Never Events in Radiology and Strategies to Reduce Preventable Serious Adverse Events

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The National Quality Forum was created in 1999 by public and private sector leaders after a commission empowered by President Clinton concluded that an organization was needed to ensure patient protections and health care quality through measurement and public reporting (1). The National Quality Forum’s measures and health care practices are considered the best evidence-based approaches to improving patient care.

The term never event in medicine was originally coined by Kenneth W. Kizer, MD, MPH, former chief executive officer of the National Quality Forum, to describe particularly shocking medical errors that should never occur, such as wrong-site surgery or death associated with introduction of a metallic object into the MRI area. With time, the list has been expanded to include adverse events that are unambiguous, serious, and usually preventable. In this article, the never event framework has been used to describe (a) the errors that may occur in an imaging department that are serious and usually preventable with a review of the causative factors and (b) strategies to eliminate and reduce the adverse effects of these avoidable errors. These errors are often rooted in communication breakdowns and can only be eliminated with a true shift to a culture of open reporting and patient safety.

Introduction

The National Quality Forum identified 27 never events, or “serious reportable events,” in 2002, and the list was expanded to 29 serious reportable events in 2011. These events are grouped into seven categories: surgical or procedural events, product or device events, patient protection events, care management events, environmental events, radiologic events, and criminal events (2). The one listed radiologic event is “death or serious injury of a patient or staff associated with introduction of a metallic object into the MRI area” (2).

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According to the sentinel event alert, the most common contributing factors with regard to falls pertain to (a) inadequate patient assessment; (b) communication failures; (c) lack of adherence to protocols and safety practices; (d) inadequate staff orientation, supervision, staffing levels, or skill mix; (e) deficiencies in the physical environment; and (f) a lack of leadership.

The purpose of this article is to use the never event model of the National Quality Forum to describe the preventable serious adverse events and the one listed never event that can occur within a radiology department, describe the prevalence and causes of these events, and discuss various tactics to prevent them. Examples of sentinel events that can occur in a radiology department have been described previously, along with an approach to manage these events when they do occur.

Death or Serious Injury of a Patient or Staff Associated with Introduction of a Metallic Object into the MRI Area

This event is the one radiologic event on the National Quality Forum’s list. Numerous incidents have been reported of projectile injuries related to MRI, including medical canisters, patient beds, chairs, and firearms being discharged. A more recent event in India resulted in the death of a patient’s relative who was carrying an unsafe metallic oxygen tank; the incident resulted in the arrest of the physician and a junior staff member for causing “death due to negligence”.

The MRI environment poses a risk to patients, accompanying visitors, health care professionals, security personnel, housekeeping staff, firefighters, and police. The American College of Radiology (ACR) last updated its “ACR Guidance Document on MR Safe Practices” in 2013, and this document establishes the industry standards for safe practices in use of MRI.

Departments must have a comprehensive MRI safety program, with an MRI medical director at each site. ACR accreditation requires an annual assessment of the safety program. Sites should have a process for reporting all MRI safety incidents and near misses. Clear delineation of the four zones of MRI safety helps ensure that only MRI-safe personnel and devices enter restricted areas.

Physical barriers at the entry to zone 4 can impede access to MRI equipment. Zone 4 should be clearly marked near its entrance with a sign stating “The Magnet Is ALWAYS On” or “Magnet in Use” to emphasize that the magnetic fields are constant. Non-MRI personnel working within zone 3 should undergo safety training. All non-MRI personnel who enter zone 3 or beyond must be screened each time they enter. All portable metallic or partially metallic devices that are external to the patient should be identified as MRI unsafe or MRI safe and labeled before zone 3 is entered.

At our institution, consecutive safety events caused primarily by nonradiology staff with MRI access led to a comprehensive review of our MRI safety policies. MRI had often been perceived as the “safe” imaging environment by non-MRI personnel owing to the lack of ionizing radiation and a general unfamiliarity with the full spectrum of MRI safety. A multidisciplinary task force was developed, which improved MRI safety by limiting the number of staff with access to MRI, developing new educational modules and training required for MRI access, and empowering MRI staff to fully enforce safety policies. A key component to the intervention involved the hiring of a staff member solely responsible for screening for MRI. A considerable amount of time was spent testing and ultimately purchasing a variety of types of safety equipment, including video cameras, screening devices, and barriers.

Diagnostic Imaging or Imaging-guided Procedure Performed on the Wrong Body Part or Wrong Patient

Imaging and imaging-guided procedures performed on the wrong body part or the wrong patient can be considered together, and these serious adverse events are most often rooted in
location are not considered unique identifiers, according to the Joint Commission guidelines.

