Investigating Errors in Medical Imaging: Lessons for Practice From Medicolegal Closed Claims

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Abstract

Purpose: Radiology has lagged behind other disciplines in using medicolegal data to improve patient safety. The aim of this study was to characterize a sample of closed claims files to inform radiology practice and identify opportunities for system change.

Methods: A retrospective analysis of 443 medicolegal closed claims provided to the Radiology Events Register. Data were provided by 2 medical defense organizations that provide medical indemnity insurance to Australian private practitioners. We calculated a procedural risk ratio (prevalence in the closed claims dataset divided by prevalence among all diagnostic imaging procedures reimbursed by the Australian Government over the corresponding timeframe) for each modality (CT, ultrasound, radiography, MRI, nuclear medicine) and some procedures. For each closed claim, the incident type was determined, and a classification of 12 patient safety fields was conducted.

Results: Misdiagnosis (delay or failure to correctly read imaging) accounted for 62% of error types. Modalities and procedures at higher risk of leading to a claim were: mammography (risk ratio [RR] = 4.0, 95% CI 2.9-5.5); breast ultrasound (RR = 2.8, 95% CI 1.7-4.7); total MRI (RR = 3.4, 95% CI 2.0-5.6); total CT (RR = 1.9, 95% CI 1.5-2.5), and obstetrics and gynecology ultrasound (RR = 1.9, 95% CI 1.4-2.4). Lower-risk modalities and procedures were: cardiac ultrasound (RR = 0.1, 95% CI 0.0-0.8); radiography extremities (RR = 0.7, 95% CI 0.5-0.9); and total radiography (RR = 0.8, 95% CI 0.7-0.9). Information to inform patient safety classification was limited, with a mean of 5.8 ± 1.8 (SD) fields available.

Conclusions: Despite its limitations, medicolegal data deserve further attention from patient safety analysts.

Key Words: Closed claims, Radiology Events Register, patient safety, medical imaging, adverse events

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INTRODUCTION

Inadvertent health care—associated harm is the daily work of medical defense organizations (MDOs). Closed claims review (CCR), like large-scale incident reporting systems, may be helpful for providing information on rare events that are not easily detectable by routine reviews or observation [1]. Analyses of closed claims can provide useful

information about the types of patients, conditions, and imaging modalities and tests that most often result in litigation. In turn, this information can inform areas of clinical practice in which new or revised standards or systems could result in reductions in error, patient harm, and litigation.

Claims provide 1 perspective on the many-faceted problems that manifest as near misses, adverse events, and sentinel events for patients. Cheney [2] reflected on the benefits of CCR for anesthesia events and concluded that: "Closed claims data can reveal important and previously unappreciated aspects of adverse...outcomes. These insights can be used to formulate hypotheses aimed at improving the quality of...care, thus providing a tool for advancing patient safety and reducing liability exposure...."

Material provided by MDOs tends to emphasize actual diagnostic and procedural error, rather than the many near misses that occur at all points in the episode of

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care, beginning with referral for imaging [3]. This focus can lead to a narrow perspective on the contributors to an error, and limit our ability to use this information to change practice [4]. Medical negligence claims are biased by the likelihood of a successful claim, as well as the magnitude of the anticipated financial rewards from litigation. They therefore represent only part of the spectrum of incidents that may harm patients.

In addition, because data contributed by MDOs have been collected for reasons other than to inform quality improvement or system redesign, they have inherent limitations that can prevent contributors to error from being understood or even identified [5]. Other limitations to claims data include lack of denominator, bias toward severe injury cases, problems in reliability of judgments, outcome and hindsight bias, and unrepresentativeness [1].

Previous studies of CCRs have concentrated on anesthesiology, and to a lesser extent, surgery, medicine, obstetrics, primary care, and mental health [1,6,7]. No study has been previously published on a CCR in medical imaging in Australia. Internationally published studies of CCRs in medical imaging have not focused on what closed claims can teach us about systems changes, as a means to improve patient safety [8-10].

Given the known limitations and benefits of claims data, Vincent et al [1] proposed a set of basic criteria for the methodology of CCR. These criteria include prospective identification of the relevant questions and variables, adequacy and completeness of the dataset, availability of expert reviewers, use of a central database with clinical expertise for maintaining quality control, and clear protocols for review. The aim of the current study was to use these criteria as the basis of a CCR in medical imaging to: (1) determine error types and imaging modalities; (2) compare the proportion of modalities and specific procedures in the MDO data with total services billed to Medicare Australia; and (3) evaluate whether MDO data can inform understanding and systems changes (ie, mitigation and prevention strategies) related to patient safety for clinical practice.

METHODS

Study Design and Setting

Ethics approval for this study was provided by the South Australian Department of Health Human Research Ethics Committee (276/01/2012). As part of the Radiology Events Register (RaER, www.raer.org.au), in 2008, two Australian MDOs provided a total of 443 medical

imaging—related closed claims. The RaER database was established in 2006, as a means for Australian and New Zealand radiologists to report adverse events and near misses for quality improvement purposes. The RaER is operated and managed by the Australian Patient Safety Foundation and owned by the Royal Australian and New Zealand College of Radiologists. Closed claims data entered in the RaER were the sole source of claims data for this study. The authors had full access to all data relating to this study.

Inclusion and Exclusion Criteria

The closed claims data were first analyzed to establish that they related to medical imaging and that related patient harm was the reason for the claim. Claims were excluded if either condition was not met. Duplicate entries of the same claim were excluded.

Principal Natural Category, Modality, and Procedure Analysis

An investigator (TS) with 7 years of experience in patient safety research iteratively classified the claims data according to principal natural categories (PNCs), using a previously validated method [11]. A PNC represents a grouping of similar error types. A single claim might have >1 PNC; when this occurred, the claim was reviewed by 2 investigators, a practicing radiologist (SG) with >25 years of experience, and a trained patient safety incident coder (AD) with >10 years of experience; a consensus decision was reached. Additionally, the radiologist determined the imaging modality and type of procedure for each claim.

The Medicare Australia system for items in the Diagnostic Imaging Services Table was used as the basis for the classification of modality and procedure type [12]. The Medicare Benefits Schedule (MBS) [12] is a searchable database of all Medicare services that have been subsidized by the Australian Government since 1993. Medicare Australia defines a diagnostic imaging procedure as [12] "a procedure for the production of images (for example x-rays, computerised tomography scans, ultrasound scans, magnetic resonance imaging scans and nuclear scans) for use in the rendering of diagnostic imaging services." Only "clinically relevant" services (generally accepted in the profession as being necessary for the appropriate management of a patient) rendered by an appropriate health practitioner may be listed in the Schedule.

Based on the same Medicare Australia classification [12], the database was searched to obtain the total number of services undertaken during the period in

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