Review

Dana Siegal*, Lindsay M. Stratchko and Courtney DeRoo

The role of radiology in diagnostic error: a medical malpractice claims review

DOI 10.1515/dx-2017-0025
Received April 12, 2017; accepted June 8, 2017

Abstract: Just as radiologic studies allow us to see past the surface to the vulnerable and broken parts of the human body, medical malpractice claims help us see past the surface of medical errors to the deeper vulnerabilities and potentially broken aspects of our healthcare delivery system. And just as the insights we gain through radiologic studies provide focus for a treatment plan for healing, so too can the analysis of malpractice claims provide insights to improve the delivery of safe patient care. We review 1325 coded claims where Radiology was the primary service provider to better understand the problems leading to patient harm, and the opportunities most likely to improve diagnostic care in the future.

Keywords: diagnostic error; malpractice claims; radiology.

Overview

The medical diagnostic process involves a complex network of interactions between the patient and the healthcare system. This process is also dynamic, requiring one or more cycles of patient interaction, information-gathering and data synthesis in order to understand the intricacies of each patient's clinical picture and pathology. Failures can occur at any point along the continuum of care, each of which has the potential to result in inaccurate or delayed diagnosis as well as inappropriate treatment. While radiology typically does not play the initial role in the diagnostic process, misinterpretation or delayed communication of imaging findings can certainly lead to a breakdown in the progression towards clarity of diagnosis and appropriate patient care.

Analysis of the CRICO Comparative Benchmarking System (CBS) determined that 29,777 medical malpractice cases, asserted between 2010 and 2014, had completed an in-depth review by CRICO's team of Clinical Taxonomy Specialists. Reviewing the medical and legal files of each of these cases, an experienced clinician used CRICO's propriety coding taxonomy to capture and code multiple case attributes including allegation, patient demographics, diagnosis and injury, location, tests and services, and the key causation factors contributing to the clinical error or failure.

Of the 29,777 medical malpractice cases available for analysis, 1325 cases named Radiology as the Primary Responsible Service – 42% resulted in high severity (based on National Associationn of Insurance Commissioners clinical injury severity score) clinical injuries including 235 deaths (Figure 1). Diagnostic related events represent nearly 60% of the 1325 radiology claims, followed by procedural issues (22%), equipment issues, (7%) and falls and safety issues (6%). In those cases involving diagnostic radiology, nearly 50% of the cases involved one of these four modalities: computed tomography (CT) scans (20%), mammography (11%), magnetic resonance imaging (MRI) (10%) and diagnostic ultrasound (4%). Cases occurred in a variety of settings though ambulatory cases were the most common at 63% followed by inpatient (26%) and emergency department (11%).

In many cases, Radiology is not the only clinical service identified as "responsible" or contributing to the error or series of errors that led to the claim. Given the complexities of the care process, and the number of providers involved in a patient's care, the coding taxonomy used to classify this data allows for the identification of a primary responsible service, as well as any additional (secondary) services that were determined to have contributed to the series of events that led to the medical error or patient harm. While it is easy to understand that many of these cases are driven by communication gaps between provider services, many reflect interpretation issues, complicated by clinical and communication failures of additional providers involved in the care. Detailed review of the clinical and legal facts of each claim allows for the

***Corresponding author: Dana Siegal,** RN CPHRM CPPS, CRICO Strategies, CRICO of the Harvard Medical Institutes, 1325 Boylston Street, Boston, MA, USA, O 617.450.5552,
E-mail: dsiegal@rmf.harvard.edu
Lindsay M. Stratchko: Penn State Milton S. Hershey Medical Center, Hershey, PA, USA, E-mail: lstratchko1@pennstatehealth.psu.edu
Courtney DeRoo: CRICO/Risk Management Foundation of the Harvard Medical Institutions, Boston, MA, USA,
E-mail: cderoo@rmf.harvard.edu