Previously, groups of investigators have described an array of solutions to address this problem, including warning systems alerting readers to potential patient mismatch, use of photography to match patients to their examinations, and a two-person verification approach—all with varying degrees of success (15–17). In our institution, we have implemented a variety of interventions over time to combat these issues. Most recently, we began using checklists in high-risk imaging areas, such as critical care units with sedated patients, to ensure that all steps of the procedural pause and double identification are completed (Fig 4). We use stickers labeled right (R) and left (L) that are placed directly on the patient for all extremity imaging to minimize left- and right-sided errors (Fig 5). We have also implemented a policy whereby technologists can no longer hand off cases that have been initiated, to minimize errors associated with transitions of care. These errors are considered critical and are monitored quarterly through our department dashboard, with a review of all cases.

**Patient Death or Serious Injury Associated with a Medication Error**

An allergic-like reaction to modern iodinated contrast media is rare, with an incidence of allergic-like reactions of 0.6% and an incidence of severe reactions of 0.01% (18). For gadolinium-based contrast media, the incidence of an allergic-like reaction is 0.01%–0.22%, and the incidence of severe reactions is 0.008% (19). Although anaphylactoid-like reactions are extremely rare, they have been reported with nonvascular administration of iodinated contrast media during gastrointestinal imaging, cystography, sialography, and hysterosalpingography (20). Intravenous radioactive contrast agents are considered a high-alert medication by the Institute for Safe Medication Practices, suggesting a heightened risk of causing substantial patient harm (21).

Owing to their inclusion on this list, reactions to these intravenous radioactive contrast agents can be considered a sentinel event by The Joint Commission (22). The three most common categories of medication errors for physicians are wrong dose, wrong drug, and known patient allergy (23). These errors persist despite the growing role of computerized physician order entry (24).

The *ACR Manual on Contrast Media* addresses allergies to contrast media and has become the standard across radiology (25). Patients with a prior allergic-like reaction to a contrast medium have a fivefold increased risk of a future allergic-like reaction if exposed to the same contrast

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**Figure 1.** Photograph shows an example of a physical barrier used to demarcate zone 4 and prevent unmonitored access to the MRI equipment.

**Figure 2.** Photograph shows an example of the type of sign that should be placed at the entry to zone 4, emphasizing that the MRI magnet is always on.
medium (26). Patients with unrelated allergies, including allergies to shellfish and povidone-iodine (Betadine; Purdue Pharma, Stamford, Conn), have a two- to threefold increased risk of an allergic-like contrast media reaction; however, premedication is not warranted (27).

Before administering medications, patients should be identified by using two unique identifiers. When performing interventional procedures, medications should be labeled when transferred. All medication labels should be verified verbally and visually. At our institution, we rely on patient identification and allergy identification through the electronic medical record to minimize these errors.

Performance of an Imaging-guided Intervention without Satisfactory Completion of a Procedural Pause

In 2003, The Joint Commission made the elimination of wrong-site surgeries a national patient safety goal and adopted the Joint Commission “Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery” (13). These surgical events are considered sentinel events. The Joint Commission’s Universal Protocol requires three steps, consisting of the proper identification of the patient by the members of the team; marking of the surgical site; and a final time-out, or procedural pause, just before the surgery (28).

According to The Joint Commission’s Universal Protocol, a procedural pause, or time-out, must happen before invasive procedures performed by interventional radiology and other radiology divisions. A procedural pause is not required for routine diagnostic radiologic imaging. The Society for Interventional Radiology has issued guidelines addressing The Joint Commission’s Universal Protocol (29).

The procedural pause can be audited through retrospective chart reviews. Best practices suggest that the pause should be done close to the beginning of the procedure, should be performed by the responsible physician, and should actively involve all staff. Supporting documentation should be used, which in our institution involves the printed order sheet. One group of investigators found a 25% improvement in the safety climate in interventional radiology and a 4.5% improvement in mammography after implementation of The Joint Commission’s Universal Protocol (30).

Performing an Imaging Study in a Pregnant Patient without Appropriate Screening and Discussing Potential Risks and Benefits with the Patient

Management of potentially pregnant patients and the role of imaging require a discussion of risks and benefits with patients, radiologists, referring clinicians, and physicists. All patients who are
pregnant or could potentially be pregnant should be appropriately identified and screened before pertinent imaging examinations are performed. This topic is addressed in the “ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation” (31), which includes sample policies and screening forms. In the results of prior studies, investigators have found that 0.3% of female trauma patients were unknowingly pregnant and that 0.8% of pregnant female trauma patients discovered their pregnancy at CT examination in the setting of the emergency department (32,33).

