Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ADVERSE EVENTS IN HOSPITALS: CASE STUDY OF INCIDENCE AMONG MEDICARE BENEFICIARIES IN TWO SELECTED COUNTIES

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EXECUTIVE SUMMARY

OBJECTIVE

To estimate the incidence of adverse events for hospitalized Medicare beneficiaries in two selected counties.

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 healthcare setting." The Tax Relief and Health Care Act of 2006 (the Act) mandates that the Office of Inspector General (OIG) report to Congress regarding the incidence of never events among Medicare beneficiaries, payment by Medicare or beneficiaries for services in connection with such events, and Centers for Medicare & Medicaid Services (CMS) processes to identify events and deny payment. This report is one in a series to fulfill requirements in the Act. OIG work on this topic will continue through 2009.

We reviewed a random sample of 278 hospitalized Medicare beneficiaries selected from all beneficiaries hospitalized in two selected counties during a 1-week period in August 2008. Physician reviewers determined whether an adverse event occurred, whether the event was on NQF's list of Serious Reportable Events or CMS's list of hospital-acquired conditions, and the level of harm to the patient based on an established harm scale. To establish an estimated adverse event incidence rate, we included events on the NQF and CMS lists and also events resulting in the most serious categories on the harm scale (prolonged hospital stay, permanent harm, life-sustaining intervention, or death). We also determined whether events on the NQF and CMS lists caused higher Medicare reimbursement. Lastly, we identified additional events that resulted in temporary patient harm but were not comparable to the more serious events in our overall rate.

FINDINGS

Fifteen percent of hospitalized Medicare beneficiaries in two selected counties experienced an adverse event during their hospital stays. Of the 278 Medicare beneficiaries in our sample, 41 experienced an adverse event during their hospital stay that met one or more of our three criteria for an estimated adverse event rate of

15 percent. Six of these forty-one patients experienced multiple adverse events, for a total of 51 adverse events. Incidence rates for adverse events that met our three criteria were as follows: fewer than 1 percent of beneficiaries experienced an adverse event on NQF's list of Serious Reportable Events, 4 percent experienced an adverse event on CMS's list of hospital-acquired conditions, and 13 percent experienced an adverse event resulting in the four most serious categories on the patient harm scale. (Some adverse events met more than one criterion.) Of adverse events on CMS's list of hospital-acquired conditions and NQF's list of Serious Reportable Events, only one resulted in higher Medicare reimbursement to the hospital.

Identified adverse events illustrate differences in the lists and criteria that define adverse events. A difficulty in determining adverse events incidence rates involves differences in the definitions used by various entities. The NQF list of Serious Reportable Events and the CMS list of hospital-acquired conditions often address the same adverse event but define the event differently. For example, our sample included two adverse events involving poor glycemic control, both of which resulted in serious harm. However, because of differences in the way specific adverse events are defined, one case met the criteria of NQF's list and the other met the CMS criteria.

An additional 15 percent of Medicare beneficiaries in the two selected counties experienced events during their hospital stays that resulted in temporary harm. In addition to the adverse events previously discussed, another 15 percent of Medicare beneficiaries experienced events classified as temporary harm requiring medical intervention. This category of harm represents a wide array of events, from swelling at a treatment site to low-level infections. In some cases, the events resulted from standard medical treatment that caused an undesirable outcome in the patient, such as an allergic reaction to medication. Because these temporary events did not prolong the hospital stay or result in permanent harm, they are not included in our overall rate of adverse events. However, these events are of interest to hospitals and others seeking to improve patient safety because they are potential indicators of patient care problems and/or improvement opportunities. For a number of these patients, physician reviewers indicated that these temporary harm events could have developed into more serious adverse events with a greater degree of harm without timely intervention.

CONCLUSION

The Act requires that OIG report to Congress regarding harm caused in health care settings. This study is one of several designed to meet this mandate, providing an estimate of the incidence of adverse events among hospitalized Medicare beneficiaries in two selected counties.

Although these results are not nationally representative, the extent of adverse events and temporary harm found in this case study substantiates concerns about the incidence of adverse events in hospitals and the importance of safety initiatives to reduce occurrences. Our analysis also calls attention to the difficulty of determining what events should be considered in an adverse event incidence rate and how those events should be identified and defined.

The Act also directs OIG to make recommendations for such legislation and administrative action as OIG determines is appropriate. The Act specifically authorized funding to continue through calendar year 2009 and OIG will devote this funding to additional studies involving adverse events. Future reports in this series will include recommendations as appropriate.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

We received positive comments on a draft of this report from the Agency for Healthcare Research and Quality and from CMS. CMS reiterated its policies to encourage the prevention of adverse events, including the provision to deny payment for care associated with hospital-acquired conditions, and indicated that OIG identification of hospital-acquired conditions and their effect on Medicare payment allowed for a deeper understanding of the payment policy in practice. CMS also offered clarification regarding one of the hospital-acquired conditions, catheter-associated urinary tract infection, and recommended further evaluation of this issue. OIG agrees that further evaluation is warranted and will address this issue in future work in this series.

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INTRODUCTION

OBJECTIVE

To estimate the incidence of adverse events for hospitalized Medicare beneficiaries in two selected counties.

BACKGROUND

Statutory Mandate and Office of Inspector General Response

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

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. In 2006, 12.5 million Medicare beneficiaries were hospitalized,[1] with inpatient hospital costs constituting the largest portion of Medicare expenditures (32 percent in 2006).[2] Government agencies and private entities have also targeted hospitals for patient-safety initiatives.

A variety of terms, lists, and definitions are used to identify and address health care events that result in patient harm. (For a glossary of selected terms, see Appendix B.) The National Quality Forum (NQF) used the term "never event" to describe a specific list of events associated primarily with patient death or serious disability that

[1] CMS, "Statistics Book," Table IV.1: Medicare/short-stay hospital utilization, 2008, p. 43. Available online at http://www.cms.hhs.gov/CapMarketUpdates/Downloads/2008CMSStats_xls.pdf. Accessed on November 12, 2008.

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

"should never occur in a health care setting."[3] NQF currently uses the term "Serious Reportable Events" to describe this list. (For a list of NQF Serious Reportable Events, see Appendix C.) Since enactment of the Act, patient safety issues have continued to receive much attention by policymakers, the health care industry, and patient advocates. The term "adverse events" is now used more commonly than never events within the health care community to refer to harm experienced by a patient as a result of medical care. As a result, and after consulting with selected congressional committee staff in 2007, OIG modified our approach and terminology to be consistent with evolving patient safety research and industry trends. In doing so, we expanded our focus beyond the list of 28 never events specified by NQF to a broader view of adverse events causing harm to patients.

The term "adverse event" describes harm to a patient as a result of medical care. Although an adverse event indicates that the care resulted in an undesirable clinical outcome and may involve medical errors, adverse events do not always involve errors, negligence, or poor quality of care and may not always be preventable.[4] As such, research and policy to ensure patient safety and reduce the occurrence of adverse events often focuses on identifying and addressing systemic problems that may lead to patient harm and avoids labeling the event as an outcome of negligence or poor quality.

This broad definition of adverse events reflects not only a variety of possible causes of events, but also a wide range in their effect on patients. Depending on their purpose, 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. For example, NQF's list of Serious Reportable Events focuses on events that cause serious disability and death. The National Coordination Council for Medication Errors Reporting and Prevention (NCC MERP) developed a scale to categorize the level of patient harm resulting from medication errors. The NCC MERP Index for Categorizing Errors considers factors such as whether the occurrences had any effect on the patient and, if so, the degree of harm (see Table 1). The scale includes categories for

[3] NQF is a public-private membership organization created to develop and implement a national strategy for health care quality measurement and reporting. The list is available online at http://www.qualityforum.org/about. Accessed on October 21, 2008.

[4] R.M. Wachter, "Understanding Patient Safety," McGraw-Hill, 2008.

circumstances or occurrences wherein harm did not reach the patient (categories A-D), often referred to as "near misses," and those wherein the patient was actually harmed (categories E-I). Researchers have modified this scale for use in measuring and distinguishing adverse events of all types, rather than only medication errors.[5]

Table 1: The National Coordinating Council for Medication Errors Reporting and Prevention Index for Categorizing Errors

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

Medicare Payment for Adverse Events

Medicare traditionally did not distinguish between costs incurred for treating existing illnesses and those incurred as the result of adverse events. Medicare reimbursement to inpatient acute care hospitals is generally determined by grouping patient conditions into Diagnosis-Related Groups (DRG) based on the average cost of care for patients with similar conditions. Historically, if a Medicare beneficiary experienced harm from an adverse event that resulted in assignment of

[5] 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.

a more expensive DRG, CMS paid the full claim without any payment reduction.[6]

Hospital-Acquired Conditions. The Deficit Reduction Act of 2005 (DRA) required CMS to select at least two hospital-acquired conditions for which hospitals would not be paid higher Medicare reimbursement.[7] CMS issued a final regulation in August 2007 allowing it to deny hospitals higher payment for admissions complicated by any of eight categories of hospital-acquired conditions. CMS chose the categories of conditions in collaboration with the Centers for Disease Control and Prevention and used the following criteria:

- conditions that are high cost, high volume, or both;
- conditions that, when present as a secondary diagnosis, result in assignment of a case to a DRG that has a higher payment;
- conditions that could be reasonably prevented by using readily available evidence-based guidelines; and
- conditions that are identifiable based on one or more unique diagnosis codes.[8]

In July 2008, CMS issued a final rule expanding the list of hospital-acquired conditions to 10. Effective October 1, 2008, CMS began denying hospitals higher payment for Medicare admissions complicated by these conditions.[9] For the list of CMS categories of hospital-acquired conditions, see Appendix D.

