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ADVERSE EVENTS IN REHABILITATION HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES

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EXECUTIVE SUMMARY: ADVERSE EVENTS IN REHABILITATION HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES
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WHY WE DID THIS STUDY

This report is part of a series on adverse events in healthcare settings, defined as harm resulting from medical care. Previous OIG work identified harm rates of about 30 percent in both acute-care hospitals and skilled nursing facilities (SNF), with an attendant toll on patient health and taxpayers' costs, the latter amounting to billions of dollars annually. This report extends our work by evaluating care provided in rehabilitation (rehab) hospitals. Rehab hospitals are post-acute providers that specialize in intensive rehabilitative care for patients recovering from illness, injury, or surgery. While in recent years stakeholders have paid considerable attention to patient safety in acute-care hospitals and increasingly in SNFs, less is known about adverse events in other health care settings. An increased understanding of adverse events that occur in this unique setting would better equip health care providers and other stakeholders in taking actions to improve the safety of patient care in rehab hospitals.

HOW WE DID THIS STUDY

We reviewed medical records to estimate the national incidence rate, preventability, and costs of adverse events in rehab hospitals. We reviewed a nationally representative sample of 417 Medicare beneficiaries discharged from rehab hospitals in March 2012.

WHAT WE FOUND

An estimated 29 percent of Medicare beneficiaries experienced adverse or temporary harm events during their rehab hospital stays, resulting in temporary harm; prolonged stays or transfers to other hospitals; permanent harm; life-sustaining intervention; or death. This harm rate is in line with what we found in hospitals (27 percent) and in SNFs (33 percent). Physician reviewers determined that 46 percent of these adverse and temporary harm events were clearly or likely preventable. Physicians attributed much of the preventable harm to substandard treatment, inadequate patient monitoring, and failure to provide needed treatment. Nearly one-quarter of the patients who experienced adverse or temporary harm events were transferred to an acute-care hospital for treatment, with an estimated cost to Medicare of at least $7.7 million in one month, or at least $92 million in one year, assuming a constant rate of hospitalization throughout the year.

WHAT WE RECOMMEND

The incidence of adverse events in rehab hospitals is similar to that in acute-care hospitals and SNFs, as reflected in previous OIG findings, confirming the need and opportunity to significantly reduce the incidence of adverse events across health care settings. We recommend that the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) raise awareness of patient safety issues in rehab hospitals and seek to reduce patient harm. This effort should include: (1) collaboration to create and disseminate a list of potential adverse events that occur in rehab hospitals and (2) the addition of information about potential adverse events in quality guidance to rehab hospitals. CMS and AHRQ concurred with our recommendations.

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OBJECTIVES

1. To estimate the incidence of adverse and temporary harm events for Medicare beneficiaries admitted to rehabilitation (rehab) hospitals for post-acute care.
2. To assess the extent to which adverse and temporary harm events were preventable and identify contributing factors.
3. To estimate the extent and cost of acute-care hospital admissions and emergency department visits that resulted from adverse and temporary harm events.

BACKGROUND

Adverse Events in Health Care

The term "adverse event" describes harm to a patient as a result of medical care, including the failure to provide needed care.[1] An adverse event indicates that the care resulted in an undesirable clinical outcome not caused by underlying disease. Adverse events include medical errors and general substandard care that result in patient harm, such as infections caused by the use of contaminated equipment. However, adverse events do not always involve errors or poor quality of care and are not always preventable.[2]

Office of Inspector General Reports on Adverse Events

In a series of reports from 2008–2014, the Office of Inspector General (OIG) demonstrated that adverse events are common and costly to the Medicare program.[3] In a 2010 study, OIG found that 27 percent of hospitalized Medicare beneficiaries experienced adverse or temporary harm events.[4] Nearly half of the events were preventable, and care associated with events cost Medicare an estimated $4.4 billion a year. OIG also found that most hospital staff did not recognize or report patient harm when it occurred.[5] In a 2014 study, OIG found that 33 percent of Medicare residents in post-acute Skilled Nursing Facility (SNF) stays

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[1] For the purposes of analysis in this report, we divide adverse events into two groups: adverse events and temporary harm events. We define temporary harm events as events that harmed patients and required medical intervention but did not cause lasting harm.

[2] R. M. Wachter, *Understanding Patient Safety*, Second Edition, McGraw-Hill, 2012, p. 17.

[3] OIG issued 11 reports regarding adverse events from 2008–2014, including reports about the incidence of adverse events, methods for identifying adverse events, hospital incident reporting systems, and public disclosure of event information. All reports are available at https://oig.hhs.gov/reports-and-publications/oei/a.asp#adverse_care.

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

[5] OIG, *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm*, OEI-06-09-00091, January 2012.

experienced adverse and temporary harm events.[6] Over half (59 percent) of these SNF events were preventable, and care associated with these events cost Medicare an estimated $2.8 billion in a single year.

Post-Acute Care in Rehab Hospitals

Rehab hospitals are independently run inpatient facilities that specialize in providing intensive rehabilitation therapy to patients recovering from illness, injury, or surgery.[7] Patients entering rehab hospitals must be able to tolerate and benefit from at least 3 hours of therapy a day, 5 days a week.[8] This limits the patient profile in these facilities to individuals who need and can tolerate a physically demanding therapy regimen following hospitalization. Commonly treated conditions in rehab hospitals include strokes, neurological disorders, and major lower extremity joint replacements (e.g., knee and hip replacements). Hospital-based rehabilitation units provide similar care and are reimbursed through the same prospective payment system but are managed as one part of a larger acute-care hospital.

In fiscal year (FY) 2012, 234 rehab hospitals provided care to Medicare beneficiaries accounting for a total of $2.4 billion in Medicare spending. Table 1 compares rehab hospitals to other types of providers of post-acute rehabilitation services. The comparison is based on several metrics, including the average amount reimbursed by Medicare per admission and the average length of stay.

Table 1: Medicare Services in Post-Acute-Care Providers (FY 2012)

	Total Number of Facilities	Total Number of Admissions	Average Length of Stay	Average Reimbursement Per Admission
Rehab hospitals	234	139,526	13.0 days	$17,164
Hospital-based rehab units	896	192,454	12.6 days	$17,317
Long-term acute-care hospitals	420	140,463	26.2 days	$39,493
Home health agencies**	12,311	6.7 million	18.6 days	$5,247
SNFs	14,938	2.4 million	41.5 days*	$12,329*

*These figures are the average of the top and bottom quartiles presented by Medicare Payment Advisorty Commission.
**Figures for home health agencies are expressed by “episode of care” instead of by admission.
Sources: Metrics for rehab hospitals and hospital rehab units are based on OIG analysis of Medicare claims data and metrics for other provider types are based on MedPAC, *Report to the Congress: Medicare Payment Policy,* March 2014.

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[6] OIG, *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*, OEI-06-11-00370, February 2014.

[7] A rehab hospital is eligible for Medicare payment through the Inpatient Rehabilitation Facility Prospective Payment System if it meets the criteria specified in 412.29, which includes a provision that at least 60 percent of a facility’s total inpatient population have one or more of 13 listed conditions.

[8] 42 CFR § 412.622.

Federal Efforts to Improve Quality and Safety in Rehab Hospitals

Accreditation and Routine Surveys. As it does for all other Medicare- and Medicaid-certified hospitals, the Centers for Medicare & Medicaid Services (CMS) oversees rehab hospitals' compliance with a set of minimum quality and safety standards known as the Conditions of Participation (CoPs).[9] Rehab hospitals may demonstrate compliance through accreditation by a Medicare-approved program or through periodic onsite surveys by a State survey agency.[10] CMS provides guidance to these State agencies for conducting hospital surveys in its *State Operations Manual (SOM)*, including guidance specific to the rehab setting.[11]

Quality Assessment and Performance Improvement (QAPI). While many of the CoPs have an impact on quality, the QAPI CoP is the condition most explicitly focused on ensuring that facilities take actions to improve quality and safety.[12] It requires rehab hospitals to "track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital." To accomplish this, rehab hospitals must "measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations."

