Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ADVERSE EVENTS IN HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES

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EXECUTIVE SUMMARY

OBJECTIVES

To estimate the national incidence of adverse events for hospitalized Medicare beneficiaries, assess the preventability of such events, and estimate associated costs to Medicare.

BACKGROUND

The term "adverse event" describes harm to a patient as a result of medical care, such as infection associated with use of a catheter. The term "never events" refers to a specific list of serious events, such as surgery on the wrong patient, that the National Quality Forum (NQF) deemed "should never occur in a health care setting." The Tax Relief and Health Care Act of 2006 mandates that the Office of Inspector General report to Congress regarding the incidence of never events among Medicare beneficiaries, the payment for services in connection with such events, and the Centers for Medicare & Medicaid Services (CMS) processes to identify events and deny payment.

We selected a nationally representative random sample of 780 Medicare beneficiaries from all beneficiaries discharged during October 2008. Physician reviewers determined (1) whether an adverse event occurred, (2) whether the event was on the NQF list of Serious Reportable Events or the Medicare list of hospital-acquired conditions (HAC), (3) what the level of harm was to the patient, and (4) whether the event was preventable. To establish an estimated adverse event incidence rate, we included events on the NQF and the HAC lists and events resulting in the most serious harm as defined by a patient harm index (prolonged hospital stay, permanent harm, life-sustaining intervention, or death). We also determined the cost to Medicare for hospital care resulting from the events. Lastly, we identified additional events that resulted in temporary patient harm but were not comparable to the more serious events in our overall rate and assessed their preventability and cost.

FINDINGS

An estimated 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays. Of the nearly 1 million Medicare beneficiaries discharged from hospitals in October 2008, about 1 in 7 experienced an adverse event that met at least 1 of our criteria (13.5 percent). This rate projects to an estimated

134,000 Medicare beneficiaries experiencing at least 1 adverse event in hospitals during the 1-month study period. We calculated incidence rates for adverse events that met our three criteria: 0.6 percent of beneficiaries had an NQF Serious Reportable Event, 1.0 percent had a Medicare HAC event, and 13.1 percent experienced an adverse event resulting in the four most serious categories of patient harm. An estimated 1.5 percent of Medicare beneficiaries experienced an event that contributed to their deaths, which projects to 15,000 patients in a single month.

An additional 13.5 percent of Medicare beneficiaries experienced events during their hospital stays that resulted in temporary harm. Temporary harm events are those that require intervention but do not cause lasting harm. Although many cases represent fairly minor occurrences, such as hypoglycemia, others were classified as temporary harm only because the patients were in the hospital for lengthy periods as a result of other, more serious, diagnoses, allowing hospitals enough time to address the harm prior to discharge. Additionally, 28 percent of beneficiaries who experienced adverse events also had temporary harm events during the same stay.

Physician reviewers determined that 44 percent of adverse and temporary harm events were clearly or likely preventable. Physicians determined that 44 percent of all events were preventable and 51 percent were not preventable. (For the remaining 5 percent of events, physicians were unable to make determinations.) Events related to surgery or procedures were less likely to be preventable than other types of events, such as hospital-acquired infections. Preventable events were linked most commonly to medical errors, substandard care, and lack of patient monitoring and assessment. Physician reviewers assessed events as not preventable when they occurred despite proper assessment and care or when the patients were highly susceptible to the events due to health status. Nearly all events on the NQF and Medicare lists were assessed as preventable, a key criterion of both lists.

Hospital care associated with adverse and temporary harm events cost Medicare an estimated $324 million in October 2008. Sixteen percent of sample beneficiaries in the Medicare Inpatient Prospective Payment System who experienced events incurred additional Medicare costs as a result. The added costs equate to an estimated 3.5 percent of Medicare's expenditure for inpatient care during October 2008. To give these figures an annual context,

3.5 percent of the $137 billion Medicare inpatient expenditure for FY 2009 equates to $4.4 billion spent on care associated with events. Two-thirds of Medicare costs associated with events were the result of entire additional hospital stays necessitated by harm from the events. Additionally, these Medicare cost estimates do not include additional costs required for followup care after the sample hospitalizations.

RECOMMENDATIONS

As the Federal Government's principal agency for protecting the health of Americans, the Department of Health & Human Services (HHS) is uniquely positioned to lead national efforts to reduce adverse events in hospitals. As part of a national strategy to improve health care quality mandated by the Patient Protection and Affordable Care Act (ACA), HHS is to identify areas that have the potential for improving health care quality. Because many adverse events we identified were preventable, our study confirms the need and opportunity for hospitals to significantly reduce the incidence of events. A number of agencies within HHS share responsibility for addressing this issue, most prominently the Agency for Healthcare Research and Quality (AHRQ) as a coordinating body for efforts to improve health care quality and CMS as an oversight entity and the Nation's largest health care payer.

Therefore, we recommend the following:

AHRQ and CMS should broaden patient safety efforts to include all types of adverse events. This broader definition would apply to a number of activities, including setting priorities for research, establishing guidelines for hospital reporting, developing prevention strategies, measuring health care quality, and determining payment policies.

AHRQ and CMS should enhance efforts to identify adverse events. Identifying adverse events assists policymakers and researchers in directing resources to the areas of greatest need, setting clear goals for improvement, assessing the effectiveness of specific strategies, holding hospitals accountable, and gauging progress in reducing incidence.

- AHRQ should sponsor periodic, ongoing measurement of the incidence of adverse events.
- AHRQ should continue to encourage hospital participation with Patient Safety Organizations, entities intended to receive adverse

event reports from hospitals, and forward the information to a national AHRQ database.

- CMS should use Present on Admission Indicators in billing data to calculate the frequency of adverse events occurring within hospitals.

CMS should provide further incentives for hospitals to reduce the incidence of adverse events through its payment and oversight functions. The ACA makes several changes to the HAC policy, including allowing the Secretary of HHS to expand the list of HACs. The ACA gives the HAC policy greater significance by using the list of HACs to implement Medicare payment penalties, create performance measures, and prohibit Medicaid payments for associated care. The conditions of participation for Medicare and Medicaid require that hospitals have programs to demonstrate quality improvement where evidence shows practices can improve outcomes.

- CMS should strengthen the Medicare HAC policy, such as by expanding the policy to include more events that harm beneficiaries.

- CMS should look for opportunities to hold hospitals accountable for adoption of evidence-based practice guidelines.

AGENCY COMMENTS

We received comments on the draft report from AHRQ and CMS. AHRQ concurred with our recommendations, stating that adverse events affect hospital patients at an "alarming rate" and that it must continue working to improve patient safety. AHRQ stated that it intends to foster continued improvement in both identifying and reducing adverse events through operational programs, research efforts, and further collaboration with other agencies. CMS also concurred with our recommendations, stating that it is committed to the reduction of adverse events in hospitals and other health care settings and that although it has taken significant steps to address these issues, more work needs to be done. CMS stated that it will "aggressively pursue" broadening the scope and definition of patient safety efforts to be more inclusive of various types of adverse events and more closely monitor and address hospital quality of care. CMS also outlined several current and planned efforts to both create incentives and provide support for patient safety improvements by hospitals.

We made minor changes to the report based on technical comments.

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INTRODUCTION

OBJECTIVES

To estimate the national incidence of adverse events for hospitalized Medicare beneficiaries, assess the preventability of such events, and estimate associated costs to Medicare.

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) report to Congress regarding the incidence of "never events" among Medicare beneficiaries; the extent to which the Medicare program paid, denied payment, or recouped payment for services furnished in connection with such events; and the processes that the Centers for Medicare & Medicaid Services (CMS) uses to identify such events and deny or recoup payment.[1] OIG is also to make recommendations for such legislation and administrative action as OIG determines is appropriate. (For relevant text of the Act, see Appendix A.) To meet the requirements of the Act, OIG released a series of reports beginning in 2008 and will publish additional reports based on ongoing work.[2]

Adverse Events in Hospitals

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 our work on inpatient acute care hospitals. For fiscal year (FY) 2009, Medicare costs for inpatient care were $137 billion, constituting 28 percent of total expenditures.[3] As a condition of participation in the Medicare and Medicaid programs, Federal regulations require that hospitals develop and maintain Quality Assessment and Performance Improvement (QAPI) Programs.[4] As a

[1] Tax Relief and Health Care Act of 2006, P.L. 109-432 § 203.

[2] The studies in the series published to date are: *Adverse Events in Hospitals: Overview of Key Issues*, OEI-06-07-00470; *Adverse Events in Hospitals: State Reporting Systems*, OEI-06-07-00471; and *Adverse Events in Hospitals: Case Study of Incidence Among Medicare Beneficiaries in Two Counties*, OEI-06-08-00220, all published in December 2008; *Adverse Events in Hospitals: Public Disclosure of Information About Events*, OEI-06-09-00360, January 2010; and *Adverse Events in Hospitals: Methods for Identifying Events*, OEI-06-08-00221, March 2010.

[3] CMS, *2009 CMS Statistics Book*, Table III.6, Office of Research, Development, and Information, CMS Pub. No. 03497, December 2009, p. 30.

[4] 42 CFR § 481.21.

part of their QAPI programs, hospitals must "track medical errors and adverse patient events, analyze their causes, and implement preventive actions."[5] Federal regulations do not require specific program characteristics. The QAPI provisions also require that hospitals establish programs to demonstrate improvement in quality indicators for which there is evidence that practices will improve outcomes.[6] As an additional quality effort, Quality Improvement Organizations (QIO) contract with CMS to assist hospitals in improving the quality of care for Medicare beneficiaries, including addressing patient safety issues.[7]

A variety of terms, lists, and definitions are used to identify health care events that result in patient harm. For purposes of the Act, the term "never event" means an event that is listed and endorsed as a serious reportable event by the National Quality Forum (NQF)[8] as of November 16, 2006.[9] The NQF uses the term "serious reportable events" to describe a specific list of events associated primarily with patient death or serious disability that are both egregious and preventable, concluding that they "should never occur in a health care setting." These became known as "never events." (For a list of NQF Serious Reportable Events, see Appendix B.) The NQF list is often used by patient advocates and health care payers in establishing patient safety policies.[10] The health care community now uses the term "adverse event" more commonly than "never event" to refer to harm experienced by a patient as a result of medical care. After consulting with congressional committee staff in 2007, we expanded our approach to be consistent with patient safety research and industry trends.

As used in this study, an adverse event is defined as harm to a patient as a result of medical care or in a health care setting. Although an adverse event indicates that the care resulted in an undesirable clinical

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[5] 42 CFR § 482.21(c)(2).

[6] 42 CFR § 482.21(a)(1).

[7] CMS, *QIO Overview*, last modified January 2010. Accessed at http://www.cms.hhs.gov/QualityImprovementOrgs/ on September 29, 2010.

[8] NQF is a public-private membership organization created to develop and implement a national strategy for health care quality measurement and reporting.

[9] The Act, § 203(d). The NQF list is available online at http://www.qualityforum.org.

[10] As an example, The Leapfrog Group, a national nonprofit focused on patient safety issues, encourages hospitals to adopt policies to address Serious Reportable Events. *Leapfrog Group Position Statement on Never Events*, updated November 11, 2009. Accessed at http://www.leapfroggroup.org/for_hospitals/leapfrog_hospital_survey_copy/never_events on September 29, 2010.

outcome and may involve medical errors, adverse events do not always involve errors, negligence, or poor quality of care and are not always preventable.[11] Research and policy to improve patient safety and reduce the incidence of adverse events often focus on identifying and addressing systemic problems that may lead to patient harm and avoid labeling the event as an outcome of negligence or poor quality. Additionally, researchers, policymakers, and health care entities sometimes adopt different standards for distinguishing between degrees of patient harm in determining whether they classify an occurrence as an adverse event. Thus, entities tracking events may find different results depending on the list used to identify and classify events.

The National Coordinating Council for Medication Errors Reporting and Prevention (NCC MERP) Index for Categorizing Errors can be used to classify adverse events by level of patient harm. The NCC MERP Index was initially developed to categorize the effect of medication errors and considers whether the occurrences had an effect on the patients and, if so, how harmful they were. The index includes categories for circumstances or occurrences that presented a risk but did not cause harm, often referred to as "near misses," and those that caused harm. Table 1 shows the NCC MERP Index for Categorizing Errors.

Table 1: The NCC MERP Index for Categorizing Errors

Level	Description	Event
A	Circumstances or events occurred that had the capacity to cause error.	Harm does not reach patient
B	Error occurred but did not reach the patient.	
C	Error occurred that reached the patient but did not cause patient harm.	
D	Error occurred that reached the patient and required monitoring to preclude harm or confirm that it caused no harm.	
E	Error occurred that may have contributed to or resulted in temporary harm and required intervention.	Harm reaches patient
F	Error occurred that may have contributed to or resulted in harm and required an initial or prolonged hospital stay.	
G	Error occurred that contributed to or resulted in permanent patient harm.	
H	Error occurred that required intervention to sustain the patient's life.	
I	Error occurred that may have contributed to or resulted in patient death.	

Source: NCC MERP Index for Categorizing Errors, Press Release, *Medication Errors Council Revises and Expands Index for Categorizing Errors: Definitions of Medication Errors Broadened*, June 12, 2001.

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

Researchers have used the NCC MERP index for measuring and distinguishing other types of adverse events, rather than only medication errors. For example, the Institute for Healthcare Improvement (IHI), a nonprofit organization that advises hospitals regarding health care quality, uses a modified version of the NCC MERP index to measure the degree of patient harm, regardless of whether the harm was the result of an error.[12]

Present on Admission Indicators and Medicare's Hospital-Acquired Conditions Policy

Medicare reimbursement to acute care hospitals through the Inpatient Prospective Payment System (IPPS) is generally determined by grouping codes representing patient conditions into Diagnosis-Related Groups (DRG) based on the average cost of care for patients with similar conditions.[13] Hospitals may submit Medicare claims under IPPS using nine diagnosis codes and six procedure codes for each hospital stay. Historically, if a Medicare beneficiary experienced an adverse event that resulted in assignment of a more costly DRG, CMS paid the higher DRG.[14]

Beginning October 1, 2007, hospitals are required to assign a Present on Admission (POA) Indicator to each principal and secondary diagnosis for acute IPPS claims for all discharges.[15] This was an initial step in complying with the Deficit Reduction Act of 2005 (DRA), which required CMS to select at least two hospital-acquired conditions (HAC) for which hospitals would not be paid higher Medicare reimbursement.[16]

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[12] F.A. Griffin and R.K. Resar, *IHI Global Trigger Tool for Measuring Adverse Events*, Institute for Healthcare Improvement Innovation Series 2007, pp. 4–5.

[13] CMS, *Acute Inpatient PPS Overview*, last modified Feb. 22, 2010. The ICD-9-CM system assigns diagnoses and procedure codes associated with hospital stays and is maintained jointly by CMS and the National Center for Health Statistics. Accessed at http://www.cms.gov/AcuteInpatientPPS/01_overview.asp on September 29, 2010.

[14] CMS, Press Release, *Eliminating Serious, Preventable, and Costly Medical Errors – Never Events*, May 18, 2006.

[15] CMS, CMS Manual System, Change Request 5679 (July 20, 2007). To effectuate the use of POA indicators, the FY 2008 IPPS rule implemented 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 classes based on the presence of a complication or comorbidity. FY 2008 IPPS Final Rule, 72 Fed. Reg. 47130, 47138 (Aug. 22, 2007).

[16] DRA, P.L. 109-171 § 5001(c)(1), Social Security Act (SSA), § 1886(d)(4)(D), 42 U.S.C. § 1395ww(d)(4)(D).

In response, CMS issued regulations outlining a policy to deny hospitals higher payment for hospital admissions complicated by any of 10 categories of HACs.[17] The DRA required that the conditions meet 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]

Effective October 1, 2008, CMS began denying hospitals higher payment for care associated with these conditions.[19] Examples of HACs include catheter-associated urinary tract infections and patient injury because of a fall. For the full list of Medicare HACs, see Appendix C.

Determining the Incidence of Adverse Events

Research indicates that identifying adverse events retrospectively is a complex and difficult task, requiring extensive clinical knowledge, adequate documentation, and subjectivity on the part of the researcher.[20] Medical records review is often considered the most definitive method for detecting adverse events because it can provide detail about both the adverse event and the circumstances, such as the patient's condition prior to and following the event.[21] However, medical records reviews can be costly, requiring hospital staff to make records available and substantial effort by physicians or other clinicians to review them. To limit physician medical records reviews required to identify adverse events, cases can be screened to identify potential

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[17] FY 2008 IPPS Final Rule, 72 Fed. Reg. 47130, 47202 (Aug. 22, 2007); and FY 2009 IPPS Final Rule, 73 Fed. Reg. 48434, 48471–48491 (Aug. 19, 2008).

[18] SSA, § 1886(d)(4)(D)(iv).

[19] FY 2009 IPPS Final Rule, 73 Fed. Reg. 48434, 48471–48472 (Aug. 19, 2008); CMS, CMS Manual System, Change Request 6189 (Oct. 3, 2008).

[20] E.J. Thomas and L.A. Peterson, *Measuring Errors and Adverse Events in Health Care*, Journal of General Internal Medicine, 18(1), 2003, pp. 61–67.

[21] 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.

adverse events using other methods, such as nurse reviews of medical records and analysis of POA indicators in hospital claims data.

Nurse review of medical records. Medical records screening can identify potential adverse events based on information in the medical records. The IHI Global Trigger Tool (GTT) uses a review of medical records to identify "triggers" that could signal patient harm, thereby identifying potential adverse events. A trigger could be a description of the harm itself or a reference that indicates harm occurred (such as a return to surgery). The review is designed to be completed by nurse reviewers, with the results then confirmed or refuted by a physician. Barriers to medical records screening include incomplete records and high labor costs for review.

Analysis of POA indicators. Automated computer programs can review Medicare billing data, specifically the POA indicator codes assigned to each diagnosis, to identify conditions that developed during hospital stays and possibly constitute adverse events. Although these programs enable examination of large numbers of hospital stays, barriers exist to POA analysis, including inaccurate or incomplete data. CMS's POA coding requirement began in October 2007, and the accuracy and completeness of hospital coding of POA indicators have not yet been validated. Additionally, conditions can be acquired in hospitals that are not related to medical care and therefore not adverse events.

OIG case study. Prior to this study, we conducted a case study of the incidence of adverse events occurring during October 2008 for a random sample of 278 Medicare beneficiaries' hospital stays in 2 counties.[22] We estimated that 15 percent of Medicare beneficiaries in the two counties experienced events meeting at least one of the following criteria: events on the NQF list of Serious Reportable Events; events on Medicare's list of HACs; or events involving prolonged hospital stays, permanent harm, life-sustaining intervention, or death (classified as F-I level of harm on the NCC MERP index). An additional 15 percent of beneficiaries experienced events involving temporary harm (classified as E level of harm on the NCC MERP index). The case study served in part to test the usefulness of various methods for identifying adverse events. We found that, combined, nurse screening of medical records and analysis

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

of POA indicator codes in billing data identified 94 percent of occurrences that physicians ultimately determined to be adverse or temporary harm events.[23]

Determining the Preventability of Adverse Events

To provide additional context regarding adverse events, some researchers have assessed whether adverse events were preventable and described the circumstances associated with events. A 2008 review of eight preventability studies found that the median percentage of adverse events judged preventable was 43.5 percent.[24] Assessing preventability can provide greater understanding of the causes of adverse events, which can be used to develop actionable solutions to the systemic problems that lead to events. Also, preventability is a statutory criterion of Medicare's nonpayment policy for HACs; CMS was required to select only conditions that can be "reasonably prevented by using readily available evidence-based guidelines."[25]

Reducing the Incidence of Adverse Events

Reducing the incidence of adverse events in hospitals is a critical component of efforts to improve patient safety and quality care. The Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health System*, focused widespread attention on the problem of adverse events. IOM cited two studies that used medical records reviews to identify adverse events and assess whether events were preventable. IOM concluded that preventable adverse events caused "at least 44,000 and perhaps as many as 98,000 deaths in hospitals each year" and outlined a national plan to address adverse events.[26]

As part of its plan, IOM recommended the creation of a nationwide system for the collection of standardized adverse event data by State governments. As reported by OIG, 25 States and the District of Columbia had adverse event reporting systems in 2008, 11 of which

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[23] OIG, *Adverse Events in Hospitals: Methods for Identifying Events*, OEI-06-08-00221, March 2010.