Changes to CMS Payment. In addition to designating the list of hospital-acquired conditions, the FY 2008 Inpatient Prospective Payment System 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 individual classes based

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[6] U.S. Department of Health and Human Services, CMS, Press Release, "Eliminating Serious, Preventable, and Costly Medical Errors – Never Events," May 18, 2006. Available online at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1863. Accessed on August 28, 2008.

[7] DRA, § 5001(c), P.L. No. 109-171 (adding Social Security Act, § 1886(d)(4)(D); 42 U.S.C. § 1395ww(d)(4)(D)), provided for a quality adjustment in DRG payments for certain hospital-acquired conditions.

[8] Social Security Act, § 1886(d)(4)(D)(iv); Fiscal Year (FY) 2008 Final Inpatient Prospective Payment Systems (IPPS) Rule, 72 Fed. Reg. 47130, 47202 (Aug. 22, 2007).

[9] Social Security Act, § 1886(d)(4)(D)(i); FY 2009 Final IPPS Rule, 73 Fed. Reg. 48434, 48471—48472 (Aug. 19, 2008).

on the presence of a complication or comorbidity.[10] Beginning October 1, 2007, each medical diagnosis (ICD-9-CM) code[11] submitted must include a new indicator designating whether the condition is present on admission (POA).[12]

Determining the Incidence of Adverse Events in Hospitals

Research indicates that calculating the incidence of adverse events is a complex and difficult task and that no single method is likely to identify all adverse events.[13] Further, researchers often use different definitions and methods, making comparison of adverse event incidence rates problematic. Through a literature review, we identified the following prominent methods for identifying adverse events in hospitals:

Patient Survey or Interview. A number of studies have sought to identify adverse events by asking patients and their families whether they detected any problems during their hospital stays, typically through interviews or mail surveys. This information is considered most useful when patients or families are asked about events shortly after they occur. Disadvantages associated with patient surveys include low response rates, poor recollection by patients, and lack of understanding of adverse events or the expected course of treatment.

Administrative Data Screening. Automated programs can be used to review administrative data, such as payment claims and hospital discharge data, to identify possible adverse events. Using administrative data allows researchers to screen for adverse events among large numbers of hospitalizations. Prominent administrative data screening methods include:

- Patient Safety Indicators (PSI) Algorithms: AHRQ developed software programs to calculate PSIs using administrative data and distributes this software free of charge to hospitals and researchers. The software is based on a series of algorithms using data commonly available in administrative datasets, such as billing data. These

[10] 42 CFR § 412.10; Final FY 2008 IPPS Rule, 72 Fed. Reg. 47130, 47138 (Aug. 22, 2007).

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

[12] Social Security Act, § 1886(d)(4)(D)(iii).

[13] 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.

algorithms detect indicators (e.g., death in a low-risk patient) to help identify potential adverse events.

- Identification of POA Indicators: POA codes were added as a requirement for Medicare billing data in August 2007 to facilitate CMS's implementation of the new policy for nonpayment of certain hospital-acquired conditions. Hospitals include these indicators with each diagnosis code, allowing analysts to identify conditions that developed during the hospital stay.

Review of In-Hospital Incident Reports. Hospitals must measure, analyze, and track quality indicators, including adverse patient events, as a condition of participation for Medicare and Medicaid certification.[14] To accomplish this, hospital staff typically complete "in-house incident reports" when notable events occur. For example, a hospital may require staff to complete an incident report if a patient falls. Hospital managers can use information contained in incident reports to gain awareness of quality improvement needs and address substandard care. Although incident reports are likely a valuable source of information, research indicates that not all events are reported.

Medical Record Screening. Although it is not a complete medical record review, medical record screening can identify potential adverse events based on information in the medical record. One prominent screening tool, the Institute for Healthcare Improvement (IHI) Global Trigger Tool (GTT), uses a retrospective review of medical records to identify "triggers" that could signal patient harm.[15] The GTT also categorizes the level of harm using the NCC MERP patient harm scale. The purpose of the NCC MERP index is to track errors in a consistent, systematic manner.[16] IHI adapted the index for use as part of the GTT to classify harm associated with adverse events.

Medical Record Review. Medical record review is often considered the most definitive method for detecting adverse events because it can provide much detail about both the adverse event and the surrounding

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[14] 42 CFR § 482.21(a)(2).

[15] Some triggers are adverse events by definition. Additionally, reviewers may identify adverse events without a trigger and may find triggers that are not adverse events.

[16] NCC MERP, Press Release. "Medication Errors Council Revises and Expands Index for Categorizing Medication Errors: Definitions of Medication Errors Broadened," June 12, 2001. Available online at http://www.nccmerp.org/press/press2001-06-12.html#index. Accessed on October 14, 2008.

circumstances. For example, medical record reviews can provide information about the patient's condition prior to and following the event. However, researchers report that records often have incomplete descriptions and insufficient documentation.[17] Also, record reviews rely on the subjective judgment of the reviewer, and conditions caused by adverse events can be difficult to distinguish from preexisting or unpreventable conditions.

METHODOLOGY

Scope

In this report, we provide an estimated rate of adverse events for Medicare beneficiaries discharged from hospitals in two counties during a 1-week period in August 2008, as well as specific rates of incidence for adverse events included on NQF's and CMS's lists. To determine a meaningful rate of adverse events, we incorporated criteria developed by NQF, CMS, and NCC MERP. We included in our analysis all patient harm that occurred during the hospitalization, regardless of whether it was preventable. We conducted these activities during August–October 2008. For a detailed description of our methodology, see Appendix E.

Sample Selection

To determine adverse event incidence rates, we sampled Medicare hospital discharges within two counties in different States.[18] From each of the population of 24 hospitals in the two counties, we obtained lists of all Medicare-enrolled beneficiaries who were discharged during the week of August 10–16, 2008. From a combined list of 2,549 hospital discharges, we randomly selected a total of 310 Medicare hospitalizations. Unless otherwise noted, results in this report are projected to all eligible discharges from the 24 hospitals during the sampled week. We determined that 32 sample hospitalizations were ineligible for review, typically because the Medicare beneficiary was not an inpatient for at least 24 hours. A total of 278 sample hospitalizations met our criteria for review and are the focus of this report. Among the 278 Medicare beneficiaries in the sample, the average age was

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

[18] Because the Act stipulates that OIG shall not release facility-specific information, we do not name the counties in this report.

77 years, with a range of 24 to 102 years; and the average length of hospitalization was 6 days, with a range of 1 to 53 days.

Analysis

We conducted a two-stage review to identify adverse events. The first stage included five distinct screening processes designed to identify sampled hospitalizations that appeared likely to include an adverse event. The screening processes included:

- beneficiary interviews,
- administrative data screening using AHRQ's PSI program,
- analysis of POA indicators included in administrative billing data,
- reviews of hospital incident reports related to the hospitalization, and
- targeted medical record screening using the IHI GTT protocol.

For the second stage of review, we included only hospitalizations with potential adverse events flagged by one or more of these screening processes. This stage consisted of a full physician review of the medical record. The use of multiple screening processes allowed us to test the utility of various screening methods in preparation for future work to determine a national adverse events incidence rate. The screening processes also allowed us to reduce the number of hospitalizations requiring medical record review by a physician.

In the second stage of review, contracted physicians conducted an onsite medical review (183 hospitalizations were flagged for this stage of review). The medical review protocol included a review of the information from the five screening processes for the flagged hospitalizations and the full medical record. Physician reviewers completed a structured medical review protocol that required them to describe the adverse event, the documentation that led to their identification of the event, and the level of harm to the patient using the NCC MERP harm scale. We include in this report only adverse events identified or confirmed by the physician reviewers.

Based on the results of the physician medical record review, we calculated adverse event incidence rates as the proportion of Medicare beneficiaries with at least one qualifying adverse event. To calculate an overall adverse event incidence rate, we focused on the areas of interest outlined in the Act: serious adverse events that may have payment implications for Medicare or beneficiaries. Therefore, we calculated an

overall adverse event incidence rate to include events meeting any of the following criteria:

1. NQF's list of Serious Reportable Events, as the Act mandates;
2. CMS's list of hospital-acquired conditions; and
3. level of patient harm determined by physicians to have resulted in a prolonged hospital stay, permanent harm, life-sustaining intervention, or death (classified as F–I on the NCC MERP scale).

