The Institute of Medicine’s landmark 2000 report *To Err Is Human* exposed the world of medical errors to the public and challenged the health care industry to take action. The report recommended that providers report adverse events, as a means to learn from errors and make care safer. State regulatory agencies have been working with health care providers to steadily advance adverse event reporting, and yet there has not been a clear accounting of the costs or benefits associated with this sea change in public accountability.

Among the many types of adverse events that occur across all settings of care, serious reportable events (SREs) are considered to be the most important. SREs, which have been defined by the National Quality Forum (NQF), were initially called “never events” with the thought that these should never occur in health care settings. In 2011 NQF updated its 2006 published list of 28 SREs to include 29 SREs, which are defined as “unambiguous, largely, if not entirely, preventable, serious, and any of the following: adverse, indicative of a problem in a healthcare setting’s safety systems, [or] important for public credibility or public accountability.”

These 29 events are each classified under one of seven categories: surgical or invasive procedure, product or device, patient protection, care management, environmental, radiologic, or potential criminal. In an effort to eliminate these events, in 2006 the Centers for Medicare & Medicaid Services (CMS) endorsed the NQF’s definitions and urged all state bodies to adopt these definitions for reporting. Reporting is intended to help providers identify and learn from SREs while also raising transparency and promoting a culture of safety. It is also a signal to the public that the hospital is doing everything it can to make care safer.

Reporting serious patient safety events did not originate with NQF’s definitions of SREs. The Joint Commission adopted a formal Sentinel Event Policy in 1996 to help hospitals that experience serious adverse events improve safety and learn from those sentinel events. Sentinel events are patient safety events that cause death, permanent harm, or severe temporary harm. Although the Joint Commission policy is intended to encourage hospitals to investigate and respond to events, many states require public reporting of NQF’s SREs. Moreover, to date, more than half the states (26) and the District of Columbia have enacted state-level reporting systems to help stakeholders learn from SREs. Massachusetts, one such state and the state under study, has required hospitals to publicly report NQF’s SREs since 2008. Hospitals are required to report SREs to the Massachusetts Department of Public Health (DPH), and, in addition, hospitals must disclose the event to the patient and family. In Massachusetts, hospitals are required to submit a report to DPH within 7 days of the event. An updated report—including documentation of the root cause analysis (RCA) findings and the determination of preventability—is required within 30 days of the event. These reports are made available to the patient and family, and an abridged version
is available to the public. In addition, when an event is determined to be preventable, hospitals are required to refrain from billing the charges related to the services that were provided which led to the event as well as the charges for services required to address the injury.  

There is an incomplete literature that begins to describe the costs associated with adverse events, the costs associated with fulfilling aspects of state regulatory requirements, and the costs associated with malpractice payments. We know that hospitals spend upward of $4.4 billion annually in healthcare delivery costs as a result of SREs and other adverse events, as many patients receive additional health care services and stay in the hospital longer. In 2008 one study estimated the cost of all medical errors to be approximately $17 billion a year, with an estimated total cost of $3.7 billion for SREs or what Medicare calls “never events,” 22% of the total cost of medical errors. Some recent studies have begun to look at the cost of quality and safety programs and the reporting of quality metrics to various credentialing agencies and to payers. One study, for example, estimated that $15.4 billion is spent by physician practices credentialing agencies and to payers. One study, for example, estimated that $15.4 billion is spent by physician practices on quality reporting.  

SRE reporting requirements, while potentially an important tool to improve patient safety, are time-consuming, potentially redundant with other reporting activities, and costly to the provider. Although we are beginning to understand the hospital infrastructure costs to monitor adverse and safety events and to create a culture of safety, the costs of investigating and reporting SREs are unknown.

The objective of this study was to identify the administrative costs incurred to investigate and report SREs, using the experience at one academic medical center (AMC) as a case study. Although hospitals can estimate the revenue lost and the additional healthcare delivery costs incurred, there is limited understanding of the administrative financial cost incurred when an SRE occurs.

**METHODS**

**Setting**

Using case study methods, we conducted a study to estimate the administrative cost of investigating, processing, and reporting SREs at one AMC and its physicians’ organization with an established Center for Quality and Safety (CQS). The CQS had well-documented processes and procedures in place, was known to be transparent, and had established a model of national interest. While not necessarily generalizable, this hospital’s cost should be similar to that of other AMCs and directionally similar to hospitals in general. This study, which we conducted during fiscal years (FYs) 2014 and 2015, examined the SREs that occurred during FY 2013 (October 2012 through September 2013). These SREs were reported to the Massachusetts DPH and are included among the calendar year events on the AMC’s public Internet website.

**Approach**

Case study methods included extensive interviewing of staff to identify tasks and time to process each SRE, reviewing case file documentation and e-mails, and reviewing financial and accounting data. Prior to the specific investigation (for this study) of the time and effort spent by hospital staff processing each SRE, two of the authors [B.B.B., B.A.] interviewed senior and administrative CQS staff to understand both the timing and the tasks that occur when an SRE is reported to CQS. We created a framework to identify detailed tasks performed and to categorize tasks into broad areas or cost classifications. This task-based framework was used to conduct semistructured interviews across the hospital, which we now describe.

**SRE Interviews and Estimating Time**

Two authors [B.B.B. and B.A.] together interviewed, in a series of individual sessions, hospital staff (that is, nurses and physicians on the hospital floor or ambulatory setting where the event occurred, as well as supervisors, patient care services, managers, and others), asking for recall of time and effort associated with the investigation of the event. They then, together, conducted a second set of interviews of staff (CQS, compliance, risk management, legal, accounting, and other staff) responsible for processing and investigating each specific SRE. Time and effort data were again collected in the second set of interviews.

Semistructured interview techniques were used to identify the time spent on each task, in 15-minute intervals, required to process the SRE. Self-reported times were identified after staff reviewed e-mail, case files, and notes. The specific staff person or job category was noted so that subsequent allocation of salaries would be accurate. Estimated time was aggregated by individual SRE, SRE type, and cost classification to allow for analysis.

Key stakeholders, including frontline clinical staff, quality chairs, compliance and risk management staff, CQS staff, finance, and others, validated the documented processes and estimates of time. Summaries of tasks and times were reviewed with CQS staff and compared by authors to paper SRE files that included documentation and e-mails in order to validate the recall of the staff interviewed.

**Calculating Cost**

The primary costs associated with each SRE are the direct labor costs associated with the time (minutes/hours) invested by staff to process each SRE. Direct labor costs, including salaries and institutional fringe benefits, were estimated using job categories and benefit and salary information obtained from department managers and human resources. Labor costs, which were allocated to the aggregated summary of time for each staff person, were estimated using a modified time-driven activity-based costing.

**Calculating Direct Labor Costs**

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