[24] E.N. De Vries, M.A. Ramrattan, et al., *The Incidence and Nature of In-Hospital Adverse Events: A Systematic Review*, British Medical Journal – Quality and Safety in Health Care, 17(3): 216–23, June 2008.

[25] SSA, § 1886(d)(4)(D)(iv), 42 CFR § 412.10; FY 2008 IPPS Final Rule, 72 Fed. Reg. 47130, 47202 (Aug. 22, 2007).

[26] 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*, p. 102, IOM, National Academy Press, 2000.

used the NQF list of Serious Reportable Events or a modified version of the list to define what events are reportable.[27] To date, no national adverse event reporting system exists and there are no Federal standards regarding State systems.

Following the IOM report, the Federal Government formed the Center for Quality Improvement and Patient Safety (CQuIPS) within AHRQ to provide national leadership in improving patient safety. In a 2009 report, AHRQ identified its core agency objectives for CQuIPS as developing a solid evidence base, designing useful tools for providers, and disseminating information for implementation.[28] As mandated by Congress, AHRQ releases an annual report to the Nation about health care quality that is produced by CQuIPS and includes measures of patient safety.[29] The National Healthcare Quality Report includes measures of the incidence of certain types of adverse events, using data from sources such as the Medicare Patient Safety Monitoring System (MPSMS), an AHRQ-CMS collaborative effort to identify adverse events through analyses of medical records and Medicare claims data for beneficiaries' hospital stays.[30] AHRQ is also responsible for implementation and oversight of the certification process for Patient Safety Organizations (PSO) created by the Patient Safety Act and Quality Improvement Act of 2005.[31] PSOs are in the early stages of development, but are intended to receive adverse event reports from hospitals and forward the information to a national AHRQ database from which CQuIPS will analyze aggregated data. AHRQ developed a set of event definitions and reporting tools known as the Common Formats, which PSOs can choose to use and which contain data elements that AHRQ determined are important for a complete and

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[27] OIG, *Adverse Events in Hospitals: State Reporting Systems*, OEI-06-07-00471, December 2008.

[28] AHRQ, *Advancing Patient Safety: A Decade of Evidence, Design, and Implementation*, AHRQ Publication No. 09(10)-0084, November 2009. Accessed at http://www.ahrq.gov/qual/advptsafety.htm on September 29, 2010.

[29] Healthcare Research and Quality Act of 1999, P.L. 106-129 § 2(a); Public Health Service Act (PHSA), § 913, 42 U.S.C. § 299b-2.

[30] D.R. Hunt, N. Verzier, et al., "Fundamentals of Medicare Patient Safety Surveillance: Intent, Relevance, and Transparency," *Advances in Patient Safety*, 2005, p. 105. Accessed at www.ahrq.gov/downloads/pub/advances/vol2/Hunt.pdf on September 29, 2010.

[31] The Secretary of Health and Human Services (Secretary) delegated authority to AHRQ to make these determinations, as well as to fulfill other requirements of the Patient Safety Act. Patient Safety and Quality Improvement Act of 2005, P.L. 109-41 § 2, PHSA, § 924, 42 U.S.C. § 299b-24; 73 Fed. Reg. 70732 (Nov. 21, 2008).

useful adverse event report.[32] A variety of organizations are eligible to become PSOs, including hospital associations, hospital chains, and patient safety consulting groups.[33] For a 2009 OIG study, staff from selected PSOs reported barriers that could limit hospital participation in PSOs and questioned the usefulness of submitting data for aggregation.[34] Finally, the American Recovery and Reinvestment Act of 2009 appropriated $300 million to AHRQ to sponsor and disseminate research that compares the effectiveness of clinical care options, the purpose of which is to promote evidence-based medical care.[35]

In March 2010, Congress passed health care reform legislation in the form of the Patient Protection and Affordable Care Act (ACA).[36] The ACA includes a number of provisions to take effect over multiple years, including expanded funding and authority to the Department of Health and Human Services (HHS) to address health care quality issues. Among the initial efforts to implement the ACA, the Secretary is to establish a national strategy for quality improvement in health care by January 1, 2011.[37] The law requires that the strategy address eight national priority areas, one of which is to improve patient safety.[38] It also increases funding to CQuIPS for research grants to explore best practices.[39] Among its payment provisions, the ACA expands the Medicare HAC policy to mandate hospital payment penalties for high rates of HACs,[40] create new quality measures,[41] and require State Medicaid agencies to deny higher reimbursement for care associated with HACs.[42]

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[32] AHRQ, *Common Formats for Patient Safety Data Collection and Event Reporting, Notice of Availability: Common Formats Version 1.0*, September 2, 2009. Accessed at http://www.pso.ahrq.gov/formats/commonfmtv1_0fr.htm on October 12, 2010.

[33] PHSA, § 924(b), 42 U.S.C. § 299b-24(b).

[34] OIG, *Adverse Events in Hospitals: Public Disclosure of Information About Events*, OEI-06-09-00360, January 2010.

[35] American Recovery and Reinvestment Act of 2009, P.L. 111-5, Division A, Title VIII.

[36] ACA, P.L. 111-148, was signed into law on March 23, 2010, after we had completed data collection and analysis for this study.

[37] P.L. 111-148 § 3011, PHSA, § 399HH, 42 U.S.C. § 280j.

[38] P.L. 111-148 § 3011, PHSA, § 399HH(a)(2)(B)(vii), 42 U.S.C. § 280j(a)(2)(B)(vii).

[39] P.L. 111-148 § 3501, PHSA, §§ 933 and 934.

[40] P.L. 111-148 § 3008(a), SSA, § 1886(p), 42 U.S.C. § 1395ww(p).

[41] P.L. 111-148 § 3013 inserted new section 931 of the PHSA, 42 U.S.C. § 299b-31, and added section 1890A(e) of the SSA, 42 U.S.C. § 1395aaa-1(e).

[42] P.L. 111-148 § 2702.

METHODOLOGY

Scope

This report estimates the national incidence of adverse events based on a representative sample of Medicare beneficiaries discharged from inpatient acute care hospitals during October 2008. Our results are projectable to all Medicare beneficiaries hospitalized during this period nationwide. To determine the estimated rate of adverse events, we used criteria developed by NQF, CMS, and NCC MERP. We included in the estimated national incidence rate all patient harm that occurred during the hospital stay, regardless of whether it was preventable. Also, the report provides a physician assessment of the extent to which identified events were preventable and analysis of billing data to estimate the cost to the Medicare program for increased reimbursement resulting from all events and preventable events.

Sample Selection

We selected a sample of Medicare beneficiaries from the National Claims History (NCH). Of the 999,645 beneficiaries discharged from acute care hospitals during October 2008, we selected a random sample of 785 beneficiaries. We excluded 5 beneficiaries as ineligible because the hospital was currently under OIG investigation, resulting in a sample of 780 beneficiaries. In July–October 2009, we requested and received medical records from hospitals regarding sample beneficiaries' hospital stays. Fifty-four of the beneficiaries had more than 1 hospital stay during October (50 had 2 stays and 4 had 3 stays). Combined, sample beneficiaries had 838 hospital stays with discharges in October 2008 and an average length of stay of 5.2 days.[43]

Identifying Adverse Events and Determining Preventability

We conducted a two-stage review to identify adverse events experienced by each beneficiary. The first stage used three screening methods to identify cases likely to include an event. This enabled us to reduce the number of cases requiring the second-stage physician review. During the first stage, we identified cases that met one or more of the following conditions: (1) certified medical coders identified codes in the Medicare claims data that were listed as not present on admission, (2) nurse reviewers found evidence of a potential adverse event in the medical

[43] The average length of stay for hospitalized Medicare beneficiaries overall in 2007 was 5.6 days. CMS, *2009 CMS Statistics*, Table IV.1 Medicare Short-stay Hospital Utilization, 2009, Tab 1.

records, or (3) the beneficiary had a hospital admission within 30 days after discharge for his or her last sample hospital stay ending in October 2008.[44]

We identified 420 cases for the second stage of review, which entailed a review of the full medical records by physicians to identify events. To ensure consistency across physician reviewers, we facilitated weekly conference calls during which all physician reviewers discussed cases that either were complex or had possible implications for other cases. We included events experienced by patients during hospital stays or during prior, contiguous outpatient visits (wherein patients were transferred directly from outpatient care to inpatient care within the same facility). For example, we included in our count an adverse event that occurred in a hospital emergency department immediately preceding admission to inpatient care. We did not include events that occurred prior to a beneficiary's arrival on the hospital campus. When an initial event caused a series of related events for the same patient, we collapsed the events into a "cascade event," which counted as a single event.[45] For a glossary of selected clinical terms used to describe events, see Appendix D.

As part of the structured protocol, physician reviewers also determined the extent to which the identified events were preventable. Generally speaking, physicians assessed events as preventable when they determined that harm could have been avoided through improved assessments or alternative actions. Physicians assessed an event as not preventable when they determined that harm could not have been avoided given the complexity of the patient's condition or the care required. The physician protocol used the following response scale for assessing the preventability of events: clearly preventable, likely preventable, clearly not preventable, likely not preventable, and unable to determine. Physicians used their clinical experience and judgment to make preventability determinations. They considered all evidence in

[44] We reviewed records for admissions that occurred within 30 days of the last beneficiary discharge. Therefore, the 30-day window for reviewing readmissions did not span a fixed timeframe but began on the unique final discharge date for each beneficiary with the last possible admission occurring on November 30, 2008 (30 days following the final possible October 31, 2008, discharge).

[45] Based on OIG interviews with IHI staff, IHI defines a cascade event as one in which an initial event causes a series of related events for the same patient and advocates collapsing these into a single event.

the medical records, including the actions of hospital and medical staff and the patient's condition. Assessing an event as *clearly* preventable or *clearly* not preventable required a greater degree of certainty on the part of the reviewer. For detailed information about the methodology for identifying events and determining preventability, see Appendix E.

Data Analysis

We performed analysis and generated estimates about adverse events for three categories: incidence of events, preventability of events, and Medicare cost associated with events. We also calculated separate estimates regarding these categories for temporary harm events. For estimates and corresponding 95-percent confidence intervals for all statistical analyses, see Appendix F.

Adverse event incidence analysis. We calculated the estimated national adverse event incidence rate as the percentage of Medicare beneficiaries with at least one adverse event. We defined adverse events as events that met at least one of the following criteria:

1. the event was on the NQF list of Serious Reportable Events, as the Act mandates;
2. the event was on Medicare's list of HACs for which it denies higher payment; or
3. the event resulted in one of the four most serious categories on the NCC MERP index (classified on the index as F-I):
   - prolonged hospital stay,
   - permanent harm,
   - life-sustaining intervention, or
   - death.

We also calculated individual rates for adverse events on the NQF list, the Medicare HAC list, and events classified as F-I on the NCC MERP index. The overall adverse event incidence rate does not include events that physician reviewers identified as temporary harm events, defined as events that required intervention but did not cause lasting harm (classified as E level harm on the NCC MERP index). We excluded these temporary harm events from our overall rate because we determined, in consultation with physician reviewers, that the effect of these events was not comparable to the more serious events meeting the three criteria. We calculated a separate incidence rate for beneficiaries who experienced only temporary harm events. We projected incidence rates to the population of Medicare beneficiaries discharged from inpatient acute care hospital stays during October 2008.

As an additional measure of adverse event rates, we calculated 2 ratios of adverse event incidence density: events per 1,000 patient days and events per 100 hospital admissions. These measures are commonly used by hospitals and medical researchers.[46] For the resulting metrics and an explanation of the calculation method, see Appendix G.

Preventability analysis. The findings related to preventability are based on determinations made by the physician reviewers for each adverse event and temporary harm event. We calculated percentages for each preventability classification and for different types of events, the results of which are projectable to the population. We also conducted statistical tests to identify differences in preventability rates between adverse events and temporary harm events and across various categories of adverse events, such as medication-related and infection-related events.

Medicare cost analysis. We estimated the cost to Medicare resulting from care associated with adverse events and temporary harm events. This analysis included only Medicare claims that were paid under the IPPS and were subject to the Medicare HAC policy (84 percent of sample beneficiaries).[47] Certified medical coders reviewed the medical records, the medical review protocols, and the associated Medicare claims to identify diagnosis and procedure codes that would not have been included in the claims if the events had not occurred. We then used CMS's MS-DRG Grouper and Medicare Code Editor Version 27 (Grouper) to determine the DRG for the claims and used the FY 2009 IPPS personal computer Pricer (Pricer) to determine the resulting Medicare reimbursement amounts.[48] For each claim, we calculated the DRG and reimbursement amount, including information from the

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[46] K.M. Arias, *Outbreak Investigation, Prevention, and Control in Health Care Settings*, Second Edition, Jones and Bartlett Publishers, 2009, pp. 330–331.

[47] The cost analysis does not include claims for beneficiaries whose Medicare coverage is not paid under the IPPS. This includes Medicare managed care organizations and care provided at hospitals excluded from the Medicare IPPS system, including hospitals in the State of Maryland and some specialty hospitals nationwide, such as cancer treatment centers and critical access hospitals. CMS, *HAC Fact Sheet*. Accessed at http://www.cms.gov/HospitalAcqCond/Downloads/HACFactsheet.pdf on September 29, 2010.

[48] The Grouper software classifies hospital claims into MS-DRG categories expected to have similar hospital resource requirements. MS-DRGs are based on the nine diagnoses associated with HACs and corresponding POA indicators, six procedure codes, and demographic data contained in the NCHs. MS-DRGs typically split into two or three individual classes based on the presence of a complication or comorbidity. This software was developed by CMS and 3M and is sold by the National Technical Information Service. Accessed at http://www.ntis.gov on September 29, 2010.

hospital Medicare claim. We then calculated the reimbursement amount excluding diagnosis and procedure codes that coders determined were the direct result of any adverse event or temporary harm event experienced by the beneficiary. We projected the difference between the two hospital reimbursement amounts to estimate the additional cost to Medicare for care associated with events. When an entire hospital stay was the result of an adverse event, we included the total reimbursement amounts indicated by the Pricer as the cost of the adverse event.

Limitations

Beyond the challenges associated with identifying adverse events and assessing preventability, the methodology presents two specific limitations. First, it is unlikely that the study identified all adverse and temporary harm events within the sample. To the extent that the study did not identify an event, it was likely because the three screening methods failed to flag the case for physician review or because documentation in the medical records was incomplete. Second, cost estimates did not include all costs of care associated with events, excluding stays not covered under the Medicare IPPS, additional hospital stays caused by sample events but occurring after October 2008, additional care outside the hospital (such as followup physician office visits or rehabilitation services), and changes in Medicare outlier payments.[49]

Standards

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

[49] Medicare outlier payments are supplemental payments to hospitals for patients who incur extraordinarily high costs. Outlier payments are based on the degree to which costs on a claim exceed specific hospital and MS-DRG fixed-loss thresholds and fluctuate depending on the MS-DRG to which the claim is grouped. The Pricer analysis involved a revision of the MS-DRG. This revision resulted in new outlier payments for three sample cases and increased outlier payments for two sample cases. The revised outlier payments decreased the cost attributed to adverse events in our estimate.

An estimated 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays

Of the nearly 1 million Medicare beneficiaries discharged from hospitals in October 2008, about 1 in 7 experienced an adverse event (13.5 percent), defined as an event that met at least 1 of the following 3 criteria: the event was on the NQF list of Serious Reportable Events; the event was on Medicare's list of HACs; or the event resulted in 1 of the 4 most serious categories on the NCC MERP index (prolonged hospital stay, permanent harm, life-sustaining intervention, or death). This incidence rate projects to approximately 134,000 Medicare beneficiaries experiencing at least 1 adverse event in hospitals during the study period. Table 2 lists the incidence rate for each of the three criteria.

Table 2: Estimated National Incidence of Adverse Events Among Medicare Beneficiaries Discharged in October 2008

Category of Events	Estimated Percentage of Medicare Beneficiaries	Estimated Number of Medicare Beneficiaries
NQF Serious Reportable Events*	0.6%	6,367
Medicare HACs*	1.0%	10,187
NCC MERP F-I Level Events	13.1%	129,890
(Overlap)**	(1.3%)	(12,734)
Total	**13.5%*** **	**133,710**

See Appendix F for confidence intervals.
*Given the small proportions, confidence intervals for projected numbers exceed 50-percent relative precision.
**The 1.3 percent represents beneficiaries who experienced adverse events in more than one category. We counted these beneficiaries only once in determining the overall incidence rate.
***Column does not sum to 13.5 percent because of rounding.
Source: OIG analysis of hospital stays for 780 Medicare beneficiaries discharged in October 2008.

We classified the identified adverse events into four clinical categories: events related to medication (31 percent), events related to ongoing patient care (28 percent), events related to surgery or other procedures (26 percent), and events related to infection (15 percent). Table 3 lists the 128 adverse events found in the sample within these categories. See Appendix H for a list of the events with more complete descriptions, the level of harm patients incurred, and indications of whether the events were on the NQF and HAC lists.

Table 3: Adverse Events Identified Among Sample Medicare Beneficiaries by Clinical Category (n=128)

Types of Adverse Events	Number of Events and Percentages of Total Events
Events Related to Medication	31% (40)
Excessive bleeding	12
Delirium or change in mental status	7
Hypoglycemic event	6
Acute renal insufficiency (kidney failure)	4
Severe hypotension	4
Respiratory complications	4
Severe allergic reactions	3
Events Related to Patient Care	28% (36)
Intravenous volume overload	10
Aspiration	8
Deep vein thrombosis or pulmonary embolism	5
Exacerbation of preexisting medical condition	5
Stage III pressure ulcer	3
Breakdown of surgical wound	1
Congestive heart failure	1
Hypoxia (oxygen deficiency)	1
Patient fall with injury	1
Prolonged weakness and dizziness	1
Events Related to Surgery or Other Procedures	26% (33)
Excessive bleeding	5
Severe hypotension	4
Respiratory complication	4
Iatrogenic pneumothorax	3
Postoperative ileus	3
Postoperative urinary retention	3
Acute coronary syndrome	2
Blood clot and other occlusion	2
Cardiac complication	2
Cardiac dysrhythmia	1
Delay in surgery because of equipment malfunction	1
Hemorrhage at surgical site	1
Seroma (fluid) following stomach resection	1
Urinary catheter-associated trauma	1
Events Related to Infection	15% (19)
Urinary tract infection	5
Vascular catheter-associated infection (central or peripheral line)	4
Other bloodstream infection	4
Respiratory infection	4
Surgical or procedural site infection	2

Source: OIG analysis of hospital stays for 780 Medicare beneficiaries in October 2008.

Of beneficiaries who experienced adverse events, 18 percent had more than one adverse event. Most of the beneficiaries who experienced multiple events had two events, but others had as many as three

unrelated events in the same hospitalization. For example, an elderly heart patient with a history of mental illness experienced three adverse events of different types, including two events that prolonged hospitalization and a third that required life-sustaining intervention. (This beneficiary also experienced three temporary harm events associated with patient care.)