This overall adverse event incidence rate does not include events that physician reviewers identified as temporary harm events (classified as E-level of harm on the NCC MERP scale). 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 these temporary harm events, as well as separate rates for the NQF list, the CMS list, and the events classified as F-I on the NCC MERP scale.

We also analyzed administrative billing data for adverse events that were included on NQF's or CMS's list. We calculated the effect of adverse events on Medicare payment using CMS's MS-DRG Assignment with Medicare Code Editor V25. We did not calculate the effect on Medicare payment for adverse events not on the CMS or NQF lists.

Limitations

Findings from this study are limited to the particular geographic area and timeframe covered by our review and cannot be generalized to the Medicare population at large. Further, it is unlikely that our methodology identified all adverse events within our sample. The screening processes may have failed to flag adverse events and we included adverse events only when the medical record confirmed the event. In some cases, missing information in medical records, if available, may have identified additional instances of adverse events.

Quality Standards

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

FINDINGS

Fifteen percent of hospitalized Medicare beneficiaries in two selected counties experienced an adverse event during their hospital stays

Of the 278 Medicare beneficiaries in our sample, 41 experienced an adverse event during their hospital stays that met at least one of our criteria: events on NQF's list of Serious Reportable Events, events on CMS's list of hospital-acquired conditions, or events involving a prolonged hospital stay, permanent harm, life-sustaining intervention, or death (classified as F-I on the NCC MERP scale). This overall rate does not include events that cause only temporary harm to patients because we determined these events were not comparable to the more serious events included in the rate.

After applying statistical methods, we project an estimated 15 percent adverse event incidence rate for the two counties (see Appendix F for confidence intervals). Six of these forty-one hospital patients experienced multiple adverse events, for a total of 51 adverse events. Table 2 lists the number of events, number of affected Medicare beneficiaries, and incidence rate for each of the three criteria.

Table 2: Incidence of Adverse Events Among Medicare Beneficiaries in Two Selected Counties

	Sample		Projected
Category of Events	Number of Identified Events	Number of Medicare Beneficiaries	Percentage of Medicare Beneficiaries
NQF Serious Reportable Events	3	2	0.7%
CMS Hospital-Acquired Conditions	11	10	3.7%
NCC MERP F-I Level Events	43	36	13.2%
(Overlapping Events)*	(6)	(7)	(2.6%)
Total	**51**	**41**	**15.0%**

Source: OIG analysis of 278 Medicare beneficiary hospitalizations in two selected counties, 2008.

*Some adverse events met more than one criterion and overlap the three categories.

We grouped the 51 adverse events into four broad categories: complications associated with surgery or other hospital procedures (43 percent), hospital-acquired infections (35 percent), medication-related events (12 percent), and events related to patient care (10 percent). Table 3 lists the 51 adverse events by these four clinical

categories. For a list of all adverse events with more complete definitions and the associated level of harm, see Appendix G.

Table 3: Adverse Events Identified Among Hospitalized Medicare Beneficiaries in Two Selected Counties by Type (n = 51)

Types of Adverse Events	Adverse Events and Percentage of Total Events
Events Related to Surgery or Other Procedures	22 (43%)
Excessive bleeding following surgery or procedure	4
Respiratory complications related to surgery or procedure	4
Postoperative ileus	4
Cardiac complications related to surgery or procedure	3
Hypotension/blood loss	3
Blood clots and other occlusions related to surgery or procedure	2
Post colostomy bowel obstruction	1
Premature extubation causing respiratory failure	1
Hospital-Acquired Infections	18 (35%)
Urinary tract infection associated with Foley catheter	6
Surgical infection	3
Respiratory infection (not ventilator associated)	3
Central line infection	2
Ventilator-associated pneumonia	2
Gastrointestinal infection	1
Sepsis as result of delay in performing surgery	1
Events Related to Medication	6 (12%)
Medication-related hypotension	2
Medication-related delirium	1
Medication-related gastrointestinal bleed	1
Kidney damage because of use of contrast	1
Medication-related acute renal insufficiency	1
Events Related to Patient Care	5 (10%)
Stage III pressure ulcer	2
Stroke and resulting paralysis related to hypoglycemia	1
Hypoglycemic coma	1
Intravenous volume overload	1

Source: OIG analysis of 278 Medicare beneficiary hospitalizations in two selected counties, 2008.

Seven of the fifty-one adverse events in our sample were "cascade" events wherein an initial adverse event caused a series of additional, related events for the same patient. Our analysis grouped cascade events together into one adverse event. These cascade events were some of the most serious adverse events identified, with six of the seven cascade events identified resulting in life-sustaining intervention, serious disability or death. Six of the seven cascade events began as the

result of postsurgical complications. For example, one cascade event involved a patient undergoing surgery and developing a bowel obstruction postoperatively, which resulted in hypotension, excessive bleeding, and ultimately required both a blood transfusion and corrective surgery. Two of the postoperative cascades led to patient death; for example, one beneficiary experienced a series of postoperative events including renal and respiratory failure, and subsequently died of a heart attack.

Fewer than 1 percent of Medicare beneficiaries in two selected counties experienced an event on the National Quality Forum list of Serious Reportable Events

Two beneficiaries experienced an adverse event on the NQF list of Serious Reportable Events, and one of these beneficiaries experienced two events on the list. The three NQF events we identified involved two beneficiaries for an estimated incidence rate in the two counties of less than 1 percent (0.7 percent). Both of the beneficiaries developed Stage III pressure ulcers during their hospital stays. (Stage III pressure ulcers are defined as having both skin loss and damage to the tissue below the skin.[19]) In both cases, the pressure ulcers were classified by physician reviewers as constituting temporary harm because they did not prolong the hospital stay or cause permanent disability to the beneficiary.

One of these two patients had a second adverse event on NQF's list: serious patient disability resulting from poor glycemic control. NQF defines serious disability as loss of a body part, or disability or loss of bodily function lasting more than 7 days or still present at discharge.[20] In this case, the patient developed partial paralysis after experiencing a stroke associated with severe hypoglycemia. This same patient died as the result of another adverse event not on NQF's list: septic shock caused by a bacterial infection.

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[19] 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," February 2007. Available online at http://www.npuap.org/pr2.htm. Accessed on November 18, 2008.

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

One of the three adverse events on NQF's list resulted in a higher Medicare reimbursement. In this case, the Medicare beneficiary was a nursing home resident who developed a Stage III pressure ulcer during a 12-day hospital stay. Including the pressure ulcer on the list of billable diagnoses changed the MS-DRG from a class associated with lower-level complications or comorbidities to a class associated with major complications or comorbidities. We determined that this increased the Medicare reimbursement from $7,086 to $9,138, a difference of $2,052 or 29 percent.[21] In the other two cases, the patients' other complications or comorbidities increased reimbursement to the maximum allowed for the MS-DRG.

Four percent of Medicare beneficiaries in two selected counties experienced an event on CMS's list of hospital-acquired conditions; in one case, the condition resulted in a higher Medicare reimbursement

An estimated 3.7 percent of hospitalized Medicare beneficiaries in the two counties had an adverse event on CMS's list. We identified a total of 11 adverse events in our sample that are on CMS's list of hospital-acquired conditions; 1 beneficiary experienced 2 of these events, resulting in a total of 10 Medicare beneficiary hospitalizations with an adverse event. Six of the eleven adverse events were catheter-associated urinary tract infections and two were associated with vascular infections of a central line catheter. The remaining three adverse events on CMS's list were two Stage III pressure ulcers (the same events counted on NQF's list of Serious Reportable Events) and one case of poor glycemic control resulting in a hypoglycemic coma.

One of the eleven adverse events on CMS's list of hospital-acquired conditions resulted in higher Medicare reimbursement to the hospital. The adverse event on the CMS list that resulted in higher reimbursement is the same adverse event on the NQF list of Serious Reportable Events that resulted in a higher Medicare reimbursement. For the remaining 10 hospitalizations with adverse events on CMS's list, the hospital-acquired conditions did not lead to higher Medicare reimbursement because the beneficiaries' other conditions elevated their MS-DRG assignment to a class that included major complications or comorbidities.

[21] CMS implemented a new ICD-9 code for Stage III pressure ulcers, effective October 1, 2008. Because there was no diagnosis code specifying the condition at the time of this hospital stay, we calculated the cost difference using an analogous code (70703).