Reporting of Quality Data. Congress established a quality reporting program for rehab hospitals and other post-acute-care providers in the 2010 Patient Protection and Affordable Care Act (ACA).[13] CMS refers to this program as the Inpatient Rehabilitation Facilities (IRF) Quality Reporting Program (QRP).[14, 15] As part of the IRF QRP, CMS plans to adjust rehab hospital payment based on five quality measures, such as the percentage of residents with pressure ulcers that are new or worsened.[16]

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[9] The Secretary's authority to establish the CoPs is at SSA, § 1861(e)(9). The current CoPs are defined at 42 CFR § 482.

[10] Social Security Act, §§ 1864 and 1865, 42 U.S.C. §§ 1395aa and 1395bb.

[11] CMS, *SOM, Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals*, Pub. 100-07.

[12] 42 CFR § 482.21.

[13] ACA, P.L. 111-148 § 3004(a); SSA § 1886(j)(7).

[14] 76 Fed. Reg. 47836, 47873–83 (Aug. 5, 2011).

[15] CMS, *IRF Quality Reporting*, October 24, 2014 update. Accessed at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/ on October 29, 2014.

[16] 79 Fed. Reg. 45871, 45918 (Aug. 6, 2014).

In addition to the reporting required by the IRF QRP, the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) included new reporting requirements for post-acute-care providers, including rehab hospitals.[17] Upon implementation, the IMPACT Act will require that rehab hospitals, along with other post-acute-care providers, report data on falls resulting in injury, pressure ulcers, and other quality issues.

METHODOLOGY

We estimated the incidence of adverse events (including temporary harm events) using a sample of Medicare patients who received inpatient care in rehab hospitals. Our study population was composed of Medicare beneficiaries discharged from rehab hospitals in March 2012. The beneficiaries were included only if a claim was submitted to Medicare and the stay began within 3 days of the beneficiary's discharge from an acute-care hospital.

We excluded beneficiaries who received care in hospital-based rehab units or through other post-acute-care providers. The hospital-based rehab units associated with the excluded beneficiaries in our sample constitute 80 percent of IRFs.[18] We chose to focus instead on the smaller number of independently run rehab hospitals in an effort to align our findings and recommendations with the unique situation of these providers, which may not have the same capacity to provide acute-level services and receive separate oversight by CMS.

Sample Selection and Profile

Using Medicare claims data from the National Claims History (NCH) file, we selected a simple random sample of 417 Medicare beneficiaries out of the 12,328 beneficiaries who had rehab hospital stays that met the sample criteria defined above. Nine sample beneficiaries had two stays during March. In these cases, we reviewed both stays. As a result, the 417 sample beneficiaries had 426 rehab hospital stays that ended in March 2012. The length of stay averaged 12.7 days.

Data Collection

We requested and received complete medical records for the sampled beneficiaries' rehab hospital stays. As part of this request, we asked administrators from the rehab hospitals to provide discharge summaries and other key medical record documents from the acute-care hospital stays

[17] IMPACT Act of 2014, P.L. 113-185 § 2(a), SSA § 1899B. The IMPACT Act has a phased implementation schedule, with full implementation for rehab hospitals expected by October 2018.

[18] MedPAC, *Report to the Congress: Medicare Payment Policy*, March 2014, p. 243 – 244.

that preceded the rehab hospital stays. We also requested discharge summaries and other key medical record documents for any acute-care hospital stay that occurred between the rehab hospital admission and 14 days after discharge. In addition to collecting the medical records, we collected billing data for the rehab hospital stays and any associated payments to hospitals from Medicare inpatient and outpatient claims files.

Identification of Adverse and Temporary Harm Events. We conducted a two-stage medical record review to identify adverse events in the sampled records.[19] The first stage was a screening process designed to identify beneficiaries who may have experienced an adverse event during their stay(s). During this stage, one of two registered nurses with extensive experience performing trigger tool reviews (referred to as "screeners") reviewed the medical records of the sampled beneficiaries' rehab and acute-care hospital stays, as well as associated administrative data collected by OIG.[20] The screeners flagged the records of 182 beneficiaries who were likely to have experienced an adverse event.

In the second stage, 1 or more of the 6 contracted physicians reviewed the medical records of the 182 beneficiaries flagged by screeners as likely to have experienced adverse events. The physicians examined the charts for possible adverse events and described these events using a structured data collection instrument.

Data Analysis

We used the results of the review to generate estimates about adverse events in three categories: incidence of events, preventability of events, and Medicare cost associated with events. In addition to projected estimates, we described the sample when we had too few sample occurrences to make reliable projections. For more information on the estimates and corresponding 95-percent confidence intervals, see Appendix C.

Event Incidence Analysis. To calculate incidence rates, we determined the percentage of sample Medicare rehab hospital patients who experienced at least one event (e.g., adverse event, temporary harm event) within the sample and projected the results to the population from which we selected the sample.

Severity Analysis. The physician reviewers assigned each event to one of the five harm levels, using a modified version of the National Coordinating Council for Medication Error Reporting and Prevention

[19] See Appendix A for a detailed description of the methodology used to identify adverse and temporary harm events.

[20] See Appendix B for a description of the tool the screeners used to review the records.

(NCC MERP) Index. We make a distinction between "adverse events" (levels F-I on the index) and "temporary harm events" (level E on the index) to separate events that caused the most serious harm. Both groups represent harm to patients resulting from medical care or in a health care setting. (See Table 3.)

Table 3: Modified Version of the NCC MERP Index for Categorizing Errors Used in the OIG Study of Adverse Events in Rehab Hospitals

	Level	Description
Adverse Event	I	Harm occurred that may have contributed to or resulted in patient death
	H	Harm occurred that required intervention to sustain the patient's life
	G	Harm occurred that contributed to or resulted in permanent patient harm
	F	Harm occurred that prolonged the stay or led to a transfer to a different rehab hospital, another post-acute facility, or an acute-care hospital for observation, emergency treatment, or inpatient care
Temporary Harm	E	Harm occurred that caused temporary harm that required intervention

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

Preventability Analysis. The physician reviewers also assigned each event to one of five preventability determinations—clearly preventable, likely preventable, unable to determine, likely not preventable, or clearly not preventable. We calculated percentages for each preventability classification and projected the results to the population from which we selected the sample.

Medicare Cost Analysis. We conservatively estimated the amount Medicare paid for acute-care hospital stays and emergency department visits resulting from adverse events in rehab hospitals. We identified the Medicare cost of acute-care hospital stays and/or emergency department visits that occurred as a result of physician-identified adverse events. We projected this dollar amount to the population but present the lower bound of the 95-percent confidence interval associated with the cost estimate. We provide the conservative lower bound—instead of the point estimate—because the small number of sample occurrences made the point estimate unreliable. The actual amount paid by Medicare for adverse events in rehab hospitals is likely to be at least the value of the reported amount (the lower bound of the corresponding 95-percent confidence interval). Further, additional costs paid by Medicare or the beneficiary for followup care are not included.

Limitations

The methodology presents several limitations. First, all findings related to identified events are limited to the population from which we selected the sample. Specifically, findings reflect only rehab hospital stays that ended in March 2012 and began within one day of the beneficiary's discharge

from a hospital. Beneficiaries who received care in hospital-based rehab units are excluded.[21] Second, it is unlikely that the study identified all adverse events within the sample of rehab hospital patients. To the extent that we did not identify all adverse events, omissions may be the result of incomplete documentation in the medical records or a failure of the reviewers to correctly identify the patient harm. Third, the cost estimate does not include all costs of care associated with adverse events, including additional care after the hospitalizations (such as physician office visits), or increased payments to the rehab hospitals.

Standards

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

[21] Some rehab hospitals are co-located with an acute-care provider but are managed independently. These rehab hospitals were included in our sampling frame.

