Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

# ADVERSE EVENTS IN HOSPITALS: METHODS FOR IDENTIFYING EVENTS

## OBJECTIVE

To evaluate the usefulness of selected methods for identifying events that harm hospitalized Medicare beneficiaries.

## BACKGROUND

The term "adverse event" describes harm to a patient as a result of medical care or harm that occurs in a health care setting. The term "never events" refers to a specific list of serious events, such as surgery on the wrong patient, that the National Quality Forum deemed "should never occur in a healthcare setting." The Tax Relief and Health Care Act of 2006 (the Act) mandated that the Office of Inspector General (OIG) report to Congress about such events, including making recommendations about processes for identifying events. To meet the requirements of the Act, OIG published a series of reports in 2008 and will publish additional reports based on ongoing work.

In 2008, we conducted a case study to determine the incidence of adverse events (hereinafter referred to as events) by reviewing a random sample of 278 Medicare beneficiary hospitalizations selected from all Medicare discharges from acute care hospitals in two selected counties during a 1-week period in August 2008. Using a two-stage review process, the case study identified 120 events. The first stage consisted of using five selected methods to screen for events, including nurse reviews of medical records, interviews of Medicare beneficiaries, two types of billing data analysis, and reviews of internal hospital incident reports. Each time a screening method indicated the possibility that an event occurred during the hospitalization, we designated the possible event as a "flag." The second stage consisted of physician reviews of medical records for 183 of the 278 beneficiary hospitalizations—those with at least 1 flag. This report provides an indepth examination of the usefulness of the five screening methods used for identifying events. We considered the most useful methods to be those that identified the greatest number of events.

## FINDINGS

**The five screening methods were useful in identifying events that harmed patients; however, most flags were not associated with events.** Physician reviews determined that 256 of the 662 flags (39 percent) generated by the screening methods were associated with

1 or more of the 120 events found by the case study.  Nurse reviews and one type of billing data analysis identified the greatest number of events.  Although the five screening methods helped to identify events, they also generated many flags (61 percent) that were not associated with events.

**Shortcomings in two screening methods have implications for Medicare payments and Federal initiatives to identify, track, and monitor events.**  Our analysis revealed vulnerabilities regarding both accuracy and completeness of two critical sources of information about events.  Through analysis of the billing data, we found that diagnosis codes were inaccurate or absent for 7 of the 11 Medicare hospital-acquired conditions identified by the case study.  These problems would prevent Medicare's automated payment software from identifying the hospital-acquired conditions, which could result in Medicare overpayments and inhibit use of billing data to monitor quality of care in hospitals.  We also found that hospitals participating in the case study apparently did not have any internal incident reports for 112 of the 120 events (93 percent), including some of the most serious events involving death or permanent disability to the patients.  The lack of such reports could prevent hospitals from tracking events as required by regulation or reporting events to outside entities.  It also suggests that hospital incident-reporting systems may be an unreliable source of information for Patient Safety Organizations (PSO), which are entities that aggregate and analyze information about events voluntarily reported by hospitals.

## RECOMMENDATIONS

Overall, the case study findings suggest that an effective way to identify events is through review of medical records by nurses and/or physicians, whereas other screening methods identified far fewer events.  Additionally, it demonstrated opportunities to address shortcomings that limited the usefulness of some screening methods.

Therefore, we recommend to the Centers for Medicare & Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ) that:

**CMS and AHRQ should explore opportunities to identify events when conducting medical record reviews for other purposes.**
Examples of such efforts include, but are not limited to:  CMS's Medicare Comprehensive Error Rate Testing and the work of Quality Improvement

Organizations; AHRQ grant awards for patient safety research; and State survey agency work in certifying hospital compliance with the Medicare conditions of participation.

**CMS should ensure that hospitals code claims accurately and completely to allow for identification of hospital-acquired conditions affected by Medicare's payment policy.** To identify Medicare hospital-acquired conditions, CMS relies on hospitals to code diagnoses and present on admission (POA) indicators (which indicate whether diagnoses were present upon admission). CMS should determine whether additional guidance is needed to ensure that hospitals code diagnoses and POA indicators accurately and completely.

**CMS should provide interpretive guidelines for State survey agencies to assess hospital compliance with requirements to track and monitor adverse events.** The CMS *State Operations Manual* contains no guidance to State survey agencies regarding assessing hospital compliance with Federal requirements to track and monitor events; therefore, it is unclear how surveyors are to assess hospitals' compliance.

**AHRQ should inform PSOs that internal hospital incident reporting may be insufficient to provide needed information about events to PSOs.** As the key Federal agency involved with PSOs, AHRQ indicated that PSOs will rely primarily upon hospitals for identifying, tracking, and reporting information about events. However, we found that hospital incident reports existed for only 8 of the 120 events identified in the case study. In providing technical assistance to support PSOs, AHRQ should convey the importance of hospitals' having strong internal incident-reporting procedures.

## AGENCY COMMENTS

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

AHRQ concurred with the report as written.

CMS stated that it agrees with recommendations relevant to its programs.

# ➤ T A B L E   O F   C O N T E N T S

# ➤ I N T R O D U C T I O N

## OBJECTIVE

To evaluate the usefulness of selected methods for identifying events that harm hospitalized Medicare beneficiaries.

## BACKGROUND

### Statutory Mandate and Office of Inspector General Response

The Tax Relief and Health Care Act of 2006 (the Act) requires that the Office of Inspector General (OIG) report to Congress regarding the incidence of "never events" among Medicare beneficiaries, payment by Medicare or beneficiaries for services furnished in connection with such events, and the processes that the Centers for Medicare & Medicaid Services (CMS) uses to identify such events and deny or recoup payment.[1, 2]  (For relevant text of the Act, see Appendix A.)  The Act also requires that OIG make recommendations, as appropriate, regarding processes for identifying such events.  To meet the requirements of the Act, OIG published a series of reports and will publish additional reports based on ongoing work.[3]

Expanding beyond the term "never events," OIG studies use the term "adverse event" to allow for a more comprehensive examination of the topic.  As used in these studies, the term "adverse event" describes harm to a patient as a result of medical care or harm that occurs in a health care setting.  Although an adverse event often 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]

---

[1] The Act, P.L. 109-432 § 203.

[2] For purposes of the Act, the term "never events" means "an event that is listed and endorsed as a serious reportable event by the National Quality Forum (NQF) as of November 16, 2006."  The Act, § 203(d).  The NQF used the term "Serious Reportable Events" to describe a specific list of events associated primarily with patient death or serious disability that "should never occur in a healthcare setting."  These colloquially became known as "never events."  Available online at http://www.qualityforum.org/Topics/Safety.aspx.  Accessed on August 12, 2009.

[3] OIG, *Adverse Events in Hospitals:  Overview of Key Issues*, OEI-06-07-00470, December 2008; OIG, *Adverse Events in Hospitals:  State Reporting Systems*, OEI-06-07-00471, December 2008; and OIG, *Adverse Events in Hospitals:  Case Study of Incidence Among Medicare Beneficiaries in Two Counties*, OEI-06-08-00220, December 2008; OIG, *Adverse Events in Hospitals:  Public Disclosure of Information About Events*, OEI-06-09-00360.

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

Following a review of Medicare policies and expenditures, as well as consultation with officials from CMS and the Agency for Healthcare Research and Quality (AHRQ), we chose to focus much of our work on inpatient acute care hospitals.  In 2006, 12.5 million Medicare beneficiaries were hospitalized,[5] with inpatient hospital costs constituting the largest portion of Medicare expenditures (32 percent in 2006).[6]  Federal regulations require that hospitals, as a condition of participation in the Medicare and Medicaid programs, develop and maintain a quality assessment and performance improvement (QAPI) program.[7]  As a part of the QAPI program, hospitals must "measure, analyze, and track quality indicators, including adverse patient events."[8]  To accomplish this, hospitals must "track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital."[9]  State health agencies, otherwise referred to as State survey agencies, perform survey and review functions for Medicare and certify that hospitals comply with these Federal requirements.[10]

Hospitals may also report information about adverse events to various entities, such as Patient Safety Organizations (PSO), which seek to improve quality of patient care by identifying and reducing the risks and hazards associated with care. [11, 12]  PSOs must certify that they

---

[5] CMS, *Statistics Book*, p. 43, Table IV.1:  Medicare/short-stay hospital utilization, 2008.

[6] Based on data from 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.

[7] 42 CFR § 482.21.  In the preamble to the final rule adding QAPI to the conditions of participation, CMS said QAPI focuses providers on the care delivered to patients, the performance of the hospital as an organization, and the effect of treatment.
68 Fed. Reg. 3435 (Jan. 24, 2003).

[8] 42 CFR § 482.21(a)(2).

[9] 42 CFR § 482.21(c)(2).

[10] 42 CFR § 488.10.  Providers accredited by an accreditation organization are deemed to be in compliance with Medicare conditions of participation.  42 CFR § 488.5.

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

[12] Other entities, such as States operating adverse event reporting systems and the Joint Commission, also accept reports from hospitals regarding adverse events.

have policies and procedures in place to perform "patient safety activities," such as aggregation and analysis of reported events received from hospitals that voluntarily report patient safety information.[13] The Secretary of Health & Human Services has delegated to AHRQ the responsibility for determining whether certifications submitted by entities seeking to be PSOs meet Federal requirements.[14] The Secretary may also provide technical assistance to PSOs on matters such as methodology, communication, data collection, or privacy concerns.[15] An AHRQ-funded study found that 98 percent of hospitals reported having adverse event reporting systems and nearly all hospitals have safety and quality functions that would facilitate participating in a PSO.[16] HHS indicated that PSOs would rely primarily on "existing hospital activities," such as internal procedures for identifying and reporting adverse events.[17]

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

Since October 1, 2007, hospitals have been required to assign a present on admission (POA) indicator to each principal and secondary diagnosis for acute Inpatient Prospective Payment System (IPPS) claims for all discharges.[18] This was an initial step in complying with the Deficit Reduction Act of 2005 (DRA), which required CMS to select at least two hospital-acquired conditions for which hospitals would not be paid higher Medicare reimbursement than if the conditions had not occurred for discharges occurring on or after October 1, 2008.[19] In the fiscal year (FY) 2009 IPPS Final Rule, CMS established the Medicare policy to deny hospitals higher payment for hospital admissions complicated by any of 10 categories of hospital-acquired conditions, that is, conditions that were not present upon admission.[20] Appendix B contains a list of these 10 hospital-acquired conditions.

---

[13] Public Health Service Act, § 924(a), 42 U.S.C. § 299b-24(a).

[14] 73 Fed. Reg. 70732 (Nov. 21, 2008).

[15] Public Health Service Act, § 925, 42 U.S.C. § 922b-25.

[16] 73 Fed. Reg. 70732, 70793 (Nov. 21, 2008).

[17] Ibid.

[18] CMS, *CMS Manual System,* Change Request 5679 (July 20, 2007).