Hospitals did not always include diagnosis codes reflecting hospital-acquired conditions in claims for Medicare reimbursement. Of the 11 hospital-acquired conditions we identified in our sample from CMS's list, 7 conditions were not included in the billing data provided by hospitals.[22] Six of these seven cases involved catheter-associated urinary tract infections and the seventh involved poor glycemic control. The exclusion of the diagnosis code for urinary tract infections could result in Medicare paying for associated care without recognizing that a hospital-acquired infection occurred. When a catheter-associated urinary tract infection is acquired in the hospital and included on the bill to Medicare, CMS excludes both the catheter-associated urinary tract infection code and certain associated infection codes in calculating the MS-DRG. However, when the hospital does not include the catheter-associated urinary tract infection code, the remaining associated infection codes may still be included in the calculation and could result in higher reimbursement. Of the six hospitalizations in which the hospitals omitted the catheter-associated urinary tract infection code from the billing data, two hospitalizations included these additional codes that could increase reimbursement.

Thirteen percent of Medicare beneficiaries in two selected counties experienced adverse events classified as F-I on the NCC MERP harm scale

Based on our medical review, 43 Medicare beneficiaries in two selected counties (13.2 percent) experienced adverse events classified in the four most serious harm categories on the NCC MERP index. For a number of patients, the same type of adverse event, such as infection or medication-related events resulted in a different level of harm depending upon such factors as intervention and the condition of the patient. Table 4 on the next page lists the adverse events by level of harm, using the NCC MERP scale of patient harm.

Table 4: Adverse Events Classified as F-I on the NCC MERP Index of Patient Harm (n = 43)

Category	Description	Adverse Events
F	Temporary harm, requiring a prolonged hospital stay	28
G	Permanent harm	4
H	Life-sustaining intervention required	8
I	Contributing to death	3

Source: OIG analysis of 278 Medicare beneficiary hospitalizations in two selected counties, 2008.

[22] We requested billing data directly from the hospitals within a week of discharge.

Identified adverse events illustrate differences in the lists and criteria that define adverse events

Differences in the criteria used by various entities to define adverse events can present a challenge in determining an adverse event incidence rate. The following two examples of adverse events identified in our review illustrate these differences. These examples underscore the differences in the definitions used in the three sets of criteria that make up our overall rate of adverse events: NQF Serious Reportable Events, CMS hospital-acquired conditions, and events classified as F-I on the NCC MERP patient harm scale.

NQF's list of Serious Reportable Events and CMS's list of hospital-acquired conditions often address the same adverse event but define the event differently. As an example, both lists cite poor glycemic control as a category of adverse event. In our sample of hospitalizations, we identified two adverse events that were manifestations of poor glycemic control and resulted in serious patient harm; one event is represented on NQF's list and one on CMS's list. Both adverse events represented serious harm, but they do not count on both lists because of differences in the definition of adverse events by NQF and CMS. Generally speaking, manifestations of poor glycemic control are defined on NQF's list by the severity of harm and on CMS's list by the specific type of condition.

NQF's list includes as a reportable event patient death or serious disability associated with hypoglycemia, the onset of which occurs during care at the health care facility. In the case that met this definition, the patient experienced severe hypoglycemia to the point of being near respiratory arrest and resulting in a stroke with permanent partial paralysis on one side of the body. Our physician reviewers classified this event as "G-level" harm on the NCC MERP scale, but it did not meet CMS's definition of a hospital-acquired condition because the severe hypoglycemia did not lead to a coma (the specific condition related to hypoglycemia within CMS's category for poor glycemic control).

The second sample case met CMS's definition because the patient's severe hypoglycemia resulted in a hypoglycemic coma. In this case, a patient with hypoglycemia became nonresponsive and fell into a coma. The coma required life-sustaining intervention to correct, therefore registering as "H-level" harm on the NCC MERP scale. However,

because the patient did not die or become seriously disabled, the case did not meet NQF's criteria for a serious reportable event.

Five beneficiaries had adverse events that resulted in permanent disability or death that were not on the National Quality Forum list of Serious Reportable Events. The NCC MERP patient harm scale classifies adverse events by level of patient harm rather than by the type of adverse event, with categories for permanent harm and death. NQF's list focuses largely on serious patient disability or patient death, but the disability or death is reportable only if it is the result of specific events. In addition to the two patients previously noted who experienced events on NQF's list, two other beneficiaries experienced adverse events that resulted in death and three more experienced adverse events that resulted in permanent disability. In one of these cases, the patient experienced a series of adverse events following a decision to delay surgery and died of sepsis after 51 days in the hospital. In another case, the patient died as the result of a heart attack following surgery. The remaining three patients all experienced surgical or postsurgical complications that resulted in permanent disability. For each of the five adverse events (all of which are included in our overall rate), the patients incurred serious harm but the contributing adverse event was not on NQF's list or CMS's list.

An additional 15 percent of Medicare beneficiaries in two selected counties experienced events during their hospital stays that resulted in temporary harm

In addition to the adverse events previously discussed, another 43 Medicare beneficiaries (15.2 percent) experienced events classified on the NCC MERP scale as E-level harm, defined as temporary harm requiring medical intervention (52 events). Also, 16 of the 41 beneficiaries who experienced a more serious adverse event in our overall rate also experienced a temporary harm event (17 events). In consultation with physician reviewers, we determined that these temporary events were not comparable to the more serious adverse events included in our overall adverse event rate.

The 69 events classified as temporary harm represent a wide array of events, from swelling at a treatment site to low-level infections (see Table 5). In some cases, the events resulted from standard medical treatment that caused an undesirable outcome in the patient, such as an allergic reaction to medication. These events are of interest to hospitals and others seeking to improve patient safety because they are

potential indicators of patient care problems and/or systems improvement opportunities. Although many cases of temporary harm represent fairly minor occurrences, others were classified as E-level harm because the patients were in the hospital for lengthy periods as a result of other, more serious, diagnoses, allowing hospitals to address the temporary harm prior to discharge. For a list of all temporary harm events with more complete descriptions, see Appendix G.

Table 5: Additional Temporary Harm Events Identified Among Hospitalized Medicare Beneficiaries in Two Selected Counties by Type (n = 69)

Types of Adverse Events	Adverse Events and Percentage of Events
Events Related to Medication	29 (42%)
Medication-related change in mental state	10
Medication-related skin problems	8
Other medication-related problems	7
Medication-related hypotension	4
Events Related to Skin Care	13 (20%)
Stage I or II pressure ulcer	10
Skin tear, abrasion, or other breakdown	3
Events Related to Surgery and Other Procedures	13 (19%)
Postoperative hypotension	4
Abnormal bleeding following surgery or procedure	3
Respiratory complications related to surgery or procedure	2
Complications related to insertion of endotracheal tube	1
Swelling developed at site of central line insertion	1
Postoperative urinary retention	1
Occlusion of blood supply during procedure	1
Events Related to Glycemic Control	4 (7%)
Episodes of hypoglycemia	3
Acute nonresponsive episode (not a coma)	1
Events Related to Intravenous Fluids	5 (7%)
Intravenous volume overload	3
Intravenous infiltrate	2
Hospital-Acquired Infections	2 (3%)
Gastrointestinal infection	2
Other	3 (4%)
Nonmedication allergic reaction	2
Fall leading to skin abrasions	1

Source: OIG analysis of 278 Medicare beneficiary hospitalizations in two selected counties, 2008.

In a number of cases, physician reviewers indicated that these temporary harm events could have developed into more serious adverse events with a greater degree of harm without timely intervention. For example, we identified 11 Stage I or Stage II pressure ulcers in our sample. These early stage ulcers can escalate quickly to Stage III or Stage IV without additional medical attention.[23] As another example, one sample Medicare beneficiary experienced a temporary blood vessel blockage in a leg following surgery. Clinical staff identified the problem after discovering that the leg was cool to the touch and restored the blood supply. Our physician reviewers indicated that, had the problem not been addressed, the lack of blood supply would likely have led to gangrene and amputation. Also, if episodes of severe hypoglycemia are closely monitored and addressed quickly, subsequent strokes and other serious complications may be avoided. Finally, our review found three events of E-level Clostridium difficile (C-diff), a highly contagious and potentially dangerous condition of interest to health officials. (C-diff was included on CMS's list of proposed hospital-acquired conditions in April 2008.) We included only one of the three cases of C-diff in our adverse event rate. In the other two cases of C-diff, clinical staff identified the problem in earlier stages and treated the patient without increased hospitalization.

The most common temporary harm events we identified were related to medication. The harm associated with these events was most often changes in the patient's mental status (such as confusion); hypotension; and skin reactions, such as rashes and hives. The most common interventions to address these problems were to stop giving or to change the medication.

[23] J.L. Zeller, C. Lynm, R.M. Glass, "Pressure Ulcers," Journal of the American Medical Association, 296(8), August 23/30, 2006, p. 1020. Available online at http://jama.ama-assn.org/cgi/reprint/296/8/1020.pdf. Accessed on November 18, 2008.

CONCLUSION

The Act requires that OIG report to Congress regarding harm caused in health care settings. This study is one of a series of OIG studies designed to meet the requirements of the Act and provides an estimated adverse events incidence rate among hospitalized Medicare beneficiaries in two selected counties.

