ABR | AMERICAN BOARD OF RADIOLOGY

Radiation Oncology

NON-CLINICAL SKILLS DOMAIN: A SYLLABUS

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Contents

Introduction

Within the past two decades, a significant body of academic and practical material has been published to educate and guide providers regarding non-clinical skills. The ABR believes that significant guidance for examination preparation should be provided to diplomates, as these topics are included within the MOC cognitive examination. This syllabus also has been **developed to** provide material that the Board feels is critical to the day-to-day practice of radiation oncology.

Part I: Patient Safety

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 number of projected deaths exceeded those from motor vehicle accidents, breast cancer, or AIDS.

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

- Establishing a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety; recommending that Congress create a Center for Patient Safety, funded with $100 million annually.
- Identifying and learning from errors by developing a nationwide, public, mandatory reporting system and by encouraging healthcare organizations and practitioners to develop and

participate in voluntary reporting systems; recommending that Congress enact laws to protect confidentiality of information from litigation.

- Raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of healthcare.
- Implementing safety systems in healthcare organizations to ensure safe practices at the delivery level.

The report resulted in Congressional hearings and the appropriation in 2000 of $50 million to fund the Agency for Healthcare Research and Quality (AHRQ). They contracted with the National Quality Forum (NQF) to create a list of "never events" for states to use as a basis of a mandatory reporting system. These easily preventable events are of sufficient importance that they should never occur in a properly functioning healthcare environment. The Leapfrog Group, an association of private and public-sector group purchasers, has also initiated a market-based strategy to improve safety.

http://www.iom.edu/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx - Accessed 6.17.2014.

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

In 2002, The Joint Commission (TJC) (formerly the Joint Commission on Accreditation of Hospitals /JCAH) 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. TJC also created a "do not use" list of abbreviations in 2004 to avoid acronyms and symbols that lead to misinterpretation.

The NPSGs 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. TJC then determines the highest priority patient safety issues and how best to address them. The NPSGs for each program and more information are available on the TJC website.

http://www.jointcommission.org/assets/1/6/2015_NPSG_AHC1.PDF - Accessed 7/7/2015.

Key NPSGs most applicable to radiation oncology practices (hospital and ambulatory) include:

- Use at least two patient identifiers when providing care, treatment, and services (NPSG.01.01.01).
- 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).
- 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).

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:

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.

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.

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.

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.

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.

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.

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.

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

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

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.

Communication

Communication plays a role in achieving patient safety, removing barriers that affect patient-practitioner interactions, and disclosing 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 and improved transitions of care-specific strategies.

Culture of Safety

A culture of safety includes beliefs, attitudes, and values about work, risk, and safety—mainly the distinction between errors resulting from deliberate unsafe acts and errors that are a result of system failures.

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 determination to achieve consistently safe operations
- Blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment
- Encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems
- Organizational commitment of resources to address safety concerns

Improving the culture of safety within healthcare is an essential component of preventing or reducing errors and improving overall healthcare quality. Studies have documented considerable variation in perceptions of safety culture across organizations and job descriptions. In prior surveys, nurses have consistently complained about 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 an underdeveloped healthcare safety culture are complex, with poor teamwork and communication, a "culture of low expectations," and authority gradients all playing a role.

Measuring and Achieving a Culture of Safety

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

Safety culture has been defined and can be measured, and perceived poor safety culture has been linked to increased error rates. However, achieving sustained improvements in safety culture can be difficult. Specific measures, such as teamwork 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 (Situation, Background, Assessment and Recommendation), 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 determinants of safety culture depend on interprofessional relationships and other local circumstances, and thus change in safety culture occurs at a micro-system level. Some organizational behavior experts therefore believe that safety culture improvement needs to emphasize incremental changes to providers' everyday behaviors, "growing new [safety] culture that can be layered onto the old."

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

http://www.jointcommission.org/sentinel_event.aspx - Accessed 6/17/2014

Root Cause Analysis

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

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

As an example, a classic paper described a patient who underwent a cardiac procedure intended for another patient with a similar name. 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.”

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.

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 had 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.

Time-out

The Joint Commission has developed a Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™. This protocol includes the concept of a "time-out," which includes verification of the correct patient identity, the correct site of the procedure or treatment, and the procedure to be performed. A time-out should be conducted immediately before starting a procedure. Marking the treatment 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 should be marked by a licensed independent practitioner who is ultimately accountable for the procedure and will be present when the procedure is performed.

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, "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.

The Joint Commission National Patient Safety Goals Effective January 1, 2014 – Hospital Accreditation Program
http://www.jointcommission.org/standards_information/npsgs.aspx - Accessed 9/26/2014

Agency for Healthcare Research and Quality (AHRQ). Patient Safety Primers – Medication Reconciliation. Available at:
http://psnet.ahrq.gov/primer.aspx?primerID=1 - Accessed 6/17/2014

Patient Safety in the Practice of Radiation Oncology

In 2012, the American Society for Radiation Oncology (ASTRO) convened a panel of representatives of the principal radiation oncology stakeholder organizations to consider issues specifically related to the processes and procedures in the practice of radiation oncology. This document will be updated as appropriate. Chapter 3 (Pages 19-26) of the document is focused exclusively on safety in radiation oncology, and this link to that document has been provided with the permission of ASTRO:

https://www.astro.org/Clinical-Practice/Patient-Safety/Safety-Book/Safety-Is-No-Accident.aspx - Accessed 9/3/2015

Part II: Quality Assurance and Improvement

Traditional Definitions of Quality in Healthcare

Quality improvement (QI) is a more recent phenomenon in healthcare, but many are familiar with the term quality assurance (QA) as it was previously a common term. QA can be considered reactive, generally retrospective, occasionally involving policing, and in many ways interpreted as punitive or finger pointing. It often involves determining who was at fault after a medical error. The term QA is older and less frequently used today.

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."

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).

Limitations of Traditional QI Techniques in Healthcare

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. The traditional approach tends to focus on physician performance and to underemphasize the contributions of non-physicians and organizational processes, and as such, it 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.

Application of Industrial Quality Management Science to Healthcare

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 were not met.

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.

The New Paradigmatic Approach to Quality Science

Redefined quality in healthcare is a 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.

- Measuring quality: recognition and analysis of variation is fundamental to thinking of quality measurement.
- 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.
- Personnel management: centered on the treatment of employees and professionals as valuable resources.

Six Institute of Medicine (IOM) Quality Aims

Care that is:

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

Six Core Competencies of Maintenance of Certification (MOC)

- **Practice-based Learning and Improvement**: Show an ability to investigate and evaluate patient care practices, appraise and assimilate scientific evidence, and improve the practice of medicine.
- **Patient Care and Procedural Skills**: Provide care that is compassionate, appropriate, and effective treatment for health problems and to promote health.
- **Systems-based Practice**: Demonstrate awareness of and responsibility to the larger context and systems of healthcare. Be able to call on system resources to provide optimal care (e.g., coordinating care across sites or serving as the primary case manager when care involves multiple specialties, professions, or sites).
- **Medical Knowledge**: Demonstrate knowledge about established and evolving biomedical, clinical, and cognate sciences and their application in patient care.

- **Interpersonal and Communication Skills**: Demonstrate skills that result in effective information exchange and teaming with patients, their families, and professional associates (e.g., fostering a therapeutic relationship that is ethically sound and uses effective listening skills with nonverbal and verbal communication, working as both a team member and at times as a leader).
- **Professionalism**: Demonstrate a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to diverse patient populations.

Best Practices

Since unnecessary variation causes poor quality, developing consensus about best practices is justified. They should be updated regularly, and they should be distinguished from mandatory adherence to static guidelines/standards.

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 - Accessed 6/17/2014

Benchmarking

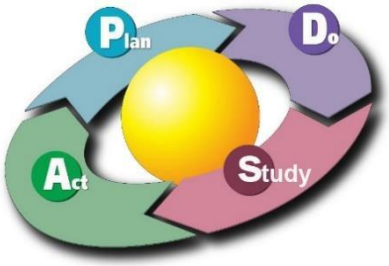
"A measurement of the quality of an organization's policies, products, programs, strategies, etc., and their comparison with standard measurements or similar measurements of its peers. The objectives of benchmarking are (1) to determine what and where improvements are called for, (2) to analyze how other organizations achieve their high performance levels, and (3) to use this information to improve performance."

http://www.businessdictionary.com/definition/benchmarking.html - Accessed 6/17/2014

Methodologies

PDSA Cycle

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.



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 PDSA 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 PDSA 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 1:

- Area of Interest (Topic): Verification of patient identification
- Quality Question: In my practice, in what percentage of daily external beam radiation treatments was an independent verification of patient identification performed?
- Measurement To Be Taken: Number of individual external beam radiation treatments in which independent patient identification verification occurred/total number of daily treatments procedures x 100%.
- Desired Target Level (Goal) of Performance: Independent patient identification verification before beginning a treatment session in 100 percent of cases.
- Baseline Measurement Prediction: Upon initial measurement, I believe that the measure will show independent patient identification verification before beginning of external beam radiation treatments in 70 percent of cases.