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

[20] FY 2009 Final IPPS Rule, 73 Fed. Reg. 48434, 48471-48491 (Aug. 19, 2008). Effective October 1, 2008, CMS began denying hospitals higher payment for Medicare

Efforts by CMS to identify and deny payment for certain adverse events are part of a broader quality improvement initiative.  In 2005, CMS released its Quality Improvement Roadmap, which expressed a vision for health care quality—"The right care for every person every time."[21] To achieve this vision, CMS stated its commitment to safe, effective, timely, patient-centered, efficient, and equitable medical care.  A central part of quality improvement is the value-based purchasing (VBP) initiative, which ties payment to quality medical care.  Medicare's hospital-acquired conditions policy is part of the VBP initiative.[22]

In the preamble to the FY 2009 IPPS Proposed Rule, CMS indicated that evaluating POA indicators in Medicare billing data could be used to better understand and prevent the occurrences of hospital-acquired conditions.  CMS posed that this information could be used to measure hospital performance as part of the VBP program.  Such information could also be publicly reported, enabling consumers to make more informed choices about their health care.  Additionally, CMS indicated that researchers could use POA data in a variety of ways to increase understanding and identify best practices for prevention of hospital-acquired conditions.[23]

**Case Study of Events That Harmed Hospitalized Medicare Beneficiaries**
To best respond to the Act, we conducted a pilot study in 2008 to determine the incidence of adverse events among the Medicare population in two selected counties so that we could learn about various methods for identifying adverse events.  The results of that study, *Adverse Events in Hospitals:  Case Study of Incidence Among Medicare Beneficiaries in Two Counties* (hereinafter referred to as "case study"), are the basis of this report.[24]

In the case study, we found that an estimated 15 percent of hospitalized Medicare beneficiaries in two selected counties experienced adverse

admissions complicated by these conditions.  CMS, *CMS Manual System*, Change Request 6189 (October 3, 2008).

[21] CMS *Quality Improvement Roadmap*.  Available online at http://www.cms.hhs.gov/CouncilonTechInnov/downloads/qualityroadmap.pdf.  Accessed on June 30, 2009.

[22] FY 2009 Final IPPS Rule, 73 Fed. Reg. 48434, 48471 (Aug. 19, 2008); CMS, "Roadmap for Implementing Value Driven Healthcare in the Traditional Fee-for-Service Program," pp. 10-12.

[23] FY 2009 Proposed IPPS Rule, 73 Fed. Reg.  23528, 23561 (Apr. 30, 2008).

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

events that resulted in harm during their hospital stays.[25]  The case study was based on a random sample of 278 Medicare beneficiary hospitalizations selected from all Medicare discharges from acute care hospitals in two selected counties during a 1-week period in August 2008.  We calculated the estimated adverse event incidence rate as the percentage of Medicare beneficiaries with at least one qualifying adverse event.

Qualifying adverse events met one or more of the following criteria:

1.    included in NQF's list of Serious Reportable Events;

2.    included in Medicare's list of hospital-acquired conditions; and

3.    resulted in a level of patient harm determined by physician reviewers to be associated with a prolonged hospital stay, permanent harm, life-sustaining intervention, or death.

Further, we found that another 15 percent of beneficiaries experienced less serious occurrences that resulted in harm that was temporary but required intervention, referred to as "temporary harm events" in the case study.[26]  For the purposes of this report, we refer to all occurrences that harmed patients (both adverse events and temporary harm events) as "events."  The case study identified a total of 120 events that affected sample beneficiaries.

**Methods for Identifying Events in the Case Study**
We used a two-stage review process to identify events in the case study. The first stage consisted of screening for possible events using the following five screening methods:  nurse reviews of medical records, interviews of Medicare beneficiaries, two types of billing data analysis, and reviews of internal hospital incident reports.  If any screening method identified a possible event, it was labeled a "flag" and the medical record proceeded to the second stage of review.  The second stage consisted of physician reviews of those medical records for which at least one of the screening methods indicated that an event had possibly occurred.

*First-Stage Review:  Screening Methods*

• Method 1:  Nurse Reviews.  Contracted registered nurses reviewed medical records for each sampled Medicare beneficiary's

---

[25] Case study, p. 10.

[26] Case study, p. 16.

hospitalization.  Nurses used a standardized review process developed by the Institute for Healthcare Improvement (IHI) as part of its Global Trigger Tool (GTT) protocol, which we adapted for use in the case study.[27]  The nurse review used IHI's GTT worksheet that listed 54 "triggers" that could be found within a medical record to indicate the possibility of an event.  Examples of triggers include transfusions or a return to surgery.[28]  (For a glossary of clinical terms, see Appendix C.)  When a trigger was found, the nurse reviewer explored the medical record further to identify possible events and associated level of harm.  (See Appendix D for a copy of the nurse review protocol and the IHI GTT worksheet.)

- Method 2:  Analysis of POA Indicators.  For the case study, we obtained administrative billing data directly from hospitals for each of the 278 sample Medicare beneficiary hospitalizations.[29]  We used POA indicators in the billing data to identify hospitalizations that may have had events.  When the POA indicator showed that a diagnosis was not present upon admission, we concluded that the condition developed during the hospital stay and might have been the result of an event.[30]  For example, a diagnosis code for acute renal failure that was not present upon admission may be a sign that an event occurred during the hospital stay.

- Method 3:  Beneficiary Interviews.  We conducted telephone interviews with 220 of the 278 Medicare beneficiaries or their family members to learn about the medical care experienced during sampled hospitalizations.[31]  The interview protocol was designed to determine

---

[27] For more information about the IHI GTT protocol, see F.A. Griffin and R.K. Resar, *IHI Global Trigger Tool for Measuring Adverse Events*, IHI Innovation Series white paper. Cambridge, MA:  Institute for Healthcare Improvement Innovation Series 2007.

[28] The case study used the 2007 version of the IHI GTT worksheet.  A revised version with 53 triggers was published in 2009.  Available online at http://www.ihi.org/IHI/Results/WhitePapers/IHIGlobalTriggerToolWhitePaper.htm. Accessed June 15, 2009.

[29] Hospital administrative billing data may include up to 30 diagnosis codes with POA indicators.  In contrast, Medicare claims data submitted by hospitals to CMS for payment are limited to nine diagnosis codes with POA indicators.

[30] 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 Rev., Clinical Modification (ICD-9-CM), 6th Edition*, was issued for use beginning October 1, 2007.

[31] The remaining 58 beneficiaries or family members either could not be reached or declined to be interviewed.

whether beneficiaries experienced any episodes while in the hospital that might have involved events. It also included questions about such topics as medications, procedures, infections, and falls. Interviews typically lasted 5–7 minutes, but often took longer when interviewees reported occurrences and the interviewer probed for details. (See Appendix E for a list of interview questions.)

- Method 4: Hospital Incident Reports. We requested that hospitals provide any internal incident reports, such as submissions to any hospital incident-reporting systems, adverse drug reaction reports, complaints, peer reviews, and mortality and morbidity reviews associated with the 278 sample Medicare beneficiary hospitalizations. Reports provided by hospitals included issues related to risk management, hospital infections, surgical management, and others.

- Method 5: Analysis of Patient Safety Indicators. We applied AHRQ's Patient Safety Indicator (PSI) software program to hospital administrative billing data for the 278 sample Medicare beneficiary hospitalizations. AHRQ developed the PSI software to monitor health care quality using administrative data, such as patient demographics (e.g., age, gender), and diagnoses and procedure codes.[32] The PSI software is based upon a series of algorithms that detect 20 provider-level complications that indicate possible events (e.g., death of a low-risk patient).[33] (See Appendix F for a list of provider-level PSIs.)

*Flags.* As mentioned, each time a screening method indicated the possibility that an event occurred during the hospitalization, we designated the possible event as a "flag." For example, if a nurse review indicated that a patient contracted an infection during the sampled hospitalization, we considered that a flag. If the nurse review also indicated that the same patient fell during the hospital stay, the fall was considered another flag for the same patient. Similarly, possible events identified through any of the other screening methods were all considered flags. Thus, each sampled hospitalization could have multiple flags from one or more screening methods. Medical records for

---

[32] AHRQ, *Guide to Patient Safety Indicators,* AHRQ Quality Indicators. March 2003. Available online at http://www.qualityindicators.ahrq.gov/archives/psi/psi_guide_v30.pdf. Accessed on June, 4, 2008.

[33] AHRQ also has seven "area-level" PSIs designed to indicate possible events on a regional level, which were not used for the case study.

hospitalizations with one or more flags were forwarded to the second stage of review (i.e., physician review of medical records).

*Second-Stage Review:  Physician Review of Medical Records*

During the second stage of the case study review, 3 contracted physicians reviewed medical records for 183 of the 278 beneficiary hospitalizations—those with at least 1 flag.  The physicians reviewed both the full medical records and the information concerning each flag.  Physicians completed a structured medical review protocol through which they described each incident that had been flagged in the first-stage review and noted what documentation led to flagging the incident.  The physicians then determined whether the incidents flagged in the first-stage review qualified as events for purposes of our study.  (See Appendix G for a copy of the Protocol for Physician Reviews of Medical Records.)

To ensure consistency among the three physician reviewers, we conducted weekly conference calls to discuss issues and reach consensus about complex cases.  Additionally, after physicians initially identified 122 events, we gave the associated hospitals an opportunity to provide additional information or documentation.  We received 18 hospital submissions; the additional information led the physicians to change their determinations for 2 cases and reduce the number of events to 120.  Only events that were identified and confirmed by physicians were included in the case study results.

## METHODOLOGY

### Scope

This study provides an in-depth examination of the usefulness of the five screening methods for identifying events in the case study.  The case study was based on a random sample of 278 Medicare beneficiary hospitalizations selected from all Medicare discharges from acute care hospitals in 2 selected counties during a 1-week period in August 2008.

### Data Collection and Analysis

To evaluate the usefulness of the methods for identifying events, we compared all flags generated by each method to the 120 events identified and/or confirmed through physician reviews.  We classified each flag as either "associated with an event" (i.e., it provided information that led the physician to identify an event) or "not associated with an event" (i.e., the possible event did not meet our

criteria to be classified as an event).  We then calculated the number and percentage of flags associated and not associated with events.  We considered the most useful methods to be those that identified the greatest number of events.  We also examined the types of events identified through each method and determined which events had no associated flags (i.e., events identified only through physician reviews of the medical records).

**Limitations**

Several aspects of the case study warrant mention because of possible implications and limitations for this report.  First, results of the case study can be projected only to the population of Medicare beneficiaries hospitalized in the two selected counties during a 1-week period in August 2008.  Second, it is possible that the case study underestimated incidence of adverse events in the sample.  Specifically, the two-stage methodology meant that physicians conducted medical record reviews for only 183 of the 278 Medicare beneficiary hospitalizations.  Therefore, it is unknown whether the 95 hospitalizations with no flags had any events.  Third, the case study included beneficiary interviews for only 220 of the 278 sampled hospitalizations.  It is unknown whether interviews with the other 58 beneficiaries would have identified additional flags or events.  Fourth, it is possible that hospitals did not provide all incident reports associated with the Medicare beneficiaries' hospitalizations.  Finally, because data collection occurred soon after the sample beneficiary hospitalizations, staff from a few hospitals indicated that the hospital billing data had not undergone complete data cleaning and validation.  We do not know whether this additional processing by hospitals would have affected any screening results.

**Standards**

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

## ➤ F I N D I N G S

**The five screening methods were useful in identifying adverse events; however, most flags were not associated with events**

The 5 screening methods used in the case study generated a total of 662 flags (i.e., possible events). (See Figure 1.) Physician reviews determined that 256 of the 662 flags (39 percent) were associated with events and 406 of the 662 flags (61 percent) were not associated with events. Because more than 1 flag identified many events, the 256 flags revealed a total of 114 events. Physicians identified an additional 6 (of the 120) events in their medical record reviews, finding events within cases that were flagged for other reasons. (See Appendix H for an expanded graphic of the results of the screening methods.)

