The Concept of Error and Malpractice in Radiology

Antonio Pinto, MD, PhD,* Luca Brunese, MD,† Fabio Pinto, MD,* Riccardo Reali, MD,‡ Stefania Daniele, MD,* and Luigia Romano, MD*

Since the early 1970s, physicians have been subjected to an increasing number of medical malpractice claims. Radiology is one of the specialties most liable to claims of medical negligence. The etiology of radiological error is multifactorial. Errors fall into recurrent patterns. Errors arise from poor technique, failures of perception, lack of knowledge, and misjudgments. Every radiologist should understand the sources of error in diagnostic radiology as well as the elements of negligence that form the basis of malpractice litigation. Errors are an inevitable part of human life, and every health professional has made mistakes. To improve patient safety and reduce the risk from harm, we must accept that some errors are inevitable during the delivery of health care. We must play a cultural change in medicine, wherein errors are actively sought, openly discussed, and aggressively addressed.

Semin Ultrasound CT MRI 33:275-279 © 2012 Elsevier Inc. All rights reserved.

Error in medicine has become headline news in recent years. To err is human, yet society demands that medical professionals be faultless. For radiologists, being held to such standards is particularly challenging because of the rapidly advancing science of image acquisition, the art of digital image interpretation in an era of multiplanar availability, and our reliance on referring physicians to provide us with appropriate clinical information.1

Within radiology, the important progress in demonstrating disease has left error analysis a subject not usually explicitly explored. The work of diagnostic radiology consists of the complete detection of all abnormalities in an imaging examination and their accurate diagnosis.2 Approximately 4% of radiologic interpretations rendered by radiologists in their daily practice contain errors.3 Fortunately, most of these errors are of such minor degree, or if serious errors are found and corrected with sufficient promptness, that they do not cause injury to patients. Nevertheless, many radiologic errors do harm patients, and, as a result, medical malpractice lawsuits are generated.3

There is, thus, the need to analyze the extent and causes of the phenomenon, which would also help to identify the most effective measures in terms of clinical risk management.

The Concept of Error

The Institute of Medicine defines error as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim” and estimates that between 44,000 and 98,000 Americans die each year because of medical errors.4 The estimated financial cost of medical errors in the United States is approximately $37.6 billion each year, with $17 billion of these costs associated with preventable errors.4 Error, as defined by Stedman’s Medical Dictionary, is “a defect in structure or function. A mistaken decision.”5 Wu and colleagues6 define medical error as “a commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were any negative consequences.” These errors may occur in hospitals, clinics, outpatient surgery clinics, nursing homes, doctors’ offices, pharmacies, and patients’ homes. Errors may involve medicines, surgery, diagnosis, equipment, and reports. The Agency for Health Care Research and Quality defines patient safety as “the absence of the potential for, or the occurrence of, health care associated injury to patients created by avoiding medical errors as well as taking action to prevent errors from causing injury.”7 In addition, medical errors are defined as “mistakes made in the process of care that result in or have the potential to result in harm to patients. Mistakes include the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. These can be the result of an action that is taken (error or commission) or an action that is not taken (error of omission).”7

---

*Department of Radiology, Cardarelli Hospital, Naples, Italy.
†Department of Health Science, University of Molise, Campobasso, Italy.
‡Section of Diagnostic and Interventional Radiology, “S. Maria della Misericordia” Hospital, University of Perugia, Perugia, Italy.
Address reprint requests to Antonio Pinto, MD, PhD, Department of Radiology, Cardarelli Hospital, Via Posillipo 168/D, I-80123 Naples, Italy.
E-mail: antopinto1968@libero.it
A medication error is defined as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.” Adverse drug event is another term that is frequently used, especially in the medicine and pharmacy literature, to refer to incidents when the patient is harmed by a drug. This term is more comprehensive than “medication errors” because it includes harm as a result of an error in addition to adverse reactions, such as rash, anaphylaxis, nephrotoxicity, hepatotoxicity, or blood dyscrasias.