Example 2:

- Area of Interest (Topic): Acute urinary retention following prostate brachytherapy

- Quality Question: In my practice, in what percentage of prostate brachytherapy patients did urinary retention occur over the first post-implant month?
- Measurement To Be Taken: Number of prostate brachytherapy cases in which acute retention occurred/total number of prostate brachytherapy procedures x 100%.
- Desired Target Level (Goal) of Performance: A rate of acute urinary retention below 10 percent of cases, a number derived from the literature of rates at centers of excellence.
- Baseline Measurement Prediction: Upon initial measurement, I believe that the measure will show acute urinary retention in 20 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. In the case of Example 1, it might be to mandate a hard stop before each treatment that includes an identity check. In the case of Example 2, it could be to be in some way more selective in cases chosen for brachytherapy, to use alpha-blocking medication post-implant, or to limit the number of passes for each needle to reduce trauma and edema. The action will depend upon the root cause analysis.

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.

Target Identification

The process of QI requires choosing a part of the radiation oncologist'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 radiation oncology organization doing the project. Target identification involves two steps:

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

Key Performance Indicators

Key performance indicators (KPIs) are measures that are selected to evaluate organizational success; they can be quality measures, financial measures, or both. An ideal KPI would be something amenable to reproducible measurement and re-measurement. KPIs for radiation oncology are not universal; each facility must establish its own—but typically they will include measures of patient safety and quality of care, customer service, appropriateness of utilization, and measures of productivity and financial performance (e.g., analysis of revenue and expenses, variance from budget, etc.). Ideally, the choice of KPIs should reflect what is important to the facility and be in line with the facility's stated vision and mission.

In an academic center, KPIs might also be established related to research and teaching, such as number of publications in peer-reviewed journals, possibly weighted by the journal impact factor, the relative rank of authors, the amount and sources of research funding received, and patents generated. With regard to clinical service, the external communication turnaround time is an occasionally used KPI, as are patient satisfaction scores from Press-Gainey or similar surveys. KPIs are commonly reported by means of colorful organizational "dashboards," i.e., graphic visual representations of each of the relevant measures typically generated and made available electronically. When measurements are frequent and the data are made accessible and easily grasped (as with a well-designed "dashboard"), the KPIs may be the best tool to assess the overall "health" of the organization and determine whether interventions are actually improving organizational performance.

Quality Improvement Tools

QI tools are established techniques/instruments used to improve a structure, process, and/or outcome measure. Among the many tools available are several familiar to radiation oncologists:

1. Flowcharts
2. Checklists
3. Cause and Effect Diagrams
4. Trend Charts
5. Brainstorming
6. Voice of the Patient Exercises
7. Walkthroughs/rounding

Quality Assurance and Quality Improvement in the Practice of Radiation Oncology

The delivery of therapeutic doses of radiation to normal and malignant tissues carries with it significant risks. The nature and potential impact of these risks is such that quality of care must be part of the daily culture of practice, not simply a theoretical backward- or forward-looking exercise. Every member of the radiation oncology treatment team must be aware of the risks and methods to reduce or hopefully eliminate these risks. Academic publications related to QA and QI rarely review potential problems or develop strategies for improvement specific to the practice of radiation oncology.

In 2012, the American Society for Radiation Oncology (ASTRO) convened a panel of individuals representing all segments of the profession, including academic and private practice radiation oncologists, medical physicists, and practice administrators, to develop a document that could serve as a resource for the profession. That document, Safety Is No Accident, has a section specifically devoted to QA/QI (pp. 29-45). Because of copyright restrictions, provision of that text is not possible, but with the permission of ASTRO, the link below is provided.

https://www.astro.org/Clinical-Practice/Patient-Safety/Safety-Book/Safety-Is-No-Accident.aspx

ASTRO has also produced a number of publications devoted to professional peer review and QA/QI topics specifically related to the practice of high-dose-rate brachytherapy (HDR), image-guided radiation therapy (IGRT), intensity-modulated radiation therapy (IMRT), and stereotactic radiosurgery/stereotactic body radiation therapy (SRS/SBRT). These publications are also felt to be critical resources, and links to them are also available with the permission of ASTRO.

http://www.practicalradonc.org/article/S1879-8500(12)00207-X/fulltext - Peer Review
http://www.practicalradonc.org/article/S1879-8500(13)00419-0/fulltext - HDR
http://www.practicalradonc.org/article/S1879-8500(13)00007-6/fulltext - IGRT
http://www.practicalradonc.org/article/S1879-8500(11)00162-7/fulltext - IMRT
http://www.practicalradonc.org/article/S1879-8500(11)00216-5/fulltext - SRS/SBRT

Part III: Professionalism and Ethics

The American Board of Radiology believes that issues related to medical professionalism, professional ethics, and professional liability are inextricably linked, and that belief is demonstrated by linkage of the topics in this section. As noted in citations provided, some of the materials included relate to all healthcare professionals and others have been developed by teams of radiology, radiation oncology, and medical physics professionals for the American College of Radiology (ACR). In some instances, text has been altered to expand inclusion to physicians in general or radiation oncologists, specifically.

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 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.

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.

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. The "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.

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Code of Ethics as Promulgated by the American College of Radiology (ACR)

The ACR Code of Ethics is embedded within the ACR Bylaws as Article XI. Its stated purpose is "to aid the radiology community, individually and collectively, in maintaining a high level of ethical conduct." The Code is intended as "a framework by which radiologists, radiation oncologists, and medical physicists may determine the propriety of conduct in their relationship with patients, with the public, with colleagues, and with members of allied professions."

The major components of the Code of Ethics are the Principles of Ethics and the Rules of Ethics (excerpted below). The Code of Ethics represents a standard of ethical and professional behavior that reflects expectations of the broader medical profession and the public, and as such it should be followed by all radiologists: diagnostic, interventional, and therapeutic.

ACR Principles of Ethics

The principal objective of the medical profession is to render service to people with full respect for human dignity and in the best interest of the patient. Members should merit the confidence of patients entrusted to their care, rendering to each a full measure of service and commitment.

Physicians should strive continually to improve their medical knowledge and skill and make these improvements available to their patients and colleagues. Members should at all times be aware of their limitations and be willing to seek consultations in clinical situations where appropriate. These limitations should be appropriately disclosed to patients and referring physicians.

The medical profession should safeguard the public and itself against physicians deficient in moral character or professional competence by reporting, to the appropriate body, without hesitation, perceived illegal or unethical conduct of members of the medical profession. Members should uphold all

laws, uphold the dignity and honor of the medical profession and accept its self-imposed discipline, and deal honestly and fairly with patients and colleagues.

The honored ideals of the medical profession imply that responsibilities of members extend to society in general as well as their patients. These responsibilities include the interest and participation of members in activities that improve the health and well-being of the individual and the community.

Physicians may not reveal confidences entrusted to them in the course of medical attendance, or deficiencies they may observe in the character of patients, unless they are required to do so by law, or unless it becomes necessary to protect the welfare of the individual or the community.

The decision to render a service by a radiation oncologist or medical physicist is a matter of individual physician and patient choice governed by the best interest of the patient.

The traditional bond among radiation oncologists and medical physicists, particularly in their professional relationships with each other, is a powerful aid in the service of patients and should not be used for personal advantage.

ACR Rules of Ethics (revised for broader inclusivity)

The practice of physicians referring patients to healthcare facilities in which they have a financial interest is not in the best interest of patients. Self-referral may improperly influence the professional judgments of those physicians referring patients to such facilities. Physicians with ownership interests participating in such arrangements may be in violation of these professional ethics, depending on a variety of circumstances.

Physicians should relate to other members of the healthcare team with mutual respect and refrain from harassment or unfair discriminatory behavior.

Physicians should have the right to enter into whatever lawful contractual arrangements with healthcare systems they deem desirable and necessary, but they should seek to ensure that the system of healthcare delivery in which they practice does not unduly influence the selection and performance of appropriate available imaging studies or therapeutic procedures.

Physicians should not enter into an agreement that prohibits the provision of medically necessary care or that requires care at below acceptable standards. Notwithstanding policies of a health plan, radiation oncologists should advocate cost-effective appropriate studies or therapies that will benefit the patient, whose welfare is paramount.

Physicians should clearly and adequately respond to inquiries by patients regarding fees and/or any financial incentive. A radiation oncologist should not participate in a billing arrangement that misleads patients or third party payers concerning the fees charged. Radiation oncologists shall not divide their fees either directly or by any subterfuge.

In providing expert medical testimony, physicians should exercise extreme caution to ensure that the testimony provided is non-partisan, scientifically correct, and clinically accurate. The radiation oncologist should not accept compensation that is contingent upon the outcome of litigation.

Radiation research must be performed with integrity and be honestly reported. Members should not claim as their intellectual property that which is not theirs. Plagiarism or the use of others' work without attribution is unethical.

Physicians should not publicize themselves through any medium or forum of public communication in an untruthful, misleading, or deceptive manner or in a fashion demeaning to the profession.

http://www.acr.org/~/media/ACR/Documents/PDF/Membership/Governance/2014_2015%20Code%20of%20Ethics.pdf – Accessed 8/16/2014

Professional Ethics and Research: the Belmont Report

On April 18, 1979, the Office of the Secretary of the U.S. Department of Health, Education and Welfare (DHEW), subsequently reconfigured as the U.S. Department of Health and Human Services (DHHS), released a report entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, prepared for the Department by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. As a work product of meetings carried out at the Belmont Conference Center, a unit of the Smithsonian Institution at the time, the report has subsequently been referred to as the Belmont Report. Originally promulgated as guidelines for ethical principles involved in the protection of human research subjects, the report, which remains federal government policy, has generally been adopted to include the broader population of providers and patients, including those not directly involved in clinical research. The report is felt to be of such significance that it is reproduced below in its entirety.

THE BELMONT REPORT

SUMMARY

On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: **(i)** the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, **(ii)** the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, **(iii)** appropriate guidelines for the selection of human subjects for participation in such research and **(iv)** the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in

fulfilling this part of its charge, is available as DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. The Department requests public comment on this recommendation.