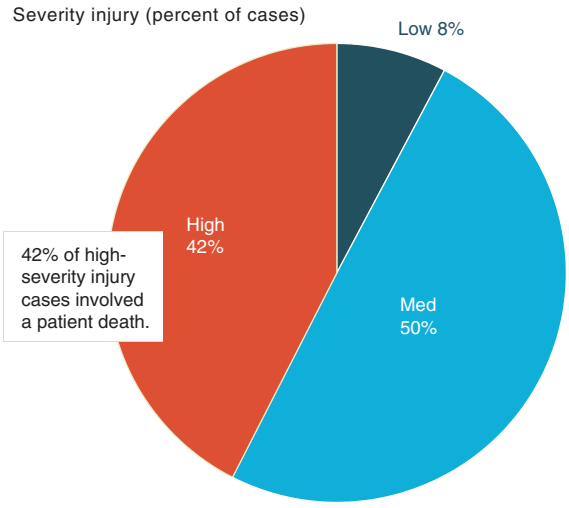


Figure 1: Distribution of radiology events by injury severity. CBS n = 1325 MPL cases asserted 1/1/10–12/31/14 with radiology as the primary responsible service; $263M total incurred losses. Severity scale: High = death, permanent grave, permanent major, or permanent significant; Medium = permanent minor, temporary major, or temporary minor; Low = temporary insignificant, emotional only, or legal issue only.

identification of and distinction between primary and secondary contributors in each case.

In the 1325 cases where Radiology is identified as the primary responsible service, 572 cases noted a secondary responsible service, most frequently Emergency Medicine (150 cases), and General Internal Medicine (122 cases).

While the main focus of this study is the 1325 cases where Radiology is the primary responsible service, it bears noting that of the 29,777 cases in the main study group, Radiology was identified as a secondary provider in an additional 724 cases. In these cases, Emergency Medicine and General Medicine are again the most frequently co-named service, though in these cases they were determined to be the primary responsible service.

While Radiology is not the largest clinical service contributing to cases with a diagnostic-related allegation, there is much to be gained by understanding how radiology events contribute to diagnostic failures. More importantly, this understanding can provide a road map to mitigating risk – to providers and patients – in radiological care, thus supporting our overall efforts in improving diagnostic medicine.

Background

CRICO Strategies, a division of CRICO, the malpractice captive insurer of the Harvard Medical Institutions, has partnered with captive and commercial insurers across the country to create a national database of medical malpractice claims for the purpose of studying and reporting on medical error. Containing nearly 400,000 malpractice cases, this robust database, known as the Comparative Benchmarking System (CBS) represents more than 400 healthcare entities and 165,000 insured providers, and includes inpatient and outpatient claims from both academic and community organizations across the country. Though a malpractice case may have multiple defendants (and thus multiple claims), the clinical events in this database are reviewed, categorized and reported at the case level, and are defined by the individual event (or series of events) and/or patient outcome that triggered the claim(s).

Each case is reviewed by an experienced clinician, who captures data from medical and legal files using a multi-tiered coding taxonomy with hundreds of data elements including allegation or case type, responsible service, and contributing factors that categorize and trend the key clinical drivers of medical error and malpractice claims. With extensive data management, auditing and governance, the taxonomy – first developed by CRICO more than 40 years ago as the foundation of its own medical management and patient safety programs – captures ongoing, new and emerging trends in clinical vulnerabilities, patient harm and financial outcomes. The individual and comparative analyses drawn from these data allow organizations to identify key issues driving errors and claims in their organizations, benchmark against “like peers”, and determine where to focus human and financial resources to improve provider and patient safety throughout their organizations.

Findings

Interpretation of diagnostic studies

Of the 1325 cases in this analysis that named Radiology as the Primary Responsible Service, nearly 60% (766) were directly related to an allegation of diagnostic failure (see Figure 2). Analysis of the specific issues in these cases revealed that 48% of these cases involved a misinterpretation of a diagnostic study that led to a delay in the (correct) diagnosis and/or treatment of the patient’s condition. Of those cases classified as a misinterpretation of a diagnostic study (see Figure 3), primary malignancies and/or metastases were the most commonly missed diagnoses, with breast and lung cancer representing the most common case types. Of the 89 cases with a failed diagnosis of breast cancer, 76 involved a mammography study.

