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HOSPITAL INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM

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EXECUTIVE SUMMARY

OBJECTIVES

1. To describe how hospitals use incident reporting systems and incident reports.
2. To determine the extent to which hospital incident reporting systems capture patient harm that occurs within hospitals.
3. To determine the extent to which accreditors review incident reporting systems when assessing hospital compliance with Federal requirements to track instances of patient harm.

BACKGROUND

The term "adverse event" describes harm to a patient as a result of medical care. This report is one in a series about adverse events in hospitals. Hospitals must track and analyze instances of patient harm as a condition of participation in the Medicare program. Incident reporting systems are a common means that hospitals use to meet this condition. Hospitals can demonstrate their compliance with this and all other conditions through a survey by a State survey agency or accreditation under an approved Medicare accreditation program. To standardize hospital event reporting, the Agency for Healthcare Research and Quality (AHRQ) developed a set of event definitions and incident reporting tools known as the Common Formats.

In a 2010 report, the Office of Inspector General found that 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays that resulted in prolonged hospitalization, required life-sustaining intervention, caused permanent disability, or resulted in death. An additional 13.5 percent experienced temporary harm events that required treatment. For this report, we collected incident reports from hospitals where these adverse and temporary harm events (events) occurred and interviewed administrators from hospitals and representatives of accreditors.

FINDINGS

All sampled hospitals had incident reporting systems to capture events, and administrators we interviewed rely heavily on these systems to identify problems. All of the 189 hospitals we surveyed reported using incident reporting systems designed to capture instances

of patient harm. Administrators from all hospitals with reported events (34 hospitals) indicated that they rely on incident reporting systems to capture a large portion of the information about events that they use to conduct patient safety improvement activities. The administrators acknowledged that incident reporting systems provide incomplete information about how often events occur, but they continue to rely on the systems primarily because they value staff accounts of events.

Hospital staff did not report 86 percent of events to incident reporting systems, partly because of staff misperceptions about what constitutes patient harm. Of the events experienced by Medicare beneficiaries discharged in October 2008, hospital incident reporting systems captured only an estimated 14 percent. In the absence of clear event reporting requirements, administrators classified 86 percent of unreported events as either events that staff did not perceive as reportable (62 percent of all events) or that staff commonly reported but did not report in this case (25 percent).

Nurses most often reported events, typically identified through the regular course of care; 28 of the 40 reported events led to investigations and 5 led to policy changes. Nurses most often identified events through patient observation and routine hospital safety assessments. Information regarding one-quarter of events was not accessible to the staff responsible for monitoring patient safety within the hospitals and for making policy changes. Hospitals investigated the events they considered most likely to yield information that would inform quality and safety improvement efforts and made few changes to policy or practices as a result of reported events.

Hospital accreditors reported that in evaluating hospital safety practices, they focus on how event information is used rather than how it is collected. Accreditors view incident reports within the context of larger hospital quality and patient safety efforts. Officials indicated that to assess hospitals, surveyors are most likely to review the results rather than review the methods used to track hospital adverse events. Surveyors would not specifically investigate these methods, such as incident reporting systems, unless evidence of a problem emerged through the survey process.

RECOMMENDATIONS

Because hospitals rely on incident reporting systems to track and analyze events, improving the usefulness of these systems is critical to hospital efforts to improve patient safety. As Federal health care research and oversight agencies, AHRQ and the Centers for Medicare & Medicaid Services (CMS) are positioned to provide guidance and incentives to hospitals to use incident reporting systems more fully. We recommend the following actions:

AHRQ and CMS should collaborate to create a list of potentially reportable events and provide technical assistance to hospitals in using the list. AHRQ and CMS should create and promote a list for use by hospitals, other health care providers, and clinical educators, such as medical and nursing schools. The list would educate hospital staff about the full range of patient harm that occurs in hospitals and would assist hospital administrators in assessing incident reporting systems. AHRQ and CMS should make it clear in promoting the list that listed events do not need to be reported outside the hospital, but rather that the list is a learning tool intended to broaden and improve staff understanding. The agencies could promote this list through guidance and training documents aimed at hospitals, other health care settings, and clinical education settings, as well as through guidance documents to State and accrediting surveyors. AHRQ could also promote the list through technical assistance targeted at encouraging hospital use of the Common Formats.

CMS should provide guidance to accreditors regarding surveyor assessment of hospital efforts to track and analyze events and should scrutinize survey processes when approving accreditation programs. CMS is testing draft interpretive guidelines for surveyors regarding the requirement to track and analyze events. We recommend that this guidance include information about how surveyors should assess the adequacy of hospital event collection efforts, including incident reporting systems, and should include the list of potentially reportable events to be developed by AHRQ and CMS. CMS should also suggest that surveyors evaluate the information collected by hospitals using AHRQ's Common Formats. Additionally, CMS should scrutinize survey standards for assessing hospital compliance with the requirement to track and analyze events and reinforce assessment of incident reporting systems as a key tool to improve event tracking.

AGENCY COMMENTS

We received comments on the draft report from AHRQ and CMS. AHRQ concurred with our recommendation directed to it, stating that it will collaborate with CMS to create a list of potentially reportable events and provide technical assistance to hospitals in using the list. AHRQ stated that it will meet with CMS staff to continue collaboration on the potential use of Common Formats with surveyors and hospital adverse event reporting systems. CMS concurred with both of our recommendations, stating that strengthening hospital reporting systems and practices is an essential component of efforts to prevent patient harm. CMS stated that a voluntary list of adverse events used for informational purposes could be highly beneficial for improving incident reporting practices. CMS also indicated that it is developing draft guidance for surveyors regarding assessment of patient safety improvement efforts within hospitals.

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BACKGROUND

Office of Inspector General Reports About Adverse Events

This report follows a series of Office of Inspector General (OIG) reports about adverse and temporary harm events in hospitals.[1] For this series of reports, we defined "adverse events" as significant harm experienced by patients as a result of medical care. We defined "temporary harm events" as harm that required medical intervention but did not cause lasting harm. Although an adverse or temporary harm event indicates that the care resulted in an undesirable clinical outcome and may involve medical errors, adverse events do not always involve errors, negligence, or poor quality of care and may not always be preventable.[2] Practices and policies to ensure patient safety and reduce the incidence of adverse events often involve identifying and learning from causes and contributing factors. Efforts to meet this objective often rely on hospital-staff-generated incident reports.

Hospital Incident Reporting Systems

Hospitals use incident reporting systems to monitor adverse events and other patient safety issues.[3] Incident reporting systems, which vary in design and functionality, capture and maintain reports of patient-safety-related events documented by physicians, nursing staff, or other hospital staff. Reported patient safety events could include

[1] The most recent reports in the series are *Adverse Events in Hospitals: Methods for Identifying Events,* OEI-06-08-00221, March 2010; and *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090, November 2010.

[2] R.M. Wachter, *Understanding Patient Safety*, McGraw-Hill, 2008.

[3] D.O. Farley, "Adverse-Event-Reporting Practices by US Hospitals: Results of a National Survey," *Quality and Safety in Health Care*, 17, 2008, pp. 416–423.

adverse events, "near-misses," or situations with the potential to harm patients. Completed reports typically include first-person accounts and other descriptive information about the events. Incident reports may also include information about the impact of the event on the patient and the causes of the events, if known. Hospital staff can submit reports in writing or electronically, depending on the reporting system. See Appendix A for an example of an incident report.

The 1999 Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health System*, encouraged the use of incident reporting systems, maintaining that hospitals can address patient safety problems only if events are identified and adequately described by caregivers.[4, 5] In a followup report, IOM recommended that hospitals develop comprehensive patient safety improvement plans based on data collected from internal incident reporting systems and other event detection methods.[6] IOM advised hospitals to analyze these data to identify the causes of events and to develop strategies to prevent recurrence.