Ethical Principles & Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

A. Boundaries Between Practice and Research

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term "research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable

knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

B. Basic Ethical Principles

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

1. **Respect for Persons. --** Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

   An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

   However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

   Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The

extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. **Beneficence. --** Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

   The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

   The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

   The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children -- even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be

dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. **Justice. --** Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are:

   (1) to each person an equal share,
   (2) to each person according to individual need,
   (3) to each person according to individual effort,
   (4) to each person according to societal contribution, and
   (5) to each person according to merit.

   Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

   Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and

that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

C. Applications

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. **Informed Consent. --** Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

   While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

   Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

   However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

   A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that:

   1) incomplete disclosure is truly necessary to accomplish the goals of the research
   2) there are no undisclosed risks to subjects that are more than minimal

3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them

Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension. The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited -- for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disable patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a

subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitle.

2. **Assessment of Risks and Benefits. --** The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

   The Nature and Scope of Risks and Benefits. The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

   The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Unlike, "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

   Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

   The Systematic Assessment of Risks and Benefits. It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will

quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, non-arbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations:

1) Brutal or inhumane treatment of human subjects is never morally justified.
2) Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures.
3) When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject -- or, in some rare cases, to the manifest voluntariness of the participation).
4) When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits.
5) Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

3. **Selection of Subjects. --** Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

1) Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.
2) Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.
3) Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the

Commission believes that the problem ought to be addressed by one of its successor bodies.

Belmont Report. Available at: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html - Accessed 7/12/2015

Informed Consent

Informed consent is required for radiation oncology diagnostic-related or therapeutic 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 physician even when local policy does not require the physician to initiate an informed consent process.

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 any 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."

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

Institutional Review Boards (IRB)

Under FDA regulations, an Institutional Review Board (IRB) is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to

secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

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

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

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

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

http://www.fda.gov/regulatoryinformation/guidances/ucm126420.htm - Accessed 9/20/2014

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The **Health Insurance Portability and Accountability Act of 1996** (**HIPAA**; Pub.L. 104–191, 110 Stat. 1996, was enacted by the United States Congress and signed by President Bill Clinton in 1996. It has been known as the Kennedy-Kassebaum Act or Kassebaum-Kennedy Act after two of its leading sponsors. Title I of HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs. Title II of HIPAA, known as the Administrative Simplification (AS) provisions, requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. Title II also includes Privacy Rules (2.1) and Security Rules (2.3) that have been widely adopted.

HIPAA Privacy Rule

The HIPAA Privacy Rule represents a set of national standards whose 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 healthcare. The rules address use and disclosure of individually identifiable health information (protected health information, PHI). Information that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual is protected. Individually identifiable health information includes many common identifiers (e.g., name, address, birthdate, Social Security number). The rule applies to health plans, healthcare clearinghouses, and healthcare providers that transmit health information in electronic format.

Situations in which identifiable data can be transmitted without individual authorization include but are not limited to: to the individual at his or her request, in the course of treatment, for payment activities and to healthcare operations involving quality or competency assurance, fraud or abuse detection, or compliance activities. In addition, when required by law, information can be released to public health authorities; during investigation of abuse, neglect, or domestic violence; to oversight agencies; for judicial and administrative proceedings; for law enforcement purposes; and for worker's compensation.

http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf - Accessed 6/17/2014

HIPAA Law. Available at: *http://www.gpo.gov/fdsys/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf* - Accessed 7/24/2015

HIPAA Security Rule

The HIPAA Security Rule establishes national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity. The Security Rule requires appropriate administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information.

The Security Rule is located at 45 CFR Part 160 and Subparts A and C of Part 164.

http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/ - Accessed 7/13/2015

Professional Liability

The Elements of Medical Malpractice: An Overview

Physicians sometimes fail to meet their patients' expectations. A suit for medical malpractice can follow whenever the level of patient dissatisfaction leads individuals to seek a legal remedy.

Most physicians will be involved in a medical malpractice case sometime in their careers in one of several capacities; for example, as a defendant, a treating physician, or an expert witness. Proving that malpractice has been committed is based on substantiation of a variety of elements and issues.

The basic theories or types of claims of malpractice are:

1) Lack of due care
2) Lack of informed consent/battery
3) Vicarious liability/respondeat superior/negligent supervision
4) Injury to third parties
5) Abandonment

While these elements hold true in general, the laws of malpractice, the procedures involved, and the judicial process vary from state to state and from country to country. Claims of medical malpractice are an important part of general patient dissatisfaction with modern healthcare. According to surveys, only 1 in 30 calls of inquiry to legal firms about malpractice actually results in the filing of a suit. Patients file malpractice lawsuits because of a variety of factors, including poor relationships with their doctors that antedate the alleged malpractice, medical advice to seek a legal remedy, and media advertising. If ~1 percent of hospitalizations result in adverse events because of potential physician negligence and that figure is extrapolated to the ~33.5 million hospitalizations that occur in the United States annually, then each year there are ~340,000 potential cases of malpractice arising from care in hospitals. In a study of 30,195 randomly selected hospital charts, it was found that 3.7 percent of patients had injuries and that negligent care was responsible for 285 of these injuries. Approximately 50 percent resulted from operations and included wound infections, which accounted for one of seven adverse events.

Complications related to treatment with drugs accounted for 19 percent of adverse events. The most frequent drug-related adverse events were associated with the use of antibiotics, which accounted for 16 percent of all adverse drug reactions. Drug-related adverse events were more common in elderly patients (> 65 years) than in any other age group, while the 45- to 64-year-old age group accounted for the most wound infections. It was not noted whether the antimicrobial-related adverse events were the result of the practices of generalists or specialists or a combination of the two. Consequently, during their professional career, most physicians will have some experience with a malpractice lawsuit, either as the defendant or as one of several named defendants. Others will be involved as a treating physician or as an expert witness. Regardless of the circumstances surrounding a lawsuit, it is helpful to be able to put malpractice claims in context and to understand the elements of malpractice.

Medical malpractice cases, although often grouped under the one heading of "medical malpractice" or "medical negligence," actually comprise several distinct areas of potential liability for medical professionals.

Lack of Due Care

Lack of due care is the most common stated cause for the filing of a malpractice lawsuit. This term is what most people would initially associate with the phrase "medical malpractice" and connotes a lack of proper medical care or improper medical treatment of a patient. To prevail on this type of malpractice claim, the patient must establish at least three elements:

1) *The existence of a patient-physician relationship.* This means that the physician has formally consulted about, treated, or given advice to a patient, no matter how superficially or briefly. Informal "curbside" hypothetical consultations generally do not rise to the level of a patient-physician relationship. It is the existence of this relationship that creates the duty on the part of the physician to treat the patient and to treat him or her properly. To withdraw from a patient's care, a physician must give adequate notice to the patient, allowing him or her time (no specific time is defined, and this is decided on a case- by-case basis) to find other care.

2) *The violation of the "standard of care."* The plaintiff/patient must establish that the care he or she was given was inadequate in comparison with that provided by the majority or a respectable minority of physicians practicing under similar circumstances. This means that generalists and

specialists are held to different standards unless a generalist attempts to treat a specialized problem that would ordinarily call for a referral. In that case, the generalist will be held to the standard of the specialist. Similarly, circumstances may vary as to rural versus urban environments, although such geographical distinctions are generally disappearing.

3) *The failure to meet "the standard of care" was a substantial factor in causing the damage.* This is the basic rule of "no harm, no foul." The patient must be able to prove that actual damage did occur, although in some situations, the patient will be assisted by the doctrine of res ipsa loquitur, which essentially provides that certain results do not occur in the absence of negligence. Although physicians are generally required to exercise the degree of care ordinarily possessed by fellow practitioners ("peers") under similar circumstances, there are numerous factual situations in which this basic rule can be applied, and the analysis must be adapted for each situation. For example, the non-specialist may be held liable for medical malpractice for failing to call in a specialist. The non-specialist could be held liable if it were proven to a judge or jury that a majority of non-specialists under the same circumstances would normally have called in a specialist. This rule applies to the ordering of diagnostic tests, the interpretation of test results, the institution of therapy, or the withholding of therapy. In addition, one must still prove causation for this element to be of significance. Proof of the standard of care, i.e., proof of what a reasonable doctor would or would not have done under given circumstances, in most instances must be established by the "expert testimony" of another physician. Many physicians assume that there are general, concrete guidelines generated from textbooks, published peer-reviewed articles, or local customs for establishing, guiding, and evaluating their actions against "the standard." However, although such sources may be used in court, the standard is generally established by expert witness testimony as subjectively interpreted by the judge or jury. Sometimes, verisimilitude can be a matter of the expert's credentials, the attorney's presentation of the credentials of the expert witness, or how well the expert withstands cross-examination. Ultimately, it is the believability of the particular expert's testimony by the jury, rather than any absolute medical doctrine, that usually determines the specifics of standard of care in any particular case. One would hope that the physician who chooses to become an expert witness would impartially review the case records, give advice to the attorney who has solicited the testimony on the basis of reasonable care guidelines, and not be influenced by the attorney's strategy. Unfortunately, this is often not the case. Again, there are circumstances where the proof of damage does not require expert testimony. In instances where the negligence would be obvious, even to a layperson, such as that of a surgeon who cuts off the wrong leg, then there need not be expert testimony to establish this element. The doctrine of res ipsa loquitur, referred to above, would apply.