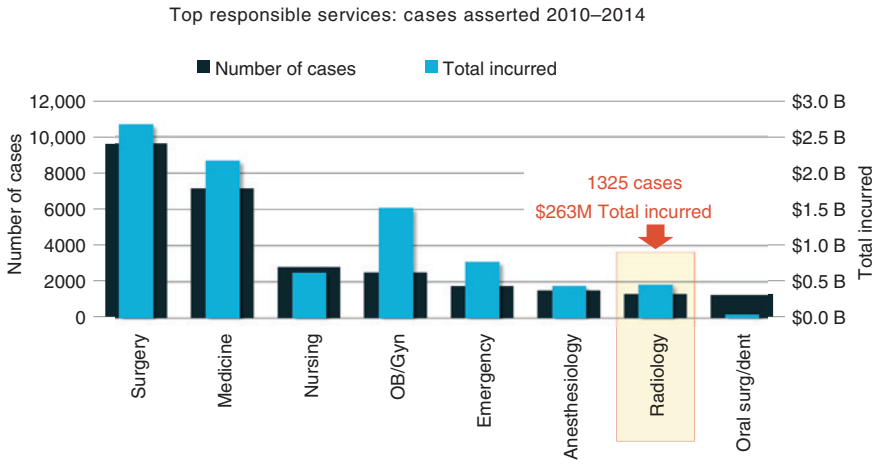


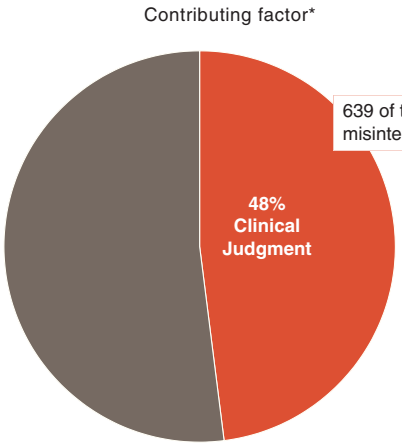
Figure 2: Distribution of top service categories in MPL claims by volume and dollars.
CBS n = 29,777 MPL cases asserted 1/1/10–12/31/14; $5.7B total incurred losses. Total incurred includes reserves on open and payments on closed cases. Surgery includes general surgery and all surgical sub-specialties. Medicine includes general medicine and all medicine sub-specialties.

Radiology-related Allegations	# Cases	Total incurred
1. Diagnosis-related	766	$202,714,000
Cognitive/clinical judgment (interpretation)		
Communication (to and from, providers & patients)		
2. Medical treatment	287	$40,880,000
Improper performance of tx/procedure		
Improper management of treatment course		
Retained foreign body		
3. Equipment-related	90	$3,609,000
Improper inspection/maintenance		
Equipment malfunction/failure (inc. user error)		
4. Safety & Security	75	$2,844,000
Fail to ensure safety, falls		
Fail to ensure safety, other injury during care		

Figure 3: Distribution of radiology events by top allegation.
CBS n = 1325 MPL cases asserted 1/1/10–12/31/14 with radiology as the primary responsible service; $263M total incurred losses. Total incurred includes reserves on open and payments on closed cases.

In 47 cases involving lung cancer, 30 of them involved routine chest radiographs. The second largest category of cases with a misinterpretation factor (see Figure 4), involve fractures, with routine radiography the primary modality. Specific examples include:

- Failure to properly interpret a mammogram resulted in a 2 year delay in diagnosing invasive ductal breast cancer with subsequent metastases and patient death.
- Misread CT resulted in a 22-month delay in diagnosing lung cancer with poor prognosis.
- Failure to diagnose multiple dislocations associated with carpal-metacarpal fractures (dorsal dislocations 2nd through 5th digits right hand) resulted in multiple unsuccessful surgical repairs and permanent loss of function.
- Failure to properly interpret CT scan (spine) resulted in delayed diagnosis of cervical fracture/cord compression and paralysis.
- Misinterpretation of CT scan (head) resulted in delayed diagnosis of subdural hematoma and death.