Incident reporting systems have limitations. First, it can be difficult to determine incidence rates based on reported data because of variability in the rate and consistency of reporting.[7] Second, research suggests that incident reporting systems capture only a small percentage of adverse events and that some categories of events are underrepresented.[8, 9] Additionally, the rate and consistency of event reporting by hospital staff often varies.[10]

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[4] L.T. Kohn, J.M. Corrigan, and M.S. Donaldson, eds., *To Err Is Human: Building a Safer Health System*, A Report of the Committee on Quality of Health Care in America, 2000, p. 100.

[5] P.J. Provonost, "Using Incident Reporting to Improve Patient Safety: A Conceptual Model," *Journal of Patient Safety*, 3(1), 2007, pp. 27–33.

[6] P. Aspden, *Patient Safety: Achieving a New Standard for Care*, The National Academies Press, Washington, D.C., 2004.

[7] Agency for Healthcare Research and Quality (AHRQ), *Users Guide: AHRQ* Common Formats *Version 1.1,* March 2010, p. 1-2.

[8] T.K. Nuckols, "Rates and Types of Events Reported to Established Incident Reporting Systems in Two US Hospitals," *Quality and Safety in Health Care*, 16, 2007, pp. 164–168.

[9] OIG, *Adverse Events in Hospitals: Case Study of Incidence Among Medicare Beneficiaries in Two Counties*, OEI-06-08-00220, December 2008.

[10] AHRQ, *Users Guide: AHRQ* Common Formats *Version 1.1,* March 2010, p. 1-2.

Despite these limitations, stakeholders note that incident reporting systems have advantages. These include systems' familiarity among hospital staff and the advantages derived from involving frontline personnel in identifying safety hazards for the organization.[11] Compared to other event detection methods commonly used in hospitals, incident reporting systems are thought to capture a wider range of events at a lower cost to hospitals.[12]

Requirements To Improve Patient Safety by Measuring Adverse Events

As a condition of participation (CoP) in Medicare, Federal regulations require that hospitals develop and maintain a Quality Assessment and Performance Improvement (QAPI) program.[13] To satisfy QAPI requirements, hospitals must "track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital."[14] To accomplish this, hospitals must "measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service, and operations."[15] Federal regulations do not specify means for meeting the requirements, nor do they explicitly define what "quality indicators" or "adverse patient events" hospitals should measure.[16]

Hospital Accreditation

Most hospitals (89 percent) demonstrate their compliance with QAPI and the other CoPs to the Centers for Medicare & Medicaid Services (CMS) through a survey by a State survey agency or accreditation under an approved Medicare accreditation program, a process known as "deeming."[17, 18] Currently, three national accreditors review hospitals: the Joint Commission, the American Osteopathic Association (referred

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[11] AHRQ, *Voluntary Patient Safety Event Reporting (Incident Reporting).* Accessed at http://www.psnet.ahrq.gov/primer.aspx?primerID=13 on March 31, 2011.

[12] K.G. Shojania, "The Elephant of Patient Safety: What You See Depends on How You Look," *The Joint Commission Journal on Quality and Patient Safety*, 36, 2010, pp. 399–401.

[13] 42 CFR § 482.21.

[14] 42 CFR § 482.21(c)(2).

[15] 42 CFR § 482.21(a)(2).

[16] 68 Fed. Reg. 3435, 3438–39 (Jan. 24, 2003).

[17] CMS, *CMS Financial Report: Fiscal Year 2009.*

[18] Social Security Act, § 1861(e), 42 U.S.C. § 1395x(e).

to as "HFAP"), and Det Norske Veritas (DNV) Healthcare.[19] The Secretary of Health and Human Services (HHS) granted deeming authority to each of these accreditors after CMS determined that the accreditation programs' standards met or exceeded the requirements listed in the CoPs.[20] Hospitals that do not opt for accreditation can be certified as meeting CoPs by State survey and certification agencies.[21] The accreditation and certification processes rely on periodic, onsite inspections—called surveys—of hospitals. CMS provides guidance to State survey and certification agencies for conducting surveys in its *State Operations Manual*.[22]

All three accreditors include QAPI-based quality, safety, and performance provisions in their hospital requirements. These provisions, like the QAPI CoP, typically include identifying adverse events as part of broader quality and performance improvement requirements and do not specify the means hospitals should use to identify and analyze events. For example, one accreditor's manual specifies that hospitals should "use data and information to guide decisions" and have an "organization-wide, integrated patient safety program."[23] This is similar to the QAPI CoP requirement that hospitals "must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program."[24] Each of the three accreditors defines what constitutes an adverse event. Their lists of events vary and include events that cause harm to patients, such as adverse medication reactions; and process breakdowns that could lead to harm, such as erroneous laboratory reports.[25, 26]

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[19] CMS, *CMS-Approved Accreditation Organization Contact Information*, 2011.

[20] Social Security Act, § 1865, 42 U.S.C. § 1395bb.

[21] The remaining 11 percent of hospitals were certified in compliance with the CoPs by State survey and certification agencies. According to CMS, the percentage of hospitals certified by State survey and certification agencies will begin to decrease after 2010 because CMS has directed these agencies to prioritize other activities over initial hospital certifications. CMS, *CMS Financial Report Fiscal Year: 2010*, pp. 130–131.

[22] CMS, *State Operations Manual,* Pub. 100-07.

[23] The Joint Commission, *Hospital Accreditation Operations Manual*, LD.03.02.01 and LD 04.04.05.

[24] 42 CFR § 482.21.

[25] The Joint Commission, *Hospital Accreditation Operations Manual*, PI.01.01.01.

[26] DNV, *NIAHO Standards and Interpretive Guidelines*, QM 7 SR 1-18.

AHRQ's Common Format Event Reporting Tools

To support and standardize hospital event reporting, AHRQ developed a set of event definitions and incident reporting tools known as the Common Formats.[27] AHRQ defines the Common Formats as "clinical definitions and technical requirements developed for the uniform collection and reporting of patient safety data." AHRQ developed the Common Formats to assist hospitals in developing standardized reporting methods and in reporting information to PSOs.[28] Under AHRQ's oversight, PSOs receive adverse event reports from hospitals, analyze the reports in aggregate, and provide hospitals with analysis and recommendations for improving patient safety.[29] AHRQ announced Common Formats Version 1.1 in the Federal Register on March 31, 2010. Version 1.1 includes instructions for reporting events that harm patients and "near-misses" (circumstances that have the capacity to cause harm).[30]

The Common Formats include descriptions of patient safety events and unsafe conditions to be reported, specifications for aggregate event reports and individual event summaries, delineation of data elements to be collected for specific types of events, a user's guide, and technical specifications for electronic data collection and reporting. The Common Formats allow PSOs to aggregate event and contributing factor information from across hospitals for comparisons and trend analyses. The Common Formats' three event reporting forms focus on specific areas: information describing the event, information describing the impact on the patient, and summary and contributing factor information. The Common Formats also contain event-specific modules that provide additional detail for high-volume or high-harm events.

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[27] AHRQ developed the Common Formats as part of HHS's congressional mandate to provide technical assistance to Patient Safety Organizations (PSO) on matters such as methodology, communication, data collection, and privacy concerns. Public Health Service Act, § 925, 42 U.S.C. § 922b-25.

[28] Sections 923 and 924 of the Public Health Service Act, which were added by the Patient Safety and Quality Improvement Act of 2005, required HHS to determine that PSOs meet certain criteria to perform "patient safety activities" and establish a network of patient safety databases to receive, analyze, and report on patient safety information submitted by the PSOs. Patient Safety and Quality Improvement Act of 2005, P.L. 109-41 § 2; Public Health Service Act, §§ 923 and 924; 42 U.S.C. §§ 299b-23 and 24.