The official ACR practice parameter recommends at least verbal screening for pregnancy before performing radiologic examinations of female patients 12–50 years of age (31). For procedures expected to deliver high doses to a conceptus, a pregnancy test should be obtained within 72 hours, unless prevented by medical necessity. These procedures should be documented in the facility’s policies. Screening may be unnecessary when the risk is negligible, such as with radiography of an extremity.

In the results of a study evaluating female patients aged 10–18 years with either leukemia or emergency department admissions, investigators found rates of screening ranging from 35% to 64% (34). At our institution, all inpatient and emergency department patients require screening through the electronic medical record. Outpatients are given a paper questionnaire, with 81.2% compliance during a sample period (J.A.F., unpublished data, April 2018). Compliance has been markedly improved with modifications in the form, clarifications of staff roles, and implementation of hard stops in the process.

Patient Death or Serious Injury Resulting from Failure to Follow Up or Communicate

Along with this type of event being considered a never event, there is a specific Joint Commission National Patient Safety Goal (NPSG.02.03.01) that says “Report critical results of tests and diagnostic procedures on a timely basis” (14). The Joint Commission requires documentation of written procedures for managing critical results, implementing procedures for managing these results, and evaluating the timeliness of reporting these results. “Write down and read back” is required. The 2014 “ACR Practice Parameter for Communication of Diagnostic Imaging Findings” provides nonspecific guidance stating that “in emergent or other nonroutine clinical situations, the interpreting physician should expedite the delivery of a diagnostic imaging report (preliminary or final) in a manner that reasonably ensures timely receipt of the findings” (35). The Massachusetts Coalition for the Prevention of Medical Errors had previously led an initiative targeting communication of critical test results and has provided a set of safe practice recommendations, along with a “starter set” of test results the group deems critical (36).
The ACR previously formed the ACR Actionable Reporting Work Group, which proposed three categories of findings that required non-routine communication (37). These categories were findings requiring communication within minutes, communication within hours, and communication within days. Development of a policy addressing these findings should include a list of critical findings, the timeliness and appropriate modes of delivery of results, an escalation process to ensure timely communication, and the required documentation of delivery of results. Multiple commercial options exist, with varying levels of automation, to address these results. Development of a successful departmental protocol will ultimately require the cooperation and participation of both the radiology department and the referring physicians to ensure that the process works for all relevant stakeholders (Fig 6). Communication tools embedded in the electronic health record or the picture archiving and communication system (PACS) may assist in this process and its subsequent documentation.

**Patient Death or Serious Injury Associated with a Fall while Being Cared for in a Health Care Setting**

Patient falls in the health care setting remain one of the never events listed under care management events. In 2015, The Joint Commission released “Sentinel Event Alert 55: Preventing Falls and Fall-related Injuries in Health Care Facilities” (38), which found that 30%–50% of falls result in injury, requiring 6.3 additional days of hospital stay, with an average cost of about $14000. Falls with serious injury remain among the top 10 sentinel events, with 465 reports from 2009 to 2015. Of those falls, approximately 63% resulted in death.

Many radiology departments have a predominant outpatient presence in which the risk of falling is less well known. In the results of one study from a large academic radiology department, investigators found an incidence of 0.46 falls per 10,000 examinations (39). Of the reported falls, 80% involved outpatients, and 6% of falls were reported in visitors. Eighty-five percent of the falls involved patients with at least one predisposing risk for falling, and 72% of falls occurred while the patient was standing or ambulating (39).

According to the sentinel event alert, the most common contributing factors with regard to falls pertain to (a) inadequate patient assessment; (b) communication failures; (c) lack of adherence to protocols and safety practices; (d) inadequate staff orientation, supervision, staffing levels, or skill mix; (e) deficiencies in the physical environment; and (f) a lack of leadership (38). According to reports from the Pennsylvania Patient Safety Authority, the themes that occurred in more than half of reported falls in the radiology department include syncope, slips, trips, loss of balance, falls from stretchers, and medication-related events (40).
The Joint Commission lists six specific actions to help prevent falls and fall-related injuries (38). These actions include (a) leading an effort to raise awareness of the need to prevent falls; (b) establishing an interdisciplinary falls injury prevention team; (c) using a standardized, validated tool to identify risk factors for falls; (d) developing an individualized plan of care that is based on identified fall and injury risks; (e) standardizing and applying practices and interventions demonstrated to be effective; and (f) conducting postfall management, which includes transparent reporting of these incidents (38). Many products are available to help reduce the risk of fall in these patients (Fig 7).

