportunity for private conversation between the patient and the physician should be allowed. The physician should keep inquiries and history-taking, especially those of a sensitive nature, to a minimum during the course of the chaperoned examination."

        http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion821.page

B. Off-label use
Under the Food, Drug, and Cosmetic Act, the Food and Drug Administration (FDA) is responsible for ensuring the safety and efficacy of all drugs and medical devices. The FDA issues approval of a drug or device for a specific diagnosis or intended use, which is stated on the drug/device package insert. With respect to drugs, this is also published in the PDR. The approval includes not only the specific acceptable disease process or condition, but also the route of administration, dosage, and target patient population.

While a drug or device is approved for a specific disease or indication, physicians are given wide latitude in their use under the "practice-of-medicine" doctrine, in which the FDA gives physicians the authority "to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate healthcare practitioner-patient relationship"(1). In fact, the FDA regulates the marketing of drugs and devices, while individual states regulate their use by physicians. As a result, a physician is free to use a drug or device for any purpose he/she feels is appropriate or necessary for patient care. For example, propranolol was initially approved for oral or IM use for dysrythmias. It was soon used, however, in IV as well as oral form for treatment of hypertension. Neither the IV route nor the use for hypertension was listed as approved by the FDA.

The use of a drug or device in a manner that does not conform to the FDA-approved labeling is referred to as off-label use. This could mean use for a different diagnosis, by a different route of administration, in a different dosing regimen, or in a different patient population (many drugs, for example, are not approved for use in pediatric patients). This generally does not imply that a drug is harmful or ineffective, but simply that it either hasn't been studied in that population or that the manufacturer hasn't chosen to go through the formal FDA approval process for that indication. The process is time-consuming and expensive, so manufacturers often do not pursue more expansive approvals once a drug/device is on the market.

Many drugs are often used off-label, several of which are germane to radiology. Examples include:

- MRI contrast agents are not approved for use in pediatric patients less than two years of age;
- MRI agents are not approved for IV injections greater than 2cc/sec, (i.e., lower than the usual rate for MRA), or for use via power injectors;
- MRI agents are contraindicated in patients with renal failure;
- Low-osmolar contrast agents are not approved for nonvascular use, i.e., arthrography and enteric use;
- tPA was initially approved only for coronary use;
- Fenoldopam and N-acetylcysteine, sometimes used for renal protection for CIN, are not approved for that use;
- Contrast is not approved for pregnant patients.

Some interventional devices are used off-label as well. The first stent approved for use in humans was approved only for palliative use in the biliary tree. It was soon used in the peripheral arterial circulation and then in the venous circulation, to the extent that approximately 90 percent of biliary stents are now deployed intravascularly.

Off-label use is obviously commonplace, not only in radiology, but in medicine in general, and is a perfectly acceptable and legal practice. There are, however, several issues to consider in off-label use. These are primarily medicolegal, regulatory, and research-related.

1. Medicolegal
   As noted, physicians are permitted to use any drug in whatever manner they choose in order to address the need of the patient. This generally poses no medicolegal difficulty, especially if the particular use has become commonplace, as in the case of Gadolinium-based agents for MRA. However, a physician does assume the responsibility to have an acceptable rationale for his decision. The main concern centers on informed consent. Most, but not all, courts have held that off-label use need not be disclosed in obtaining informed consent, but there are grey areas, primarily related to non-routine off-label use.

2. Regulatory
   Whereas a physician can use a drug off-label at his or her discretion, he or she is prohibited by FDA regulations from advertising its use. Considering the above situation, one cannot, for example, market one's new contrast-enhanced MRA procedures to the public. Similarly, the manufacturer cannot market a drug or device to physicians for a specific use that is not approved.

3. Research-related
   One is not required to disclose off-label use to a patient in the course of routine care when used in an established manner, such as the examples listed above. Drugs or devices used as part of a research study, however, must be disclosed. Devices without approval can only be used under an investigational device exemption (IDE), which also requires its use as part of a research protocol with approval from the hospital's Institutional Review Board (IRB).

   Smith, JJ. Off-Label Use of Medical Devices in Radiology: Regulatory Standards and Recent Developments. J Am Coll Radiol 2010; 7:115-119

   Henderson, JA and Smith, JJ. Medical Devices and the US Food and Drug Administration: Regulating the Tools of Radiology. J Am Coll Radiol 2005; 2:504-510

   SIR Policy on Off-Label Use. Society of Interventional Radiology, Nov 18, 2007

   American College of Radiology, Manual on Contrast Media, 7th Edition, 2010

   Radiology Feb 2001; 218:329-335

C. Centers for Medicare and Medicaid Services (CMS)
   Definitions

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

   2. ICD-9: International Classification of Diseases (ICD) 9 is the 9th revision of a medical classification list formulated during an international conference sponsored by the World Health Organization (WHO). Each code has at least 3 digits and can be modified by a fourth (for example, the code for appendicitis is 540; appendicitis with peritonitis is 540.0 and without peritonitis is 540.9).There is an ICD-10 that is not widely used as conversion from ICD-9 to ICD-10 has proven problematic. Work on ICD-11 has already begun.

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

4. PQRS refers to Physician Quality Reporting System, a Medicare incentive system that provides cash incentives to physicians who report quality clinical data on prescribed treatments for certain medical conditions. As of now, participation is voluntary; but may become mandatory for full Medicare reimbursements.

5. Meaningful use is a government initiative whereby certified electronic health record (EHR) technology will be used to improve quality, safety, efficiency and reduce health disparities; engage patients and their families; improve patient care coordination and population and public health; and maintain privacy and security of patient health information. Ultimately it is hoped that meaningful use compliance will lead to better clinical outcomes; improved population health outcomes, increased transparency and efficiency, empowered individuals and more robust research on health systems. Meaningful use is being implemented in 3 stages: 2011-2012—stage 1: data capture and sharing; 2013—stage 2: advance clinical processes; 2015—stage 3: improved outcomes.

The following section contains excerpts from the *Medicare RBVS: The Physicians' Guide 2012*, published by the American Medical Association, Sherry L. Smith, MS, CPA, editor (reprinted by permission).

Excerpted from Chapter 2 of *Medicare RBRVS: The Physicians' Guide 2012:*

Legislation Creating the Medicare RBRVS Payment System

In 1989, after years of debate within the medical profession about the distortions in historical charges, battles with Congress and the administration over rising expenditures, and a four-year wait for the results of the Harvard resource-based relative value scale (RBRVS) study, Congress finally enacted a new Medicare physician payment system. The process that led to enactment of the payment reform legislation was in many ways more historic than the law itself: the unprecedented partnership forged between the medical profession, beneficiary groups, the Congress, and the Bush administration. The law resulting from this process gave participants a reasonable measure of what they had sought:

- RBRVS-based payment schedule for physicians that narrowed specialty and geographic differences

- Continued limits on balance billing for patients

- A system for monitoring expenditure increases for the government

The three congressional subcommittees with jurisdiction over the Medicare program include:

- The Health Subcommittee of the House Ways and Means Committee

- The Subcommittee on Health and the Environment of the House Energy and Commerce Committee

- The Subcommittee on Medicare and Long-Term Care of the Senate Finance Committee

OBRA 89 Physician Payment Reform Provisions

In December 1989, Congress passed and President Bush signed the Omnibus Budget Reconciliation Act of 1989 (OBRA 89), enacting the Medicare physician payment reform provisions into law. The legislation called for a payment schedule based on an RBRVS composed of the following three components:

- The relative physician work involved in providing a service

- Practice expenses

- Professional liability insurance (PLI) costs

The OBRA 89 defined the following key features of Medicare's new payment system for physicians' services:

- A five-year transition to the new system beginning on January 1, 1992

- Adjusting each of the 3 components of the RBRVS for each service to account for geographic differences in resource costs

- Eliminating specialty differentials in payment for the same service

- Calculating a "budget neutral" conversion factor for 1992 that would neither increase nor decrease Medicare expenditures from what they would have been under a continuation of "customary, prevailing and reasonable" (CPR) payments

- A process for determining the annual update in the conversion factor

- Tighter limits on balance billing beginning in 1991

- A Medicare Volume Performance Standard (MVPS) to help Congress understand and respond to increases in the volume and intensity of services provided to Medicare beneficiaries

The RBRVS

The physician work component of the RBRVS is based on data from the Harvard study. Physician work refers to the physician's individual effort in providing the service: the physician's time, the technical difficulty of the procedure, the average severity of the patient's medical problems, and the physical and mental effort required.

The practice cost method included in OBRA 89 separated practice costs from physician work and attempted to maintain the total practice cost revenue of a physician specialty at roughly the same as it had been under the previous reimbursement system of CPR. Practice cost relative values were based on the average proportion of a specialty's overall revenues devoted to practice expenses as a percentage of the average Medicare payment under CPR. For example, if practice costs on average account for 45% of radiologists' gross revenue, for a service that is provided only by radiologists and for which the average Medicare approved amount under CPR was $1000, the practice cost component of the new payment schedule would be about $450. The actual calculation is a bit more complicated, however; the example illustrates the basic idea. In 1994 Congress adopted legislation that required the development of resource-based practice expenses, with full implementation in 1998. Since that time, new legislation signed by President Clinton in August 1997 revised the implementation timeline. The Balanced Budget Act (BBA) of 1997 called for the Centers for Medicare and Medicaid Services (CMS) to collect additional data for use in developing the new practice expenses. The resource-based practice expense relative values became fully implemented on January 1, 2002.

Geographic Adjustments

There is general agreement that the RBRVS should, to some degree, be geographically adjusted. Many physicians, especially those in rural areas, believed that a floor should exist whereby physicians in geographic areas where office rents, wages of non-physician office staff, PLI costs, and cost of living are lower should not be economically disadvantaged. Alternatively, geographic areas with higher than average expenses should receive compensation for these higher expenses. The geographic practice cost indicator (GPCI) is a multiplier of practice expense to correct for geographic variations.

Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 required that the physician work GPCI cannot be less than 1.00.

Balance Billing Limits

Retaining the right to charge patients the difference between the Medicare approved amount and the physician's full fee for the service has been a cornerstone of the Medicare program since its inception.

Since January 1, 1993, the limiting charge for a given service in a given Medicare payment locality has been 15% greater than the Medicare approved amount for the service. It is the same for every physician who provides that service.

In addition, effective January 1, 1995, CMS has statutory authority to prohibit physicians and suppliers from billing Medicare patients, as well as supplemental insurers, above the limiting charge and to require that any excess charges be refunded or credited to the patient.

The OBRA 89 also retained the Participating Physician Program under the new Medicare payment system. "Participating" physicians are those who agree to accept assignment (meaning they will accept what Medicare pays and will not seek to collect excess fess from the patient) for all services that they provide to patients enrolled in the Medicare program. To give physicians an incentive to sign such an agreement, the full Medicare payment schedule amount for "nonparticipating" physicians is only 95% of the full payment schedule for participating physicians. Because the limiting charge is, in turn, based on the payment schedule for nonparticipating physicians, the effective limiting charge is 9.25% above the full Medicare payment schedule (i.e., 115% x 95% = 109.25%). In 2009, 96.5% of practicing physicians elected to participate.

