

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ADVERSE EVENTS IN HOSPITALS:
OVERVIEW OF KEY ISSUES**



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E X E C U T I V E S U M M A R Y

OBJECTIVE

To provide a descriptive analysis of the key issues regarding adverse events in hospitals.

BACKGROUND

The term “adverse event” describes any harm to a patient as a result of medical care, such as infection because of contaminated equipment. The Tax Relief and Health Care Act of 2006 (the Act) mandates that the Office of Inspector General (OIG) report to Congress regarding the incidence of “never events” among Medicare beneficiaries, payment by Medicare or beneficiaries for services furnished in connection with such events, and the processes that the Centers for Medicare & Medicaid Services (CMS) uses to identify events and deny payment. Never events are a specific list of serious events, such as surgery on the wrong patient, that the National Quality Forum deemed “should never occur in a health care setting.” Expanding beyond this specific list, this and subsequent OIG reports use the broader term “adverse event” to provide for a more comprehensive examination of key issues. This report is one in a series to fulfill the requirements in the Act and inform decisionmakers. OIG work in this area will continue through 2009.

To facilitate OIG efforts to comply with the mandate, we first sought to identify key issues regarding adverse events in hospitals to provide direction and context for our work. This overview report combines evidence, analysis, and opinion from a wide range of sources. These sources, which we refer to collectively as “stakeholders,” represent diverse entities involved in addressing adverse events in hospitals, including government agencies and other policymakers, professional associations, oversight organizations, patient safety groups, providers, and researchers.

KEY ISSUES

We identified the following seven issues as most critical to understanding the landscape of adverse events in hospitals:

Issue 1: Estimates of the incidence of adverse events in hospitals vary widely and measurement is difficult. Research estimates of the frequency of adverse events in hospitals vary from 3 percent to 20 percent of hospital admissions, in part because there

is no optimal method for measuring incidence. Research also indicates that elderly patients are particularly vulnerable.

Issue 2: Nonpayment policies for adverse events are gaining in prominence and are viewed as a powerful incentive to reduce incidence but raise potential drawbacks. CMS's new policy will deny hospitals higher payment for admissions complicated by selected adverse events, and private health care payers are adopting similar policies. Stakeholders generally believe that nonpayment provides an incentive to prevent costly adverse events. Potential drawbacks of nonpayment raised by stakeholders include limited access to care, increased hospital costs, and reduced hospital revenue.

Issue 3: Hospitals rely on staff and managers to report adverse events internally, but barriers can inhibit reporting. Reporting events and suspected causes can help hospitals improve practices to prevent adverse events and ensure accountability for poor care. Hospitals also use reported information to inform affected patients and families, which is thought to boost public trust, and to improve clinical decisionmaking and compliance in treatment. However, hospital staff may not report events because they do not believe that reports will lead to improvement, do not have time, or fear punitive action.

Issue 4: Hospitals report adverse events to various oversight entities, although stakeholders suspect substantial underreporting. Although there is no comprehensive national reporting system for adverse events, a number of Federal, State, and nongovernmental entities receive adverse event reports from hospitals. Hospitals are believed to underreport adverse events, although it is difficult to know to what extent. However, stakeholders indicated that reporting every adverse event is not necessary to achieve the aim of improving practices to prevent adverse events.

Issue 5: Public disclosure of adverse events can benefit patients but also raises legal concerns for patients and providers. Access to adverse event information provides public scrutiny that may pressure hospitals to improve practices. However, concerns that hospitals, clinicians, and patients can lose legal protections when adverse event information is reported can inhibit full disclosure of adverse events.

Issue 6: Information to help prevent adverse events is widely available, but some hospitals and clinicians may be slow to adopt or routinely apply recommended practices. Hospitals and clinicians are sometimes slow to adopt recommended practices, such as evidence-based clinical practice guidelines, which outline systematically developed procedures to improve care. Literature indicates that hospital staff and clinicians may believe that the guidelines are not relevant to their setting or that they value individual practitioner judgment more than regimented standards of care.

Issue 7: Interviews and literature reveal strategies that may accelerate progress in reducing the incidence of adverse events in hospitals. Strategies included the following:

- assessing the desirability and feasibility of a national body to lead patient safety efforts, which would help to coordinate, but not replace, current efforts by government agencies and private entities;
- focusing on hospital use of recommended practices and evidence-based guidelines to reduce the incidence of adverse events, including measuring hospital use;
- establishing methods for measuring the incidence of adverse events, including tools for practical and accurate data collection;
- expanding the use of electronic health records within and between hospitals, thus improving communication and continuity of care to potentially reduce the incidence of adverse events;
- monitoring the impact of policies to deny hospitals higher payment for admissions complicated by selected adverse events; and
- improving the utility of adverse event reporting, including evaluating the comparability of data reported across entities and streamlining reporting mechanisms to reduce burden on hospitals.

SUMMARY

The extensive range of entities involved in researching and addressing adverse events shows that reducing the incidence of adverse events is a high priority. Stakeholders described the current environment among hospitals and policymakers as being on the threshold of accelerated progress. They point to a large body of research as improving understanding, including recognition of the critical role of hospital systems in guarding against adverse events. Additionally, new policies,

such as denying hospitals higher payment for admissions complicated by certain adverse events and public disclosure of events, strengthen hospital incentives to develop safer practices. These advancements in clinical understanding, combined with heightened controls, hold promise for reducing the incidence of adverse events in hospitals and improving the quality of care.

AGENCY COMMENTS

We received comments on a draft of this report from the Agency for Healthcare Research and Quality (AHRQ) and CMS.

AHRQ concurred with the report's findings.

CMS commended OIG on succinctly capturing the numerous issues surrounding this complex topic, acknowledged technical assistance provided to OIG in conducting this study, and indicated that it welcomed continued work with OIG on this issue.

CMS reiterated its policies to encourage the prevention of adverse events that are enumerated in the report, particularly the nonpayment provision for hospital-acquired conditions, noting that OIG's work is supportive of and will enable more effective CMS implementation of the provision. CMS agreed that nonpayment for care associated with adverse events strengthens hospitals' incentives to develop safety practices and reduces health care costs in the long term. CMS also addressed the three potential drawbacks of nonpayment policies raised by stakeholders, providing further discussion to indicate that it believes these drawbacks are unlikely to occur.

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OBJECTIVE

To provide a descriptive analysis of the key issues regarding adverse events in hospitals.

BACKGROUND

Statutory Mandate and Office of Inspector General Response

The Tax Relief and Health Care Act of 2006 (the Act) requires that the Office of Inspector General (OIG) study events that cause harm to Medicare beneficiaries. The Act specifically mandates that OIG study the incidence of “never events” among Medicare beneficiaries, payment by Medicare or beneficiaries for services furnished in connection with such events, and administrative processes of the Centers for Medicare & Medicaid Services (CMS) to identify events and deny or recoup payment. OIG is also to report to Congress on the study conducted, including recommendations for such legislation and administrative action as OIG determines appropriate. (For relevant text of the Act, see Appendix A.)

A variety of terms, lists, and definitions are used to identify and address harmful health care events. (For a glossary of selected terms, see Appendix B.) The term “never event” is used to describe a specific list of serious events that the National Quality Forum (NQF) determined “should never occur in a health care setting” and are associated primarily with patient death or serious disability.¹ NQF currently uses the term “serious reportable events” to describe this list. (For a list of NQF serious reportable events, see Appendix C.) Expanding beyond the specific events defined by NQF, this and subsequent OIG reports use the broader and more common term “adverse event” to provide for a more comprehensive examination of key issues.

Following a review of Medicare policies and expenditures, as well as consultation with CMS and the Agency for Healthcare Research and Quality (AHRQ), we chose to focus much of our work on the hospital setting. Costs for inpatient hospital care constitute the largest portion

¹ NQF is a not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting. The list is available online at <http://www.qualityforum.org/about>. Accessed on October 21, 2008.

of Medicare expenditures (29.6 percent in 2007).² Also, many current efforts by government agencies and private entities to research and address adverse events target care provided in hospitals.

OIG is conducting a series of studies through 2009 to fulfill the requirements in the Act and to inform decisionmakers regarding adverse events. To facilitate OIG efforts to comply with the Act, we first sought to identify key issues regarding adverse events in hospitals to provide direction and context for our future work. To describe these key issues, this overview report combines evidence, analysis, and opinion from a wide range of sources. Key issues include current analysis and discourse regarding the primary components of the Act: incidence, payment (including CMS processes), and the balance between protecting patient privacy and providing information to improve patient safety. Other OIG studies focus on estimating the incidence of adverse events among Medicare beneficiaries, State efforts to operate adverse event reporting systems, Medicare beneficiaries receiving potentially inappropriate drug pairs that may reflect medication errors, and hospital actions to address and prevent adverse events.

Adverse Events in Hospitals

The term “adverse event” describes any harm to a patient as a result of medical care. An adverse event indicates that the care resulted in an undesirable clinical outcome and that the clinical outcome was not caused by an underlying disease. Adverse events include medical errors, such as use of incompatible blood products. They may also include more general substandard care that results in harm, such as infection because of contaminated equipment, incorrect diagnoses, and lack of patient monitoring during treatment. Research, policies, and action taken to reduce adverse events often focus on mistakes and systemic problems with care. However, adverse events do not always involve errors, negligence, or poor quality of care and may not always be preventable.

Reducing the incidence of adverse events in hospitals is a critical component of efforts to ensure patient safety and to provide quality health care. The Institute of Medicine (IOM) report, “To Err is Human: Building a Safer Health System,” is often credited with first drawing

² Based on data contained in Congressional Budget Office (CBO) “Fact Sheet for CBO’s March 2007 Baseline: Medicare,” March 7, 2007. Available online at <http://www.cbo.gov/budget/factsheets/2007b/medicare.pdf>. Accessed on September 8, 2008.

widespread attention to the issue of adverse events in hospitals.³ IOM cited two studies that used medical record reviews to identify adverse events (defined as injuries caused by medical management) with similar results. The first study, using hospitalizations in a single State, found that 3.7 percent of hospital patients experienced adverse events, 58 percent of these events were preventable, and 13.6 percent resulted in death.⁴ A second study, replicating the methodology in two other States, found that 2.9 percent of hospital patients experienced adverse events, of which 53 percent were preventable and 6.6 percent resulted in death.⁵ IOM extrapolated these results to hospital admissions nationwide for 1997, concluding that preventable adverse events caused “at least 44,000 and perhaps as many as 98,000 deaths in hospitals each year.”⁶

Following the IOM report, the Federal Government formed the Center for Patient Safety and Quality Improvement within AHRQ to coordinate research regarding patient safety. Since that time, AHRQ has conducted and funded many research efforts regarding adverse events, promulgated recommended practice guidelines, and provided much analysis and guidance regarding patient safety issues. As of September 2008, the patient safety Web site operated by AHRQ, Patient Safety Network (PSnet), provides over 3,500 publications related to patient safety and adds an average of 10 publications a week.⁷

Hospital Oversight and Guidance

Various government agencies and other entities are responsible for addressing adverse events in hospitals, often as part of overall efforts to ensure that minimum standards are met and improve health care quality. Federal and State governments, nonprofit entities, academic

³ 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, Institute of Medicine, Washington, DC, National Academy Press, 1999.

⁴ T. A. Brennan, L. L. Leape, N. M. Laird, et al., “Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study 1,” *New England Journal of Medicine*, 324(6), 1991, pp. 370–376. Abstract available online at <http://content.nejm.org/cgi/content/abstract/324/6/370>. Accessed on October 10, 2008.

⁵ E. J. Thomas, D. M. Studdert, H. R. Burstin, et al., “Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado,” *Medical Care*, 38(3), 2000, pp. 261–271. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/10718351>. Accessed on October 10, 2008.

⁶ 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, Institute of Medicine, Washington, DC, National Academy Press, 1999.

⁷ Estimate of number of publications based on interviews with PSnet editors. AHRQ PSnet is available online at <http://www.psnet.ahrq.gov/>. Accessed on October 9, 2008.

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institutions, professional organizations, and accrediting bodies have set standards, issued guidance, and provided technical assistance to hospitals. Additionally, hospitals must track and analyze adverse events as a condition of participation for Medicare and Medicaid certification.⁸ Although hospitals are required by CMS to develop and maintain systems for tracking adverse events, Federal regulations do not require specific system characteristics.