Less than 1 percent of Medicare beneficiaries experienced an event on the NQF list of Serious Reportable Events

An estimated 0.6 percent of Medicare beneficiaries experienced an event on the NQF list, which projects to approximately 6,400 beneficiaries nationally for the study period. The low number of NQF events in the sample is notable because of the prominence of the list as a measure of patient harm and its use by a number of State adverse event reporting systems and other entities. We identified a total of five NQF events in the sample: two medication-related deaths and three Stage III pressure ulcers.[50] One of the medication-related deaths illustrates the nature of the NQF list as a measure of the most egregious preventable outcomes. In this case, a disabled Medicare beneficiary with muscular dystrophy affecting the respiratory system entered the hospital for signs of respiratory failure. Medical staff at the hospital gave the beneficiary a medication known to further suppress respiration, resulting in progressive respiratory distress and subsequent death. Physician reviewers concluded that medical staff administered the wrong medication because they lacked clinical understanding of the patient's unique condition.

Many serious events that we identified were not on the NQF list of Serious Reportable Events, including some events that resulted in patient deaths and serious disability. The NQF list focuses largely on serious disability or death, but is restricted to a specific set of events. Of the 18 adverse events that physician reviewers found to result in serious disability or patient death, only 2 were on the NQF list (i.e., the medication errors resulting in death). The three Stage III pressure ulcers identified in the sample were sufficiently treated prior to

[50] Pressure ulcers are classified into four stages by the National Pressure Ulcer Advisory Panel (NPUAP): Stage I is intact skin with nonblanchable redness; Stage II is a shallow ulcer or blister indicating damage to the epidermis; Stage III is damage extending through all the layers of the skin; and Stage IV is damage through all the layers of the skin and underlying muscle, tendons, or bone. NPUAP, *Pressure Ulcer Stages Revised by NPUAP*. Accessed at http://www.npuap.org on November 12, 2009.

discharge from the hospital and determined by physicians to have caused only temporary harm.

Medicare HACs rarely occurred, affecting just 1 percent of beneficiaries

An estimated 1 percent of hospitalized Medicare beneficiaries experienced Medicare HACs, which projects to approximately 10,000 beneficiaries nationally. We identified a total of nine Medicare HACs experienced by beneficiaries in the sample: five catheter-associated urinary tract infections, two vascular catheter-associated infections of the central line, one patient fall resulting in injury (a compression fracture), and one Stage III pressure ulcer. One beneficiary experienced two of these events, resulting in a total of eight sample beneficiaries with Medicare HACs. Two catheter-associated urinary tract infections caused more substantial harm than is typically associated with this condition: one resulted in a prolonged hospital stay and the other in permanent harm. The two vascular catheter-associated infections of a central line resulted in prolonged hospital stays. None of the nine Medicare HACs identified by physicians on the medical records were included in the associated Medicare claims. In four of the nine cases (all catheter-associated urinary tract infections), diagnosis codes on the claims identified the infections, but they were not the precise codes that CMS uses to identify these HACs. The other five claims had no diagnosis codes related to the HACs. Therefore, the HACs were not identifiable through the claims data that CMS uses to implement the HAC policy.

Thirteen percent of Medicare beneficiaries experienced adverse events classified in the most serious categories on the NCC MERP harm index

Based on our physician medical review, 13.1 percent of Medicare beneficiaries experienced adverse events classified in the four most serious harm categories on the NCC MERP harm index: events resulting in prolonged hospital stay, events resulting in permanent harm, events requiring life-sustaining intervention, and events contributing to death. This rate projects nationally to approximately 130,000 beneficiaries experiencing such adverse events during the study period. Often, adverse events within the same clinical category, such as infection, resulted in a different level of harm depending on the intervention required and the condition of the patient. Table 4 lists the percentage of adverse events in the sample that were classified in the four most serious harm categories and the projected national numbers of events by level of patient harm.

Table 4: Adverse Events Classified as F-I on the NCC MERP Patient Harm Index by Level of Harm

Level of Harm	Percentage of Adverse Events
F level: Requiring prolonged hospital stay	62%
G level: Permanent harm*	5%
H level: Life-sustaining intervention required	23%
I level: Contributing to death*	10%

See Appendix F for confidence intervals.

*Given the small proportions, confidence intervals for projected numbers exceed 50-percent relative precision.

Source: OIG analysis of hospital stays for 780 Medicare beneficiaries discharged in October 2008.

An estimated 1.5 percent of hospitalized Medicare beneficiaries experienced events that contributed to their deaths

Among the 128 adverse events that we identified in the sample, 12 events (9 percent of 128 events) contributed to the deaths of beneficiaries. This projects to an estimated 1.5 percent of hospitalized Medicare beneficiaries experiencing events that contributed to death or approximately 15,000 beneficiaries during the study period. Seven of the twelve deaths were related to medication, either the result of improper administration of medication (wrong drug or wrong dosage) or inadequate treatment of known side effects. The most common type of medication-related death (five deaths) involved excessive bleeding from blood-thinning medication. The two other medication-related deaths involved inadequate insulin management resulting in hypoglycemic coma and respiratory failure resulting from oversedation. Of the five non-medication-related deaths, two were from bloodstream infections; two involved aspiration (which led to pneumonia and cardiac arrest, respectively); and the other involved a ventilator-associated pneumonia. As stated previously, only 2 of the 12 adverse events that contributed to death were on the NQF list and none were Medicare HACs.

Twenty-seven percent of beneficiaries who experienced adverse events had at least one "cascade" event, wherein multiple, related events occurred in succession

The sample included a total of 28 cascade events, defined as adverse events that included a series of multiple, related events. We counted these as single events. These cascade events were some of the most serious adverse events identified in the sample, with nine cases requiring life-sustaining intervention and six cases contributing to death. The most common type of cascade events were events related to

surgery and other procedures (nine events). Two of these events began with excessive bleeding following surgery or a procedure. For example, one beneficiary had excessive bleeding after his kidney dialysis needle was inadvertently removed, which resulted in circulatory shock, a transfer to the intensive care unit, and emergency insertion of a tube into the trachea (windpipe) to ease breathing. When the tube was removed the following day, the patient aspirated (inhaled foreign material into his lungs), which required a life-sustaining intervention.

An additional 13.5 percent of Medicare beneficiaries experienced events during their hospital stays that resulted in temporary harm

An additional 13.5 percent of Medicare beneficiaries experienced events during the study period classified as E level harm on the NCC MERP index, defined as events that required medical intervention but did not cause lasting harm. This rate projects to approximately 134,000 Medicare beneficiaries experiencing temporary harm events during the study period. Of these beneficiaries, 22 percent had more than one unrelated event (the highest occurrence was five unrelated events in a single hospital stay). Additionally, 28 percent of beneficiaries who experienced adverse events (and are included in our primary rate) also had temporary harm events during the same stay.

Events classified as temporary harm represented a wide array of conditions, such as prolonged vomiting and hypoglycemia (see Table 5). The most common events related to medication (42 percent). Although many cases of temporary harm represented fairly minor occurrences, we classified others as temporary because the patients were in the hospital for a lengthy period because of other, more serious, diagnoses, allowing the hospital enough time to address the harm prior to discharge. Physician reviewers indicated that many temporary harm events could have developed into more serious adverse events, but hospitals provided timely intervention. For example, Stage I or Stage II pressure ulcers can escalate quickly to Stage III or Stage IV without proper care[51] and episodes of hypoglycemia can lead to stroke and even death.[52]

[51] J.L. Zeller, C. Lynm, and R.M. Glass, *Pressure Ulcers*, Journal of the AMA, 296(8), August 23/30, 2006, p. 1020. Accessed at http://jama.ama-assn.org on December 1, 2009.

[52] P. Mandava and T. Kent, *Metabolic Disease & Stroke: Hyperglycemia/Hypoglycemia*, Journal of Diabetes Science and Technology, 17, April 4, 2006, p. 8. Accessed at http://emedicine.medscape.com on December 1, 2009.

Table H-2 in Appendix H contains a list of the 174 temporary harm events identified in the sample with more complete descriptions.

Table 5: Temporary Harm Events Identified Among Sample Medicare Beneficiaries by Clinical Category (n=174)

Types of Temporary Harm Events	Number of Events and Percentage of Total Events
Events Related to Medication	42% (73)
Delirium or change in mental status	22
Hypoglycemic event	11
Thrush and other opportunistic infection	7
Allergic reaction or side effect related to skin	6
Gastrointestinal complication	5
Hypotension	5
Dysrhythmia	3
Excessive bleeding	3
Severe headache or dizziness	3
Acute renal failure or insufficiency	2
Allergic reaction to blood or related products	2
Respiratory complication	2
Other events related to medication	2
Events Related to Patient Care	36% (63)
Stage I, Stage II, or unstaged pressure ulcer	20
Intravenous volume overload	15
Skin tear, laceration, abrasion, or other breakdown	9
Intravenous infiltrate with symptoms	6
Patient fall with injury	5
Aspiration	3
Failure to treat constipation or obstipation	3
Tachycardia or dysrhythmia	2
Events Related to Surgery or Other Procedures	18% (32)
Urinary retention	8
Excessive bleeding	6
Cardiac complication	4
Surgical tear or laceration	3
Urinary catheter-related trauma	3
Prolonged nausea and vomiting	2
Postoperative or postprocedural hypotension	2
Respiratory complication	2
Other events related to surgery or other procedures	2
Events Related to Infection	4% (6)
Surgical site infection	2
Bacterial infection	1
Respiratory infection	1
Urinary tract infection	1
Vascular catheter-associated infection	1

Source: OIG analysis of hospital stays for 780 Medicare beneficiaries in October 2008.

Physician reviewers determined that 44 percent of adverse events and temporary harm events were clearly or likely preventable

Physician reviewers assessed the extent to which events were preventable based on information in the medical records, their clinical experience with similar circumstances, research literature about the preventability of specific events, and group discussion to reach consensus. Combining adverse events and temporary harm events, physicians determined that 44 percent were preventable and 51 percent were not preventable.[53] (There was no statistically significant difference between the preventability rates of adverse events and temporary harm events.)[54] For the remaining 5 percent of events, physicians were unable to make determinations because of incomplete documentation in the medical records or extreme complexities in the patients' conditions or in the hospital care provided. Table 6 provides the percentage of events by the physician preventability assessment.

Table 6: Events by Physician Preventability Assessment

Preventability Assessment	Percentage of Events
Preventable—Harm could have been avoided through improved assessment or alternative actions	44%
Clearly preventable	9%
Likely preventable	35%
Not preventable—Harm could not have been avoided given the complexity of the patient's condition or care required	51%
Clearly not preventable	18%
Likely not preventable	33%
Unable To Determine Preventability	5%

Source: OIG analysis of hospital stays for 780 Medicare beneficiaries discharged in October 2008.

Physician reviewers assessed the preventability of events similarly for three of the four clinical categories (medication, patient care, and infections). However, events related to surgery and other procedures were significantly less likely to be determined preventable than events in the other three clinical categories; only 17 percent of surgical events were

[53] The preventability rate of 44 percent is similar to the rate of 43.5 percent found by a 2008 review of 8 adverse event preventability studies previously referenced on p. 7.

[54] The Cochran-Mantel-Haenszel chi square test was not significant at the 95-percent confidence level (p=0.0568). See Appendix F for detailed preventability statistics for adverse events and temporary harm events.

preventable in contrast to 50 percent or more in each of the other three groups.[55] Physician reviewers indicated that the reasons surgical events were more likely to be assessed as not preventable were the high level of complexity in both the care involved and the patients' conditions. Table 7 provides the percentage of preventable events by clinical category.

Table 7: Preventable Events Within Clinical Categories

Clinical Category	Percentage of Events Assessed as Preventable
Infection	60%
Medication	50%
Patient care	51%
Surgery and other procedures	17%

Source: OIG analysis of hospital stays for 780 Medicare beneficiaries discharged in October 2008.

Within the clinical categories, physician reviewers sometimes gave the same preventability assessment for events with similar characteristics. For example, they assessed 10 of 12 events related to allergic reactions as not preventable. But for other types of events, preventability determinations for similar events differed based on the patients' conditions and risk factors. For example, in two cases of excessive stomach bleeding caused by blood thinners, physicians assessed one event affecting a relatively healthy patient as preventable and the other event affecting a patient with stomach ulcers as not preventable because of the patient's susceptibility. In another case, physician reviewers determined that some pressure ulcers were not preventable because of the poor conditions of the patients and because documentation in the medical records showed that the hospital staff employed appropriate preventive care. However, physicians assessed another pressure ulcer case as preventable because the medical staff declined to order a specialty mattress for an at-risk bedridden patient until after the pressure ulcer had developed, even though the medical record indicated that the specialty bed was available.

[55] The Cochran-Mantel-Haenszel chi square test was significant at the 95-percent confidence level for the overall relationship between preventability and clinical category ($p<0.0001$) as well as for each set of pair-wise comparisons between the surgical category and each of the other three clinical categories ($p<0.01$ for each pair). Preventability rates were 62 percent for infections, 50 percent for medication, and 50 percent for patient care.

Counting only preventable events, the estimated national incidence rate of adverse events among Medicare beneficiaries would be 7.4 percent

The estimated adverse event incidence rate of 13.5 percent is based on all adverse events' meeting one of the three criteria, regardless of whether the events were preventable. Including only the adverse events determined by physician reviewers to be clearly or likely preventable, the estimated incidence rate of adverse events among Medicare beneficiaries would be 7.4 percent. The 13.5 percent rate of additional beneficiaries experiencing temporary harm events would be 6.3 percent if only preventable events were included.

Eleven of the thirteen NQF Serious Reportable Events and Medicare HACs in the sample were preventable, a key criterion of both lists

Although we found few in the sample, all but two adverse events on the NQF and HAC lists were assessed as clearly or likely preventable.[56] After the adverse events on each list were separated, four of the five events on the NQF list were preventable and eight of the nine Medicare HACs were preventable (one event was on both lists). A key criterion of both lists is that the events be largely preventable. The two events on the lists that physicians assessed as not preventable were (1) an NQF event consisting of a pressure ulcer that progressed from Stage I to Stage III in a chronically ill patient with multiple complications and susceptibility to skin breakdown and (2) a Medicare HAC consisting of a compression fracture incurred during a fall by a morbidly obese patient.

Preventable events were most commonly linked to medical errors, substandard treatment, and inadequate patient monitoring or assessment

Physician reviewers selected one or more rationales to support each preventability determination from a list developed by the physician panel. To develop these rationales, physicians gleaned information from medical records, such as clinical staff actions, hospital environmental factors, and patient condition unrelated to the event. Among events assessed as preventable, 58 percent were linked to errors by clinical staff in medical judgment, skill, or patient management. Such errors often involved prescribing or administering the wrong medication. Nearly half of preventable events (46 percent) involved care provided in a substandard way, most frequently because of delay in diagnosis or

[56] The number of NQF and HAC events was too small to test the preventability measure for statistical significance with an acceptable degree of precision or to project the measure to the national sampling frame.

treatment. Table 8 provides physician preventability rationales for events within each assessment category.

Table 8: Events by Physician Preventability Rationales

Preventability Rationale	Percentage of Events*
Preventable Events (n=133)	
Error was related to medical judgment, skill, or patient management	58%
Appropriate treatment was provided in a substandard way	46%
The patient's progress was not adequately monitored	38%
The patient's health status was not adequately assessed	23%
Necessary treatment was not provided	17%
Event rarely happens when proper precautions and procedures are followed**	14%
Communication between caregivers was poor**	8%
Facility's patient safety systems and policies were inadequate or flawed**	3%
Breakdown in hospital environment occurred (equipment failure, etc.)**	2%
Nonpreventable Events (n=155)	
Event occurred despite proper assessment and procedures followed	62%
Patient was highly susceptible to event because of health status	50%
Care provider could not have anticipated event given information available	35%
Patient's diagnosis was unusual or complex, making care difficult	29%
Harm was anticipated but risk considered acceptable given alternatives**	14%

See Appendix F for confidence intervals.

*Percentages do not add to 100 because physician reviewers often selected more than 1 rationale.

**Given the small percentages, confidence intervals for projected numbers exceed 50-percent relative precision.

Source: OIG analysis of hospital stays for 780 Medicare beneficiaries discharged in October 2008.

Other common factors associated with preventable events were inadequate monitoring of patients (38 percent) and inadequate assessment of patients (23 percent). These factors often led to delays in treatment and worsening of patient conditions. In several of these cases, patients displayed symptoms of infection but were not given antibiotics until they reached the point of sepsis. In one case, the patient exhibited signs of shock upon arrival at the hospital, but clinical staff did not monitor the patient's blood pressure for the first 8 hours and did not provide related treatment for another 16 hours. This delay caused the patient to experience severe hypotension, requiring life-sustaining intervention.

Physician reviewers assessed events as clearly or likely not preventable when the events occurred despite proper procedures or when the patients were highly susceptible to the events

For 62 percent of the nonpreventable events in our sample, physician reviewers found that care was rendered according to accepted standards of practice. In these cases, physicians determined that the care provided was sufficient and appropriate and that there was no evidence of errors or other problems. This rationale was often given in combination with the second most common factor—that the patients' other conditions made them highly susceptible to the event (50 percent of nonpreventable events). For example, one beneficiary, admitted to the hospital with a bowel obstruction, experienced a surgical cut of the intestine that would have been difficult to avoid because of significant damage to the bowel from prior surgery.

Other common rationales for assessing events as not preventable also focused on the difficulty of providing care. For 35 percent of nonpreventable events, physicians determined that the medical and hospital staff could not have anticipated the events given information available about the patients at the time of care delivery. For 29 percent of nonpreventable events, physicians determined that the patients' diagnoses were unusual or complex, making care particularly difficult. Finally, in 14 percent of nonpreventable cases, the adverse events were anticipated by caregivers, but the harm associated with the adverse events was considered less harmful than not providing care. For example, in four sample cases, patients experienced harm as a result of an overload of intravenous fluid, yet the medical review found that the patients were in such dire need of fluids (e.g., at risk for hypoglycemic shock) that caregivers had little choice but to execute vigorous intravenous fluid replacement despite the risk of overload.

Hospital care associated with adverse events and temporary harm events cost Medicare an estimated $324 million in October 2008

Sixteen percent of sample beneficiaries under the Medicare IPPS who experienced events incurred additional Medicare hospital costs as a result. Most of the additional costs (87 percent) resulted from care associated with adverse events, with temporary harm events generating the remaining costs.[57] These additional costs project to an estimated $324 million, which equates to 3.5 percent of the $9.2 billion that Medicare spent for inpatient care during October 2008.[58] To give these figures an annual context, 3.5 percent of the $137 billion Medicare inpatient expenditure in FY 2009 equates to $4.4 billion spent on care associated with adverse events.[59]

Costs associated with preventable events accounted for an estimated $119 million of the $324 million additional cost, equating to 1.3 percent of the $9.2 billion Medicare inpatient expenditures for the month or about $1.8 billion annually.

Despite this outlay, most events did not affect Medicare costs; none of the Medicare HACs resulted in a higher reimbursement

Of beneficiaries who experienced adverse events or temporary harm events in hospitals covered under the Medicare IPPS, 84 percent did not incur additional costs for care associated with the events. This occurred primarily because many Medicare claims for beneficiaries who experienced events did not include diagnosis or procedure codes relating to the events. When Medicare claims included codes associated with the events, the codes often had no effect on costs because the claims included other costly diagnoses or procedure codes that elevated the reimbursement to equivalent or higher amounts.

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[57] One Medicare claim included codes for two events—one adverse event and one temporary harm event—and incurred an identical payment impact. This claim overlaps both groups and consequently the percentages do not total 100 percent: 87 percent of costs resulted from care associated with adverse events and 15 percent of costs resulted from care associated with temporary harm events.

[58] These cost estimates include only claims under the IPPS, representing 708 sample Medicare claims (85 percent), but do not include costs for the remaining 130 sample beneficiaries (15 percent) who had sample admissions not covered under IPPS.