Informed Consent

Although usually included under the same heading of medical malpractice, the issue of "informed consent" usually arises apart from, or parallel with, issues of lack of due care. Except in very limited cases, failure to provide patients with sufficient information regarding their treatment to enable them to make an informed decision constitutes lack of informed consent. As noted below, a claim for more aggravated misconduct known as battery can also arise when there was no consent whatsoever to a particular procedure or treatment of a portion of the body.

The Negligence Issue

Informing a patient about treatment options, including the option of no treatment, and the likely ramifications of each particular treatment is considered by the law to be an integral part of the physician's overall obligation to the patient. In other words, the physician has a duty to make a reasonable disclosure of available choices with respect to a proposed treatment option and of the significant or common dangers potentially involved with each choice. Failing to provide such disclosure creates a basis for a claim of lack of informed consent. To prevail in such a case, the patient must show

1) that the physician failed to provide the patient with adequate information to enable him or her to make an intelligent choice regarding the course of treatment, and
2) that a reasonable patient would not have consented to a given course of treatment or procedure, had the appropriate and pertinent information been disclosed.

The significance or material nature of the information is generally not the subject of expert testimony. Rather, the judge or jury is asked to determine for themselves whether or not a reasonable patient would have consented to or refused a given treatment or procedure if the omitted information had, in fact, been provided. Such information may be transmitted in writing or verbally, or it may even be implied in limited circumstances. In emergency situations, consent to treatment is usually presumed by law. Verbal informed consent is inferior from the physician's perspective because recollection of the exact discussion of consent by the plaintiff and the defendant often varies. Yet, written informed consent alone may not be sufficient and is merely a way of showing that the patient has been advised of certain risks. A blanket informed consent that a patient may sign on admission to the hospital will frequently not cover an individual situation, which must be specifically addressed by the physician. The infectious diseases specialist must consider various ramifications and situations. For example, what does one need to tell a patient about the potential nephrotoxicity or ototoxicity related to the use of aminoglycosides or about the use of a cephalosporin antimicrobial agent when the patient is allergic to penicillin? In some situations, it is preferable that the patient signs a form acknowledging such risks. The courts have recognized that clinicians could not reasonably be expected to fully disclose every possible risk. The California Supreme Court articulately expressed this rationale as follows: "The patient's interest in information does not extend to a lengthy, polysyllabic disclosure on all possible complications. A mini-course in medical service is not required; the patient is concerned with the risk of death or bodily harm, and the problems of recuperation. Second, there is no physician's duty to discuss the relatively minor risks inherent in common procedures when it is common knowledge that such risks are of very low incidence." The use of experimental agents or participation in a research protocol has its own set of guidelines and comes under the heading and province of Human Use (a.k.a. Human Protection or Research) Committees. More stringent federal guidelines may apply in such situations.

Battery

Informed consent issues are almost always treated as a subcategory of medical negligence. However, in certain instances, the fact that the patient has not consented to a given treatment or procedure in the first place can give rise to a claim of battery (unconsented touching), with claims for punitive damages. The law generally discourages punitive damage claims against physicians, and legislatures have enacted statutes that place additional hurdles in front of patients seeking to make such claims. For example, California law states: "In any action for damage arising out of professional negligence of a health care provider, no claim for punitive damages shall be included in the complaint . . . unless the court enters an order allowing an amended pleading." That section further requires that to obtain such a court order,

patients must establish that there is a substantial probability that they will prevail on such a claim. Nevertheless, such suits can, and do, arise. For example, should a surgeon receive authorization to perform a given operation and then performs an additional or alternative procedure without the patient's consent, such conduct can give rise to a battery claim. In other words, receiving consent to perform a given procedure such as tubal ligation and failing to inform the patient of possible complications of the procedure and/or alternative methods of sterilization could give rise to a negligence claim on the basis of lack of informed consent. Receiving consent to perform a tubal ligation, and instead performing a hysterectomy, could give rise to a battery claim.

Vicarious Liability

Under the doctrine of vicarious liability or respondeat superior, physicians may be held liable for the negligent acts of their agents; i.e., those persons actually acting or appearing to act on their behalf, including employees, even though the doctor is innocent of wrongful conduct. Such liability can be imposed when the agent's or employee's negligent conduct occurs while acting within the scope of the agency or employment. For example, a doctor may be held liable for the negligence of a nurse committed while acting as the doctor's employee or under his instruction. Generally, however, a physician will not be held liable for the negligence of another doctor who has been called in on a given case, because the relationship between physicians is typically that of independent contractors. On the other hand, theories of negligent supervision and hiring might create liability if the referring doctor should have known that the consultant was not competent.

Third-Party Claims

Generally, a physician's duty does not extend beyond the patient to a third party who is not a patient. However, under certain limited circumstances, a duty to non-patients can arise. For example, a person could suffer emotional distress as a witness to a doctor's negligent conduct; i.e., a mother could suffer emotional distress witnessing the medical abandonment of her child. In addition, some courts have found that a physician owes a duty to a person when the physician knows a patient may cause harm to that person. Specifically, a psychotherapist has a duty to protect certain third parties from a patient's dangerous propensities. For example, one California Jury Instruction states: "If in exercising the degree of learning and skill required . . . a physician is, or should be able to reasonably foresee or predict that a patient's condition poses a serious danger of injury or damage to a third person, then the physician owes a duty to the third person to exercise reasonable care under the circumstances..... " In support of this concept, the court found that a doctor was liable to a person injured in an auto accident when the doctor failed to warn the patient not to drive in an uncontrolled diabetic condition.

Abandonment

Once the physician or other healthcare practitioner undertakes the responsibility of treating a patient, the physician has a duty to continue that treatment as long as immediately necessary, unless they mutually terminate the relationship, or the patient dismisses the physician. For the physician to withdraw from a patient's care, the physician must give the patient due notice and ample opportunity to secure other medical attendants. For example, one California Jury Instruction states: "once a physician has undertaken to treat a patient, the employment and duty..... to a patient continues until ended by consent or request of the patient or the physician withdraws from the case after giving the patient notice and a reasonable time to employ another doctor [or] [the condition of the patient is such that the physician's services are no longer reasonably required] .....A physician may limit his or her obligation to

a patient by undertaking to treat the patient only for a certain ailment [or only at a certain time or place]."

Conclusion

These are the elements that make up most malpractice actions. Each case should be evaluated using these criteria as a general guide. However, local laws and peculiarities of local law vary and take precedence.

Extracted from: Gittler, GJ and Goldstein, JC. The elements of medical malpractice; an overview. Clinical Infectious Diseases 1996; 23:1152-5.

Medical Malpractice in Radiation Oncology

There are very few studies of how often malpractice claims are made against radiation oncologists, what their allegations are, or what their outcomes are. A physician survey done around 1990 suggested that the chance of being sued at least once after 30 years in practice in radiation oncology was about 65 percent (1). However, a more recent systematic study of closed malpractice claims collected by a nationwide medical liability insurance trade association (Physician Insurers Association of America) found that 1517 claims were filed against radiation oncologists from 1985 to 2012, the fewest of any of the 22 specialties included in their database (2). Claims were made against an estimated maximum of only 2.4 percent of the radiation oncology workforce; however, the number of covered physicians was not recorded in the database, so true per capita rates of claims filed could not be calculated. The total number of annual claims filed decreased over this period. Of note, the proportion of solo practitioners amongst sued physicians was high, compared with physicians in other types of practices, but their proportion of all claims filed dropped from 72 to 52 percent for the last 10 years of the study.

There are also few data on why claims are filed. One study of 13 cases involving prostate brachytherapy found claims typically alleged a breach of the standard of care (3). In another study of 20 malpractice suits, the most common allegations were delays in diagnosis, breach of the standard of care, and failure to obtain a second opinion (4).

A systematic study of the outcome of malpractice claims against radiation oncologists found that 22.5 percent resulted in payment to the plaintiff (2). Average and median indemnity payments were $276,792 and $122,500, ranking fifth and eighth, respectively, among the 22 specialties examined. Average litigation expenses increased over time, but there was no significant change in average indemnity payments.

Thus, medical professional liability claims against radiation oncologists do not appear to be common. Only a minority of these result in payments to the plaintiff. When made, such payments are substantial. Peer review and other quality assurance mechanisms can help limit the chance of making errors that result in patient injury. Nonetheless, such events will occur, despite the best precautions. When they do, prompt and full disclosure to the patient is perhaps the most ethical approach and may also help prevent a suit from being filed (5).

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Impaired Physicians

The issue of medical professionals with impairments secondary to disability and/or addiction, who appear to be incompetent, or have committed breaches of ethical principles has been recognized for many years. Colleagues are often the first to note problems in the workplace regarding these issues but are often reluctant to intervene. Responsibility to protect patients and aid colleagues requires that appropriate actions be taken. The American Medical Association Code of Medical Ethics has established what has become the governing set of principles in this regard, published as Opinion 9.031 of Council on Ethical and Judicial Affairs.

Reporting Impaired, Incompetent, or Unethical Colleagues

Physicians have an ethical obligation to report impaired, incompetent, and/or unethical colleagues in accordance with the legal requirements in each state and assisted by the following guidelines:

1. **Impairment:**

   Physicians' responsibilities to colleagues who are impaired by a condition that interferes with their ability to engage safely in professional activities include timely intervention to ensure that these colleagues cease practicing and receive appropriate assistance from a physician health program (see Opinion E-9.0305, "Physician Health and Wellness"). Ethically and legally, it may be necessary to report an impaired physician who continues to practice despite reasonable offers of assistance and referral to a hospital or state physician health program. The duty to report under such circumstances, which stems from physicians' obligation to protect patients against harm, may entail reporting to the licensing authority.