Oversight of hospitals is generally conducted by States and accreditation organizations, most prominently the Joint Commission. The Joint Commission establishes standards for hospitals, conducts periodic surveys to review policies and to observe operations onsite, and accepts hospital reports of adverse events. Accreditation by the Joint Commission is voluntary, and approximately 80 percent of U.S. hospitals are accredited. Accreditation requires that hospitals comply with many standards, some of which relate specifically to patient safety.⁹ In 2002, the Joint Commission established its National Patient Safety Goals program to provide hospitals with recommended practices related to “persistent patient safety problems.” National Patient Safety Goals include preventing patients from falling and preventing surgical errors.¹⁰ For 2009, the program added three goals specific to health care-associated infections.¹¹

State health departments address adverse events and quality-of-care issues through hospital licensing. To be licensed, hospitals must meet minimum care standards established by the States. In some States, a Joint Commission accreditation serves as evidence that these standards have been met. Additionally, State health departments may conduct onsite surveys of hospitals in response to complaints by patients or families. Other private organizations establish standards for quality of care or patient safety and give hospitals accreditation status or ratings based on meeting standards and demonstrating results. Federally

⁸ 42 CFR § 482.21.

⁹ The Joint Commission, The Joint Commission Requirements Hospital Page, “Requirements for Accreditation,” updated October 29, 2008. Available online at <http://www.jcrinc.com/TJC-Requirements-Hospital-Page/>. Accessed on December 5, 2008.

¹⁰ The Joint Commission, “2009 Hospital National Patient Safety Goals,” October 2008. Available online at http://www.jointcommission.org/NR/rdonlyres/40A7233C-C4F7-4680-9861-80CDFD5F62C6/0/09_NPSG_HAP_gp.pdf. Accessed on October 21, 2008.

¹¹ The Joint Commission, “News Release: The Joint Commission Announces 2009 National Patient Safety Goals,” June 17, 2008. Available online at http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/09_hap_npsgs.htm. Accessed on August 28, 2008.

funded Quality Improvement Organizations, private entities that contract with CMS to support quality of care, also provide guidance and technical assistance to hospitals and other Medicare providers.

Various health care entities often use different terms and definitions for adverse events. Some of these entities have developed lists of adverse events for more precise definition and measurement of events, including the following prominent lists:

- NQF—serious reportable events, originally referred to as never events because they should never happen in a health care setting;¹²
- The Joint Commission—sentinel events, the term “sentinel” denoting a serious event that signals the need for immediate investigation and response;¹³
- AHRQ—Patient Safety Indicators (PSI), conditions or circumstances identifiable in administrative data, such as discharge and billing records;¹⁴ and
- CMS—categories of hospital-acquired conditions for which Medicare will not pay hospitals higher reimbursement.¹⁵

Medicare Payment for Adverse Events

Medicare traditionally did not distinguish between costs incurred in treating existing illness from those incurred as the result of adverse events. Medicare reimbursement to hospitals is generally determined by grouping patient conditions into diagnosis-related groups (DRG) based on the average cost of care for patients with similar conditions. Historically, if a Medicare beneficiary experienced harm from an

¹² NQF, “Serious Reportable Events in Healthcare 2006 Update: A Consensus Report,” Washington, DC, 2007, p. 7. Available online at <http://www.qualityforum.org/pdf/reports/sre/txsrepublic.pdf>. Accessed on October 10, 2008.

¹³ The Joint Commission, “Sentinel Events Fact Sheet,” Section IV, Reviewable Sentinel Events, updated July 2007, p. 3. Available online at http://www.jointcommission.org/NR/rdonlyvres/F84F9DC6-A5DA-490F-A91F-A9FCE26347C4/0/SE_chapter_july07.pdf. Accessed on October 10, 2008.

¹⁴ AHRQ, “Patient Safety Indicators Overview,” AHRQ Quality Indicators, February 2006. Available online at http://www.qualityindicators.ahrq.gov/psi_overview.htm. Accessed on August 28, 2008.

¹⁵ CMS, “Hospital-Acquired Conditions,” August 19, 2008. Available online at http://www.cms.hhs.gov/HospitalAcqCond/06_Hospital-Acquired_Conditions.asp#TopOfPage. Accessed on October 10, 2008.

adverse event that resulted in assignment of a more expensive DRG, CMS paid the full claim without any payment reduction.¹⁶

Hospital-Acquired Conditions. The Deficit Reduction Act of 2005 (DRA) required CMS to select at least two hospital-acquired conditions for which hospitals would not be paid higher Medicare reimbursement.¹⁷ CMS issued a final regulation in August 2007 to initiate policy for which CMS would deny hospitals higher payment for admissions complicated by eight categories of hospital-acquired conditions. CMS chose the categories of conditions in collaboration with the Centers for Disease Control and Prevention (CDC) and used the following criteria:

- conditions that are high cost, high volume, or both;
- conditions that, when present as a secondary diagnosis, result in assignment of a case to a DRG that has a higher payment;
- conditions that could be reasonably prevented by using readily available evidence-based guidelines; and
- conditions that are identifiable based on one or more unique diagnosis codes.¹⁸

Changes to CMS Payment. In addition to designating the list of categories of hospital-acquired conditions, the final regulation implements a more specific list of DRGs called Medicare Severity Diagnosis-Related Groups (MS-DRG). MS-DRGs split some of the prior DRGs into two or three individual classes based on the presence of a complication or comorbidity.¹⁹ Each medical diagnosis (ICD-9-CM) code²⁰ submitted must include a new indicator designating whether the condition is or is not “present on admission” (POA).²¹ The final rule applies only to traditional fee-for-service Medicare and does not apply to

¹⁶ Department of Health and Human Services (HHS), CMS, Press Release, “Eliminating Serious, Preventable, and Costly Medical Errors – Never Events,” May 18, 2006. Available online at <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1863>. Accessed on August 28, 2008.

¹⁷ DRA, § 5001(c), P.L. No. 109-171 (adding Social Security Act, § 1886(d)(4)(D)), provided for a quality adjustment in DRG payments for certain hospital-acquired conditions.

¹⁸ Ibid.

¹⁹ 42 CFR § 412.10, fiscal year (FY) 2008 Inpatient Prospective Payment System (IPPS) Final Rule, 72 Fed. Reg. 47130, 47138 (Aug. 22, 2007).

²⁰ The ICD-9-CM system assigns diagnoses and procedure codes associated with hospitalizations and is maintained jointly by the National Center for Health Statistics (NCHS) and CMS. NCHS, “The International Classification of Diseases, 9th Revision, Clinical Modification” (ICD-9-CM), Sixth Edition, issued for use beginning October 1, 2007.

²¹ DRA, P.L. No. 109-171, § 5001(c), adding Social Security Act, § 1886(d)(4)(D).

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Medicare managed care (Medicare Advantage Organizations (MAO)). To determine how MAOs can be held accountable for adverse events, CMS will begin in 2010 to collect data from MAOs regarding care associated with adverse events.²²

In July 2008, CMS issued a final rule to expand the list of hospital-acquired conditions for a total of 10 categories of conditions. Effective October 1, 2008, CMS will deny hospitals higher payment for Medicare admissions complicated by these categories of conditions:²³

- Foreign object retained after surgery
- Air embolism
- Blood incompatibility
- Pressure ulcers (Stages III and IV)
- Falls resulting in fracture, dislocation, intracranial injury, or crushing injury; category also includes burn and electric shock
- Manifestations of poor glycemic control resulting in certain conditions
- Catheter-associated urinary tract infection
- Vascular-catheter-associated infection
- Deep vein thrombosis/pulmonary embolism associated with total knee replacement or hip replacement
- Surgical site infection associated with certain surgeries

Also in 2008, CMS began analysis of its coverage policy regarding certain events on the NQF list of serious reportable events²⁴ and issued a letter to State Medicaid directors providing guidance for State implementation of a coordinated denial of higher payment for admissions wherein Medicaid serves as a secondary payer.²⁵

²² Supporting Statement for Paperwork Reduction Act Submissions: Part C Medicare Advantage Reporting Requirements and Supporting Regulations, 42 CFR § 422.516 (a).

²³ FY 2009 Final IPPS Rule, 73 Fed. Reg. 48434 and 48471 (Aug. 19, 2008).

²⁴ Social Security Act § 1862(a)(1)(A) provides authority for CMS to determine whether a service or an item is reasonable and necessary. CMS, Medicare Coverage Database, “National Coverage Analyses: Surgery on the Wrong Body Part; Surgery on the Wrong Patient; and Wrong Surgery Performed on a Patient,” updated May 30, 2008. Available online at http://www.cms.hhs.gov/mcd/index_list.asp?list_type=nca. Accessed on November 4, 2008.

²⁵ CMS, Letter to State Medicaid Directors, SMDL #08-004, July 31, 2008. Available online at <http://www.cms.hhs.gov/SMDL/downloads/SMD073108.pdf>. Accessed on October 20, 2008.

SCOPE AND METHODOLOGY

Scope

This report describes key issues regarding adverse events in hospitals. We conducted a literature review of a wide range of published work covering not only adverse events but also the broader topic of patient safety. We also conducted structured interviews with stakeholders, including researchers; clinicians; and officials from government agencies, oversight entities, and patient safety groups. These activities occurred between March 2007 and November 2008.

Literature Review

The literature review included professional and academic journal articles and government reports. We selected literature based on its relevancy to the topic, currency, and citation by other sources. We identified published works using a variety of sources, including:

- input from staff at AHRQ, CMS, and other stakeholders;
- Internet search tools, e.g., AHRQ's PSnet, Health Services Research Library, and Medline; and
- bibliographies in literature identified by these sources.

Stakeholder Interviews

We conducted 85 structured interviews with a variety of stakeholders to gain insight into policies, practices, and viewpoints regarding adverse events. The interview protocol covered a range of issues related to adverse events and patient safety, including the causes and frequency of events, strategies for addressing events, and payment for related care. In many cases, we had follow-up conversations with stakeholders later during our study period.

In compiling the group of stakeholders, we sought to represent a broad spectrum of interests and viewpoints. Interview respondents included experts in adverse events from a variety of perspectives, including national oversight, advocacy, and professional organizations, as well as health plans, hospitals, and practitioners experienced in identifying and addressing adverse events. Additionally, stakeholders included many prominent researchers and policymakers in the field of patient safety, including several members of the initial NQF committee that developed the list of serious reportable events. We identified stakeholders for interviews using a variety of sources, including:

- a list of patient safety entities and contacts provided by AHRQ’s Center for Quality and Patient Safety, the National Patient Safety Foundation, and the Joint Commission;
- entities and contacts referenced in the literature; and
- referrals from other stakeholders as our interviews progressed.

We completed interviews with 98 percent of the identified stakeholders (78 of 80). For cases in which we were not able to interview the identified stakeholders, we ensured that our list included stakeholders from similar entities. For example, we interviewed staff from four State agencies identified as exhibiting a range of approaches to patient safety issues. The viewpoints of the individuals we interviewed do not represent official positions of their organizations. We selected representatives from each of the following broad groups. (For a list of responding stakeholder entities, see Appendix D.)

- Federal agencies—8 interviews
- State agencies—4 interviews
- Professional associations—10 interviews
- Oversight/standard-setting organizations—5 interviews
- Patient safety advocacy groups—7 interviews
- Public policy groups—9 interviews
- Providers (hospitals and networks)—28 interviews
- Private Payers (managed care organizations)—4 interviews
- University researchers—5 interviews
- Service contractors²⁶—5 interviews

Additional Data From Companion Study

In our discussion of State adverse event reporting systems on pages 23–26, we use information about State policies and practices collected for a companion study in this series, “Adverse Events in Hospitals: State Reporting Systems” (OEI-06-07-00471). The data were collected through interviews with and document requests of all States and the District of Columbia between January and April 2008.

²⁶ Service contractors include private entities that provide products or services to hospitals that are related to patient safety or quality of care, such as adverse event reporting software and medical record review.

Data Analysis

Our analysis of information from literature and interviews focused on four primary tasks:

- identifying and refining key issues;
- gathering expert opinions, insight, and evidence regarding these key issues;
- synthesizing this information to determine both prevailing and countervailing viewpoints of stakeholders and literature; and
- identifying examples to illustrate and clarify these points.

When we refer to stakeholder viewpoints in the report, these summary statements represent the predominant viewpoint of the stakeholders interviewed. Despite the range of viewpoints represented, we found a great deal of agreement among stakeholders and the literature regarding the status of current efforts to address adverse events in hospitals. Where we found widespread agreement, the report provides summary statements that reflect the predominant viewpoint of these sources. Because of the variety of sources and the often nuanced discourse regarding these complex issues, this report does not provide stakeholder responses by percentage. Rather, the report includes selected discussion and examples to illustrate the prevailing view or to add insight. For examples of our analysis and quantified responses to key questions, see Appendix E.