We found that 15 percent of Medicare beneficiaries in our sample experienced an adverse event during their hospital stays, few of which were NQF Serious Reportable Events or CMS hospital-acquired conditions. Further, of the 11 adverse events on CMS's list of hospital-acquired conditions and the 3 adverse events on NQF's list of Serious Reportable Events, only 1 resulted in higher Medicare reimbursement to the hospital. We also found that another 15 percent of Medicare beneficiaries experienced events that caused temporary harm that, while not comparable to the more serious adverse events included in our overall rate, may reflect patient care problems and learning opportunities.

Although these results are not nationally representative, the extent of adverse events and temporary harm found in this case study substantiates concerns about the incidence of adverse events in hospitals and the importance of safety initiatives to reduce occurrences. Our analysis also calls attention to the difficulty of determining what events should be considered in an adverse event incidence rate and how those events should be identified and defined. Focusing our review on a limited geographic area (two counties) allowed OIG to learn about various methods for identifying adverse events in hospitals. OIG is continuing this work through 2009 and is currently expanding our study of incidence to provide a national estimate of adverse events among hospitalized Medicare beneficiaries.

The Act also directs OIG to make recommendations for such legislation and administrative action as OIG determines is appropriate. The Act specifically authorized funding to continue through calendar year 2009 and OIG will devote this funding to additional studies involving adverse events. Future reports in this series will include recommendations as appropriate.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

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

AHRQ commented that the report was methodologically sound and well-written and indicated that it had no recommendations for any modifications to the report.

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

CMS reiterated its policies to encourage the prevention of adverse events, including quality measurement and reporting, financial incentives, and program oversight. Regarding financial incentives, CMS outlined the provision to deny payment for care associated with hospital-acquired conditions, indicating that OIG identification of hospital-acquired conditions and their effect on Medicare payment allowed CMS to gain a deeper understanding of the payment policy in practice.

CMS also offered a point of clarification regarding the discussion of one of the hospital-acquired conditions, catheter-associated urinary tract infection. We found that in two of six cases of catheter-associated urinary tract infections, hospitals omitted the code that identifies the hospital-acquired condition but submitted other associated infection codes that could result in higher reimbursement. CMS indicated that it is not clear whether the hospitals deliberately omitted the hospital-acquired condition code, which could allow the hospitals to avoid the payment penalty imposed by the hospital-acquired condition payment provision. CMS recommended further evaluation of this issue in OIG's subsequent study to estimate the national incidence of adverse events. OIG agrees that further evaluation is warranted and will address this issue in future work in this series.

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

APPENDIX ~ A

Tax Relief and Health Care Act of 2006[24]

P.L. No. 109-432

DIVISION B – MEDICARE AND OTHER HEALTH PROVISIONS
TITLE II—MEDICARE BENEFICIARY PROTECTIONS
SEC 203 OIG STUDY OF NEVER EVENTS

(a) Study.—

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

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

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

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

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

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

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

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

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

[24] The Tax Relief and Health Care Act of 2006, P.L. No. 109-432 § 203.

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

Glossary of Selected Terms

General Terms[25]

Adverse event—Harm caused by medical care. Identifying adverse events does not imply an error, negligence, or poor quality of care. It does indicate that the care resulted in an undesirable clinical outcome and that the clinical outcome is not related to an underlying disease.

Cascade—An adverse event wherein one event led causally to another.

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

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

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

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

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

Temporary harm event—Event classified as the lowest level of patient harm on the National Coordinating Council for Medication Errors Reporting Prevention Index for Categorizing Errors. This level of harm is identified as an adverse event that may have contributed to or resulted in temporary harm to the patient and required intervention.

[25] Sources: Definitions derived from a variety of sources including L.T. Kohn, J.M. Corrigan, and M.S. Donaldson, Eds, "To Err is Human: Building a Safer Health System," A Report of the Committee on Quality of Health Care in America, Institute of Medicine, Washington, DC, National Academy Press, 1999; R.M. Wachter, "Understanding Patient Safety," McGraw–Hill, 2008; and the glossary of the Agency for Healthcare Research and Quality Patient Safety Network. Available online at http://www.psnet.ahrq.gov/glossary.aspx. Accessed on October 10, 2008.

Clinical Terms[26]

Acidosis—An abnormal condition of reduced alkalinity of the blood and tissues that is marked by sickly sweet breath, headache, nausea and vomiting, and visual disturbances and is usually a result of excessive acid production.

Blood clot—A coagulated mass produced by clotting of blood.

Coronary artery bypass graft (CABG)—Heart bypass surgery performed to route blood flow around clogged arteries supplying the heart.

Central line infection—An infection of the intravenous (IV) line that is inserted into a large vein (as the superior vena cava) typically in the neck or near the heart for therapeutic or diagnostic purposes (as to administer medicines or fluids or withdraw blood).

Deep vein thrombosis (DVT)—A condition marked by the formation of a thrombus within a deep vein (as of the leg or pelvis) that may be asymptomatic or be accompanied by symptoms (as swelling and pain) and that is potentially life threatening if dislodgment of the thrombus results in pulmonary embolism.

Hemiparesis—Muscular weakness or partial paralysis restricted to one side of the body.

Hypertension—Abnormally high arterial blood pressure that is chiefly of unknown cause but may be attributable to a preexisting condition (as a renal or endocrine disorder), that typically results in a thickening and inelasticity of arterial walls and hypertrophy of the left heart ventricle, and that is a risk factor for various pathological conditions or events (such as heart attack, heart failure, stroke, end-stage renal disease, or retinal hemorrhage).

Hypotension—Abnormally low pressure of the blood; also called low blood pressure.

Hypoglycemia—Abnormal decrease of sugar in the blood.

Ileus—An obstruction of the bowel; specifically, a condition that is commonly marked by a painful distended abdomen, vomiting of dark or

[26] National Institutes of Health, U.S. National Library of Medicine, "Medline Plus Medical Dictionary," updated February 4, 2003. Available online at http://www.nlm.nih.gov/medlineplus/mplusdictionary.html. Accessed on November 10, 2008.

fecal matter, toxemia, and dehydration and that results when the intestinal contents back up because peristalsis fails although the lumen is not occluded.

Pressure ulcer—An ulceration of tissue deprived of adequate blood supply by prolonged pressure; called also decubitus, decubitus ulcer, and pressure sore.

Pulmonary edema—Abnormal accumulation of fluid in the lungs.

Sepsis—A systemic response typically to a serious, usually localized infection (as of the abdomen or lungs) especially of bacterial origin that is usually marked by abnormal body temperature and white blood cell count, tachycardia, and tachypnea; specifically, systemic inflammatory response syndrome induced by a documented infection.

Urinary tract infection (UTI)—An infection of the tract through which urine passes and which consists of the renal tubules and renal pelvis of the kidney, the ureters, the bladder, and the urethra.

Ventilator associated pneumonia (VAP)—A disease of the lungs that is characterized especially by inflammation and consolidation of lung tissue followed by resolution; is accompanied by fever, chills, cough, and difficulty in breathing; and is caused chiefly by infection that enters the lungs through a ventilator.

APPENDIX ~ C

National Quality Forum Serious Reportable Events[27]

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

Table C1: The National Quality Forum List of Serious Reportable Events

Surgical Events	
A.	Surgery performed on the wrong body part
B.	Surgery performed on the wrong patient
C.	Wrong surgical procedure performed on a patient
D.	Unintended retention of foreign object in a patient after surgery or procedure
E.	Intraoperative or immediately postoperative death
Product or Device Events	
A.	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility
B.	Patient death or serious disability associated with use or function of a device in patient care in which the device is used or functions other than as intended
C.	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility
Patient Protection Events	
A.	Infant discharged to the wrong person
B.	Patient death or serious disability associated with patient elopement
C.	Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility
Care Management Events	
A.	Patient death or serious disability associated with a medication error
B.	Patient death or serious disability associated with a hemolytic reaction 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 being cared for in a health care facility
D.	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while patient is 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 fall while cared for in a health care facility
E.	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility
Criminal Events	
A.	Care provided by someone impersonating a health care provider
B.	Abduction of a patient of any age
C.	Sexual assault on a patient within or on the grounds of a health care facility
D.	Death or significant injury resulting from a physical assault that occurs within or on the grounds of the facility

[27] NQF, "Serious Reportable Events in Healthcare 2006 Update: A Consensus Report," National Quality Forum, Washington, DC, 2007, p. 7. Available online at http://www.qualityforum.org/pdf/reports/sre/txsrepublic.pdf. Accessed on October 10, 2008.

APPENDIX ~ D

Centers for Medicare & Medicaid Services Categories of Hospital-Acquired Conditions

The Centers for Medicare & Medicaid Services (CMS) list of hospital-acquired conditions is divided into 10 categories. Effective October 1, 2008, CMS no longer pays a higher reimbursement for hospitalizations complicated by these categories of conditions.