[29] 73 Fed. Reg. 70733 (Nov. 21, 2008).

[30] 75 Fed. Reg. 16140, 16141-42 (Mar. 31, 2010).

National Incidence of Adverse Events

In a November 2010 report, OIG estimated the national incidence rate of adverse and temporary events in hospitals.[31] We found that 27 percent of hospitalized Medicare beneficiaries experienced at least one adverse event (13.5 percent) or temporary harm event (13.5 percent) during hospitalizations that ended in October 2008. These rates were projected to all beneficiaries hospitalized during October 2008.

To determine the national incidence rate, we selected a sample of beneficiaries. Of the 999,645 beneficiaries discharged from acute care hospitals during October 2008, we selected a random sample of 785. We excluded 5 beneficiaries as ineligible because the hospitals where they were treated were under OIG investigation, resulting in a sample of 780 beneficiaries. These sample beneficiaries had a combined total of 838 hospital stays with discharges in October 2008.

To identify adverse events experienced by sampled beneficiaries, we conducted a two-stage review of their medical records. During the first stage, we identified cases that met one or more of the following conditions: (1) a certified medical coder identified a diagnosis in the Medicare claims data that was coded as not present when the beneficiary was admitted to the hospital, (2) nurse reviewers found evidence of a potential adverse event in the medical records, or (3) the beneficiary was readmitted to the hospital within 30 days after discharge following a hospital stay ending in October 2008.[32]

Based on findings from the first stage of review, we advanced 420 cases to the second stage, in which physicians reviewed the beneficiaries' hospital medical records to identify events. Physicians identified 128 adverse events that met at least one of three criteria: (1) events on the National Quality Forum's (NQF) list of Serious Reportable Events;[33] (2) events for which CMS will no longer pay a

[31] OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090, November 2010.

[32] The nurse reviewers used a modified version of the Institute for Healthcare Improvement's Global Trigger Tool. F.A. Griffin and R.K. Resar, *IHI Global Trigger Tool for Measuring Adverse Events*, Institute for Health Care Improvement Innovation Series 2007, pp. 4–5.

[33] NQF, *Serious Reportable Events,* October 2008.

higher Medicare reimbursement (known as hospital-acquired conditions (HAC));[34] and (3) events resulting in a prolonged hospital stay, permanent harm, life-sustaining intervention, or death. Physicians also identified 174 temporary harm events, which we defined as events requiring intervention but not rising to the level of patient harm associated with adverse events. In total, they identified 302 patient harm events.

METHODOLOGY

Scope

This report estimates the national rate at which hospital incident reporting systems captured events experienced by Medicare beneficiaries discharged from acute care hospitals during October 2008. This reporting rate and hospital administrators' explanations for the reasons staff did not report events are projectable nationwide to all Medicare beneficiaries hospitalized during this period. To determine the estimated rate of reporting, we requested incident report information from the 195 hospitals associated with the 302 events that we identified for the national incidence study. This report also provides findings regarding hospital use of incident reporting systems and information included in reports, which pertain only to the sample of reported events and are not projectable. Lastly, this report provides information about how hospital accreditors assess incident reporting systems during hospital surveys.

Data Collection

Hospital surveys. To determine whether the hospitals associated with the events had incident reporting systems designed to capture patient harm events, we sent a survey to each of 195 hospitals associated with the events. In the survey, we asked the hospitals to describe each of the incident reporting systems they used to capture event information and the types of information they expected to collect through the systems. We received responses from 189 of the 195 hospitals describing 293 of the 302 events (a 97-percent response rate).

[34] CMS, *Hospital-Acquired Conditions (HAC) in Acute Inpatient Prospective Payment System (IPPS) Hospitals*, October 2010.

Information requests. To identify which of the 302 events hospitals captured in internal incident reporting systems, we sent information requests to each of the 195 hospitals associated with the events. Each information request identified the patient who experienced the event, the stay in which the event occurred, and a description of the event that physician reviewers identified. We asked each of the hospitals whether the identified events had been captured by an incident reporting system and, if so, to provide supporting documentation. If an event was not captured, we asked the hospital for an explanation. Because we sent the information requests along with the hospital surveys and received information from each of the hospitals that returned a survey, we received information for 293 events (a 97-percent response rate).

We also obtained supporting documentation from hospitals for all captured events. Supporting documentation included incident reports, copies of infection-tracking logs, skin-care management logs, peer review documentation, and patient safety committee minutes. See Appendix B for a description of the information in the completed incident reporting system forms provided by the hospitals.

Hospital interviews. We conducted structured interviews with administrative staff from each of the 34 hospitals in which an event was reported to an incident reporting system.[35] We conducted the interviews in response to a request from CMS to determine what actions the hospitals took following the reports of events. We asked each hospital administrator to describe how information about an event was shared within the hospital, the extent to which staff analyzed the event, and whether the reporting of the event led to policy or process changes. Findings pertaining to these interviews are not projectable and represent only the actions of the 34 hospitals.

Accreditation organization interviews. We interviewed staff from the three hospital accreditors. We gathered information on the extent to which the accreditors review incident reporting systems when evaluating hospital compliance with accreditation standards related to quality and safety.

[35] In almost all cases, we interviewed the hospitals' risk managers, patient safety officers, and/or quality improvement specialists. We refer collectively to these staff members as hospital administrators.

We focused on accreditors because they certified compliance for 89 percent of all hospitals in 2008. Within our sample of 189 hospitals, CMS deemed 98 percent to be in compliance with Medicare's CoPs following accreditation by one of the three hospital accreditors: the Joint Commission accredited 89 percent of sample hospitals, HFAP accredited 5 percent, and DNV accredited 4 percent.

Data Analysis

We calculated the percentage of events that hospitals indicated their incident reporting systems captured among the 293 events identified in our national sample and included in our analysis. We also calculated percentages for the reasons hospitals reported that incident reporting systems did not capture the other events. We computed all rates and corresponding 95-percent confidence intervals using the computer program Sudaan, which provides standard errors for complex sampling designs. See Appendix C for estimates, confidence intervals, and key statistics.

Limitations

Hospitals may not have provided information about all events captured by incident reporting systems. This could be due to a number of factors, including the 2-year interval between the events and our information request, concern about preserving the confidentiality of sensitive report documents and potential liability in releasing such information, and lack of effective hospital recordkeeping. These limitations could result in our underestimating the extent to which hospital incident reporting systems capture events.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

All sampled hospitals had incident reporting systems to capture events, and administrators we interviewed rely heavily on these systems to identify problems

All of the 189 hospitals in which an event occurred reported using general incident reporting systems designed to capture information about instances of patient harm from across hospital departments. Additionally, most hospitals used specialized incident reporting systems to capture events within specific hospital departments, such as pharmacy; or to capture specific types of adverse events, such as patient falls. The most common specialized systems focused on infections, medication events, and patient complaints. See Table 1 for the types of incident reporting systems that hospitals used to capture events.

Table 1: Types of Hospital Incident Reporting Systems (n=189)

Type of System	Number of Hospitals With System
General incident reporting system designed to capture all instances of patient harm	**189**
Specialized incident reporting system	**132**
Infection tracking	98
Pharmacy or medication error tracking	43
Patient complaint tracking	40
Security issues	14
Harm to staff	7
Regulatory compliance	4

Source: OIG analysis of information requests completed by the 189 hospitals where the 293 events occurred.