Limitations

In collecting information, we sought to include widely recognized literature and stakeholders and to represent a wide variety of viewpoints based on research and analysis. Additionally, the number of potential stakeholders was very large, necessitating selection of representatives to speak for each broader group of entities. As a result, we may have excluded input that could have provided additional or different insight.

Standards

This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.



Issue 1: Estimates of the incidence of adverse events in hospitals vary widely and measurement is difficult

Most stakeholders reported that, although it is difficult to measure, they perceive that the incidence remains close to that cited by IOM in 1999: roughly 3 percent of hospitalized patients experience adverse events. No subsequent study has attempted to determine a broad, national estimate of adverse events, such as was reported by IOM; however, researchers have conducted a number of smaller studies focusing on specific events and populations. These efforts have provided a wide range of estimates—from less than 3 percent to greater than 20 percent of patients experiencing adverse events. See Appendix F for examples of this research, including rates and methods. A number of stakeholders reported that when discussing the incidence of adverse events in general terms, they assume a slightly higher rate: 10 percent of hospital stays involve some type of health care-related problem, with about half (5 percent of hospital stays) resulting in some degree of harm to the patient and thereby constituting an adverse event.

Research indicates that elderly patients have a greater number of preexisting conditions and face greater risks of experiencing adverse events.²⁷ Stakeholders reported that adverse events are more common among the elderly because of the clinical complexity of their care, including multiple medications, higher rates of surgery, and longer hospital stays. Elderly are particularly vulnerable to medication-related adverse events, in large part because of administration of multiple medications.²⁸

Researchers use a variety of methods to measure incidence, but accurate identification of events is challenging and no single method is optimal

Given the often complex nature of illness and injury, determining whether an adverse event occurred can be difficult. Identifying adverse events may require evaluating the prior condition of the patient; determining what occurred in the delivery of health care; and

²⁷ T. A. Brennan and E. J. Thomas, “Incidence and Types of Preventable Adverse Events in Elderly Patients: Population Based Review of Medical Records,” *BMJ*, 320, March 18, 2000, pp. 741–744. Available online at <http://www.bmj.com/cgi/reprint/320/7237/741>. Accessed on October 10, 2008.

²⁸ D. M. Picone, M. G. Titler, J. Dochterman, et al., “Predictors of Medication Error Among Elderly Hospitalized Patients,” *American Journal of Medical Quality*, 23(2), March–April 2008, pp. 115–127. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/18305099>. Accessed on October 10, 2008.

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distinguishing between the effect of the occurrence, the prior condition, and any natural progression of an illness or injury. Stakeholders report that this difficulty can be compounded in a hospital setting, with patients receiving care from multiple caregivers and patients are subject to intricate hospital systems. In some cases, patients and caregivers may not be aware that an event occurred and therefore do not record information useful for identifying the event retrospectively.

Entities that address adverse events sometimes categorize them by the severity of harm incurred and may choose to focus on adverse events with the greatest degree of harm. A commonly used scale of harm was developed by the National Coordinating Council for Medication Errors Reporting and Prevention (NCC MERP).²⁹ The scale classifies events beginning with circumstances that have the capacity to cause error (near miss) and escalating through levels of patient harm (prolonged hospitalization, temporary disability) and eventually to patient death. NQF's list of serious reportable events and the Joint Commission's list of sentinel events include medication-related adverse events only when the patient suffers serious disability or death.³⁰

Researchers and hospitals use various methods to determine the incidence of adverse events and appear to have little agreement about the most reliable method. Studies comparing the results of various methods have found widely divergent outcomes. When researchers attempted to find the same adverse events using different data collection methods, results varied substantially. For example, one study found that 8 percent of hospitalized patients reported an adverse event, but only half of these events were documented in the medical record, and none of the events were documented in the hospital incident reporting system.³¹ Comparisons of adverse event rates are difficult because researchers may use different definitions and methods for identifying adverse events. For example, only two specific adverse events are characterized in the same way on all four of the prominent

²⁹ The National Coordinating Council for Medication Error Reporting and Prevention, "NCC MERP: The First Ten Years, Defining the Problem and Developing Solutions," December 2005, Figure 1, p. 29. Available online at <http://www.nccmerp.org/pdf/reportFinal2005-11-29.pdf>. Accessed on October 10, 2008.

³⁰ Sources referenced in footnotes 13 and 14 on p. 5.

³¹ S. N. Weingart, O. Pagovich, D. Z. Sands, et al., "What Can Hospitalized Patients Tell Us About Adverse Events? Learning from Patient-Reported Incidents," *Journal of General Internal Medicine*, 20(9), 2005, pp. 830–836. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/16117751>. Accessed on October 10, 2008.

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lists referenced on page 5 (AHRQ, CMS, Joint Commission, and NQF): object left in patient after surgery and blood incompatibility.

In some cases, events on different lists might cover the same circumstances even though they are defined differently. For example, the Joint Commission list of Sentinel Events includes the broad definition of an event resulting in “unanticipated death or permanent loss of function.”³² The NQF list of Serious Reportable Events focuses primarily on events that result in “death or serious disability,” specifying the cause of the event, such as device contamination or medication error (see Appendix C).³³ Additionally, CMS has taken steps to analyze the relationship between the NQF list and the CMS categories of hospital-acquired conditions. In proposing conditions to be added to its list for FY 2009, a CMS press release indicated that the NQF list was used to inform selection of the hospital-acquired conditions.³⁴

Measurement challenges make it difficult to determine the actual incidence of adverse events and to gauge progress in reducing them. In general, stakeholders advocate routine monitoring through automated methods to identify adverse events, followed by periodic use of more extensive methods to confirm results and uncover potential causes. Common methods include:

- ***Administrative Data Screening.*** Automated programs can review administrative data, such as payment claims and hospital discharge data, to identify possible adverse events. For example, AHRQ developed software programs to calculate its PSIs using administrative data and distributes this software free of charge to hospitals, oversight entities, and researchers. Using administrative data allows researchers to screen for adverse events among large

³² The Joint Commission, “Sentinel Event Policy and Procedures,” Reviewable Sentinel Events, updated July 2007, p. 3. Available online at http://www.jointcommission.org/NR/rdonlyres/F84F9DC6-A5DA-490F-A91F-A9FCE26347C4/0/SE_chapter_july07.pdf. Accessed on August 28, 2008.

³³ NQF, “Serious Reportable Events in Health Care: 2005–2006 Update,” October 16, 2006. Available online at <http://www.qualityforum.org/projects/completed/sre/fact-sheet.asp>. Accessed on August 28, 2008.

³⁴ HHS, CMS, “Incorporating Selected NQF and Never Events into Medicare’s List of Hospital-Acquired Conditions,” Press Release, April 14, 2008. Available online at <http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=3043&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&choOrder=date>. Accessed on August 28, 2008.

numbers of cases and also provides a denominator for establishing a rate of events. However, adverse events can be difficult to identify using automated methods, and research indicates that screening detects different types of adverse events at different rates.³⁵ The newly required POA indicators will likely improve the effectiveness of screening for adverse events within Medicare claims data.

- ***Electronic Medical Record Surveillance.*** Routine surveillance of medical records is an emerging technology that serves as an initial screen to identify potential adverse events for further review. Surveillance systems detect adverse events in medical records by identifying unusual circumstances, such as prolonged hospitalizations or administration of an antidote. Researchers report optimism that advances in these systems will enable hospitals to detect some adverse events as they occur.³⁶ However, many hospitals lack computerized medical records and surveillance systems can be expensive to implement.³⁷
- ***Medical Record Review.*** Medical records typically provide more complete information than administrative data regarding the impact of an event by including information about the patient's condition prior to and following the event. However, researchers report that records often have incomplete descriptions and insufficient documentation.³⁸ Also, record reviews rely on the subjective judgment of the reviewer, and conditions caused by adverse events can be difficult to distinguish from preexisting conditions. To improve validity, studies may rely on two or more reviewers to confirm the results of each chart review; however, researchers in one

³⁵ A. N. West, W. B. Weeks, and J. P. Bagian, "Rare Adverse Events in VA Inpatient Care: Reliability Limits to Using Patient Safety Indicators as Performance Measures," *Health Services Research*, 2007, pp. 249–266. Available online at <http://www3.interscience.wiley.com/cgi-bin/fulltext/119390777/PDFSTART>. Accessed on October 10, 2008.

³⁶ M. K. Szekendi, C. Sullivan, A. Bobb, et al., "Active Surveillance Using Electronic Triggers to Detect Adverse Events in Hospitalized Patients," *Quality and Safety in Health Care*, 15, 2006, pp. 184–190. Available online at <http://qshc.bmj.com/cgi/content/full/15/3/184?rss=1>. Accessed on August 10, 2008.

³⁷ M. F. Furukawa, T. S. Raghu, T. J. Spaulding, and A. Vinze, "Adoption of Health Information Technology for Medication Safety in U.S. Hospitals, 2006," *Health Affairs*, 27(3), May–June 2008, pp. 865–875. Abstract available online at <http://content.healthaffairs.org/cgi/content/abstract/27/3/865>. Accessed on October 10, 2008.

³⁸ M. M. Rosenthal, P. L. Cornett, K. M. Sutcliffe, and E. Lewton, "Beyond the Medical Record: Other Modes of Error Acknowledgment," *Journal of General Internal Medicine*, 20(5), May 2005, pp. 404–409. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/15963161>. Accessed on October 10, 2008.

prominent study found moderate to poor interrater reliability between reviewers.³⁹

- **Patient Surveys or Interviews.** A number of studies have sought to identify adverse events by asking patients and their families whether they detected any problems during hospitalization, typically through interviews or mail surveys. This information is considered most useful when patients or families are asked about events shortly after they occur. One study found that patients contacted within 10 days of discharge identified more adverse events affecting their care than medical record reviewers and hospital incident reports.⁴⁰ Another study of medical errors received survey responses from 2,000 hospital patients and found that 11 percent of patients described problems but that, when verified against medical records, only 2 percent described events that represented actual medical errors.⁴¹ Stakeholders indicated that potential drawbacks with patient surveys include low response rate, poor recollection by patients, and lack of understanding of adverse events.
- **Observation of Patient Care.** Clinical observation relies on collecting information during or immediately after the delivery of care. Observational data can derive from direct clinical observation (in person or by recording) and surveys of clinicians. Based on a review of several studies using this method, observation typically finds a higher incidence of adverse events than other methods and is thought to provide more precise descriptions of adverse events than other methods.⁴² For example, one study of operating room anesthesia found a 30-percent rate of adverse events identified

³⁹ E. J. Thomas, D. M. Studdert, and T. A. Brennan, “The Reliability of Medical Record Review for Estimating Adverse Event Rates,” *Annals of Internal Medicine*, 136(11), June 2002, pp. 812–816. Available online at <http://www.annals.org/cgi/reprint/136/11/812.pdf?ijkey=0235f38f381989d08b8fb62bde3bf9fae94951c>. Accessed on October 10, 2008.

⁴⁰ S. N. Weingart, O. Pagovich, D. Z. Sands, et al., “What Can Hospitalized Patients Tell Us About Adverse Events? Learning from Patient-Reported Incidents,” 2005, pp. 830–836. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/16117751>. Accessed on October 9, 2008.

⁴¹ L. I. Solberg, S. E. Asche, and B. M. Averbeck, “Can Patient Safety Be Measured by Surveys of Patient Experiences?” *The Joint Commission Journal on Quality and Patient Safety*, 34(5). May 2008, pp. 266–274. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/18491690>. Accessed on October 9, 2008.

⁴² J. M. Rothschild, C. P. Landrigan, J. W. Cronin, et al., “The Critical Care Safety Study: the Incidence and Nature of Adverse Events and Serious Medical Errors in Intensive Care,” *Critical Care Medicine*, 33, 2005, pp. 1694–1700. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/16096443>. Accessed on October 10, 2008.

through a physician survey administered immediately following surgery.⁴³ Drawbacks to observation of patient care reported by stakeholders include high labor costs, the necessity for highly trained observers, human error in recognizing adverse events, and concerns about patient confidentiality.