Table D1: The Centers for Medicare & Medicaid Services List of Hospital-Acquired 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
A. Total knee replacement
B. Hip replacement
10. Surgical site infection
A. Mediastinitis after coronary artery bypass graft (CABG)
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. Laprascopic 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 ~ E

Detailed Methodology

Geographic Area Selection

For this case study, we selected hospitals in two counties. We chose the narrow geographic scope to minimize logistical difficulties. In determining the geographic areas for our case study, we considered a number of factors. We chose one county from each of two States to provide greater diversity in our population of hospitalizations. We selected counties that (1) had a sufficient number of hospitals so that no single hospital would bear a significant burden in meeting our data collection requests; and (2) had similar demographics, such as population, percentage of residents aged 65 and older, per capita income, and number of hospitals. The selected counties each have 12 acute care hospitals, all of which were included in our review. The 24 hospitals provided diversity in key characteristics, such as a range of bed sizes from 78 to 780; an ownership mix including nonprofit, public, and private; and both large networks and single-ownership facilities.

Sample Selection

From each of the 24 hospitals in the two-county area,[28] we obtained lists of all Medicare-enrolled beneficiaries who were discharged during the week of August 10–16, 2008. From a combined list of 2,549 discharges, we randomly selected a total of 310 (300 from one stratum and 10 from another stratum). Unless otherwise noted, results in this report are projected to all eligible discharges from the 24 hospitals in the two counties during this timeframe. Hospitalizations for individual patients were eligible for selection if they met the following criteria:

- the patient was enrolled in Medicare;
- the patient was an inpatient for at least 24 hours;
- the patient was treated as an acute care inpatient (excluding inpatients in psychiatric services, rehabilitation-only services, or long term care); and
- the patient was discharged during our target week: August 10–16, 2008.

We initially selected 300 Medicare hospitalizations using a simple random sampling technique. However, one hospital initially provided

[28] Because the Tax Relief and Healthcare Act of 2006 stipulates that OIG shall not release facility-specific information, we do not name the counties in this report.

us with an incomplete list of discharges that affected our sampling frame. We then obtained a complete list from this hospital, which resulted in an additional stratum of 46 discharges, from which we randomly selected 10.

From among the 300 hospitalizations initially selected, we excluded a total of 32 that were ineligible for review because they did not meet the criteria listed above. Following this, 278 hospitalizations remained in the sample for review. Among the 278 Medicare beneficiaries in the sample hospitalizations, the average age was 77 years with a range of 24 to 102 years, and the average length of hospitalization was 6 days with a range of 1 to 53 days. A summary of the sampling design is provided in Table E1.

Table E1: Sample Selection

	Stratum 1	Stratum 2	Total
Sampling Frame	2,503	46	2,549
Original Sample	300	10	310
Ineligible	32	0	32
Final Sample	268	10	278

Source: Office of Inspector General analysis of 278 Medicare beneficiary hospitalizations in two selected counties, 2008.

Screening for Potential Adverse Events

We conducted a two-stage review to identify adverse events. The first stage included five distinct screening processes designed to identify hospitalizations that appeared likely to include an adverse event. The screening processes included:

- beneficiary interviews,
- administrative data screening using the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicator (PSI) program,
- analysis of present on admission (POA) indicators included in administrative billing data,
- reviews of hospital incident reports related to the hospitalization, and
- targeted medical record screening using the Institute for Healthcare Improvement (IHI) Global Trigger Tool (GTT) protocol.

The use of multiple screening processes allowed us to test the feasibility and effectiveness of various methods that we are considering for use in future work. The screening processes also allowed us to reduce the number of hospitalizations requiring a full physician medical review.

Beneficiary Interviews. For each selected hospitalization, we attempted to conduct structured telephone interviews with the patient or a designated representative to learn about the medical care experienced during the hospital stay. The interview protocol was designed to determine whether patients experienced any episodes that might be considered an adverse event while in the hospital and included questions about medication, procedures, infections, and other events on the National Quality Forum (NQF) and the Centers for Medicare & Medicaid Services (CMS) lists. We completed interviews for patients associated with 79 percent of sampled hospitalizations (220 of 278) and identified 42 hospitalizations for the second stage of review.

Analysis of Patient Safety Indicators. Using administrative billing data requested directly from the hospitals, we applied AHRQ's PSI program to our sample hospitalizations. The PSI program includes algorithms that calculate 27 quality-of-care indicators, 20 of which are provider-level indicators that specify that an adverse event may have occurred. We identified a total of 13 PSIs related to 11 patients and flagged these hospitalizations for the second stage of review.

Analysis of Present on Admission Indicators. Using the same administrative billing data, we used POA indicators to identify claims that included diagnoses that were coded as not part of the patient's condition upon admission. A relatively new requirement for Medicare Part A claims, POA indicator codes require hospitals to make a deliberate clinical distinction about whether diagnoses are present at the time of admission. POA indicators identified 112 hospitalizations that had at least one diagnosis not present at the time of admission. We included these 112 hospitalizations in the second stage of review.

Review of In-Hospital Incident Reports. We requested that hospitals provide any internal incident reports associated with our sample hospitalizations. We received 47 incident reports relating to 36 sample hospitalizations from this request. These 36 hospitalizations were flagged for the second stage of review.

Targeted Medical Record Screening. Contracted registered nurses conducted a preliminary review of medical records onsite at each hospital to identify potential adverse events. They followed IHI's GTT

protocol, which allows reviewers to identify "triggers" in the medical record that may be indicative of adverse events and then explore the record further to determine whether an event occurred and its resulting level of harm. This protocol relies on a systematic method of reviewing medical records that takes less than 20 minutes per chart. Targeted medical reviews were completed for all sampled hospitalizations and identified 122 hospitalizations for inclusion in the second stage of review.

Flagged Hospitalizations. Based on the combined results of these screening processes, we identified 183 hospitalizations for the second stage of reviews: a review of the full medical record by a physician. The five screening processes flagged many of the same hospitalizations.

Medical Record Review of Flagged Hospitalizations

Three contracted physicians conducted an onsite medical record review of the 183 hospitalizations flagged for potential adverse events. The medical review protocol included a review of the results of the screening processes that flagged the case for review (medical record screening, beneficiary interview, hospital incident report, and/or administrative data), and then a review of the full medical record. Physician reviewers completed a structured medical review protocol that required them to describe the adverse event, the documentation that led to their identification of the event, and the level of harm to the patient using the National Coordination Council for Medication Errors Reporting and Prevention (NCC MERP) Index for Categorizing Medication Errors.

Adverse Event Criteria

To determine a meaningful overall rate of adverse events among hospitalized Medicare beneficiaries, this study incorporates criteria developed by NQF, CMS, and NCC MERP. We included in our analysis all patient harm incurred during the hospitalization, regardless of whether it was considered preventable. We did not include patient harm that occurred prior to entering the hospital.

Data Analysis

Physician Review of Findings. Following the onsite medical record review, we verified the adverse event findings with all physician reviewers to ensure that cases were determined consistently and to ensure consensus about complex cases. This process resulted in some changes to our initial adverse event findings. Most changes were exclusions because the identified event did not meet our study definition, most frequently because the adverse event was related to a

prior admission. We made additional changes because the physicians determined that the harm was part of the normal progression of the disease or a series of events was redefined into a single "cascade" event. Physician reviewers reached consensus for all hospitalizations.

Statistical Analysis. Using information from the physician medical record review, we calculated adverse events incidence rates as the proportion of Medicare beneficiaries with at least one qualifying adverse event. We calculated an overall adverse event incidence rate to include events meeting any of the following criteria:

1. NQF's list of Serious Reportable Events, as the Act mandates;
2. CMS's list of hospital-acquired conditions; and
3. the level of patient harm determined by physicians to have resulted in a prolonged hospital stay, permanent harm, life-sustaining intervention, or death (classified as F–I on the NCC MERP scale).

This overall adverse event incidence rate does not include events that physician reviewers identified as temporary harm events (classified as E-level of harm on the NCC MERP scale). 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 these temporary harm events, as well as separate rates for the NQF list, the CMS list, and the events classified as F-I on the NCC MERP scale.

These rates were projected to all hospitalizations meeting our selection criteria in the two counties. Projections were calculated in SUDAAN using a logit transformation with a 95-percent confidence interval.

Analysis of Medicare Payments. Following physician review and consensus, we analyzed administrative billing data for adverse events that were included on NQF's or CMS's lists. We calculated the anticipated Medicare payment amount and the amount that Medicare would have reimbursed for the hospitalization if the adverse event had not occurred. Medicare payment amounts were calculated using CMS's MS-DRG Assignment with Medicare Code Editor V25 and Inpatient Prospective Payment System pricing software. These amounts were compared to determine any cost difference. We did not calculate the effect on Medicare payment for adverse events we identified that were not on the CMS or NQF lists.