2. **Incompetence:**

   Initial reports of incompetence should be made to the appropriate clinical authority who would be empowered to assess the potential impact on patient welfare and to facilitate remedial action. The hospital peer review body should be notified where appropriate. Incompetence that poses an immediate threat to the health and safety of patients should be reported directly to the state licensing board. Incompetence by physicians without a hospital affiliation should be reported to the local or state medical society and/or the state licensing or disciplinary board.

3. Unethical conduct:

With the exception of incompetence or impairment, unethical behavior should be reported in accordance with the following guidelines and, considering, as necessary, the right to privacy of any patients involved:

Unethical conduct that threatens patient care or welfare should be reported to the appropriate authority for a particular clinical service. Unethical conduct that violates state licensing provisions should be reported to the state licensing board. It is appropriate to report unethical conduct that potentially violates criminal statutes to law enforcement authorities. All other unethical conduct should be reported to the local or state professional medical organization.

When the inappropriate conduct of a physician continues despite the initial report(s), the reporting physician should report to a higher or additional authority. The person or body receiving the initial report should notify the reporting physician when appropriate action has been taken. Physicians who receive reports of inappropriate behavior, including reports submitted anonymously, have an ethical duty to critically, objectively, and confidentially evaluate the reported information and assure that identified deficiencies are either remedied or further reported to a higher or additional authority. Information regarding reports or investigations of impairment, or of incompetent or unethical behavior should be held in confidence until the matter is resolved. (II)

http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9031.page

Issued March 1992 based on the report "Reporting Impaired, Incompetent, or Unethical Colleagues," adopted December 1991 (J Miss St Med Assoc. 1992;33:176-77); updated June 1994; updated June 1996; and updated June 2004, based on the report "Physician Health and Wellness ," adopted December 2003.

Communications

Good communication with patients and caregivers, and among and between providers, is an essential element of professionalism, relating to clinical care, ethics, medical liability, and quality assurance. The importance of these issues is such that the ACR and ASTRO have collaborated on a document: ACR–ASTRO PRACTICE PARAMETER FOR COMMUNICATION: RADIATION ONCOLOGY. With the permission of both organizations, the document is provided below. For references, participants, and acknowledgments, the reader is referred to the original document.

http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Comm_Radiation_Oncology.pdf

ACR-ASTRO PRACTICE PARAMETER FOR COMMUNICATION: RADIATION ONCOLOGY

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiation oncology care for patients. Practice Parameters and Technical Standards are not inflexible rules or

requirements of practice and are not intended, nor should they be used, to establish a legal standard of care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

1 - Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ____N.W.2d____(Iowa 2013) Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the American Society for Radiation Oncology (ASTRO).

Timely, accurate, and effective communications are critical to quality in contemporary medical practices. Radiation oncology incorporates the science and technology of complex, integrated radiation treatment delivery and the art of managing individual patients. Through written physical (i.e., hardcopy) and/or electronic (e.g., digital) reports and direct communication, radiation oncologists convey their knowledge regarding patient care, services provided, and quality of care to others involved in the care of the patient. This communication should involve primary care physicians, medical oncologists, surgeons, other non-radiation oncology health care providers, as well as members of the radiation oncology treatment team (such as other physicians, nurses, radiation therapists, dosimetrists, medical physicists, tumor registrars, and quality assurance personnel) [1].

Radiation oncology activities must be clearly articulated for communications objectives to be met. Although not all technical aspects of treatment have to be included, certain basic information must be reflected in physician correspondence: an evaluation and assessment of the patient's clinical problems; a summary of any multidisciplinary cancer care; the plan and delivery of radiation therapy treatments; the monitoring of response, side effects, and outcome; and the plan for subsequent care (conference, discussion, or clinic). These should be communicated, at a minimum, by an initial consultation, treatment (completion) summary, and follow-up evaluation.

There remains no substitute for direct, timely personal communication on all clinically relevant matters with the patient, the patient's family or support system, and physicians or other healthcare professionals.

The communication of certain Protected Health Information (PHI) concerning patients is regulated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the HIPAA Privacy Rule. Any use, disclosure, or creation of PHI must be in accordance with the Privacy Rule. Particular attention should be given to the use of electronic or digital means of communicating with both physicians and patients. Appropriate privacy, security, and technical safeguards should be established and consistent with the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH).

II. COMMUNICATIONS: GENERAL

A. Medical Record

Practice parameters need to be revised periodically regarding medical record documentation for professional and technical components of services delivered. Criteria unique to radiation therapy services are also contained in the ACR Practice Parameter for Radiation Oncology [2].

The medical record should address the following:

1. Permanent documents should be prepared legibly and in a timely, useful, and clinically appropriate manner. Institutions, medical staff bylaws, and third-party payers frequently have requirements regarding the timeliness of completing medical records. However, in general, consultation notes, progress notes, letters, follow-up notes, and treatment summaries should be in the medical record within 1 to 2 weeks after the visit or the completion of treatment.
2. The material should be reviewed to minimize typographic errors and confusing or conflicting statements. Systems in which correspondence is disseminated without review "to expedite communication" are discouraged. Abbreviations and other notations should follow prevailing standards. Jargon, abbreviations, and acronyms unique to radiation oncology should be avoided.
3. Proper mechanisms for signature (authentication) and policies for distribution of any correspondence should be in place, assuring security and confidentiality.
4. The timely distribution of the final document must be assured by transmission via direct mail, fax, and/or electronic means as dictated by the nature and urgency of the clinical setting.
5. The communications are a part of the patient's permanent medical record. Record retention must be in compliance with state and federal requirements.

B. Electronic Communications

Electronic charting and treatment management (record-and-verify) systems are becoming increasingly prevalent. These systems must meet the federal government's HIPAA security standards for handling electronic media and PHI. These security standards address the protection, security and integrity of electronically maintained patient information. Any reports from these systems, including voice recognition-generated documents, should be reviewed by the radiation oncologist or designee for clarity, succinctness, content, accuracy and ease of understanding by all intended recipients.

C. Doctor-Patient Communication

Effective communication between physicians and patients is a primary goal of the radiation oncologist in all clinical and treatment matters. Efforts should focus on establishing a supportive and interactive relationship with patients and collaborative working relationships with other caregivers to ensure sufficient information is provided to and understood by the patient. Alternative management options should be presented and discussed prior to initiation of therapy, and changes in treatment plans should be addressed and communicated in a timely fashion with the patient and other concerned persons [3]. Such interactions help emphasize and promote a patient-oriented perspective. Direct dialogue is typically the primary form of communication between physician and patient, but it may be [4] enhanced through the use of pertinent printed materials, computer-accessible information, video presentations and other aids [5-8]. Conversations with patients should be documented in the medical record.

Increasingly, direct electronic mail communication with collaborating and referring physicians, as well as with patients, is occurring. With other physicians engaged in the management of the patient, this electronic communication can be both effective and efficient, however risks of unintended sharing of PHI do exist. All parties must establish reasonable safeguards to minimize the risk of inappropriate distribution of information through policies, procedures, and secure mail services.

The HIPAA Privacy Rule allows covered health care providers to communicate electronically with their patients, such as through e-mail, provided they apply reasonable safeguards when doing so. See 45 C.F.R. § 164.530(c). For example, certain precautions may need to be taken when using e-mail to avoid unintentional disclosures, such as checking the e-mail address for accuracy before sending, or sending an e-mail alert to the patient for address confirmation prior to sending the message. Health care providers must also be aware that although the Privacy Rule allows the communication of unencrypted PHI by e-mail, the disclosure of such information may require notification of such "breach" in accordance with the Breach Notification Rules of HIPAA2. 2 45 CFR Parts 160 and 164, Breach Notification for Unsecured Protected Health Information, August 24, 2009.

Use of social media (e.g., Facebook®, Twitter®) to communicate with patients should not be used as these methods do not have the appropriate safeguards to protect patients and providers from unintended dissemination of information.

The use of short message service (SMS) text and instant messaging services to transmit identifiable patient data or other medical information should be used with caution. Department or institutional policy governing the transmission of PHI by personal communication devices should be followed. For further information and guidance see the ACR–SIIM Practice Parameter for Electronic Medical Information Privacy and Security [9].

III. RADIATION ONCOLOGY REPORTS

A. Consultation

1. Specifics

a. The consultation report should include the following:

1. Chief complaint
2. History of present illness
3. Past medical illness including any prior radiation or other cancer therapies
4. Current medications and pertinent allergies (e.g., medications, contrast agents, foods, latex)
5. Family medical and patient social history
6. Review of systems
7. Vital signs, and pain, psychological, and nutritional assessments, ideally using available scales
8. Performance classification (e.g., Karnofsky or Zubrod)
9. Physical examination
10. Diagnostic test results, particularly pathology, imaging, and staging studies
11. TNM classification of the tumor(s) and/or the clinically appropriate staging
12. Impression or clinical assessment
13. Plan of care or management

The consultation should include statements about the decision-making process and recommendations for subsequent care. Particular attention should be given to documenting oncology aspects and any comorbid diseases and risk factors that may affect radiation therapy and overall patient care.