FINDINGS

An estimated 29 percent of Medicare patients in rehab hospitals experienced adverse or temporary harm events

Approximately 3 in 10 Medicare beneficiaries who had rehab hospital stays that ended in March 2012 experienced at least one adverse or temporary harm event during their stays (29 percent).[22] The events fall into two groups depending on the level of harm to the patient: adverse events and temporary harm events (see Table 4).

Table 4: Number of Adverse and Temporary Harm Events within the Sample by Level of Harm

Event Type	Level of Harm on the Modified NCC MERP Harm Index	Number within Sample (n=158)
Adverse Events	I-level: Contributed to or resulted in patient death	3
	H-level: Required intervention to sustain the patient's life	7
	G-level: Contributed to or resulted in permanent patient harm	3
	F-level: Resulted in prolonged rehab hospital stay or transfer to an acute-care hospital for observation, emergency treatment, or inpatient care.	33
Temporary Harm Events	E-level: Harm occurred that caused temporary harm that required intervention	112

Source: OIG analysis of rehab hospital stays for 417 Medicare beneficiaries discharged in March 2012.

Ten percent of Medicare patients in rehab hospitals experienced adverse events

Ten percent of Medicare patients experienced adverse events during their stays in rehab hospitals. Adverse events caused harm that led to a prolonged rehab hospital stay or transfer to an acute-care hospital; caused permanent harm; required a life-sustaining intervention; or contributed to or resulted in death (i.e., equivalent to categories F–I on the modified NCC MERP Index). We estimate that 1,271 post-acute Medicare rehab hospital patients in our study population experienced at least one adverse event during their stays.

An additional 18 percent of Medicare patients in rehab hospitals experienced temporary harm events

Another 18 percent of Medicare patients experienced a temporary harm event during their stays in rehab hospitals. Temporary harm events required medical intervention but did not prolong the stays, necessitate

[22] The combined adverse event and temporary harm event rate (29 percent) exceeds the sum of the adverse event rate (10 percent) and temporary harm event rate (18 percent) because of rounding. For these and all other estimates presented in this report, see Appendix D for point estimates and confidence intervals.

transfer to an acute-care hospital, or life-saving intervention, nor did it cause permanent harm or contribute to death (i.e., equivalent to E-level harm on our modified NCC MERP Index). We estimate that 2,247 post-acute Medicare rehab hospital patients who did not experience an adverse event experienced at least 1 temporary harm event during their stays. Because these patients did not experience events causing harm equivalent to F – I on the harm index, they are not included in the adverse event rate.

Less than 1 percent of Medicare patients in rehab hospitals experienced events that contributed to their deaths

We estimate that 3 of 411 rehab hospital patients (0.7 percent) experienced adverse events that contributed to or resulted in their death. Two additional patients in our sample died during their stays, but those deaths were not associated with an adverse event. One adverse event that contributed to death involved a patient with cancer recovering in the rehab hospital from a recent cerebral hemorrhage. That patient experienced a central line-infection characterized by sepsis-like symptoms (i.e., hypotension and lethargy) that resulted in death. The physician review team determined that this event was likely preventable. In a second case, a patient recovering from a lymphoma-related shortness of breath and night sweats contracted pneumonia. The pneumonia was not initially recognized by staff and therefore the necessary treatment was delayed. Without timely treatment, the pneumonia led to sepsis along with severe hypotension that contributed to the patient's death. The reviewers determined this event to be clearly preventable. The third event, determined to be clearly *not* preventable, involved an elderly patient who experienced partial paralysis and difficulty swallowing after a major stroke. A feeding tube was placed, but the patient experienced chronic aspirations. The aspirations led to pneumonitis and the family decided to withhold treatment and place the patient in hospice care.

Less than 2 percent of Medicare patients in rehab hospitals experienced at least one "cascade" event, wherein multiple, related events occurred in succession

We estimate that 1.7 percent of rehab hospital patients experienced a "cascade" event. A cascade event is defined as a series of multiple, related adverse or temporary harm events that are considered a single event for the purpose of analysis. In one cascade event, a patient recovering from a knee arthroplasty (replacement) became severely dehydrated as a result of a newly acquired *Clostridium difficile* infection. The dehydration led to multiple, related events, including acute kidney injury, hyponatremia (a low sodium concentration in the blood), significant delirium, and metabolic acidosis (a pH imbalance caused by accumulation of acid).

Medication and patient care led to most harm affecting patients; infections were the least frequent cause of harm

Consistent with findings in previous OIG studies of adverse events, medication and patient care led to most of the adverse and temporary harm events affecting patients. The most frequent events within the sample were medication-induced delirium and pressure ulcers. Table 5 presents the percentage of events within each of three clinical categories and lists subcategories of events found within the sample.

Table 5: Adverse and Temporary Harm Events by Clinical Category

Adverse and Temporary Harm Events by Clinical Category	Number of Sample Events within Category
Events Related to Medication*	**46% (*72*)**
Delirium or change in mental status due to medications	24
Hypoglycemic events related to medication	9
Hypotension secondary to medication	7
Constipation, obstipation, or ileus from medication	6
Allergic reaction to medication	5
Diarrhea secondary to medication	4
Excessive bleeding due to medication	4
Dehydration and related electrolyte disorders associated with medication	3
Nausea and vomiting secondary to medications	3
Thrush	3
Other	4
Events Related to Patient Care*	**40% (*63*)**
Pressure ulcer	14
Constipation, obstipation, or ileus	9
Skin tear, abrasion, or breakdown (other than pressure ulcer)	9
Exacerbations of preexisting conditions, including those resulting from omissions of care	8
Fall associated with patient care	6
Device trauma or malfunction	4
Dehydration and related electrolyte disorders associated with patient care	3
Venous thromboembolism, deep vein thrombosis (DVT), or pulmonary embolism (PE)	3
Allergic reaction to equipment (e.g., tape)	2
Edema or volume overload	2
Other	3
Events Related to Infections*	**15% (*23*)**
Catheter-associated urinary tract infection (CAUTI)	5
Soft tissue or other nonsurgical infection	4
Clostridium difficile infection	3
Surgical site infection (SSI)	3
Sepsis	2
Aspiration pneumonia and other respiratory infections	2
Other	4

*The sum of the percentages in this table exceed 100 percent because of rounding. See Appendix C for point estimates and 95-percent confidence intervals.
Source: OIG analysis of rehab hospital stays for 417 Medicare beneficiaries discharged in March 2012.

Forty-six percent of adverse and temporary harm events were preventable

Physicians determined that 46 percent of the adverse and temporary harm events combined were preventable, and 51 percent were not preventable. Physicians were unable to make determinations for the remaining events because of incomplete documentation or complexities in the patients' conditions. Table 6 presents the percentage of events in each category of preventability.

Table 6: Adverse and Temporary Harm Events by Preventability Determination

Preventability Assessment	Percentage of Events
Preventable—Harm could have been avoided through improved assessment or alternative actions	**46%**
Clearly preventable	8%
Likely preventable	38%
Not preventable—Harm could not have been avoided given the complexity of the patient's condition or care required	**51%**
Clearly not preventable	6%
Likely not preventable	46%
Unable To Determine Preventability	**3%**

As a result of rounding, subgroups for the 'not preventable' category do not total 51 percent.
See Appendix C for point estimates and 95-percent confidence intervals.
Source: OIG analysis of rehab hospital stays for 417 Medicare beneficiaries discharged in March 2012.

When deciding whether an event was preventable, the reviewers consulted a list of contributing factors and selected the factors that best defined their rationale for the preventability determination. Table 7 (on the next page) provides the preventability rationales cited by the reviewers for all events in the sample.