APPENDIX ~ F

Estimates and Confidence Intervals

Table F1 provides estimates and 95-percent confidence intervals for key statistics based on analysis of 278 sample hospitalizations. Some of the statistics in Table F1 represent results for subgroups within our sample that we do not reference in the text of the report.

Table F1: Estimates and Confidence Intervals for Key Statistics

		95-Percent Confidence Interval	
	Estimate	**Lower Bound**	**Upper Bound**
Percentage of Eligible Hospitalizations (n = 278)			
Overall Rate of Adverse Events	15.00%	11.43%	19.44%
NQF Rate	0.73%	0.20%	2.67%
CMS Rate	3.66%	2.05%	6.45%
F through I Rate	13.17%	9.82%	17.43%
Additional E-Level Harm Not in Overall Rate	15.22%	11.65%	19.65%
All E Rate	17.05%	13.27%	21.64%
Multiple Event Rate	8.78%	6.07%	12.50%
Percentage of Hospitalizations With an Adverse Event (n = 42)			
NQF Rate	4.88%	1.32%	16.41%
CMS Rate	24.39%	14.13%	38.74%
F through I Rate	87.81%	74.85%	94.57%
Highest Harm Level is E	12.20%	5.43%	25.15%
Highest Harm Level is F	54.76%	40.54%	68.24%
Highest Harm Level is G	7.32%	2.54%	19.33%
Highest Harm Level is H	19.51%	10.46%	33.46%
Highest Harm Level is I	7.32%	2.54%	19.33%
Multiple Event Rate	43.90%	30.41%	58.36%
Percentage of Adverse Events (n = 52)			
NQF Rate	5.88%	1.54%	19.67%
CMS Rate	21.57%	13.16%	33.29%
F through I Rate	84.31%	73.39%	91.29%
Harm Level is E	15.67%	8.71%	26.62%
Harm Level is F	54.90%	42.13%	67.06%
Harm Level is G	7.84%	3.33%	17.37%
Harm Level is H	15.69%	8.31%	27.63%
Harm Level is I	5.88%	2.24%	14.56%
Cascade Rate	13.73%	7.71%	23.24%

Source: Office of Inspector General analysis and medical review of 278 Medicare beneficiaries hospitalized in two selected counties, 2008.

APPENDIX ~ G

Tables of All Adverse Events and Temporary Harm Events Identified in Sample

Table G1 lists information about all adverse events that made up our overall rate of 15 percent of hospitalized Medicare beneficiaries (51 adverse events). Table G2 lists information about all additional temporary harm events we identified (69 events).

Table G1: Adverse Events Identified Among Medicare Beneficiaries Hospitalized in Two Selected Counties by Type, Harm Level, and Whether the Events are National Quality Forum (NQF) Serious Reportable Events or Centers for Medicare & Medicaid Services (CMS) Hospital-Acquired Conditions (n = 51)

Adverse Event	Harm Level	NQF List	CMS List
Events Related to Surgery or Other Procedures (22)			
Excessive bleeding following surgery or procedure (4)			
1. Right groin hematoma at puncture site following stent placement	F		
2. Wound site infection and hematoma following left knee arthroplasty	F		
3. Trauma and several days of bleeding caused by insertion of Foley catheter	F		
4. Cascade event in which a hematoma and a pseudoanurysm of the right femoral artery developed following interventional catheterization and stent placement	F		
Respiratory complications related to surgery or procedure (4)			
1. Acute respiratory failure following cardiac surgery	F		
2. Partial lung tissue collapse after surgical lung tissue excision	G		
3. Acute respiratory failure following percutaneous endoscopic gastric feeding tube placement	H		
4. Respiratory stridor following procedure	H		
Postoperative ileus (4)			
1. Significant ileus following partial colon resection	F		
2. Significant ileus following partial colon resection	F		
3. Significant ileus following partial colon resection	F		
4. Significant ileus following partial colon resection	F		
Cardiac complications related to surgery or procedure (3)			
1. Cascade event in which right coronary artery dissection and right ventricle laceration occurred during coronary angioplasty surgery	H		
2. Rapid atrial flutter	H		
3. Cascade event following aortic valve replacement characterized by myocardial infarction, respiratory failure, oliguric renal failure and cardiac arrest	I		
Hypotension/blood loss related to surgery or procedure (3)			
1. Hypotensive episode during hemodialysis treatment	F		
2. Postoperative hemodynamic instability	H		
3. Hypotensive episode during hemodialysis treatment	H		
Blood clots and other occlusions (2)			
1. Deep vein thrombosis of the subclavian vein following the insertion of an intravascular device	F		
2. Cascade event which included two declotting procedures for the arteriovenous fistula and a subsequent revision of the fistula	G		
Post colostomy bowel obstruction (1)			
Cascade event in which a small bowel obstruction along with hypotension and gastrointestinal bleeding resulted following a partial colon resection	G		
Premature extubation causing respiratory distress (1)			
Respiratory failure following premature extubation necessitating reintubation	H		

Table G1: Adverse Events Identified Among Medicare Beneficiaries Hospitalized in Two Selected Counties by Type, Harm Level, and Whether the Events are National Quality Forum (NQF) Serious Reportable Events or Centers for Medicare & Medicaid Services (CMS) Hospital-Acquired Conditions (n =51) (continued)

Adverse Event	Harm Level	NQF List	CMS List
Hospital-Acquired Infections (18)			
Urinary tract infection (6)			
1. Urinary tract infection (resistant pseudomonas) associated with a Foley catheter	E		X
2. Urinary tract infection (Proteus mirabilis) associated with a Foley catheter	E		X
3. Urinary tract infection (Klebsiella oxytoca) associated with Foley catheter	E		X
4. Urinary tract infection (Candida) associated with Foley catheter	E		X
5. Urinary tract infection (Morganella morganii) associated with Foley catheter	E		X
6. Urinary tract infection (enterococcus) associated with a Foley catheter	E		X
Surgical infection (3)			
1. Surgical site infection following procedure	F		
2. Prolonged fever following surgical procedure	F		
3. Cascade event in which postoperative persistent enterococcal bacteremia led to multiple complications including significant cardiovascular instability and respiratory failure leading to cardiac arrest	I		
Respiratory infection (not ventilator associated) (3)			
1. Postoperative lower respiratory infection	F		
2. Hospital-acquired pneumonia	F		
3. Hospital-acquired pneumonia	F		
Central line infection (2)			
1. Central line infection (Vancomycin-resistant enterococcus)	F		X
2. Central catheter line sepsis (Staphylococcus epidermidis)	F		X
Ventilator-associated pneumonia (2)			
1. Ventilator-associated MRSA (Methicillin-resistant Staphylococcus aureus) infection	F		
2. Ventilator-associated pneumonia	F		
Gastrointestinal infection (1)			
Gastrointestinal infection (Clostridium difficile) following antibiotic treatment	F		
Sepsis as result of delay in performing surgery (1)			
Cascade event in which septic shock led to respiratory failure, a sacral pressure ulcer, wound disruption, gangrene, bilateral pleural effusions requiring chest tube insertion, renal failure and ultimately a venous thrombo-embolism (deep vein thrombosis and pulmonary embolism)	I		
Events Related to Medication (6)			
Medication-related hypotension (2)			
1. Hypotensive episode while on pain medication (opioid)	F		
2. Hypotensive episode secondary to cardiac medication (β-blocker)	F		
Medication-related delirium (1)			
Delirium associated with medication (benzodiazepines)	F		
Medication-related gastrointestinal bleed (1)			
Gastrointestinal bleeding from a cecal ulcer on the large ascending colon associated with anti-coagulation medication	F		
Kidney damage associated with use of contrast (1)			
Kidney dysfunction associated with contrast media	F		
Medication-related acute renal insufficiency (1)			
Acute renal failure associated with dehydration secondary to colchicine induced diarrhea	F		
Events Related to Patient Care (5)			
Pressure ulcer (2)			
1. Stage III pressure ulcer	E	X	X
2. Stage III pressure ulcer	E	X	X
Stroke and resulting paralysis related to hypoglycemia (1)			
Stroke and permanent left hemiparesis associated with severe hypoglycemia	G	X	
Hypoglycemic coma (1)			
Temporary hypoglycemic coma secondary to insulin	H		X
Intravenous volume overload (1)			
Fluid overload that led to pulmonary edema	F		

Source: Office of Inspector General (OIG) analysis and medical review of 278 Medicare beneficiaries hospitalized in two selected counties, 2008.