Errors in radiology are the flip side of quality. Thus, improvement efforts tend to focus on their occurrence, causes, and potential preventive measures. Variations in practice are thought to imply the presence of error, but this is not always the case. Variation may reflect error on the part of some practitioners on one hand or a genuine difference of opinion, for example, about the correct interpretation of an image, on the other. Variability is often examined with regard to image quality, radiation dosage, and identification of lesions; the measurement and characterization of features; diagnosis; and patient management. Variability can occur as inconsistencies in practice by the same radiologist on different occasions or as discrepancies between practitioners. Although technological advances have resulted in higher quality images, barriers have persisted to minimize the differences between observers’ readings. Three sources of this variability are as follows: (1) differences in visual observation (ie, detection), (2) the same abnormality perceived differently (ie, interpretation), and (3) different thresholds of concern about perceived abnormalities (ie, levels of confidence).

Standard of care refers to a level of practice or quality of care performed by a physician or radiologist using ordinary skill, care, and diligence. It refers to actions that a reasonably prudent physician or specialist would undertake under similar circumstances. The American College of Radiology (ACR) began creating a list of standards of practice in the mid-1980s to assist radiologists in practicing effective, efficient, consistent, and safe medical care. In 2003, the appellation of these standards of practice was changed to practice guidelines and technical standards to avoid confusion between a practice standard and standard of care. It should be noted that these practice guidelines and technical standards are different from the ACR appropriateness criteria that were created, beginning in 1995, to guide physicians in the use of imaging techniques. The goal of the practice guidelines and technical standards is that they should generally produce desired health care outcomes. Practice guidelines do not alone establish a standard of care.

They do help to define an expected level of quality of care. In that regard, they have been used by both defense and plaintiff attorneys. Almost the entire effect radiologists have on patients’ health is mediated through other medical providers. Radiologists provide information, which then guides the management of patients’ illnesses. Therefore, the final metrics of radiologist quality are the treatment that patients undergo after imaging and their final outcomes. Radiologist professionals bear responsibility not only for producing reports of diagnostic imaging studies but also for ensuring that appropriate action is taken on the basis of those reports.

Our mission in health care is to improve or maintain the health of patients. Thus, any omission or commission on the part of any health care provider or system that leads to the active or passive delivery of inappropriate services, or withholding of appropriate services, constitutes a medical error.

### Classification of Errors in Radiology

In general, there are 4 main reasons why radiologists are sued: observer errors, errors in interpretation, failure to suggest the next appropriate procedure, and failure to communicate in a timely and clinically appropriate manner.

#### Observer Errors

Kundel et al described 3 types of observer error. Scanning error is the result of failure of the radiologist to fixate in the area of the lesion. Recognition error involves fixating in the territory of the lesion yet failing to detect the lesion. The most common error is decision-making error, which accounted for approximately 45% of observer error in the study by Kundel et al. This error is due to incorrect interpretation of a malignant lesion as a normal structure after detection. Another form of observer error that may contribute to lesions being overlooked is satisfaction of search error. This error is the result of diversion of the radiologist’s attention from a tumor by an eye-catching, but unrelated, finding. Moreover, another issue that may affect observer performance is intentional underreading, that is, a conscious tendency to interpret equivocal radiographic shadows as negative. Such a phenomenon may occur because of collegial pressure to reduce the number of false-positive interpretations and, thereby, decrease unnecessary work-ups. Failures of abnormality detection in film reading (ie, perceptual errors) are subject to psychophysiological factors of human visual perception. Perceptual errors, in general, are related to multiple psychophysiological factors, including level of observer alertness, observer fatigue, duration of the observation task, any distracting factors, conspicuity of the abnormality, and many others. An additional source of error results from the influence a radiology report has over another radiologist. This type of perceptual error occurs because the radiologist reads the old report before looking at the films. If the first radiologist missed it, the next radiologist will likely miss it as well.

#### Errors in Interpretation

There are many reasons why radiologists make errors in identifying and interpreting abnormalities. Factors such as clinical history, the presence or absence of previous studies, index of suspicion, the presence of an abnormality, the reading room environment, and the level of vigilance of the interpreter are various sources of error. Eye position studies have determined that obvious abnormalities on a radiograph are
detected first and decrease vigilance for unrelated and subtle findings.25

There are also errors during the reporting phase: discrepancy in size or location of the lesions reported,26 voice recognition errors, transcription errors, and skill of the radiologist or unsupervised junior doctor. Consequences of these errors can be anything from harmless to fatal for a patient. In a study by Sangwaiya et al,26 the incidence of errors in laterality between body of report and impression sections was quoted at 0.31%.