Among the *preventable* events for sampled rehab hospital patients, the reviewers frequently cited as factors the provision of appropriate treatment in a substandard way and failure to adequately monitor a patient's progress. In one case of a preventable event, an elderly patient admitted to an rehab hospital after a stroke (a cerebrovascular accident, or CVA) and a recent diagnosis of hypertension experienced medication- related transient neurological symptoms (e.g., weakness and unsteady gait). The physician reviewer attributed these symptoms to an unnecessarily aggressive and poorly monitored use of an antihypertensive medication (amlodipine). The rehab hospital significantly increased the dose within 24 hours of starting the medication. The patient's symptoms resolved after the rehab hospital staff reduced the dose of the antihypertensive.

Table 7: Preventability Rationales for Adverse and Temporary Harm Events within Sample

Preventability Rationale (n=158)	Number of Times Cited By Reviewers
Preventable Events	
Appropriate treatment was provided in a substandard way	28
Error was related to medical judgment, skill, or patient management	23
The patient's progress was not adequately monitored	18
Necessary treatment was not provided	17
Patient care plan was inadequate	17
Not Preventable Events	
Patient was highly susceptible to event because of health status	48
Event occurred despite proper assessment and procedures followed	29
Patient's diagnosis was unusual or complex, making care difficult	12
Care provider could not have anticipated event given information available	9

The counts in this table exceed the total number of events because the reviewers often gave multiple rationales.
Source: OIG analysis of rehab hospital stays for 417 Medicare beneficiaries discharged in March 2012.

Not preventable events often occurred with patients who were highly susceptible to a particular type of event or experienced the events despite staff efforts to avoid harm. In many of these cases, the reviewers noted that the clinicians in the rehab hospitals took reasonable precautions to prevent the event. In one case, a patient recovering from a stroke (a left side subcortical infarction with right-sided weakness) experienced permanent (G-level) harm after refusing to take prescribed medications (i.e., clopidogrel and enoxaparin sodium) that might have prevented a recurrent stroke. Without appropriate medications, the patient experienced an extension of the prior stroke, resulting in increased—and permanent—right-sided weakness. The reviewers determined that in light of the patient's decision, the event was not preventable by the staff.

Nearly one-quarter of the Medicare patients who experienced an adverse or temporary harm event in a rehab hospital were transferred to an acute-care hospital for treatment

We estimated that 3,518 Medicare rehab hospital patients experienced at least 1 adverse or temporary harm event. Of these patients, an estimated 828 (23.5 percent) went to an acute-care hospital for treatment as a result of the events. This includes both those admitted as inpatients and those who had outpatient emergency department visits only.[23] These patients

[23] Within the sample, there were 28 patients who had hospital admissions or emergency department visits. Twenty-five of these patients were admitted (some of the admissions followed an emergency department visit), and three were treated in the emergency department only.

constitute 7 percent of all Medicare beneficiaries who had rehab hospital stays that ended in March 2012.

We estimate that acute-care hospital admissions and emergency department visits resulting from adverse and temporary harm events for Medicare beneficiaries with rehab hospital stays ending in March 2012 cost Medicare at least $7.7 million.[24] Assuming that Medicare spending on hospitalizations due to adverse and temporary harm events in rehab hospitals remained constant throughout the year, Medicare inpatient expenditures would amount to at least $92 million annually.[25] These estimates do not include related costs paid by Medicare or other payers—including beneficiaries—for followup medical care needed as a result of an event.

[24] As noted in the methodology section of this report, we present the estimate of cost as the lower bound of the confidence interval. See Appendix C for the point estimate and 95-percent confidence intervals.

[25] The annual cost estimate of $92 million assumes that Medicare expenditures for adverse and temporary harm events in rehab hospitals remained constant at $7.7 million in each month of the year.

CONCLUSION AND RECOMMENDATIONS

The findings in this report confirm the need and opportunity to significantly reduce the incidence of adverse events in rehab hospitals, thereby improving the quality of care that patients receive. Using the information presented in this report, health care providers and other stakeholders should take actions to further understand the causes of adverse events in rehab hospitals and reduce the incidence and impact of these events. We found that 29 percent of Medicare beneficiaries experienced adverse events or temporary harm events during their rehab hospital stays, resulting in temporary harm; prolonged stays or acute-care hospitalizations; permanent harm; life-sustaining intervention; or death. This harm rate is similar to those in our previous findings for hospitals (27 percent) and SNFs (33 percent). Forty-six percent of events in rehab hospitals were preventable, which is again similar to our previous results for hospitals (44 percent) and SNFs (59 percent). Hospitalizations necessitated by the events increased costs to Medicare by at least $7.7 million in a single month, or $92 million, annualized, in 2012, suggesting the opportunity for savings from reducing the incidence of adverse events that occur in rehab hospitals.

The similarity of results across multiple health care settings suggests that research and interventions to reduce adverse and temporary harm events may be applicable across settings. In our prior reports on adverse events, we made a series of recommendations to AHRQ, the coordinating body for health care quality improvement, and to CMS, the largest health care payer and Federal overseer. In response, AHRQ and CMS expressed a commitment to implement our recommendations and pursue strategies to improve care. In this report, we recommend that AHRQ and CMS implement similar strategies for improved patient safety in rehab hospitals.

AHRQ and CMS should raise awareness of adverse events in rehab hospitals and work to reduce harm to patients

In response to OIG recommendations in our earlier reports on adverse events in hospitals and SNFs, AHRQ and CMS began collaborating to create a list of potentially reportable adverse events to educate health care staff and to measure facility performance. CMS also began developing surveyor training to assist State survey agencies in assessing safety practices in SNFs; and, AHRQ and CMS worked to reconcile conflicts between the Patient Safety and Quality Improvement Act of 2005 and CMS's QAPI requirements. Broadening these and other patient safety improvement efforts to include rehab hospitals would ensure that safe care practices promoted in acute-care hospitals and SNFs would extend to other

post-acute-care providers. Agency response to this recommendation should address the following two subrecommendations:

- **AHRQ and CMS should collaborate to create and promote a list of potential rehab hospital events** – Staff identification of patient harm is critical to the success of patient safety efforts in rehab hospitals, giving staff the opportunity to correct problems and reduce harm, as well as report problems contributing to events. AHRQ and CMS should ensure that rehab hospital staff are able to identify a broad range of adverse and temporary harm events. Toward that end, AHRQ and CMS should collaborate to create and disseminate a list of potentially reportable events for rehab hospitals. The list should go beyond conventional post-acute-care issues (e.g., falls, pressure ulcers) and include a comprehensive range of possible patient harm, emphasizing the unique case mix in rehab hospitals and the rehabilitation needs of affected patients. Appendix E of this report provides descriptions of events such a list could include. The list may be extended to be consistent with the full body of research on this topic and should incorporate the unique challenges of this setting rather than duplicating lists of SNF or hospital events.

- **CMS should include information about potential events and patient harm in its quality guidance to rehab hospitals** – To participate in the Medicare program, rehab hospitals must comply with the CoPs for hospitals, including requirements for a QAPI program to improve facility performance. CMS reported to OIG in 2013 that it is testing draft interpretive guidelines for surveyors related to QAPI, including guidance for surveyors assessing facility efforts to improve patient safety. CMS should expand this effort to include information on potential events in rehab hospitals and continue to seek opportunities to provide patient safety guidance relevant to rehab hospitals. Guidance should include a definition of "adverse events;" a list of potential adverse events for staff education on the range of harm that patients can experience; strategies for detecting, measuring, and preventing adverse events; and, best practices for improving staff recognition and reporting of adverse events. Issuing similar guidance to rehab hospitals, acute-care hospitals, and SNFs may improve communication and collaboration regarding shared safety concerns and patient transitions among facilities.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS and AHRQ concurred with our recommendations. CMS responded that it will continue to collaborate with AHRQ and other partners to identify and address adverse events in rehab hospitals, including development of a list of potential rehab hospital events and expansion of the current QAPI guidance to include information specific to rehab hospitals. CMS also plans to look into using the Quality Improvement Organization Program to assist with quality improvement efforts in rehab hospitals. AHRQ responded that it will work with CMS to identify adverse events in rehab hospitals, as it has done for other healthcare settings. AHRQ also believes it would be helpful to review the types of events identified in this report to determine how they relate to the current AHRQ Common Formats. If AHRQ identifies a need, it will consider adding new event options in future updates to the Common Formats. We look forward to receiving updates from CMS and AHRQ regarding their progress in implementing these recommendations. Appendix F contains the full text of comments from both agencies.