2. Medical decision making

The clinical impression and management recommendations (or plan) should clearly explain and address the following:

a. The clinical impression indicating the primary tumor site, histology, and TNM stage [10]
b. The differential diagnosis and natural history of disease (prognosis), as appropriate
c. Identification of comorbid conditions that may influence treatment decisions
d. Diagnostic tests to be reviewed
e. Treatment options, including the intent of therapy (e.g., cure, adjuvant, palliation, local control)
f. The plan of care, including any additional recommended diagnostic studies, combined modality approaches, and plans coordinated with other disciplines
g. The risks/benefits of the recommended therapy that were discussed with the patient, including the expected outcome as well as possible side effects and toxicities that may occur (for more details regarding informed consent, see the ACR Practice Parameter on Informed Consent – Radiation Oncology.) [11]
h. The anticipated treatment region(s); a description of protocols, guidelines, or references being followed can be noted.

Radiation oncologists may prefer to make a summary communication with the referring physician and other physicians noting the pertinent aspects of history, physical examination, clinical assessment, and treatment plan [12]. Regardless of the specifics of the external communication, a completed and detailed internal document (containing all the necessary elements of evaluation and management) should be generated and maintained in the patient's permanent radiation therapy record.

B. Clinical Treatment Management Notes (Including Inpatient Communication)

Radiation oncologists evaluate and document at least weekly the progress of patients who are under routine therapy. This evaluation and documentation should include appropriate observations related specifically to the course of radiation, including response and toxicity, but in addition, should include observations relevant to general medical status, pain, nutrition, emotional well-being and general provision of care. In addition, relevant verbal or written communications with other members of the health care team should be documented in the medical record. Verbal physician-to-physician communication is recommended for urgent issues.

Documentation of clinical treatment management includes the following:

a. Accumulated radiation dose, patient's tolerance to treatment, and progress toward the treatment goal, with analysis of any new pertinent data
b. Issues raised by the patient or treatment team (dietary, social service, etc.)
c. Clinically relevant change in status or treatment plan (change in treatment intent, need for treatment break, etc.)
d. Review of the technical aspects of the radiation therapy treatment plan and patient setup
e. Review of treatment localization (portal images, films, localization images or data) should be documented in the treatment management note or as a separate note of the patient's technical treatment parameters.

Hospitalized patients receiving radiation therapy should have their daily treatment documented in their inpatient medical records.

C. Treatment (Completion) Summary

1. Introduction

The technical details and images related to actual clinical management and radiation therapy delivery must be retained in the radiation oncology permanent record and must be made available to others upon request if authorized by the patient or the patient's power of attorney. A summary should be generated and distributed to the patient's other pertinent healthcare providers that accurately describes the treatment process, the doses delivered to the target/tumor volume and other key organs, relevant assessment of tolerance to and progress toward the treatment goals, and subsequent care plans.

The style will reflect the radiation oncologist's individual practice convention and the referral provider's needs. Some may use a standardized reporting format, and others a more descriptive personal letter. Narrative explanations of highly technical aspects of the treatment may be included in the treatment summary when considered to be informative,

but these, at a minimum, should be included in the patient's permanent record. Images and other documentation regarding the site of radiation therapy and the radiation dose distribution must be available on request when medically required or indicated.

2. Specifics

The treatment (completion) summary's key elements should include the following:

a. Components for the summary of radiation therapy delivery
    i. Patient identification and report date
    ii. Recipients of report (including tumor registry, if appropriate)
    iii. Diagnosis and TNM stage of disease
    iv. Treatment dates
    v. Treatment status (e.g., treatment course completed as planned, changed, suspended)
    vi. Clinical course, including side effects and management thereof and use of ancillary services (nutritional, psychosocial, etc.)
        1. Treatment response with details deemed clinically useful, including activity/performance status
        2. Side effects and management thereof
        3. Interruptions or unplanned breaks in treatment
    vii. In addition the treatment summary should include the following elements:
        1. External beam: treatment technique (3-D conformal therapy, intensity modulated radiation therapy, stereotactic radiation therapy, etc.), modality (x-rays, electrons, protons, etc.), total dose, treatment fractions, dose to tumor/target volumes, and any key regions (including nodal areas and key organs), as appropriate
        2. Concomitant/concurrent chemotherapy or other systemic treatment
        3. Brachytherapy: Radionuclide, specification of treatment target and target dose; dose rate (high-dose rate, pulsed-dose rate, or low-dose rate), permanent versus temporary, and type of applicator or procedure (e.g., intra-cavitary versus interstitial); administration dates of temporary brachytherapy or date of insertion for permanent implants
        4. Radionuclide therapy: the administered radionuclide (chemical form [colloidal, tagged to antibody, etc.], and name), route of administration, total activity, and date administered
    viii. Follow-up plans including referrals to other health care providers, instructions, and/or diagnostic studies.
    ix. Discharge instructions regarding aftercare following radiation therapy
b. Optional items of technical nature may include the following:
    i. Details of external beam radiation therapy (beam orientation, beam energy)
    ii. Organ localization techniques and methods of simulation
    iii. Organ motion management and image guidance
    iv. Treatment aids or devices (eg, wedges, bolus)
    v. Pertinent quality assurance measures (eg, diodes, treatment images, etc.)

The style, content and detail of this summary must be tailored to the clinical setting and prevailing practice standards. It should contain elements that accurately and succinctly reflect the program of care administered in a language understandable to physicians who are not radiation oncologists [13].

D. Follow-Up Visits

1. Introduction

The continuity of patient care after radiation delivery is reflected by the initial and subsequent clinical evaluations performed by the radiation oncologist. Although other physicians participate in patient follow-up care, radiation oncologists with specific training and experience are familiar with the effects of radiation and can provide a uniquely qualified and important diagnostic and management perspective. Correct diagnosis and management of acute, sub-acute, and late effects from either radiation alone or combined modality programs, detection of recurrent disease, and advice on additional diagnostic and treatment strategies are examples of the special services provided by the radiation oncologist. Follow-up assessments are integral to high-quality patient care.

2. Specifics

The form and content of a follow-up visit should remain consistent with the initial consultation and treatment summary.

a. Subjective
   i. Interval history since the last patient encounter
   ii. Cancer-related symptoms and problems, including a general and oncologic review of systems
   iii. Status of symptoms related to cancer therapy
   iv. Other clinical issues to be addressed, including quality of life, pain and nutritional assessments, and the patient's emotional concerns

b. Objective
   i. Pertinent clinical findings in any irradiated field(s)
   ii. Multisystem examination to detect any evidence of active oncologic disease
   iii. General or focused physical examination, as appropriate
   iv. Statement reviewing any pertinent diagnostic data
   v. When applicable, a description to allow assessment of radiation therapy's late effects on tissues and organs; a comparison of current assessments to prior examinations to reflect continuity of care

c. Impression or assessment statement
   i. General patient and cancer status
   ii. Time since diagnosis and/or completion of radiation therapy
   iii. Performance or functional activity status
   iv. Current cancer therapies being administered to the patient
   v. Description of radiation related side effects; several designations are available using standard criteria such as the *Common Toxicity Criteria for Adverse Events (CTCAE), Version 4.0.*

d. Disposition and plan of care
   i. Pertinent recommendations to patient, referring physicians, and other health care providers

ii. Recommendations for subsequent diagnostic studies and treatment strategies, as appropriate
iii. Changes in medications and documentation of new prescriptions, as appropriate
iv. Next follow-up visit

If it is anticipated that the radiation oncologist will not follow up with the patient, it is recommended that the report to the referring physician include a request for periodic updates on the patient's progress. These updates will facilitate continuity of care should the patient require further radiation therapy.

IV. SUMMARY

The radiation oncologist's participation in the multidisciplinary management of patients is reflected in timely, medically appropriate, and informative communication with the referring physician and other members of the health care team. The timely generation, authentication, and dissemination of these reports significantly improves their utility and improves the quality of patient care. Written reports containing standardized components are a matter of course, and they should be in compliance with accepted professional standards. However, documentation must remain sufficiently specific to address the patient's individual medical management needs and overall clinical environment in which the care is given. In short, the radiation oncologist must communicate effectively with patients, caregivers, other physicians, and the other members of the health care system.

Revised 2014 (CSC/BOC) – Effective June 25, 2014

http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Comm_Radiation_Oncology.pdf - Accessed 7/15/2015

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 must be honored if at all possible.

"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 - Accessed 8/16/2014

Part IV: Research and the Literature

Basic Statistics for Literature Interpretation in Radiation Oncology

Types of Data

It is important to correctly identify the type of data, as this determines the most appropriate statistical tests.

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

Types of Variables

- Categorical: Basic units are not quantifiable (examples: race, gender). These can be nominal (low information content) or ordinal (intermediate information content).
- Continuous or ordered discrete: Can take values within a given interval (example: time, age, blood pressure) and generally have higher information content relative to a categorized or discretized representation of the same variable (example: tumor size categories vs. continuous measure).

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.

Central Tendency (Mean, Median, and Mode)–relevant for continuous data and some ordinal data (scores, etc.)

Measures of central tendency describe one aspect of how values of a variable in a population tend to be distributed. The estimated 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. The mode is most often used when variables of interest tend to be more discrete (age in years) or ordinal (ordered values), because for truly continuous measures, each observed value may be unique.

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. Variance describes the amount of spread around the mean of a data set. Variance is calculated by subtracting the estimated 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:

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

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.