### Failure to Suggest the Next Appropriate Procedure

Most ordering physicians actually know the next appropriate procedure to suggest when an abnormality is found on the imaging study they originally ordered. However, if the patient becomes a plaintiff in a lawsuit against the ordering physician, the radiologist can almost be assured that the ordering physician will claim ignorance as to what to do next because the radiologist did not specify what to order next. Radiologists must ensure that their recommendations or suggestions for any additional radiologic procedures are appropriate and will add meaningful information to clarify, confirm, or rule out the initial impression. The ACR “Practice Guideline for Communication of Diagnostic Imaging Findings”27 states that “follow-up or additional diagnostic studies to clarify or confirm the impression should be suggested when appropriate.” The words “when appropriate” are not defined, and thus, the circumstances under which radiologists should suggest additional radiologic studies are left to the radiologist’s own judgment.28

### Failure to Communicate in a Timely and Clinically Appropriate Manner

The duty of the radiologist involves the supervision of obtaining reasonable images, a reasonable interpretation of those images, and the effective communication of that interpretation.29 Errors in communication are the fourth most frequent allegation against radiologists in medical malpractice claims.30 Failure to communicate is one area in which the radiologist can take a direct role in reducing the risk of malpractice. When communication is not documented, the radiologist risks losing a lawsuit when there are adverse or unexpected clinical outcomes. Documentation should include the date, time, name of the person spoken to, and what was discussed.31

### The Concept of Malpractice

“Malpractice” refers to professional misconduct, which requires proof of an unreasonable lack of skill or fidelity in performing professional or fiduciary duties. The word “fiduciary” refers to the duty of care one has when entrusted with something that belongs to another person. In the medical context, it refers to the duty of a physician to a patient whose care has been entrusted to the physician. The purpose of the medical malpractice lawsuit is to afford a recovery for injuries suffered when physicians fail to exercise ordinary and reasonable care in the diagnosis and treatment of patients. To prove negligence in a medical malpractice, claim requires that a plaintiff establish 4 elements of a malpractice claim: (1) a physician–patient relationship; (2) the radiologist must have committed a negligent act (a breach of the standard of care); (3) the negligent act must have caused injury to the plaintiff–patient (proximate cause); and (4) that the patient must have sustained an injury. The physician–patient relationship may be direct or indirect. The relationship between a radiologist and the patient is most often indirect, as the patient often does not meet the radiologist personally. Except in unusual circumstances, 3 of these 4 elements (the physician–patient relationship, proximate cause, and patient injury) are not contentious issues in a lawsuit. The remaining allegation that must be proven for a plaintiff to succeed in a malpractice lawsuit, the one claiming that the defendant’s conduct has breached the standard of care, is the most frequently contested.34 If a breach of the standard of care is found, then the plaintiff must also prove that the breach shown by expert testimony was the proximate cause of the damages claimed by the plaintiff. Legal causation is divided into 2 categories: cause-in-fact and proximate cause. Cause-in-fact means that the injury would not have occurred “but for” the physician’s negligence. Proximate cause means that the physician’s negligence was a “substantial factor” in bringing about the patient’s injuries; however, it need not be the only cause. Expert testimony is also introduced to establish proximate cause.35 It is true that most of such adverse events in medicine are a result of medication errors, and most of them do not eventuate in malpractice suits. However, adverse events in radiology are commonly related to diagnostic errors, the evidence of which is enduring and often readily retrievable by reviewers. It is no wonder that even though only 4% of all medical practitioners are radiologists,36 they rank sixth among all specialties in the frequency of malpractice suits and sixth among 28 specialties in money paid either at settlement or by virtue of a jury verdict for the plaintiff.37 The presence of error is a necessary but not a sole requisite for the determination of negligence. Negligence occurs not when there is merely an error, but when the degree of error exceeds an acceptable norm.34

It is important to recognize the difference between adverse outcomes and malpractice. In both cases, patients and health professionals may suffer.38 There are a variety of ways in which health professionals may respond to such incidents. Common immediate responses include surprise, anger, guilt, and humiliation. With time, feelings of remorse and depression may supervene. As health professionals continue to practice, an accusation of malpractice may lead to increased fear of making mistakes; a loss of confidence in knowledge, skills, and judgment; and a variety of signs of stress, including difficulty sleeping and concentrating. In some cases, health professionals may experience a loss of fulfillment in the practice of medicine.38
Malpractice Issues in Radiology

In general, the radiologist is liable for all aspects of his practice, including decisions and actions, indications for a diagnostic or therapeutic procedure, information to the patients, instrumentation, and maintenance of his competence and continuous education. Additionally, legal issues may influence radiology in many ways, such as the business affairs of radiologists (employment contracts, hospital privileges, group relations, and bylaws) and the radiologist’s duty to perform to a standard of care.

