Interventional radiology is an invasive specialty with the potential for errors as with other invasive specialties. A critical analysis of the different types of errors may help radiologist undertake the corrective measures. Standardize interventional procedures with protocols applicable to clinical practice are necessary to avoid the malpractice and, therefore, the related medical–legal issues. In this article, we present an overview of principal differences between errors and malpractice with particular regard to the issues in interventional radiology. Specific topics discussed in this article are the approaches to preventing errors and, thus, to avoiding the malpractice in interventional radiology.

Errors

“To Err is Human . . .”

An error is deviation from the expected norm, regardless of whether it results in any harm. It is frequently merely a symptom of a flawed underlying process that can be remedied.2 An adverse event is a harmful consequence, and it is categorized as a spectrum ranging from a near-miss experience to loss of a life.3

Individuals who make errors are not inherently less experienced, more careless, or less well trained than those who do not; indeed, the Institute of Medicine reported that 90% of medical errors result from systemic problems rather than individual factors.4

Errors will continue to occur unless the initial error is properly addressed and potential contributing factors from the individuals involved are addressed and resolved.

Classification

For a medical error, there must be a convergence of human factors (active failures) facilitated by a combination of predisposing factors (latent) failures.2 Classifying errors permits the development and implementation of detection and analysis systems to minimize the occurrence of errors or the degree of their resulting harm.3 A critical appraisal of the different types of error, also in radiology, may help practitioners undertake the essential corrective measures.6

Latent Failures

Latent failures represent predisposing conditions that enable an error to occur. Latent conditions (also learned-resident pathogens) possess 2 important properties: firstly, the effects usually are longer lasting than those created by active failures; and secondly, they are present within the system before an adverse event and can be detected and repaired before they cause harm. As such, they represent the primary targets of any safety management system.7 These factors are categorized as technical or system related.

Technical latent factors. Technical latent factors are particularly relevant in a radiology department and include these relating to:

- Equipment and engineering (construction and design flaws, ease of use);
- Departmental design;
● Workflow design;  
● Hardware;  
● Software;  
● Picture archiving and communication system and digital environment;  
● Materials and material management (contrast agents, devices);  
● Protocols;  
● Policies, rules, and regulations;  
● Routine maintenance of all systems involved;

System latent factors. System latent factors occur because of failures of a higher-level decision maker, managers, and maintenance personnel. Although remote from the error itself, system failures generally have substantial influence. They include, for example, duty hours, ergonomics, and departmental culture of safety and training.

Active Failures
Active failures include procedural complications or mistakes and diagnostic misses and misinterpretations. They are usually person-related, and their consequences are immediately felt. Human failures include the following:

● Slip errors: problem of attention  
● Lapses: mistakes related to memory  
● Rule-based mistakes: when a physician misapplies a good rule owing to failure to notice contraindications  
● Knowledge-based mistakes.

Communication Errors
Poor communication is at the heart of many medical errors. Communication errors in IR can be considered in 3 orders: with patient, with own team, and with referring clinicians. They include incomplete or inaccurate information, questionable consent of procedure and disclosure process, inadequate documentation, failure to ineffective performance of preprocedural “time-out,” and failure to transmit important or critical information between radiologist and clinician colleagues.

Moreover, in radiology communication, failures need not be limited to verbal interchange. They may be in written or electronic format with incorrect or inaccurate radiology reports, representing a large source of communication errors.

Sentinel Event A Sentinel Event (SE) 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.”

The terms SE and medical error are not synonymous; not all SE occur because of an error, and not all errors result in SE. Such events are called “sentinel” because they signal the need for immediate investigation and response.

Malpractice
“... Persevere is Diabolic”

A malpractice claim arises when a patient believes that improper medical care has resulted in bodily harm. The term malpractice is derived from Latin terms mala praxis, injuries caused by the neglect or unskillful management by physicians, which breaks the trust between patient and physician. The legal basis for professional liability is not well appreciated by many people, and therefore, there is confusion on the definition of negligence and malpractice. The legal standard for malpractice requires the following:

a. Physician/patient relationship that establishes the duty of care;  
b. An adverse outcome with actual injury or harm;  
c. Negligence by provider (often interpreted as failure to provide the standard of care); and  
d. Direct causality between negligence and outcome.

Thus, the basis of medical malpractice lawsuits includes negligence, its hybrid, res ipsa loquitur, and battery.

Negligence, the most common reason for alleging medical malpractice, may result in various types of injuries—physical, emotional, and/or familial. Under tort law, to prove a professional negligence claim, the plaintiff must show a breach of standard of care that proximately causes injury or damage.

The second basis for medical malpractice is res ipsa loquitur, which literally means “the thing speaks for itself.” Indeed, the presumption is that the error has been so obvious and egregious that the act speaks for itself.