Hospital administrators indicated that they encourage staff to report any instance of patient harm to incident reporting systems

During followup interviews, administrators at 34 of the 189 hospitals indicated that they expect staff to report any instance of patient harm and even circumstances that could lead to harm. They explained that staff have broad instructions to report all patient safety problems. Additionally, these hospitals typically provide training focused on reporting specific types of events commonly understood as patient harm, such as pressure ulcers. However, none of the hospitals maintained a list of events required to be reported to incident reporting systems.

Hospital administrators we interviewed explained that they rely heavily on incident reporting systems to identify safety problems

Administrators from all 34 hospitals indicated that they rely on incident reporting systems to capture much of the information used to conduct patient safety improvement activities. Many administrators reported that they combine reported information with data collected through other event detection methods, including medical record reviews (18 administrators), administrative data screening (17), manual or automated review for evidence of hospital-acquired infections (8), and postprocedure checklists to identify complications (8).

Administrators also reported a number of benefits to capturing information through incident reporting systems. Foremost, administrators explained that reports from staff who are directly involved with events provide greater detail and insight about the patient, circumstances, and possible contributing factors (such as specific breakdowns in processes) than information provided by other event detection methods. Other reported benefits of incident reporting systems include identifying a broad range of events (reported by 12 administrators) and focusing staff attention on patient safety issues (reported by 9).

Hospital administrators we interviewed also noted several factors that limit the usefulness of incident reporting systems

Although administrators largely expressed confidence in their systems to generate useful information, many identified limitations. Twenty-two of the thirty-four administrators indicated that underreporting of events by hospital staff leads to inaccurate measurement of patient harm. Administrators expressed concern that underreporting can affect patient safety efforts by potentially skewing resources toward prevention of more easily identifiable occurrences that happen at a point in time (such as patient falls) rather than complex events that occur over a longer period and are more difficult to detect (such as blood clots). Sixteen administrators noted that reports to their systems often require additional investigation, such as a root-cause analysis, to provide meaningful information. Further, 10 administrators noted that it is sometimes difficult to interpret data from their systems. For example, an increase in reports about a certain type of event could reflect either an increase in occurrences or improved reporting.

Hospital staff did not report 86 percent of events to incident reporting systems, partly because of staff misperceptions about what constitutes patient harm

Despite the existence of incident reporting systems, hospital staff did not report most events that harmed Medicare beneficiaries. Of the events experienced by a national sample of beneficiaries discharged in October 2008, hospital incident reporting systems captured only an estimated 14 percent of events.[36] Further, hospital staff reported only 2 of the 18 most serious events in our sample (i.e., those events that resulted in permanent disability or death). Serious events not captured by incident reporting systems included hospital-acquired infections, such as a case of septic shock leading to death; and medication-related events, such as four cases of excessive bleeding because of the administration of blood-thinning medication that also led to death. Incident reporting systems did not capture any of the five NQF Serious Reportable Events and only one of the eight Medicare HAC events in our sample. Medicare does not require hospitals to capture information about these events through incident reporting systems. However, because events on the NQF and Medicare HAC lists are widely recognized among medical professionals as constituting patient harm, many among the public and in the health care community may expect them to be reported by hospital staff.

Administrators conceded that it was likely not clear to staff which events to report, given the wide range of patient harm that can occur in hospitals

In the absence of clear reporting requirements for events, it is difficult for staff to determine hospital expectations for reporting incidents. Although administrators indicated that they want staff to report all instances of harm, when asked about specific events administrators conceded that staff may often be confused about what constitutes harm and is, therefore, reportable. For each of the events that staff did not report (86 percent of all events), hospital administrators indicated whether they would expect staff to recognize the events as reportable patient harm. They classified most unreported events as events that hospital staff most likely did not perceive as reportable (62 percent of all events) and the remaining unreported events (25 percent) as events that

[36] Because we found no statistically significant difference in reporting rates between adverse and temporary harm events, we refer to adverse events and temporary harm events collectively as "events." The Cochran-Mantel-Haenszel chi-square test was not significant at the 95-percent confidence level (p=0.7380).

staff commonly reported but did not report in this particular case. See Table 2 for detailed information on why staff didn't report events.

Table 2: Events by Reporting Category and Reasons Administrators Gave for Why Staff Did Not Report (n=293)

Event Category	Percentage of All Events
Events Captured by Incident Reporting Systems (n=40)	14%
Events Not Captured by Incident Reporting Systems (n=253)	86%
Event was not reported; staff did not perceive event as reportable because:	62%*
Event was not caused by a perceptible error	12%
Event was an expected outcome or side effect	12%
Event caused little harm and/or harm was ameliorated	11%
Event was not on hospital's mandatory reporting list	9%
Event occurs frequently in hospitals	8%
Event symptoms became apparent after discharge	5%
Event occurred in patient with a history of similar events	4%
No reason given for why staff did not perceive event as reportable	2%
Event was not reported although event type is commonly reported	25%*
Total	100%

Source: OIG analysis of the 293 information requests completed by hospitals where events occurred.

* Percentages do not sum to 86 percent because of rounding.

For the 62 percent of events not reported because staff did not perceive them as reportable, administrators indicated that staff likely did not recognize that the event caused harm or realize that they should complete a report. The most common reason administrators gave for staff underreporting was that no perceptible error occurred (12 percent), indicating that staff commonly equate the need to complete incident reports with medical errors. Other reasons for underreporting include staff becoming accustomed to common occurrences and therefore not submitting reports, such as events that were expected side effects (12 percent) or occurred frequently (8 percent). For example, staff reported only 1 of 17 sample events related to catheter usage (e.g., infection and urinary retention), a common cause of harm to Medicare beneficiaries. In other cases, the symptoms of the event did not become apparent until after the hospital discharged the patient (5 percent). Administrators reported that such events are unlikely to be captured by hospital incident reporting systems unless patients return to the hospital and staff uncover a causal link with the prior hospitalization.

Administrators indicated that the remaining 25 percent of events were types of harm that staff commonly report to incident reporting systems and that they would expect staff to report. Administrators believed these events were clearly reportable because hospital staff received specific training to report this type of event and/or the event had characteristics that staff commonly associated with patient harm, such as the result of a specific action. For example, staff reported all patient falls, an event that is often the focus of hospital safety efforts. If hospital staff had reported the 25 percent of events that are commonly reported, the rate of reporting would have increased from 14 to 38 percent. It is difficult to determine why staff did not report these events, but administrators suspected both limited staff time and misperceptions that other staff would report the event.

Nurses most often reported events, typically identified through the regular course of care; 28 of the 40 reported events led to investigations and 5 led to policy changes

Information in incident reports typically described the reported event and its impact on the patient. Administrators from each of the hospitals with a reported event (34 hospitals) indicated that they attempted to use the information to improve patient safety, typically as a starting place for further investigation and analysis. Hospitals conducted investigations for two-thirds of events, although few events resulted in changes to hospital policies or practices.

Nurses reported 31 of the 40 events to incident reporting systems, with the remaining 9 events reported by a variety of other hospital staff

The hospitals designed most incident reporting systems to allow reporting by any staff member or associated clinician, such as physicians and therapists; in some cases the systems also allowed reporting by parties other than hospital staff, such as patients and families. Hospital administrators said that they encourage all staff to report, including those in specialized departments and those following patients through a course of care. For example, one administrator said that his or her hospital relies on case managers to identify events that transpire over multiple days or are the result of patient transfers between departments.

Nurses discovered 24 reported events through observation of patients in the regular course of care. Nurses and other staff, such as infection control specialists and case managers, discovered the remaining 16 reported events by completing hospital safety assessments designed to identify problems. When staff identified events through hospital safety assessments, the results of the assessments prompted staff to create incident reports. Staff identified 10 of these 16 events using criteria-based patient evaluations (such as skin assessments required for all patients at risk for developing pressure ulcers) and the remaining 6 events through more general screening of patient records (such as a nurse's review of patient condition at the end of a shift). See Table 4 for a list of how staff first identified the events they reported.