Payment Updates and the Medicare Volume Performance Standard

The OBRA 89 provisions that were ultimately adopted authorized Congress to annually update the conversion factor based on the percentage increase in the Medicare Economic Index (MEl), a comparison of the Medicare Volume Performance Standard (MVPS) with the actual increase in spending, and other factors. The MVPS is set annually, by either Congress or a statutory default formula, to reflect the expected growth rate in Medicare spending for physicians' services. It is supposed to encompass all the factors that contribute to this growth, including changes in payment levels, the size and age composition of the Medicare population, technology, utilization patterns, and access to care. The concept behind the conversion factor updating process is that establishing a link between payment updates and increases in the volume of services provided to Medicare patients gives physicians an incentive to decrease unnecessary and inappropriate services.

The Balanced Budget Act of 1997 replaced the MVPS with a new sustainable growth rate (SGR) system to control Medicare expenditure growth. The SGR does not rely on historical patterns of growth in volume and intensity of physician services, as did the MVPS; rather, it uses projected growth in real gross domestic product per capita.

Budget Neutrality Adjustment

The OBRA 89 mandated that revisions to relative values resulting from changes in medical practice, coding, new data, or the addition of new services may not cause Part B expenditures to differ by more than $20 million from the spending level that would have occurred without these adjustments. Every year since 1993, CMS has projected net expenditure increases exceeding this limitation and, to limit the increase in Medicare expenditures has made budget neutrality adjustments to the payment schedule.

CMS has applied different types of "budget neutrality" adjustments. These include reducing all relative value units (RVUs) across all services, adjustment of conversion factors, a combination of

both RVU adjustment and adjustment of conversion factors, and the use of a separate work adjustor. The latter adjustment reflects CMS's belief that the volume and intensity of physician services will increase in response to payment schedule reductions, thus lessening their impact on overall Medicare expenditures.

The American Medical Association (AMA) and other physician groups opposed the application of a separate work adjustor. Because the Medicare Physician Payment Schedule is used widely by private and public payers to determine physician payment and physician group practices to determine compensation plans and/or to utilize as a benchmarking tool, adjusting work RVUs may compromise the integrity and relativity of the RBRVS. Since CMS first indicated that a work adjustor may be used, the AMA along with the majority of specialty societies have advocated for the adjustment to be applied instead to the conversion factor Legislation in 2008 required that the budget neutrality adjustment be applied to the conversion factor and not the work relative values for 2009-2012.

Changes in Law and Regulations

It is the general consensus of the physician community that the sustainable growth rate formula is flawed in part because it links physician reimbursement to factors beyond physicians' control. This flawed formula requires untenable reductions in physician reimbursement that if enacted, would likely result in physician reimbursement levels below physician expenses. Therefore physicians would likely be forced to decline to care for Medicare patients. Because of fear of this sequence of events, Congress has repeatedly provided one year "patch fixes" to the conversion factor formula. The flawed formula remains in effect with the continued looming potential for a huge correction should Congress refuse to legislate a patch fix in any given year. The AMA and other physician groups are working on a permanent repeal of the sustainable growth rate (SGR). They believe that short-term fixes to the annual conversion factor have exacerbated the problem.

Excerpted from Chapter 4 of *Medicare RBRVS: The Physicians' Guide 2012:*

The Physician Work Component

Figure 4-1. Components of the Medicare RBRVS

Practice expense 47.439%

PLI costs 4.295%

Physician work 48.266%
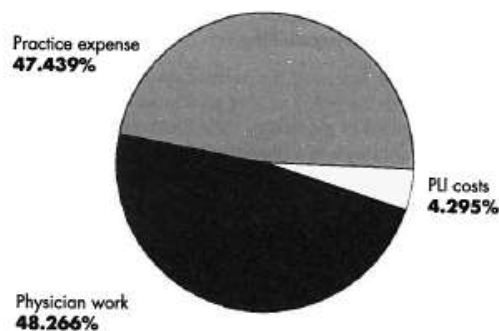
The greatest challenge in developing an RBRVS-based payment schedule was overcoming the lack of any available method or data for assigning specific values to physicians' work. The Harvard RBRVS study played a critical role in the evolution of Medicare's payment system. Although the study contained several weaknesses, critical reviews of the data and methods concluded that it provided a reasonably valid basis for assigning relative values to the physician work component of the payment schedule. The physician work component now accounts for an average of 48.266% of the total relative value for a service due to the rebasing and revising of the Medicare Economic Index (MEI). The MEI is an index intended to measure the annual growth in physicians' practice costs and general inflation in the cost of operating a medical practice. For 2011 CMS is rebasing and revising the MEI to use a 2006 base year in place of a 2000 base year. This change will result in revised percentages

for work, practice expense and professional liability insurance for the total relative value of a service as listed below:

- Physician work percentage will decrease from 52.466% to 48.266%
- Practice expense percentage will increase from 43.669% to 47.439%
- Professional liability insurance will increase from 3.865% to 4.295%

Further, these changes will result in adjusted work, practice expense and professional liability insurance RVUs to match these percentage changes. This is the first time the MEI has been rebased and revised since 2004.

The Harvard University School of Public Health, under a cooperative agreement with CMS conducted the study that led to the initial relative work values, which appeared in the November 1991 *Final Rule* (a *Final Rule* is the portion of the Federal Register that contains a summary of the final regulations for implementing the Medicare RBRVS payment schedule for a particular year. It generally includes updated RVUs for all physician services payable under the payment schedule, revised payment rules, analyses of comments on the previous proposed rule and CMS's response, updated GPCIs, and an impact analysis of the new rules on physicians and beneficiaries). The core of Harvard's landmark study was a nationwide survey of physicians to determine the work involved in each of about 800 services. About 4300 relative value estimates of the nearly 6000 services included in the 1992 Medicare relative value scale (RVS) were based directly on findings from the Harvard RBRVS study. Besides the Harvard study, the 1992 Medicare RVS also relied on findings from CMS's "refinement process," which it developed in response to public comments on the 1992 values. This refinement process also has contributed to updating the payment schedule since 1993.

Values for new and revised procedures in *Physicians' Current Procedural Terminology (CPT®)* are also contained in the updated relative value scales for each year. To develop recommendations for CMS regarding relative values to be assigned to new and revised codes, the AMA and national medical specialty societies established the AMA/Specialty Society RVS Update Process.

The three major sources of the physician work component relative values are:

- The Harvard RBRVS study
- The 1992 RVS refinement process
- The AMA/Specialty Society RVS Update Process

The Harvard RBRVS Study

Physician Work Defined

Before work on the RBRVS surveys could begin, researchers needed to define physician work. The Harvard RBRVS study initially conceptualized work as the time a physician spends providing a service and the intensity with which the time is spent. To better define the non-time-related elements of work, the researchers interviewed physicians, including members of the study's Technical Consulting Groups (TCGs). The TCGs were small groups of physicians in each studied specialty who were nominated by national medical specialty societies in a process coordinated by the AMA. As a result of these interviews, the Harvard study defined the elements of physician work as the following:

- Time required to perform the service
- Technical skill and physical effort
- Mental effort and judgment

- Psychological stress associated with the physician's concern about iatrogenic risk to the patient

This definition often caused confusion because some physicians thought that work relative value units (RVUs) are determined only by the time required to perform a service. Work RVUs are based on direct estimates of physician work; no separate measures of time are used.

The Harvard study further divided physician work into the work involved before, during, and after a service. The work involved in actually providing a service or performing a procedure is termed "intraservice work." For office visits, the intraservice period is defined as patient encounter time; for hospital visits, it is the time spent on the patient's floor; and for surgical procedures, it is the period from the initial incision to the closure of the incision (i.e., "skin-to-skin" time).

Work prior to and following provision of a service, such as surgical preparation time, writing or reviewing records, or discussion with other physicians, is referred to as "preservice and postservice work." When preservice, intraservice, and postservice work are combined, the result is referred to as the "total work" involved in a service. For surgical procedures, the total work period is the same as the global surgical period, including recovery room time, normal postoperative hospital care, and office visits after discharge, as well as preoperative and intraoperative work.

Although the Harvard study defined physician work according to these distinct components, it did not measure work in this manner. Earlier attempts to separately measure time and intensity had produced unsatisfactory results. Instead, the study directly measured the work involved in a service. The RBRVS study's definition of physician work is important because data from this study are the major basis for the physician work component of the Medicare payment schedule. A service on the schedule with more physician work RVUs than another means that the former service involves more time, skill, effort, judgment, and stress than the latter. Efforts to refine and update the RBRVS have employed the same definition of work as the Harvard study.

Having defined and separated work into its component parts, the researchers then ensured that all surveyed physicians had the same basic service in mind when rating the work for value. The coding system used in the RBRVS is the American Medical Association's Current Procedural Terminology (CPT) coding system. To allow physicians to rate the work of a service, the TCGs for each specialty developed "vignettes" for each coded service included in the survey of that specialty. In many cases, the vignette came directly from CPT, as in the following description:

In other cases, particularly for visits and consultations, the TCGs designed vignettes to be representative of an average patient for the particular service being rated by that specialty. For these services, the development of a vignette ensured that each surveyed physician had the same basic service in mind.

Preservice and Postservice Work

The RBRVS study employed several different methods to assign relative values to the preservice and postservice work involved in the surveyed services, depending on the type of service. For invasive procedures, surgeons were surveyed about the preservice and postservice time of specific components of procedures. For instance, general surgeons were surveyed about the time and work involved in a "hospital visit, three days post uncomplicated cholecystectomy with common bile duct exploration." Researchers then derived an "intensity per unit of time" factor from the survey data and used it to estimate preservice and postservice work from data on preservice and postservice time.

Assigning RVUs to Nonsurveyed Services

The researchers surveyed physicians about the work involved in 800 services and extrapolated work values for the remaining services. The extrapolation method grouped services into "families." For

example, all coded services involving coronary artery bypass surgery became a family, as did all new patient office visits. The researchers theorized that the differences in average charges for services within a family would approximate the differences in physician work. Thus, if a nonsurveyed service in a family had a 20% higher average charge than the surveyed service, then the physician work involved in the former should be 20% higher than the latter. In practice, however, the extrapolation method often produced RVUs that seemed incongruous or paradoxical.

A mechanism to update the RBRVS on an ongoing basis was included as part of OBRA 89. The statute requires that CMS conduct a comprehensive review of work relative values every five years.

The AMA/Specialty Society RVS Update Process

Besides refinements to correct errors in the initial RVUs, the Medicare RVS also must be updated to reflect changes in practice and technology. The AMA updates the CPT coding system annually under an agreement with CMS to reflect such changes. The AMA maintains the coding sys tem through the CPT Editorial Panel. Annual updates to the physician work relative values are based on recommendations from a committee involving the AMA and national medical specialty societies. The AMA/Specialty RVS Update Committee (RUC) was formed in 1991 to make recommendations to CMS on the relative values assigned to new or revised codes in CPT.

The core of the RVS Update Process is the RUC. During its first year, the RUC established procedures for specialty societies to reconcile their different viewpoints and agree on relative value recommendations. The RUC has now completed 20 cycles of recommendations for updating the physician work component of the RBRVS. The RUC has recently embarked on establishing recommendations on direct practice expense inputs for new and revised codes.