Misinterpretation of diagnostic studies (639 cases)	
Top procedures	% Cases
CT scan (abd, head, chest)	18%
Diagnostic radiology (e.g., CXR)	13%
Mammography	10%
MRI	10%
Diagnostic ultrasound	3%

Figure 4: Clinical judgement issues in radiology cases.
*A case will often have multiple factors identified. CBS n = 1325 MPL cases asserted 1/1/10–12/31/14 with radiology as the primary responsible service; $263M total incurred losses.

Communication of test results

The Institute of Medicine (IOM) report *Improving Diagnosis in Health Care*, published September 22, 2015, offers a new definition of diagnostic failure that includes not only "(a) the failure to establish an accurate and timely explanation of the patient's health problem(s)", but also "(b); the failure to communicate that explanation to the patient" [1].

Data from this study demonstrates that communication failures were noted in 23% of the radiology cases (see Figure 5). Of those, communication to the ordering provider accounted for 13% of the cases while communication to the patient was noted as a contributing factor in 10%. Specific examples include:

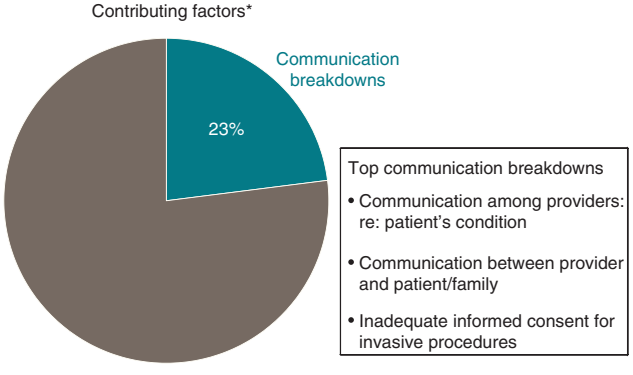


Figure 5: Communication issues in radiology.
*A case will often have multiple factors identified. CBS n = 1325 MPL cases asserted 1/1/10–12/31/14 with radiology as the primary responsible service; $263M total incurred losses.

- Failure to communicate critical over-read of a neck radiograph, first read (by a resident) as mild swelling, but follow-up read found significant potential for airway obstruction. While the over-read was documented, its urgency was not verbally reported per the "critical result" process. The patient returned to the ED in full respiratory arrest and died of a vascular rupture before the updated report was communicated to the patient
- Failure to properly document (thus notify the ordering provider of) an incidental finding of small pulmonary nodule with recommendation for follow-up. The requested study for rib pain was negative, however, the radiologist did not mark the "abnormal result" box as a variance in the medical record, so the primary care provider was unaware of the positive finding and recommendation that should have been relayed to the patient. Three years later the patient was diagnosed with bronchogenic carcinoma with poor prognosis.

The IOM report on diagnostic error

The IOM report on diagnosis notes in Recommendation 4 that, "Health care organizations should monitor the diagnostic process and identify, learn from, and reduce diagnostic errors and near misses….and implement procedures and practices to provide systematic feedback on diagnostic performance to individual health care professionals, care teams and clinical and organizational leaders" [1]. Additionally, recommendation 6D notes, "Professional liability insurance carriers and

captive insurers should collaborate with health care professionals on opportunities to improve diagnostic performance through education, training, and practice improvement approaches and increase participation in such programs" [1]. By analyzing Medical Professional Liability (MPL) claims, we can learn from the specific patterns and trends that contribute to diagnostic failure thus appropriately allocating resources and implementing targeted interventions that address those specific issues.

Given the influential role of radiology in the diagnostic process, it is imperative to monitor the practice and provide feedback from radiologic events including what is learned from MPL claims. While issues of competencies in reading and interpreting studies may be a focus within the service of radiology, the issues of communication require much broader solutions across the healthcare team. However, the unifying issue in addressing both of these problems is raising awareness of the specific vulnerabilities that put our staff, our providers and our patients at risk. Sharing this, and similar data reports, analyses and case studies, is critical to helping providers understand the most vulnerable processes and diagnoses in hopes of increasing awareness and vigilance in these trending errors.