### Figure 1: Flags and Events Identified Through Case Study Screening Methods
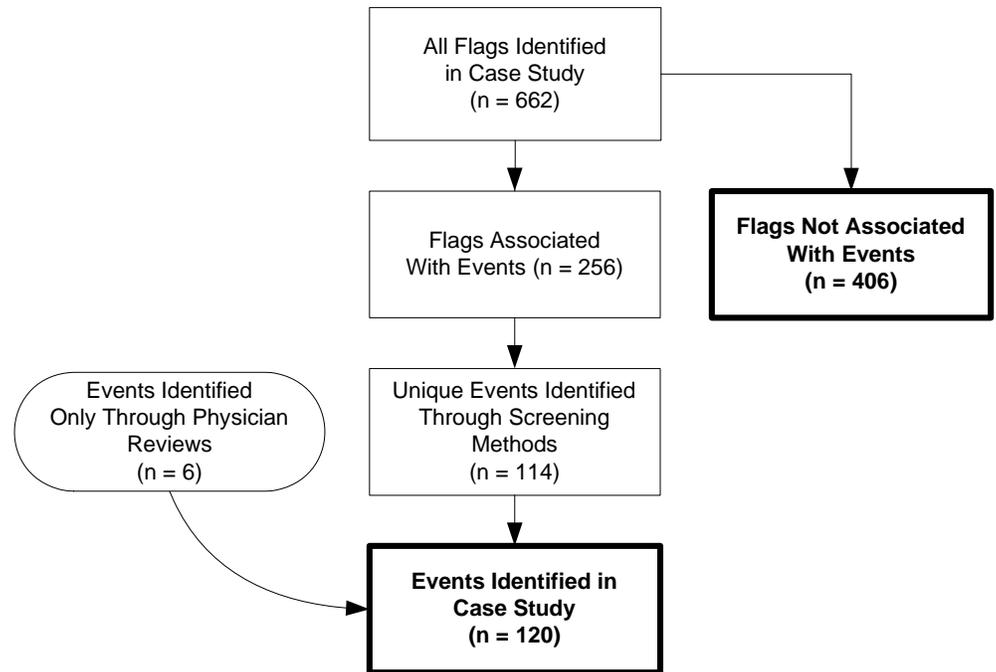


Source: OIG analysis of 278 Medicare beneficiaries' hospitalizations in 2 selected counties, 2008.

**Nurse reviews and POA analysis identified the greatest number of events**
Nurse reviews identified 93 of the 120 events in the case study and POA analysis identified 61 events. (See Table 1.) The third most useful screening method, beneficiary interviews, identified 22 events, and the remaining 2 screening methods identified 8 events each.

**Table 1: Number and Percentage of Events Identified Through Each Screening Method**

| Method | Number of Events* | Percentage of 120 Events |
|---|---|---|
| Nurse Reviews | 93 | 78% |
| POA Analysis | 61 | 51% |
| Beneficiary Interviews | 22 | 18% |
| Hospital Incident Reports | 8 | 7% |
| PSI Analysis | 8 | 7% |

Source: OIG analysis of 278 Medicare beneficiary hospitalizations in 2 selected counties, 2008.

*Column does not sum to 120 because many events were identified through more than 1 method.

The usefulness of nurse reviews and POA analysis appears attributable to both the breadth and precision of each of these methods. Both were broad, in that nurse reviews examined all documents in the medical records and POA analysis considered up to 30 diagnosis codes representing patient conditions. This allowed for a review of a range of possible events unlike, for example, a hospital incident report related specifically to a medication error. Both methods were also precise. The nurse review protocol provided a clinical description of the health care condition; the ICD-9-CM codes used for POA analysis specified each patient diagnosis. This specific clinical information later enabled the physicians to more easily pinpoint related information in the medical records.

The usefulness of nurse reviews and POA analysis is further demonstrated by their performance in identifying events not flagged by any other screening methods. Of the 120 events, 55 (46 percent) were identified by only 1 screening method. Nurse reviews identified 35 events not flagged by any other screening method, (29 percent of the 120 events) and POA analysis alone flagged 14 events (12 percent).

**Although the five screening methods were useful in identifying events, most flags were not associated with events**

As reported on page 11, 406 of the 662 flags generated by the screening methods were not associated with any of the 120 events identified in the case study. The POA analysis generated the most flags that were not associated with events (183 flags) and PSI analysis generated the fewest (4 flags). (See Figure 2.)

*Figure 2: Number of Flags Not Associated With Events and Associated With Events by Screening Method*



Source: OIG analysis of 278 Medicare beneficiary hospitalizations in 2 selected counties, 2008.
Note: Some flags were associated with more than one event, and some events were identified through more than one flag.
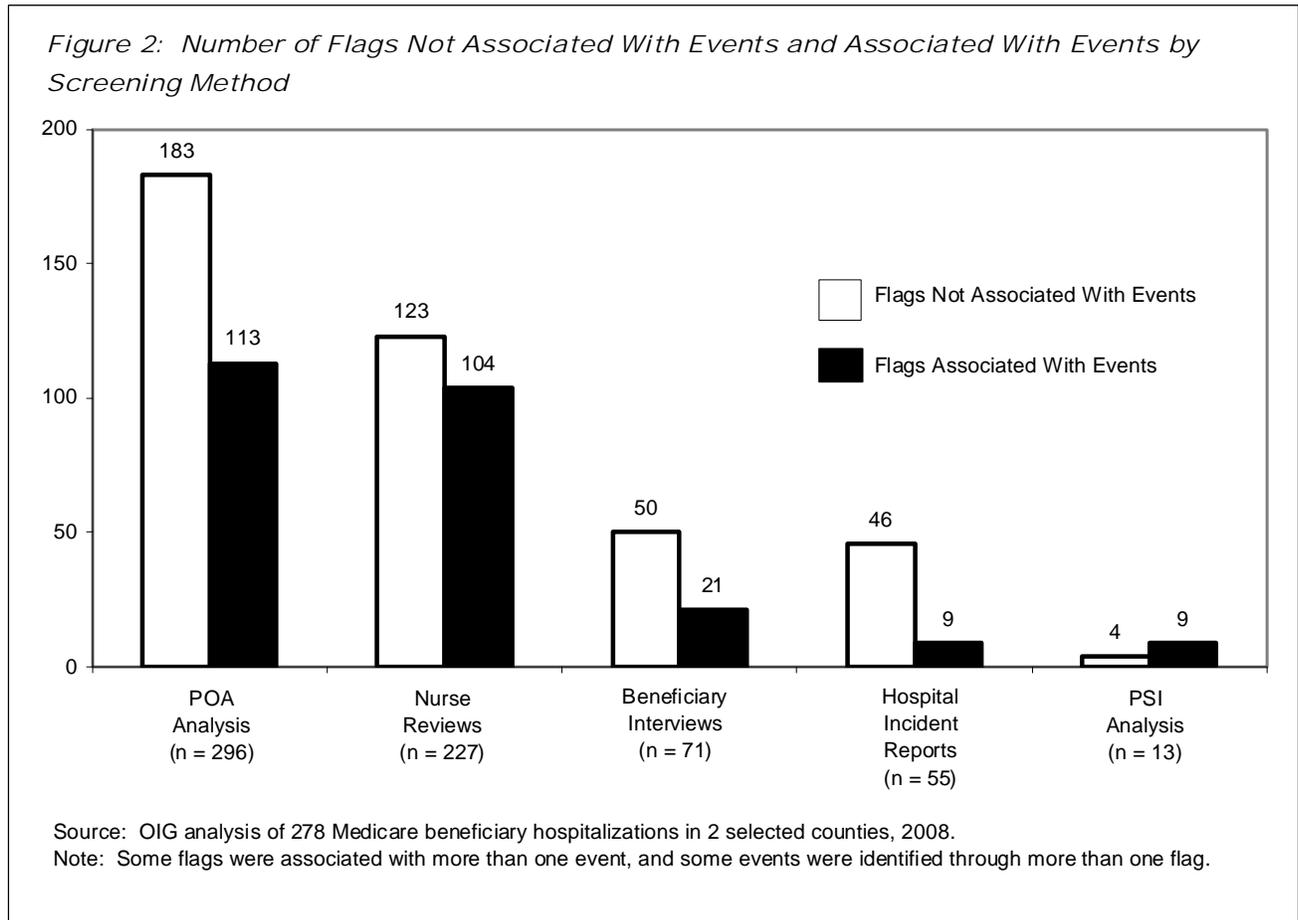
We noted several possible explanations for the large number of flags that were not associated with events:

- First, physician reviews determined that many flags represented conditions or occurrences that did not cause harm to the patients. For example, six hospital incident reports described beneficiary falls that, according to the medical record, did not result in injury or require additional treatment.

- Second, physician reviews determined that some flags represented occurrences that were part of the natural course of the patients' disease or medical condition.  In one such case, a flag from the nurse review indicated that a beneficiary experienced postoperative atrial fibrillation.  However, the physician review determined that this was not an event because the beneficiary's underlying medical condition likely led to the atrial fibrillation, rather than care provided during the hospitalization.

- Third, in some cases, physician reviews did not find supporting documentation in the medical records to determine that flags were associated with events.  For example, a beneficiary interview included a report of pressure ulcers, yet the physician reviewer did not find pressure ulcers documented in the medical record and therefore could not determine that an event occurred.

- Finally, to ensure that physicians reviewed medical records with any chance of an event, we defaulted to including all flags, even when the screening method suggested only a slight possibility of harm.  For example, physicians reviewed all cases for which the hospitals provided associated incident reports, even if the reports did not initially appear to be related to patient harm.

Although some events were flagged by one screening method, other events were flagged by multiple methods, especially in cases in which the patients had several complicating health care conditions.  For example, one of the most complex hospitalizations involved a patient who died during the hospitalization.  Even though the family declined to be interviewed, the 4 remaining screening methods generated a total of 29 flags.  Physician reviews determined that the patient experienced 4 events.  One of the four events was a "cascade" with 19 associated flags.[34]  This cascade included several events, such as deep vein thrombosis, respiratory failure, renal failure, and sepsis.  Two other events were hospital-acquired infections, which were both flagged by nurse reviews and POA analysis.  The fourth event involved kidney damage, which was flagged by nurse review and POA analysis.  Overall,

---

[34] IHI defines cascade event as one in which an initial event causes a series of additional, related events for the same patient, and advocates collapsing these series into single events in determining event counts.  F.A. Griffin and R.K. Resar, *IHI Global Trigger Tool for Measuring Adverse Events*, IHI Innovation Series white paper.  Cambridge, MA:  Institute for Healthcare Improvement Innovation Series 2007, p. 11.

physician reviews determined that 26 of the 29 flags were associated with events, and the remaining 3 flags were not associated with events. For more details on each screening method, see page 21.

## Shortcomings in two screening methods have implications for Medicare payments and Federal initiatives to identify, track, and monitor events

For the Medicare program and other entities to learn of events that harm patients, they must receive accurate and complete information from hospitals. Two critical sources of such information are hospital billing data (diagnosis codes and associated POA indicators) and hospital incident reports. Our analysis of data from these sources revealed vulnerabilities regarding both accuracy and completeness, which could result in Medicare overpayments and inhibit initiatives to improve patient safety.

### POA analysis revealed problems that could inhibit CMS's ability to identify hospital-acquired conditions and appropriately deny Medicare payments

In the case study, we found that only 4 of the 11 events involving Medicare hospital-acquired conditions could be identified through the POA indicators contained in billing data.[35] As previously stated, Federal regulations require that hospitals submit with each diagnosis code on a Medicare claim a POA indicator designating whether the condition was present upon admission. The ICD-9-CM codes and POA indicators submitted by hospitals enable Medicare's automated payment processing software to identify claims with hospital-acquired conditions, enabling denial of payment for associated care and also providing valuable information for use in monitoring quality of care in hospitals.

Among the seven hospital-acquired conditions found in the case study that POA analysis did not flag, five had no related ICD-9-CM code in the hospital billing data.[36] Thus, Medicare automated payment processing software could not determine that a hospital-acquired condition had occurred. Although the hospital would not receive additional payment for care associated with the conditions (the desired

---

[35] Medicare's payment policy for hospital-acquired conditions was not yet in effect at the time of the case study, and therefore these findings do not indicate that Medicare made any improper or incorrect reimbursements for claims associated with these hospital-acquired conditions.