The AMA and physician groups believe that updating and maintaining the Medicare RVS is a clinical and scientific activity that must remain in the hands of the medical profession and regards the RUC as the principal vehicle for refining the work and practice expense components of the RBRVS. From the AMA's perspective, the RUC provides a vital opportunity for the medical profession to continue to shape its own payment environment. For this reason, these groups have strongly advocated that Medicare adopt the RUC's recommendations.

Structure and Process

The RUC represents the entire medical profession, with 23 of its 29 members appointed by major national specialty societies including those recognized by the American Board of Medical Specialties, those with a large percentage of physicians in patient care, and those that account for high percentages of Medicare expenditures. Three seats rotate on a two-year basis, with two reserved for internal medicine subspecialty and one for any other specialty. The RUC chair, the co-chair of the Health Care Professionals Advisory Committee (HCPAC; an advisory committee representing non-MD/DO health professionals); the chair of the Practice Expense Review Committee (PERC); and representatives of the American Medical Association, American Osteopathic Association, and CPT Editorial Panel hold the remaining five seats.

The major source of specialty input for the updating process is the RUC's *Advisory Committee*, which is open to all 122 specialty societies in the AMA House of Delegates. Specialty societies that are not in the House of Delegates also may be invited to participate in developing relative values for coding changes of particular relevance to their members. Advisory Committee members designate an *RVS Committee* for their specialty, which is responsible for generating relative value recommendations using a survey method developed by the RUC. Advisors attend the RUC meeting and present their societies' recommendations, which the RUC evaluates. Specialties represented on both the RUC and the Advisory Committees are required to appoint different physicians to each committee to distinguish the role of advocate from that of evaluator.

The RUC refers procedural and methodological issues to the *Research Subcommittee*, which is composed of about one-third the members of the full RUC. This subcommittee's principal responsibility is to develop and refine the RUC's methods and processes.

The RUC also established the *Practice Expense Subco*mmittee to examine the many issues relating to the development of practice expense relative values. This subcommittee also is composed of one-third of the members of the full RUC.

The *Administrative Subcommittee* also includes one-third of the RUC members and is primarily charged with the maintenance of the committee's procedural issues.

In 1992, the AMA recommended that a *Health Care Professionals Advisory Committee (HCPAC)* be established to allow for participation of limited license practitioners and allied health professionals in both the RUC and CPT processes. All of these professionals use CPT to report the services they provide independently to Medicare patients, and they are paid for these services based on the RBRVS physician payment schedule. Organizations representing physician assistants, nurses, occupational and physical therapists, optometrists, podiatrists, psychologists, registered dietitians, social workers, chiropractors, audiologists, and speech pathologists have been invited to nominate representatives to the CPT and RUC HCPACs. The CPT HCPAC fosters participation in and solicits comments from these professional organizations in coding changes affecting their members, while the RUC HCPAC allows those organizations to participate in developing relative values for new and revised codes within their scope of practice.

To further facilitate the decision-making process on issues of concern to both MDs/DOs and non-MDs/ DOs, *CPT and RUC HCPAC Review Boards* were also formed. The review boards bring MDs/DOs and non-MDs/ DOs together to discuss coding issues and relative value proposals. The RUC HCPAC Review Board comprises all 11 members of the current RUC HCPAC and three RUC members. For codes used by both MDs/DOs and non-MDs/DOs, the HCPAC Review Board acts much like an RUC facilitation committee. For codes used only by non-MDs/DOs, the RUC HCPAC Review Board replaces the RUC as the body responsible for developing recommendations for CMS.

The *Professional Liability Insurance (PLI) Workgroup* was created in 2002 to review and suggest refinements to the PLI relative value methodology.

The need for objective review of potential misvaluation has been a priority of the RUC, CMS, and MedPAC in recent years. The *Relativity Assessment Workgroup*, has implemented several screens to identify potentially misvalued codes, including: site-of-service anomalies, high volume growth, services surveyed by one specialty and now performed by a different specialty, Harvard valued codes, new technology, codes inherently performed together, services with low work RVUs but high volume based on Medicare claims data, services with low work RVUs that are commonly billed with multiple units in a single encounter, services on the Multi-Specialty Points of Comparison List, and high expenditure procedural codes. To date, the Workgroup has identified over 1200 codes for review of which 900 have been reviewed by the RUC. *Facilitation Committees* are established as needed during the RUC meetings to resolve differences of opinion about relative value recommendations before they are submitted to CMS.

The RUC closely coordinates its annual cycle for developing recommendations with the CPT Editorial Panel's schedule for annual code revisions and with CMS's annual updates to the Medicare payment schedule.

The RUC process for developing relative value recommendations is as follows:

Step 1   The CPT Editorial Panel transmits its new and revised codes to the RUC staff, which then prepares a "Level of Interest" form. The form summarizes the Panel's coding actions.

Step 2 Members of the RUC Advisory Committee review the summary and indicate their societies' level of interest in developing a relative value recommendation. The societies have several options. They can:

A. Survey their members to obtain data on the amount of work involved in a service and develop recommendations based on the survey results.

B. Comment in writing on recommendations developed by other societies.

C. Decide, in the case of revised codes, that the coding change requires no action because it does not significantly alter the nature of the service.

D. Take no action because the codes are not used by physicians in their specialty.

Step 3 AMA staff develops survey instruments for the specialty societies. The specialty societies are required to survey at least 30 practicing physicians. The RUC survey instrument asks physicians to use a list of 10 to 20 services as reference points that have been selected by the specialty RVS committee.

Physicians receiving the survey are asked to evaluate the work involved in the new or revised code relative to the reference points. The survey data may be augmented by analysis of Medicare claims data and information from other studies of the procedure, such as the Harvard RBRVS study.

Step 4 The specialty RVS committees conduct the surveys, review the results, and prepare their recommendations to the RUC. When two or more societies are involved in developing recommendations, the RUC encourages them to coordinate their survey procedures and develop a consensus recommendation. The written recommendations are disseminated to the RUC before the meeting.

Step 5 The specialty advisors present the recommendations at the RUC meeting. The Advisory Committee members' presentations are followed by a thorough question-and-answer period during which the advisors must defend every aspect of their proposal(s).

Step 6 The RUC may decide to adopt a specialty society's recommendation, refer it back to the specialty society, or modify it before submitting it to CMS. Final recommendations to CMS must be adopted by a two-thirds majority of the RUC members. Recommendations that require additional evaluation by the RUC are referred to a Facilitation Committee.

Step 7 The RUC's recommendations are forwarded to CMS in May of each year. CMS convenes a meeting of selected medical directors to review the RUC's recommendations. Step 8 The Medicare Physician Fee Schedule, which includes CMS's review of the RUC recommendations, is published in late fall. The new values are considered "interim" for one year and are open for public comment. After one year, the values are considered final.

Updating Work Relative Values

Each year the RUC submits recommendations to CMS for physician work relative values based on CPT coding changes to be included in the Medicare payment schedule. The RUC has submitted more than 4100 relative value recommendations for new and revised codes for the 1993—2012 RBRVS updates. Each year CMS has relied heavily upon these recommendations when establishing interim values for new and revised CPT codes.

Five-Year Review

In addition to annual updates reflecting changes in CPT, CMS is required to comprehensively review all relative values at least every five years and make any needed adjustments. The RUC sought a significant role in this comprehensive review of physician work relative values and appointed a subcommittee on the Five-Year. Consensus emerged about how to conduct the five-year review and

revolved around the following major points: (1) the RUC should play a key role; (2) the refinement should focus on correcting errors and accounting for changes in medical practice, not the whole RVS; and (3) the methods should build upon the current RUC methodology for valuing codes.

Scope of the Five-Year Reviews

The five-year reviews have presented an unprecedented opportunity to improve the accuracy of the physician work component of the RBRVS, as well as a significant challenge to the medical community. To date there have been 4 of these reviews beginning in 1997. During each of these reviews, misvalued services are eligible and vulnerable for review.

In approaching its task, the RUC determined that a high standard of proof would be required for all proposed changes in work values. For example, specialties were required to present a "compelling argument" in order to maintain current values for services that the comments had identified as overvalued. The RUC's methodology for evaluating codes identified by public comment was similar to that used previously for the annual updates, with some innovations designed to require compelling arguments to support requested changes. The survey was modified to require additional information regarding comparisons with the key reference services selected, as well as the extent to which the service had changed over the previous five years.

The RUC also established multidisciplinary work groups to help manage the large number of comments referred and to ensure objective review of potentially overvalued services. These work groups evaluated the public and Carrier Medical Director comments and developed recommendations. The full RUC treated the recommendations as consent calendars, with other RUC members and specialty society representatives extracting for discussion any work group recommendations with which they disagreed.

The RUC also considered outside studies conducted at the request of three medical specialty societies.

CMS stated that the next Five-Year review of PE RVUs will be addressed in 2014. Examples of changes occurring as a result of the RUC 5 year review include:

- Recommendations on diagnostic mammography in the second 5 year review. The RUC reviewed data submitted by the American College of Radiology (ACR) that indicated an increase in physician work created by the implementation of the Mammography Quality Standards Act of 1992 (MQSA). The RUC agreed that these regulations and ACR standards did require more physician time and work. CMS implemented these increases on January 1, 2002.

- Consideration of values of all Evaluation and Management (E/M) services in the third 5 year review. The RUC agreed that incorrect assumptions were made in the previous valuation of E/M services. The RUC recommended and CMS approved an increase in work RVUs for 28 services and maintained work RVUs for seven services. This recommendation is important because of the huge utilization of these codes and the requirement for budget neutrality. With increases in the utilization of these and any other CPT codes comes a requirement to reduce the value of other services, including imaging codes to achieve budget neutrality.

- Review of radiology codes in the third 5 year review. This included maxillofacial X-rays, radiation therapy, and general X-rays. Of all of the radiological procedures addressed by the RUC, 50 of 80 procedures' work values were recommended by the RUC and approved by CMS to be maintained.

Future Plans

As the trend continues toward adopting the Medicare RBRVS by non-Medicare payers, including state Medicaid programs, workers' compensation plans, TRICARE, and state health system reform

plans, it is critical that the physician work component be complete and appropriate for all patient populations.

The RUC is committed to improving and maintaining the validity of the RBRVS over time. Through the RUC, the AMA and specialty societies have worked aggressively to identify and correct flaws and gaps in the RBRVS. The RUC will continue to review all services considered to be inappropriately valued. CMS will now call for public comments on an annual basis as part of the comment process on the *Final Rule* each year. The next opportunity for comment will be November 2012.

The RUC will rely on the recommendations of the Relativity Assessment Workgroup, based on established objective criteria, to identify codes that will be considered for reevaluation on an ongoing basis. The Relativity Assessment Workgroup also develops objective criteria to identify "new technology" services and has established a review process and schedule for "new technology" services and will maintain the review process. The RUC's efforts led to more than $100 million in annual work value redistribution, applied via a slight increase to the conversion factors in 2009 and 2010. In 2011, the redistribution was more substantial, with $400 million in work value decreases redistributed via a 0.4% increase to the 2011 conversion factor. The RUC's efforts led to approximately $200 million in work value redistribution to the 2012 Medicare conversion factor (0.2% increase). When combined with the practice expense and PLI changes resulting from this specific effort, at least $1.5 billion has been redistributed within the Medicare Physician Payment Schedule from 2009—2012.