Table G2: Temporary Harm Events, E-level on the National Coordinating Council for Medication Errors Reporting and Prevention Index for Categorizing Errors (NCC MERP) Patient Harm Scale, Identified Among Medicare Beneficiaries in Two Selected Counties by Type (n = 69)

Adverse Event
Events Related to Medication (29)
Medication-related change in mental state (10)
1. Hallucinations secondary to pain medication (opioid)
2. Delirium and combativeness secondary to pain medication (hydromorphone)
3. Delusions and psychosis secondary to pain medication (opioid)
4. Confusion secondary to pain medication (narcotics)
5. Confusion and combativeness secondary to medication (benzodiazepine)
6. Confusion secondary to medication (hydromorphone)
7. Confusion secondary to pain medication (opioid)
8. Confusion secondary to pain medication (opioid)
9. Change of mental status and slurred speech secondary to medication (butyrophenone)
10. Change of mental status secondary to medication (digoxin)
Medication-related skin problems (8)
1. Significant itching secondary to seizure medication
2. Significant itching secondary to medication (opioid)
3. Rash secondary to antibiotics (fluoroquinolone)
4. Significant itching at epidural anesthesia needle insertion site
5. Skin rash secondary to antibiotic treatment (fluoroquinolone)
6. Hives secondary to intravenous (IV) contrast
7. Global rash secondary to steroid treatment (corticosteroid)
8. Itching secondary to pain medication (opioid)
Other medication-related problems (7)
1. Urinary retention secondary to pain medication (opioid)
2. Leg weakness secondary to epidural anesthesia
3. Constipation secondary to pain medication (opioid)
4. Hematuria secondary to anticoagulation therapy (heparin)
5. Thrush (Candida) infection secondary to antibiotics
6. Significant white blood cell reduction secondary to antibiotics (glycopeptide)
7. Constipation secondary to pain medication (narcotics)
Medication-related hypotension (4)
1. Hypotension secondary to cardiac medication (β-blocker)
2. Hypotensive episode secondary to pain medication (opioid)
3. Hypotension secondary to medication (antiandrogen)
4. Hypotension and bradycardia secondary to multiple medications
Events Related to Skin Care (13)
Pressure ulcer (10)
1. Stage II pressure ulcer
2. Stage II pressure ulcer
3. Stage II pressure ulcer
4. Stage II pressure ulcer
5. Stage II pressure ulcer
6. Stage II pressure ulcer
7. Stage II pressure ulcer
8. Stage II pressure ulcer
9. Stage I pressure ulcer
10. Stage I pressure ulcer
Skin tear, abrasion or other breakdown (3)
1. Cascade event in which digoxin toxicity led to diarrhea and dehydration followed by a Stage I skin breakdown
2. Skin tear
3. Skin abrasion caused by goggles worn during procedure

Table G2: Temporary Harm Events, E-level on the National Coordinating Council for Medication Errors Reporting and Prevention Index for Categorizing Errors (NCC MERP) Patient Harm Scale, Identified Among Medicare Beneficiaries in Two Selected Counties by Type (n = 69) (continued)

Adverse Event
Events Related to Surgery and Other Procedures (13)
Postoperative hypotension (4)
1. Postoperative hypotension of indeterminate etiology
2. Transient hypotension following endovascular procedure
3. Hypotensive episode following an endovascular procedure
4. Postoperative hypovolemia
Abnormal bleeding following surgery or procedure (3)
1. Traumatic bleeding due to nastrogastric tube insertion
2. Excessive bleeding at epidural anesthesia needle insertion site
3. Swelling and hematoma at the surgical site
Respiratory complications related to surgery or procedure (2)
1. Respiratory distress and subcutaneous emphysema (air trapped in the subcutaneous layer of the skin)
2. Significant right plural effusion following aortic valve replacement surgery
Complications related to endotracheal tube (1)
Difficulty swallowing due to trauma incurred during insertion of endotracheal tube
Swelling developed at site of central line insertion (1)
Lymphedema developed around site of central line insertion point
Postoperative urinary retention (1)
Postoperative urinary retention
Occlusion of blood supply during procedure (1)
Transient occlusion of left lower extremity blood supply during endovascular procedure
Events Related to Glycemic Control (4)
Episodes of hypoglycemia (3)
1. Several episodes of hypoglycemia secondary to insulin
2. Several episodes of hypoglycemia secondary to insulin
3. Transient hypoglycemia secondary to insulin during a period of fasting for surgery
Acute nonresponsive episode related to hypoglycemia (1)
Hypoglycemic event that led to period of unresponsiveness
Events Related to Intravenous Fluids (5)
Intravenous volume overload (3)
1. Postoperative fluid overload
2. Fluid overload that led to exacerbation of chronic heart failure
3. Fluid volume overload that led to respiratory decompensation
Intravenous infiltrate (2)
1. Intravenous infiltrate resulting in pain and swelling
2. Significant local intravenous antibiotic infiltrate
Hospital-Acquired Infections (2)
Gastrointestinal infection (2)
1. Infection (Clostridium difficile) that developed following treatment for bacterial pneumonia
2. Infection (Clostridium difficile) that developed following antimicrobial treatment for enterococcal septicemia
Other (3)
Nonmedication allergic reaction (2)
1. Contact dermatitis
2. Allergic reaction to adhesive tape
Fall (1)
Fall occurring during the hospital stay

Source: OIG analysis and medical review of 278 Medicare beneficiaries hospitalized in two selected counties, 2008

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
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NOV 28 2008

TO: Director, Division of Office of Evaluation and Program Support
Office of Evaluation and Inspections, OIG

FROM: Deputy Ethics Counselor

SUBJECT: OEI-06-08-00220 Adverse Events in Hospitals: Case Study of Incidence Among Medicare Beneficiaries

On behalf of the Agency's Deputy Director, I want to thank your office for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled, OEI-06-08-00220 Adverse Events in Hospitals: Case Study of Incidence Among Medicare Beneficiaries. Our comments area s follows:

- The report is methodically sound and well written.
- AHRQ has no recommendations for any modifications for the above-cited report.

Please feel free to contact me should you have any questions concerning this matter.

Bruce Immerman

Agency Comments: Center for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: DEC 12 2008

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems
Acting Administrator

SUBJECT: Office of Inspector General's Draft Report: Adverse Events in Hospitals: Case Study of Incidence Among Medicare Beneficiaries in Two Selected Counties (OEI-06-08-00220)

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

The CMS has a number of tools within the statutory authorities of the Medicare program to encourage the prevention of adverse events, including quality measurement, financial incentives, public reporting of quality information, conditions of participation, and the Quality Improvement Organization (QIO) program. One of the financial incentive initiatives is the hospital-acquired conditions (HAC) provision. The statute requires that the selected HACs be high cost, high volume, or both; trigger a higher-paying Medicare Severity Diagnosis-Related Group (MS-DRG) when present as a secondary diagnosis; and be considered reasonably preventable through the application of evidence-based guidelines. Under the statutory authority for the HAC payment provision, beginning on October 1, 2008, CMS no longer assigns an inpatient hospital discharge to a higher paying MS-DRG if a selected HAC is not present on admission.

Implementing the HAC payment provision requires a deep understanding of the adverse events that could be selected as HACs and how those potential HACs fit with the statutory selection criteria. We appreciate your identification of 11 HACs, through medical record review, and that 1 of the 11 adverse events on CMS' list of hospital-acquired conditions resulted in higher Medicare reimbursement to the hospital. We were interested to review all of your findings and your medical record review allowed us to gain a deeper understanding of the HAC payment policy in practice.

Page 2 – Daniel R. Levinson

We offer one point of clarification regarding the discussion of one of our selected HACs: Catheter-Associated Urinary Tract Infection (UTI). CMS' recognition of Catheter-Associated UTI as an HAC is defined by ICD-9-CM code 996.64; however, CMS also will not pay for a series of additional related infection codes when 999.64 is coded as not present on admission (Table 1). Your report indicates that in two out of six Catheter-Associated UTI cases, the hospital did not submit ICD-9-CM code 996.64. It is not clear whether the hospital deliberately omitted the reporting of HAC code 996.64 while still reporting the other specific codes defining the nature of the infection. By omitting code 996.64 hospitals could avoid the payment penalty imposed by the HAC payment provision. We recommend that the OIG attend to the coding and reporting of Catheter-Associated UTI as you proceed with your next study to estimate the national incidence of adverse events.

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

Table 1: ICD-9-CM Codes Recognizing Catheter-Associated Urinary Tract Infections as an HAC

ICD-9-CM Code	**Descriptor**
996.64	Infection and inflammatory reaction due to indwelling urinary catheter
Also excludes the following from acting as a CC/MCC when 996.64 is coded as not present on admission:	
112.2	Candidiasis of other urogenital sites
590.10	Acute pyelonephritis without lesion of renal medullary necrosis
590.11	Acute pyelonephritis with lesion of renal medullary necrosis
590.2	Renal and perinephric abscess
590.3	Pyeloureteritis cystica
590.80	Pyeloureteritis unspecified
590.81	Pyelitis or pyeloureteritis in diseases classified elsewhere
595.0	Acute cystitis
597.0	Urethral abscess
599.0	Urinary tract infection, site not specified

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