[36] It was beyond the scope of the case study to determine the underlying causes for these absent or inaccurate codes.

outcome of the Medicare payment policy), the absence of these codes inhibits the usefulness of billing data for gauging how often such events occur and for monitoring quality of care in hospitals.

In the two remaining cases, hospital billing data contained diagnosis codes related to the hospital-acquired condition, but the codes were not specific enough to invoke the Medicare payment policy.  In each of these two cases, physician reviews determined that the beneficiary experienced a "catheter-associated urinary tract infection," yet the billing data included a more general diagnosis code for "urinary tract infections, not otherwise specified."  Although these less descriptive diagnosis codes led physicians to identify the events in these cases, they would not have allowed Medicare's automated payment-processing software to identify the hospital-acquired conditions and, therefore, could have resulted in Medicare overpayments to the hospitals if the payment policy had been in effect at the time of the case study.  Such discrepancies would also affect use of Medicare claims and POA indicator data to monitor events and quality of care in hospitals.

**The lack of hospital incident reports could prevent hospitals from tracking events as required or reporting events to outside entities**
Identifying events within hospitals and capturing event information in hospital incident reports are critical first steps toward addressing problems that lead to patient harm.  We requested that hospitals provide any internal incident reports involved with the hospitalization, including submissions to the hospital incidence-reporting systems, adverse drug reaction reports, complaints, peer reviews, and morbidity and mortality reviews, for the 278 sample Medicare beneficiary hospitalizations.  However, hospitals did not provide, and apparently did not have, any reports for 112 of the 120 events (93 percent) found in the case study.  Further, hospitals had no incident reports for two of the three events that resulted in death to the patients or two of the four events that resulted in serious disability.

The implications of hospitals' failure to identify and capture event information can be significant.  First, although we did not assess hospital compliance with Federal requirements to "track medical errors and adverse patient events," it raises concerns that only four of the seven most serious events had no associated hospital incident reports.  Further, the lack of incident reports for 93 percent of events suggests that hospital incident-reporting systems may be an unreliable source of information for PSOs, States operating adverse event reporting

systems, and other entities.  These entities often seek to learn from the combined experiences of many hospitals to generate lessons to improve patient safety.  Unless events are reported within the hospital first, the event information is unlikely to be available to outside entities for learning.

# ▶ R E C O M M E N D A T I O N S

Identifying events that harm hospital patients is a topic of interest to Congress, HHS, and the health care community and is important to reduce their occurrence. This report found that, combined, the selected screening methods used for the case study were useful in identifying events. However, we also identified weaknesses in their use; physicians determined that most flags generated by the five screening methods were not associated with events. Further, we found that shortcomings revealed within two screening methods have implications for Medicare payments and Federal initiatives to identify, track, and monitor events.

Overall, the case study findings suggest that an effective way to identify events that result in harm to patients is through review of medical records by nurses and/or physicians, methods that are both costly and time consuming. Other less costly and time-consuming methods, such as analyzing billing data or examining hospital incident reports, would identify far fewer events. Nonetheless, there is no current mandate for HHS to conduct medical reviews to identify events.

Therefore, we recommend that:

**CMS and AHRQ should explore opportunities to identify events when conducting medical record reviews for other purposes**
CMS and AHRQ could reduce the cost of efforts to identify adverse events by adding such efforts to ongoing medical record reviews. Examples of such efforts include, but are not limited to: CMS's Medicare Comprehensive Error Rate Testing (CERT) and the work of Quality Improvement Organizations (QIO); AHRQ grant awards for patient safety research; and State survey agency work in certifying hospital compliance with the Medicare conditions of participation.

**CMS should ensure that hospitals code claims accurately and completely to allow for identification of hospital-acquired conditions affected by Medicare's payment policy**
CMS relies on hospitals to code diagnoses and POA indicators to identify Medicare hospital-acquired conditions subject to the payment policy. However, we found that ICD-9-CM codes were inaccurate or absent for 7 of the 11 events that involved Medicare hospital-acquired conditions found in the case study. Because the payment component of the Medicare hospital-acquired conditions policy was not in effect at the time of the case study, this problem did not result in improper payments to any providers. However, given that the payment policy is now in effect, similar problems

could result in improper payments. Further, incorrect or absence of diagnosis codes would prevent CMS from determining that the events occurred, which would inhibit its ability to measure rates of hospital-acquired conditions and limit public reporting of the measured rates. CMS should determine whether additional guidance or other action is needed to ensure that hospitals code diagnoses and POA indicators accurately and completely. We are conducting further research examining the accuracy of claims related to hospital-acquired conditions for a nationally representative sample of Medicare beneficiaries' hospitalizations.

**CMS should provide interpretive guidelines for State survey agencies to assess hospital compliance with requirements to track and monitor adverse events**

Although hospitals must "track medical errors and adverse patient events" under Medicare's conditions of participation, few events found in the case study had associated hospital incident reports. The *State Operations Manual*, through which CMS provides guidance to State survey agencies that assess hospital compliance with Federal regulations, contains no interpretive guidelines regarding these requirements.[37] Therefore, when State agency staff perform surveys of hospitals (e.g., standard compliance surveys and surveys based on complaints), it is unclear how surveyors are to assess hospital operations for tracking medical errors and other events that result in harm to patients. CMS should provide guidance to surveyors for assessing hospitals' compliance with these requirements. Such guidance could include what types of medical errors and adverse patient events hospitals should track and monitor, as well as what information should be captured in hospital incident reports.

**AHRQ should inform PSOs that internal hospital incident reporting may be insufficient to provide needed information about events to PSOs**

PSOs were established to aggregate and analyze events that pose risks to patient safety. AHRQ indicated that it expects PSOs will rely primarily upon existing hospital infrastructures for identifying, tracking, and reporting information about events to PSOs. However, we found that hospital incident reports existed for only 8 of the 120 events

---

[37] CMS, *State Operations Manual*, 2009, Appendix A, A-0267; A-0286 through A-0288. Available online at http://www.cms.hhs.gov/manuals/downloads/som107ap_a_hospitals.pdf. Accessed on September 1, 2009.

identified in the case study. In providing technical assistance to support PSOs, AHRQ should convey the importance of strong hospital internal incident-reporting procedures that capture relevant information about events that cause harm to patients.

## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

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

AHRQ concurred with the report as written. CMS stated that it appreciates the original contribution that the report makes in advancing the patient safety agenda in hospitals and agrees with the recommendations made to CMS. We made no changes to the report based on agency comments.

In its comments, CMS outlined several opportunities to identify events when conducting medical record reviews for other purposes. First, CMS noted that it expects State Survey Agencies to investigate patient adverse events while conducting a survey of a hospital's compliance with the Medicare conditions of participation. Second, CMS stated that it is increasingly investigating the extent to which adverse events are tracked and analyzed by hospital internal quality assurance and performance systems. Third, CMS noted that the QIO program addresses many quality-of-care concerns through the beneficiary complaint and medical review processes or through referral by other entities. Regarding QIOs, CMS indicated that it has proposed policy revisions to the QIO beneficiary complaint and quality-of-care review process to include adverse events as indicators of quality and will explore a possible quality-referral mechanism between the CERT contractor and the QIO program. Lastly, CMS stated that it is collaborating with AHRQ on the Medicare Patient Safety Monitoring System to estimate prevalence of certain conditions and adverse events.

CMS indicated that to ensure that hospitals accurately code claims to enable identification of hospital-acquired conditions, it has established a process for providing coding advice to hospitals. Further, CMS indicated that it will study the accuracy of coding hospital-acquired conditions and reporting of POA indictors to use in developing refinements in coding instructions or to focus review on areas of inaccurate reporting.

CMS indicated that it will ensure that the *State Operations Manual* includes full guidance for surveyors to assess hospital QAPI systems and strengthen CMS surveyor-training programs to enhance surveyor abilities to evaluate compliance with the QAPI requirements.

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

## ➤ S C R E E N I N G   M E T H O D S

The following section provides specific results for each of the screening methods used for identifying events in the case study, as well as factors that appeared to affect their usefulness.

## Method 1:  Nurse Reviews of Medical Records

### Nurse reviews identified the most events among the screening methods and also generated many flags that were not associated with events

Nurse reviews generated 227 flags across 127 Medicare beneficiaries: 1 flag each for 70 beneficiaries and more than 1 flag for the remaining 57 beneficiaries.  In an unusually complex case, the nurse reviewer identified 11 flags.  Because the nurse review protocol required a broad-based examination of the medical record, nurses identified flags associated with a variety of conditions and occurrences.  The most prominent types of flags related to surgery and other procedures, medication, and infections.  (See Table 2.)

**Table 2:  Number of Flags and Events Identified by Nurse Reviews of Medical Records**

| Type of Conditions or Occurrences | Number of Flags | |
|---|---|---|
| | Identified by Method | Associated With Events |
| Surgery and other procedures | 58 | 34 |
| Medication | 51 | 29 |
| Infections | 45 | 20 |
| Skin care | 19 | 11 |
| Patient care | 9 | 5 |
| Glycemic control | 8 | 3 |
| Patient fall | 7 | 1 |
| Readmission | 7 | 0 |
| Intravenous fluid | 4 | 2 |
| Use of restraints | 4 | 0 |
| Other | 15 | 0 |
| **Total** | **227** | **104*** |

Source:  OIG analysis of 278 Medicare beneficiary hospitalizations in 2 selected counties, 2008.
*Column will not sum to 104 because some flags were associated with more than 1 event and some events were identified through more than 1 flag.

Physician reviews determined that 104 of the 227 flags (46 percent) identified by nurse reviews were associated with events. Because more than 1 flag was associated with some of the events, this method identified a total of 93 events (78 percent of the 120 events in the case study). Physician reviews determined that 123 of the 227 flags (54 percent) generated by nurse reviews were not associated with events. These flags were typically not associated with events because the condition or occurrence flagged did not involve harm to the patient or was related to the patient's underlying disease or medical condition or because the medical record did not contain sufficient documentation to determine that an event occurred.

## Method 2: Analysis of Present on Admission Indicators

**POA analysis generated the most flags among the five methods and identified about half of the events**

To identify diagnoses that were not coded as present on admission and therefore presumed to be hospital acquired, POA analysis of hospital billing data considered up to 30 ICD-9-CM codes and POA indicators for each case. This analysis generated 296 flags across 98 Medicare beneficiaries: 1 flag for 40 beneficiaries and more than 1 flag for the remaining 58 beneficiaries. The method generated 10 or more flags for each of 4 beneficiaries who had very complex hospitalizations.

The 296 flags included 155 different ICD-9-CM codes across the 98 beneficiaries. Of these 155 codes, 95 were flagged once (i.e., for only 1 beneficiary). The most frequently represented code, anemia because of blood loss, was flagged for 16 different beneficiaries. (See Table 3.)

Physician reviews determined that 113 of the 296 flags (38 percent) identified through POA analysis were associated with events. Because more than 1 flag was associated with some of the events, the method identified a total of 61 events (51 percent of the 120 events in the case study).[38] However, POA analysis generated the largest number flags

---

[38] POA analysis would have identified 34 percent fewer events (21 of 61 events) if we had used Medicare claims data rather than billing data obtained directly from hospitals. For these 21 events, either there were no Medicare claims for the hospitalizations or the relevant diagnosis codes were not in the Medicare claims. (Medicare claims data include only the first nine diagnosis codes and POA indicators for each hospitalization.) This suggests that researchers who cannot obtain billing data directly from hospitals may identify a smaller percentage of adverse events than suggested by the case study results.

that were not associated with events (183) among the screening
methods (62 percent of the 296 POA analysis flags). For POA flags that
were not associated with events, physician reviews determined that
they typically did not involve harm to the patient or were related to the
patients' diseases or medical conditions or that the medical records did
not contain documentation to determine that events occurred. For
example, physician reviews often did not find accompanying patient
signs or symptoms associated with laboratory tests that caused actual
harm or required an intervention or prolonging of the hospital stay.
Physician reviewers reported that the three most frequently occurring
POA flags—anemia because of acute blood loss, potassium deficiency,
and acute renal failure—each represented temporary laboratory
findings common during care for complex patients.