[59] The annual cost estimate of $4.4 billion is 3.5 percent of the $137 billion Medicare inpatient costs for FY 2009, which assumes the same proportion of costs for adverse events for the other 11 months that we found in October 2008. Annual Medicare inpatient cost figures are from CMS, *2009 CMS Statistics Book*, Table III.6, Office of Research, Development, and Information, CMS Pub. No. 03497, December 2009, p. 30.

None of the nine Medicare HACs identified in the sample resulted in a higher level of Medicare reimbursement. Although the Medicare HAC policy is intended to limit costs associated with the specified events, our review showed that none of the HACs in the sample would have invoked a higher Medicare reimbursement. None of the associated Medicare claims included the specific diagnosis codes that CMS uses to identify HACs. However, even if the codes had been included on the claims, the HAC policy would still not have resulted in payment reductions for these cases because other diagnosis or procedure codes would have elevated the reimbursement to a higher amount.

Two-thirds of Medicare costs associated with events were the result of additional hospital stays necessitated by harm from events

Sixty-five percent of the additional costs to Medicare ($210 million of the $324 million) were the result of entire, additional hospital stays required to treat the harm resulting from the adverse events. In some of these cases, the events occurred during outpatient services at the hospital (such as an emergency room visit or an outpatient surgery) and necessitated unplanned admissions to the inpatient facilities. In other cases, the events occurred during inpatient care and the beneficiaries were released from the hospital, but the aftereffects of the events necessitated subsequent hospital stays within the study period. The average Medicare cost of these additional hospital stays for sample beneficiaries was $13,745, compared with an average additional cost of $5,601 for event-related care that hospitals provided during the initial hospital stay in situations that did not necessitate additional stays.[60, 61]

Medicare cost estimates do not include additional costs required for followup care after the sample hospitalization

Because our cost analysis included only hospital stays that ended during October 2008, Medicare costs associated with care resulting from adverse events and temporary harm events are greater than our estimate. Beneficiaries may have had additional event-related hospital stays beyond our study period and may have incurred expenses to Medicare or personal expenses for followup care not reflected in inpatient claims, such as physician office visits, medication, and rehabilitation services during and after our study period.

[60] Averages reflect only costs greater than zero.

[61] The Student's T-test comparing difference of means was significant at the 95-percent confidence level (p=0.0104).

As an example of an event resulting in subsequent Medicare costs not captured by our cost analysis, one sample beneficiary was initially admitted to the hospital in mid-October 2008 for a stroke. During this hospital stay, he experienced an allergic reaction to medication and was discharged with no additional cost associated with the event. However, following discharge, the allergic reaction progressed to a life-threatening condition known as Stevens-Johnson Syndrome.[62] The beneficiary returned to the hospital during October for treatment, incurring the cost of an entire hospital stay as a result of the event, but was misdiagnosed and again discharged. The patient then incurred two additional hospital stays within the next 30 days to correctly diagnose and treat the condition. The total estimated inpatient cost to Medicare for the latter three hospital stays was $43,050, all necessitated by the event. Only $10,982 of this amount was incurred during the study period and included in our cost estimate. Physician reviewers determined that the medication-related event was preventable because the medication was known to be highly reactive and the condition was not diagnosed correctly, delaying treatment.

[62] This condition typically begins with a skin rash and fever and, if untreated, progresses to an array of conditions constituting serious harm, such as lung damage and renal failure.

RECOMMENDATIONS

In the decade since the IOM report, the need to improve patient safety has received much attention from Federal and State governments, advocacy groups, and the health care industry. Despite this attention, we found that 13.5 percent of Medicare beneficiaries experienced adverse events during their hospital stays in October 2008, most of which resulted in prolonged hospital stays, permanent harm, life-sustaining interventions, or death. An additional 13.5 percent of beneficiaries experienced temporary harm as the result of events. Physician reviewers determined that 44 percent of events were preventable and that preventable events often involved medical errors, substandard care, and inadequate monitoring or assessment of patients. We found that in addition to causing the harm to patients, adverse events and temporary harm events increased costs to Medicare by an estimated $324 million in a single month, or 3.5 percent of Medicare inpatient expenditures, suggesting potential savings from reducing the incidence of events.

As the Federal Government's principal agency for protecting the health of Americans,[63] HHS is uniquely positioned to lead national efforts to reduce adverse events in hospitals. As part of the national strategy to improve health care quality mandated by the ACA, HHS is to "identify areas in the delivery of health care services that have the potential for rapid improvement in the quality and efficiency of patient care."[64]

Because many adverse events that we identified were preventable, our study confirms the need and opportunity for hospitals to significantly reduce the incidence of events. A number of agencies within HHS share responsibility for addressing this issue, most prominently AHRQ as a coordinating body for efforts to improve health care quality and CMS as the Nation's largest health care payer and an oversight entity.

Therefore, we recommend the following:

AHRQ and CMS should broaden patient safety efforts to include all types of adverse events

Efforts to improve patient safety often focus on a small subset of events that harm hospital patients. For example, NQF Serious Reportable Events or Medicare HACs represented only a fraction of

[63] HHS, *HHS Agency Mission Statement*, updated February 2004. Accessed at http://www.hhs.gov/about/ on March 23, 2010.

[64] P.L. 111-148 § 3501.

the adverse events we identified in this report. Additionally, patient safety provisions in the ACA often refer specifically to reducing medical errors, rather than to the broader range of adverse events. AHRQ and CMS should avoid focusing patient safety efforts too narrowly on a small list of specific events, possibly failing to address the wider array of events that lead to most instances of patient harm. Rather, AHRQ and CMS should promote a definition of adverse events that more fully encompasses harm resulting from medical care. This broader definition would apply to a number of patient safety activities, including setting priorities for research, establishing guidelines for hospital reporting of events, developing prevention strategies, measuring health care quality, and determining payment policies.

AHRQ and CMS should enhance efforts to identify adverse events

Identifying adverse events assists policymakers and clinical researchers in directing prevention resources to the areas of greatest need, setting clear goals for improvement, assessing the effectiveness of specific strategies, holding hospitals accountable, and gauging progress in reducing incidence.

- **AHRQ should sponsor periodic, ongoing measurement of the incidence of adverse events.** To facilitate measurement, AHRQ should establish a standard protocol for identifying events and analyzing information about incidence and causes. AHRQ should also consider providing hospitals with methods for measuring their incidence of events, goals for incidence reduction, and benchmarks or other means for comparing rates among providers.
- **AHRQ should continue to encourage hospitals to report to PSOs.** Hospital reporting of adverse event information to PSOs can provide AHRQ with aggregated data about the nature and causes of events. To maximize the usefulness of PSO-reported data for national measurement and analysis, AHRQ should continue working toward establishing standard adverse event definitions and reporting formats and encouraging hospital reporting.
- **CMS should use POA indicators in hospital billing data to calculate the frequency of adverse events occurring within hospitals.** These POA indicator data represent a rich source of information for identifying certain adverse events in claims data. CMS should establish routine methods for using POA indicators to guide patient safety improvement efforts. For example, CMS could direct that

QIOs use POA indicators to monitor hospital rates of specific conditions.

CMS should provide further incentives for hospitals to reduce the incidence of adverse events through its payment and oversight functions CMS, as both a payer and an oversight entity, is positioned to influence hospitals to provide high-quality care. CMS should explore avenues to reduce the incidence of adverse events through both program participation and payment policy.

- **CMS should strengthen the Medicare HAC policy.** We found that HACs represent a small proportion of preventable events and that they are not always coded as such in Medicare claims. The ACA makes several changes to the HAC policy, including allowing the Secretary to expand the list of HACs. The law also gives the HAC policy greater significance by using the list of HACs to implement Medicare payment penalties, create performance measures, and prohibit Medicaid payments for associated care. Given their low incidence, continued use of the 10 HACs already established by CMS may limit the intended effect of the statute. To strengthen the policy, CMS should consider expanding the list of Medicare HACs to include more conditions that may result in harm to beneficiaries. CMS should also take additional steps to ensure that hospitals accurately code Medicare claims to show when HACs occur, as recommended in our prior report.[65]

- **CMS should look for opportunities to hold hospitals accountable for adoption of evidence-based practice guidelines.** The conditions of participation for Medicare and Medicaid require that hospitals have programs to demonstrate quality improvement where evidence shows practices can improve outcomes. CMS should further influence hospitals to reduce adverse events through enforcement of the conditions of participation. This could include more closely examining patient safety issues through the survey and certification process, as recommended in our prior report.[66] This could also include encouraging hospitals to adopt evidence-based practices shown to prevent adverse events.

[65] OIG, *Adverse Events in Hospitals: Methods for Identifying Events*, OEI-06-08-00221, March 2010.

[66] Ibid.

AGENCY COMMENTS

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

AHRQ. AHRQ concurred with our recommendations, stating that adverse events affect hospital patients at an "alarming rate" and that it must continue working to improve patient safety.

In response to our recommendation to broaden patient safety efforts to include all types of adverse events, AHRQ noted that the types of events vary widely and that efforts should be broadened beyond prescribed lists of adverse events. AHRQ stated that it has sponsored efforts to address specific types of adverse events and to address causes that contribute to a wide variety of adverse events. AHRQ also cited the recent development of its Common Formats, a set of event definitions and reporting forms not limited to a specific list of events designed for hospitals to use to report events to PSOs.

In response to our recommendation to enhance efforts to identify adverse events, AHRQ stated that it intends to foster continued improvement in both identifying and reducing adverse events through operational programs, research efforts, and further collaboration with other agencies. Specifically, AHRQ noted that the Common Formats facilitate identification of events for both internal hospital purposes and reporting to PSOs. AHRQ also cited a continued commitment to its Patient Safety Indicators methodology as a way to identify events in administrative data and a planned expansion of the MPSMS program, which identifies adverse events in medical records acquired through CMS. AHRQ plans to expand the MPSMS by broadening the areas of clinical investigation, seeking to address all patient populations rather than only Medicare beneficiaries, and working toward sharing the MPSMS methodology with other organizations.

CMS. CMS concurred with our recommendations and stated that it is committed to the reduction of adverse events in hospitals and other health care settings. CMS provided details about current activities and future plans to reduce adverse events, concluding that although it has taken significant steps to address these issues, more work needs to be done.

In response to our recommendation to broaden patient safety efforts to include all types of adverse events, CMS stated that it will "aggressively pursue" broadening the scope and definition of patient safety efforts to be more inclusive of various types of adverse events. As an example,

CMS noted that it is expanding hospital reporting of quality data to include more measures of adverse events.

In response to our recommendation to enhance efforts to identify adverse events, CMS stated that it will continue to use POA indicators in implementing its Medicare HAC policy. CMS also referenced the use of POA indicators by QIOs to assist hospitals in reducing high-risk pressure ulcers and indicated that it is assessing the broader use of POA indicators by QIOs to assess the incidence of adverse events and assist hospitals in developing quality improvement plans.

In response to our recommendation to provide further incentives for hospitals to reduce the incidence of adverse events through payment and oversight, CMS stated its commitment to more closely monitor and address hospital quality of care. Specifically, CMS plans to strengthen the Medicare HAC policy by considering the appropriateness of expanding the conditions included, applying the policy to more health care settings, and working to improve the coding and reporting of POA indicators. CMS also stated that it is working toward improving evaluation of the hospital conditions of participation related to patient safety, developing interpretive guidelines and training for surveyors, and tasking QIOs with greater responsibility to address adverse events in hospitals. Further, CMS points to opportunities presented by the ACA, including implementation of the Hospital Value-Based Purchasing Program, which will use hospital performance as a basis for incentive payments; and creation of the Center for Medicare & Medicaid Innovation, which will address improvement in patient safety and reduction of adverse events.

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

APPENDIX ~ A

Tax Relief and Health Care Act of 2006

P.L. No. 109-432 § 203

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 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.

APPENDIX ~ B

National Quality Forum Serious Reportable Events

Table B-1: The National Quality Forum (NQF) 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 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 because of administration of incompatible blood or blood products
C.	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while cared for in a health care facility
D.	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while patient is being cared for in a health care facility
E.	Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates
F.	Stage III or Stage IV pressure ulcers acquired after admission to a health care facility
G.	Patient death or serious disability because of 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 a fall while being 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

Source: NQF, *Serious Reportable Events in Health Care 2006 Update: Consensus Report*, NQF, Washington, DC, 2007, p. 7.

APPENDIX ~ C

Medicare Hospital-Acquired Conditions

Table C-1: Medicare Hospital-Acquired Conditions

Conditions
1. Foreign object retained after surgery
2. Air embolism
3. Blood incompatibility
4. Pressure ulcers (stages III and IV)
5. Falls
A. Fracture
B. Dislocation
C. Intracranial injury
D. Crushing injury
E. Burn
F. Electric shock
6. Manifestations of poor glycemic control
A. Hypoglycemic coma
B. Diabetic ketoacidosis
C. Nonkeototic hyperosmolar coma
D. Secondary diabetes with ketoacidosis
E. Secondary diabetes with hyperosmolarity
7. Catheter-associated urinary tract infection
8. Vascular catheter-associated infection
9. Deep vein thrombosis/pulmonary embolism associated with the following
A. Total knee replacement
B. Hip replacement
10. Surgical site infection
A. Mediastinitis after coronary artery bypass graft
B. Associated with certain orthopedic procedures involving the
a. Spine
b. Neck
c. Shoulder
d. Elbow
C. Associated with certain bariatric surgical procedures for obesity
a. Laparoscopic gastric bypass
b. Gastroenterostomy
c. Laparoscopic gastric restrictive surgery

Source: *Fiscal Year 2009 Final Inpatient Prospective Payment System Rule*, 73 Fed. Reg. 48434, 48471 (Aug. 19, 2008).

APPENDIX ~ D

Glossary of Selected Terms[67]

Acute coronary syndrome—Condition in which the heart does not receive enough oxygen-rich blood, often marked by severe chest pain, unstable angina, and/or heart attack.

Acute renal insufficiency—Sudden loss of the kidneys' ability to remove waste, also referred to as acute kidney failure.

Adverse event—Harm to a patient as a result of medical care. For purposes of this study, we defined adverse events as events that met at least one of the following criteria: an event on the National Quality Forum list of Serious Reportable Events; an event on Medicare's list of hospital-acquired conditions (HAC) for which it denies higher payment; or an event resulting in one of the four most serious categories on a patient harm index (classified on the index as F-I): prolonged hospital stay, permanent harm, life-sustaining intervention, or death.

Anticoagulant—Medication that hinders blood coagulation, typically used to avoid blood clots and referred to as blood-thinning medication.

Aspiration—Accidental inhalation of foreign material into the lungs.

Congestive heart failure—Condition in which the heart is unable to maintain adequate circulation of blood in the tissues of the body.

Deep vein thrombosis (DVT)—Formation of a thrombus (blood clot) within a deep vein (as of the leg or pelvis) that is life threatening if dislodgment results in blockage to the pulmonary (lung) artery.

Delirium—Mental disturbance characterized by confusion, disordered speech, and hallucinations.

Dialysis—Medical procedure to remove wastes and toxins from the blood, and to adjust fluid and electrolyte imbalances.

Dysrthymia—Condition of abnormal cardiac (heart) rhythm.

Hypoglycemia—Condition of abnormally low blood sugar (glucose) level.

Hypotension—Condition of abnormally low blood pressure.

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[67] Clinical definitions adapted from the National Institutes of Health, U.S. National Library of Medicine, *Medline Plus Medical Dictionary*, updated February 2003. Accessed at http://www.nlm.nih.gov on January 7, 2009.

Iatrogenic pneumothorax—Condition induced by therapeutic intervention in which air or other gas occurs in the pleural cavity.

Ileus—Partial or complete obstruction of the bowel, marked by a painful distended abdomen, vomiting, toxemia, and dehydration.

Intravenous (IV) infiltrate—Condition in which fluids administered by entering a vein accidentally enter the surrounding tissue.

Intravenous (IV) volume overload—Condition in which fluid is given by vein at a higher rate or larger volume than can be absorbed or excreted.

Obstipation—Condition of severe constipation (abnormally delayed passage of dry, hardened feces) that can result in bowel obstruction.

Pressure ulcer—Ulceration of tissue deprived of adequate blood supply by prolonged pressure, also called decubitus ulcer and bedsore. Pressure ulcers are classified into four stages: Stage I is intact skin with nonblanchable redness; Stage II is a shallow ulcer or blister indicating damage to the epidermis; Stage III is damage extending through all the layers of the skin; and Stage IV is damage through all the layers of the skin and underlying muscle, tendons, or bone.[68]

Pulmonary embolism—Obstruction of a pulmonary (lung) artery, often marked by shortness of breath; chest pain with inhalation; and, in severe cases, low blood pressure and death.

Sepsis—Systemic response to a serious, usually localized infection of bacterial origin, such as systemic inflammatory response syndrome.

Tachycardia—Condition of rapid heart rate.

Temporary harm event—Harm to patient that required intervention but did not cause lasting harm, classified as E level on patient harm index.

Thrush—Inflammation of the mouth and throat, caused by fungus.

Urinary tract infection (UTI)—Infection of the tract through which urine passes and can include the kidney, ureters, bladder, and/or urethra.

Ventilator-associated pneumonia (VAP)—Disease of the lungs characterized by inflammation of lung tissue and caused chiefly by infection that enters the lungs through a ventilator.

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[68] National Pressure Ulcer Advisory Panel (NPUAP), *Pressure Ulcer Stages Revised by NPUAP*. Accessed at http://www.npuap.org on November 12, 2009.

APPENDIX ~ E

Methodology for Identifying Events and Determining Preventability

Screening for Potential Adverse Events

We conducted a two-stage review to identify adverse events. The first stage included three screening methods designed to identify beneficiaries who appeared likely to have experienced adverse events. A beneficiary was considered likely to have experienced an adverse event if any screening method found at least one potential adverse event during any of the beneficiary's hospital stays. The screening process enabled us to reduce the number of cases requiring second-level review of the full medical records by a physician. Additionally, physician reviewers indicated that the results of the screening methods helped them to more readily identify potential adverse events for consideration.

The screening methods included:

- analysis by certified medical coders of Present on Admission (POA) Indicators included in Medicare claims data to identify any diagnoses that were acquired during the hospital stay;
- screening of medical records by nurse reviewers using a modified version of the Institute for Healthcare Improvement's Global Trigger Tool (IHI GTT) for triggers that could indicate an event, such as laboratory test results indicating an infection; and
- identification of any beneficiaries who were readmitted to the hospital within 30 days after their October 2008 hospital discharges.

Analysis of POA Indicators. Using data from the National Claims History file, certified medical coders reviewed the POA indicator data included in hospital Medicare claims for each sample beneficiary. A recent addition required of Medicare Part A claims, the POA indicator codes require hospitals to make a clinical distinction about whether diagnoses are present at the time of admission. The coders first verified the accuracy of each POA indicator by reviewing the medical records and then flagged each diagnosis that had a POA indicator of "N" (not present on admission), "W" (clinical staff unable to determine), or "U" (documentation insufficient to determine). Analysis of POA indicators identified 297 beneficiaries for the second stage of the review.

Nurse reviews of medical records. Contracted registered nurses conducted a preliminary review of medical records for each sample beneficiary to identify potential adverse events. Reviewers used a

modified version of the IHI GTT protocol, in which reviewers identified triggers in the medical records possibly indicative of adverse events and then explored the records further to determine whether events occurred and the resulting level of harm. Medical records screening identified 372 cases for inclusion in the second stage of review.

Readmissions. We identified 92 sample beneficiaries who were readmitted to the hospital within 30 days after their discharges in October 2008 and included these cases in the second stage of review. We reviewed records for admissions that occurred within 30 days of the beneficiaries' last discharges; therefore, the 30-day window for reviewing readmissions did not span a fixed timeframe but began on the discharge date for each beneficiary.