Issue 2: Nonpayment policies for adverse events are gaining in prominence and are viewed as a powerful incentive to reduce incidence but raise potential drawbacks

In 2008, CMS implemented policy to deny hospitals higher payment for admissions complicated by selected adverse events. Stakeholders reported their belief that policies of nonpayment to hospitals for care associated with adverse events will put financial pressure on providers to improve patient safety and reduce the incidence of adverse events. They also reported that nonpayment may change clinical practice and hospital procedures to more closely follow recommended guidelines for quality of care and patient safety.⁴⁴ However, stakeholders cautioned that nonpayment for adverse events may cause negative consequences, such as limiting patients' access to care and increasing costs to hospitals while reducing revenue.

Private health care payers and hospitals are increasingly adopting policies to eliminate payment for hospital-acquired conditions

A small number of hospitals and health plans instituted nonpayment policies in previous years, but these policies are becoming more widespread following the change in CMS policy. The first private health plan to deny payment for hospital-acquired conditions, a single State insurer with about 2 million enrollees, began its nonpayment policy in

⁴³ A. Oken, M. D. Rasmussen, J. M. Slagle, et al., "A Facilitated Survey Instrument Captures Significantly More Anesthesia Events Than Does Traditional Voluntary Event Reporting," *Anesthesiology*, 107(6), December 2007, pp. 909–922. Available online at <http://www.anesthesiology.org/pt/re/anes/pdfhandler.00000542-200712000-00010.pdf;jsessionid=LvyvRm2F9dD90HQ2mH2rh3HvpGQTDpppWhjlxXdNQgJkt9IHvqlp!691622333!181195628!8091!-1>. Accessed on October 9, 2008.

⁴⁴ R. M. Wachter, N. E. Foster, and R. A. Dudley, "Medicare's Decision to Withhold Payment for Hospital Errors: The Devil is in the Details," *Joint Commission Journal on Quality and Patient Safety*, February 2008, 34(2), pp. 116–123. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/18351196>. Accessed on October 9, 2008.

2005.⁴⁵ An increasing number of private health plans, including several large national companies, announced plans in 2007 and 2008 to develop nonpayment policies, although full implementation may be a year or more away. Similarly, hospitals are increasingly adopting policies to withhold billing for care associated with certain adverse events, regardless of whether the payer is the government, a health plan, or the patient. A 2007 hospital survey found that 52 percent of responding hospitals (1,285 hospitals) had adopted this “no bill” policy, most within the prior year.⁴⁶

Stakeholders predict that nonpayment policies will reduce health care costs in the long term

Potential cost savings include both savings in government and private-payer reimbursement owing directly to nonpayment and cost savings found through reducing adverse events by way of improved practices. This “business case for safety” argues that any costs expended to improve patient safety are outweighed by the reduced medical expenses, shorter recovery times, and higher quality of life for patients who avoid harm (injury or illness) associated with an adverse event.⁴⁷ Research indicates that the cost of adverse events is high and that, prior to nonpayment policies, hospitals did not bear the impact of these costs. A study of individual hospital costs found that the annual cost of care associated with adverse drug events for a 700-bed hospital was \$5.6 million,⁴⁸ and a 2003 study aggregating costs across hospitals

⁴⁵ Health Partners, Inc., “Health Partners Hospital Payment Policy: Never Events Policy.” Available online at <http://www.healthpartners.com/portal/866.html>. Accessed on September 8, 2008.

⁴⁶ Healthcare Financial Management Association News, “Half of U.S. Hospitals Reporting to Leap Frog Say They Won’t Bill for a ‘Never Event,’” September 28, 2007. Available online at <http://www.hfma.org/hfmanews/default.month.2007-09.aspx>. Accessed on September 8, 2008.

⁴⁷ M. Mello, D. Studdert, E. Thomas, et al., “Who Pays for Medical Errors: An Analysis of Adverse Event Costs, the Medical Liability System, and Incentives for Patient Safety Improvement,” *Journal of Empirical Legal Studies*, 4(4), December 2007, pp. 835–860. Available online at <http://www3.interscience.wiley.com/cgi-bin/fulltext/117994376/PDFSTART>. Accessed on October 13, 2008.

⁴⁸ D. W. Bates, N. Spell, D. J. Cullen, et al., “The costs of adverse drug events in hospitalized patients,” *the Journal of the American Medical Association*, 277(4), January 22, 2007, pp. 307–312. Abstract available online at http://jama.ama-assn.org/cgi/content/abstract/277/4/307?ikey=87ede15670fb1a6e28e177d75d105fde5d61dc17&keytype2=tf_ipsecsha. Accessed on October 13, 2008.

estimated that certain medical injuries among hospitalized patients nationwide result in excess charges of \$9.3 billion annually.⁴⁹

Potential drawbacks of nonpayment could include limiting access to care and increasing hospital costs while reducing revenue

The emergence of nonpayment policies has accelerated longstanding debates regarding adverse events, such as how readily preexisting conditions can be diagnosed and which parties are responsible for additional health care costs resulting from adverse events.

Stakeholders raised the following potential drawbacks to nonpayment:

Limiting Access to Care. Stakeholders raised concern that to avoid hospital-acquired conditions, hospitals may limit access for high-risk patients. High-risk patients, such as the elderly, are likely to have several ailments and therefore require more complicated care. Such patients might be more likely to bring conditions into hospitals that are easily missed (such as pressure ulcers) or to have poor outcomes of care as a result of their compounded ailments and frailty.

Increased Hospital Costs. Hospitals anticipate initial cost increases as a result of implementing nonpayment policies, including training and systems costs to incorporate changes in processing claims and increased costs in testing for and diagnosing conditions POA. Staff also voiced concern that unilateral testing could lead to inappropriate treatment that could place patients at clinical risk. For example, a physician specializing in emergency care noted that it is common for elderly patients to enter the hospital with mild urinary tract infections unrelated to the primary conditions that require urgent care. A positive test for infection could lead the clinician to administer antibiotics that serve little clinical benefit but could put the patient at risk for additional ailments, such as stomach ulcers, and could ultimately lead to the emergence and spread of drug-resistant microorganisms, placing patients and health care workers at risk.⁵⁰

Changes in Hospital Revenue. Hospitals could experience decreases in revenue for some admissions at the same time as their costs rise.

⁴⁹ C. Zahn and M. R. Miller, “Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization,” the Journal of the American Medical Association, 290(14), October 8, 2003, pp. 1868–1874. Available online at <http://jama.ama-assn.org/cgi/content/full/290/14/1868>. Accessed on October 9, 2008.

⁵⁰ C. Edlund and C. E. Nord, “Effect on the Human Normal Microflora of Oral Antibiotics for Treatment of Urinary Tract Infections,” Journal of Antimicrobial Chemotherapy, Suppl. 46(S1), 2000, pp. 41–48. Available online at http://jac.oxfordjournals.org/cgi/reprint/46/suppl_1/41. Accessed on October 10, 2008.

Hospitals will no longer be reimbursed for costs related to adverse events and formerly covered by Medicare and health plans. For example, if a Medicare patient entered a hospital with pneumonia and developed a urinary tract infection during the hospitalization, the hospital would be reimbursed approximately \$6,254 under the prior payment system (pneumonia with complications). Under the new rule, the hospital would be reimbursed approximately \$3,705 (simple pneumonia), a difference of approximately 40 percent.⁵¹ However, stakeholders in interviews and also CMS⁵² have estimated that because the revised CMS payment policy provides for larger Medicare reimbursements for sicker patients by considering complications and comorbidities in determining MS-DRGs, hospitals might experience an overall increase in revenue.

Issue 3: Hospitals rely on staff and managers to report adverse events internally, but barriers can inhibit reporting

Hospital managers whom we interviewed typically rely on the staff involved or department managers to report adverse events to hospital quality improvement or risk management departments. Stakeholders see routine reporting of adverse events as an important component of improving patient safety. Reporting an adverse event is thought to create a sense of transparency among providers, regulators, and patients, fostering openness, communication, and accountability for care. Reporting adverse events and suspected causes can help hospitals develop improved practices to prevent recurrence and ensures accountability for substandard care. Encouraging open staff reporting was cited as part of a growing movement toward a “just culture” that emphasizes systems problems over individual blame for mistakes.⁵³

⁵¹ M. B. Rosenthal, “Nonpayment for Performance? Medicare’s New Reimbursement Rule,” *The New England Journal of Medicine*, 357(16), October 18, 2007, pp. 1573–1575. Available online at <http://content.nejm.org/cgi/reprint/357/16/1573.pdf>. Accessed on October 10, 2008.

⁵² CMS, Office of Public Affairs, Press Release, “CMS Proposes to Expand Program for Hospital Inpatient Services in FY 2009,” April 14, 2008. Available online at <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3041&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&choOrder=date>. Accessed on October 10, 2008.

⁵³ R. M. Wachter, “Understanding Patient Safety,” McGraw–Hill, 2008, pp. 175–176.

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Hospitals may conduct a root cause analysis (RCA) following a report of an adverse event. The RCA is a focused review of systems and processes to identify the basic or contributing factors that cause adverse events. RCAs vary considerably in depth and detail, with documentation and analysis sometimes including interview transcripts, medical records, certification surveys, and billing data. Once it is complete, the RCA results can be assessed by hospital managers or quality improvement staff to help them develop a corrective action plan. Hospitals may retain RCAs and corrective action plans internally or submit them with supporting documentation to oversight entities.

Hospital staff whom we interviewed also reported using information about adverse events to inform affected patients and family members, which is thought to boost public trust and lead to improved clinical decisionmaking and compliance in treatment. One study found that providers disclosing information and accepting responsibility for adverse events was often more important to patients and families than receiving financial compensation.⁵⁴ Some health networks, including the Veterans Health Administration, have formalized this effort through “rapid response” teams that are required to immediately assess adverse event reports, provide same-day information to patients and families, and take action to mitigate harm and prevent recurrence.⁵⁵

Hospital staff may not report adverse events because they do not believe reports lead to improvement, do not have time, or fear punitive action

Stakeholders, including hospital managers, indicated that hospital staff do not report all adverse events, although estimates of how many adverse events are not reported vary widely. In interviews, hospital managers gave estimates as low as 5 percent of adverse events reported to as high as “nearly 100 percent,” attributed to focused training on identifying adverse events. Stakeholders reported the following reasons

⁵⁴ L. L. Leape, “Full Disclosure and Apology: An Idea Whose Time Has Come,” *Physician Executive*, March–April, 2006, pp. 24–26. Available online at http://findarticles.com/p/articles/mi_m0843/is_2_32/ai_n16123939. Accessed on October 9, 2008.

⁵⁵ Veterans Health Administration, 2007 VHA Research Series, “Rapid Response Teams: A Bridge Over Troubled Waters,” 2007. Available online at http://www.vha.com/portal/server.pt/gateway/PTARGS_0_2_6781_1052_505725_43/http%3B/ContentSrv.VHA.com%3B7087/publishedcontent/publish/vha_public/solutions/clinical_improvement/docs/rrt_final.pdf. Accessed on October 10, 2008.

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for not reporting in order of prominence (literature referenced provides additional discussion):^{56 57 58 59}

- lack of followup by responsible staff when reports are made,
- lack of time to complete incident reports and documentation,
- fear of punitive action against self or a colleague,
- assumption that other involved staff will report,
- failure to track care as patients move through multiple departments and caregivers, and
- difficulty in distinguishing adverse events from harm caused by underlying disease.

Stakeholders also stressed the importance of hospitals taking action to encourage staff to report adverse events through such measures as strengthening enforcement, streamlining procedures, training staff on reporting procedures, and ensuring confidentiality when possible. Allowing anonymous reporting or ensuring confidentiality of reporters has been shown to increase reporting, but can limit the usefulness of reports because those analyzing the adverse events are not able to follow up to clarify the event and possible causes.⁶⁰

⁵⁶ IPRO, "Error Reporting Systems: Feedback and Communication," Patient Safety Tools: Information and Resources on Patient Safety for Health Care Providers Across New York State, 1(5), Fall 2007. Available online at <http://providers.ipro.org/index/ps-newsletter-summer07>. Accessed on October 13, 2008.

⁵⁷ S. M. Evans, J. G. Berry, B. J. Smith, et al., "Attitudes and Barriers to Incident Reporting: A Collaborative Hospital Study," *Quality and Safety in Health Care*, 15, 2006, pp. 39–43. Abstract available at <http://qshc.bmj.com/cgi/content/abstract/15/1/39>. Accessed on October 13, 2008.

⁵⁸ C. Conerly, "Strategies to Increase Reporting of Near Misses and Adverse Events," *Journal of Nursing Care Quality*, 22(2), April–June 2007, pp. 102–106.