The RUC process is the principal method to provide recommendations to refine and maintain the Medicare RVS. The RUC represents an important opportunity for the medical profession to retain input regarding the clinical practice of medicine.

Excerpted from Chapter 8 of *Medicare RBRVS: The Physicians' Guide 2012:*

The Medicare Payment Schedule

The Medicare payment schedule's impact on a physician's Medicare payments is primarily a function of three key factors:

- The resource-based relative value scale (RBRVS)
- The geographic practice cost indexes (GPCIs)
- The monetary conversion factor

The enabling legislation and regulations, as well as Medicare carrier correspondence and forms, refer to the Medicare physician payment schedule as a "fee schedule." From the perspective of most physician groups, the distinction between a payment schedule and a fee schedule is extremely important: a fee is what physicians establish as the fair price for the services they provide; a payment is what Medicare approves as the reimbursement level for the service. All references to the "full Medicare payment schedule" include the 80% that Medicare pays and the 20% patient coinsurance.

The Formula for Calculating the Payment Schedule

The Omnibus Budget Reconciliation Act of 1989 (OBRA 89) geographic adjustment provision requires all three components of the relative value for a service—physician work relative value units (RVUs), practice expense RVUs, and professional liability insurance (PLI) RVUs—to be adjusted by the corresponding GPCI for the locality. In effect, this provision increases the number of components in the payment schedule from three to the following six:

- Physician work RVUs
- Physician work GPCI

- Practice expense RVUs
- Practice expense GPCI
- PLI RVUs
- PLI GPCI

For 2012, the formula for calculating payment schedule amounts entails adjusting RVUs, which correspond to services, by the GPCIs, which correspond to payment localities.

> *The general formula for calculating Medicare payment amounts for 2012 is expressed as:*

Total RVU = Work RVU[1] x work GPCI

> + practice expense RVU[1] x practice expense GPCI

> + malpractice RVU[1] x malpractice GPCI

Payment = Total RVU x conversion factor

[1] The 2012 physician work, practice expenses, and malpractice RVUs may be found in Part 5 of the Medicare RBRVS: The Physicians' Guide 2012.

This is an example using the 2012 conversion factor, $34.0376.

Example: Payment for CPT code 99213 is needed for an office/outpatient visit provided in a physician's office in Chicago, Illinois. The payment is calculated as follows:

Total RVU = 0.97 x 1.030 = 0.9991

> + 0.99 x 1.05 1 = 1.04049

> + 0.07 x 2.077 = 0. 14539

> = 2.227 RVUs for CPT code 99213 in the Chicago locality

> Payment = 2.227 x $34.0376 = $75.80

Table 8-1. Calculation of Locally Adjusted Payment Schedule

Service CPT Codes	Work RVU	Work GPCI	PE RVUs	PE GPCI	PLI RVUs	PLI GPCI	Total RVUs	Conversion Factor	Local Payment Schedule
99213	0.97	1.030	1.03	1.051	0.07	2.077	2.2270	$34.0376	$75.80
27130	21.79	1.030	16.39	1.051	4.29	2.077	48.5799	$34.0376	$1,653.54
33533	33.75	1.030	15.42	1.051	8.13	2.077	67.8549	$34.0376	$2,309.62
71010 26	0.18	1.030	0.07	1.051	0.01	2.077	0.2797	$34.0376	$9.52

D. Credentialing and delineation of clinical privileges
   There are two distinct but generally linked regulatory processes involved in obtaining the ability to practice medicine. This applies both to practice within an institution such as a hospital, and the ability to provide care to a particular subset of patients, such as those patients in an HMO or PPO, or contracted through a third-party provider. These processes are credentialing and privileging. While the details are institution-specific, in a hospital environment many of the requirements are mandated by the Joint Commission (TJC).

Credentialing: Credentialing is the process whereby one gains admission to a medical staff, in the case of a hospital, or to a panel of healthcare providers, in the case of an insurance company or other institution. This is essentially a verification process or background check conducted through a formal application process. It generally includes some or all of the following:

1. A formal application unique to each institution;
2. A picture to confirm your identity;
3. Confirmation of your medical school graduation, residency and
4. Fellowship completion, and any other training;
5. Confirmation of Board certification;
6. Letters of reference;
7. Complete timeline of your activities since graduation;
8. Confirmation of your health status (ability to practice);
9. Questionnaire addressing any sanctions by regulatory agencies, chemical dependency, etc.;
10. Malpractice history;
11. Criminal background check regarding arrests or investigations.

The applicant is responsible for ensuring that all of the requested information is provided. Each item is confirmed by the organization to which you are applying through primary source verification. This could be a prolonged process taking several months, particularly if you have been on staff at multiple hospitals or have multiple state licenses. The completed application is then reviewed and approved sequentially by: 1) the department chairman; 2) the Credentials Committee; 3) the Medical Executive Committee; and finally 4) the institution's Board of Directors. The Board of Directors is the only group authorized to actually grant your membership, although it is unusual for them to overrule the recommendations of the medical staff. At that point, you become a credentialed member of the medical staff. That in itself, however, does not allow you to actually practice medicine. That is determined by the process of privileging, discussed below.

Staff appointments, as with board certification, are time-limited, usually for two years, which is the maximum allowed by The Joint Commission. At that point, one files an application for reappointment. This is a simpler process, as verification of the above information need not be repeated. It generally involves an update of the questionnaire, health history, malpractice history, and your clinical activity, in terms of patient volume and quality performance.

Upon acceptance to the medical staff, one is generally admitted to the provisional staff for a period of time, usually one to two years. This gives the institution an opportunity to directly assess your skills and confirm what was represented in your initial application. Assuming there are no problems, you are then advanced to the active medical staff.

Privileging: Privileging is the process by which your experience and skills are evaluated to determine what clinical activities you will be permitted to perform. This involves the

applicant filling out a Delineation of Privileges request, itemizing what procedures he/she wishes to perform, and providing a listing of his/her previous experience to support those requests. This generally takes the form of a case log, detailing numbers of different types of exams or procedures the applicant has recently performed. Most privileges are included under the umbrella moniker of "core privileges", i.e., those procedures that any radiologist completing a residency should be competent at performing. Some more specialized procedures/exams or ones that are available to several departments may require additional documentation of training. Each department specifies the experience necessary to grant such a privilege. For example, in order to read cardiac CT angiograms, the department may require that you have Level II training. While the department generally sets its own standards and requirements, there are some privileges that are exercised by members of several different departments. For example, both cardiologists and radiologists may be privileged to interpret cardiac CTA. In those situations, the privileging requirements are required to be the same for anyone in the institution. The same hierarchy of approval process described for credentialing applies here as well.

What you are allowed to do clinically is determined by the privileges granted to you through this process. Specific requests may be denied based on an institution's awarding privileges selectively to a single specialty, for example, as in the case of an exclusive provider agreement or contract with a provider group.

At the reappointment time, delineation of privileges is also renewed, and depends on maintaining current competency through the exercise of those privileges. In other words, being able to continue to read MRI exams, for instance, depends upon how many you have read in the two years since your last reappointment.

Quality Assessment: Part of the process of credentialing is assessment of your practice quality. This has taken a number of forms over the years, but the current mechanism consists of two processes known by the acronyms FPPE and OPPE.

1. FPPE (pronounced *fippy*) stands for Focused Professional Practice Evaluation. FPPE is used in three different ways:
   a. For initial appointment to the medical staff, it represents the process, formerly referred to as proctoring, in which a current member of the medical staff is assigned to evaluate your overall performance. He/she will observe a sample of your work to cover all of your requested clinical privileges, as well as your overall medical staff "citizenship." For radiology, this generally takes the form of review of a certain number of cases from each modality, as well as a certain number of procedures for interventional privileges. The exact requirements are determined by one's department. Ideally, FPPE is completed as soon as possible, but in any event, typically covers the first six months of your staff membership.
   b. For existing members of the medical staff desiring to add a new privilege, it represents the process in which one's performance of that specific privilege is assessed. That is generally conducted by a member of the medical staff currently holding that privilege. If it is a new procedure for the institution, it may take the form of committee evaluation, or may be referred to a practitioner outside of the institution's medical staff with expertise in that area. One cannot perform that procedure independently until this process is satisfactorily completed.

c. For existing members of the medical staff with whom there is concern about the quality of their practice, either in general or for a specific procedure, FPPE is used for that assessment. It is generally conducted by a member of the medical staff with the privileges in question.

In each of these situations, the reviewer's report and recommendation is forwarded to the department chairman and then to the Credentials Committee for approval.

2. OPPE (pronounced *oh'-pee*) stands for Ongoing Professional Practice Evaluation. Exactly as the name implies, this is the process whereby one's practice performance is continually monitored. Again, each department determines the scope of that review for specific privileges. In addition, the medical staff also has generic metrics for all physicians. OPPE data is typically reviewed by the department chairman or department quality review committee every six months consecutively. That information is provided to you, and is also used at the time of your reappointment.

E. Appropriateness guidelines 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 (ARC 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 AC guidelines 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.

Several other international radiology organizations have similar documents that address appropriate imaging. These include the Royal College of Radiologists (United Kingdom) referral guidelines, "Making the best use of clinical radiology services", and the Canadian Association of Radiologists "Diagnostic Imaging Referral Guidelines."

Related to the concept of appropriate imaging are Radiology Benefits Managers (RBMs). RBMs are private companies that contract with insurers to provide prior authorization for imaging services, usually advanced (and therefore more expensive) modalities such as CT, MRI, Nuclear Medicine, and PET. These firms have their own proprietary algorithms to determine appropriateness. Many RBMs state that their algorithms are based on the ACR Appropriateness Criteria® and other similar criteria, but unlike the ACR Appropriateness Criteria® that are publicly available on line, the RBM algorithms are proprietary and not publicly accessible.

Lee et al. described the mechanisms the RBMs use to decrease utilization as "denying coverage for services, diverting patients to less expensive imaging services, educating physicians about appropriate imaging and providing feedback about their image ordering relative to their peers, and acting as the gatekeeper or "sentinel," whereby physicians may be less likely to order imaging studies simply because they are being monitored." They also note that "physicians may also choose to order fewer tests to avoid the cost or "hassle" of complying with RBMs' prior authorization procedures."

Lee et al. studied the cost impact of RBMs by creating mathematical models. While it is clear that RBMs decrease costs for the insurer, even after paying the RBM for its services, costs to the providers were increased in order to meet the requirements of the RBMs.

Whether overall costs to society were increased or decreased depended on assumptions of their various models.