APPENDIX A

Methodology for Identifying Events and Determining Preventability

We conducted a two-stage medical record review to identify adverse and temporary harm events (for the purposes of this section, we refer to adverse events and temporary harm events as "events"). In the first stage, two registered nurses (referred to as "screeners") identified sample beneficiaries who were likely to have experienced events during their rehab hospital stays. In the second stage, physicians reviewed the records for the subset of beneficiaries flagged by screeners as likely to have experienced events. Each record was reviewed by a screener and, if flagged, reviewed by a physician.

Screening for Beneficiaries Who Likely Experienced Events. To identify beneficiaries who were likely to have experienced events during their stays, screeners reviewed complete medical records for the rehab hospital stays and other information in their records. The other information included discharge summaries, lab results, and other key documents from the medical records of the acute-care hospital stays that preceded the sampled stays. We also requested discharge summaries; history and physical examinations; and emergency department or observation unit medical records from any hospital stays or emergency department visits that followed the selected admission and occurred up to 14 days after discharge from the rehab hospital. In addition, we reviewed the claims data for the preceding and subsequent hospital stays and emergency department visits.

To standardize their reviews, we required screeners use a trigger tool to identify triggers in the medical record. The trigger tool was based on the IHI Global Trigger Tool (GTT) instrument and was modified for the post-acute rehab hospital environment. If screeners found a trigger, they explored the record further to determine whether events occurred and, if so, documented the level of harm. Of the 417 beneficiaries in the sample, screeners "flagged" 182 beneficiaries' records (44 percent) for physician review.

The screening process enabled us to reduce the number of cases requiring second-level review of the full medical records by a physician. As in the other OIG studies of adverse event incidence, physician reviewers indicated that the results of the screening methods helped them to readily identify potential events for consideration.

Physician Identification of Events within Flagged Rehab Hospital Records. One of 6 contracted physicians reviewed the medical records for each of the 182 beneficiaries flagged in the initial screening. The physician reviewers represented a variety of specializations and experience: a

neurologist/physiatrist with experience as a medical director of a rehab hospital, an infectious disease specialist, a cardiologist, an orthopedic surgeon, an internal medicine specialist, and a geriatrician with extensive experience as a SNF medical director. All six had many years of clinical experience, and five had prior experience in detecting adverse events in retrospective medical record reviews. Four of the six served as physician reviewers for the 2010 OIG study of adverse events in hospitals, and five of the six served as physician reviewers for the 2014 OIG study of adverse events in SNFs.

To identify events experienced by patients during their stays, the physicians reviewed results of the screeners' reviews as well as all the information made available to the screeners. In addition to reviewing records from the rehab hospitals, the physicians reviewed documents and data from any preceding and subsequent hospital stays to look for evidence of events that occurred during the rehab hospital stays.

Over 10 weeks, physician reviewers examined the 191 records of the 182 beneficiaries flagged by screeners. Physician reviewers used a structured medical review protocol that required them to describe each harm event and specify the level of harm experienced by the patient. Harm was categorized in accordance with a modified version of the NCC MERP Index of Categorizing Medication Errors (see Table 3).

We recorded all events that physician reviewers determined to be attributable to care provided during the rehab hospital stays. We excluded events that were part of the underlying disease process, occurred before the beneficiary entered the rehab hospital, or were attributable to the care provided in a preceding hospitalization. When an initial event caused a series of related and dependent events, we combined the events into a "cascade" event and counted it as a single event. When a patient experienced a specific type of event more than once during a stay (e.g., two episodes of hypoglycemia), we counted them as a single event if the second event occurred within 7 days of the first and occurred under the same circumstances. We counted them as separate events if the second event occurred more than 7 days after the first or if the circumstances that led to the event were substantially different.

Determining Preventability for Each Event. Physician reviewers included an assessment of the extent to which events were preventable and factors that contributed to events. They used a five-point response scale, described in Table A-1. Assessing an event as clearly preventable or clearly not preventable required a greater degree of certainty on the part of the reviewer. Although the five-point scale enabled physicians to make more precise determinations, we collapsed the *clearly* and *likely* subcategories in our primary statistics.

Table A-1: Preventability Scale for Categorizing Adverse Events

Likelihood That Event Could Have Been Prevented:	
Preventable Events	Clearly Preventable—Patient harm could definitely have been avoided through improved assessment or alternative actions.
	Likely Preventable—Patient harm could have been avoided through improved assessment or alternative actions.
Not Preventable Events	Likely Not Preventable—Patient harm could not have been avoided given the complexity of the resident's condition or the care required.
	Clearly Not Preventable—Patient harm could definitely not have been avoided given the complexity of the resident's condition or the care required.
Unable to Determine Events	Unable to Determine—Physicians were unable to determine preventability because of incomplete documentation or case complexity.

Physician reviewers used a decision algorithm to improve consistency in making preventability determinations. We worked with the reviewers to develop the algorithm during practice reviews consisting of a series of questions that led the reviewers to a suggested response. Questions addressed issues such as whether there was a medical error, whether the event could have been anticipated, and how frequently the event occurs given proper care. Physicians did not automatically accept the suggested response, but determined whether it was appropriate in the particular case.

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

Consistency Discussions and Review. Throughout our medical records review, we facilitated nine conference calls during which physician reviewers discussed the review protocol and sample cases that either were complex or had possible implications for other cases. The goal of these calls

was to reach consensus on difficult and complex cases and to establish consistency among reviewers. On the calls, physicians solicited the opinions of the other panelists to help make determinations on difficult cases. During the weekly conference calls, we required physicians to discuss all *clearly preventable* and *clearly not preventable* determinations and events that potentially contributed to a patient's death, and we encouraged them to bring other cases for discussion if they had difficulty or felt the cases would inform other determinations. Physicians also often brought cases to group discussion if they involved care specific to another physician's specialization. We documented the discussions and conclusions made during these weekly calls, continually revising a written physician guidance document to further promote consistency. Physicians reviewed or discussed the majority of the identified events as well as possible events, which the group ultimately determined did not meet the study threshold.

Following the medical records review, we analyzed the identified events, harm-level determinations, and preventability determinations to identify any inconsistencies and discussed these with physician reviewers. This process resulted in changes to the initial determinations of some events.

APPENDIX B

Triggers Listed on the Trigger Tool Worksheet

Table B-1: Trigger Tool Worksheet

	Care Module Triggers		**Care Module Triggers (continued)**
C1	Acute mental status change	C26	Diagnostic radiology or imaging studies
C2	Aspiration	C27	Care-Other
C3	Call to physician or family members		**Medication Module Triggers**
C4	Code, Rapid Response Team (RRT), or Emergency Medical Services (EMS)	M1	Abnormal electrolytes
C5	Death	M2	Abrupt medication stop
C6	Drop in hemoglobin/hematocrit	M3	Anti-emetic use
C7	Studies for emboli, PE or DVT	M4	Diphenhydramine (Benadryl) use
C8	Fall	M5	Elevated international normalized ration (INR)
C9	Family complaint	M6	Glucose <50, Glucagon or Dextrose supplement
C10	Any infection	M7	Abrupt onset hypotension
C11	New or increased diuretics	M8	Naloxone (Narcan) use
C12	High or low body temperature	M9	Sodium Polystyrene (Kayexalate administration)
C13	Stroke or transient ischemic attack in rehab hospital	M10	Abnormal drug levels
C14	New onset of incontinence	M11	Thrombocytopenia
C15	Insertion or use of urinary catheter	M12	Total WBC < 3,000 or >12,000
C16	Functional Independence Measure ™ [FIM™ score] decrease or no change from admission to discharge	M13	Vitamin K administration (Aqua-Mephyton)
C17	Resident incident or accident	M14	Antibiotics started in the rehab hospital
C18	Pressure ulcer	M15	Increasing pain medication needs
C19	Emergency department visit	M16	Administration of parenteral fluid
C20	Transfer to acute-care hospital, observation unit, or unplanned transfer to another rehab hospital	M17	Medication-Other
C21	Restraint use		**Procedure Module Triggers**
C22	Rising serum creatinine	P1	Postoperative/post-procedure complication
C23	Urinary retention	P2	Procedure reintubation/new Biphasic Positive Airway Pressure (BiPAP) / new Continuous Positive Airway Pressure (CPAP)
C24	New onset diarrhea	P3	Procedure-Other
C25	Prolonged constipation		

Source: OIG, *Adverse Events in Inpatient Rehabilitation Hospitals: National Incidence Among Medicare Beneficiaries* (OEI-06-14-00110).