⁵⁹ J. A. Taylor, D. Brownstein, D. A. Christakis, et al., "Use of Incident Reports by Physicians and Nurses to Document Medical Errors in Pediatric Patients," *Pediatrics*, 114(3), September 2004, pp. 729–735. Available online at <http://pediatrics.aappublications.org/cgi/reprint/114/3/729>. Accessed on October 13, 2008.

⁶⁰ J. Stow, "Using Medical Error Reporting to Drive Patient Safety Efforts," *AORN Journal: Association of periOperative Registered Nurses*, September 2006, pp. 13–17. Available online at http://findarticles.com/p/articles/mi_m0FSL/is_3_84/ai_n27000693. Accessed on October 13, 2008.

Issue 4: Hospitals report adverse events to various oversight entities, although stakeholders suspect substantial underreporting

Although no comprehensive national reporting system for adverse events currently exists, various government agencies and other entities receive adverse event reports from hospitals. These outside entities typically require or request reports about only a subset of adverse events, usually the most serious (such as wrong surgery) or those likely to affect the broader hospital population (such as infections). For example, the quality assurance director of one 102-bed hospital reported receiving between 250 and 300 reports of adverse events or near misses⁶¹ a month from hospital staff, of which only “2 or 3” typically meet severity levels requiring a report to the State or accrediting body.

IOM and other stakeholders advocate a two-tiered national system of mandatory reporting of serious adverse events and voluntary reporting of less serious adverse events and near misses because both systems have unique advantages.⁶² Mandatory reporting of serious events is thought to ensure provider accountability for medical errors and substandard care. Voluntary reporting can capture a broader range and may uncover underlying problems more readily than a smaller number of serious adverse events. Some researchers advocate reporting near misses in particular, believing that because a person or system was in place to prevent harm, they uncover not only the cause of potential adverse events but possible solutions because harm was averted. Including a broader range of adverse events, however, can make the number of reports unmanageable.⁶³ One State modified its reporting system from including all “unusual occurrences that threaten welfare, safety, or health” to only the 28 adverse events on the NQF list, reporting that the original was “too global” to be administered well.⁶⁴

⁶¹ A near miss is an event or a situation that did not result in patient injury, but only because of intervening factors, such as patient health or timely intervention.

⁶² 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, Institute of Medicine, Washington, DC, National Academy Press, 1999.

⁶³ T. A. Brennan, A. Gawande, E. Thomas, and D. Studdert, “Accidental Deaths, Saved Lives and Improved Quality, Sounding Board,” *The New England Journal of Medicine*, 353(13), September 29, 2005. Available online at <http://content.nejm.org/cgi/reprint/353/13/1405.pdf>. Accessed on October 10, 2008.

⁶⁴ Stakeholder interview with staff of the California Department of Health, January 2008.

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State Reporting Systems. Public health departments in 25 States and the District of Columbia operate adverse events reporting systems.⁶⁵ States may also have systems targeted toward specific events; for example, the Government Accountability Office reported in 2008 that 23 States require mandatory reporting of health care-associated infections in hospitals.⁶⁶ States typically require that adverse events be reported within a specific timeframe. They may also require that hospitals submit the RCA results along with the adverse event report and a corrective action plan that outlines how the hospital plans to address the problem. State staff reported using information in a variety of ways, including issuing periodic alerts to caution providers about specific problems and trends, reporting to the public as a hospital quality measure, and routing information about the most egregious adverse events to State oversight agencies.

National Reporting Systems. Two Federal agencies operate national reporting systems—CDC and the Food and Drug Administration (FDA)—and a variety of accreditation, oversight, and advocacy groups operate additional systems. Some of these national reporting systems collect information on a full range of adverse events, such as the Joint Commission’s Sentinel Event Reporting System and the Veterans Health Administration’s Patient Safety Reporting System. Others focus on particular types of adverse events. For example, FDA operates systems that monitor adverse events associated with drugs, medical devices, vaccines, and blood products, and CDC operates a system to monitor health care-associated infections and comanages the vaccine system with FDA.

Patient Safety Organizations. The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) established a national network of Patient Safety Organizations (PSO), certified by HHS, to, among other tasks, accept voluntary reports of adverse events from hospitals.⁶⁷ Further, HHS must develop common formats that PSOs can choose to use for reporting information and must maintain a

⁶⁵ OIG analysis of interviews and documentation from all States and the District of Columbia, collected January–April, 2008.

⁶⁶ Government Accountability Office, “Health-Care-Associated Infections in Hospitals: An Overview of State Reporting Programs and Individual Hospital Initiatives to Reduce Certain Infections,” September 2008, p. 2. Available online at <http://www.gao.gov/new.items/d08808.pdf>. Accessed on October 10, 2008.

⁶⁷ P.L. No. 109-41, § 923 (July 29, 2005).

national database to analyze adverse events reported by PSOs.⁶⁸ (The Patient Safety Act provides Federal legal privilege and confidentiality protections for reported information.⁶⁹) A variety of entities, including hospital networks and health plans, are expected to submit applications to serve as PSOs in 2009 and to be operational by 2010. AHRQ is tasked with reviewing these applications, determining which entities will serve as PSOs, and developing operational guidelines (including common definitions for adverse events). PSOs will have flexibility in developing policies and practices and will receive no Federal funding.

Some stakeholders expressed concerns regarding PSO implementation, including hospitals that may be reluctant to pay contract costs for PSOs when many already report to States; analysis of adverse event information reported by PSOs may be difficult because the PSOs are not required to use the common formats for defining adverse events; and hospitals may report the same adverse events to multiple PSOs, causing duplicate reports that could skew aggregated data.

Stakeholders indicate that adverse events are underreported and that oversight entities may not have mechanisms to promote compliance

Stakeholders suspect substantial underreporting of adverse events to outside entities, although it is difficult to know the extent to which adverse events go unreported. Underreporting could result from the range of barriers and disincentives to report and the inherent difficulty in recognizing all adverse events, such as those resulting in only temporary harm to the patient. Stakeholders question whether the value of reporting systems is worth the administrative costs, particularly when the entity that receives reports does not reciprocate by providing information for improving quality of care.

The number of reports received by various oversight entities varies substantially. For example, States reported that they received as few as 6 and as many as 16,000 reports in 2006.⁷⁰ One State that collects reports for events on the NQF list of Serious Reportable Events received 125 reports for approximately 2.8 million patient days between

⁶⁸ PSO regulations were developed jointly by AHRQ and the Office of Civil Rights. Proposed regulations were published February 12, 2008, (73 Fed. Reg. 8112) and are expected to be final by early 2009.

⁶⁹ P.L. No. 109-41, § 922 (July 29, 2005).

⁷⁰ OIG analysis of interviews and documentation from all States and the District of Columbia, collected January–April 2008.

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October 2006 and October 2007.⁷¹ National reporting systems also indicate a wide range in the number of reports that they receive from hospitals. For example, an FDA source estimated that 10 percent of adverse drug events are reported to its reporting system, Medwatch, and also expressed concern that many reports are of “poor quality”—incomplete and poorly documented.⁷² Officials at the Joint Commission estimate that its voluntary Sentinel Event Reporting System captures only “1/10th of 1 percent” of sentinel events that occur in accredited hospitals.⁷³

Detailed and duplicative reporting requirements may also lead to underreporting. Hospitals are often required to report adverse events—sometimes the same event—to several different entities, which hospital staff indicated takes considerable staff time and effort. For example, in one State, a single adverse event involving a medication error may require reporting to eight different entities, each with different reporting mechanisms and standards. Further, some oversight entities require substantial information for each reported event, such as an RCA, a corrective action plan, staff surveys, and medical records.

Stakeholders raised concern that even prominent oversight entities have limited ability to ensure that serious adverse events are reported consistently and accurately. This was thought to be in part because several key reporting systems have only voluntary reporting, and also because there may be subjectivity in determining what conditions are reported. Even when reporting is mandatory, systems may have little active oversight and enforcement. Hospitals can have few incentives to report adverse events, particularly when reporting involves risks of disclosure and punitive action.⁷⁴ Stakeholders indicated that oversight entities do not know the extent of underreporting, so they cannot

⁷¹ Minnesota Department of Health, “Adverse Health Events in Minnesota: Fourth Annual Public Report,” January 2008, p. 9. Available online at <http://www.health.state.mn.us/patientsafety/ae/aereport0108.pdf>. Accessed on July 3, 2008.

⁷² Board on Health Sciences Policy, “Adverse Drug Event Reporting: The Roles of Consumers and Health-Care Professionals,” 2007. Available online at http://books.nap.edu/openbook.php?record_id=11897&page=14. Accessed on October 10, 2008.

⁷³ Stakeholder interviews with staff of the Joint Commission, March and September 2007.

⁷⁴ J. S. Weissman, C. L. Annas, A. M. Epstein, et al., “Error Reporting and Disclosure Systems: Views from Hospital Leaders,” the *Journal of the American Medical Association*, 293(11), March 16, 2005, pp. 1359–1366. Abstract available online at <http://jama.ama-assn.org/cgi/content/abstract/293/11/1359>. Accessed on October 13, 2008.

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determine whether analysis of reported information is an accurate characterization of adverse events.

Many researchers indicated that full reporting of all adverse events may be less useful than receiving detailed reports of fewer adverse events

Many stakeholders conducting research in adverse events assert that it is more important for quality improvement to receive detailed information about reported adverse events, such as the results of RCAs, than to ensure reporting of all adverse events. These researchers maintained that counting particular adverse events is not as critical as the underlying problems within hospital processes that resulted in the specific events. Because of underreporting, the number of reported adverse events is not considered to be a reliable measure of the incidence of adverse events in hospitals. Researchers note that counting types of adverse events can contribute to faulty analysis of problems because it does not concentrate on the underlying systems or actions, which they view as more important to the goal of reducing adverse events. For example, two medication errors might be counted together for a study of incidence, although one is caused by poor product labeling and the other by poor communication between nurses and pharmacists.

Issue 5: Public disclosure of adverse events can benefit patients, but also raises legal concerns for patients and providers

Much debate goes on regarding disclosure of adverse event information to affected patients and families, oversight entities, and the public. Hospital disclosure of adverse event information can be highly beneficial and is viewed by many stakeholders as an ethical obligation among health care providers. However, disclosure can have legal ramifications for both patients and providers.

Disclosure of adverse event information can assist patients in making decisions about care and pressure hospitals to improve patient safety

Stakeholders indicated that public disclosure of adverse events by hospitals or oversight entities can provide benefits to patients. Access to event information may allow patients to make informed decisions about treatment, and may also provide public scrutiny that could pressure hospitals to improve prevention practices. IOM has promoted public disclosure as a principal goal of adverse event reporting,

particularly for the most serious adverse events.⁷⁵ Most State reporting systems have traditionally released adverse event data received from hospitals, although in aggregate and deidentified form.⁷⁶ At least one State provides a searchable Internet database that displays reported adverse events for individual hospitals.⁷⁷

Hospitals, clinicians, and patients can lose legal protections when adverse event information is reported outside the hospital

Stakeholders indicated that legal liability can impose constraints on disclosure of adverse event information to outside reporting entities. In-hospital systems are typically subject to State legal provisions, known as peer review protections, which protect information shared within hospitals for quality improvement purposes. This could include, for example, information disclosed in an adverse event report or discussed in meetings among hospital physicians and staff.

However, this protection may be lost if information is transmitted outside an individual hospital. Some outside systems allow for anonymous reporting to reduce the implication of individuals, but according to one stakeholder serving as a risk manager in a large urban hospital, this protection may not be useful if the event was serious and well-known. Other reporting systems do not purport to maintain confidentiality, other than protecting the identity of patients, and in some cases publicly disclose adverse events. Hospitals potentially report information to many entities, such as professional licensing and accrediting bodies, State health departments, and patients and families. This disclosure to many entities, which one stakeholder called a “leaking sieve” of information, can increase the likelihood that individual cases are known and result in loss of patient confidentiality.⁷⁸

⁷⁵ 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, Institute of Medicine, Washington, DC, National Academy Press, 1999.

⁷⁶ M. Marchev, “Medical Malpractice and Medical Error Disclosure: Balancing Facts and Fears,” National Academy for State Health Policy, December 2003, p. 10. Available online at http://www.nashp.org/Files/Medical_Malpractice_and_Medical_Error_Disclosure.pdf. Accessed on October 9, 2008.

⁷⁷ Adverse Health Events Reporting, Minnesota Department of Health, Database. Available online at <http://www.health.state.mn.us/patientsafety/adverseselect.cfm>. Accessed on October 9, 2008.