Table 4: Hospital Detection Methods That Identified Events Reported to Incident Reporting Systems (n=40)

Method of Event Identification	Events Identified
Identified by Staff Through Patient Observation During the Regular Course of Care	**24**
Identified After Criteria-Based Patient Status Reviews	**10**
Skin integrity assessment	3
Blood culture analysis to identify patients likely to develop an infection	2
Chart review of patient who met hospital-defined criteria	1
Medication review following emergency rescue medication	1
Medication review following potential contraindication	1
Potential complication questionnaire following procedure	1
Chart review following patient complaint	1
Identified Through Routine Screening of Hospital Tests	**6**
Blood culture analysis	2
Case management review	2
Skin care assessment	2

Source: OIG analysis of interviews with administrators at hospitals where the 40 reported events occurred.

Information regarding one-quarter of events was not immediately accessible to the staff responsible for monitoring patient safety within hospitals

Hospital staff reported 29 events to general incident reporting systems that staff responsible for hospitalwide event tracking and monitoring (e.g., patient safety staff, such as risk managers or patient safety officers) used to monitor event occurrence. These systems either automatically sent an alert to relevant staff (e.g., event specialists or department managers) or stored the event in a database for later

review. The hospital administrators we interviewed reported that patient safety staff reviewed events captured by these systems daily or at the end of each shift.

Hospital staff reported the other 11 events to department-specific specialized systems (e.g., infection tracking systems), making them immediately accessible to centralized patient safety staff. In most of these cases, centralized patient safety staff became aware of the events only after receiving aggregate event summaries generated by these systems. Hospital administrators reported that patient safety staff generally do not have immediate access to the information collected in these specialized systems and rely on the system managers to forward reports periodically. For example, in one instance when a nurse entered a pressure ulcer event into a skin wound event tracking log, patient safety staff had access to the information only after a summary was forwarded at the end of the month. Hospital administrators also indicated that high rates of reporting to department-specific systems that are not readily accessible to centralized patient safety staff can lead to compartmentalization of information. They stated that this can impede efforts to track and monitor adverse events across the hospital.

Hospitals investigated the events they considered most likely to inform quality and safety improvement activities

The hospital administrators we interviewed reported that they investigated and analyzed 28 of the 40 events for evidence of system failures or medical errors to inform quality and safety improvement activities. Patient safety staff conducted half of these investigations (14 events); the rest were conducted by managers of departments where the events occurred or by clinical event specialists, such as wound care nurses or infection-control specialists. These reviews ranged from informal reviews immediately following the incidents to structured analyses intended to comprehensively identify errors that contributed to adverse events (i.e., root-cause analyses). Hospital administrators reported that they did not investigate the remaining 12 events because they suspected that the events were isolated incidents unlikely to recur. Therefore little benefit would derive from a quality improvement investigation.

The most common type of investigation was a clinical review of a single event, but hospital administrators reported that they regularly analyze events in aggregated event reviews. Aggregated event reviews involved reviewing data about multiple events to identify trends and common causes. Administrators indicated that clinical reviews are usually conducted by patient safety staff or department managers in collaboration with the staff members directly involved with the event. These clinical reviews were similar to root-cause analyses but contained less detail and used fewer resources. The most frequently discussed questions during these clinical reviews included whether staff correctly assessed patients before treatment began; whether the standard of care was met by the attending physicians; and what contributing factors led to the event, such as medication mislabeling or poor communication during shift changes.

Hospitals made few changes to policies or practices as a result of the reported events

Hospital administrators reported that only 5 of the 40 sample incident reports led to a hospital policy or practice change. Two of these events led directly to changes in hospital policy or practice, and staff included the other three in an aggregate event review that led to changes. According to administrators, the remaining 35 reported events did not result in a policy or practice change primarily because hospitals reviewed the event information and determined that the occurrences did not represent systemic quality problems within the hospitals. Administrators reported that changes to hospital policies or practices as a result of a single event are rare unless the event is found to represent a systemic problem within the hospital. In other cases, hospital administrators reported that they may already have procedures in place to avoid a specific type of event. For example, hospitals may use special pressure-reducing mattresses and have rigorous policies and training regarding patient turning, yet still see some pressure ulcers develop.

Hospital accreditors reported that in evaluating hospital safety practices, they focus on how event information is used rather than how it is collected

In interviews, officials from hospital accreditors noted the importance of incident reporting systems to hospital patient safety efforts. However, they also reported that they are unlikely to scrutinize the effectiveness of event detection methods, such as incident reporting systems, during hospital surveys.

Hospital accreditors view incident reporting systems within the context of larger hospital quality and patient safety efforts

Officials from the three accreditors confirmed that their standards require hospitals to track adverse events to inform safety improvement efforts, as mandated by QAPI CoP, and that hospitals often use incident reporting systems to satisfy this requirement. Officials indicated that their surveyors are directed to assess hospital efforts by reviewing the results of patient safety improvement efforts. Surveyors would not specifically investigate mechanisms of hospital adverse event tracking unless evidence of a problem emerged through their standard survey process.

As an example, one accreditor described how surveyors assessed a hospital's efforts to track hospital-acquired infections. In this case, surveyors focused on the care provided to individual patients as part of the survey protocol. If a selected patient developed an infection, the surveyor would investigate the circumstances of the infection, including whether it was detected by an automated surveillance tool and reported to an incident reporting system. The surveyor reviewed the report and any noted corrective action. Although the review was described as fairly thorough by the official, it was dependent upon whether a selected patient contracted an infection or experienced some other reportable event.

Surveyors may view data in an incident reporting system as part of their review but do little investigation of the specific incident reporting system, the mechanism of reporting, usability by staff, or typical information in the reports (including the frequency of reported events). One accreditation official explained that hospital administrators could choose to demonstrate their incident reporting system as an example of QAPI compliance or could choose to highlight event detection methods, such as an electronic surveillance system or a medical record review process.

Accreditors cited a number of reasons their surveyors do not scrutinize incident reporting systems or other event detection methods during hospital surveys. Most of the reasons rested on the perception that event detection methods are complex and varied. First, hospitals collect event data from a variety of sources, and it can be difficult to discern which information is from a report and which is from a surveillance record or medical record review. Second, surveyors may not have the expertise to assess the reporting mechanism itself and provide recommendations to improve reporting. Third, officials questioned the value of requiring hospitals to collect event information in a particular way, arguing that a prescribed approach may inhibit innovation. Given this, some officials reasoned that it was better to focus on the output than on the systems, but they conceded that this lack of focus on how hospitals collect event information meant there was little scrutiny of the reporting systems' event data that hospitals use to inform their patient safety improvement efforts.

Previous OIG work determined that, despite significant attention from stakeholders in recent years, adverse events continue to pose a serious risk to hospitalized Medicare beneficiaries. Identifying events helps hospital administrators set goals for improvement, direct resources, and assess the effectiveness of prevention strategies. Hospital administrators indicated that, although they employ a number of methods to detect patient safety problems, incident reporting by staff is the primary tool used to identify events. However, we found that incident reporting systems did not capture 86 percent of events that caused patient harm in a national sample of Medicare beneficiaries. Further, hospital staff often did not report events because they did not perceive them as causing reportable patient harm.

AHRQ and CMS are positioned to provide guidance and incentives for hospitals to more effectively track and analyze adverse events. AHRQ oversees critical research efforts, the PSO program, and the Common Format event reporting tools. CMS oversees hospital accreditation, which includes ensuring that hospitals have a data-driven performance improvement plan that meets the standards detailed in the Medicare CoP.