The same radiology department referenced previously (39) implemented an outpatient falls guideline to help identify at-risk patients (41). Overall, these investigators found approximately 25% of their patients to be at risk for falls. During the study, the investigators found an initial increase in reported falls, followed by a plateau, and ultimately a decrease in the rate of falls over time with implementation of this prevention program.

The rate of falls in our department is closely monitored through a quarterly run chart with analysis of all falls, with and without associated injury (Fig 8). We are currently in the process of implementing a risk assessment tool for falls, with altered imaging protocols for patients at risk for falls who cannot stand alone for imaging or need additional assistance.

Mislabling or Losing Specimens

Imaging-guided biopsies remain a core service provided by the radiology department. Specimen-labeling errors have been previously identified as a safety metric relevant to the radiology department and have garnered considerably more attention in the pathologic and surgical fields (42). Specimen-labeling errors may range from completely unlabeled specimens being submitted to errors in required specimen documentation, including patient identification, biopsy site, and laterality. In the results of one study involving an interventional radiology department, investigators found an overall specimen-labeling error rate of 4.2%, which decreased to 1% after multiple interventions (43). This finding is in line with published error rates for laboratory services, which range from 0.1% to 5% (44). It is likely that most of these labeling errors do not result in adverse patient outcomes, with harm only occurring in approximately 5%–10% of these cases. Of these specimen-labeling errors, 85% are detected before the specimen is run and results are released by the laboratory (45). All accredited laboratories should have a documented policy for handling specimens that do not meet satisfactory labeling requirements. Similarly, each radiology department should have a documented procedure for ensuring satisfactory labeling that meets their respective laboratory standards.

Many types of interventions can be implemented to address specimen-labeling errors in the radiology department. According to the Joint Commission requirements, patients must be identified by using two unique patient identifiers, such as name and date of birth, when collecting blood samples and other specimens. Sample containers must be labeled in the presence of the patient to decrease the risk of misidentification (46).
In our practice, we noticed that one individual section had a noticeably lower rate of specimen-labeling errors, compared with the rest of the department, and had not reported a single error during a 12-month period. The section had implemented a process to confirm proper labeling in which all specimen labels are confirmed by two staff members independently before submission to the pathology department. This process has been identified as a best practice and has subsequently been implemented across the department.

Death or Serious Injury of a Patient or Staff Member Resulting from a Physical Assault within or on the Grounds of a Health Care Facility

Violence in the work environment can cover a wide variety of activities, including physical abuse. Previously, some of this violent behavior might have been accepted as being “part of the job”; however, now there is much less tolerance for bad behavior against the health care team (47). Violence can involve staff, patients, visitors, or intruders. Although incidents are reported, the true prevalence and spectrum of this problem are not well known (8). In the results of one study in Italy, investigators found that 6.8% of radiologists in public hospitals experience some physical abuse during a 12-month period, either from patients or their colleagues (49). Investigators in Hong Kong found that 61% of radiographers had experienced violence during a 3-year period, most commonly in the emergency department (50).

To prevent and manage potential workplace violence, each department should have a written violence prevention plan, which may play an important role in reducing the severity of injuries sustained in these attacks. Most important, these plans should state that violence will not be tolerated and that there will be no reprisals against employees who report or experience violence, and the plans should encourage prompt reporting of all violent incidents. Adequate staffing should be ensured at all times to minimize the risk to individual staff members. Finally, appropriate engineering controls should be used to provide security, including concealed panic buttons in the clinical area, improved lighting and video surveillance, and use of an escort or buddy system when dealing with a high-risk patient (51) (Fig 9).

The Joint Commission Environment of Care Standards require that accredited hospitals establish procedures for identification and management of safety and security risks, including workplace violence, to safeguard patients, visitors, and staff (52). The Joint Commission Sentinel Alert 45, dated June 3, 2010, and updated in 2017, recommended 13 action items to prevent rape, assault, and homicide (53). The Joint Commission also has a dedicated portal for “Workplace Violence Prevention Resources for Health Care,” with numerous additional resources (54).

Conclusion

The term never events describes those medical errors that are serious and should never occur. This model provides an excellent framework to assess errors in an imaging department. Ultimately, communication breakdowns are responsible for about two-thirds of Joint Commission sentinel events and a large portion of these never events (55). Process improvement strategies to prevent and eventually eliminate these errors will ultimately require a commitment to improving communication and establishing a generalized culture of patient safety.

References