**Table 3:  Seven Most Frequently Occurring Flags With Diagnoses
Not Coded as Present on Admission**

| ICD-9-CM Code | Description | Number of Flags | |
|---|---|---|---|
| | | Identified by Method | Associated With Events |
| 285.1 | Anemia because of acute blood loss | 16 | 2 |
| 276.8 | Potassium (K) deficiency | 12 | 0 |
| 584.9 | Acute renal failure | 10 | 4 |
| 48.6 | Other enterovirus diseases of central nervous system | 6 | 4 |
| 511.9 | Unspecified pleural effusion | 6 | 1 |
| 707.03 | Decubitus ulcer | 5 | 5 |
| 997.1 | Cardiac complications | 5 | 1 |

Source:  OIG analysis of 278 Medicare beneficiary hospitalizations in 2 selected counties, 2008.

## Method 3:  Beneficiary Interviews

**Beneficiary interview was the only method to rely on information from
outside the hospitals and identified 21 percent of events**
Beneficiary interviews identified 70 flags across 42 Medicare
beneficiaries:  1 flag each for 25 beneficiaries and more than 1 flag for
each of the remaining 17 beneficiaries. Two beneficiaries each reported
five different flags, the most reported during interviews. Flags from
interviews covered a smaller range of conditions and occurrences than
nurse reviews or POA analysis. (See Table 4.)

**Table 4:  Number of Types of Flags and Events Identified Through Beneficiary Interviews**

| Type of Condition or Care | Number of Flags | |
|---|---|---|
| | Identified by Method | Associated With Events |
| Medication | 18 | 8 |
| Skin care | 14 | 3 |
| Hospital-acquired infections | 13 | 3 |
| Surgery and other procedures | 12 | 6 |
| Patient falls | 4 | 1 |
| Intravenous volume overload | 1 | 1 |
| Other general care complaints | 8 | 0 |
| **Total** | **70** | **21\*** |

Source:  OIG analysis of 220 Medicare beneficiaries' interviews.
*Column does not sum to 21 because 1 flag was associated with 2 events.

During interviews, beneficiaries and their representatives revealed both specific and general concerns.  Among the 70 flags, 62 involved specific health care circumstances (e.g., medication problems, infections).  For the other eight flags, interviews gleaned general complaints about the quality or outcome of care.  For example, one beneficiary indicated that his mobility changed shortly after the hospital stay.  To ensure that we did not miss events, we considered each of these 8 as flags and forwarded them to physicians for medical record reviews, along with the 62 specific flags.

Several reasons may explain why beneficiary interviews identified relatively few flags as compared to some of the other methods.  Although we conducted interviews within about 1 month of their hospitalizations, a number of beneficiaries had difficulty recalling their experiences, although some remembered more as the interview proceeded.  For example, during the initial series of general questions, several respondents indicated that they had no problems, yet later identified problems when asked about specific topic areas such as medication or falls.  Respondents who had more than one recent hospital stay often had difficulty distinguishing during which stay problems occurred.  Although assured that information would be kept confidential, a few beneficiaries expressed concern that hospitals would disapprove of their participating in the interviews.  Finally, this method

generated no flags for the 58 sample beneficiaries that we could not contact or declined to be interviewed.

Despite these barriers, physician reviews determined that 21 of the 70 flags (30 percent) generated from beneficiary interviews were associated with events.  One event that was flagged through an interview but missed by the other screening methods demonstrates the usefulness of beneficiary interviews in learning about events.  In this case, the beneficiary experienced an allergic reaction determined by the physicians to be an event.  The beneficiary indicated in the interview that hospital staff had been informed in advance of the allergy.

## Method 4:  Hospital Incident Reports

**Although few hospital incident reports were associated with events, these were useful in understanding what transpired**
Counting each incident report as a flag, this method identified 55 flags across 40 Medicare beneficiaries.  Hospitals submitted a single incident report each for 29 of these beneficiaries and multiple reports for each of the other 11 beneficiaries.  In a few of the cases with multiple reports, the reports were related to the same condition or occurrence, with initial reports and then subsequent reports detailing further analysis and outcomes.  In the other cases, the multiple reports indicate that the beneficiaries experienced multiple unrelated occurrences.

We grouped the 55 incident reports into 3 distinct categories:  patient incidents (29 reports), systems incidents (21 reports), and nonmedical incidents (5 reports).  (See Table 5.)  Each patient incident report involved a medical condition or occurrence specific to one of the sample Medicare beneficiaries.  The most common of these reports involved adverse medication reactions.  The systems incident reports also related to particular patients, but the reports described incidents related to hospital systems rather than the patients' conditions.  The most common hospital systems incident report addressed medication administration errors that, despite involving errors, did not cause harm to the patients.  Finally, nonmedical incident reports were unrelated to the health care provided to the patients, such as two reports about stolen property.

**Table 5:  Hospital Incident Reports by Category**

| Category of Hospital Incident Reports | Number of Flags | |
|---|---|---|
| | Identified by Method | Associated With Events |
| PATIENT INCIDENTS | 29 | 9 |
| Adverse medication reactions | 11 | 3 |
| Skin care-related incidents | 7 | 3 |
| Falls | 6 | 0 |
| Other patient incidents | 5 | 3 |
| SYSTEMS INCIDENTS | 21 | 0 |
| Medication administration errors | 7 | 0 |
| Hospital policy-driven reports* | 6 | 0 |
| Other systems incidents | 5 | 0 |
| Staff care incidents | 3 | 0 |
| NONMEDICAL INCIDENTS | 5 | 0 |
| **Total** | **55** | **9** |

Source:  OIG analysis of 278 Medicare beneficiary hospitalizations in 2 selected counties, 2008.
*These reports were generated because of hospital policies that called for such reports whenever specific circumstances occurred, such as an unplanned readmission of a patient.

Physician reviews determined that 9 of the 55 flags (16 percent) were associated with events.  (The method identified eight unique events because one event had two associated incident reports.)  The events involved three adverse medication reactions, two skin care events, two surgical complications, and one blood-clotting event.  The eight events involved only reports that we categorized as patient incident reports, indicating that reports related to hospital systems and nonmedical incidents were not useful for identifying events.

The detail included in the hospital incident reports was useful in understanding what transpired.  These reports typically described the nature and types of incidents and their effect on patients.  Some reports also indicated whether the events were reportable to other entities, such as States operating adverse event reporting systems.  More serious events tended to require reporting to other entities and sometimes resulted in highly detailed and/or multiple reports.  For example, for one beneficiary, who experienced multiple complications following surgery, the hospital generated three separate incident reports:  a

report describing a hospital-acquired infection that led to sepsis, a report describing the patient's return to surgery for a bowel obstruction, and a more general report about hypotension and confusion.

The low number of events identified through hospital incident reports (8), and the relatively high number of incident reports not related to events (46), suggest a disconnect between the hospitals' purpose for internal incident-reporting systems and the goal of identifying events that result in patient harm. Reports often referred to incidents with hospital systems and nonmedical issues that could be useful for hospital administration purposes, but the incidents did not involve harm to patients.

## Method 5:  Analysis of Patient Safety Indicators

**PSI analysis identified the fewest flags among the screening methods and did not identify some events related to conditions covered by PSI software**
PSI analysis identified 13 flags across 11 Medicare beneficiaries, the lowest number of flags among the screening methods used in the case study.[39]  (See Table 6.)  This low number of flags is, in part, because PSI software is limited to only 20 health care conditions.[40]  The most frequently occurring condition with a PSI was pressure ulcer (five flags).

Physician reviews determined that 9 of the 13 flags (69 percent) generated by PSI analysis were associated with events.  (The method identified eight events because one of the events had two associated PSIs.)  Although this method was one of the methods that identified the fewest events among the screening methods, it also had the fewest flags that were not associated with events (four).

---

[39] The PSI analysis identified 1 flag for 10 of these 11 beneficiaries and 3 flags for the other beneficiary.

[40] Additionally, 4 of these 20 PSIs involved obstetrics and were therefore unlikely to affect the Medicare beneficiary population included in the case study.

**Table 6:  Number of Flags and Events Identified Through PSI Analysis**

| Patient Safety Indicator | Number of Flags | |
|---|---|---|
| | Identified by Method | Associated With Events |
| Pressure ulcer | 5 | 5 |
| Postoperative pulmonary embolism or deep vein thrombosis | 3 | 2 |
| Accidental puncture or laceration | 2 | 1 |
| Selected infections because of medical care | 1 | 1 |
| Iatrogenic pneumothorax | 1 | 0 |
| Complications of anesthesia | 1 | 0 |
| **Total** | **13** | **9** |

Source: OIG analysis of 278 Medicare beneficiary hospitalizations in 2 selected counties, 2008.

Additionally, PSI analysis did not identify as flags some events involving health care conditions targeted by the PSI software typically because related diagnosis codes were not included in the billing data provided to OIG.  For example, although PSI software is designed to identify pressure ulcers, our PSI analysis identified only 5 of the 13 pressure ulcers found in the case study.  Regarding the other eight hospitalizations with pressure ulcers, billing data for seven had no ICD-9-CM diagnosis codes indicating that the Medicare beneficiaries had pressure ulcers.  The remaining case had an ICD-9-CM diagnosis code for the pressure ulcer, but the PSI software intentionally invoked an exemption because the hospitalization had another complication, specifically anoxic brain damage.  In the absence of the brain damage, PSI analysis would likely have flagged the pressure ulcer.

## ➤ A P P E N D I X   ~   A

### Tax Relief and Health Care Act of 2006

P.L. 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 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.

## Medicare List 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 that were not present upon admission.

### Table B-1:  Medicare 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 |
|    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, 48490–48491 (Aug. 19, 2008).

## Glossary of Selected Clinical Terms[41]

**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.

**Acute renal failure**—A sudden loss of the ability of the kidneys to remove waste and concentrate urine without losing electrolytes.

**Anemia**—A condition in which the blood is deficient in red blood cells, in hemoglobin, or in total volume.

**Anoxic brain damage**—Brain damage that occurs when the brain does not receive sufficient oxygen.

**Atrial fibrillation**—Very rapid uncoordinated contractions of the atria of the heart resulting in a lack of synchronism between the heartbeat and pulse beat.

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

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

**Deep vein thrombosis**—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 (such as swelling and pain) and that is potentially life threatening if dislodgment of the thrombus results in pulmonary embolism.

**Enterovirus Disease**—A kind of ribonucleic virus that multiplies especially in the gastrointestinal tract but may infect other tissues, such as nerve and muscle.

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

**Hypoglycemia**—Abnormal decrease of sugar in the blood.

---

[41] 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 June 23, 2009.

**Pleural effusion**—An oozing of fluid from the blood or lymph into a pleural cavity.

**Potassium deficiency**—Also known as hypokalemia, a lower than normal amount of potassium in the blood. It may result from a number of conditions.

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

**Pulmonary embolism**—A sudden blockage of a lung artery or one of its branches that is produced by foreign matter; most often a blood clot originating in a vein of the leg or pelvis.

**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**—An infection of the tract through which urine passes. It consists of the renal tubules and renal pelvis of the kidney, the ureters, the bladder, and the urethra.

## Case Study Protocol for Nurse Reviews

Figure D-1 presents the form used by nurses to record the results of medical record reviews for the first stage for the case study. Figure D-2 contains the Institute for Healthcare Improvement (IHI) Global Trigger Tool (GTT) worksheet..