Many other medical organizations have similar documents to guide clinical practice, some of which also address imaging. In particular, the American College of Cardiology (ACC) Practice Guidelines and Quality Standards include a set of Appropriate Use Criteria. The ACC Appropriate Use Criteria use a similar 1-9 rating system as the ACR Appropriateness Criteria with groupings of Inappropriate (1-3), Uncertain (4-6) and Appropriate (7-9). However, the ACC structure starts with the imaging modality (such as Cardiac CT, Cardiac MRI or Cardiac Radionuclide Imaging) and rates various clinical indications as opposed to the ACR structure that starts with the clinical indications (conditions and variants) and rates the appropriateness of the imaging modalities. The ACC also has Practice Guidelines that discuss clinical management of many common cardiovascular conditions. The American College of Physicians is an example of another clinical organization that has developed multiple "clinical guidelines", often in collaboration with other organizations, which discuss the diagnosis and management of many common clinical conditions. In general, these documents are more similar to the ACR Appropriateness Criteria® than the Practice Guidelines, although there may be similar elements to both types of ACR documents. Some of these clinical documents may at least briefly discuss imaging issues.

Lee DW, Rawson JV, Wade SW. Radiology Benefits Managers: Cost Savings or Cost Shifting? J Am Coll Radiol 2011; 8:393-401.

Levin DC, Bree RL, Rao VM, Johnson J. A prior authorization program of a radiology benefit management company and how it has affected utilization of advanced diagnostic imaging. J Am Coll Radiol. 2010; 7:33–38.

Taylor AJ, Cerqueira M, Hodgson JM, et al. ACCF/SCCT/ACR/AHA/ASE/ASNC/NASCI/SCAI/SCMR 2010 Appropriate Use Criteria for Cardiac Computed Tomography. J Am Coll Cardiol, 2010; 56:1864-1894.

ACR Appropriateness Criteria®. Available online at:
http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx. Accessed 10-1-11.

F. 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.

> *ACR Practice Guidelines and Technical Standards. Available online at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines.aspx. Accessed 10-1-11.*

V.   Research and Screening

A. Basic statistics for literature interpretation in imaging

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

2. Types of variables
    a. Categorical: basic units are not quantifiable (examples: race, gender). These can be nominal (lower information content) or ordinal (intermediate information content);
    b. Continuous or ordered discrete: can take values within a given interval and generally have higher information content (example: time, age, blood pressure).

3. True positive: when a person with a positive test result does have the disease in question;

4. True negative: when a person with a negative test result does not have the disease in question;

5. False positive: when a person has a positive test result but does not have the disease in question;

6. False negative: when a person has a negative test result but does have the disease in question;

7. Frequency tables: The frequency of a value is the number of times that value occurs in a data set. The relative frequency of a value is the proportion of observations in the

data set with that particular value. Frequency tables are a commonly used format to present data, so that frequency, relative frequency, and cumulative frequency (the sum of relative frequencies for variables in a column in the table) are indicated for each value observed;

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

9. Measuring variability in data: Measuring variability in data, including standard deviation: Variability in a data set can be described by multiple methods. Range is defined as the difference between the largest observed value and the smallest observed value. Percentiles describe the shape of a distribution of values; the 25th percentile is the value at which 25 percent of the data lie below that observed value and the rest lie above it. Variance describes the amount of spread around the mean of a data set. Variance is calculated by subtracting the mean of a set of values from each of the observations, squaring these differences, adding them up, and dividing by one less than the number of observations in the data set:

$$\text{variance} = \sum(\text{observed value} - \text{mean})^2 / (\text{no. of observations} - 1)$$

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

Pagano M, Gauvreau K (2000). Principles of Biostatistics. Pacific Grove, Duxbury Press. Ch 3.

10. Normal distribution and standard scores: A probability distribution uses the theory of probability to describe the behavior of a random variable. In the case of discrete variables, a probability distribution specifies all possible outcomes of the variable along with the probability that each will occur. In the case of continuous variables, a probability distribution specifies the probabilities associated with a specified range of values. Two of the probability distributions that are most commonly used in radiology are the binomial and normal distributions. The binomial distribution describes the chance of an event occurring when each trial (e.g., flip of a coin) is independent, outcomes are mutually exclusive, and the probability of success ("heads") is the same for each trial. The normal distribution describes the probabilities for a continuous outcome that is the result of averaging a large number of independent, random observations. The normal distribution is sometimes described as bell-shaped. This distribution depends on the mean and the standard deviation (SD). The height of the curve at any point, x, is determined by the *z score* (standardized score). The *z score* is the difference between x and the mean, in units of SD. [$z = (x - \text{mean})/\text{SD}$] By transforming x into z, one can use tables of areas computed for the standard normal curve to estimate probabilities associated with x. Approximately 95.4 percent of the area under the standard normal curve lies within +/- 2 standard deviations from the mean.
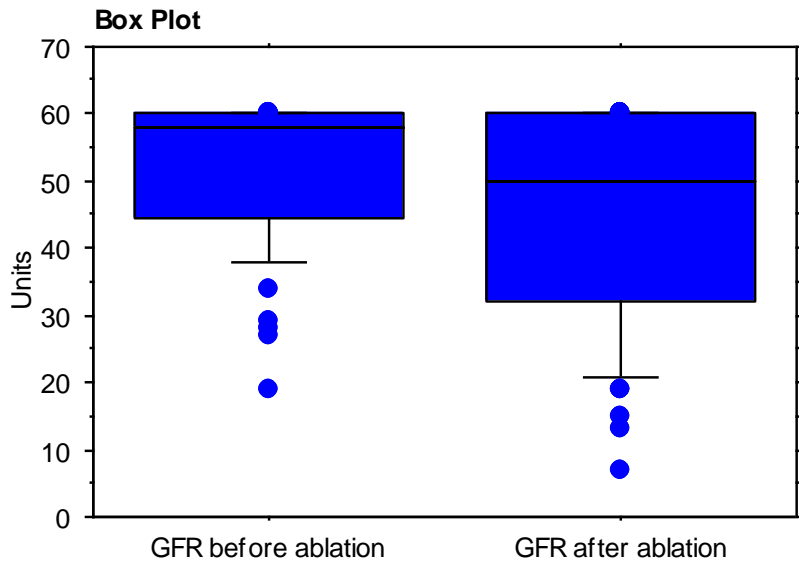
Halpern EF, Gazelle GS (2003). Probability in radiology. Radiology 226(1): 12-15.

Pagano M, Gauvreau K (2000). Principles of Biostatistics. Pacific Grove, Duxbury Press. Ch 7.

Graphic methods for depicting data:

ABR Exam: 3rd Yr ONLY
Clinical Diagnostic Radiology
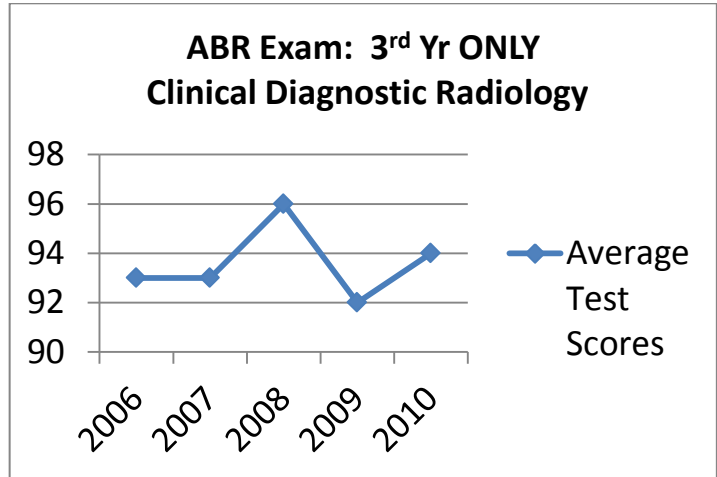
Line graph shows change in average test scores (y axis) over time in years (x axis).

Box Plot

Box plot shows higher variation in GFR after ablation than before. The long horizontal black line is the median. The shaded box represents boundaries of the upper and lower quartiles, with the blue dots being data points outside of these quartiles.

Where would you go for help in understanding this report?
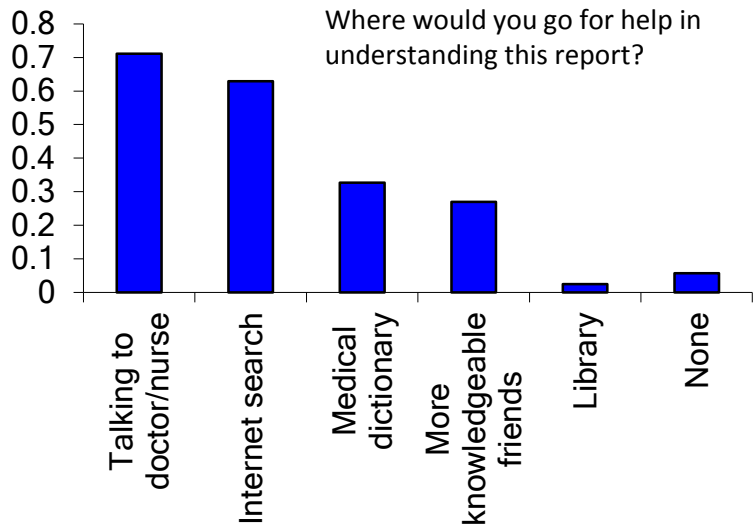
After completing the clinical simulations including reading radiology reports written in typical medical terminology, patient participants were asked what educational resources, if any, they might use to better understand radiology report contents. Bar graph demonstrates the mean (for all simulations) relative frequencies that participants thought they would use various resources.

Age of Study Participants

- 18-30
- 31-45
- 46-60
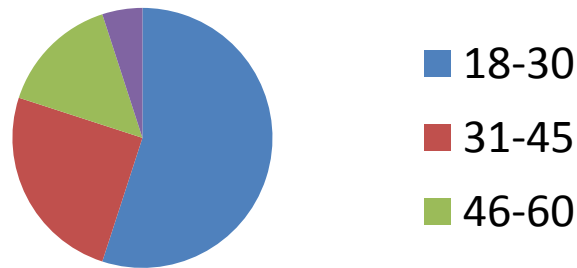
Pie chart summarizes the age of study participants, as categorized into investigator-defined age brackets.

Amount of skull base fatty tissue among subjects

Number of subjects

Fat area measurement
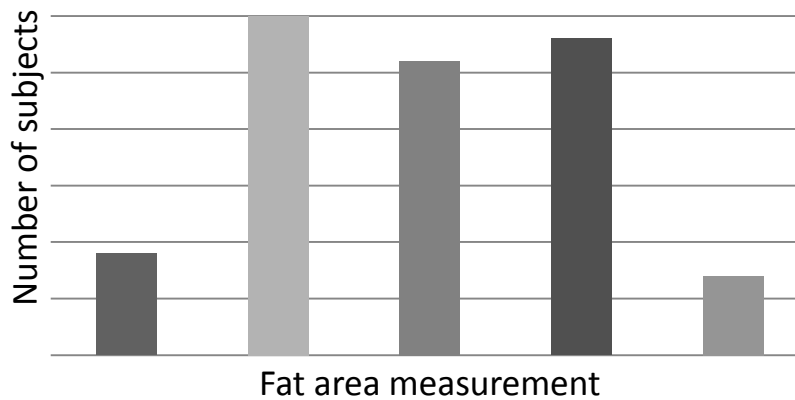
Histogram shows the distribution of fatty tissue as measured from the pterygoid plate to the roof of the orbits on T1-weighted MRI. Measurements were obtained in a group of outpatients undergoing concurrent brain MRI and abdominal CT.