Therefore, we recommend the following:

AHRQ and CMS should collaborate to create a list of potentially reportable events and provide technical assistance to hospitals in using the list

Hospital staff identification of patient harm is critical to the success of patient safety efforts. Hospital administrators reported that the most common reason hospital staff do not report patient harm is that they do not perceive the harm as a reportable event. As such, hospital efforts to improve patient safety may be limited by focusing on only a small subset of events that get more attention because they are more often reported by staff. Given the importance of incident reporting to hospital safety efforts, AHRQ and CMS should take steps to improve reporting by hospital staff.

AHRQ and CMS should collaborate to create and promote a list of potentially reportable events for hospitals, other health care providers, and clinical educators, such as medical and nursing schools. We do not recommend that AHRQ or CMS require hospitals to report the events on the list. Rather, the list of events would educate hospital staff about the full range of patient harm that occurs in hospitals and should be

reported to incident reporting systems. The list should go beyond the fairly rare harm events included in the NQF and Medicare HAC lists and include a comprehensive range of possible patient harm. Events on the list could include those identified in prior OIG work and by other researchers.[37] The list could also include "near-miss" occurrences, given that AHRQ has promoted the reporting of near-misses as important for improving practices. AHRQ and CMS should be clear in publishing the list that they do not require external hospital reporting of listed events, but provide the list to broaden and improve staff understanding.

The two agencies could promote this list as a guidance and training document for hospitals, other health care settings, and clinical education settings, as well as for State and accrediting surveyors. AHRQ could also promote the list through technical assistance targeted at encouraging hospital use of the Common Formats.

CMS should provide guidance to accreditors for assessment of hospital efforts to track and analyze events and should scrutinize survey processes when approving accreditation programs

Under the Medicare QAPI CoP, hospitals must track and analyze adverse events. Administrators indicated that incident reporting systems are critical to identifying and tracking events. Although reporting systems captured few events, we found that accreditors do not routinely assess incident reporting systems or other methods for identifying events during hospital surveys.

CMS is testing draft interpretive guidelines for surveyors regarding the QAPI CoP, including guidance about how surveyors are to assess hospital operations for tracking patient harm. To facilitate more extensive hospital detection of events, we recommend that this guidance include information about how surveyors should assess hospital event collection efforts, including incident reporting systems, and should include the list of potentially reportable events to be developed by AHRQ and CMS (addressed in our first recommendation).

CMS should also suggest that surveyors evaluate the information collected by hospitals and compare it to the data elements of AHRQ's

[37] *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI 06-09-00090, pp. 51–61. See Appendix D for rates of reporting within the subcategories of events identified in the national incidence study.

Common Format event reporting tools, which include the information that AHRQ has found to be most useful in patient safety efforts. This comparison could serve not only to assess the quality of reported information but also would further promote use of the Common Formats by hospitals in developing their internal incident reporting systems.

Additionally, CMS should scrutinize survey standards for assessing hospital compliance with the requirement to track and analyze events and reinforce assessment of incident reporting systems as a key tool to improve event identification and tracking. Given the low reporting rates and lack of assessment by accreditors during hospital surveys, CMS should ensure that accreditation survey practices bring about a meaningful examination of systems that identify events, including mechanisms for reporting events, and hospital efforts to address underreporting and use information.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

We received comments on the draft report from AHRQ and CMS.

AHRQ. AHRQ concurred with our recommendation to collaborate with CMS in creating a list of potentially reportable events and providing technical assistance to hospitals in using the list. AHRQ stated that it will meet with CMS staff to continue collaboration on the potential use of Common Formats by surveyors and hospital adverse event reporting systems.

CMS. CMS concurred with our recommendations and stated that strengthening hospital reporting systems and practices is an essential component of efforts to prevent patient harm. CMS provided information about future plans to improve patient safety, including the public-private "Partnership for Patients," a national initiative intended to reduce adverse events and complications caused during transitions from hospitals to other health care settings.

In response to our recommendation that CMS collaborate with AHRQ in creating a list of potentially reportable events, CMS stated that a voluntary list of adverse events used for informational purposes could be highly beneficial for improving incident reporting practices, and it has initiated this collaboration. In response to our recommendation that CMS provide guidance to accreditors, CMS stated that it is

developing draft guidance for surveyors regarding assessment of the QAPI CoP within hospitals. This guidance will include the expectation that hospitals provide staff with "detailed, unambiguous instructions on the types of events that should be reported." Further, CMS stated that it will recommend that hospitals use both the list of potentially reportable events and the AHRQ Common Formats in developing these staff instructions.

For the full text of AHRQ and CMS comments, see Appendix E.
We made minor changes to the report based on technical comments.

Example Incident Report

Below is a reproduction of an incident report we received during data collection. We redacted all patient and hospital information.

Incident Info: Patient Fall	**People Involved:**
Incident Number: 8726	(Reporting Employee Name)
Log Date: 10/01/2008 2:25:21 PM	**Other People Involved:**
Incident Date: 10/01/2008 2:20:00 PM	Witness
Location: BATHROOM	(Attending Physician Name)
Primary Person Involved: (Patient Name)	(Employee Reviewer Name)
Account Number:	(Employee Reviewer Name)
Birth Date:	(Employee Reviewer Name)

Comments/Incident Description/Additional Details

Review Comment *Made by: (Employee Name)*

RN and LPN had walked patient to bathroom several times. Patient used call light and or they checked in with her and walked her back from bathroom. At the time of this fall, the patient unexpectedly got up unassisted and fell. C/o rib pain, physician notified, no injury confirmed per radiology. The plan of care was updated with communication regarding nature of fall.

Details

Falls

Type of Fall	-To/In bathroom
Injury Type	-Other: *LT RIB DISCOMFORT* -Abrasion/ Laceration/ Bruise
Restraints/Siderails	-Mattress sensor -SR up x2
Physician	-Physician was notified
Was equipment involved?	-No
Mental status at time of fall	-Other: *FORGETFUL* -Alert and oriented x3
Current Documented Risk Assessment Level Prior to this Fall	-High
Could medication have been factor in fall?	-No

Patient Outcomes

Were the healthcare personnel caring for the patient notified?	-Yes
Was additional treatment provided to the patient?	-No
Patient Outcomes	-14 Other: *PAIN LT RIB* -03 Abrasion/Bruise

Severity of Injury

Severity of Injury:	*-MINOR-NO TREATMENT REQUIRED OR MINIMAL TREATMENT (FIRST AID)*

Level 1 Review

Contributing Factors	-N/A
Follow Up Actions	-Additional Data Collection

Level 2 Review

Was the bill adjusted?	-N/A

Level 3 Review

Has a memo been drafted to Medical Staff Leadership?	-N/A

Content Analysis of the Sample Event Incident Reports

Supporting Documentation Provided by Hospitals

Hospitals provided supporting documentation for each of the 40 events reported by staff to an incident reporting system. Of the 40 supporting documents, 19 consisted of full copies of the report forms that hospital staff completed when they reported events to an incident reporting system. We refer to these as incident reporting forms. For the other 21 reported events, hospitals did not provide the full incident report. In these cases, hospitals had not retained the full report but provided archived information to confirm that a report was made. This often included only basic information, such as the event type and date and did not represent the initial incident report. Therefore, we did not include the provided information for these 21 events in our content analysis.

We examined each of the 19 incident report forms and compared them to the Agency for Healthcare Research and Quality (AHRQ) Common Formats.[38, 39] AHRQ did not provide hospitals with the Common Formats until after our sample hospitals reported these events, and even now their use by hospitals is voluntary. However, the Common Formats represent a Federal effort to determine what information hospitals should include in incident reports, and in the absence of Federal requirements for report content, we used the Common Formats as a tool to compare the information in sample hospital incident reports.