Radiology interpretation errors

Radiology, like all fields of medicine, requires a commitment to continued education and practice improvement. While many practice environments are unique, there are several commonalities that can be focused upon, starting with residency training. The Accreditation Council for Graduate Medical Education (ACGME) program requirements for graduate medical education necessitates a board certified radiologist to review images and sign all resident-generated reports [2]. This process not only facilitates resident education, it also aims to provide an additional level of security by allowing multiple providers the opportunity to evaluate images. Similarly, some practices allow non-radiologists to interpret imaging studies. Multiple studies have reported a broad range of discrepancy rates between radiologists and non-radiologists, however, of the noted discrepancies, many fell into categories our review found to be high-litigation diagnoses such as missed fractures and pulmonary nodules or malignancies [3–6]. It is our goal to improve prompt identification of these important findings by recommending the adoption of comparable review processes whereby a radiologist "over-reads" imaging studies initially interpreted by non-radiologists.

Peer review

It is equally as important for radiology practices to internally adopt established peer review and audit procedures to detect trends and help identify opportunities to support radiologist education if unfavorable variability is encountered [7]. This recommendation aims to help reduce one of the most significant barriers of practice-based continued learning in radiology, which is inconsistent and often delayed feedback on reported findings. Continued learning and practice improvement through peer review and audit systems intend to enhance the diagnostic process with the ultimate objective to provide appropriate and timely patient care.

In addition to introspectively analyzing individual practice trends, increasing awareness of reported regional and/or national data is useful in identifying larger scale tendencies and potential vulnerabilities towards diagnostic error [8]. By bringing light to these areas, radiologists can use this information to refine image interpretation and improve patient diagnosis. For example, our review identified missed breast cancers as one of the most common diagnostic-related allegations. As anticipated, the majority of these missed cancers involved mammography, however, in a small number of cases of the unidentified breast cancer cases were missed on chest CT examinations. This finding brings light to the importance of being vigilant in the evaluation of anatomy outside the primary area of interest on imaging studies, such as the subcutaneous tissues on a chest CT where the anatomy of interest typically includes the cardiovascular and respiratory systems.

Communication errors

While the accurate interpretation of radiologic studies is key to diagnostic safety, communication of diagnostic results to the ordering provider and ultimately to the patient is equally as important. As previously noted, the IOM report on Improving Diagnosis in Health Care creates an imperative to address the communication aspects of test result management [1]. Despite the fact that our claims analysis cited communication errors less frequently than failures in diagnosis, policy improvement targeting flaws in this process has the ability to produce widespread and measurable change [9]. This can be achieved by implementing clear and well-communicated processes defining the methods and accountability for information transfer between radiologists, clinicians and patients [10].

Due to inherent differences in practice environments, unique policies may be required to suit the demands and optimize the resources of specific care settings. For example, incidental imaging findings encountered in the emergency department setting are at risk for delayed or failed follow-up for a variety of reasons, some of which include discontinuity of care and limited availability of diagnostic reports and patient records [11].

In response to this problem, Dutta et al. [12], researched the use of natural language process algorithms to incorporate additional imaging recommendations into emergency department discharge summaries. In other settings, the process of how the incidental findings are documented is a key contributor to the communication failure. Aware that clinicians reading reports may not always look beyond the result that prompted the order, some organizations have reconfigured their radiology reports to provide a more prominent display of the incidental finding. Solutions such as these align with the IOM goal to "develop and implement processes to ensure effective and timely communication between diagnostic testing health care professionals and treating health care professionals across all health care delivery settings" [1].