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

Hulley SB, Cummings SR, et al. (2001). Designing Clinical Research An Epidemiologic Approach. Philadeplhia, PA, Lippincott Williams & Wilkins.

Pagano M, Gauvreau K (2000). Principles of Biostatistics. Pacific Grove, Duxbury Press. Ch 10.

12. Confidence limits: A confidence interval (CI) is a range of reasonable values that are intended to contain the parameter of interest (e.g., the mean) with a certain degree of

confidence. CIs are used to estimate population values without having data from all members of the population. CIs for population estimates provide information about how precise the estimate is (wider CIs indicates less precision). CIs quantify the precision of the estimate. The desired degree of confidence is most often chosen at 95 percent. For a normally distributed sample with known standard deviation (or population with unknown SD but normally distributed and large), 95 percent CI = mean +/- z (SD/$\sqrt{n}$), noting that for a 95 percent CI, z = 1.96. If the population standard deviation is not known and the sample is small, the Student's t distribution, rather than the standard normal distribution (z score) is used. The t distribution resembles the normal distribution but its shape depends on sample size, with shape depending on the number of degrees of freedom. Degrees of freedom (defined as df = n -1) measures the reliability of the sample SD as an estimate of the population SD. Using other formulas, CIs may be calculated for point estimates (e.g., odds ratios) or proportions (e.g., sensitivity and specificity). Whereas p values indicate a statistically significant result, CIs provide a range of values, in the units of the variable of interest, which help the reader interpret implications of the results at either end of the range.

> *Medina LS, Zurakowski D (2003). Measurement variability and confidence intervals in medicine: why should radiologists care? Radiology 226(2): 297-301.*
>
> *Pagano M, Gauvreau K (2000). Principles of Biostatistics. Pacific Grove, Duxbury Press. Ch 9.*

13. Sensitivity: The sensitivity of a test is the proportion of people who have the disease and test positive for it. Sensitivity (and specificity) are intrinsic properties of a test and do not depend on the population being tested. Use of the 2 x 2 table below can be helpful in understanding this definition as well as other commonly used statistical measures. (Please note that cells within this table are commonly annotated as "a, b, c, d" as indicated below).

	Disease +	Disease -	
Test +	True positive (TP) a	False positive (FP) b	Positive predictive value (PPV) = TP/(all Test +)
Test -	False negative (FN) c	True negative (TN) d	Negative predictive value (NPV) = TN/(all Test -)
	Sensitivity = TP/(all Disease +)	Specificity = TN/(all Disease -)	

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

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

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

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

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

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

> *Obuchowski NA (2003). Receiver operating characteristic curves and their use in radiology. Radiology 229(1): 3-8.*

Lusted LB (1971). Signal detectability and medical decision-making. Science 171(3977): 1217-1219.

19. Correlation and agreement: A correlation analysis measures and interprets the strength of a linear or nonlinear relationship between two continuous variables. Pearson (parametric) and Spearman (nonparametric) correlation coefficients each have values between -1 and +1, with the sign of the correlation indicating the direction of the relationship and the absolute value of the coefficient indicating the strength of the correlation. The Pearson correlation coefficient is used only with interval or continuous outcome variables, whereas the Spearman (rank) coefficient can be used with ordinal or continuous outcome variables. As with other nonparametric tests, the Spearman coefficient is less influenced by skewed data and outliers. Correlation analysis is often used for observational studies and to generate hypotheses for further testing. Correlation analysis is of limited utility for establishing causation: high correlation is insufficient to prove causation.

To evaluate categorical data, measures of agreement are used. Observer agreement can provide information about the reliability of imaging-based diagnoses, consistency of a method (human or computer) for classifying extent of disease and value of an imaging technique when an independent reference standard proof of diagnosis is difficult to obtain. κ is a measure of agreement that is corrected for chance. A κ of zero means that there is no agreement beyond that expected by chance, and a κ of 1 means that there is perfect agreement. Agreement (κ) is affected by prevalence. Agreement is not a surrogate for accuracy (high accuracy implies high agreement, but high agreement does not necessarily imply high accuracy).

*Zou KH, Tuncali K , et al. (2003). Correlation and simple linear regression. <u>Radiology</u> **227**(3): 617-622.*

*Kundel HL, Polansky M (2003). Measurement of observer agreement. <u>Radiology</u> **228**(2): 303-308.*

20. Regression: As opposed to correlation analysis (which measures the strength of the relationship between variables), a regression analysis evaluates the impact of a predictor (aka: independent, explanatory) variable on an outcome (aka: dependent, response) variable. The purpose of a regression analysis may be to estimate the effect of a predictor variable or to predict the value of the outcome variable on the basis of the values of the predictor variables. A simple linear regression model contains one predictor variable, X_i, for i = 1, ..., n subjects, and has a linear relationship with the outcome variable, Y_i:

$$Y_i = a + bX_i + e_i$$

where "a" is the intercept on the y axis, and "b" is the slope of the regression line. Thus, "a" is the expected value of the outcome variable when the predictor variable is set to 0; "b" is the average change in the outcome variable that corresponds with an increase of one unit in the predictor variable. (The "e_i" is the random error term, assumed to have a mean of 0 and constant variance.) The goal of linear regression is to fit a straight line through the data that predicts Y based on X. To estimate the parameters that determine this line, the least squares method is often used: the sum of squared residuals (differences between observed values and fitted values of the outcome variable) are minimized.

Multiple regression analyses are performed to evaluate the relationship between an outcome variable and several predictor variables. Multiple regression analyses may be used to examine the impact of multiple predictor variables on a single outcome of

interest, to adjust analyses for potential confounders (removing them from the analysis), or to predict the value of an outcome variable using the predictor variables. If the outcome is a continuous variable, then a linear regression is often used. If the outcome is a dichotomous variable, then a logistic regression is commonly used. Multiple linear regression is similar to simple linear regression but more complex.

In logistic regression (used when the outcome variable is dichotomous), the expected value of outcome Y is equal to the probability that Y = 1 (i.e., the probability that the event of interest has occurred). The odds ratio (i.e., the odds of a particular outcome in the test group compared with the odds of that outcome in the control group) is a common way to express results of a logistic regression.

In linear or logistic regressions, the association between one predictor variable and the outcome variable may vary across values of other predictor variables. This is called an interaction, suggesting that the effect of one predictor variable X1 depends on the value of X2. Main effects cannot be interpreted without also considering any significant interactions.

Important issues with regression analyses:

- have assumptions been met and how well do the data fit with the model;
- even if a strong relationship is seen, this does not prove causation;
- the model should not be used to predict outcomes outside the range of the values of the predictor variables in the sample tested.

Zou KH, Tuncali K , et al. (2003). Correlation and simple linear regression. Radiology 227(3): 617-622.

Gareen IF, Gatsonis C (2003). Primer on multiple regression models for diagnostic imaging research. Radiology 229(2): 305-310.

21. Bayes theorem

   a. Pre-test probability of disease: The prevalence of the disease in the test population.
   b. Post-test probability of disease: The probability (prob) of an outcome is defined as the number of times the outcome is observed divided by the total number of observations. The odds of an outcome are defined as the probability that the outcome does occur divided by the probability that it does not occur.
      Odds = prob/ (1 – prob), and
      Prob = odds/(1 + odds).

   The post-test probability of disease is determined by both the prevalence (pre-test probability) and the test information (likelihood ratio). Post-test odds is defined as the pre-test odds times the likelihood ratio (LR). The LR is the probability of getting a specific test result if the patient has the disease divided by the probability of that result if the patient is healthy.

   positive likelihood ratio (LRp) = sensitivity / (1 – specificity)

   negative likelihood ratio (LRn) = (1 – sensitivity) / specificity

   LRp greater than 10 and LRn less than 0.1 provide convincing diagnostic evidence; LRp greater than 5 and LRn less than 0.2 provide strong diagnostic evidence.

c. Odds ratio: The odds ratio (OR) is the odds of disease in the exposed (or test positive) group divided by the odds of disease in the unexposed (or test negative) group. Using annotations for the 2 x 2 table (see xii above), OR = ad/bc.

The relative risk (RR) is the probability of disease in the exposed group divided by the probability of disease in the unexposed group. For rare diseases, the OR is a close approximation of the RR.

Medina L, Blackmore C (2006). Evidence-Based Imaging: Optimizing Imaging in Patient Care. New York, Springer. Ch 1.

Sistrom CL, Garvan CW (2004). Proportions, odds, and risk. Radiology 230(1): 12-19.

22. Power and sample size: β is the probability of making a Type II error (defined as failing to reject the null hypothesis when it is false). Power is defined as (1 – β); that is, power is the probability of avoiding a Type II error. In planning a study, researchers typically need to determine the sample size necessary to provide a desired power level. (This issue of sample size has ethical implications: if a study is not designed to include enough subjects to adequately test the hypothesis, then the study exposes subjects to risk when there is no potential for scientific gain.) Sample size depends on the ratio between standard deviation and the smallest meaningful difference (a.k.a. effect size) between the two means being compared. Decreasing the standard deviation (e.g., by using more precise measurement techniques or by using a more homogeneous patient population) or increasing the effect size are ways to decrease the sample size. There are formulas for sample size calculations for simpler study designs. For more complex study designs, simulations are often done in which mathematical models are used to generate a synthetic data set so that a p value can be determined.

Eng J. (2004). Sample size estimation: a glimpse beyond simple formulas. Radiology 230(3): 606-612.

Pagano M, Gauvreau K (2000). Principles of Biostatistics. Pacific Grove, Duxbury Press. Ch 10.

23. Commonly used statistical tests in the radiology literature:

a. For normal distribution of continuous variables, looking for differences in means:
- Comparing means from two independent populations – t test;
- Comparing means from paired samples (e.g., same subject tested at two different times) – paired t test;
- Comparing more than two means from two or more independent groups – ANOVA;

b. For continuous data that are not normally distributed:
- Comparing means from two independent populations – Mann-Whitney U test;
- Comparing means from paired samples – Wilcoxon Signed Rank test;
- Comparing paired data when symmetric distribution of the variable around the median is not assumed – Sign test.

c. For categorical data:

- Comparing observed frequencies with expected frequencies, often in 2 x 2 table (especially for test homogeneity between two groups or independence of two variables in one group) – χ2 test;
- Comparing observed frequencies with expected frequencies when sample size is small (< 30) or number of observations in any one cell in the 2 x 2 table is < 5 – Fisher Exact test;
- Comparing paired count data (e.g., two measurements from the same subject) – McNemar test.

Tello R, Crewson PE (2003). Hypothesis testing II: means. Radiology 227(1): 1-4.

Applegate KE, Tello R, et al. (2003). Hypothesis testing III: counts and medians. Radiology 228(3): 603-608.