⁷⁸ Proposed PSO regulations at 73 Fed. Reg. 8112 (Feb. 12, 2008) would require that information reported to PSOs by providers receive significant legal protections through both legal privilege and confidentiality requirements.

Issue 6: Information to help prevent adverse events is widely available, but some hospitals and clinicians may be slow to adopt or routinely apply recommended practices

Information about methods to improve patient safety is considered readily accessible to clinicians and hospitals because of the efforts of active professional associations and government and private entities to improve health care quality. There is substantial debate about which adverse events are considered preventable, but little question that the use of recommended guidelines can improve patient safety. Current policy and practice, including CMS's nonpayment policy, hold hospitals accountable for conditions that "could be reasonably prevented by using readily available evidence-based guidelines."⁷⁹ Still, studies indicate that hospitals and clinicians may be slow to implement or to fully integrate recommended practices (such as evidence-based clinical practice guidelines).

Strategies and guidelines to help prevent adverse events often focus on improving complex hospital systems and processes

Patient safety research shows that some adverse events can be the result of breakdowns in systems as well as individual human error.⁸⁰ The systems approach to improving patient safety emphasizes the interaction between medical systems (e.g., protocols, devices, and infrastructure) and individual practitioners. A systems approach advocates both improving the tools at the disposal of health care providers, such as by automating health records, providing clear medication labels, and creating checks to catch problems or errors before they cause harm. (This approach aligns with the idea introduced previously of a "just culture," aspiring to full disclosure of adverse events by focusing on systemic issues rather than individual blame.)

The underpinning of this system approach is recognition of the complexity of modern health care and the difficulty even for highly trained clinicians of considering all information. For example, one article describes a study that found patients in an intensive care unit

⁷⁹ DRA, § 5001(c), P.L. No. 109-171 (adding Social Security Act, § 1886(d)(4)(D)), provided for a quality adjustment in DRG payments for certain hospital-acquired conditions.

⁸⁰ R. M. Wachter, "Understanding Patient Safety," McGraw-Hill, 2008, pp. 17–26.

required an average of 178 different actions per day.⁸¹ As one clinician points out, the number of potential mistakes is so high and the potential impact is so great that “even a 99.9 percent level of proficiency may not be adequate” to ensure patient safety. Stakeholders and literature gave examples of positive results from the systems approach, particularly when efforts addressed specific needs. For example, anesthesiologists nationally have reduced the number of adverse events associated with administration of anesthesia by targeting and addressing systems breakdowns,⁸² and the Veterans Health Administration has reduced medication errors by as much as 86 percent by adopting medication barcoding.⁸³

Following recommended guidelines, which are readily accessible to hospitals and clinicians, can help prevent adverse events and improve quality of care

As the issue of patient safety has gained prominence, a number of entities have targeted clinical solutions and recommended practices to improve safety and reduce the occurrence of certain adverse events. National entities have launched substantial patient safety efforts that focus on this technical assistance, including the following:

- IOM identified 20 diseases and clinical conditions that may be significantly improved or effectively managed by using best practice treatment guidelines.⁸⁴

⁸¹ A. Gawande, “Annals of Medicine: The Checklist,” *The New Yorker*, 83, December 10, 2007, pp. 86–95. Available online at http://www.newyorker.com/reporting/2007/12/10/071210fa_fact_gawande?printable=true. Accessed on October 10, 2008.

⁸² D. M. Gaba, “Anaesthesiology as a Model for Patient Safety in Health Care,” *BMJ*, March 18, 2000, 320, pp. 785–788. Available online at <http://www.bmj.com/cgi/content/full/320/7237/785>. Accessed on October 20, 2008. J. B. Cooper, “An Analysis of Major Errors and Equipment Failures in Anesthesia Management: Considerations for Prevention and Detection.” Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/6691595>. Accessed on October 20, 2008.

⁸³ M. Glabman, “Health Plans Can Learn from VHA Turnaround: While Plans, Hospitals, and Physician Groups Talk the Talk, the Veterans Health Administration is Walking the Walk,” *Managed Care Magazine*, 16(2), February 2007, pp. 26–29, 34–36, and 38. Available online at <http://www.managedcaremag.com/archives/0702/0702.veterans.html>. Accessed on August 28, 2008.

⁸⁴ K. Adams and J. M. Corrigan, eds., Committee on Identifying Priority Areas for Quality Improvement, “Priority Areas for National Action: Transforming Health Care Quality,” Institute of Medicine, Washington, DC, 2003. Available online at <http://www.ahrq.gov/qual/iompriorities.htm>. Accessed on October 13, 2008.

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- A patient safety advocacy group began providing free onsite assistance to hospitals launching safety interventions, including clinician assistance and analysis of results.⁸⁵
- AHRQ released 17 Patient Safety Toolkits that are publicly available and are designed to help practitioners, hospital managers, and patients reduce certain adverse events.⁸⁶

Evidence-based clinical practice guidelines, generated by systematic and evidentiary research, have been shown to be highly effective in preventing certain adverse events, particularly in the area of infection control. Statutory criteria for CMS selection of categories of hospital-acquired conditions for which hospitals would not be paid for more expensive DRGs include the provision that the conditions be reasonably preventable using readily available evidence-based guidelines.⁸⁷ In many cases, such practices are straightforward and can be implemented with little or no cost. For example, a study of hospital intensive care units found that using a checklist of safety steps when inserting central line catheters, including draping patients' entire bodies instead of only affected areas, reduced the incidence of line infections nearly to zero, preventing an estimated 43 infections, and eight deaths, and saving nearly \$2 million per hospital.⁸⁸

Some hospitals and clinicians can be slow to adopt or routinely apply recommended practices to prevent certain adverse events

A number of studies indicate that hospital implementation of recommended practices can be slow and that not all guidelines are practiced widely. For example, one study found that an average of 17 years is needed before new knowledge generated through research becomes incorporated into widespread clinical practice.⁸⁹ Further

⁸⁵ Institute for Healthcare Improvement, "Overview of the Five Million Lives Campaign," 2006. Available online at <http://www.ihl.org/IHI/Programs/Campaign/Campaign.htm?TabId=1>. Accessed on August 28, 2008.

⁸⁶ AHRQ, Patient Safety Tools: Improving Safety at the Point of Care. Program Brief. AHRQ Publication No. 08-P006, revised April 2008. Available online at <http://www.ahrq.gov/qual/pips/pstoolsbrf.htm>. Accessed on September 8, 2008.

⁸⁷ DRA, P.L. No. 109-171 § 5001(c), amends the Social Security Act, § 1886(d)(4).

⁸⁸ S. M. Berenholtz, P. J. Pronovost, P. A. Lipsett, et al., "Eliminating Catheter-Related Bloodstream Infections in the Intensive Care Unit," *Critical Care Medicine*, 32(10), October 2006, pp. 2014–2020. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/15483409>. Accessed on October 10, 2008.

⁸⁹ AHRQ, "Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies Fact Sheet," AHRQ Publication No. 04-P014, March 2004. Available online at <http://www.ahrq.gov/clinic/epc/ggapfact.htm>. Accessed on August 28, 2008.

research indicates that a large number of hospitals do not routinely practice all patient safety precautions. As recently as 2001, AHRQ reported that a sample of hospitals did not routinely perform the 11 interventions that researchers deemed most critical to improving patient safety, such as administering antibiotics prior to surgery.⁹⁰ Additionally, a survey of 1,256 hospitals in 2007 indicated that only 25 percent followed all 27 safe practices guidelines established by NQF and only 13 percent followed all guidelines related to preventing common infections.⁹¹ Moreover, studies have shown that clinicians often do not comply with some of the most fundamental patient safety measures; one study found that hospital physicians wash their hands about half as often as is recommended while providing care.⁹²

One explanation for slow adoption of recommended guidelines is that some hospitals and clinicians may perceive guidelines as not being practical in the “real world.” For example, although surgical units might count the number of sponges used during surgery to ensure that none is retained, in the case of an injured patient, ambulance and emergency room staff may employ an unknown number of sponges in stabilizing the patient prior to surgery. Hospitals may also lack the infrastructure to implement new strategies, particularly if the strategy requires new technology. Further, patient safety provisions may have countervailing implications, as in the example of limiting resident work hours. Accreditation bodies set standards in 2003 to limit medical residents’ hours to 80 per week to combat fatigue,⁹³ but one study found

⁹⁰ AHRQ, “Making Health Care Safe: A Critical Analysis of Patient Safety Practices,” Chapter 57: Practices Rated by Strength of Evidence, 2001. Available online at <http://www.ahrq.gov/clinic/ptsafety/>. Accessed on August 28, 2008.

⁹¹ The Leapfrog Group, “41 Hospitals are Designated ‘Leapfrog Top Hospitals’ for 2007, Significant Gaps in Safety and Quality Practices Among Other Hospitals Still the Norm,” September 18, 2007. Available online at http://www.leapfroggroup.org/media/file/Release_2007_Leapfrog_Survey_and_Top_Hospitals_9-18.pdf. Accessed on October 10, 2008. The Leapfrog Group, “87 Percent of U.S. Hospitals Do Not Take Recommended Steps to Prevent Avoidable Infections,” September 10, 2007. Available online at http://www.leapfroggroup.org/media/file/Leapfrog_hospital_acquired_infections_release.pdf. Accessed on October 10, 2008.

⁹² D. Pittet, A. Simon, S. Hugonnet, C. L. Pessoa-Silva, and V. Sauvan, “Hand Hygiene Among Physicians: Performance, Beliefs, and Perceptions,” *Annals of Internal Medicine*, 141(1), July 6, 2004, pp. 1–8. Available online at <http://www.annals.org/cgi/reprint/141/1/1.pdf>. Accessed on October 9, 2008.

⁹³ Accreditation Council for Graduate Medical Education, Common Program Requirements, Chapter VI: “Resident Duty Hours in the Learning and Working Environment,” updated February 2007, effective July 1, 2007. Available online at http://www.acgme.org/acWebsite/dutyhours/dh_ComProgrRequirementsDutyHours0707.pdf. Accessed on October 9, 2008.

that clinicians perceive limiting shift lengths can cause a greater incidence of medical errors resulting from loss of continuity in care.⁹⁴

Studies also indicate that clinicians may also be slow to incorporate lessons from their own experiences, treating adverse events as isolated incidents and arguing that individual practitioner ingenuity is more important than regimented standards of care.⁹⁵ Researchers explain that these clinicians may also believe that systems improvements, such as computerized decision support systems, can suppress the knowledge, experience, and judgment of the practitioner. Adding to this, physicians are usually independent of the hospital and may not have to meet hospital training or operational standards.

Issue 7: Interviews and literature reveal strategies that may accelerate progress in reducing the incidence of adverse events in hospitals

Stakeholders described the current environment among hospitals and policymakers as being on the verge of accelerating progress and indicated that with continued focus, hospitals can reduce the overall incidence of adverse events and improve quality of care. Information from interviews and literature suggests the following strategies:

- Assessing the desirability and feasibility of a national body to lead patient safety efforts. This could entail evaluating the impact of involved organizations and determining what tasks a national coordinating body might perform. Stakeholders described adverse events as “a public health issue” that demands an aggressive agenda and active policy enforcement. They indicated that current efforts

⁹⁴ J. S. Myers, L. M. Bellini, J. B. Morris, et al., “Internal Medicine and General Surgery Residents’ Attitudes About the ACGME Duty Hour Regulations: A Multi-Center Study,” *Academic Medicine*, 81(12), December 2006, pp. 1017–1020. Available online at <http://www.academicmedicine.org/pt/re/acmed/pdfhandler.00001888-200612000-00008.pdf;jsessionid=LyBMNyx0pk10K8sRJs2DmTQD5DPJRQXSnjtJrS7yrGmdv7LKXgl!475884353!181195629!8091!-1>. Accessed on October 9, 2008.

⁹⁵ F. B. Garfield and J. M. Garfield, “Clinical Judgment and Clinical Practice Guidelines,” *International Journal of Technology Assessment in Health Care*, 16, 2000, pp. 1050–1060. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/11155827>. Accessed on October 13, 2008.

S. J. Genuis, “The Proliferation of Clinical Practice Guidelines: Professional Development or Medicine-by-Numbers,” *Journal of the American Board of Family Medicine*, 18(5), September–October 2005, pp. 419–425. Available online at <http://www.jabfm.org/cgi/reprint/18/5/419>. Accessed on October 13, 2008.