Analysis of Data in the Incident Reports

We compared the individual data points in each incident reporting form to specific AHRQ Common Formats data elements. To determine whether an element was present, we reviewed the forms for fields indicating that the hospital requested the information from the reporter and that the request was fulfilled. If the information was requested but not completed (indicated by a blank field), we did not consider the element present. We collapsed the Common Format data elements into three categories based on AHRQ's event reporting forms: basic event

[38] AHRQ, Common Formats. Accessed at https://www.psoppc.org/web/patientsafety on March 31, 2011.

[39] We used AHRQ's Common Formats event reporting tools because they represent AHRQ's efforts to consolidate the necessary elements of an incident report for the purposes of patient safety improvement. AHRQ announced Version 1.0 of the Common Formats in the Federal Register in September 2009 and Version 1.1 in March 2010.

information, patient impact information, and summary and contributing factors.

Results of Content Analysis

In assessing these 19 incident reports, we found that report form and content were largely similar among hospital incident reporting systems. Incident reports most often focused on information that is likely readily available to staff who report, such as when and where the event occurred and the type of event. When compared to the AHRQ Common Formats, most incident reports contained basic event information and patient impact information, but few contained summary information and details about factors contributing to the event. Table B-1 provides a summary of the 19 incident reports listed by the categories and elements suggested in the AHRQ Common Formats.

Table B-1: Common Format Data Elements Present on the Complete Incident Reports (n=19)

Element Description	Number of Reports With Element
Basic Event Information	
Date the event was discovered	19
Location of the event	19
Clinical category of the event	19
Whether the event was an adverse event, near-miss, or unsafe condition	17
Narrative description of the event	16
Patient Impact Information	
Time between event and assessment of harm	16
Whether rescue steps were taken	16
Level of harm caused by event	14
Whether the event prolonged the patient's length of stay	2
Contributing Factor Information	
Whether and which factors contributed to the event	10
Patient safety staff's summary of the event and followup	6
Preventability of the event	6
Whether the event was a National Quality Forum Serious Reportable Event	0
Whether a patient handoff was associated with the event	3

Source: Office of Inspector General analysis of 19 full incident reports associated with reported events.

Basic Event Information. Each of the 19 incident reports included basic event information. The incident reports generally captured and

summarized basic information about the event and the patient involved, including the date, location, and type of event. Most incident reports (17 of 19 reports) also included elements for assessing whether the incident caused patient harm (an actual event) or represented only a near-miss or unsafe condition. To capture this information, reports used a structured format with specific questions and scaled responses, which hospital administrators indicated are useful for initially sorting events. For example, administrators reported that they often review the frequency of particular types of events using preset categories, such as "excessive bleeding" or "surgical-site infection." They reported that more detailed reviews may then be targeted at more frequent events.

Patient Impact Information. Incident reports commonly included descriptions of the impact of the event on the patient and actions taken by staff as a result of the event, such as the time between the event and an assessment (16 of 19 reports) and whether rescue steps were taken (16 of 19 reports). Hospital administrators indicated that patient impact information is often used to prioritize event investigations and, in the case of severe events, trigger special procedures. For example, one administrator said that when staff report events that have caused severe harm, alerts are sent automatically to specially trained response staff.

Contributing Factor Information. Incident reports were not likely to contain analytic information included in the Common Formats, such as factors that contributed to the event (10 of 19 reports). A number of hospital administrators indicated that this is the most useful information for conducting patient safety activities because it enables them to understand whether particular contributing factors, such as confusing medication labels, are a common cause of multiple types of events.

APPENDIX ~ C

Estimates, Confidence Intervals, and Key Statistics

We computed incidence rates and corresponding 95-percent confidence intervals using appropriate statistical methods based on the sample.

Table C-1: Estimates and Confidence Intervals

Events and Reasons Events Were Not Reported	Percentage Estimate	95-Percent Confidence Interval	
		Lower Bound	Upper Bound
Reporting Rate of Adverse and Temporary Harm Events (n=293)			
Events not captured	86.4%	81.6%	90.0%
Events captured	13.7%	10.0%	18.4%
Commonly reported to incident reporting system	24.6%	19.0%	31.2%
Not commonly reported to incident reporting system	61.8%	55.4%	67.8%
Not caused by a perceptible error	12.0%	8.5%	16.5%
Was an expected outcome or side effect	11.6%	8.3%	16.0%
Caused little harm and/or harm was ameliorated	10.6%	7.4%	14.9%
Was not on hospital's mandatory reporting list	8.5%	5.5%	12.9%
Occurs frequently in hospitals	7.9%	5.2%	11.6%
Symptoms became apparent after discharge	5.1%	2.8%	9.1%
Occurred in patient with a history of similar events	3.8%	2.1%	6.7%
Administrator did not provide a reason*	2.4%	1.2%	4.9%
Events captured and events commonly reported to incident reporting systems	38.2%	32.2%	44.6%
Reporting Rate of Adverse Events (n=124)			
Captured adverse events	12.9%	8.3%	19.6%
Reporting Rate of Temporary Harm Events (n=169)			
Captured temporary harm events	14.2%	9.4%	20.8%

*Given the small proportions, confidence intervals for projected numbers exceed 50-percent relative precision.
Source: Office of Inspector General (OIG) analysis of surveys associated with the 293 events identified by OIG.

Figure C-1: Statistical Test Results

Statistical Test	P-Value for Difference in Proportions
Test for relationship among harm events (i.e., adverse event or temporary harm event) and whether incident reporting systems captured the events	0.7380

Note: Weighted chi-square and Cochran-Mantel-Haenszel chi-square produced similar results.
Source: OIG analysis of surveys associated with the 293 events identified by OIG.

APPENDIX ~ D

Rates of Reporting by Event Category

Table D-1 contains information about the rate of reporting for events identified in the sample by type of event.

Table D-1: Rates of Reporting by Event Category (n=293)

Type of Event	Number of Sample Events	Number of Captured Events	Percentage of Captured Events
Events Related to Medication	111	14	13%
Acute renal insufficiency (kidney failure)	6	0	0%
Allergic reaction or side effect related to skin	6	0	0%
Allergic reaction to blood or related product	2	1	50%
Delirium or change in mental status	29	7	24%
Dysrhythmia	3	0	0%
Excessive bleeding	15	2	13%
Gastrointestinal complication	4	0	0%
Hypoglycemic event	17	2	12%
Hypotension	5	1	20%
Other events related to medication	2	0	0%
Respiratory complication	6	1	17%
Severe allergic reaction	3	0	0%
Severe headache or dizziness	3	0	0%
Severe hypotension	4	0	0%
Thrush and other opportunistic infection	6	0	0%
Events Related to Patient Care	95	15	16%
Aspiration	11	1	9%
Deep vein thrombosis, pulmonary embolism	5	0	0%
Exacerbation of preexisting medical condition	4	0	0%
Failure to treat constipation or obstipation	3	0	0%
Intravenous infiltrate with symptoms	5	1	20%
Intravenous volume overload	24	0	0%
Other events related to patient care	5	2	40%
Patient fall with injury	5	5	100%
Skin tear, laceration, abrasion, or other breakdown	9	1	11%
Stage I, Stage II, or unstaged pressure ulcer	19	5	26%
Stage III pressure ulcer	3	0	0%
Tachycardia or dysrhythmia	2	0	0%

continued on next page

Table D-1: Rates of Reporting by Event Category (n=293) (Continued)

Type of Event	Number of Sample Events	Number of Captured Events	Percentage of Captured Events
Events Related to Surgery or Other Procedures	62	7	11%
Acute coronary syndrome	1	0	0%
Blood clot and other occlusion	2	0	0%
Cardiac complication	6	2	33%
Excessive bleeding	11	1	9%
Iatrogenic pneumothorax	3	1	33%
Other events related to surgery or other procedures	5	0	0%
Postoperative ileus	3	0	0%
Postoperative or postprocedural hypotension	2	0	0%
Postoperative urinary retention	3	0	0%
Prolonged nausea and vomiting	2	0	0%
Respiratory complication	6	2	33%
Severe hypotension	4	1	25%
Surgical tear or laceration	3	0	0%
Urinary catheter-associated trauma	3	0	0%
Urinary retention	8	0	0%
Events Related to Infection	25	4	16%
Bacterial infection	1	0	0%
Other bloodstream infection	4	1	25%
Respiratory infection	5	1	20%
Surgical or procedural site infection	4	1	25%
Urinary tract infection	6	0	0%
Vascular catheter-associated infection (central or peripheral line)	5	1	20%

Source: Office of Inspector General (OIG) analysis of incident reports associated with the 293 events identified by OIG.