**Figure D-1: Nurse Review Results Form**

**IHI GTT – TRIGGER TOOL RESULTS – OEI-06-08-00220**          **Start Time:_____AM / PM**

DATE: _____ RN ID: _____ OIG CASE ID: _____ HOSPITAL: _____

Beneficiary Information

NAME: _____          MR#: _____

**PHYSICIAN REVIEW INFORMATION**

Should this case be reviewed by a physician?
- ☐ YES, Adverse Event Identified
- ☐ YES, Other (please explain reason in notes below)
- ☐ NO

Notes:

**ADVERSE EVENT INFORMATION**

Assign AE Number:_____(#) of _____(#)
(Ex: 2 of 3 – this is $2^{nd}$ of 3 adverse events identified for this patient)

Harm Category: _____

Adverse Event Description:

| **Harm Category Key:** |
| --- |
| E – Temporary harm, intervention required |
| F – Temporary harm, initial or prolonged hospitalization |
| G – Permanent patient harm |
| H – Life-sustaining intervention required |
| I – Contributing to death |

Notes to Physician about Adverse Event (e.g., date, location in chart, questions)

                                        **End Time:_____AM / PM**

## Figure D-2:  IHI GTT Worksheet (2007)[42]

**Appendix B: IHI Global Trigger Tool for Measuring Adverse Events Worksheet**

| Cares Module Triggers | + | Event Description and Harm Category (E-I) |
|---|---|---|
| C1 Transfusion or use of blood products | | |
| C2 Any code or arrest | | |
| C3 Dialysis | | |
| C4 Positive blood culture | | |
| C5 X-ray or Doppler studies for emboli | | |
| C6 Abrupt drop of greater than 25% in hemoglobin or hematocrit | | |
| C7 Patient fall | | |
| C8 Pressure ulcers | | |
| C9 Readmission within 30 days | | |
| C10 Restraint use | | |
| C11 Healthcare-associated infection of any kind | | |
| C12 In-hospital stroke | | |
| C13 Transfer to higher level of care | | |
| C14 Any procedure complication | | |
| C15 Other | | |
| **Surgical Module Triggers** | | |
| S1 Return to surgery | | |
| S2 Change in procedure | | |
| S3 Admission to intensive care post-op | | |
| S4 Intubation/reintubation/BiPap in Post Anesthesia Care Unit (PACU) | | |
| S5 X-ray intra-op or in PACU | | |
| S6 Intra-op or post-op death | | |
| S7 Mechanical ventilation greater than 24 hours post-op | | |
| S8 Intra-op epinephrine or norepinephrine | | |
| S9 Post-op troponin level greater than 1.5 ng/ml | | |
| S10 Change of anesthetic during surgery | | |
| S11 Consult requested in PACU | | |
| S12 Pathology report normal or unrelated to diagnosis | | |
| S13 Insertion of arterial or central venous line during surgery | | |
| S14 Operative time greater than 6 hours | | |
| S15 Removal/injury or repair of organ | | |

| Medication Module Triggers | + | Event Description and Harm Category (E-I) |
|---|---|---|
| M1 *Clostridium difficile* positive culture | | |
| M2 Partial thromboplastin time greater than 100 seconds | | |
| M3 International Normalized Ratio (INR) greater than 6 | | |
| M4 Glucose less than 50 mg/dl | | |
| M5 Rising BUN or serum creatinine greater than 2 times baseline | | |
| M6 Vitamin K administration | | |
| M7 Benadryl (Diphenhydramine) use | | |
| M8 Romazicon (Humazenil) use | | |
| M9 Narcan (Naloxone) use | | |
| M10 Anti-emetic use | | |
| M11 Over-sedation/hypotension | | |
| M12 Abrupt medication stop | | |
| M13 Other | | |
| **Intensive Care Module Triggers** | | |
| I1 Pneumonia onset | | |
| I2 Readmission to intensive care | | |
| I3 In-unit procedure | | |
| I4 Intubation/reintubation | | |
| **Perinatal Module Triggers** | | |
| P1 Apgar score less than 7 at 5 minutes | | |
| P2 Maternal/neonatal transport/transfer | | |
| P3 Magnesium sulfate or terbutaline use | | |
| P4 3rd- or 4th-degree lacerations | | |
| P5 Induction of delivery | | |
| **Emergency Department Module Triggers** | | |
| E1 Readmission to ED within 48 hours | | |
| E2 Time in ED greater than 6 hours | | |

Patient Identifier _____  Total Events _____  Total LOS _____  Write descriptions of the events in greater detail on reverse of Worksheet

[Photocopy Worksheet single-sided. Leave opposite side blank for notes.]

[42] F.A. Griffin and R.K. Resar, *IHI Global Trigger Tool for Measuring Adverse Events*, IHI Innovation Series white paper.  Cambridge, MA:  Institute for Healthcare Improvement Innovation Series 2007, Appendix B.

## Medicare Beneficiary Interview Questions

Table E-1 provides the list of the questions asked of Medicare beneficiaries to screen for possible events that may have occurred during the target hospitalization in the case study.

**Table E-1. Beneficiary Interview Questions**

| Part A: General Questions |
|---|
| 1. Why did you go to the hospital? |
| 2. In general, were there any problems that happened during this hospital stay? (If NO, go to Question 4.)<br><br>  If YES or UNSURE/ CANNOT DECIDE:<br>    A.  Please tell me more about that.<br>    B.  Please describe how this affected you.<br>    C.  How, if at all, did this affect the rest of your medical care at this hospital?<br>    D.  Describe how you became aware of this problem. For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it? |
| 3. Were there any other problems? (If NO, go to Question 4.)<br><br>  If YES or UNSURE/ CANNOT DECIDE:<br>    A.  Please tell me more about that.<br>    B.  Please describe how this affected you.<br>    C.  How, if at all, did this affect the rest of your medical care at this hospital?<br>    D.  Describe how you became aware of this problem. For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it? |
| 4. Was there anything [else] that seemed unusual about your medical care or anything else during your stay in this hospital? ( If NO, go to Question 5)<br><br>  If YES or UNSURE/ CANNOT DECIDE:<br>    A.  Please tell me more about that.<br>    B.  Please describe how this affected you.<br>    C.  How, if at all, did this affect the rest of your medical care at this hospital?<br>    D.  Describe how you became aware of this problem. For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it? |

## Table E-1. Beneficiary Interview Questions

| Part B: Medication Questions |
| --- |

5. Did you receive any medications or anesthesia during this hospital stay? (If NO, go to Question 8.)

6. Were there any problems with the medication you were given? (If NO, go to Question 8.)

    If YES or UNSURE/ CANNOT DECIDE:
       A.    Were you given the wrong type of medication? Yes or No.
       B.    Were you given the wrong dosage or amount of medication? Yes or No.
       C.    Did you have an allergic reaction to the medication? Yes or No.
       D.    Or did you have some other problem with the medication? Yes or No.
       E.    Was the medicine administered correctly? Yes or No.

    Please tell me more about that [these issues]:
       A.    What was the name of the medication? If you can't remember the name, please tell me what the medication was for: [Name/ Purpose]
       B.    Please describe how this affected you.
       C.    How, if at all, did this affect the rest of your medical care at this hospital?
       D.    Describe how you became aware of this problem. For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it?

7. Were there any other problems related to the medication you received during your stay at this hospital? (If NO, go to Question 8.)

    If YES or UNSURE/ CANNOT DECIDE:
       A.    Please tell me more about that.
       B.    Please describe how this affected you.
       C.    How, if at all, did this affect the rest of your medical care at this hospital?
       D.    Describe how you became aware of this problem. For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it?

| Part C: Procedure Questions |
| --- |

8. Did you have any surgeries or procedures in this hospital stay? (If NO, go to Question 11.)

9. Were there any problems related to the surgery? (If NO, go to Question 11.)

    If YES:
       A.    Please tell me more about that.
       B.    Please describe how this affected you.
       C.    How, if at all, did this affect the rest of your medical care at this hospital?
       D.    Describe how you became aware of this problem. For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it?

10. Were there any other problems related to the surgery? (If NO, go to Question 11.)

    If YES:
       A.    Please tell me more about that.
       B.    Please describe how this affected you.
       C.    How, if at all, did this affect the rest of your medical care at this hospital?
       D.    Describe how you became aware of this problem. For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it?

## Table E-1. Beneficiary Interview Questions

| Part C: Procedure Questions (Continued) |
|---|
| 11. Did you have any blood transfusions while you were in this hospital stay?  (If NO, go to Question 14.) |
| 12. Were there any problems related to the transfusion?  (If NO, go to Question 14.) |
| If YES or UNSURE/ CANNOT DECIDE:<br>    A. Please tell me more about that.<br>    B. Please describe how this affected you.<br>    C. How, if at all, did this affect the rest of your medical care at this hospital?<br>    D. Describe how you became aware of this problem.  For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it? |
| 13. Were there any other problems related to the blood transfusion?  (If NO, go to Question 14.) |
| If YES or UNSURE/ CANNOT DECIDE:<br>    A. Please tell me more about that.<br>    B. Please describe how this affected you.<br>    C. How, if at all, did this affect the rest of your medical care at this hospital?<br>    D. Describe how you became aware of this problem.  For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it? |
| 14. Were there any problems with the equipment?  (If NO, go to Question 15.) |
| If YES or UNSURE/ CANNOT DECIDE:<br>    A. Please tell me more about that.<br>    B. Please describe how this affected you.<br>    C. How, if at all, did this affect the rest of your medical care at this hospital?<br>    D. Describe how you became aware of this problem.  For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it? |
| **Part D: Infections and Other Issues** |
| 15. Did you develop any infections during this hospital stay?  (If NO, go to Question 17.) |
| If YES:<br>    A. Please tell me more about that.<br>    B. Please describe how this affected you.<br>    C. How, if at all, did this affect the rest of your medical care at this hospital?<br>    D. Describe how you became aware of this problem.  For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it? |
| 16. Did you develop any additional infections during this hospital stay that we have not already discussed?  (If NO, go to Question 17.) |
| If YES:<br>    A. Please tell me more about that.<br>    B. Please describe how this affected you.<br>    C. How, if at all, did this affect the rest of your medical care at this hospital?<br>    D. Describe how you became aware of this problem.  For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it? |

## Table E-1.  Beneficiary Interview Questions

| Part D:  Infections and Other Issues (Continued) |
|---|
| 17.  Did you develop any bedsores during the hospital stay?  (If NO, go to Question 18.)<br><br>If YES:<br>    A.    Please tell me more about that.<br>    B.    Please describe how this affected you.<br>    C.    How, if at all, did this affect the rest of your medical care at this hospital?<br>    D.    Describe how you became aware of this problem.  For example, did you notice it yourself or did a physician, nurse, or someone else from this hospital tell you about it? |
| 18.  Did you ever fall during this hospital stay?  (If NO, go to Question 19.)<br><br>If YES:<br>    A.    Please tell me more about that.<br>    B.    Please describe how this affected you.<br>    C.    How, if at all, did this affect the rest of your medical care at this hospital? |
| 19.  Did you ever feel unsafe during this hospital stay?  (If NO, go to question 20.)<br><br>If YES:<br>    A.    Please tell me more about that.<br>    B.    Please describe how this affected you.<br>    C.    How, if at all, did this affect the rest of your medical care at this hospital? |
| 20.  Did a physician or other health care official tell you that you received the wrong diagnosis while you were in this hospital?  (If NO, go to Question 21.)<br><br>If YES:<br>    A.    Please tell me more about that.<br>    B.    Please describe how this affected you.<br>    C.    How, if at all, did this affect the rest of your medical care at this hospital? |
| 21.  Did you discover any problems with the care you received at this hospital, once you were discharged?  (If NO, go to Question 22.)<br><br>If YES:<br>    A.    Please tell me more about that.<br>    B.    Please describe how this affected you.<br>    C.    How, if at all, did this affect the rest of your medical care at this hospital? |
| **Part E:  Hospital Response** |
| 22.  Did you file a formal complaint about this hospital stay for any reason?  (If NO, go to Question 23.)<br><br>If YES:<br>    A.    Please describe the nature of the complaint.<br>    B.    How did this hospital stay respond to your complaint?<br>    C.    Were you fully satisfied by this hospital stay's response to your complaint? |
| 23.  Did anyone from this hospital talk to you about the issues you have described today? (Note:  Asked only if a possible event was discussed in prior questions.  (If NO, go to Question 24.)<br><br>If YES:<br>    A.    If you can recall, who spoke to you about these issues?<br>    B.    What did they say?<br>    C.    How, if at all, did they address your concerns?<br>    D.    Were you fully satisfied by this hospital stay's response? |
| **Part F:  Close** |
| 24.  Is there anything else you would like to tell us about the care you received at this hospital? |

Source:  Office of Inspector General interview protocol used to collect information about Medicare beneficiaries.