The third legal theory, potentially the most problematic for the defendant physician, is a battery that consists of an unauthorized touching.

Legal action against physicians for presumed malpractice is an increasing problem in all countries and in all specialties, and the cost of compensation awards to patients is rapidly becoming prohibitive. As IR procedures grow in number, medical malpractice lawsuits and size of legal payments also may grow.

In a report from Italy, which analyzed the insurance claims of Italian radiologists during the 1993-2006 period, claims for radiologic techniques and procedures accounted for 11.5% of claims (164 cases), most of which (98 cases) involved interventional radiologic procedures.

The interventional radiologist is likely to become an increasingly frequent defendant by virtue of several factors: first, the surgical and procedural nature of IR; second, the sporadic complications that can occur; and finally, the possible unrealized expectations by patients and occasional need to alter initially planned therapy. The improvement of medical negligence actions is driving promising young radiologists away from IR because of its high risk of negligence claims.

The prevention of these problems may be primarily achieved by competency, which must be combined with
good liability insurance and ongoing vigilance supported by appropriate continuous medical education.

**Off-Label Use of Devices: An Example of Possible Malpractice in IR**

An off-label use or experimental use of devices without European Conformity marking may be malpractice, unless there is ethical committee approval and patient consent.\(^{20}\)

There are serious unexpected potential consequences of modifying medical devices, and physicians are warned by the Medicines and Healthcare products Regulatory Agency that when using devices off-label or after modification, users and patients are exposed to “unknown and therefore unacceptable risks with potential legal and ethical implications.”\(^{21}\)

Despite these warnings, many studies show that off-label use and device modification are common in IR.\(^{22}\) Smith and Berlin\(^{23}\) recommend that interventional radiologists should use medical devices off-label only for indications that are widely recognized in their specialty. Indeed, such off-label indications are commonly described in scientific journals or discussed at professional meetings, and the radiologist should gather data for gaining Food and Drug Administration or ethical committee approval and to thoroughly inform the patient; however, the practitioner must be familiar with the limitations of the product.

About this issue, the Society of Interventional Radiology (SIR) in 2007 affirmed “[...] SIR strongly supports the development of Level I evidence to support the use of devices and drugs in ‘off-label’ applications whenever possible, but does not consider the absence of this data a reason to restrict ‘off-label’ use when it is supported by lower levels of evidence, based on sound medical opinion, and, in the opinion of the physician, in the best interest of the patient.”\(^{24}\)

**Preventing Errors and Malpractice in IR**

Nothing (except abstinence usually), absolutely, prevents a lawsuit in radiology, much less in IR.\(^{16}\) Fortunately, with appropriate patient selection, preprocedural evaluation and postprocedural follow-up, errors in IR can be kept low and malpractice can be evaded.\(^{25}\)

**Root Cause Analysis (RCA)**

RCA is a relatively recent technique for evaluating adverse events and “close calls” that result from medical error. This powerful method allows for investigating and preventing medical errors.\(^{25}\)

RCA is based on an evolution of the Department of Veterans Affairs’ 1997 Patient Safety Improvement initiative, the aim of which was to prevent adverse events through understanding the underlying causes and using these to take corrective actions.\(^{26}\)

The focus is on not only the “what and how” of adverse events but also, most importantly, the “why.” An example of RCA, applicable in an IR suite, is that done by the American College of Radiology’s (ACR) Task Force on Patient Safety where preventable patient errors are identified that should be considered (Table 1).\(^{27}\) It colud be reported to departmental and institutional quality assurance committees and be in compliance with state and local law.

**Joint Commission Guidelines**

The purpose of this guideline is to outline an implementation of the Universal Protocol for prevention of wrong site, wrong procedure, wrong person surgery (WS) in an IR practice, providing standards for a safe, accurate, and consistent process for verifying the interventional procedure and, in particular, procedural site.\(^{28}\) The guideline stages are summarized as follows:

**Planning**

The planning stage consists of correct scheduling of the procedure. It also is important to have available previous radiologic studies of patient and, if it is possible, to annotate procedure site and side at the time of scheduling.

**Preprocedural Marking**

Joint Commission for surgery protocols recommends “A marker that is sufficiently permanent to remain visible [...] . It should be done prior to moving the patient into the room where the procedure will be done, if possible, with the involvement of the patient.”\(^{29}\) Preprocedural marking is only rarely required in IR procedures. Patient marking is necessary only when direct puncture into the area of interest is done based on external landmarks and there is a possibility for left/right or level errors.

The interventional radiologist or designee is responsible for insuring that the correct structure and side are identified in previous study.