Normal Distribution and Standard Scores

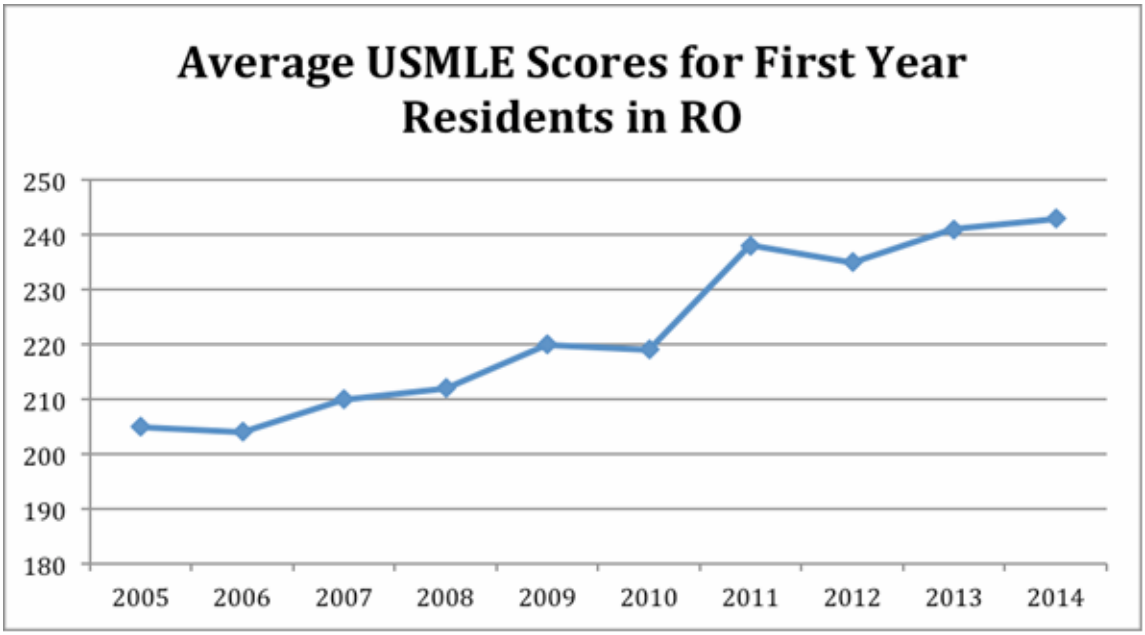
A probability distribution uses the theory of probability to describe the behavior of a random variable. In the case of discrete variables, a probability distribution specifies all possible outcomes of the variable along with the probability that each will occur. In the case of continuous variables, 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 68% of the area under the standard normal curve lies within ±1 SD from the mean. Approximately 95.4% of the area under the standard normal curve lies within ±2 SD from the mean.

Halpern EF, Gazelle GS (2003). Probability in radiology. Radiology 226(1): 12-15.

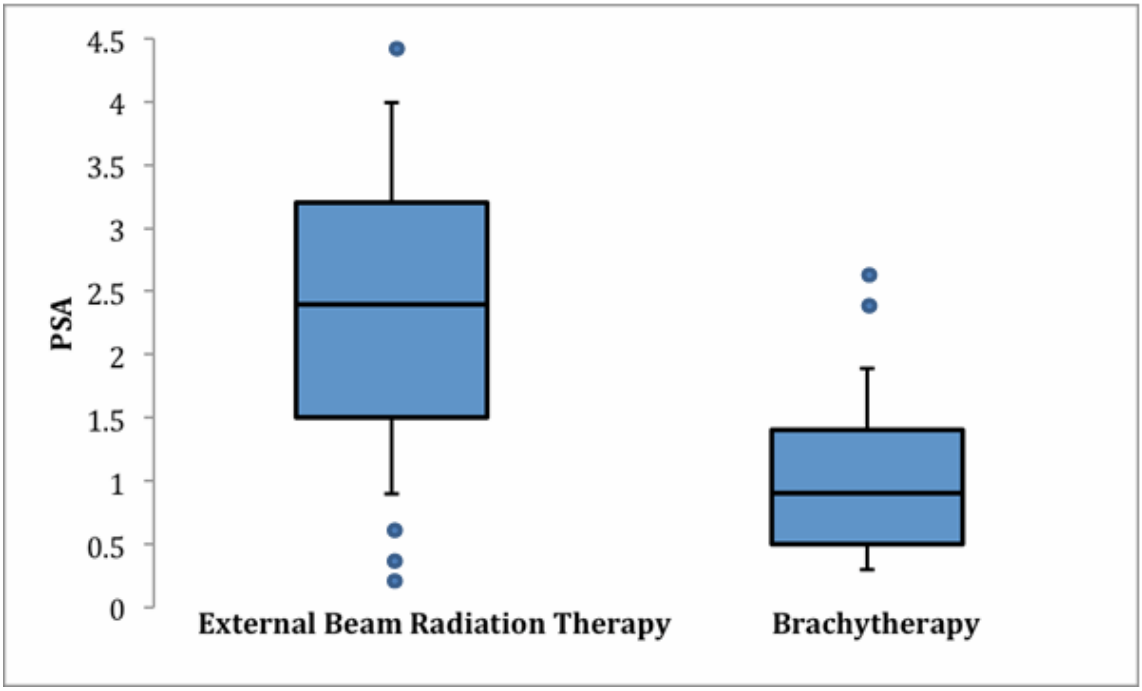
Pagano M, Gauvreau K (2000). Principles of Biostatistics. Pacific Grove, Duxbury Press. Ch 7.

Graphic Methods for Depicting Data

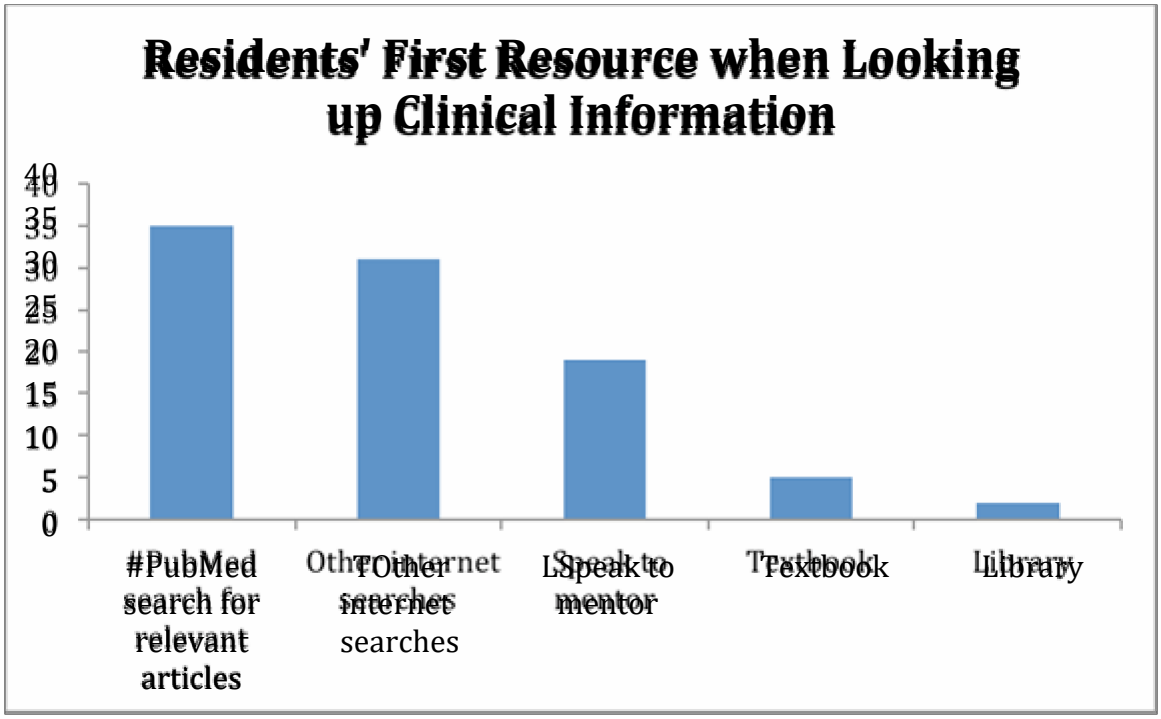
The line graph below shows change in USMLE Step 1 test scores (y axis) over time in years (x axis) for those entering Radiation Oncology residency programs.



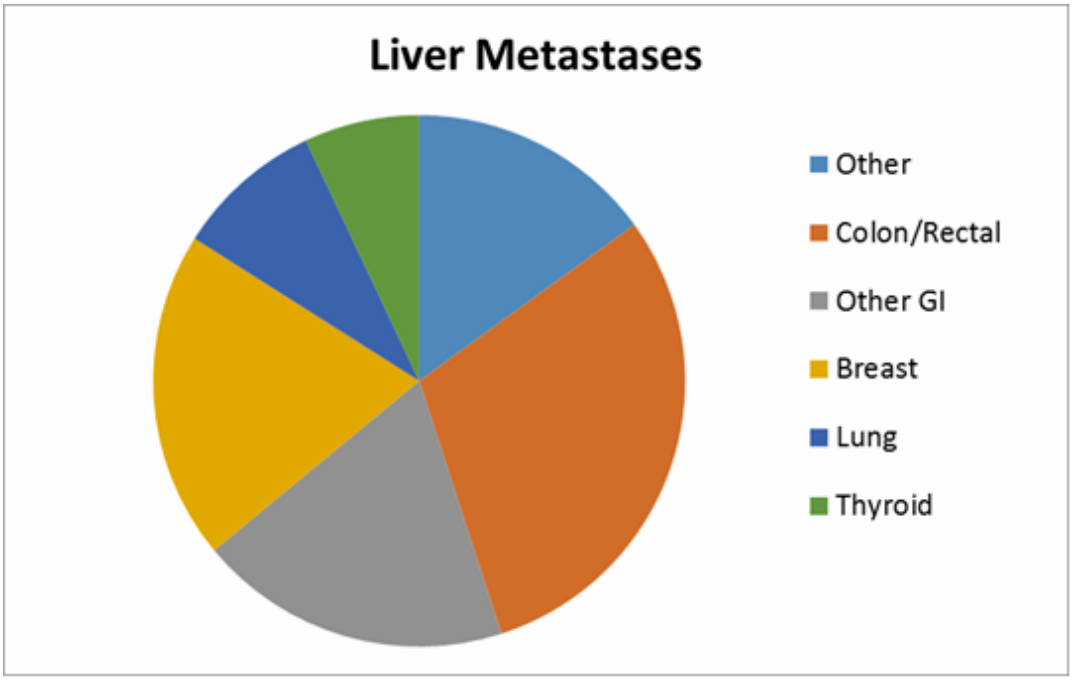
The box plot below shows higher variation in PSA and higher medians in PSA two years after external radiation for prostate cancer than after brachytherapy. The long horizontal black line is the median. The shaded box represents the boundaries of the upper and lower quartiles, with the blue dots being data points outside these quartiles.