### Patient Safety Indicators

Table F-1 lists the provider-level Patient Safety Indicators developed by the Agency for Healthcare Research and Quality (AHRQ), which, when flagged, may indicate possible adverse events.

**Table F-1:  AHRQ Patient Safety Indicators (Provider-Level)**

| Patient Safety Indicators | PSI Number |
|---|---|
| Complications of anesthesia | 1 |
| Death in low mortality | 2 |
| Decubitus ulcer | 3 |
| Failure to rescue | 4 |
| Foreign body left in during procedure | 5 |
| Iatrogenic pneumothorax | 6 |
| Selected infections due to medical care | 7 |
| Postoperative hip fracture | 8 |
| Postoperative hemorrhage or hematoma | 9 |
| Postoperative physiologic and metabolic derangements | 10 |
| Postoperative respiratory failure | 11 |
| Postoperative pulmonary embolism or deep vein thrombosis | 12 |
| Postoperative sepsis | 13 |
| Postoperative wound dehiscence in abdominopelvic surgical patients | 14 |
| Accidental puncture and laceration | 15 |
| Transfusion reaction | 16 |
| Birth trauma - injury to neonate | 17 |
| Obstetric trauma - vaginal delivery with instrument | 18 |
| Obstetric trauma - vaginal delivery without instrument | 19 |
| Obstetric trauma - cesarean delivery | 20 |

Source:  AHRQ, *Guide to Patient Safety Indicators*, AHRQ Quality Indicators.  March 2003.  Available online at http://www.qualityindicators.ahrq.gov/archives/psi/psi_guide_v30.pdf.  Accessed on June, 4, 2008

## Case Study Protocol for Physician Reviews

Figure G-1 presents the form used by physicians to record the results of medical record reviews for the second stage of review in the case study. Physicians generated one form for each adverse event. Figure G-2 is the case summary completed by physicians at the end of their reviews. Table G-1 describes the categories used to classify the level of harm to the patient caused by the event.

**Figure G-1: Adverse Event Review Form**

CASE ID: _____

### *Medical Review Protocol - OIG Case Study of Adverse Events*

### *Adverse Event Review*

**1.** Adverse Event #: _____ (Case # + Alpha)

**2.** Please briefly identify the **adverse event**: _____

_____

**3.** Please provide a **full description** of the adverse event, including the:
  – circumstances of the adverse event *(note as AE)*,
  – possible contributing factors *(note as CF)*, and
  – impact of the adverse event on the patient *(note as PI)*.

+-------------------------------------------------------------+
| **AE:**                                                     |
|                                                             |
|                                                             |
|                                                             |
| **CF:**                                                     |
|                                                             |
|                                                             |
|                                                             |
| **PI:**                                                     |
|                                                             |
|                                                             |
+-------------------------------------------------------------+

**Figure G-1:  Adverse Event Review Form (Continued)**

CASE ID: _____

**4.** Using the NCC MERP **categories of harm**, what level of harm resulted from the event?

- ☐ E – Temporary harm, intervention required
- ☐ F – Temporary harm, initial or prolonged hospitalization
- ☐ G – Permanent patient harm
- ☐ H – Life-sustaining intervention required
- ☐ I – Contributing to death

**5.** Does the harm incurred appear to be the result of a **"cascade"**?

- ☐ Yes (If yes, please insure that Q3 includes the sequence of occurrences.)
- ☐ No

If yes, please lay out the sequence of occurrences below (with arrows):

**6.** On what **date or range of dates** did the adverse event occur?

**7.** During which time period did the adverse event occur?
- ☐ During time in emergency department
- ☐ During time in observation
- ☐ During the targeted inpatient hospitalization
- ☐ Other, please describe:

**Figure G-1:  Adverse Event Review Form (Continued)**

CASE ID: _____

**8.**  Please review the provided billing summary of diagnosis and procedure codes.  Which (if any) appear to **result from this adverse event**?

| ICD-9 Code | Brief Description |
|---|---|
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**9.**  Which **case flags** reflected information about the specific adverse event? (Check all that apply.)

☐   Patient interview
☐   Global Trigger Tool summary
☐   POA analysis
☐   PSI analysis
☐   Hospital incident report or other hospital report
☐   No case flags reflected this adverse event

**10.**  Is there anything additional you would like to **note about the case flags** for this adverse event? (case flag or element of a case flag that was particularly valuable in leading you to the event, thoughts about selecting case flags for our future work, etc.)

**Figure G-1:  Adverse Event Review Form (Continued)**

CASE ID: _____

PLEASE IDENTIFY THE EVENTS/CONDITIONS AND CHECK ALL THAT APPLY

## NQF Serious Reportable Events:

Any degree of harm (E – I):

- ☐ Unintended retention of foreign object after surgery or procedure
- ☐ Surgery on the wrong body part or wrong patient
- ☐ Wrong surgical procedure performed on patient
- ☐ Care provided by someone impersonating provide
- ☐ Abduction of patient receiving care
- ☐ Sexual assault of a patient in facility or grounds
- ☐ Pressure ulcers (Stages III & IV)
- ☐ Line for oxygen or other gas contains the wrong gas or is contaminated by toxic substances

Patient death or serious disability associated:

(serious disability = loss of a body part, disability or loss of bodily function lasting more than 7 days or still present at discharge)

- ☐ Intravascular air embolism that occurs while being cared for in a health care facility
- ☐ Medication error (wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)
- ☐ Hemolytic reaction because of administration of incompatible blood or blood products
- ☐ Electric shock or elective cardioversion
- ☐ Use of contaminated drugs, devices, or biologics provided by the health care facility
- ☐ Use or function of a device in patient care, when device is used or functions other than as intended
- ☐ Use of restraints or bedrails while being cared for in a health care facility
- ☐ Patient suicide or attempted suicide
- ☐ Physical assault
- ☐ Hypoglycemia, the onset of which occurs during care at the health care facility
- ☐ Spinal manipulative therapy
- ☐ Burn
- ☐ Fall
- ☐ Patient elopement

Patient death associated:

- ☐ Intraoperative or immediately postoperative

**Was this event represented on the NQF list?**

- ☐ Yes
- ☐ No

## CMS Hospital-Acquired Conditions:

Any degree of harm (E – I):

- ☐ Foreign object retained after surgery
- ☐ Air embolism
- ☐ Blood incompatibility
- ☐ Pressure ulcers (Stages III & IV)
- ☐ Falls
  - ☐ Fracture
  - ☐ Dislocation
  - ☐ Intracranial injury
  - ☐ Crushing injury
  - ☐ Burn
  - ☐ Electric shock
- ☐ Manifestations of poor glycemic control
  - ☐ Hypoglycemic coma
  - ☐ Diabetic ketoacidosis
  - ☐ Nonkeototic hyperosmolar coma
  - ☐ Secondary diabetes with ketoacidosis
  - ☐ Secondary diabetes with hyperosmolarity
- ☐ Catheter-associated urinary tract infection
- ☐ Vascular catheter-associated infection
- ☐ Deep vein thrombosis/pulmonary embolism
  - ☐ Total knee replacement
  - ☐ Hip replacement
- ☐ Surgical site infection
  - ☐ Mediastinitis after CABG
  - ☐ Certain orthopedic procedures
    - ☐ Spine
    - ☐ Neck
    - ☐ Shoulder
    - ☐ Elbow
  - ☐ Bariatric surgery for obesity
    - ☐ Laprascopic gastric bypass
    - ☐ Gastroenterostomy
    - ☐ Laparoscopic gastric restrictive surgery

**Was this event represented on the CMS list?**

- ☐ Yes
- ☐ No

**Figure G-2:  Case Summary**

### *Medical Review Protocol - OIG Case Study of Adverse Events*
### *Case Cover Page*

Review Date:    _____, 2008

Physician Initials: _____

| |
|---|
| Hospital: _____ |
| Patient name: _____ |
| OIG ID#: _____    MR#: _____ |

Directions:    Review the provided case documents and medical record.
Complete **Adverse Event Review** for any adverse events.
Complete **Summary Questions** and **Exit Check List**.

## Beneficiary Information

Name: _____    D.O.B.:_____

Dates of Stay: _____    L.O.S. (days):_____

Principal Diagnosis: _____

Flags:          ___ Beneficiary Interview         ___ IHI Global Trigger Tool Review
                ___ POA Analysis                  ___ Hospital Incident Report
                ___ PSI Analysis                  ___ Other: _____

## Summary Questions

**1. Is this review complete?**
☐  Yes
☐  Partially complete, estimate _____ additional time needed

**2. Did you identify any adverse event(s)?**
☐  Yes, how many?  _____
☐  No

   AE #s and brief descriptions:
   _____          _____
   _____          _____
   _____          _____
   _____          _____

**3. Should this case be targeted for further discussion?**
☐  Yes
☐  No
If yes, please briefly state reason:

**Figure G-2: Case Summary (Continued)**

CASE ID: _____

# *Case Exit Check List*

**1.** Which of the following **information sources** did you review?  (Check all that apply.)
- ☐  Medical record
- ☐  Results of administrative data reviews
- ☐  Patient interview
- ☐  Hospital incident report or other hospital report
- ☐  Other, please describe:_____

**2.** Please circle on the scale below to assess the **documentation** in the medical record.  A scale of 1=worst (unclear, difficult to determine event) and 5=best (well-described and definitive).

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|

**3.** Was the **medical record** recorded as (check both if applies):
- ☐  Paper records?
  - ☐  Easy to navigate
  - ☐  Some difficulty navigating
  - ☐  Difficult to navigate
- ☐  Electronic records?
  - ☐  Easy to navigate
  - ☐  Some difficulty navigating
  - ☐  Difficult to navigate

**4.** Did you **consult** with another physician reviewer?
- ☐  Yes
- ☐  No

If yes, please describe: _____

**5.** How **much time** did you spend on this review (including any consultation with others)?
- ☐  Less than 30 minutes
- ☐  Between 30 minutes – one hour
- ☐  Between one hour – two hours
- ☐  More than two hours
- ☐  Difficult to determine because of stop and start and/or consultation

**6.** Did this case suggest **modifications** of this form to improve subsequent studies?
- ☐  Yes
- ☐  No

If yes, please describe: _____

_____

**7.** Is there **anything else** about this case that you would like to note? _____

_____

## Patient Harm Index

Table G-1 lists the categories of patient harm adapted by the Institute for Healthcare Improvement (IHI) and used by the Office of Inspector General in the case study.  The National Coordinating Council for Medication Errors Reporting and Prevention (NCC MERP) developed an index to categorize the level of patient harm resulting from medication errors.  Researchers have modified this index for use in measuring and distinguishing adverse events of all types, rather than only medication errors.  IHI adapted the index to reflect only events that cause harm to patients.

