ORIGINAL ARTICLE

Auditing an Online Self-reported Interventional Radiology Adverse Event Database for Compliance and Accuracy

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Abstract

The purpose of this study was to determine whether auditing an online self-reported interventional radiology quality assurance database improves compliance with record entry or improves the accuracy of adverse event (AE) reporting and grading. Physicians were trained in using the database before the study began. An audit of all database entries for the first 3 months, or the first quarter, was performed, at which point physicians were informed of the audit process; entries for the subsequent 3 months, or the second quarter, were again audited. Results between quarters were compared. Compliance with record entry improved from the first to second quarter, but reminders were necessary to ensure 100% compliance with record entry. Knowledge of the audit process did not significantly improve self-reporting of AE or accuracy of AE grading. However, auditing significantly changed the final AE reporting rates and grades.

Key Words: Quality assurance, quality improvement, adverse events, interventional radiology

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INTRODUCTION

Estimates from *To Err is Human* show that more than 1 million preventable adverse events (AE) occur annually in the delivery of health care [1]. One of the recommended strategies for reducing AE is developing mandatory and voluntary AE reporting. The purpose of AE reporting is to learn from experience, so that AE are recognized and so that progress in reducing AE can be tracked [2].

AE occur in radiology, as in other fields of medicine, and are often related to systems issues [3]. In the age of value-based care, improving systems to reduce AE is particularly important, and is consistent with the ACR's Imaging 3.0 focus on quality and safety. The Society of Interventional Radiology also recognizes the importance of AE and cites procedure-related complication rates as one of the primary indicators of procedural success [4]. However, self-reported AE by health care providers have been shown in many studies to be either underreported or inaccurately reported [5-10]. The purpose of this study was to determine whether auditing an online self-reported interventional radiology quality assurance (QA) database improves compliance with record entry or improves the accuracy of AE reporting and grading.

METHODS

A database for cross-sectional image-guided procedures was built and implemented on July 1, 2014, using the REDCap online database tool at an academic medical center. This retrospective study was institutional review board approved and HIPAA compliant. The study involved a review of records for the first two quarters of data collection: quarter 1 (Q1), representing July 1 to September 30, 2014; and quarter 2 (Q2), representing October 1 to December 31, 2014. The procedures included percutaneous ultrasound, computed tomography, and MRI-guided interventions such as biopsies, fluid aspirations, catheter drainages, and therapeutic injections. Data elements included patient demographics, procedural details, AE, and outcomes. All staff radiologists were encouraged to review and comment on preliminary draft versions of the online database during its development. Before the launch of

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the online QA database, information regarding the purpose, structure, and use of the database, including AE definitions, was disseminated to staff radiologists through a staff meeting and multiple training e-mails. The training included step-by-step instructions on how to enter data in the various field types and a link to the database itself where sample records could be reviewed and test cases could be entered. The requirement of entering every procedure performed by the service into the database was explained.

Procedures were performed and/or supervised by 26 attending radiologists in Q1 and 27 radiologists in Q2. Staff included subspecialty radiologists in abdominal, musculoskeletal, thoracic, and neuroradiology. Most procedures involved trainees, either residents or fellows, who created the database record and entered the demographics and procedural details. The attending then completed the record, including AE and outcomes; the attending was required to verify the accuracy and completeness of the record by selecting the "yes" option for the field labeled "attending attestation." Grading of AE utilized a 5-point scale and was adapted from the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 4.0, and the Clavien-Dindo surgical classification, both of which use 5-point scales [9,11]. The CTCAE in particular was used because of its extensive classification of AE by grade and its widespread use in oncologic and nononcologic clinical studies. AE grade definitions were further modified to better reflect the AE encountered in a cross-sectional interventional radiology practice (Table 1).

Auditing for compliance with QA database record entry was performed by an administrative assistant and accomplished by comparing billing data with the QA database. If a procedure record was missing in the QA database, a reminder e-mail was sent out at least 1 week after the procedure and the number of cases requiring a reminder e-mail was recorded. The clerical audit and e-mail process provided continuous feedback to non-compliant physicians throughout both quarters regarding record entry.

An unannounced QA audit of all records from Q1 to assess the accuracy of AE reporting and grading was performed through physician review of the electronic medical record (EMR) for 30 days after each procedure. The review included comparing each entry in the REDCap database with the dictated radiology report for that procedure and with the EMR, including clinic, hospital, and Emergency Department notes, as well as subsequent imaging and laboratory reports. A review of images, from the initial procedure and from subsequent pertinent studies, was included. The review was initially conducted by one of three radiology residents, and all findings suggesting inaccurate AE reporting or grading were then re-reviewed by the resident, with one attending radiologist, for a consensus decision. Timely feedback to the attending radiologists regarding the accuracy of their AE reporting or grading was limited during the study period owing to the need for at least 30 days of

Table 1. Adverse event definitions by grade

Grade	Definition
1 (Mild)	Requires no therapy or minor supportive care such as intravenous fluids, analgesics, antipyretics, single-dose antihypertensive, or extended same-day observation; no lasting sequelae. Near miss (eg, wrong site of patient prepped but corrected before procedure, etc.). Includes asymptomatic hematoma with mass effect, ie, more than minimal hemorrhage. Asymptomatic small pneumothorax visible on chest x-ray. More than usual procedural or postprocedural pain.
2 (Moderate)	Requires moderate escalation of care: pharmacologic intervention such as oral antibiotics, cardiovascular drugs, or blood transfusions; minor interventions such as nonemergent chest tube insertion; unexpected overnight observation or return to Emergency Department. Moderate to severe pain, well controlled within 24 hours. No lasting sequelae.
3 (Severe)	Requires marked escalation of care: radiologic, endoscopic, or surgical intervention (complex or requiring GA), significant escalation of care such as unexpected multiple-day hospital admission, transfer to intensive care unit, outpatient urgent return to Emergency Department. Severe postprocedural pain refractory to routine narcotic doses and lasting more than 1-2 days or requiring inpatient management.
4 (Life-threatening)	Life-threatening or disabling events such as hemorrhage or septic shock, myocardial infarction, unanticipated dialysis, meningitis, paralysis, loss of limb or organ function. Severely symptomatic tension pneumothorax.
5 (Death)	Patient death or unexpected pregnancy abortion.