APPENDIX C

Estimates, Confidence Intervals, and Key Statistics

Table C-1: Beneficiary Level Estimates, Confidence Intervals, and Key Statistics

Estimate Description	Sample Size (n)	Percentage	95-Percent Confidence Interval		Frequency	95-Percent Confidence Interval	
			Lower Bound	Upper Bound		Lower Bound	Upper Bound
Event Experiences for All Beneficiaries							
Experienced at least one adverse event	417	10.3%	7.8%	13.6%	1271	916	1626
Experienced at least one temporary harm event and did not experience an adverse event	417	18.2%	14.8%	22.2%	2247	1796	2698
Experienced at least one adverse event or at least one temporary harm event	417	28.5%	24.5%	33.0%	3518	2991	4046
Experienced only preventable adverse and temporary harm events	417	15.1%	12.0%	18.8%	1863	1444	2281
Experienced only preventable adverse events	417	6.7%	4.7%	9.5%	828	535	1120
Experienced only preventable temporary harm events and no adverse events	417	7.9%	5.7%	10.9%	976	660	1291
Experienced adverse events that contributed to death*	417	0.7%	0.2%	2.2%	--	--	--
Experienced transfer to an acute-care hospital because of an adverse or temporary harm event	417	6.7%	4.7%	9.5%	828	535	1120
Experienced a cascade adverse event*	417	1.7%	0.8%	3.4%	207	57	357
Beneficiaries Who Experienced at Least One Adverse Event or One Temporary Harm Event							
Experienced at least one transfer to an acute-care hospital that was the result of an adverse or temporary harm event	119	23.5%	16.8%	31.9%	828	535	1120

* We are unable to reliably project the frequency estimates for this item because of the small number of sample occurrences.
Source: OIG analysis of rehab hospital stays and Medicare claims for 417 Medicare beneficiaries discharged in March 2012.

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

Estimate Description	Sample Size (n)	Percentage	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Clinical Category for All Adverse and Temporary Harm Events				
▪ Medication adverse and temporary harm events	158	45.6 %	37.9%	53.2%
▪ Patient care adverse and temporary harm events	158	39.9%	31.9%	47.8%
▪ Infection adverse and temporary harm events	158	14.6%	9.2%	19.9%
Preventability Classification for All Adverse Events and Temporary Harm Events				
▪ Preventable adverse and temporary harm events	158	46.2%	38.0%	54.4%
○ Clearly preventable adverse and temporary harm events	158	8.2%	3.7%	12.8%
○ Likely preventable adverse and temporary harm events	158	38.0%	29.9%	46.1%
▪ Not preventable adverse and temporary harm events	158	51.3%	42.9%	59.6%
○ Clearly not preventable adverse and temporary harm events	158	5.7%	2.2%	9.2%
○ Likely not preventable adverse and temporary harm events	158	45.6%	37.7%	53.5%
▪ Unable to determine adverse and temporary harm events	158	2.5%	0.1%	4.9%

Source: OIG analysis of RH stays and Medicare claims for 417 Medicare beneficiaries discharged in March 2012.

Table C-3: Estimates, Confidence Intervals, and Key Statistics

Estimates of Acute-Care Hospitalizations and Medicare Payments Associated with Adverse Events in Rehab Hospitals	Total	95-Percent Confidence Interval	
		Lower Bound	Upper Bound
Acute-care hospitalizations associated with adverse and temporary harm events	887	564	1210
Medicare payment for acute-care hospitalizations associated with adverse events in RHs	$16,325,640	$7,670,132	$24,981,147

Source: OIG analysis of rehab hospital stays and Medicare claims for 417 Medicare beneficiaries discharged in March 2012

APPENDIX D

Rates of Adverse Events and Temporary Harm Events in Rehab Hospitals by Patient Days and by Admissions

Health care facilities commonly measure adverse events by incidence density, which takes into account the period during which patients are observed. For example, incidence density is often used in measuring healthcare-acquired infections because risk can increase with the length of exposure to the health care environment.[26] IHI, a nonprofit advisory group to hospitals, cites advantages to using incidence density metrics over standard incidence rates that measure the number of events per patient.[27] IHI reports that measuring total events by patient days or hospital admissions enables hospitals to count multiple events experienced by the same beneficiary.

The sample of 417 Medicare beneficiaries discharged during March 2012 included 426 total rehab hospital stays and a combined total of 5,400 patient days in the facilities. We calculated patient days by subtracting the admission date for each rehab hospital stay from its discharge date. Table D-1 provides ratios for adverse events and temporary harm events in the sample per 1,000 patient days and per 100 admissions.

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

Category	Per 1,000 Patient Days	Per 100 Admissions
Adverse events	9	11
Temporary harm events	21	26
Adverse and temporary harm events combined	29	37

Source: OIG analysis of rehab hospital stays for 417 Medicare beneficiaries discharged in March 2012

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

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

APPENDIX E

Adverse Events and Temporary Harm Events Identified in the Sample

Tables E-1 and E-2 contain information about adverse events and temporary harm events identified in the sample, including description, harm level, and preventability. Table E-1 contains information about adverse events (46 adverse events).[28] Table E-2 contains information about temporary harm events (112 events).

Table E-1: Adverse Events by Clinical Category, Harm Level, and Preventability (n=46)

Adverse Event	Harm Level	Preventability
Adverse Events Related to Medication (18)		
Delirium or change in mental status due to medications (5)		
1. Multiple episodes of unresponsiveness secondary to benzodiazepine (clonazepam) and hypnotic (zolpidem) requiring an emergency reversal agent (flumazenil)	H	CP
2. Confusion and lethargy secondary to opioids (oxycodone and tramadol) that extended stay	F	LNP
3. Lethargy and syncopal episode secondary to opioid (hydrocodone/acetaminophen) resulting in transfer to an acute-care hospital	F	LP
4. Confusion and agitation secondary to opioids (oxycodone) resulting in transfer to an acute-care hospital	F	LNP
5. Cascade in which medication-induced confusion and agitation secondary to benzodiazepine (lorazepam) led to patient pulling urinary catheter with resultant injury and bleeding	F	LP
Excessive bleeding due to medication (3)		
1. Bleeding from gastric ulcers secondary to anticoagulants (warfarin and aspirin) resulting in transfer to an acute-care hospital	H	CP
2. Gastrointestinal hemorrhage secondary to anticoagulants (dabigatran and aspirin) resulting in transfer to an acute-care hospital	F	CNP
3. Peri-incisional hematoma in thigh secondary to multiple anticoagulants (warfarin, aspirin, and enoxaparin sodium)	F	CP
Hypotension secondary to medication (3)		
1. Hypotensive-event (syncope) secondary to beta-blocker used to treat multiple conditions, including hypertension (metoprolol), resulting in transfer to an acute-care hospital	F	LP
2. Hypotension secondary to medication used to treat fluid retention (hydrochlorothiazide)	F	LNP
3. Orthostatic hypotension secondary to medication used to treat hypertension (hydralazine)	F	LP
Dehydration and related electrolyte disorders associated with medication (2)		
1. Hyperkalemia secondary to diuretic and antihypertensive (spironolactone)	H	LP
2. Acute renal failure, hyperkalemia (high potassium), and dehydration secondary to diuretics resulting in transfer to an acute-care hospital	F	CP
Diarrhea secondary to medication (2)		
1. Diarrhea and dehydration secondary to antibiotics and resulting in transfer to an acute-care hospital	F	LNP
2. Diarrhea and dehydration from antibiotic	F	LNP

Continued on next page.