Flagged hospital stays. We identified 420 beneficiaries for the second stage of review, a review of the hospital medical records by physicians. Of the 420 beneficiaries, we identified 391 with the 3 screening methods and 29 from additional analysis. In the 29 additional cases, the beneficiaries were not flagged on the 3 screening methods, but staff involved in the screening process (nurses, coders, or analysts) believed complexities in the cases warranted physician review.

Identifying Events Within Flagged Cases

Five contracted physicians conducted medical records review of the 420 cases identified by the screening methods. Physician reviewers represented a variety of specializations and experience: an infectious disease specialist, a cardiologist, an orthopedic surgeon, an intensivist (intensive care specialist), and an internist. All five had many years of clinical experience, as well as prior experience in detecting adverse events in medical records. Three of the five served as physician reviewers for a 2008 Office of Inspector General (OIG) case study.[69]

Over 12 weeks, the physician reviewers examined hospital medical records for each of the 420 cases.[70] Physician reviewers used a structured medical review protocol that required them to describe each adverse event; identify the medical record documentation that led to

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

[70] These included medical records for all hospital stays for sample beneficiaries ending with October 2008 discharges. Additionally, physicians reviewed records for any readmissions of sample beneficiaries that occurred within 30 days after their final October discharges to look for evidence of events that occurred during the October 2008-discharged stays.

their identification of the event; and specify the level of harm experienced by the patient, with harm categorized in accordance with the National Coordination Council for Medication Errors Reporting and Prevention Index of Categorizing Medication Errors.

Throughout our study preparation, medical records review, and analysis, we facilitated 22 weekly conference calls during which the physician reviewers discussed the review protocol and sample cases that either were complex or had possible implications for other cases. These calls assisted in making determinations for difficult cases and helped achieve consistency across reviewers. The physicians determined that the following types of cases would require group discussion: events assessed as clearly preventable; events contributing to death; and cases involving respiratory failure, hypoglycemia, hypotension, urinary tract infections, and complex and/or lengthy surgeries. Physicians also often brought cases to group discussion if they involved care specific to a specialization of another physician. We documented the discussions and conclusions made during these weekly calls, continually revising a written physician guidance document to further promote consistency. The physicians discussed 162 of the 302 events (54 percent) and other cases that the group ultimately determined did not include events.

Determining Preventability for Each Event

As part of the structured medical review protocol, reviewers also assessed the likelihood that the events were preventable. In collaboration with the physicians, we created an initial response scale:

- Preventable—Patient harm could have been avoided through improved assessment or alternative actions.
- Not preventable—Patient harm could not have been avoided given the complexity of the patient's condition or the care required.
- Unable to determine—Physicians were unable to determine preventability because of incomplete documentation or case complexity.

Through the pretest process, we expanded the scale to enable physicians to more precisely gauge the extent to which an event was preventable. The expanded scale divided the preventable and nonpreventable responses with the descriptors *clearly* and *likely*. Assessing an event as *clearly* preventable or *clearly* not preventable required a greater degree of certainty on the part of the reviewer. The expanded scale enabled

physicians to make more precise determinations, while our primary statistics continued to collapse *clearly* and *likely*.

To make distinctions about the circumstances in each case, physicians used their clinical experience and judgment. They considered all evidence in the medical records, including staff actions and the patient's condition. Physicians also used information about accepted standards of care, the frequency with which certain events occurred despite appropriate assessment and care, the physicians' individual clinical experiences, guidance developed during the review process, and group discussion of cases. Using a list of contributing factors gleaned from prior research, physicians indicated the rationale for each determination and provided a narrative description for each case.

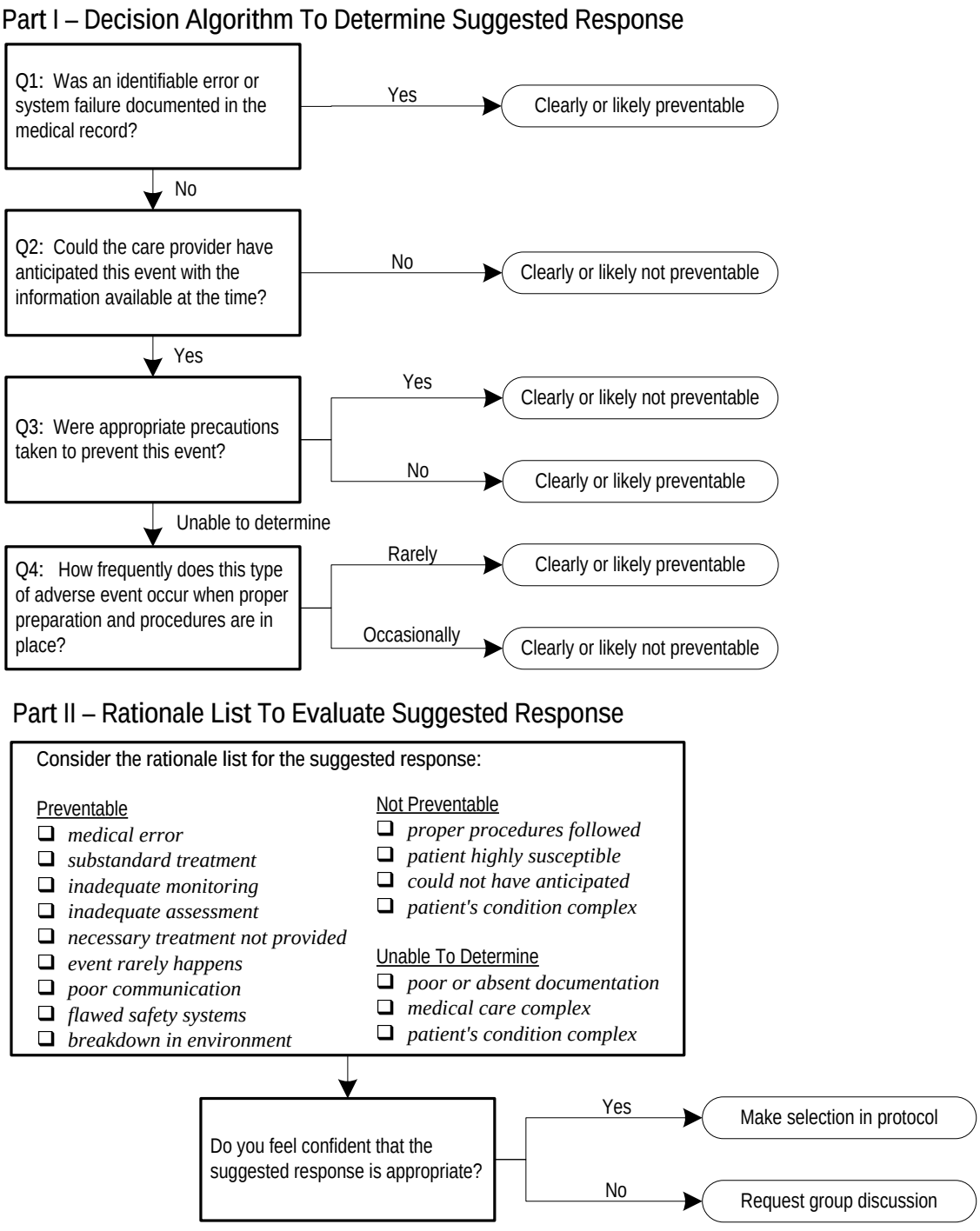
To improve consistency, physician reviewers used a uniform method for reviewing preventability. Reviewers developed a decision algorithm during practice reviews consisting of a series of questions that led the reviewers to a suggested response. Questions addressed issues such as whether there was a medical error, whether the event could have been anticipated, and how frequently the event occurred given proper care. Physicians did not automatically accept the suggested response, but assessed whether it was appropriate for each case. In completing the rationale section of the protocol, physicians assessed contributing factors. The list of contributing factors included broad concepts from the decision algorithm, such as errors, and more nuanced factors, such as whether the patient was monitored or was susceptible to the event. We required that physicians discuss all *clearly preventable* determinations during group meetings (as they required greater certainty), and encouraged them to bring other cases for discussion if they had difficulty or felt the cases would inform other determinations. Figure E-1 illustrates the preventability review process.

Physician Review of Findings

Following the medical records review, we analyzed the identified events, harm levels, and preventability determinations to identify any inconsistencies and discussed these with the full physician group. This process resulted in some changes to the initial determinations, such as collapsing a series of events into a single cascade event.[71]

[71] Based on OIG interviews with IHI staff, IHI defines a cascade event as one in which an initial event causes a series of related events for the same patient and advocates collapsing these into a single event.

Figure E-1: Physician Review Process for Determining Preventability



Source: OIG illustration of physician medical record review process for determining preventability.

APPENDIX ~ F

Estimates, Confidence Intervals, and Key Statistics

We computed incidence rates and corresponding 95-percent confidence intervals using the computer program Sudaan. Sudaan is a statistical analysis program with appropriate standard statistical formulas for calculating correct standard errors for complex sampling designs.

Table F-1: Estimates, Confidence Intervals, and Key Statistics

	n	Estimated Percentage of Beneficiaries	95-Percent Confidence Interval		Estimated Number of Beneficiaries	95-Percent Confidence Interval	
			Lower Bound	Upper Bound		Lower Bound	Upper Bound
Event Experiences for All Beneficiaries (n=780)							
Experienced adverse events	105	13.46%	11.24%	16.05%	133,710	111,644	159,421
▪ National Quality Forum Serious Reportable Events*	5	0.64%	0.27%	1.53%	6,367	2,682	15,197
▪ Medicare hospital-acquired conditions*	8	1.03%	0.51%	2.04%	10,187	5,066	20,263
▪ F-I level adverse events	102	13.08%	10.88%	15.63%	129,890	108,069	155,249
▪ Events that overlap at least two categories*	9	1.15%	0.60%	2.20%	11,461	5,960	21,852
▪ Events that overlap all three categories*	1	0.13%	0.02%	0.91%	1,273	199	9,039
Experienced temporary harm events	105	13.46%	11.24%	16.05%	133,710	111,644	159,421
Experienced only preventable adverse events	58	7.44%	5.79%	9.50%	73,859	57,511	94,361
Experienced only preventable temporary harm events	49	6.28%	4.78%	8.22%	62,398	47,479	81,647
Experienced adverse events that contributed to death*	12	1.54%	0.87%	2.69%	15,281	8,642	26,719
Beneficiaries Who Experienced at Least One Adverse Event (n=105)							
Experienced multiple adverse events	19	18.10%	11.84%	26.66%	24,195	15,831	35,647
Experienced temporary harm in addition to adverse events	29	27.62%	19.91%	36.94%	36,929	26,622	49,392
Experienced cascade events	28	26.67%	19.08%	35.93%	35,656	25,512	48,042
Beneficiaries Who Experienced at Least One Temporary Harm Event (excluding those who experienced adverse events) (n=105)							
Experienced multiple temporary harm events	23	21.90%	15.00%	30.83%	29,289	20,057	41,223
Beneficiaries Who Experienced Events and Were Covered Under the Inpatient Prospective Payment System (IPPS) (n=171)							
Incurred additional costs	28	16.37%	11.54%	22.71%	35,656	25,129	49,453
Did not incur additional costs	143	83.63%	77.29%	88.46%	182,101	168,304	192,628

*Given the small proportions, confidence intervals for projected numbers exceed 50-percent relative precision.
Source: Office of Inspector General (OIG) analysis of hospital stays and Medicare claims for 780 Medicare beneficiaries discharged in October 2008.

Table F-2: Estimates, Confidence Intervals, and Key Statistics

	n	Percentage Estimate	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Preventability Classification for All Adverse Events and Temporary Harm Events (n=302)				
All adverse and temporary harm events	**302**	**100%**	**NA**	**NA**
▪ **Preventable events**	**133**	**44.04%**	**38.06%**	**50.19%**
o Clearly preventable events	28	9.27%	6.53%	13.01%
o Likely preventable events	105	34.77%	29.20%	40.79%
▪ **Not preventable events**	**155**	**51.32%**	**45.22%**	**57.39%**
o Clearly not preventable events	55	18.21%	13.92%	23.47%
o Likely not preventable events	100	33.11%	27.59%	39.14%
▪ **Unable to determine***	**14**	**4.64%**	**2.80%**	**7.59%**
Clinical Category for All Adverse Events (n=128)				
All clinical categories	**128**	**100%**	**NA**	**NA**
▪ Medication	40	31.25%	23.35%	40.41%
▪ Patient care	36	28.13%	20.92%	36.66%
▪ Surgery and other procedures	33	25.78%	18.77%	34.31%
▪ Infection	19	14.84%	9.64%	22.18%
Clinical Category for All Temporary Harm Events (n=174)				
All clinical categories	**174**	**100%**	**NA**	**NA**
▪ Medication	73	41.95%	34.74%	49.53%
▪ Patient care	63	36.21%	29.09%	43.98%
▪ Surgery and other procedures	32	18.39%	12.92%	25.50%
▪ Infection	6	3.45%	1.58%	7.36%
Harm Level for All National Coordinating Council Medication Errors Reporting and Prevention Index for Categorizing Errors F-I Level Events (n=122)**				
All NCC MERP harm levels	**122**	**100%**	**NA**	**NA**
▪ Harm F	76	62.30%	53.42%	70.41%
▪ Harm G*	6	4.92%	2.22%	10.54%
▪ Harm H	28	22.95%	16.15%	31.54%
▪ Harm I*	12	9.84%	5.75%	16.33%
Preventable Adverse and Temporary Harm Events Within Each Clinical Category				
▪ Infection (n=25)	15	60.00%	39.72%	77.35%
▪ Medication (n=113)	57	50.44%	40.98%	59.87%
▪ Patient care (n=99)	50	50.51%	40.47%	60.50%
▪ Surgery and other procedures (n=65)	11	16.92%	9.51%	28.30%

continued on next page

*Given the small proportions, confidence intervals for projected numbers exceed 50-percent relative precision.
** National Coordinating Council for Medication Errors Reporting and Prevention Index for Categorizing Errors (NCC MERP).

Table F-2: Estimates, Confidence Intervals, and Key Statistics (Continued)

	n	Percentage Estimate	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Physician Rationale for All Preventable Events (n=133)				
Error related to medical judgment, skill, or patient management	77	57.89%	49.04%	66.27%
Appropriate treatment was provided in a substandard way	61	45.86%	37.64%	54.33%
Patient's progress was not adequately monitored	50	37.59%	29.76%	46.14%
Patient's health status was not adequately assessed	30	22.56%	15.87%	31.02%
Necessary treatments were not provided	22	16.54%	11.10%	23.92%
Event rarely happens when proper precautions and procedures are followed	18	13.53%	8.46%	20.95%
Poor communication between caregivers*	10	7.52%	3.86%	14.14%
Facility's patient safety systems and policies were inadequate or flawed*	4	3.01%	1.12%	7.81%
Breakdown in hospital environment occurred (equipment failure, etc.)*	2	1.50%	0.38%	5.80%
Physician Rationale for All Nonpreventable Events (n=155)				
Event occurred despite proper assessment and procedures followed	96	61.94%	52.82%	70.28%
Patient was highly susceptible to event because of health status	77	49.68%	41.34%	58.04%
Care provider could not have anticipated event given information available	54	34.84%	27.54%	42.92%
Patient's diagnosis was unusual or complex, making care difficult	45	29.03%	21.67%	37.70%
Harm was anticipated but was considered acceptable given alternatives*	21	13.55%	8.75%	20.40%

*Given the small proportions, confidence intervals for projected numbers exceed 50-percent relative precision.
Source: OIG analysis of hospital stays for 780 Medicare beneficiaries discharged in October 2008.

Table F-3: Statistical Test Results for Preventability Subanalysis

Statistical Test	P-Value for Difference in Proportions
Test for relationship among preventability determinations and harm events (i.e., adverse event or temporary harm event)	0.0568
Test for relationship between preventability determinations and clinical categories (e.g., surgical event, medication event, patient care event, or infection)	<0.0001*
Test for difference between preventability determinations	
• Surgical events versus infection events	0.0013*
• Surgical events versus medication events	<0.0001*
• Surgical events versus patient care events	<0.0001*
Test for difference of means between average additional costs incurred by entire stays and average additional costs attributed to events within the initial hospital stays	0.0104*

Note: Weighted chi square and Cochran-Mantel-Haenszel chi square produced similar results.
* P-values are statistically significant at the 95 precent confidence level.
Source: OIG analysis of hospital stays and Medicare claims for 780 Medicare beneficiaries discharged in October 2008.

Table F-4: Projections and Confidence Intervals for Analysis of Medicare Costs Associated With Adverse Events and Temporary Harm Events

	Projected Population	Projected Cost Estimate	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Medicare Inpatient Costs for Projected Population (n=657)				
Estimate of Medicare inpatient costs	836,646	$9,167,576,966	$8,505,456,013	$9,829,697,918
Medicare Inpatient Costs for Projected Population Associated With Adverse and Temporary Harm Events (n=657)				
Costs associated with all events	836,646	$324,155,814	$161,745,099	$486,566,529
Costs associated with preventable events	836,646	$118,720,272	$33,915,875	$203,524,670

Source: OIG analysis of hospital stays and Medicare claims for 780 Medicare beneficiaries discharged in October 2008.
* Medicare costs are calculated based on the 657 sample cases in the IPPS.

Table F-5: Projections and Confidence Intervals for Average Additional Medicare Costs Associated With Adverse Events and Temporary Harm Events

Events Resulting in Increased Medicare Costs	Projected Average Additional Cost	95-Percent Confidence Interval	
		Lower Bound	Upper Bound
Events resulting in increased costs for additional hospital stays (n=12)	$13,745	$7,760	$19,730
Events resulting in increased costs for initial hospital stays (n=16)	$5,601	$3,889	$7,313

Source: OIG analysis of hospital stays and Medicare claims for 780 Medicare beneficiaries discharged in October 2008.

Table F-6: Percentage Estimates and Confidence Intervals for Medicare Costs Associated With Adverse Events and Temporary Harm Events

	Percentage Estimate	95-Percent Confidence Interval	
		Lower Bound	Upper Bound
Percentage of Total Medicare IPPS Costs			
All adverse and temporary harm events	3.54%	1.82%	5.26%
Preventable adverse and temporary harm events	1.30%*	0.38%	2.21%
Percentage of Medicare IPPS Costs Attributed to Adverse Events and Temporary Harm Events			
Associated with adverse events	87.48%	73.70%	100.00%
Associated with temporary harm events	14.93%*	0.34%	29.52%
Associated with entire additional hospital stays	64.80%	43.82%	85.77%

*Given the small proportions, confidence intervals for projected numbers exceed 50-percent relative precision.
Source: OIG analysis of hospital stays and Medicare claims for 780 Medicare beneficiaries discharged in October 2008.

Rates of Adverse Events and Temporary Harm Events by Patient Days and Hospital Admissions

Hospitals commonly measure adverse events by incidence density, which takes into account the period during which patients are observed. For example, incidence density is often used in measuring hospital-acquired infections because risk can increase with the length of exposure to the health care environment.[72] The Institute for Healthcare Improvement (IHI), a nonprofit advisory group to hospitals, cites advantages to using incidence density metrics over standard incidence rates that measure the number of events per patient.[73] IHI reports that measuring total events by patient days or hospital admissions enables hospitals to count multiple events experienced by the same beneficiary.

The sample of 780 Medicare beneficiaries discharged during October 2008 included 838 total hospital stays (admissions) and a total of 4,354 days in the hospital (patient days). We calculated patient days by subtracting the admission date for each hospital stay from its discharge date.[74] Table G-1 provides ratios for adverse events and temporary harm events in the sample per 1,000 patient days and per 100 admissions.

Table G-1: Rates of Adverse and Temporary Harm Events in the Sample by Patient Days and Hospital Admissions

Category	Per 1,000 Patient-Days	Per 100 Admissions
Adverse events	29	15
Temporary harm events	40	21
Adverse events and temporary harm events combined	69	36

Source: Office of Inspector General analysis of hospital stays for 780 Medicare beneficiaries in October 2008.