B. Research design, methodology

1. Cross-sectional studies: With this design, the investigator makes all measurements at one point in time. It is well suited to describing variables and their distribution patterns. Since all measurements are from one point in time, this design yields prevalence (defined as the proportion of a population who has a disease). A major strength of this design is that it is relatively fast and inexpensive. A major weakness is difficulty in establishing causation (since prevalence depends on both disease incidence and disease duration).

2. Case—control studies: This design is generally retrospective. Investigators identify a group of subjects with the disease (cases) and a group without the disease (controls), then look back to find differences in predictor variables (risk factors) between cases and controls. This design yields odds ratios (estimates of the strength of association between risk factors and the presence of disease) but cannot yield prevalence or incidence of a disease. A major strength of this design is its efficiency for studying rare diseases. A major weakness is this design's susceptibility to bias, especially sampling bias and differential measurement bias (i.e., because of retrospective data). Methods to help minimize sampling bias include using matching and using hospital-based controls or disease registries.

3. Cohort studies: This design involves investigators following subjects over time and can be prospective or retrospective. In the prospective variety, the investigator defines the sample cohort and measures predictor variables before outcomes have occurred. In the retrospective variety, the investigator identifies a cohort that has been defined in the past and collects data on predictor variables that have been measured in the past. Strengths of the cohort design include that it yields incidence (defined as the proportion of people who get a disease over a period of time), establishes the sequence of events (which is helpful in inferring causation), and can study several outcomes. A particular advantage of the prospective cohort design is that it allows for complete and accurate measurements of variables (note is made that the strength of this design is seriously undermined by incomplete follow-up of subjects). Weaknesses of the prospective cohort design include it being expensive and inefficient, especially as diseases being studied become less common. A particular strength of the retrospective cohort design is that it is generally less expensive to perform. The major weakness of the retrospective cohort design is that the existing data may be inaccurate or incomplete for the investigator's purposes.

4. Experimental studies (randomized controlled trials): In clinical trials, the investigator applies an intervention and evaluates the effect on outcome. Major advantages of a

trial over an observational study (e.g., case-control, cross-sectional, cohort) include ability to demonstrate causality, eliminate confounders, and minimize some biases. Random assignment of subjects helps eliminate confounding variables since these should be distributed equally (by chance) between groups. Blinding helps minimize treatment differences between groups as well as biased assessment of outcomes.

Hulley SB, Cummings SR, et al. (2001). Designing Clinical Research An Epidemiologic Approach. Philadeplhia, PA, Lippincott Williams & Wilkins.

5. Technology assessment: Technology assessment in healthcare has been defined as any process of examining and reporting properties of a medical technology used in healthcare, such as safety, efficacy, feasibility, and the indications for use, cost and cost effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended. This definition is broad and involves epidemiology, biostatistics, clinical decision-making, efficacy determination, outcome assessment, technical knowledge, financial management, productivity, and ethical and social impact. A 6-tiered hierarchical model of a continuum for efficacy has been developed which helps to relate efficacy to technology assessment and outcomes research:
    a. Level 1: Technical efficacy (e.g., image resolution, noise);
    b. Level 2: Diagnostic accuracy efficacy (e.g., sensitivity, specificity, area under the receiver-operating-characteristic (ROC) curve);
    c. Level 3: Diagnostic thinking efficacy (e.g., percentage of cases in which imaging is judged as helpful in making a diagnosis, difference in clinicians' estimated diagnostic probabilities with imaging vs. without imaging);
    d. Level 4: Therapeutic efficacy (e.g., percentage of times imaging is judged helpful in planning patient management, percentage of times when imaging results change management plans);
    e. Level 5: Patient outcome efficacy (e.g., percentage of patients that improve with the imaging compared to those without the imaging, value of imaging information in quality adjusted life years);
    f. Level 6: Societal efficacy (e.g., cost-effectiveness analysis of imaging from a societal perspective).

A key feature of this model is that for an imaging test to be efficacious at a higher level, it must be efficacious at lower levels. Effects on patient health and cost-effectiveness (Levels 5 and 6) typically require a randomized controlled trial (fraught with difficulty for imaging tests since outcomes are the end result of a multistep process in care, with variation at every step) or a decision analytic study.

Rettig RA (1991). Technology assessment—an update. Invest Radiol 26(2): 165-173.

Thornbury JR (1994). Eugene W. Caldwell Lecture. Clinical efficacy of diagnostic imaging: love it or leave it. AJR Am J Roentgenol 162(1): 1-8.

Fryback DG, Thornbury JR (1991). The efficacy of diagnostic imaging. Med Decis Making 11(2): 88-94.

Sunshine JH, Applegate KE (2004). Technology assessment for radiologists. Radiology 230(2): 309-314.

6. Meta-analysis: Systematic reviews are studies that review other published studies. As opposed to narrative (expert opinion) reviews, systematic reviews identify all relevant articles on the research topic in an attempt to provide an unbiased assessment of the quality of available research on a given topic. Once all relevant articles on a topic have been identified, exclusion criteria are often applied based on methodological quality. If a systematic review includes enough articles of adequate quality and similar methodology, results may be synthesized mathematically; this is

meta-analysis. Since meta-analyses are based on more data than are available in any one study, they are considered high level evidence. Statistical terms commonly used in meta-analysis relate to summary statistics:

- diagnostic odds ratio: the odds of a positive test result in patients with the disease compared with the odds of the same result in patients without the disease:

  diagnostic odds ratio = LR_p / LR_n

  (See **Bayes Theorem** above for definitions of positive [LR_p] and negative likelihood ratios [LR_n].)

- heterogeneity: variation in results between studies;
- reference test: the gold standard against which the index test is measured;
- summary ROC curve: combines several independent studies of the same diagnostic test to summarize test performance.

Halligan S, Altman DG (2007). Evidence-based practice in radiology: steps 3 and 4--appraise and apply systematic reviews and meta-analyses. Radiology 243(1): 13-27.

Jones CM, Athanasiou T (2009). Diagnostic accuracy meta-analysis: review of an important tool in radiological research and decision making. Br J Radiol 82(978): 441-446.

Moses LE, Shapiro D , et al. (1993). Combining independent studies of a diagnostic test into a summary ROC curve: data-analytic approaches and some additional considerations. Stat Med 12(14): 1293-1316.

Midgette AS, Stukel TA, et al. (1993). A meta-analytic method for summarizing diagnostic test performances: receiver-operating-characteristic-summary point estimates. Med Decis Making 13(3): 253-257.

7. Bias: There are many potential biases in research, most of which fall into one of three broad categories: selection bias, measurement bias, and confounding bias. Bias occurs when the groups of patients being studied differ in ways--other than the ones being studied--which affect outcome.
   - Selection bias occurs when comparisons are made between groups of subjects that differ in ways—other than the factors under study—that affect outcomes. Spectrum bias is a type of selection bias; it occurs when the sample is missing important subgroups. Verification bias occurs when patients with positive or negative test results are preferentially referred for the reference standard test—and then sensitivity and specificity are based only on those patients who underwent the reference test. Sampling bias occurs if some members of a population are more or less likely to be included than others. All types of selection bias may reduce the ability to generalize results to the rest of the population (i.e. external validity is compromised).
   - Measurement bias occurs when methods of measurement are dissimilar between groups of patients. Review bias is a type of measurement bias; it occurs when tests are performed or interpreted without proper blinding.
   - Confounding bias occurs when two factors are associated and the effect of one is distorted or confused by the effect of the other.
   - (also see **d. ii. Bias in screening** below for additional types of bias commonly associated with screening tests)

C. Comparative effectiveness research, evidence-based medicine (EBM)

1. Efficacy: The extent to which a specific technique or procedure produces the desired result under ideal conditions. A randomized clinical trial is generally considered the reference test (i.e., gold standard) for determining the efficacy of a therapy under highly controlled circumstances.

2. Effectiveness: A measure of the accuracy or success of a diagnostic (or therapeutic) technique when carried out in an average clinical environment. In "real world" settings, physicians and patients are much more variable and techniques and therapies are often less effective than demonstrated in clinical trials. Assessing effectiveness can sometimes be accomplished by studying secondary data.

3. Efficiency: The degree to which a process produces the desired effect with a minimum of waste, cost, and unnecessary effort. Efficiency adds an economic component to the evaluation of a technology.

4. Evidence based medicine: The integration of current best research evidence with clinical expertise and patient values.

D. Screening
   1. Criteria for determining utility of screening procedures:
      a. Population characteristics
         i. Sufficiently high prevalence of disease or condition
         ii. Likely to be compliant with subsequent tests and treatments
      b. Disease characteristics
         i. Significant morbidity and mortality
         ii. Effective and acceptable treatment available
         iii. Pre-symptomatic period detectable
         iv. Improved outcome from early treatment
      c. Test characteristics
         i. Good sensitivity and specificity
         ii. Low cost and risk
         iii. Confirmatory test available and practical

   Fletcher RF, Fletcher SW, et al. (1996). Clinical Epidemiology: The Essentials. Baltimore Williams & Wilkins.

   2. Bias in screening
      a. Screening bias: Also known as compliance bias; patients who volunteer for screening studies tend to be healthier and have better outcomes than those who do not volunteer, regardless of screening.

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

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

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

Fletcher RF, Fletcher SW, et al. (1996). Clinical Epidemiology: The Essentials. Baltimore Williams & Wilkins. Ch 8. Imaging Information

VI. Imaging Informatics

A. Work environment and facilities design

1. Ambient lighting & monitor luminance
   o Typical office lighting can reduce diagnostic efficacy (vs. lower levels of ambient lighting)
   o If no light other than that of the monitor is used, results are similar to those with excessive levels of lighting
   o With adequate window width and level, the primary diagnosis on chest radiographs is unlikely to be affected by low ambient light and monitor luminance

2. Most common workplace-related health complaints among radiologists:
   o Visual/eye strain (asthenopia)
     ▪ Related to computer video-type display, workstation design (screen resolution and contrast), image refresh rates, screen flicker and glare, working distances and angles, decreased blink rate, lighting in the viewing environment
     ▪ Symptoms include sensation of eye irritation, changes in vision (blurred or double vision), and associated symptoms such as headache
     ▪ Effects of eye strain among radiologists:
       ✓ May increase perceptual errors, performance errors
       ✓ May decrease reaction time
       ✓ May result in fatigue and burn out
     ▪ Simple strategies to improve eye strain:
       ✓ reviewing cases for less than seven hours per day
       ✓ taking short breaks at least once per hour
   o Musculoskeletal
     ▪ Carpal tunnel syndrome, cubital tunnel syndrome
       ✓ Carpal tunnel often associated with:
         o Dorsiflexion of the wrist (upward/positive tilt of keyboards at work stations)
         o Ulnar deviation of the wrist (can be achieved with ergonomically-designed split keyboards)

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- ✓ Cubital tunnel most often related to prolonged wrist flexion, as seen in cases of:
  - o Keyboard or mouse too high
  - o Handheld telephone receiver
  - o Handheld dictation microphone
  - o Ulnar nerve trauma due to unpadded or non-adjustable arm rests
- ▪ Neck & back strain/pain
  - ✓ Particularly among vascular and interventional radiologists with prolonged use of lead aprons
  - ✓ Adverse effects of bearing the weight of protective apparel worn to reduce radiation risk
  - ✓ Goal is to strive toward ultimate definition of ALARA (as close to zero radiation exposure) in the work environment, ultimately eliminating need for personal protective apparel and prevent its orthopedic and ergonomic consequences

http://www.ajronline.org/content/184/2/681.full

http://www.ajronline.org/content/181/1/37.full

http://radiology.rsna.org/content/250/2/538.full

http://radiology.rsna.org/content/232/3/762.full.pdf

http://www.ncbi.nlm.nih.gov/pubmed/17242225

B. Image data compression

Image data compression is a sophisticated method to reduce the amount of data used to record an image, using fewer bits than the original representation, while maintaining the diagnostic qualities of the image. Image compression utilizes mathematical techniques to reduce an image size on a pixel-by-pixel basis to 1) decrease storage requirements or 2) accelerate the transmission of images over teleradiology lines. Compression can be either lossy or lossless.