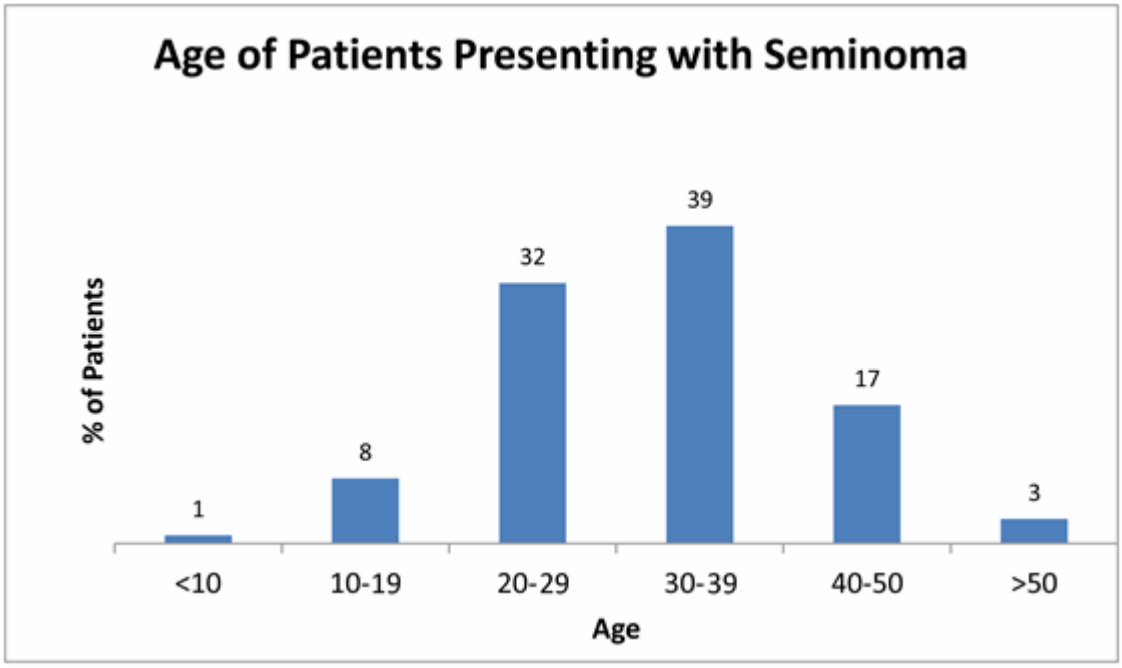
Bar graph below: This study asked radiation oncologists which information sources, if any, they might use to determine a treatment strategy when faced with a complex clinical case. The bar graph demonstrates the mean relative frequencies with which participants thought they would use various resources.



The pie chart below summarizes the cancer of origin of patients seen for stereotactic body radiotherapy (SBRT) ablation of liver metastases in an institutional clinic.



The histogram below shows the distribution by age of patients presenting with testicular seminoma.



***p* Values**

In testing a hypothesis, α is the predetermined level of statistical significance that the investigator sets as the maximum acceptable chance of committing a Type I error (defined as rejecting the null hypothesis when it is actually true). The *p* value is the observed significance level of a statistical test, as determined by analyzing the data. The *p* value is the probability of seeing an effect as big as or bigger than the one observed in the study by chance (i.e., if the null hypothesis were true). The *p* value measures the strength of evidence against the null hypothesis. A nonsignificant 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, a consistent reproducible association estimate, a dose-response relationship between the risk and the outcome, and biologic plausibility. Specific study designs, such as randomized trials, support causal inference from hypothesis tests and associated *p* values.

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

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

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%. For a normally

distributed sample with a known SD (or a population with an unknown SD, but normally distributed and large), 95% CI = mean ± *z* (SD/√n), noting that for a 95% CI, *z* = 1.96. If the population SD 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 and the number of degrees of freedom. Degrees of freedom (defined as df = n − 1) measure 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.

Test Performance

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 × 2 table below can be helpful in understanding this definition as well as other commonly used statistical measures.

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

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

Specificity

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

Types of Results

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

Bayes Theorem

The pretest probability of disease is the prevalence of the disease in the test population.

The post-test probability of disease is the probability (prob) of an outcome, 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.

$$\text{Odds} = \text{prob}/(1 - \text{prob}), \text{ and}$$

$$\text{Prob} = \text{odds}/(1 + \text{odds}).$$

The post-test probability of disease is determined by both the prevalence (pretest probability) and the test information (likelihood ratio). Post-test odds are defined as the pretest 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.

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 × 2 table (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.

Accuracy

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

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 negative predictive value (NPV) should include a prevalence of the disease in subject groups that is similar to the prevalence of disease in the population. (If these prevalences are not similar, then likelihood ratios should be used instead of PPV and NPV.) Case-control studies (which do not yield prevalence) cannot be used to estimate PPV (or NPV).

Negative Predictive Value

The 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.

Receiver Operating Characteristic Analysis

A receiver operating characteristic (ROC) curve is a plot of test sensitivity (y axis) versus FP rate (x axis). (FP 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 an 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 to be between probably benign and suspicious. Alternatively, a positive result could be defined as any interpretation other than normal, with the cut point between normal and benign. Which cut point is more appropriate depends on how the test will be used. For accuracy, as defined 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.

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. Radiology 227(3): 617-622.

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

Regression Models

As opposed to correlation analysis (which measures the strength of the relationship between variables), a regression analysis evaluates the impact of a predictor (i.e., independent, explanatory) variable on an outcome (i.e., 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, Xi, for

i = 1, …, n subjects, and has a linear relationship with the outcome variable, Yi:

$$Yi = a + bXi + ei$$

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 “ei” 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 include:

- The assumptions are met and 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.

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 (i.e., effect size) between the two means being compared. Decreasing the SD (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.

Commonly Used Statistical Tests in the Radiology Literature

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

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

For categorical data:

- Comparing observed frequencies with expected frequencies, often in a 2 × 2 table (especially for test homogeneity between two groups or independence of two variables in one group): $\chi 2$ test
- Comparing observed frequencies with expected frequencies when sample size is small (< 30) or number of observations in any one cell in the 2 × 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.

Research Design and Methodology

Clinical Trial Development

Clinical trials are conducted in a series of steps, called phases—each phase is designed to answer a separate research question.

- **Phase I:** Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- **Phase II:** The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- **Phase III:** The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it with commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- **Phase IV:** Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

National Institutes of Health: http://www.nlm.nih.gov/services/ctphases.html

Cross-Sectional Studies

With the cross-sectional 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 (because prevalence depends on both disease incidence and disease duration).

Case-Control Studies

The case-control 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 is its 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.

Cohort Studies

The cohort study 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 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.

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 the ability to demonstrate causality, eliminate confounders, and minimize some biases. Random assignment of subjects helps eliminate confounding variables because 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. Philadelphia, PA, Lippincott Williams & Wilkins.

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, the indications for use, and 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 six-tiered hierarchical model of a continuum

for efficacy has been developed that helps to relate efficacy to technology assessment and outcomes research:

- Level 1: Technical efficacy (e.g., image resolution, noise)
- Level 2: Diagnostic accuracy efficacy (e.g., sensitivity, specificity, area under the ROC curve)
- 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)
- Level 4: Therapeutic efficacy (e.g., percentage of times imaging is judged helpful in planning patient management, percentage of times when imaging results in a change in management plans)
- Level 5: Patient outcome efficacy (e.g., percentage of patients who improve with the imaging compared with those without the imaging, value of imaging information in quality-adjusted life years)
- 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.

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 = LRp / LRn
  - (See ***Bayes Theorem*** above for definitions of positive [LRp] and negative likelihood ratios [LRn].)
- 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

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 that 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.

Comparative Effectiveness Research/Evidence-Based Medicine (EBM)

- 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.
- 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.
- 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.

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

Screening

Criteria for determining utility of screening procedures:

- Population Characteristics
  - Sufficiently high prevalence of disease or condition
  - Likely to be compliant with subsequent tests and treatments
- Disease Characteristics
  - Significant morbidity and mortality
  - Effective and acceptable treatment available
  - Presymptomatic period detectable
  - Improved outcome from early treatment
- Test Characteristics
- Good sensitivity and specificity
- Low cost and risk
- Confirmatory test available and practical

Fletcher RF, Fletcher SW, et al. (1996). Clinical Epidemiology: The Essentials. Baltimore Williams & Wilkins. Accessed August 25, 2014.

https://www.rsna.org/Reporting_Initiative.aspx Accessed 8.25.2014

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