[72] K.M. Arias, *Outbreak Investigation, Prevention, and Control in Health Care Settings*, Second Edition, 2009, Jones and Bartlett Publishers, pp. 330–331.

[73] IHI, *IHI Global Trigger Tool for Measuring Adverse Events,* Second Edition, 2009, p. 13.

[74] In consultation with physician reviewers, we excluded the seven patients admitted and discharged on the same day (these patients did not experience temporary harm or adverse events). IHI recommends selecting patient records for only hospital stays of at least 24 hours.

APPENDIX ~ H

Adverse Events and Temporary Harm Events

Tables H-1 and H-2 contain information about adverse events and temporary harm events identified in the sample, including National Quality Forum (NQF) Serious Reportable Events and Medicare hospital-acquired conditions (HAC). Table H-1 contains information about adverse events (128 adverse events).[75] Table H-2 contains information about temporary harm events (174 events). The event descriptions vary somewhat depending upon the language the physician reviewers used to describe the event and the level of detail included in their notes.

Table H-1: Adverse Events by Clinical Category, Harm Level, Preventability, and Whether the Events Were NQF Serious Reportable Events or Medicare HACs (n=128)

Adverse Event	Harm Level	Preventability	NQF	HAC
Events Related to Medication (40)				
Excessive bleeding (12)				
1. Abdominal bleeding secondary to anticoagulant given for deep vein thrombosis (enoxaparin)	I	CNP		
2. Brain hemorrhage secondary to anticoagulants (aspirin and clopidogrel)	F	CNP		
3. Cascade event in which delay in care and administration of aspirin to patient with low platelet count led to pulmonary hemorrhage	I	CP	•	
4. Cascade event in which gastrointestinal bleeding and hematoma associated with aspirin and anticoagulant (clopidogrel) given following coronary stent placement resulted in acute blood loss	I	CNP		
5. Hematuria secondary to anticoagulant (warfarin)	F	LP		
6. Retroperitoneal hemorrhage secondary to anticoagulant (warfarin)	I	CP		
7. Gastrointestinal bleeding secondary to anticoagulant (enoxaparin)	I	CNP		
8. Gastrointestinal bleeding secondary to anticoagulant (warfarin)	F	LP		
9. Gastrointestinal bleeding secondary to anticoagulants (aspirin, clopidogrel, and enoxaparin)	F	CNP		
10. Gastrointestinal bleeding secondary to anticoagulants (aspirin, clopidogrel, and eptifibatide)	F	CNP		
11. Gross hematuria secondary to anticoagulants (aspirin and clopidogrel)	F	LNP		
12. Hematoma secondary to anticoagulant (heparin)	F	LP		

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[75] The harm level is classified according to the National Coordinating Council for Medication Errors Reporting and Prevention (NCC MERP) Index for Categorizing Errors (E–I). Preventability determination is reflective of the physician review index: CP = clearly preventable, LP = likely preventable, LNP = likely not preventable, CNP = clearly not preventable, and UTD = unable to determine.

Table H-1: Adverse Events by Clinical Category, Harm Level, Preventability, and Whether the Events Were NQF Serious Reportable Events or Medicare HACs (n=128) (Continued)

Adverse Event	Harm Level	Preventability	NQF	HAC
Events Related to Medication (continued)				
Delirium or change in mental status (7)				
1. Cascade event in which narcotic analgesic (hydromorphone) induced delirium, which led to use of physical restraints, patient pulling out IVs, and patient fall	F	CP		
2. Cascade event in which narcotic analgesic (oxycodone) induced delirium and resulted in patient fall	F	CP		
3. Confusion secondary to narcotic analgesics (dextropropoxyphene with acetaminophen)	F	CP		
4. Delirium secondary to sedative (benzodiazepine)	F	CNP		
5. Hallucinations and delirium secondary to antiwithdrawal medication (naloxone)	F	CNP		
6. Hallucinations and delirium secondary to narcotic analgesic (hydromorphone)	F	LP		
7. Mental status change due to narcotic analgesic (morphine)	F	CP		
Hypoglycemic event (6)				
1. Episode of severe hypoglycemia secondary to insulin management	H	LNP		
2. Hypoglycemic coma secondary to insulin management	H	LP		
3. Hypoglycemic coma secondary to insulin management	I	LP		
4. Hypoglycemic coma and permanent brain injury secondary to insulin management in patient with anoxic encephalopathy following cardiac arrest	G	CP		
5. Multiple episodes of severe hypoglycemia secondary to insulin management	H	CP		
6. Recurrent hypoglycemia secondary to diabetes medication (glipizide)	F	CP		
Acute renal insufficiency (kidney failure) (4)				
1. Acute renal failure secondary to antihypertensives and diuretics (unspecified)	F	LNP		
2. Acute renal failure secondary to blood pressure medication (enalapril)	F	LP		
3. Acute renal failure and permanent decrease of renal function secondary to dehydration from diuretic (furosemide)	G	LP		
4. Severe acute renal insufficiency and dehydration secondary to diuretics (bumetanide and spironolactone)	F	LNP		
Severe hypotension (4)				
1. Hypotension secondary to narcotic analgesic (hydromorphone)	F	LP		
2. Hypotension secondary to diuretics (unspecified)	F	LP		
3. Hypotension secondary to multiple psychiatric medications (mirtazapine, risperidone, and sertraline)	F	LP		
4. Hypotension secondary to multiple sedatives (ketamine, lorazepam, and propofol)	H	CNP		
Respiratory complication (4)				
1. Acute hypercarbic respiratory failure (excess oxygen)	H	LP		
2. Cascade event in which narcotic analgesic (hydromorphone) led to respiratory failure and recurrent somnolence	H	LP		
3. Respiratory depression secondary to antianxiety medication (lorazepam) and narcotic analgesic (morphine)	H	LP		
4. Respiratory failure secondary to sedative (benzodiazepine)	I	CP	●	
Severe allergic reaction (3)				
1. Failure to diagnose Stevens-Johnson Syndrome secondary to anticonvulsants (carbamazepine and phenytoin)	F	LP		
2. Hives and shortness of breath due to allergic reaction to antibiotic	F	CNP		
3. Throat swelling due to allergic reaction to blood transfusion	H	CNP		

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Table H-1: Adverse Events by Clinical Category, Harm Level, Preventability, and Whether the Events Were NQF Serious Reportable Events or Medicare HACs (n=128) (Continued)

Adverse Event	Harm Level	Preventability	NQF	HAC
Events Related to Patient Care (36)				
Intravenous (IV) volume overload (10)				
1. Cascade event in which cessation of diuretic (furosemide) and administration of excess saline led to acute pulmonary edema	H	LP		
2. Cascade event in which IV volume overload led to mild congestive heart failure and subsequent treatment with diuretic (furosemide) led to hypokalemia	F	LNP		
3. Hypoxic respiratory failure secondary to IV volume overload	H	LNP		
4. Hypoxic respiratory failure secondary to IV volume overload	H	LP		
5. IV volume overload with associated leg edema and complicated by preexisting pneumonia	F	LNP		
6. Pleural effusions and intermittent dyspnea secondary to IV volume overload	F	LNP		
7. Pulmonary edema and effusions secondary to IV volume overload	F	CNP		
8. Pulmonary edema and respiratory distress secondary to IV volume overload	H	LP		
9. Respiratory failure secondary to IV volume overload	H	LP		
10. Respiratory insufficiency and reintubation secondary to IV volume overload	F	LNP		
Aspiration (8)				
1. Aspiration associated with feeding tube placement	F	LP		
2. Aspiration pneumonia associated with food intake	I	UTD		
3. Aspiration pneumonia associated with unspecified infiltrate	F	LP		
4. Aspiration pneumonia associated with unspecified infiltrate	F	LNP		
5. Aspiration pneumonitis associated with unspecified infiltrate	F	LP		
6. Cascade event in which aspiration led to respiratory failure, acute renal failure, shock, and cardiac arrest	I	UTD		
7. Cascade event in which recurrent aspiration led to infection	F	LP		
8. Cascade event in which episode of vomiting led to aspiration pneumonia in patient with congestive heart failure	F	LNP		
Venous thrombosis or pulmonary embolism (5)				
1. Bilateral deep venous thrombosis	F	LP		
2. Bilateral pulmonary emboli	F	LP		
3. Deep venous thrombosis secondary to central catheter	F	UTD		
4. Multiple pulmonary emboli (right pulmonary artery)	F	LP		
5. Venous thrombosis (saphenous vein)	F	LNP		
Exacerbation of preexisting medical condition (5)				
1. Cascade event in which failure to diagnose hypotension and septic shock led to severe hypotension	H	CP		
2. Cascade event in which failure to diagnose postoperative bowel distension led to toxic megacolon, bowel perforation, abdominal sepsis, and shock	H	UTD		
3. Progressive respiratory difficulties resulting from failure to complete congestive heart failure therapy	F	LP		
4. Progressive respiratory difficulties resulting from failure to diagnose hemothorax	F	LP		
5. Progressive respiratory difficulties resulting from failure to diagnose pulmonary infiltrate and pneumonia	F	CP		
Stage III pressure ulcer (3)				
1. Progression from single stage II pressure ulcer to bilateral stage III pressure ulcers (buttocks)	E	LP	●	●
2. Progression from stage I pressure ulcer to stage III pressure ulcer (heel)	E	LP	●	
3. Stage III pressure ulcer (sacrum)	E	LP	●	

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Table H-1: Adverse Events by Clinical Category, Harm Level, Preventability, and Whether the Events Were NQF Serious Reportable Events or Medicare HACs (n=128) (Continued)

Adverse Event	Harm Level	Preventability	NQF	HAC
Events Related to Patient Care (continued)				
Other events related to patient care (5)				
1. Breakdown of surgical wound	F	UTD		
2. Congestive heart failure resulting from failure to manage high blood pressure	F	LNP		
3. Hypoxia resulting from failure to stabilize tracheostomy and provide oxygen during transfer	H	CP		
4. Severe back pain and possible vertebral compression fracture from patient fall	F	CNP		●
5. Significant episode of weakness and dizziness associated with an exacerbation of hyponatremia	F	LP		
Events Related to Surgery or Other Procedures (33)				
Excessive bleeding (5)				
1. Bleeding for several days following colonoscopy	F	LNP		
2. Bleeding from femoral artery following IV placement	F	LNP		
3. Cascade event in which hemorrhage of femoral artery at puncture site led to shock, apnea, and ultimately a myocardial infarction	H	LP		
4. Cascade event in which premature removal of dialysis needle resulted in excessive bleeding, shock, intubation, and aspiration	H	CP		
5. Hematoma following knee arthroplasty	F	LP		
Severe hypotension (4)				
1. Hypotension during hemodialysis treatment	F	LNP		
2. Hypotension following cardiac surgery	F	LNP		
3. Hypotension following endoscopic procedure	H	CNP		
4. Hypotension with atrial fibrillation and rapid ventricular response following dialysis treatment	F	LP		
Respiratory complication (4)				
1. Agonal breathing following premature extubation	H	CP		
2. Cascade event in which acute respiratory failure following cardiac procedure led to hematuria and hemoptysis	F	LNP		
3. Cascade event in which angioedema secondary to contrast used for fistulogram led to intubation, ventilator-associated pneumonia, and shock	I	CNP		
4. Respiratory distress following percutaneous tracheostomy	H	CNP		
Iatrogenic pneumothorax (3)				
1. Cascade event in which postoperative pneumothorax led to acute respiratory failure	H	LNP		
2. Cascade event in which removal of chest tube led to pneumothorax, reinsertion of chest tube, and reintubation	H	LNP		
3. Pneumothorax following chest tube placement	F	CNP		
Postoperative ileus (3)				
1. Cascade event in which outpatient surgery to repair hernia following cholecystectomy led to hospitalization for postoperative hypoxemia, atelectasis, and ileus	F	LNP		
2. Significant ileus following partial colon resection	F	CNP		
3. Significant ileus following partial colon resection	F	LNP		

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Table H-1: Adverse Events by Clinical Category, Harm Level, Preventability, and Whether the Events Were NQF Serious Reportable Events or Medicare HACs (n=128) (Continued)

Adverse Event	Harm Level	Preventability	NQF	HAC
Events Related to Surgery or Other Procedures (continued)				
Postoperative urinary retention (3)				
1. Postoperative urinary retention associated with indwelling urinary catheter	F	LNP		
2. Postoperative urinary retention associated with indwelling urinary catheter	F	LP		
3. Postoperative urinary retention associated with urinary catheter	F	LNP		
Acute coronary syndrome (2)				
1. Acute coronary syndrome following laparoscopic cholecystectomy and resulting in permanent damage to heart muscle	G	CNP		
2. Acute coronary syndrome that developed as a complication of percutaneous coronary intervention	F	CNP		
Blood clots and other occlusions (blockage within a blood vessel) (2)				
1. Acute occlusion of the popliteal artery following colonoscopy and partial colon resection	G	CNP		
2. Pericardial blood clot following cardiac surgery	F	LNP		
Cardiac complication (2)				
1. Atrial fibrillation following mitral valve replacement surgery	H	CNP		
2. Severe ventricular tachycardia following coronary artery bypass graft	H	CNP		
Other procedure-related complication (5)				
1. Cascade event in which coronary bypass surgery led to complex tachycardia complicated by hypotension	H	LNP		
2. Cascade event in which complications following bowel surgery resulted in surgical site hemorrhage	F	LNP		
3. Delay in surgery because of equipment malfunction	F	LP		
4. Hematuria due to indwelling urinary catheter-associated trauma	F	LNP		
5. Seroma (pocket of fluid) following stomach resection	F	LNP		
Events Related to Infection (19)				
Urinary tract infection (5)				
1. Cascade event in which cystoscopy eroded artificial urethral sphincter necessitating use of urinary catheter which led to urinary tract infection (E. coli)	G	LP		●
2. Urinary tract infection (E. coli) associated with urinary catheter	F	LP		●
3. Urinary tract infection (E. coli) associated with urinary catheter	E	LP		●
4. Urinary tract infection (Klebsiella) associated with urinary catheter	E	LP		●
5. Urinary tract infection (Serratia) associated with urinary catheter	E	LP		●
Vascular catheter-associated infection (central or peripheral line) (4)				
1. Cascade event in which vascular catheter led to sepsis, deep vein thrombosis, and pulmonary embolism	F	LP		●
2. Cascade event in which vascular catheter led to septicemia and deep vein thrombosis	F	LP		●
3. Forearm cellulitis (inflammation of skin or connective tissue) following vascular catheter insertion	F	CP		
4. Methicillin-resistant Staphylococcus aureus (MRSA) infection following pleural catheter insertion	H	LP		

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Table H-1: Adverse Events by Clinical Category, Harm Level, Preventability, and Whether the Events Were NQF Serious Reportable Events or Medicare HACs (n=128) (Continued)

Adverse Event	Harm Level	Preventability	NQF	HAC
Events Related to Infection (continued)				
Other bloodstream infections (excluding vascular catheter-associated Infections) (4)				
1. Cascade event in which failure to treat systemic inflammatory response syndrome led to acute renal failure and aspiration pneumonia	I	CP		
2. Cascade event in which removal of urinary catheter led to recurrence of obstructive uropathy, renal failure, sepsis, and permanent deterioration of renal function	G	CP		
3. Cascade event in which untreated febrile neutropenia led to septic shock	I	CP		
4. Sepsis (methicillin-resistant Staphylococcus epidermis)	F	LNP		
Respiratory infection (4)				
1. Pneumonia (MRSA) following abdominal surgery	F	LNP		
2. Pneumonia (unspecified) following knee surgery	F	LNP		
3. Ventilator-associated pneumonia (Klebsiella)	F	LNP		
4. Ventilator-associated pneumonia (MRSA)	H	LNP		
Surgical or procedural site infection (2)				
1. Cascade event in which anastomotic leak following colectomy led to abscesses and bacteremia	F	LP		
2. Surgical site infection following foot surgery	F	LNP		

Source: Office of Inspector General (OIG) analysis of hospital stays for 780 Medicare beneficiaries in October 2008.

Table H-2: Temporary Harm Events, E Level on the NCC MERP Index, Identified Among Medicare Beneficiaries by Clinical Category (n=174)

Temporary Harm Event	Preventability
Events Related to Medication (73)	
Delirium or change in mental status (22)	
1. Altered mental status secondary to narcotic analgesic (fentanyl) and sedative (midazolam)	LP
2. Cascade event in which delirium secondary to antipsychotic (haloperidol) led to patient pulling catheter out which resulted in hematuria	LP
3. Confusion and delirium secondary to narcotic analgesics (hydromorphone and morphine)	LP
4. Confusion secondary to narcotic analgesic (hydromorphone)	LP
5. Confusion secondary to sedative (benzodiazepine)	LP
6. Delirium secondary to anticonvulsants (valproic acid)	CNP
7. Delirium secondary to local anesthetic (lidocaine)	CNP
8. Delirium secondary to narcotic analgesic (hydromorphone)	LP
9. Delirium secondary to narcotic analgesic (hydrocodone with acetaminophen)	LP
10. Delirium secondary to narcotic analgesic (morphine)	CNP
11. Drowsiness secondary to narcotic analgesic (hydromorphone)	LNP
12. Hallucinations and delirium secondary to narcotic analgesic (morphine)	LNP
13. Hallucinations secondary to sedative (alprazolam) and multiple narcotic analgesics	UTD
14. Lethargy secondary to narcotic analgesic (hydromorphone)	LP
15. Lethargy secondary to narcotic analgesic (oxycodone with acetaminophen)	LP
16. Omission of antidepressant (fluoxetine with olanzapine) that led to episode of acute paranoia	LP
17. Oversedation secondary to antihistamine and sedative (promethazine)	LP
18. Oversedation secondary to multiple psychiatric medications (alprazolam, haloperidol, and quetiapine)	LNP
19. Oversedation secondary to narcotic analgesic (fentanyl) and sedative (midazolam)	LNP
20. Oversedation secondary to narcotic analgesic (hydromorphone)	LP
21. Paranoid delusions secondary to narcotic analgesics (hydromorphone and morphine)	LP
22. Somnolence secondary to narcotic analgesics (hydromorphone and morphine)	CP
Hypoglycemic event (11)	
1. Hypoglycemia secondary to diabetes medication (glipizide)	UTD
2. Hypoglycemia secondary to glycemic management	CP
3. Hypoglycemia secondary to glycemic management	LNP
4. Hypoglycemia secondary to glycemic management	LNP
5. Hypoglycemia secondary to glycemic management	LNP
6. Hypoglycemia secondary to glycemic management	LP
7. Hypoglycemia secondary to glycemic management	LP
8. Hypoglycemia secondary to glycemic management	LP
9. Hypoglycemia secondary to glycemic management	LP
10. Hypoglycemia secondary to glycemic management	LP
11. Volatile blood glucose secondary to insulin management	LNP
Thrush and other opportunistic infection (7)	
1. Fungal infection (cutaneous rash) secondary to antibiotics (unspecified)	CNP
2. Thrush (Candidiasis) secondary to broad spectrum antibiotics (unspecified)	CNP
3. Thrush (oropharyngeal Candida) secondary to antibiotics (piperacillin and tazobactam)	CNP
4. Thrush (unspecified) secondary to antibiotics (unspecified)	LNP
5. Thrush (unspecified) secondary to antibiotics and steroids (unspecified)	CNP
6. Thrush (unspecified) secondary to antibiotics and steroids (unspecified)	CNP
7. Thrush (unspecified) secondary to steroids (unspecified)	CNP

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Table H-2: Temporary Harm Events, E Level on the NCC MERP Index, Identified Among Medicare Beneficiaries by Clinical Category (n=174) (Continued)