Lossless compression uses various algorithms to decreases statistical redundancy in order to display data without loss of information. This is possible because of the inherently repetitive nature of some digital information. GIF (Graphics Interchange Format) images are representative of a commonly used lossless technique. A limiting factor is that these techniques have some upper end limit on compression ratios, usually 3:1.

Lossy compression reduces bits by identifying marginally important information and removing it; it is irreversible but allows for much greater compression, 10:1 or higher ratios. This is the technique that most imaging compression methods utilize, including the JPEG (Joint Photographics Experts Group) form, a commonly used and inexpensive means for significant image data compression. JPEG image compression works by approximating or "rounding off" less important visual data and is commonly used in digital cameras, to increase storage ability with only minimal degradation of image quality. This was the first lossy encoding algorithm that was supported by the Digital Imaging and Communications in Medicine (DICOM). Other forms of lossy compression include JPEG variants, discrete cosine transform (DCT), vector quantization, wavelets, and fractals. Most studies have shown that lossy compression can be applied, up to a limit, without affecting the diagnostic content of images. One of most powerful video compression techniques is interframe compression, with earlier and later frames used to substitute for the present frame. However, highly compressed video may present visible or distracting artifacts.

Medical images that have been subjected to lossy compression must be labeled per the FDA, including the approximate compression ratio used, in order to allow the user to be knowledgeable about artifacts or image degradation that may occur with compression. Digitizing radiographs is an inherently lossy compression algorithm, yet is has been shown to be clinically useful and diagnostically relevant.

Image Data Compression, Goldberg, Journ Dig Imaging, vol 10, no 3, 1997, 9-11)

C. CAD
   What is CAD/CADe?
   - Computer Aided Detection (NOT computer aided diagnosis which can also be known as CAD or CADx);
   - Technology designed to decrease observational oversights (thus lowers false negative rates) of physicians interpreting medical images.

   What is its role in radiology?
   - Combines elements of pattern recognition software and radiological & digital image processing to aid in disease detection;
   - Typical applications are in mammography, in detection of colon polyps & lung cancer;
   - CAD is currently FDA approved for use with both film and digital mammography, both screening and diagnostic; as well as for chest radiographs and chest CT.

   Benefits of CADe
   - Adjunct tool to the human eye that is not vulnerable to fatigue, environmental distractions, or emotion;
   - Plays a supporting role and cannot substitute the radiologist who is legally responsible for the interpretation of a medical image.

   http://radiology.rsna.org/content/253/1/9
   http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1665219/
   http://www.appliedradiology.com/Issues/2011/10/Tech-Trends/Why-CAD-is-here-to-stay.aspx

D. DICOM, HL7
   What is DICOM?
   - Digital Imaging and Communications in Medicine

   What is its purpose?
   - Standard for handling, storing, printing and transmitting information in medical imaging
   - Enables integration of scanners, servers, work stations, printers and network hardware from multiple sites/manufacturers into a PACS (picture achieving and communication system)

   Benefits of DICOM
   - Promotes communication of digital image information regardless of manufacturer
   - Facilitates development and expansion of PACS that can interface with other systems of hospital information
   - Allows creation of diagnostic information databases that can be accessed by a wide variety of devices distributed geographically

   DICOM standards are set by the ACR & NEMA (National Electrical Manufacturers Association) and regulate

- Data storage
- Media display
- Security profiles
- Data encoding & exchange

http://www.acr.org/SecondaryMainMenuCategories/BusinessPracticeIssues/Teleradiology/TeleradiologyDICOMampRADIOLOGYDoc5.aspx
ftp://medical.nema.org/medical/dicom/2011/09v11dif/09v11_01.doc

E. PACS, teleradiology

PACS: Picture Archiving and Communications System is a medical imaging system that allows for transmission and/or storage/archiving of digital medical images. It eliminates the need to store hard copy films and to physically transport them from one place to another. Most modern imaging involves digital images that allow for PACS implementation. Some low resource settings or rural clinics may still utilize hard copy films.

The universal format for PACS is DICOM, the Digital Imaging and Communications in Medicine protocol. There are four major components: 1) the digital imaging modalities (radiographs, ultrasound, MRI, CT, etc.); 2) a secure network for transmission of patient data; 3) work stations for reviewing and manipulating images; and 4) archives for storing and retrieving images and patient reports. This allows for replacement of hard copy film and accessory supplies (developer and fixer), for viewing of studies at a remote distance from where they were acquired, for providing an electronic image integration platform (for interfacing with the RIS, HIS, and EMR systems), and for managing workflow of patients. It also provides for more fully integrated Quality Improvement activities with practice management software implementation. PACS are offered by the major medical device manufacturers, medical IT companies, and many independent software companies.

Teleradiology: Can be defined as the electronic transmission of radiological images from one location to another for the purposes of interpretation and/or consultation. The technology uses the Internet, telephone lines, wide area network (WAN), local area network (LAN), and more recently, even the "computer cloud," for transmission from one location to another. According to the ACR, the goals of teleradiology include: providing consultative and interpretative radiological services in areas of demonstrated need; making services of radiologists available in medical facilities without on-site radiologist support; providing timely availability of radiological images and radiological image interpretation in emergency and non-emergency clinical care areas; facilitating radiological interpretation in on-call situations; providing subspecialty radiological support as needed; enhancing educational opportunities for practicing radiologists; promoting efficiency and quality improvement; and sending interpreted images to referring providers.

The personnel involved include physicians, technologists, physicists, engineers and/or communication or image systems specialists. The equipment guidelines cover two basic categories of teleradiology systems: small and large matrix sizes. Small matrix (lower resolution) systems include computed tomography (CT), magnetic resonance imaging (MRI), ultrasound, nuclear medicine and digital fluorography. According to the ACR standard the small matrix digitization (acquisition) systems should produce 500 pixel x 500 pixel x 8 bit images or better, and the small matrix display systems should produce a 500 x 480 x 8 bit display or better. Large matrix systems include digitized radiographic films and computed radiography. For these, the digitization systems should produce 2000 x 2000 x 12 bit images or better, and the display systems should produce a 2000 x 2000 x 8 bit display or better.

The ACR standard requires that both small and large matrix systems include a capability for image sequence selection for transmission and display, annotation capabilities at the

transmitting station, including patient data and brief patient history, provision for interactive windowing at the transmitting site and provision for compression (for improved transmission rates and reduced archiving/storage requirements). For the transmission of images and patient data, the ACR standard requires that new technology systems should include the ACR/NEMA data format standard and the DICOM network standard. For the display, the ACR requires that the luminance of the grey scale monitors should be at least 50 foot-lamberts (170 cd/m2). For large-matrix displays, the ACR requires interactive windowing, magnification, inversion and rotation functions, and the capability of making accurate linear measurements. For small matrix systems, the ACR requires accurate reproduction of the original study. The availability of a patient database and of software security protocols is also required.

The ACR Standard for Teleradiology: www.acr.org

F. Structured reporting, data mining, RADLEX and lexicons
    The term "structured report" may have different meanings to different people. However, it generally refers at minimum to a report that is organized into subsections and formatted in a standardized manner. Major components or headings may include demographic information, name of the examination, patient history and/or indication for the examination, comparison studies, technique of the examination and/or procedure performed by the physician, findings, and an impression. In addition, the findings section may be subdivided into anatomic regions, organs, or organ systems as appropriate to the type of examination.

    In addition to the structuring of the report, when available, a standardized lexicon may be used to describe and classify findings. Some would consider this to be a key element of a "structured report." There is an increasing number of such lexicons available, although many are limited to specific examinations or organ systems.

    One of the oldest and perhaps best known lexicons is the American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI-RADS®) Atlas. This lexicon was initially developed for mammography through a collaborative effort of the ACR with the National Cancer Institute, the Centers for Disease Control and Prevention, the Food and Drug Administration, the American Medical Association, the American College of Surgeons, and the College of American Pathologists. While some radiologists may only be aware of the BI-RADS® assessment categories that are required in all mammography reports, BI-RADS® also includes standard terminology to describe mammographic findings. Use of these descriptors may assist the radiologist in assigning the proper assessment category for the examination.

    Based on the success of the BI-RADS® Mammography system, the ACR subsequently developed BI-RADS® for Breast Ultrasound and Breast MRI. This concept has also been adapted to liver imaging in assessment for possible hepatocellular carcinoma with a lexicon known as the Liver Imaging Reporting and Data System (LI-RADS). LI-RADS also uses a defined lexicon leading to assessment categories that indicate the likelihood of hepatocellular carcinoma. This concept may be expanded to other organ systems in the future.

    Recognizing the need for a more generalized lexicon to report imaging findings across multiple modalities and organ systems, the Radiological Society of North America (RSNA) has developed RadLex, which is described as "a single unified source of radiology terms." This initiative began in 2005, and by the end of 2011 it included over 30,000 terms. RSNA has also established a "Reporting Initiative." Its goal is to "create an online library of best-practices radiology report templates for key clinical scenarios." This resource would be

"based on standard terminology, including RadLex," and could be "adapted by radiology practices based on local practice patterns."

There are many potential benefits to the use of a structured report and a standardized lexicon. These include standardization of reports among radiologists in a single group and potentially across groups, which could improve satisfaction of referring clinicians and better understanding of radiology reports. Radiologists may be less likely to overlook findings if the structure of the report improves their search pattern and the completeness of their reports. Data mining for quality monitoring or research purposes may be facilitated by more rigid structuring of the report and by the use of standardized terminology. Accurate billing may be facilitated by standardized descriptions of examination details and easier searching for that information. A structured report may also interface well with a speech recognition system and potentially improve radiologist productivity.

References:

Sistrom CL, Langlotz CP. A Framework for Improving Radiology Reporting. J Am Coll Radiol 2005; 2:159-167.

Dunnick LR, Langlotz CP. The Radiology Report of the Future: A Summary of the 2007 Intersociety Conference. J Am Coll Radiol 2008; 5:626-629.

ACR BI-RADS® Atlas. Available online at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/BIRADSAtlas.aspx. *Accessed 12-12-11.*

RSNA RadLex. Available online at: http://radlex.org/. *Accessed 12-12-11.*

RSNA Reporting Initiative. Available o line at: http://www.rsna.org/informatics/radreports.cfm. *Accessed 12-12-11.*