**Table G-1:  IHI Global Trigger Tool Adaptation of the NCC MERP Index to Categorize Harm**

| Category | Description |
|----------|-------------|
| E | Temporary harm to the patient and required intervention |
| F | Temporary harm to the patient and required an initial or prolonged hospital stay |
| G | Permanent patient harm |
| H | Intervention required to sustain life |
| I | Patient death |

Source:  F.A. Griffin and R.K. Resar, *IHI Global Trigger Tool for Measuring Adverse Events*, IHI Innovation Series white paper.  Cambridge, MA: Institute for Healthcare Improvement Innovation Series 2007, pp. 4–5.

## Results of Screening Methods

**Figure H-1: Results of Screening Methods Used for Identifying Events in Case Study**
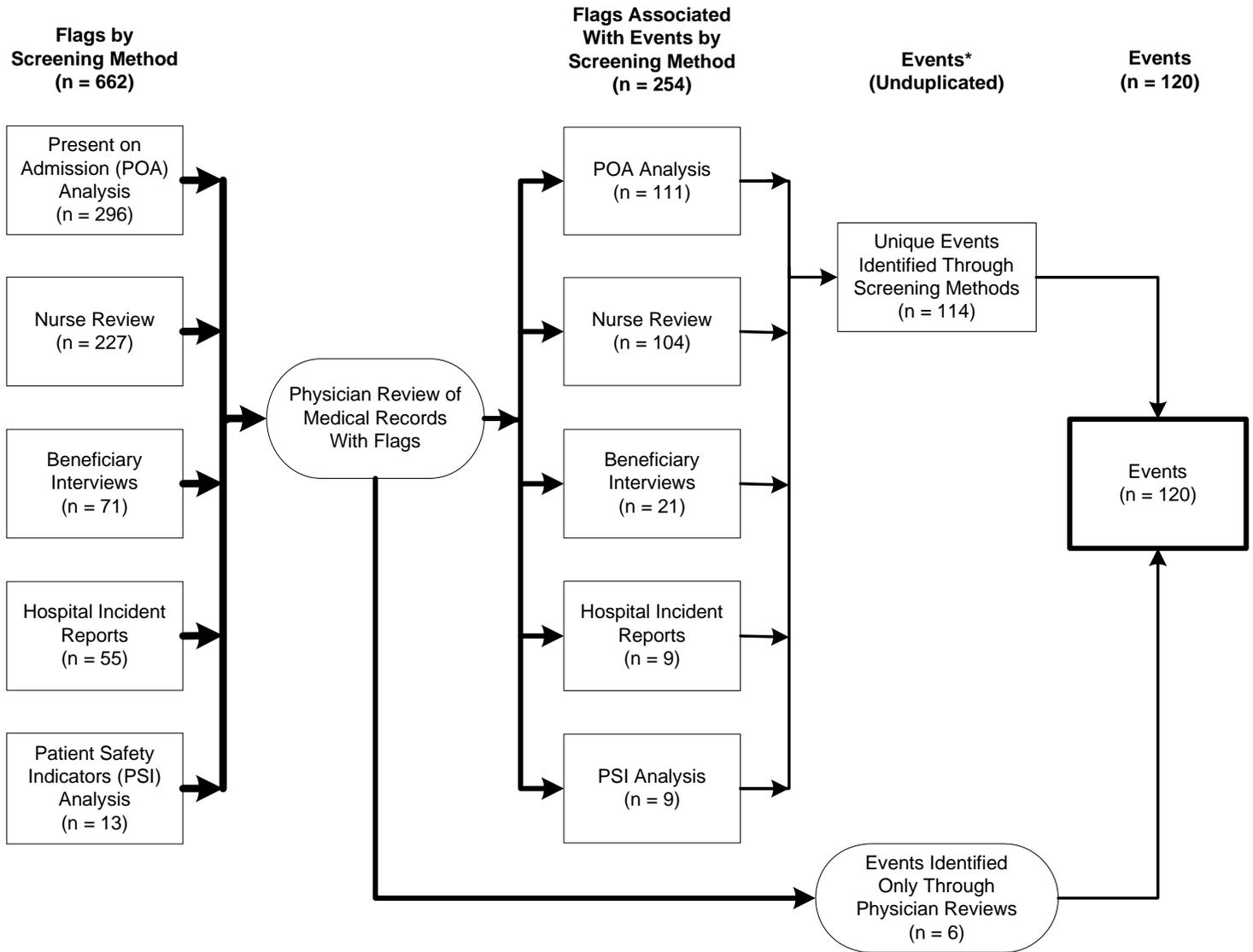
Source: Office of Inspector General analysis of 278 Medicare beneficiary hospitalizations in 2 selected counties, 2008.
*Some flags were associated with more than one event, and some events were identified through more than one flag.

## Agency Comments: Agency for Healthcare Research and Quality

DEPARTMENT OF HEALTH & HUMAN SERVICES

Agency for Healthcare
Research and Quality

540 Gaither Road
Rockville MD 20850
www.ahrq.gov

**DEC 1 6 2009**

TO:        Daniel Levinson, Inspector General

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

SUBJECT:  Comments on draft Office of Inspector General Report entitled, "Adverse
          Events in Hospitals: Methods for Identifying Events"

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

If you have any questions, please feel free to call Wendy Perry of my staff at 301-427-
1216.

## Agency Comments: Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

**Administrator**
Washington, DC 20201

DEC 1 7 2009

**TO:** Daniel R. Levinson
Deputy Inspector General

**FROM:** Charlene Frizzera  /S/
Acting Administrator

**SUBJECT:** Office Of Inspector General (OIG) Draft Report: "Adverse Events in Hospitals: Methods for Identifying Events," (OEI-06-08-00221)

Thank you for the opportunity to review and comment on this draft report, "Adverse Events in Hospitals: Methods for Identifying Events." This is a particularly useful report that offers timely recommendations. The OIG undertook original data collection to assess five different methods of identifying the occurrence of serious adverse events in short-term acute care hospitals. The OIG then identified strengths and weaknesses of each method. Finally, the OIG explored implications of its findings with regard to the ability of the Centers for Medicare & Medicaid Services (CMS) to monitor adverse events, promote value-based purchasing, and enforce quality of care and patient safety requirements.

We appreciate the original contribution that this study makes in advancing the patient safety agenda in hospitals and bolstering CMS efforts to prevent adverse events. As the OIG noted, CMS enforces quality of care expectations through its survey and certification onsite reviews. CMS has actively advanced value-based purchasing across a variety of provider types. CMS has also instituted payment policies that prevent coverage of certain serious but clearly avoidable medical events, often referred to as "Never Events." Information about the most recent policies (relating to performance of the wrong surgery or surgery on the wrong body part or on the wrong patient) can be found at:
http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6405.pdf.

We endorse each recommendation addressed to CMS, and provide more detail below.

**OIG Recommendation 1:**

CMS and the Agency for Healthcare Research and Quality (AHRQ) should explore opportunities to identify events when conducting medical record reviews for other purposes.

**CMS Response**

We agree with the recommendation and will consider creating or taking advantage of existing opportunities to identify adverse events, including consideration of the specific options identified by the OIG.

Page 2- Daniel R. Levinson

It is already a standard CMS expectation that surveyors will investigate any evidence of patient adverse events that come to the surveyors' attention when a State Survey Agency is conducting a survey of a hospital's compliance with the Medicare Conditions of Participation (CoPs). Every onsite survey gathers information through medical record reviews, staff interviews, and direct observation. Surveyors are required to determine whether the event was identified by the hospital on its own prior to the survey, and whether the hospital took appropriate corrective action after the event to reduce the likelihood of similar events in the future. We are also increasingly investigating the extent to which such adverse events have been tracked and analyzed by the hospital's own internal Quality Assurance and Performance Improvement (QAPI) system, as required by CMS CoPs.

Many quality of care concerns are also addressed by the Quality Improvement Organization (QIO) program. QIOs may discern a quality of care concern through the beneficiary complaint process, through their regular statutory and regulatory mandated medical review processes, or through referral by entities including the Fiscal Intermediaries/Medicare Administrative Contractors and Recovery Audit Contractors.

Another program referenced by the OIG is CMS' Medicare Comprehensive Error Rate Testing (CERT) program. CERT involves complex medical reviews on all sampled inpatient hospital claims to ensure proper payment of the claim. The reviews conducted by the CERT program are solely focused on payment and do identify incorrect coding. CERT does not conduct complete quality reviews. CMS will explore a possible quality referral mechanism between the CERT contractor and the QIOs.

The CMS and AHRQ are also collaborating on the Medicare Patient Safety Monitoring System. This initiative uses chart abstraction to estimate prevalence with regards to certain conditions and adverse events including health care-associated infections.

Patient safety quality data self-reported by hospitals is another potential source for potential adverse event identification. To this end, CMS under its QIO program has proposed policy revisions to the beneficiary complaint and quality of care review processes to include adverse events as indicators to evaluate quality of care issues. While Federal regulations do not allow QIOs to release the results of quality of care reviews beyond the provider unless requested by the Government Accountability Office or OIG (in accordance with 42 C.F.R. § 480.140(b)), the QIO reviews can be instrumental in helping a hospital improve its own internal quality assurance systems and taking corrective action.

**OIG Recommendation 2**

CMS should ensure that hospitals code claims accurately and completely to allow for identification of hospital-acquired conditions affected by Medicare's payment policy.

Page 3- Daniel R. Levinson

**CMS Response**

We agree with the recommendation. We concur that there is a need for hospitals to code claims accurately and completely to allow for the accurate identification of hospital-acquired conditions. As such, CMS has established a process for providing coding advice to hospitals on the reporting of Present on Admission (POA) indicators that affect the payment of cases with hospital-acquired conditions. The American Hospital Association's Editorial Advisory Board has agreed to receive questions on POA reporting and to provide advice through Coding Clinic for ICD-9-CM. CMS is a member of the board. This board already provides advice for correct coding, including coding conditions that may be hospital-acquired.

Since hospital payment adjustments for hospital-acquired conditions went into effect on October 1, 2008, we do not yet have claims data to evaluate reporting patterns for hospital-acquired conditions. We will be able to review nine months of this data beginning in December 2009. We are examining several issues involving hospital-acquired conditions. One of these tasks is to study the accuracy of coding hospital-acquired conditions and reporting POA indicators. CMS' contractor will also perform an environmental scan to determine how hospitals are approaching hospital-acquired conditions and POA reporting, including the use of any software to assist in this task. The contractor will also attempt to determine the extent of subjectivity in the coding guidelines and instructions for hospital-acquired conditions and POA coding. Feedback from this contractor will be used to develop refinements in coding instructions or to assist with focusing reviews on areas of inaccurate reporting.

**OIG Recommendation 3**

CMS should provide interpretive guidelines for State survey agencies to assess hospital compliance to track and monitor adverse events.

**CMS Response**

We agree completely with this recommendation. In recent years CMS has strengthened the requirements for providers to have internal quality assurance and performance improvement (QAPI) systems in place. Further, CMS requires that such systems include the practiced capability to track and analyze adverse events, and then make use of the analysis. The next and necessary steps are to (a) ensure that the State Operations Manual includes full guidance for surveyors to assess QAPI systems and (b) to strengthen CMS surveyor training programs to enhance surveyor abilities to evaluate compliance with the QAPI CoP. We will do so.

Page 4- Daniel R. Levinson

**OIG Recommendation 4:**

AHRQ should inform Patient Safety Organizations (PSOs) that internal hospital incident reporting may be insufficient to provide needed information about events to PSOs.

**CMS Response**

See the AHRQ response conveyed separately.

The CMS very much appreciates the opportunity that the OIG has afforded us to comment on this draft report and we look forward to working with the OIG on this and other issues in the future.

Attachment

## ▶ A C K N O W L E D G M E N T S

# Office of Inspector General

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## Office of Audit Services

The Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

## Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. Specifically, these evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, the reports also present practical recommendations for improving program operations.

## Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

## Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.