Temporary Harm Event	Preventability
Events Related to Medication (continued)	
Allergic reaction or side effect related to skin (6)	
1. Generalized pruritic (itching) rash secondary to narcotic analgesic (morphine)	CNP
2. Hives and facial swelling due to contrast used during cardiac catheterization	LNP
3. Hives and significant itching secondary to narcotic analgesic (hydromorphone)	CNP
4. Hives secondary to allergic reaction to antibiotics (moxifloxacin)	CNP
5. Itching and erythema (redness) secondary to narcotic analgesic (hydromorphone)	CNP
6. Itching secondary to antibiotics (clindamycin and cephalosporin)	CNP
Gastrointestinal complication (5)	
1. Allergic reaction (nausea and vomiting) to narcotic analgesics (hydromorphone)	CP
2. Diarrhea secondary to antibiotic (amoxicillin and clavulanate)	UTD
3. Nausea and vomiting secondary to hypertension therapy (nitroprusside)	LNP
4. Nausea and vomiting secondary to narcotic analgesic (morphine)	LNP
5. Severe diarrhea secondary to laxatives	LP
Hypotension (5)	
1. Cascade event in which diuretic (furosemide) led to sinus tachycardia, renal insufficiency, and hypotension	LP
2. Hypotension and dizziness secondary to antihypertensive medication (unspecified)	LP
3. Hypotension following administration of blood pressure medication (metoprolol)	CP
4. Hypotension secondary to multiple antihypertensives (unspecified)	LP
5. Low blood pressure secondary to aggressive diuresis (enalapril and furosemide)	LNP
Dysrhythmia (3)	
1. Dysrhythmia secondary to beta-blocker (labetalol)	LNP
2. Dysrhythmia secondary to cardiac medication (digoxin)	LP
3. Palpitations and nausea secondary to bronchodilators (albuterol)	CNP
Excessive bleeding (3)	
1. Epistaxis (nasal bleed) secondary to anticoagulant (enoxaparin)	CNP
2. Gross hematuria secondary to anticoagulant (heparin)	CNP
3. Hematuria secondary to anticoagulant (enoxaparin)	LNP
Severe headache or dizziness (3)	
1. Extended period of dizziness secondary to opioid withdrawal medication (buprenorphine)	LP
2. Headache secondary to cardiac medication (nitroglycerine)	LP
3. Nausea and headache secondary to cardiac medication (nitroglycerine)	CNP
Acute renal failure or insufficiency (2)	
1. Acute renal failure secondary to radiopaque contrast	LNP
2. Acute renal insufficiency secondary to multiple nephrotoxic agents, including kanamycin and ketorolac	CP
Allergic reaction to blood or related products (2)	
1. Allergic reaction to blood transfusion	CNP
2. Hives during infusion of fresh frozen plasma	CNP
Respiratory complication (2)	
1. Hypoxia secondary to narcotic analgesic (meperidine)	LP
2. Respiratory acidosis secondary to narcotic analgesic (hydrocodone with acetaminophen) and sedative (alprazolam)	CP
Other events related to medication (2)	
1. Fever secondary to antiulcer medication used to treat uterine atony (misoprostol)	CNP
2. Urinary retention secondary to narcotic analgesic (opioid)	LNP

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Table H-2: Temporary Harm Events, E Level on the NCC MERP Index, Identified Among Medicare Beneficiaries by Clinical Category (n=174) (Continued)

Temporary Harm Event	Preventability
Events Related to Patient Care (63)	
Stage I, Stage II, or unstaged pressure ulcer (20)	
1. Bilateral stage I pressure ulcer (buttocks)	LP
2. Deep tissue injury (buttock)	LNP
3. Progression from stage I pressure ulcer to stage II pressure ulcer (coccyx)	CNP
4. Progression from stage I pressure ulcer to stage II pressure ulcer (coccyx)	LNP
5. Progression from stage I pressure ulcer to stage II pressure ulcer (coccyx)	LNP
6. Stage I pressure ulcer (coccyx)	LNP
7. Stage I pressure ulcer (coccyx)	LNP
8. Stage I pressure ulcer (heel)	LP
9. Stage I pressure ulcer (sacrum)	LP
10. Stage I pressure ulcer (sacrum and buttocks)	LP
11. Stage I pressure ulcer (unspecified location)	LP
12. Stage I pressure ulcer secondary to restraints (sacrum and buttock)	LP
13. Stage II pressure ulcer (buttock)	LP
14. Stage II pressure ulcer (buttock)	LP
15. Stage II pressure ulcer (buttock)	UTD
16. Stage II pressure ulcer (heel and ankle)	LP
17. Stage II pressure ulcer (sacrum)	CNP
18. Stage II pressure ulcer (sacrum) and stage I pressure ulcer (heel)	LNP
19. Stage II pressure ulcer (unspecified location)	LP
20. Unstaged pressure ulcer (sacrum)	LNP
IV volume overload (15)	
1. Anasarca secondary to IV fluid resuscitation	LNP
2. Bilateral pulmonary effusion and pulmonary edema secondary to IV volume overload	LP
3. Cascade event in which excessive IV fluids administered after a procedure led to volume overload and hyponatremia	LP
4. Cascade event in which IV volume overload during a procedure led to acute respiratory distress	LP
5. Cascade event in which the delay of a procedure led to the transfusion of additional blood products and resulted in dyspnea	UTD
6. Dyspnea and pulmonary congestion secondary to IV volume overload	LNP
7. Dyspnea and pulmonary edema secondary to IV volume overload of contrast agent	LP
8. Dyspnea and pulmonary edema secondary to IV volume overload	LP
9. Dyspnea secondary to fluid overload of contrast agent used during arteriogram	LNP
10. Dyspnea secondary to IV volume overload of fluids to correct bowel obstruction	LP
11. Postoperative congestive heart failure secondary to IV volume overload	LNP
12. Pulmonary edema secondary to IV volume overload	LP
13. Pulmonary edema secondary to postoperative IV volume overload	LNP
14. Vascular congestion secondary to fluid resuscitation	LNP
15. Vascular congestion secondary to IV volume overload of fresh frozen plasma	LP
Skin tear, laceration, abrasion, or other breakdown (9)	
1. Blisters from telemetry leads (chest)	CP
2. Laceration during transfer to CT table (ankle)	CP
3. Skin abrasion from tape removal (IV site)	CNP
4. Skin breakdown with inflammation and drainage (upper arm)	LNP
5. Skin breakdown with tear (sacrum)	LP
6. Skin tear (elbow)	LNP
7. Skin tear (wrist)	LNP
8. Skin tear from prosthesis (heel)	LNP
9. Skin tears from patient turning (elbow and hand)	LNP

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Table H-2: Temporary Harm Events, E Level on the NCC MERP Index, Identified Among Medicare Beneficiaries by Clinical Category (n=174) (Continued)

Temporary Harm Event	Preventability
Events Related to Patient Care (continued)	
IV infiltrate with symptoms (6)	
1. Cellulitis secondary to IV infiltrate	LNP
2. IV infiltrate with pain and inflammation	LNP
3. IV infiltrate with pain and inflammation	LNP
4. IV infiltrate with pain, inflammation, and edema	LNP
5. Superficial phlebitis secondary to IV infiltrate	LP
6. Thrombophlebitis secondary to IV infiltrate	UTD
Patient fall with injury (5)	
1. Arm and shoulder injury resulting from patient fall	LP
2. Chest injury resulting from patient fall	LNP
3. Shoulder contusion and delay in surgery resulting from patient fall	LNP
4. Skin tear/abrasion on knees resulting from patient fall	CP
5. Status epilepticus resulting from patient fall with head trauma	LP
Aspiration (3)	
1. Aspiration associated with endotracheal tube leak	LNP
2. Aspiration associated with procedure-related infiltrate	LP
3. Aspiration pneumonitis associated with patient's secretions	CNP
Failure to treat constipation or obstipation (3)	
1. Exacerbation of constipation (impaction) secondary to narcotic analgesic (hydromorphone) due to failure to provide sufficient treatment	LP
2. Exacerbation of constipation secondary to increase in narcotic analgesics (unspecified) due to failure to provide sufficient treatment	LP
3. Extended period of constipation due to failure to provide sufficient treatment	LP
Tachycardia or dysrhythmia (2)	
1. Nonsustained ventricular tachycardic dysrhythmia	LP
2. Paroxysmal supraventricular tachycardia	UTD
Events Related to Surgery or Other Procedures (32)	
Urinary retention (8)	
1. Postoperative urinary retention associated with indwelling catheter	CNP
2. Postoperative urinary retention associated with indwelling catheter	LP
3. Postoperative urinary retention associated with indwelling catheter	LP
4. Postoperative urinary retention associated with straight catheter	LNP
5. Postoperative urinary retention associated with straight catheter	CNP
6. Postoperative urinary retention following back surgery	LNP
7. Postoperative urinary retention following hip surgery	LNP
8. Postoperative urinary retention following hip surgery	LNP
Excessive bleeding (6)	
1. Anemia following hip surgery	LNP
2. Bleeding from femoral catheter site	LNP
3. Bleeding from femoral catheter site following dialysis	LNP
4. Hematoma and bleeding from IV site	LP
5. Hematoma and drop in hemoglobin following hip surgery	LNP
6. Hematoma secondary to IV extravasation	LNP
Cardiac complication (4)	
1. Atrial fibrillation and palpitations following thoracotomy	CNP
2. Atrial fibrillation following cystoscopy	LNP
3. Minor myocardial infarction following neck surgery	CNP
4. Paroxysmal supraventricular tachycardia following surgery	LNP

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Table H-2: Temporary Harm Events, E Level on the NCC MERP Index, Identified Among Medicare Beneficiaries by Clinical Category (n=174) (Continued)

Temporary Harm Event	Preventability
Events Related to Surgery or Other Procedures (continued)	
Surgical tear or laceration (3)	
1. Dural tear during discectomy and spinal decompression	LNP
2. Dural tear during laminectomy	LNP
3. Unintentional enterotomy during surgery to relieve bowel obstruction	LNP
Urinary catheter-related trauma (3)	
1. Hematuria associated with indwelling urinary catheter	LNP
2. Postoperative hematuria associated with indwelling urinary catheter	CNP
3. Postoperative hematuria associated with indwelling urinary catheter	LNP
Prolonged nausea and vomiting (2)	
1. Prolonged nausea and vomiting following spinal surgery	LNP
2. Prolonged nausea and vomiting secondary to anesthetic given for dilation and curettage	CNP
Postoperative or postprocedural hypotension (2)	
1. Hypotension following cardiac procedure	LP
2. Hypotension following nephrectomy	LNP
Respiratory complication (2)	
1. Dyspnea following nephrectomy	UTD
2. Hypoxemia following shoulder arthroplasty	UTD
Other events related to surgery or other procedures (2)	
1. Gout following pacemaker placement procedure	CNP
2. Ileus following hip arthroplasty	LNP
Events Related to Infection (6)	
Surgical site infection (2)	
1. Surgical site infection following colostomy procedure	LNP
2. Surgical site infection following hip surgery	LP
Bacterial infection (1)	
1. Bacterial parotiditis (glandular) infection	LNP
Respiratory infection (1)	
1. Postoperative pneumonia	LNP
Urinary tract infection (1)	
1. Urinary tract infection related to urostomy	LNP
Vascular catheter-associated infection (1)	
1. Infectious phlebitis at catheter insertion site	LP

Source: OIG analysis of hospital stays for 780 Medicare beneficiaries in October 2008.

APPENDIX I

Agency Comments: Agency for Healthcare Research and Quality

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

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

SEP 2 2 2010

TO: Daniel R. Levinson
Inspector General

FROM: Carolyn M. Clancy, MD /S/
Director

SUBJECT: AHRQ Response to OIG draft report, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090.

Thank you for the opportunity to review your draft report, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090. The findings in the report are consistent with previous studies but are nonetheless disturbing. They confirm that adverse events continue to affect hospital inpatients at an alarming rate, and that the types of events that occur vary widely. The report reaffirms AHRQ's need to continue work on improving patient safety by broadening investigation to include areas that are not always seen on lists of adverse events that should never occur or should always be reported.

Responses are provided below to the report's two general recommendations that pertain to AHRQ and were provided in the July 20, 2010, draft version of the report that the Agency reviewed. AHRQ concurs with both OIG recommendations.

Recommendation: AHRQ and CMS should broaden patient safety efforts to include all types of adverse events.

AHRQ Response: CONCUR

AHRQ agrees that efforts to improve patient safety should be broad. While we have sponsored efforts to address specific types of adverse events, such as central-line-associated bloodstream infections and venous thromboembolisms, we have also supported efforts to address underlying causes that contribute to a wide variety of adverse events. For example, we have focused on improving the safety culture in healthcare by providing a widely-adopted patient safety culture survey that is used by hospitals and healthcare systems, and by providing team training to healthcare systems via the TeamSTEPPS program that we developed in concert with the Department of Defense. We have also provided broad in-person training on the topic of patient safety improvement to public sector and private sector representatives from every state via the Patient Safety Improvement Corps, which we implemented in concert with the Department of Veterans Affairs' National Center for Patient Safety. As we continue to lead and support Federal efforts in patient safety improvement, we intend to broaden efforts to improve patient safety overall (as with TeamSTEPPS), and to address specific problems, such as a targeted program to foster the widespread implementation of the CDC's guideline to prevent catheter-associated urinary tract infections.

1

Recommendation: AHRQ and CMS should enhance efforts to identify adverse events.

AHRQ Response: CONCUR

AHRQ has several efforts underway to improve identification of adverse events. The Agency has developed Common Formats (current version 1.1) that provide standard definitions, data elements, and reporting formats for all adverse events that occur in the hospital setting. Because the Common Formats are designed to address all events, not just a targeted list, they are directly responsive to OIG's recommendation to "broaden patient safety efforts to include all types of patient safety events."

Common Formats were developed for use by Patient Safety Organizations (PSOs), but can be used by any hospital. AHRQ has listed 88 PSOs as of September 15, 2010, and encourages hospitals and other healthcare providers to work with PSOs. The Agency recognizes the presence of structural, financial, and cultural barriers that impact reporting adverse events. In order to facilitate hospital and healthcare provider reporting of adverse events to PSOs, AHRQ is working to address these issues on multiple levels. Common Formats have been designed for implementation at the hospital level, and technical specifications have been released that ensure that adverse event information is collected as efficiently as possible from the reporter's perspective. The Common Formats also have been designed to provide value instantaneously at the hospital level through the use of standardized individual event reports as well as aggregate reports. While the Common Formats were developed for use by providers working with PSOs, AHRQ is encouraging their adoption by all hospitals. In addition, AHRQ is collaborating with Federal, state, and private sector organizations to harmonize reporting requirements. AHRQ and the National Quality Forum have convened representatives of state reporting systems to address issues of alignment. To foster engagement of the physician community, AHRQ is working with the American Medical Association to sponsor a series of meetings that bring together state medical societies and PSOs. These meetings allow the physician community to learn more about the benefits of establishing relationships with PSOs, employing Common Formats, and conducting confidential, privileged analyses of quality and safety reports.

To enhance the ability to identify cases of adverse events, the Patient Safety Indicators (PSIs) developed by AHRQ have been upgraded (to version 4.1). The PSIs are in wide use nationwide and identify adverse events based solely on administrative data. While the PSIs do not identify all cases when an adverse event occurs, they are relatively inexpensive, easy to implement, and can aid healthcare systems and hospital managers in their efforts to find adverse that otherwise might not have been identified and to compare their performance with that of other providers.

AHRQ has also worked with CMS on the development and implementation of the Medicare Patient Safety Monitoring System (MPSMS), and the Agency took over funding and leadership of this initiative in 2009. Selected data from the MPSMS have been used in the AHRQ National Healthcare Quality Report and have been published in the peer-reviewed literature. AHRQ intends to redesign this system over the next several years in order to broaden the areas of clinical investigation and address all payer populations, not just Medicare. The Agency will also investigate the feasibility of allowing other organizations to benefit from this methodology in their efforts to identify adverse events and measure their incidence.

Through these operational programs, the Agency's research efforts, and cooperation with other Federal agencies and the private sector, AHRQ intends to foster continued improvement in the identification and reduction of adverse events.

2

Agency Comments: Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: SEP 0 9 2010

TO: Daniel R. Levinson
Inspector General

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

SUBJECT: Office of Inspector General (OIG) Draft Report: Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries (OEI-06-09-00090)

2010 SEP 13 AM 10:36 RECEIVED

Thank you for the opportunity to review and comment on the subject OIG Draft Report, "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries, OEI-06-09-00090." We appreciate the OIG's work on this important and timely topic. When one in eight hospitalized Medicare beneficiaries experience an adverse event, most of which result in a prolonged hospital stay, permanent harm, life-saving interventions, or death, solutions need to be addressed as quickly and efficiently as possible. The Centers for Medicare & Medicaid Services (CMS) has taken significant steps to address these issues, but more work needs to be done.

The report's findings provide new information to the Department of Health and Human Services (HHS) broadly, and the Centers for Medicare & Medicaid Services (CMS) specifically, upon which to act to expand efforts to work with hospitals and clinicians to prevent adverse events. CMS seeks to promote a culture of safety across the country in all health care settings. While the report characterizes CMS as an oversight entity and the nation's largest health payer, CMS is also actively transitioning from serving solely as a regulator and passive payer of health care services to an agency that fully supports public health goals as an active payer of high quality and efficient care.

CMS is also an engine for innovation across health care. Several new legislative and regulatory efforts, including the new Center for Medicare & Medicaid Innovation, provide us with new and innovative tools to address the concerns raised in this report. In addition, we plan to continue several efforts already in progress to reduce adverse events. While this response focuses on adverse events in hospitalized patients, our efforts are also directed at addressing issues in dialysis centers and ambulatory and long term care settings, recognizing that in our dynamic and complex healthcare system a patient should expect and receive safe care, wherever that care may be provided.

While we have a number of efforts already underway (as discussed throughout this response), we are launching a number of new efforts to infuse a cross-cutting theme of safety throughout the agency to promote a coordinated effort among existing and emerging programs. These are all designed to create incentives for and support to hospitals to identify adverse events, practices to

prevent them, and to significantly decrease the rates of adverse events and make the hospital experience safer.

More specifically, the Health Information Technology for Economic and Clinical Health (HITECH) provisions in the American Recovery and Reinvestment Act (ARRA) provided HHS the opportunity to define "meaningful use" for electronic health records (EHRs). The final rule for phase one of the program included several requirements aimed at reducing adverse events in both hospitals and the offices of "eligible professionals." Phase two of HITECH will likely include other such requirements. CMS plans to design EHR meaningful use incentive programs to measure and reduce adverse event incidence through promoting EHR collection, measurement, and provider sharing of information critical to coordinating care and reducing adverse events.

The Affordable Care Act (ACA) included a variety of new opportunities to address adverse events including the Hospital Value-Based Purchasing (HVBP) Program, the creation of the Center for Medicare & Medicaid Innovation, and the expansion of the HealthCare Acquired Conditions (HAC) payment policy. Under the HVBP program, the Secretary is required to select measures in the first year of the program that include Healthcare-Associated Infections (HAIs) as measured by the metrics established in the HHS Action Plan to Prevent Healthcare-Associated Infections. The program will evolve in future years to include more performance monitoring for adverse events and associated payment reductions when established targets are not met. The new Center for Medicare & Medicaid Innovation will include improvements in patient safety and reductions of adverse events as two of its primary goals. The Center will explore efforts to identify and document the most effective steps to identify and prevent serious adverse events. The Center will also explore the establishment of the business case to incentivize the reduction of adverse events by documenting cost-effectiveness for hospitals and for the Medicare program. In addition, the Center will test innovative service delivery and payment models that can improve patient safety, reduce unnecessary and inappropriate re-admissions, prevent avoidable hospital acquired conditions, as well as promote and diffuse best practices through collaborative learning networks.