The incidence of malpractice litigation, the types of errors that lead to it, and the steps radiologists can take to reduce them have been frequent topics of presentations at professional meetings, but the impact of accusations of malpractice on physicians is a subject that deserves renewed attention.

For example, even though at least 70% of malpractice actions are eventually dropped by the plaintiffs or dismissed, the mere fact of having been named in such a suit can provoke considerable shame and distress on the part of physicians and those around them. The percentage of medical malpractice lawsuits attributed to radiology is 5%-12%. These include improper performance, performing a study when contraindicated, failure to recognize a complication of treatment, and failure to supervise or monitor a case. In the context of contrast media for radiologic imaging, specific concerns might include the lack of informed consent, incorrectly selected contrast agents, improperly selected imaging studies, or failure to recognize and properly treat an adverse effect of the administered contrast.

Informing the patient of potential hazards and risks is an essential component of good patient care. For consent to be effective, the patient must have knowledge or be provided sufficient facts on which to base her or his decision to proceed. Informed consent from the patient remains an integral part of the communication between physicians and patients, and, importantly, is offering professional protection along these lines. In case of a complication, the lack of an informed consent may result in radiologist’s punishment from the court even if he did not commit a major error. Important aspects in the consent form taking process consist of the depth of the information that the radiologist should give to the patient. For performing interventional radiology procedures, consent must be obtained in a proper way and at least 24 hours before the procedure, but ideally, this should be undertaken at the time of the patient’s admission. Explanations given on the evening before the procedure is deemed to be too late, unless there is exceptional circumstances. The patient should be allowed enough time to decide or even to refuse the proposed therapy. The radiologist should spend more than half an hour to explain what he has scheduled to perform, the possible complications, the expected benefit to the patient from this procedure, and to convince why he has chosen this type of treatment compared with conventional surgery.

Communication failures are a prominent cause of action in medical malpractice litigation. There are different contributing factors in malpractice cases associated with communications failure (Table 1). In some cases, juries have broadened radiologists’ responsibility to notify reportable findings to include patients.

In addition to economic and social effects, malpractice lawsuits have often direct effects on a physician’s health. Litigation for alleged malpractice is often associated with feelings of guilt and isolation. Medical professionals who have committed a severe error are open to a reduction in quality of life and an increase in the frequency of burnout. Perceived stress is associated with an increase in the number of errors committed in the subsequent period, thus creating a vicious cycle whereby errors lead to stress, which in turn leads to new errors. Physicians may feel a sense of guilt resulting from the error and may fear suffering professional and economic consequences and being isolated by their own colleagues and clients.

Conclusions

Medical errors represent a serious public health problem and pose a threat to patient safety. Error is inevitable in medicine. However, awareness of the types of errors leads to an attempt at their prevention, which is a good clinical practice. To improve patient safety and reduce the risk from harm, we must accept that some errors are inevitable during the delivery of health care. Strategies must be developed to minimize these occurrences through forcing functions, reminders at the point of care for the individuals, and reduction of complexity for the organizations.

Table 1 Contributing Factors in Malpractice Cases Associated with Communications Failure

<table>
<thead>
<tr>
<th>Contributing Factors</th>
<th>Malpractice Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient did not receive results: no report or wrong report</td>
<td>Radiology</td>
</tr>
<tr>
<td>Clinician did not receive results: results filed before clinician review</td>
<td>Radiology</td>
</tr>
<tr>
<td>Clinician did not receive results: report went to wrong clinician</td>
<td>Radiology</td>
</tr>
<tr>
<td>Failure or delay in reporting findings or revised findings</td>
<td>Radiology</td>
</tr>
<tr>
<td>Turnaround time for results too long</td>
<td>Radiology</td>
</tr>
</tbody>
</table>

References