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by government agencies and private entities are necessary and useful but may not be sufficient to ensure patient safety; and that a national body could coordinate, but not replace, these efforts.

- Focusing on hospital use of recommended practices and evidence-based clinical practice guidelines to reduce the incidence of adverse events, including further promulgating these practices, measuring hospital use, and improving information sharing.
- Establishing methods for measuring the incidence of adverse events, including a practical and accurate data collection method for routine measurement.
- Expanding the use of electronic health records within and among hospitals and other health care settings. Stakeholders reported that widespread use of electronic health records would enhance communication, improving continuity of care and potentially reducing the incidence of adverse events.
- Monitoring and analyzing the impact of policies to deny hospitals higher payment for admissions complicated by selected adverse events, including hospital and payer implementation, the incidence of adverse events, access to health care, and health care costs.
- Improving the utility of adverse event reporting to outside entities, including evaluating the comparability of data reported across entities and streamlining reporting mechanisms to reduce burdens to hospitals.

► S U M M A R Y

Our interviews with stakeholders and review of literature indicate that the incidence of adverse events poses a problem in hospitals, particularly among the elderly. A number of barriers exist to reducing the incidence of adverse events, including confusion over how adverse events are defined and identified, underreporting of events, and legal concerns regarding the disclosure of events. Further, challenges associated with accurately measuring the incidence of adverse events make it difficult to assess progress and to direct future research and policy efforts.

The extensive range of entities involved in researching and addressing adverse events indicates that solving the problem is a high priority for policymakers, patients, and providers. Stakeholders described the current environment among hospitals and policymakers as being on the threshold of accelerated progress and said that with continued focus, hospitals can reduce the incidence of adverse events and improve quality of care. They point to a large body of clinical and policy research that has improved the understanding of adverse events, including recognition of the critical role of hospital systems in guarding against them. Additionally, new policies, such as nonpayment for care associated with adverse events and public disclosure of events, strengthen hospitals' incentives to develop safer practices. These advancements in clinical understanding, combined with heightened controls, hold promise for reducing the incidence of adverse events in hospitals and improving the quality of care.

This overview of key issues is one of a series of OIG reports designed to respond to the congressional mandate to inform Congress about policies and practices critical to addressing adverse events. Other OIG studies focus on estimating the incidence of adverse events among Medicare beneficiaries, State efforts to operate adverse event reporting systems, Medicare beneficiaries receiving potentially inappropriate drug pairs that may reflect medication errors, and hospital actions to address and prevent adverse events.

► AGENCY COMMENTS

We received comments on a draft of this report from AHRQ and CMS.

AHRQ concurred with the report's findings.

CMS commended OIG on succinctly capturing the numerous issues surrounding this complex topic, acknowledged technical assistance provided to OIG in conducting this study, and indicated that it welcomed continued work with OIG on this issue.

CMS reiterated its policies to encourage the prevention of adverse events that are enumerated in the report, including quality measurement and reporting, financial initiatives, and program oversight. Regarding financial incentives, CMS outlined the provision to deny payment for care associated with hospital-acquired conditions, noting that OIG's work is supportive of and will enable more effective CMS implementation of the provision. CMS agreed with the report's conclusion that nonpayment for care associated with adverse events strengthens hospitals' incentives to develop safety practices and reduces health care costs in the long term.

CMS also addressed the three potential drawbacks of nonpayment policies raised by stakeholders: limiting access to care, increasing hospital costs, and changes in hospital revenue. CMS indicated that it will monitor the impact of implementation of the nonpayment provision but believes that these drawbacks are unlikely to occur. CMS provided further discussion to support this viewpoint, stating that more precise payment for high-risk patients will likely offset incentives to limit access to care, increased hospital costs to implement safety provisions will likely be offset by savings resulting from fewer complications, and decreases in hospital revenue will likely be minimal because CMS will continue to assign a discharge to a higher paying MS-DRG if the selected hospital-acquired condition is present on admission.

For the full text of AHRQ and CMS comments, see Appendix G.

TAX RELIEF AND HEALTH CARE ACT OF 2006⁹⁶

P.L. No. 109-432

DIVISION B – MEDICARE AND OTHER HEALTH PROVISIONS

TITLE II—MEDICARE BENEFICIARY PROTECTIONS

SEC 203 OIG STUDY OF NEVER EVENTS

(a) Study.—

(1) In general.—The Inspector General in the Department of Health and Human Services shall conduct a study on—

(A) incidences of never events for Medicare beneficiaries, including types of such events and payments by any party for such events;

(B) the extent to which the Medicare program paid, denied payment, or recouped payment for services furnished in connection with such events and the extent to which beneficiaries paid for such services; and

(C) the administrative processes of the Centers for Medicare & Medicaid Services to detect such events and to deny or recoup payments for services furnished in connection with such an event.

(2) Conduct of study.—In conducting the study under paragraph (1), the Inspector General—

(A) shall audit a representative sample of claims and medical records of Medicare beneficiaries to identify never events and any payment (or recouping of payment) for services furnished in connection with such events;

(B) may request access to such claims and records from any Medicare contractor; and

(C) shall not release individually identifiable information or facility-specific information.

(b) Report.—Not later than 2 years after the date of the enactment of this Act, the Inspector General shall submit a report to Congress on the study conducted under this section. Such report shall include recommendations for such

⁹⁶ Tax Relief and Health Care Act of 2006, P.L. No. 109-432, Division B, Title II, § 203, December 16, 2007.

legislation and administrative action, such as a noncoverage policy or denial of payments, as the Inspector General determines appropriate, including—

(1) recommendations on processes to identify never events and to deny or recoup payments for services furnished in connection with such events; and

(2) a recommendation on a potential process (or processes) for public disclosure of never events which—

(A) will ensure protection of patient privacy; and

(B) will permit the use of the disclosed information for a root cause analysis to inform the public and the medical community about safety issues involved.

(c) Funding.— Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Inspector General of the Department of Health and Human Services \$3,000,000 to carry out this section, to be available until January 1, 2010.

(d) Never Events Defined.—For purposes of this section, the term “never event” means an event that is listed and endorsed as a serious reportable event by the National Quality Forum as of November 16, 2006.

GLOSSARY OF SELECTED TERMS⁹⁷

Adverse event—Any harm (injury or illness) caused by medical care. Identifying adverse events indicates that the care resulted in an undesirable clinical outcome and that the clinical outcome was not caused by an underlying disease, but does not imply an error, negligence, or poor quality care.

Corrective action plan—Policy and procedural actions that hospitals prepare to respond to an adverse event and to prevent recurrence.

Evidence-based clinical practice guidelines—Practices found to increase patient safety and improve care, generated by systematic and evidentiary research.

Hospital-acquired condition—Medical condition not present prior to admission to a hospital.

Just culture—An environment in which personnel feel comfortable disclosing errors (including their own) while maintaining professional accountability; purports that individuals should not be held responsible for systems breakdowns.

Medical error—The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

Near miss—An event or a situation that did not produce patient harm, but only because of intervening factors, such as patient health or timely intervention.

Never event—An event or a situation that should never occur in a health care setting. The National Quality Forum initially used the term “never events” to describe its list of serious events but began in 2005 to refer to the list as “serious reportable events.”

Patient safety—Freedom from accidental or preventable injuries caused by medical care.

Root cause analysis—A focused review of systems and processes to identify the basic or contributing factors that cause adverse events.

Systems approach—Theory that most errors reflect predictable human failings in the context of poorly designed systems.

⁹⁷ Definitions derived from a variety of sources, including 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, Institute of Medicine, Washington, DC, National Academy Press, 1999; R. M. Wachter, “Understanding Patient Safety,” McGraw-Hill, 2008; and the glossary of the Agency for Healthcare Research and Quality Patient Safety Network. Available online at <http://www.psnet.ahrq.gov/glossary.aspx>. Accessed on October 10, 2008.

National Quality Forum Serious Reportable Events⁹⁸

The National Quality Forum (NQF) list is separated into six categories. “Serious disability” is defined as loss of a body part, disability, or loss of bodily function lasting more than 7 days or still present at time of discharge.

Table C1: The National Quality Forum List of Serious Reportable Events	
Surgical Events	
A.	Surgery performed on the wrong body part
B.	Surgery performed on the wrong patient
C.	Wrong surgical procedure performed on a patient
D.	Unintended retention of foreign object in a patient after surgery or procedure
E.	Intraoperative or immediately postoperative death
Product or Device Events	
A.	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility
B.	Patient death or serious disability associated with use or function of a device in patient care in which the device is used or functions other than as intended
C.	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility
Patient Protection Events	
A.	Infant discharged to the wrong person
B.	Patient death or serious disability associated with patient elopement
C.	Patient suicide, or attempted suicide resulting in serious disability while being cared for in a health care facility
Care Management Events	
A.	Patient death or serious disability associated with a medication error
B.	Patient death or serious disability associated with a hemolytic reaction due to administration of ABO/HLA-incompatible blood or blood products
C.	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility
D.	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while patient is cared for in a health care facility
E.	Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates
F.	Stage 3 or 4 pressure ulcers acquired after admission to a health care facility
G.	Patient death or serious disability due to spinal manipulative therapy
H.	Artificial insemination with the wrong donor sperm or wrong egg
Environmental Events	
A.	Patient death or serious disability associated with an electric shock while being cared for in a health care facility
B.	Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
C.	Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility
D.	Patient death or serious disability associated with fall while cared for in a health care facility
E.	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility
Criminal Events	
A.	Care provided by someone impersonating a health care provider
B.	Abduction of a patient of any age
C.	Sexual assault on a patient within or on the grounds of a health care facility
D.	Death or significant injury resulting from a physical assault that occurs within or on the grounds of the facility

⁹⁸ NQF, “Serious Reportable Events in Healthcare 2006 Update: A Consensus Report,” NQF, Washington, DC, 2007, p. 7. Available online at <http://www.qualityforum.org/pdf/reports/sre/txsrepublic.pdf>. Accessed on October 10, 2008.

List of Stakeholders Interviewed

We identified stakeholders using a variety of sources, including referrals from AHRQ, the National Patient Safety Foundation, the Joint Commission, and others, as well as contacts references in literature. The viewpoints of the individuals we interviewed do not represent official positions of their organizations.

Table D1–List of Stakeholder Interview Respondents
Federal Agencies
Agency for Healthcare Research and Quality (AHRQ), Center for Quality Improvement & Patient Safety (C-QUIPS)
Centers for Medicare & Medicaid Services (CMS), Medicare Management Services
Centers for Medicare & Medicaid Services (CMS), Quality Improvement Group
Centers for Disease Control and Prevention (CDC)
Department of Defense, Patient Safety Center (DOD)
Food and Drug Administration (FDA)
National Institutes of Health (NIH)
Veterans Affairs (VA), National Center for Patient Safety (NCPS)
State Agencies
California Department of Health
Georgia Department of Health and Human Services
Minnesota Department of Social Services
Pennsylvania Department of Health
Professional Associations
American Medical Association (AMA)
American Hospital Association (AHA)
American Health Lawyers Association (AHLA)
American Health Quality Association (AHQA)
American Nurses Association (ANA)
Anesthesia Patient Safety Foundation (APSF)
American Society for Healthcare Risk Management (ASHRM)
American Society of Health-System Pharmacists (ASHP)
Georgia Hospital Association: Partnership for Health and Accountability (PHA)
Minnesota Hospital Association (MHA)
Oversight/Standard-Setting Organizations
Federation of State Medical Boards of the U.S., Inc. (FSMB)
Leapfrog Group for Patient Safety
The Joint Commission
National Committee on Quality Assurance (NCQA)
U.S. Pharmacopeia (USP)

Table D1—List of Stakeholder Interview Respondents (continued)
Patient Safety Advocacy Groups
American Association of Retired Persons (AARP)
Center for Medical Consumers
Consumers Advancing Patient Safety (CAPS)
Consumers Union
Mothers Against Medical Errors (MAME)
Partnership for Patient Safety
Persons United Limiting Substandard Care and Errors in Healthcare (PULSE)
Public Policy Groups
Institute for Healthcare Improvement (IHI)
Institute of Medicine (IOM)
Massachusetts Coalition for the Prevention of Medical Errors
National Academy for State Health Policy (NASHP)
National Association for Healthcare Quality (NAHQ)
National Patient Safety Foundation (NPSF)
National Quality Forum (NQF)
Urban Institute
World Health Organization (WHO)
Private Payers
Managed Care Organizations—4 selected national and regional organizations
Providers
Hospitals—20 selected hospitals in CA, FL, GA, KS, IL, MA, MN, NY, and PA
Networks—8 selected organizations
Researchers associated with the following organizations
Columbia University—National Heart, Lung and Blood Institute (MERS – TH)
Harvard School of Public Health
Johns Hopkins University
University of California—San Francisco
University of Chicago
Service Contractors
Cardinal Health, Inc.
CRG Medical, Inc., Patient Safety Quality Management Solutions
Emergency Care Research Institute (ECRI), Inc.
Qualidigm, Inc.
University HealthSystem Consortium, Patient Safety Net (UHC/PSN)

Source: Office of Inspector General data collection, October 2007–April 2008.