We are also re-examining our activities related to Quality Improvement Organizations (QIOs) to identify enhancements to the program requirements and to address priorities in a reformed health care delivery system, such as the identification and reduction of adverse events in hospitals. It is not sufficient to only identify the events, but to have tools and resources available to ensure beneficiary safety by assisting poorly performing providers in improving and decreasing adverse events. QIOs are uniquely situated to assist in achieving national performance goals and driving improvement in the reduction of adverse events at the local level. The QIOs will actively coordinate with the Center for Medicare & Medicaid Innovation to diffuse best practices and to encourage hospitals to work with Patient Safety Organizations.

We also recognize that cross Departmental collaboration is essential for effective coordination and we are working with the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA) to identify and implement strategies to improve the measurement and reporting of adverse events and to aggressively address prevention of these events. For example, CMS is collaborating with AHRQ on the Medicare Patient Safety Monitoring System (MPSMS) project. This program has been in place since 2002 and is the only national surveillance system

for adverse events among Medicare beneficiaries. Starting in 2009, AHRQ has taken over the funding and project management of this program. However, CMS is still very involved, providing technical assistance and access to medical records for abstraction of 21 measures (10 are HACs and 4 are National Quality Forum (NQF) Never Events).

Another example of such partnership and collaboration is the Patient Safety and Clinical Pharmacy Services Collaborative, a national HRSA-led quality improvement initiative on medication patient safety that is targeted to high risk patients and high risk medications, such as insulin and warfarin. Over 100 community-based teams comprised of hospitals, health centers, pharmacies, QIOs, and others are working together in interdisciplinary teams to provide improved care coordination across acute care, outpatient, public health and specialty care organizations for their highest risk patients on the highest risk medications. These collaborative teams are achieving substantial reductions in adverse drug events and we intend to continue this collaborative work in the future.

CMS and the Food and Drug Administration (FDA) currently have a memorandum of understanding (MOU) in place concerning the exchange of data, and CMS will work collaboratively with the FDA in the sharing of all necessary information and data on adverse events in order to facilitate any necessary FDA labeling changes. Additionally, CMS will evaluate the feasibility of commissioning a technology assessment (TA) on patient safety that will broadly analyze the top five preventable safety risks in hospitals. CMS will use the results from the TA to determine 1or 2 topics to focus on at a town hall or open door forum.

These collaborations are both at a national level between our agencies, and at a State level with Medicaid agencies and AHRQ grantees (i.e., hospital associations), CDC supported State health agencies, and CMS supported QIOs. Further, through the development of the HHS Action Plan to Prevent Healthcare Associated Infections, CMS intends to strengthen its efforts to improve patient safety in all health care settings.

In summary, CMS is committed to--(1) Improving the health of the population; (2) Enhancing the patient experience of care; and (3) Decreasing or controlling the cost of care. This can be achieved through the use of the following six basic strategies which play an important role in reducing adverse events in hospitals:

1. Employing Contemporary Quality Improvement Activities including various programs and initiatives designed to identify the root causes of problems and implement evidenced based interventions that lead to improvement in overall quality. Progress is evaluated through the analysis of evidenced based measures. Technical assistance is often offered to providers in need of assistance during the course of contemporary quality improvement.
2. Improving Transparency through the availability of pertinent data for health information exchanges and public reporting. Data is shared among stakeholders, including beneficiaries, for use in care coordination, decision making, effectiveness research, quality improvement, patient safety and other appropriate uses.
3. Incorporating Innovative Incentives by aligning payment and quality to motivate improvement. Incentives include, but are not limited to the implementation of value-based purchasing to provide payment incentives when pre-established goals are met.

4. Reworking Conditions of Participation (CoPs) as often improvement efforts alone are not sufficient and must be complemented with requirements through CoPs for providers. The requirements are then enforced through effective survey and certification programs.
5. Using Evidenced-Based Coverage and Payment Decisions provide another method of aligning payment with quality by ensuring that payment is available to support appropriate clinical practices.
6. Pursuing New and Innovative Grants, Demonstrations, Pilots and Research to provide a mechanism for improving quality by developing evidenced based approaches to new and innovative quality improvement interventions.

The OIG made a number of recommendations to reduce the incidence of adverse events as reported in this study. In our response to the three main recommendations below, we will refer to and suggest deployment of innovative approaches using each of these six strategies.

OIG Recommendation 1

AHRQ and CMS should broaden patient safety efforts to include all types of adverse events. This broader definition of adverse events would apply to a number of activities, including setting priorities for research, establishing guidelines for hospital reporting, developing prevention strategies, measuring health care quality, and determining payment policies.

CMS Response

CMS concurs with this recommendation, and will continue to actively work to broaden efforts to address additional adverse events as well as broaden the activities associated with reducing these events. One such effort currently underway in the Medicare program is expanding CMS' Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program to include the reporting of several HACs and the AHRQ Patient Safety Indicator measures to the public. The RHQDAPU program links reporting of quality data to payment by reducing the Medicare annual payment update by 2 percentage points for acute care hospitals that fail to report quality measures. (For the fiscal year (FY) 2012 payment determination, there will be 55 quality measures in the RHQDAP program.)

The following eight existing Hospital Acquired Conditions are being added to the RHQDAPU measures and will be posted on Hospital Compare by FY 2011:
(1) Foreign object retained after surgery.
(2) Air embolism.
(3) Blood incompatibility.
(4) Pressure ulcer (Stages III & IV).
(5) Falls and trauma (which includes: fracture, dislocation, intracranial injury, crushing injury, burns, electric shock).
(6) Vascular catheter-associated infection.
(7) Catheter-associated urinary tract infection (UTI).
(8) Manifestations of poor glycemic control.

In addition, as part of the RHQDAPU program, CMS will publicly report hospital-level quality measures on the following seven AHRQ patient safety indicators and inpatient quality indicators on Hospital Compare in 2011:

(1) Iatrogenic pneumothorax, adult.
(2) Postoperative wound dehiscence.
(3) Accidental puncture or laceration.
(4) Abdominal aortic aneurysm (AAA) mortality rate (with or without volume).
(5) Hip fracture mortality rate.
(6) Mortality for selected medical conditions (composite).
(7) Complication/patient safety for selected indicators (composite).

We also added two additional AHRQ Patient Safety Indicators—Post-Operative Respiratory Failure and Post-Operative Pulmonary Embolism/Deep Vein Thrombosis—for public reporting starting in 2012. CMS is also building on existing reporting requirements regarding Central Line Associated Blood Stream Infections (CLABSI). Hospitals participating in the RHQDAPU program will be required to report CLABSI data to the CDC's National Healthcare Safety Network (NHSN) starting with January 2011 discharges, with public reporting on Hospital Compare in 2013. We will also require hospitals to report Surgical Site Infection (SSI) measure data to the CDC's NHSN starting with January 2012 discharges, with public reporting in 2014. Both of these measures are included in the Department of Health and Human Services Action Plan to Prevent Healthcare Associated Infections. Under these new requirements, hospitals must report CLABSI and SSI into the NHSN and agree to have their rates publicly reported on Hospital Compare in order to receive their full Medicare annual payment update.

CMS will also encourage harmonized adoption of quality information across settings that will be used by providers to compile and share patient information, including (but not limited to) medications, allergies, and other exclusions. This information is critical to identifying and reducing adverse events through timely and accurate EHR information transfer to providers at the point of care, and is designed to reduce adverse events such as drug-to-drug interactions and potentially inappropriate medications.

CMS notes that there are some risks associated with using the OIG's broad definition of adverse events including both preventable and non-preventable events. It is difficult to track them because they rely so heavily on medical review. The intensive process used by OIG worked well on a sample of claims, but could be difficult to replicate broadly. Further, this definition identifies many events that could not have been prevented. That said, we believe it is appropriate for CMS to aggressively pursue broadening the scope and definition of patient safety efforts to be more inclusive of various types of adverse events.

OIG Recommendation 2

AHRQ and CMS should enhance efforts to identify adverse events. Identifying adverse events assists policymakers and researchers in directing resources to the areas of greatest need, setting clear goals for improvement, assessing the effectiveness of specific strategies, holding hospitals accountable, and gauging progress in reducing incidence.

- ***CMS should use Present on Admission Indicators in hospital billing data to calculate the frequency of adverse events occurring within hospitals.***

CMS Response

CMS concurs with this recommendation. CMS is currently using the Present on Admission (POA) indicators to link quality of care to Medicare claims payment in its payment policy. The HAC payment policy set forth in section 1886(d)(4)(D) of the Social Security Act requires the Secretary to identify at least two conditions that are--(a) high cost or high volume or both; (b) assigned to a higher paying Medicare Severity Diagnosis Related Group (MS-DRG) when present as a secondary diagnosis (that is, conditions under the MS DRG system that are CCs or MCCs); and (c) reasonably preventable through the application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals have not received higher payments for cases in which the selected conditions were not present on admission.

Additionally, the QIOs used POA indicators between August 2008 and January 2010 to assist hospitals in the reduction of high-risk pressure ulcers. In the future, CMS plans to continue using POA indicators in its QIO program to assess adverse event incidence in its Patient Safety and Beneficiary Protection work. CMS is also assessing the use of POA indicators in its QIO program to assess adverse event incidence at hospitals when QIOs receive quality of care complaints from Medicare beneficiaries. CMS is exploring the feasibility of QIOs assisting hospitals in creating quality improvement plans to reduce adverse events when abnormally high adverse event incidence is found from POA indicator data.

OIG Recommendation 3

CMS should provide further incentives for hospitals to reduce the incidence of adverse events through its payment and oversight functions. The ACA makes several changes to the HAC policy. The ACA gives the HAC policy greater significance by using the list of HACs to implement Medicare payment penalties, create performance measures, and prohibit Medicaid payments for associated care. The CoP for Medicare and Medicaid require that hospitals have programs to demonstrate quality improvement where evidence shows practices can improve outcomes.

- ***CMS should strengthen the Medicare HAC policy.***

CMS Response

CMS concurs with this recommendation. We appreciate the recommendation and will continue to work with CDC, AHRQ, and others to strengthen our payment policies related to HACs in the Medicare and Medicaid programs. [1]

[1] For specific policies and discussion of conditions addressed in each rulemaking cycle, we direct readers to the following publications: the FY 2007 IPPS proposed rule (71 FR 24100) and final rule (71 FR 48051 through 48053); the FY 2008 IPPS proposed rule (72 FR 24716 through 24726) and final rule with comment period (72 FR 47200 through 47218); the FY 2009 IPPS proposed rule (73 FR 23547), and final rule (73 FR 48471); and the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43782).

We are considering whether it would be appropriate to expand the number of HAIs included in our policy and also to explore applying the policy to more settings of care. However, as the OIG draft report notes, HACs represent only a small percentage of identified adverse events. CMS notes that demonstrating that a condition "could reasonably have been prevented through the application of evidence-based guidelines", as required by law, is a critical, but a restrictive standard.

The OIG specifically recommends that CMS "consider expanding the list of Medicare HACs to include more conditions that may result in harm to beneficiaries." Since FY 2007, CMS has worked and continues to work diligently to implement its current Medicare HAC policy, consistent with the statutory definition of HAC, which limits candidate HACs to only those conditions that are reasonably preventable through application of evidence-based guidelines. Our experts have worked closely with public health and infectious disease professionals from across HHS, including the CDC, AHRQ, and the Office of Public Health and Science (OPHS), to identify the candidate preventable HACs, evaluate those against the statutory criteria, review comments, and select HACs. We intend to maintain this collaborative process with these partners as we continue to explore potential candidate conditions and evaluate this program.

Additionally, the OIG recommends that CMS "should also take additional steps to ensure that hospitals accurately code Medicare claims to show when HACs occur." CMS worked with the American Hospital Association (AHA) to establish a process to improve POA reporting. This process involves the use of the AHA's Editorial Advisory Board for Coding Clinic for ICD-9-CM. The board receives questions from hospitals on the correct use and reporting of POA indicators. The board also makes recommendations on refinements to the POA official coding guidelines. AHA publishes advice on POA reporting in its publication Coding Clinic for ICD-9-CM. Hospitals and review organizations use this publication as a means of determining correct coding and reporting.

Through this cooperative arrangement with the AHA, CMS believes it will facilitate improvements in POA reporting by hospitals. CMS and CDC have also collaborated on the process for hospitals to submit a POA indicator for each diagnosis listed on inpatient prospective payment system (IPPS) hospital Medicare claims and on the payment implications of the various POA reporting options. CMS has undertaken a multi-phase evaluation effort of the HAC program, working closely with public health and infectious disease professionals from across HHS, including CDC, AHRQ, and the OPHS. This effort began in the Fall 2009. A phase of this evaluation will be dedicated to assessing the accuracy of coding through a variety of methods, and include review of both claims data and medical record data. Results of this review will be shared as they become available.

CMS efforts to strengthen HAC policies will be enhanced by provisions in the ACA. Section 3008(b) of the ACA requires the Secretary to submit a report to Congress not later than January 1, 2012 that includes a study of and recommendations for expansion of this Medicare HAC payment policy to the following provider settings: long-term acute care hospitals, hospital outpatient departments, ambulatory surgery centers, health clinics, inpatient rehabilitation facilities, skilled nursing facilities, and other hospitals excluded from the IPPS. In addition, section 3008(a) of the ACA creates an additional financial incentive for hospitals to reduce HACs. Starting in FY 2015, acute care hospitals that are in the top quartile based on national, risk-adjusted HAC rates will be subject to a payment reduction of one percent.

In addition, CMS's inclusion of a number of HACs as part of the RHQDAPU program complements the agency's efforts in this area. CMS will report eight existing HACs on Hospital Compare by FY 2011 as part of the RHQDAPU program. The conditions to be reported are as follows:

Future RHQDAPU Hospital Acquired Condition Measures	
	• Foreign Object Retained After Surgery
	• Air Embolism
	• Blood Incompatibility
	• Pressure Ulcer Stages III & IV
	• Falls and Trauma: (Includes: Fracture, Dislocation, Intracranial Injury, Crushing Injury, Burns, Electric Shock)
	• Vascular Catheter-Associated Infection
	• Catheter-Associated Urinary Tract Infection (UTI)
	• Manifestations of Poor Glycemic Control

- ***CMS should look for opportunities to hold hospitals accountable for adoption of evidence-based practice guidelines.***

CMS Response

CMS concurs with this recommendation. CMS currently utilizes the Medicare CoPs, the Medicare survey and certification process, and the QIO program to hold hospitals accountable for adopting evidence-based practice guidelines. In addition, CMS will add HAIs and other adverse events to the new HVBP Program to be implemented in FY 2013.

Medicare CoPs and the Survey and Certification Process

The OIG acknowledges that the Medicare CoPs already require that hospitals have programs to demonstrate quality improvement where evidence shows that practices can improve outcomes. The OIG recommended that--(1) CMS should influence reduction of adverse events through enforcement of the CoPs; (2) Patient safety issues should be more closely examined through the survey and certification process; and (3) Hospitals should be encouraged to adopt evidence-based practices shown to prevent adverse events.

We agree that the survey and certification process should stress the evaluation of compliance with Medicare's CoPs, including the patient safety requirements of 42 CFR 482.21, and the hospital Quality Assessment and Performance Improvement (QAPI) CoP. In the spring of 2010, CMS developed and circulated draft hospital QAPI CoP interpretive guidelines to the State Survey Agencies for their review and feedback, and will integrate that feedback into broader efforts to standardize our approach to evaluation compliance with QAPI requirements across different types of providers. We are also in the process of beta testing a web-enabled surveyor training program that equips surveyors to understand the fundamentals of the discipline of patient safety. We expect both of these efforts will result, starting in 2011, in enhanced ability of surveyors to assess hospital QAPI programs.

We believe that the QIO program is well-suited to the provision of technical assistance to hospitals to encourage adoption of specific practice guidelines. We are actively exploring ways in which to complement the increased survey and certification enforcement of QAPI requirements with a complementary increase in focus within the QIO program on activities designed to facilitate compliance with QA/PI requirements.

The current hospital CoP/QAPI states those hospitals must--

a. Develop, implement & maintain an effective, ongoing, hospital-wide, data-driven QAPI;
b. Show *measurable improvements* in indicators for which there is *evidence that it will improve* health outcomes and *identify* and *reduce medical errors*;
c. Measure, analyze, and track quality indicators, *including adverse patient events*, and other aspects of performance that assess processes of care;
d. Incorporate quality indicator data to monitor effectiveness and safety of services and quality of care; identify opportunities for improvement and changes that will lead to improvement;
e. Set priorities for performance improvement activities that: focus on *high-risk, high-volume*, or *problem prone areas*; affect health outcomes, *patient safety* and *quality of care*; track medical errors and adverse patient events, analyze their causes and *implement preventive actions* and mechanisms that include feedback and learning;
f. Annually conduct and document performance improvement projects. The hospital must provide a rationale for conducting them, and must document the measurable progress made through them. The number and scope of projects must be proportionate to the scope and complexity of the hospital services and operations; and
g. Governing body/medical staff/administrative officials have *executive responsibilities* to ensure that QAPI programs are ongoing, reduce medical errors, and *improve quality of care and patient safety*.

CMS will also explore additional methods of examining how hospitals are meeting the CoP QAPI requirements, including potentially requiring hospitals to report on the impact of their efforts. The adoption of evidence-based practices is a focus of many health care specialties, professional societies, health care associations and providers and is mentioned in our hospital CoPs. Patient safety issues that can be addressed and strengthened, and which we are exploring a variety of mechanisms, including events related to medication errors, surgery or other invasive procedures, patient care events such as pressure ulcers or monitoring, and HAIs.

<u>QIOs</u>

CMS plans to engage QIOs in an even greater role as we move toward implementing HVBP and monitoring performance for payment purposes, including performance related to adverse events in hospitals. In conjunction with identifying adverse events, it is important to have tools and resources available to assist poorly performing providers in improving and decreasing adverse events. QIOs are uniquely situated to assist in achieving national performance goals and driving improvement in the reduction of adverse events at the local level.

QIOs currently provide technical assistance to hospitals to ensure accurate reporting of data and the implementation of effective interventions related to Methicillin-resistant Staphylococcus

aureus infections acquired in the hospitals. In addition, the QIO Beneficiary Protection team will begin collecting and analyzing adverse events during quality of care reviews, including beneficiary complaints. CMS plans to continue to utilize the QIOs as a vehicle for holding hospitals accountable and improving care to reduce adverse events in hospitals.

HVBP Program

The HVBP program provides CMS with another avenue to address adverse events in hospitals. Section 3001 of the ACA requires the Secretary to establish a HVBP program designed to link payment to quality outcomes for hospitals under the Medicare program. Under this program, which begins in FY 2013, value-based incentive payments will be made to hospitals that meet certain performance standards.

The HVBP program moves hospitals from reporting measures as required in the RHQDAPU program to paying hospitals based on their quality performance. The statute requires the Secretary to select certain measures for the HVBP program. For FY 2013, the Secretary must ensure that the measures selected cover at least five conditions or procedures specified in the statute, including HAIs, and that the measures selected be related to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. Under the HVBP program, payments to high-performing hospitals will be larger than those to lower performing hospitals, thereby providing a financial incentive to drive improvements in clinical quality, patient-centeredness and efficiency. Public reporting of performance on the CMS Hospital Compare website will be an essential component of the HVBP program. While the first year of the program will include HAIs as measured by the metrics established in the HHS Action Plan to Prevent Healthcare-Associated Infections, the program will evolve in future years to include increasingly more performance monitoring for adverse events and associated payment reductions when established targets are not met.

CMS is committed to the reduction of adverse events in the hospital and other settings for Medicare and Medicaid beneficiaries and the country as a whole. This is an unprecedented time in the history of this country and CMS is confident that through the many efforts identified in this report and those under development that adverse events will decrease. CMS thanks the OIG for the opportunity to review and comment on this draft report.

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