[28] Patient harm is classified according to a modified version of the NCC MERP Index for Categorizing Errors (E–I) presented in Table 3. Preventability determinations were selected from the following options: CP for clearly preventable, LP for likely preventable, LNP for likely not preventable, CNP for clearly not preventable, and UTD for unable to determine.

Table E-1: Adverse Events by Clinical Category, Harm Level, and Preventability (n=46) (Continued)

Adverse Event	Harm Level	Preventability
Adverse Events Related to Medication (18) (continued)		
Nausea and vomiting secondary to medications (2)		
1. Nausea, cramping, and vomiting due to medications given to treat constipation (magnesium hydroxide) and gastrointestinal symptoms (metoclopramide) resulting in transfer to an acute-care hospital	F	LNP
2. Nausea and vomiting due to opioid pain medication (hydrocodone)	F	LP
Hypoglycemic events related to medication (1)		
1. Multiple, severe symptomatic hypoglycemic episodes characterized by a period of unresponsiveness and blood glucose of 29 resulting in transfer to an acute-care hospital	H	LP
Adverse Events Related to Patient Care (17)		
Exacerbations of preexisting conditions and other deteriorating medical conditions (7)		
1. Omission of care led to congestive heart failure exacerbation resulting in transfer to an acute-care care hospital	F	CP
2. Sudden onset of acute respiratory decompensation resulting in transfer to an acute-care hospital	H	LNP
3. Insufficient treatment of a preexisting left subcortical infarction due to patient refusing medication led to an extension of the infarction resulting in transfer to an acute-care hospital caused in part by patients refusal to comply with associated medication regimen	G	LNP
4. Gastric ulcer found by esophagogastroduodenoscopy (EGD) while on aspirin and steroids	F	LNP
5. Cascade event in which failure to monitor progressive dysphagia led to dehydration resulting in transfer to an acute-care hospital related to poor transition of care with failure to provide BiPAP in patient with Obstructive Sleep Apnea	F	LP
6. Cardiac arrest requiring Advanced Cardiovascular Life Support (ACLS) and transfer to acute-care hospital	H	CP
7. Acute change in motor function with worsening lethargy (possible CVA) resulting in transfer to an acute-care hospital	F	UTD
Dehydration and related electrolyte disorders associated with patient care (2)		
1. Acute renal injury due to inadequate management of fluid intake resulting in dehydration and transfer to an acute-care hospital	F	LP
2. Significant dehydration due to inadequate hydration resulting in hospitalization	F	CP
Pressure ulcer (2)		
1. Progression of stage II pressure ulcer on buttocks to a stage IV pressure ulcer	G	CP
2. Progression of stage I pressure ulcer on heel to a stage IV ulcer	G	CP
Venous thromboembolism, DVT, or PE (2)		
1. Common femoral vein DVT resulting in transfer to an acute-care hospital	F	LNP
2. DVT resulting in transfer to an acute-care hospital	F	LNP
Other patient-care events (4)		
1. Allergic reaction (pruritus) to post-surgical tape	F	LNP
2. Cascade in which continuous passive movement (CPM) and anticoagulation (warfarin and enoxaparin sodium) led to bleeding and worsening contracture resulting in transfer to an acute-care hospital.	F	LP
3. Hemorrhagic cystitis in patient associated with Foley catheter and anticoagulant (warfarin)	F	LP
4. Dehiscence of surgical wound	F	UTD
Adverse Events Related to Infections or Antibiotics (11)		
Catheter-associated urinary tract infection (CAUTI) (3)		
1. Catheter-associated urinary tract infection (*Escherichia coli*)	F	LP
2. Catheter-associated urinary tract infection (*Enterobacter*)	F	LP
3. Catheter-associated urinary tract infection resulting in transfer to an acute-care hospital	F	LNP

Continued on next page.

Table E-1: Adverse Events by Clinical Category, Harm Level, and Preventability (n=46) (Continued)

Adverse Event	Harm Level	Preventability
Adverse Events Related to Infections (11) (continued)		
***Clostridium difficile* infection (2)**		
1. *Clostridium difficile* infection secondary to antibiotics	F	LP
2. Cascade event in which a *Clostridium difficile* infection (while being treated with ciprofloxacin) led to significant dehydration, acute kidney injury, hyponatremia, confusion, and metabolic acidosis resulting in transfer to an acute-care hospital	F	LP
Sepsis (2)		
1. Cascade event in which delayed recognition of pneumonia led to sepsis and then severe hypotension resulting in transfer to an acute-care hospital and finally death	I	CP
2. Cascade event in which a urosepsis (characterized by increasing confusion) developed into septic shock, which led to kidney failure and hypotension resulting in transfer to an acute-care hospital	H	LP
Other infection adverse events (4)		
1. Recurrent aspiration in post-stroke patient with feeding tube resulted in the patient's death	I	CNP
2. Peripherally inserted central catheter infection characterized by sepsis-like symptoms (hypotension, lethargy) resulting in transfer to an acute-care hospital and, finally, death	I	LP
3. Deep pelvic infection resulting in transfer to an acute-care hospital	F	LP
4. Cascade event in which aspiration pneumonia led to hypotension resulting in transfer to an acute-care hospital	F	LP

Source: OIG analysis of rehab hospital stays for 417 Medicare beneficiaries discharged in March 2012.

Table E-2: Temporary Harm Events by Clinical Category and Preventability (n=112)

Temporary Harm Event	Preventability
Temporary Harm Events Related to Medication (54)	
Medication-induced delirium or other change in mental status (19)	
1. Confusion and disorientation from medication used to treat overactive bladder (oxybutynin)	LNP
2. Multiple episodes of oversedation due to opioids in patient complicated by patient stealing and self-administering additional medications	LNP
3. Significant drowsiness and unresponsiveness secondary to antipsychotic (quetiapine)	LNP
4. Significant confusion due to opioids (oxycodone/acetaminophen)	LP
5. Multiple episodes of confusion secondary to opioids (oxycodone) and hypnotic (zolpidem)	LNP
6. Multiple episodes of confusion and decreased cognitive performance secondary to opioids (hydromorphone)	LNP
7. Significant lethargy secondary to antipsychotic (haloperidol)	LP
8. Lethargy and anxiety secondary to antidepressant (serotonin antagonist and reuptake inhibitor (SARI))	LP
9. Confusion and lethargy secondary to opioid pain medication (hydrocodone/acetaminophen)	LP
10. Delirium secondary to medication used to treat Parkinson's disease (carbidopa/levodopa)	LNP
11. Lethargy and confusion secondary to multiple medications, including an opioid analgesic (hydrocodone/acetaminophen), an atypical antipsychotic (quetiapine), and a benzodiazepine (clonazepam).	LP
12. Weakness and imbalance secondary to medication used to lower blood pressure (amlodipine)	LP
13. Lethargy secondary to opioid pain medications (hydromorphone and fentanyl)	LNP
14. Lethargy secondary to opioid pain medication (hydromorphone)	UTD
15. Lethargy, increased confusion and belligerence secondary to antihistamine (hydroxyzine) used to treat worsening of chronic dermatitis	LNP
16. Hallucinations secondary to hypnotic (zolpidem)	LP
17. Confusion secondary to benzodiazepine (alprazolam)	LP
18. Lethargy secondary to opioid pain medication (oxycodone/acetaminophen)	LP
19. Sedation and lethargy secondary to antianxiety medications (benzodiazepines)	CP
Hypoglycemic events related to medication (8)	
1. Asymptomatic hypoglycemia with a blood glucose of 47	LNP
2. Severe episode of hypoglycemia with a blood glucose of 25	LNP
3. Multiple episodes of asymptomatic hypoglycemia with blood glucose readings of 38 and 41	LP
4. Symptomatic blood glucose characterized by cold and clammy skin and a blood glucose of 47	LP
5. Asymptomatic hypoglycemic episode with a blood glucose of 39	LNP
6. Symptomatic hypoglycemic episode characterized by cold, clammy skin and lethargy and labile blood glucose with a blood glucose of 45	LNP
7. Symptomatic hypoglycemia characterized by blood glucose of 65 and nausea secondary to insulin management	LNP
8. Asymptomatic hypoglycemia characterized by blood glucose of 44 secondary to insulin management	LNP
Constipation, obstipation, and ileus from medication (6)	
1) Significant and prolonged constipation due to pain medications	LNP
2) Significant constipation secondary to opioid pain medication (hydrocodone/acetaminophen)	LP
3) Significant constipation associated with post-surgery opioid pain medication (oxycodone)	CNP
4) Significant constipation associated with post-surgery opioid pain medication (oxycodone)	CNP
5) Significant constipation associated with post-surgery opioid pain medication (hydrocodone/acetaminophen)	LNP
6) Constipation	LNP