Examples of Data Analysis: Stakeholder Interviews and Literature Review

Summary statements represent the predominant viewpoint of the 78 stakeholder entities that we interviewed as well as analysis from literature. The text of the report does not include the proportion of sources that contributed to summary statements for three reasons:

- Interview respondents represent a wide variety of entities and interests that are not easily grouped to provide a sum of responses. For example, entities included group interviews with representatives from large national organizations as well as individual interviews with hospital staff and researchers.
- Interviews and literature often entailed nuanced discussions of complex issues, and analysis of the resulting data could not be accurately quantified. In these cases, the report summarizes the range of viewpoints and provides relevant examples.
- Not all interview respondents chose to or were able to answer each question, changing the number of potential responses throughout the report. For example:
 - Ten interview respondents declined to respond regarding whether the current incidence of adverse events remains at the level reported by the Institute of Medicine (IOM), indicating that it would not be useful for them to speculate and that they were unaware of any accurate measurement.
 - The Centers for Medicare & Medicaid Services nonpayment policy was finalized only 2 months prior to our data collection period, and representatives from 11 entities declined to respond because they did not believe they were adequately informed to state an opinion.
 - In some cases, interview respondents provided information and insight based on the occurrence of adverse events in all health care settings as opposed to only the hospital setting.

Table E1 on page 42 includes examples of our analysis of interviews and literature to arrive at summary statements. Although the frequencies represent the general opinions of the interview respondents, further related discussion often provided additional insight. The report presented this additional insight when it represented a prominent alternative view or otherwise aided understanding.

Table E1. Data Analysis of Stakeholder Interviews and Literature Review

Summary Statements	Page	Interview Questions	Interview Responses
Stakeholders perceive that the incidence of adverse events remains that reported by the Institute of Medicine in 1999	11	What do you perceive is the current incidence of adverse events in hospitals?	Incidence similar = 63 Substantial progress = 5 (n = 68)
Stakeholders view nonpayment policies for adverse events as a powerful incentive to improve care	16	What impact do you anticipate will result from nonpayment policies for adverse events in hospitals?	Primarily positive impact = 65 Primarily negative impact = 2 (n = 67)
Hospitals rely on staff and managers to report adverse events internally	19	How does your hospital identify adverse events?	Hospital staff report to risk managers or quality assurance departments = 20 (n = 20)
Stakeholders suspect substantial underreporting of adverse events to outside entities	22	What proportion of adverse events do you perceive are reported?	Only a portion of events (underreporting) = 72 All events are reported (no underreporting) = 1 (n = 73)
Information about preventing adverse events is widely available, but hospitals do not always apply this knowledge	28	What are the barriers to progress in reducing adverse events in hospitals?	Most prominent—hospitals do not routinely use guidelines to increase safety = 43 (n = 78)
Suggested Policy Strategies to Accelerate Progress (n = 78)			
Assessing the desirability and feasibility of creating a national oversight organization	33	What suggestions do you have for accelerating progress in reducing adverse events in hospitals?	Consider national entity to coordinate efforts and/or provide oversight = 37
Focusing on hospital use of guidelines to reduce events			Further encourage or require hospital adherence to recommended practices = 35
Establishing methods for determining incidence			Improve methods for measuring progress = 21
Expanding use of electronic health records			Facilitate use of electronic health records = 20
Measuring and analyzing the impact of nonpayment policies			Assess the impact of nonpayment policies = 15
Improving the utility of adverse event reporting systems			Improve adverse event reporting systems = 12

Source: Office of Inspector General analysis of 78 stakeholder interviews and 117 published works, October 2007–April 2008.

Examples of Research: Incidence of Adverse Events

These examples represent a range of adverse events research using a variety of data collection methods. In some cases, the objectives of the research were other than deriving a measure of incidence.

Table F1. Incidence Rate of Adverse Events and Related Research Information

Population Studied	Incidence Rate	Method	Summary
General hospital admissions ¹	3.7%	Medical record review	Clinical reviews of 30,000 medical records from hospitalizations in New York. Cited in the Institute of Medicine (IOM) report, "To Err is Human: Building a Safer Health System."
General hospital admissions ²	17.7%	Observation	Qualitative observational study of 1,047 patients at a large urban hospital. The risk for an adverse event increased by 6 percent for each day spent at the hospital.
General hospital admissions ³	2.9%	Medical record review	Clinical reviews of 15,000 medical records from hospitalizations in Colorado and Utah. Cited in the IOM report, "To Err is Human: Building a Safer Health System."
General hospital admissions ⁴	8.0%	Medical record review and patient interview	Study of 228 patients included review of medical records and interviews with patients.
Intensive care admissions ⁵	20.2%	Observation	Study of 391 critically ill patients in yearlong review. Forty-five percent of all adverse events were preventable; 55 percent were nonpreventable.
General hospital admissions ⁶	9.0%	Hospital incident reports	Study of 1,000 incident reports at two hospitals. Nine percent of patients had at least one incident report, primarily medication administration incidents.

¹ T. A. Brennan, L. L. Leape, N. M. Laird, et al., "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study 1," *New England Journal of Medicine*, 324(6), 1991, pp. 370–376. Abstract available online at <http://content.nejm.org/cgi/content/abstract/324/6/370>. Accessed on October 10, 2008.

² L. B. Andrews, C. Stocking, T. Krizek, et al., "An Alternative Strategy for Studying Adverse Events in Medical Care," *Lancet*, 349(9048), February 1997, pp. 309–313. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/9024373>. Accessed on October 10, 2008.

³ E. J. Thomas, D. M. Studdert, H. R. Burstin, et al., "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado," *Medical Care*, 38(3), 2000, pp. 261–271. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/10718351>. Accessed on October 10, 2008.

⁴ S. N. Weingart, O. Pagovich, D. Z. Sands, et al., "What Can Hospitalized Patients Tell Us about Adverse Events? Learning from Patient-Reported Incidents," *Journal of General Internal Medicine*, 20(9), 2005, pp. 830–836. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/16117751>. Accessed on October 10, 2008.

⁵ J. M. Rothschild, C. P. Landrigan, J. W. Cronin, et al., "The Critical Care Safety Study: The Incidence and Nature of Adverse Events and Serious Medical Errors in Intensive Care," *Critical Care Medicine*, 33(8), August 2005, pp. 1694–1700. Abstract available online at <http://www.ncbi.nlm.nih.gov/pubmed/16096443>. Accessed on October 10, 2008.

⁶ T. K. Nuckols, D. S. Bell, and H. Liu, "Rates and Types of Events Reported to Established Incident Reporting Systems in Two U.S. Hospitals," by Teryl K. Nuckols, M.D., Douglas S. Bell, M.D., Honghu Liu, Ph.D., et al., in the June 2007 "Quality & Safety in Health Care" 16, pp. 164–168. Abstract available online at <http://qshc.bmj.com/cgi/content/abstract/16/3/164>. Accessed on October 10, 2008.

Source: Office of Inspector General analysis of published works, October 2007–April 2008.

▶ A P P E N D I X ~ G

Agency Comments: Agency for Healthcare Research and Quality



DEPARTMENT OF HEALTH & HUMAN SERVICES

Agency for Healthcare
Research and Quality

540 Gaither Road
Rockville MD 20850
www.ahrq.gov

NOV 25 2003

TO: Daniel Levinson, Inspector General
FROM: Carolyn Clancy, Director *CC*
SUBJECT: Comments on draft Office of Inspector General Report entitled, "Adverse Events in Hospitals: Overview of Key Issues"

Thank you for the opportunity to review the draft Office of Inspector General Report entitled, "Adverse Events in Hospitals: Overview of Key Issues." The Agency for Healthcare Research and Quality (AHRQ) concurs with the report as written.

If you have any questions, please feel free to call Kathie Crosson of my staff at 301-427-1328.

Agency Comments: Center for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DEC 4 2008

DATE:

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems
Acting Administrator

SUBJECT: Office of Inspector General's Draft Report: "Adverse Events in Hospitals: Overview of Key Issues (OEI-06-07-00470)"

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled "Adverse Events in Hospitals: Overview of Key Issues." We commend the OIG on succinctly capturing the numerous issues surrounding this complex topic. The OIG has requested extensive technical assistance from the Centers for Medicare & Medicaid Services (CMS) on this and the series of related reports on adverse events. We welcome this coordinated approach and believe that it will enhance the usefulness of the reports in informing policy makers.

The CMS has a number of tools within the statutory authorities of the Medicare program to encourage the prevention of adverse events, including quality measurement, financial incentives, public reporting of quality information, conditions of participation, and the Quality Improvement Organization (QIO) program. One of the financial incentive initiatives is the hospital-acquired conditions (HAC) provision. The statute requires that the selected HACs be high cost, high volume, or both; trigger a higher-paying Medicare Severity Diagnosis-Related Group (MS-DRG) when present as a secondary diagnosis; and be considered reasonably preventable through the application of evidence-based guidelines. Under the statutory authority for the HAC payment provision, beginning on October 1, 2008, CMS no longer assigns an inpatient hospital discharge to a higher paying MS-DRG if a selected HAC is not present on admission. As the draft report notes, CMS plans, in related but separate initiatives, to propose coverage policy regarding three surgical never events and has issued a letter to State Medicaid Directors providing guidance for State Medicaid Agencies.

Implementing the HAC payment provision requires a deep understanding of the adverse events that could be selected as HACs and how those potential HACs fit with the statutory selection criteria. We note that OIG's work in advancing the understanding of adverse events is supportive of our implementation of the HAC provision. By encouraging further development

Page 2 – Daniel R. Levinson

and refinement of evidence-based guidelines and studies demonstrating the preventive impact of those guidelines, OIG's work will enable even more effective application of the Medicare HAC policy.

We agree with the conclusion that nonpayment for care associated with adverse events strengthens hospitals' incentives to develop safer practices. The primary purpose of the HAC provision is to encourage hospitals to consistently apply evidence-based guidelines for the prevention of HACs, thereby enhancing the safety of hospital care. The HAC provision is also expected to save health care costs, not only by preventing Medicare payment for certain care that would not have been necessary if the hospital had prevented the occurrence of the condition, but also by decreasing the costs associated with complications generally. We agree with the stakeholders' prediction noted in the draft report that nonpayment policies will reduce healthcare costs in the long term. The costs of these complications are high, and the cost implications of HACs extend well beyond the hospital inpatient setting.

The draft report discusses three potential drawbacks of nonpayment policies that were raised by stakeholders: (1) limiting access to care, (2) increased hospital costs, and (3) changes in hospital revenue. We will be monitoring the impact of implementation of the HAC provision, but we believe that these eventualities are unlikely. First, implementation of the MS-DRGs, which generally result in more precise payment for high-risk patients, will likely offset the relatively small incentive to avoid high-risk patients that could result from nonpayment for a few selected conditions. Second, the hospital costs generated by following evidence-based practices for the prevention of HACs will likely be offset by the relatively large savings to hospitals resulting from fewer complications to treat. Third, the decrease to hospital revenue under the HAC policy is likely to be minimal. This is primarily because Medicare will continue to assign a discharge to a higher paying MS-DRG if the selected HAC is present on admission or if any non-selected complicating condition appears on the claim.

We trust that these comments will be helpful to the OIG in refining the report. We appreciate your efforts and look forward to continuing to work with you on this issue.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Kevin K. Golladay, Regional Inspector General for Evaluation and Inspections in the Dallas regional office, and A. Blaine Collins, Deputy Regional Inspector General for Evaluation and Inspections.

Ruth Ann Dorrill served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Dallas regional office who contributed to this report include Amy Ashcraft, Deborah Cosimo, Anthony Guerrero-Soto, Margaret Knight, Christi Macrina, Jeremy Moore, and Lyndsay Patty; central office staff who contributed to this report include Alan Levine, Ayana Everett, Mark Richardson, and Rita Wurm.