APPENDIX ~ E

Agency Comments

Agency for Healthcare Research and Quality

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

NOV 16 2011

TO: Inspector General, Department of Health and Human Services

FROM: Director

SUBJECT: OEI Inspection Number OEI-06-09-00091

Thank you for the opportunity to review and comment on the Office of Inspector General's draft report entitled, OEI-06-09-00091, *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm.*

Recommendation: ***AHRQ and CMS should collaborate to create a list of potentially reportable events and provide technical assistance to hospitals using the list.***
AHRQ concurs with this recommendation. AHRQ has begun meeting with CMS to explore the role of the Common Formats as the foundation for a list of reportable events.

Recommendation: ***CMS should provide guidance to accreditors regarding surveyor assessment of hospital efforts to track and analyze events, and should scrutinize survey processes when approving accreditation programs.***
AHRQ concurs with this recommendation. AHRQ will meet with CMS staff to continue collaboration on the potential use of Common Formats with surveyors and hospital adverse event reporting systems.

Other technical notes for OIG staff:
Page 5 – last sentence - The Common Formats' three event reporting forms focus on specific areas: information describing the event, information describing the patient, and summary and contributing factors.

We suggest adding a new sentence: "The Common Formats also contain event specific modules that provide additional detail for high volume or high harm events."

If you or your staff have any questions, please feel free to contact Dr. Bill Munier, Director, Center for Quality Improvement and Patient Safety at William.munier@ahrq.hhs.gov or 301-427-1921.

/S/

Carolyn M. Clancy

Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: NOV 18 2011

TO: Daniel R. Levinson
Inspector General

/S/

FROM: Donald M. Berwick, M.D.
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Hospital Incident Reporting Systems Do Not Capture Most Patient Harm (OEI-06-09-00091)

Thank you for the opportunity to review and comment on this very timely and important study. In the subject report, the OIG examines whether hospitals identified adverse events on their own and, if so, the types of follow-up actions they took. The OIG reviewed the characteristics of hospitals' internal incident reporting systems, as well as the methods used by hospital accrediting organizations in evaluating hospital safety practices. There is a significant opportunity for far-reaching improvement in the experience of individuals and families in the United States health care system and the patient safety arena, as well as, an opportunity for savings to the taxpayer and the beneficiary.

We note that since the incidents reviewed in this report, the Department of Health and Human Services (HHS) has launched a new and ambitious public-private partnership entitled the "Partnership for Patients." This national Partnership will help improve the quality, safety and affordability of health care for Medicare, Medicaid and CHIP beneficiaries, and for all Americans. More than 6,200 organizations – including more than 2,800 hospitals – have signed the Partnership Pledge.

HHS and the Centers for Medicare & Medicaid Services (CMS) are working with a wide variety of public and private partners to achieve the two core goals of this Partnership:

- Keeping patients from getting injured or sicker in the health care system, and
- Helping patients heal without complication by improving transitions from acute-care hospitals to other care settings, such as home or a skilled nursing facility.

Hospitals' ability to identify patient harm that has occurred is an essential component of their efforts to prevent future such harm. We are very appreciative of the contribution that the OIG is making to our knowledge of common hospital approaches to identifying harm, the limitations of the existing methods employed, and the OIG's recommendations for improvement. The recommendations in this OIG report will help us strengthen the Partnership for Patients initiative as we work with hospitals and other health care providers to improve patient safety.

Centers for Medicare & Medicaid Services (continued)

Many of the hospital administrators contacted for the OIG's report indicated that they use multiple adverse event detection methods, including medical record reviews, administrative data screening, reviews for evidence of healthcare-associated infections, and post-procedure checklists. We expect all hospitals to use multiple methods to detect patient harm that has occurred. At the same time, we recognize that the detailed physician case record reviews, such as the OIG employed in its November 2010 report to estimate the incidence of harm to Medicare beneficiaries, are labor-intensive and costly, even when use is made of trigger tools and other preliminary screening to narrow the number of records to be reviewed. As a result, these more comprehensive methods are likely to remain comparatively limited in their scope.

As the OIG's report indicates, internal hospital incident reporting systems have limitations that result in significant underreporting of adverse patient events. Since hospital administrators reported to the OIG that incident reporting systems continue to be their primary method to identify adverse events, the limitations in such systems are particularly important. We fully agree with the OIG on the need to strengthen hospital incident reporting systems.

OIG Recommendation

The Agency for Healthcare Research and Quality (AHRQ) and CMS should collaborate to create a list of potentially reportable events and provide technical assistance to hospitals in using the list.

CMS Response

The CMS fully concurs with this recommendation and have initiated communications to carry out the desired collaboration. Further, once such a list is developed we will explore methods to promote its use by hospitals and to educate their staff. We also agree that the list could be used to educate State and accreditation organization surveyors. While hospitals are not required under the existing Medicare health and safety regulations to use CMS-developed lists of adverse events, such a list can be highly beneficial in improving current incident reporting systems.

We also note the OIG observation that the purpose of this list would not be to support any external reporting, but rather to educate hospital staff about the full range of harm that occurs in hospitals and to clarify for staff those events or circumstances which should be reported internally. We concur that the purpose of such lists should not include creating any new external adverse event reporting requirements, particularly since there are a number of States that have already put external reporting systems in place.

OIG Recommendation

CMS should provide guidance to accreditors for assessment of hospital efforts to track and analyze events, and should scrutinize survey processes when approving accreditation programs.

Centers for Medicare & Medicaid Services (continued)

CMS Response

We concur with this recommendation. As the OIG states in its report, we are developing draft surveyor guidance for the hospital quality assessment and performance improvement (QAPI) requirement that currently exists as a Medicare Condition of Participation. We are also pre-testing a surveyor worksheet to assist surveyors in determining compliance with the QAPI Condition. We anticipate releasing official CMS guidance on assessing QAPI compliance in the near future. We will incorporate into that guidance our expectation that hospitals improve their internal incident reporting systems by providing hospital staff with detailed, unambiguous instructions on the types of events that should be reported. We will suggest that hospitals start with the AHRQ Common Formats in developing these instructions.

Once we issue final, formal guidance for surveyors on assessing QAPI compliance, and incorporate that guidance into standard operating procedures, the three national accreditation organizations with CMS-approved Medicare hospital accreditation programs will be required to review that guidance and ensure that their survey process is consistent with it.

At such time as CMS and AHRQ develop lists in response to the OIG's first recommendation, we will amend our guidance to make reference to these lists as an available tool to assist hospitals in instructing staff.

Thank you for your attention to this key area of health care and for specific ideas on methods by which our oversight of hospitals may be improved.

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