Practice standards and guidelines

The American College of Radiology (ACR) has established practice parameters regarding routine and nonroutine communication of imaging findings to ordering providers. When unexpected findings are encountered by the radiologist, these discoveries should be relayed to the referring clinician in a timely fashion. The practice parameter cites several situations that warrant nonroutine communication between the ordering and interpreting physicians. These conditions include findings that may require immediate or urgent intervention, conclusions that differ significantly from a preliminary report, and findings the interpreting physician feels may result in serious adverse outcomes or may worsen over time if untreated [13]. All nonroutine findings are not explicitly detailed in the practice parameter as some may be specific to certain scenarios or patient populations. It is essential for practices to define their expectations for urgent and non-routine communication to help ensure prompt and appropriate patient care [14]. Our analysis identified the outpatient setting as particularly vulnerable with missed or delayed cancer diagnoses leading to the highest number of cases resulting in severe disability and patient death. While a new diagnosis of malignancy often does not require emergent intervention, it is vital these patients be identified and integrated into a proper treatment plan as there is a greater potential for delayed management compared to a disease process with higher acuity that will result in more prompt patient return to medical care. The radiologist can help play an initial role in ensuring and expediting patient management in new cancer diagnoses by directly communicating these findings to the referring clinician.

Discrepancies between initial and final Radiology reports

Discrepancies in reported imaging findings can pose a challenge if treatment has been implemented based upon an initial radiologic interpretation that is later revised. It is the radiologist's responsibility to inform the ordering provider if there is a significant change in imaging findings from the preliminary report. Likewise, procedures must be in place to ensure the ordering physician receives the finalized radiology report. In cases where the ordering physician may not provide long-term patient care, particularly in the Emergency Department setting, it is important that policies necessitating follow-up of discordant imaging findings are routinely followed.

Conclusions

Through claims analysis, we can identify areas to improve the medical diagnostic process. Interpretation errors and failures of provider communication are two of the largest areas of litigation involving radiologists and through implementing organized and accountable processes to target these weaknesses, radiologists can play a vital role in facilitating optimal patient care.

Author contributions: All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission.
Research funding: None declared.
Employment or leadership: None declared.
Honorarium: None declared.
Competing interests: The funding organization(s) played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication.

References

1. Balogh E, Bryan M, John B, editors. Improving diagnosis in health care. Wachington, DC: National Academies, 2015.
2. ACGME Program Requirements for Graduate Medical Education in Diagnostic Radiology. Accreditation Council for Graduate Medical Education: Radiology. N.p., 1 July 2016.
3. Petinaux B, Bhat R, Boniface K, Aristizabal J. Accuracy of radiographic readings in the emergency department. Am J Emerg Med 2011;29:18–25.
4. Nitowski LA, O'Connor RE, Reese CL. The rate of clinically significant plain radiograph misinterpretation by faculty in an emergency medicine residency program. Acad Emerg Med 1996;3:782–9.
5. Gatt ME. Chest radiographs in the emergency department: is the radiologist really necessary? Postgrad Med J 2003;79:214–7.
6. Espinosa JA. Reducing errors made by emergency physicians in interpreting radiographs: longitudinal study. Br Med J 2000;320:737–40.
7. Pinto A, Caranci F, Romano L, Carrafiello G, Fonio P, Brunese L. Learning from errors in radiology: a comprehensive review. Semin Ultrasound CT MRI 2012;33:379–82.
8. Whang JS, Baker SR, Patel R, Luk L, Castro A. The causes of medical malpractice suits against radiologists in the United States. Radiology 2013;266:548–4.
9. Dibble EH, Swenson DW, Cobb C, Paul TJ, Karn AE, Portelli DC, et al. The RADCAT-3 system for closing the loop on important non-urgent radiology findings: a multidisciplinary system-wide approach. Emerg Radiol 2016;24:119–25.
10. Larson DB, Froehle CM, Johnson ND, Towbin AJ. Communication in diagnostic radiology: meeting the challenges of complexity. Am J Roentgenol 2014;203:957–64.
11. Pons E, Braun LM, Hunink MG, Kors JA. Natural language processing in radiology: a systematic review. Radiology 2016;279:329–43.
12. Dutta S, Long WJ, Brown DF, Reisner AT. Automated detection using natural language processing of radiologists recommendations for additional imaging of incidental findings. Ann Emerg Med 2013;62:162–9.
13. ACR Practice Parameter for Communication of Diagnostic Imaging Findings. The American College of Radiology. N.p., 2011.
14. Berlin L. Failure of radiologic communication: an increasing cause of malpractice litigation and harm to patients. Appl Radiol 2010;39.