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**Table 1 ACR Task Force on Patient Safety’s List of Preventable Medical Errors**

<table>
<thead>
<tr>
<th>Medical Error</th>
<th>Preventable Medical Errors</th>
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<tbody>
<tr>
<td>Misidentification/misadministration of patient</td>
<td>Wrong patient</td>
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<tr>
<td>Wrong procedure/examination/treatment</td>
<td>Wrong side for procedure/examination/treatment</td>
</tr>
<tr>
<td>Wrong side for procedure/treatment and labeling of laterality</td>
<td>Wrong contrast agent/dose</td>
</tr>
<tr>
<td>Alteration of medical records</td>
<td>Purposeful omission</td>
</tr>
<tr>
<td>Postevent alteration of medical records</td>
<td>Pencil entries/erasures/use of whiteout or post-its</td>
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<tr>
<td>Inadequate patient medical history</td>
<td>Inadequate patient medical history</td>
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<tr>
<td>Know pregnant patient or breastfeeding mother</td>
<td>Know important allergy</td>
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<tr>
<td>Know ferromagnetic risk</td>
<td>Know ferromagnetic risk</td>
</tr>
<tr>
<td>Radiation injury</td>
<td>Radiation injury</td>
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<tr>
<td>Use of unqualified/untrained personnel</td>
<td>Use of unqualified/untrained personnel</td>
</tr>
<tr>
<td>Use of known malfunctioning or uncalibrated equipment or patient support system</td>
<td>Use of known malfunctioning or uncalibrated equipment or patient support system</td>
</tr>
<tr>
<td>Lack of communication of emergent or significant findings</td>
<td>Lack of communication of emergent or significant findings</td>
</tr>
<tr>
<td>to referring physician or if necessary to the patient/guardian</td>
<td>to referring physician or if necessary to the patient/guardian</td>
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</table>
Time-out
Active communication among all members of the IR team is necessary to conduct a final verification of the correct patient, procedure, site, and, as applicable, implants/devices. It should be initiated by a designated member of the team, and the procedure should not begin until any questions or concerns are resolved.

Postprocedure
The interventional radiologist is responsible for making certain that procedure images are correctly labeled before being sent to a picture-archiving and communication system or other permanent storage medium to prevent future WS errors.

Emergency Procedure Exception
The policy may not apply in life-threatening emergency clinical situations at the discretion of the responsible physician because “none of these precautions should interfere with the timely care of the patient in an emergency situation.” However, the time-out to verify the correct patient, procedure, and site would still be appropriate.

Cardiovascular and Interventional Society of Europe Checklist
Recently, the World Health Organization produced a surgical safety checklist to decrease the morbidity and mortality associated with surgery. The advantage of also having a safety checklist for IR is that it ensures that human error will not occur in terms of forgetting key steps in patient preparation, intraprocedural care, and postoperative care.

Thus, the Cardiovascular and Interventional Society of Europe set up a task force to produce a checklist for IR. It is divided into 3 sections:

1. The first section is envisaged that this should be completed by the IR nurse/ward nurse. It contains important items, such as whether the patient is receiving anticoagulation medication, whether the patient is allergic to contrast material, and whether the patient has abnormal renal function requiring prophylaxis for contrast-induced nephropathy.

2. The second section of the checklist is a sign-in section, which can be completed by the IR resident, nurse, or staff interventional radiologist, and which deals with immediate checks that should be performed when the patient is in the IR room. These include items, such as checking that the person is the correct patient and that the correct side and site are being operated on.

3. The third section is entitled “Sign-out” and should be completed by the interventional radiologist who performed the procedure. The sign-out section encompasses patient orders, follow-up tests, and appointments made.

Informed Consent
Failure to provide adequate information to a patient and their relatives could expose a medical practitioner to action for negligence or assault. Therefore, informed consent from the patient remains an integral part of the communication between physicians and patients, and is important in offering professional protection.

The fundamental principle of consent states that patients should be given sufficient information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care.

It should include details of the proposed treatment, common and serious side effects, and the probability of success. Moreover, the patient should be made aware of alternative treatment options available. Finally, the necessary patient preparation for the treatment needs to be explained.

Radiologists must discuss their own procedures with patients; informed consent for radiological procedures cannot be left to clinicians. The person who performs the procedure or a suitable delegate should obtain the patient’s consent, preferably on the evening before the procedure, unless there are exceptional circumstances, and the patient should be allowed enough time to decide on or even to refuse the proposed therapy.

Conclusions
IR is an invasive specialty with as much potential for errors as with other invasive specialties. The existence of an error does not always translate into the presence of malpractice. A critical analysis of the different types of errors may help a radiologist undertake corrective measures and standardized interventional procedures with protocols, as applicable to clinical practice. This is necessary to avoid malpractice and, therefore, the related medical–legal issues. Informed consent and the overall communication with the patient must be an integral part of the standardized procedures.

References
1. Friedenberg RM. Malpractice reform. Radiology 231:3-6, 2004
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