Continued on next page.

Table E-2: Temporary Harm Events by Clinical Category and Preventability (n=112) (Continued)

Temporary Harm Event	Preventability
Temporary Harm Events Related to Medication (54) continued	
Allergic reactions to medications (5)	
1. Allergic reaction to antibiotic	LNP
2. Allergic reaction to antibiotic (nitrofurantoin)	CP
3. Allergic reaction (rash) secondary to antibiotic (cephalexin)	LNP
4. Allergic reaction (multiple episodes of itching) secondary to opioid pain medication (hydromorphone)	CP
5. Allergic reaction (itching and hives) to melatonin	CNP
Hypotension secondary to medication (4)	
1. Orthostatic hypotension secondary to diuretic (furosemide)	LP
2. Symptomatic bradycardia due to beta-blocker (metoprolol)-induced hypertension	LNP
3. Orthostatic hypotension secondary to medication used to treat hypertension (hydralazine)	LNP
4. Cascade event in which dehydration and medication used to treat hypertension (Lisinopril) led to hypotension and then acute kidney injury	LP
Thrush (3)	
1. Esophageal *Candida* infection secondary to antibiotics	LNP
2. Esophageal *Candida* infection secondary to immunosuppressant (prednisone) used to treat inflammatory diseases	LNP
3. Oral thrush	CNP
Adverse reaction to medication (nonallergic or not otherwise specified) (2)	
1. Excessive night sweats secondary to opioid pain medication (oxycodone)	LNP
2. Irritation of larynx secondary to inhaler-delivered asthma medication (fluticasone/salmeterol)	LNP
Diarrhea secondary to medication (2)	
1. Multifactorial diarrhea secondary to antibiotics, stool softeners, and enteral feeding	CNP
2. Significant diarrhea secondary to stool softener (docusate sodium)	LP
Other medication temporary harm events (5)	
1. Hyponatremia secondary to medication used to treat hypertension and congestive heart failure by treating fluid retention (hydrochlorothiazide)	LP
2. Bleeding from surgical incision site with associated decreased hemoglobin secondary to anticoagulants (clopidogrel and rivaroxaban)	LP
3. Fall associated with lethargy secondary to opioid (hydrocodone/acetaminophen) and opiate (morphine sulfate) pain medications	LNP
4. Nausea and vomiting due to medications (pantoprazole) given to treat gastro esophageal reflux disease	LP
5. Urinary retention secondary to antihistamine (diphenhydramine)	LP
Temporary Harm Events Related to Patient Care (46)	
Pressure ulcers (12)	
1. Multiple, stage I pressure ulcers on sacrum, coccyx and buttocks	LP
2. Stage I pressure ulcer on buttocks	LP

Continued on next page.

Table E-2: Temporary Harm Events by Clinical Category and Preventability (n=112) (Continued)

Temporary Harm Event	Preventability
Temporary Harm Events Related to Patient Care (46) (continued)	
Pressure ulcers (12) (continued)	
3. Stage I pressure ulcer on heel	LP
4. Progression of pressure ulcer from redness to excoriation with redness	LNP
5. Unstageable pressure ulcer on rear of leg	LNP
6. Stage I/II pressure ulcer on leg due to poor-fitting prosthesis	LP
7. Progression of Stage I pressure ulcer on right heel to Stage II	LP
8. Stage II pressure ulcer on buttocks	LP
9. Stage I pressure ulcers on heels	LP
10. Stage II pressure ulcer at coccyx	LP
11. Stage I pressure ulcer on sacral coccyx	LP
12. Unstageable pressure ulcer on heel (described as without breakdown)	LNP
Constipation or obstipation from patient care (9)	
1. Constipation with x-ray evidence of small bowel ileus during stay	UTD
2. Symptomatic constipation and ileus secondary to inadequate bowel care	LP
3. Symptomatic constipation and ileus characterized by nausea, vomiting, and abdominal distention	LNP
4. Prolonged constipation secondary to inadequate bowel care	LP
5. Significant constipation with impaction	LNP
6. Symptomatic constipation with x-ray showing fecal stasis	LNP
7. Significant constipation documented by abdominal x-ray	LNP
8. Significant constipation with impaction	CNP
9. Obstipation with impaction associated with inadequate bowel care	LP
Skin tear, abrasion, or breakdown (other than pressure ulcer) and other minor skin event (8)	
1. Skin tear with fungal infection that developed under brace	LP
2. Skin abrasions on elbows and knees	LNP
3. Rash on thorax, hip, and buttocks	LNP
4. Skin tears on right elbow and buttocks	LNP
5. Skin excoriation on buttocks	LP
6. Excoriation on buttocks and scrotum attributed to medication-induced delirium and agitation	LNP
7. Skin tears on legs	LNP
8. Skin tear on leg	LNP
Fall associated with patient care (6)	
1. Fall with injury (bruising) to lower back and head	LNP
2. Fall resulting in skin tear on left leg	LNP
3. Fall with injury to nose (laceration)	LNP
4. Fall with minor injuries to hip (pain) and head (temporal area swelling)	LNP
5. Fall from bed with minor injuries (elbow, knees, and small skin tear)	LP
6. Fall from wheelchair with minor injury to head and skin tear on knee	LNP
Device trauma or malfunction (4)	
1. Clotted arteriovenous shunt (dialysis access device)	LP
2. Trauma due to multiple failed Foley catheter insertions	LP
3. Hematuria secondary to intermittent catheterization	LNP
4. Skin ulcer under head of penis due to intermittent urinary catheterization	LNP

Continued on next page.

Table E-2: Temporary Harm Events by Clinical Category and Preventability (n=112)

Temporary Harm Event	Preventability
Temporary Harm Events Related to Patient Care (46) (continued)	
Edema or volume overload (2)	
1. Temporary edema at intravenous needle insertion site following blood infusion	LNP
2. Volume overload manifested by shortness of breath and lower extremity pitting edema	LP
Other patient care temporary harm events (5)	
1. Allergic reaction (skin irritation) to medical adhesive tape	LNP
2. Superficial burn on chest from hot beverage	CNP
3. Mild renal impairment and dehydration related to fluid management and trimethoprim and	LNP
4. Muscle strain with chest wall pain due to belt used in therapy	LNP
5. Significant DVT in right lower extremity despite appropriate prophylaxis in patient with history of DVT	LNP
Temporary Harm Events Related to Infections (12)	
Soft tissue or other nonsurgical infection (4)	
1. Yeast infection related to persistent moisture in the perineal area	LP
2. Yeast infection and rash under breast	LNP
3. Blisters and erythema on right thigh	LP
4. Erythema of the scrotum	LNP
Surgical site infection (SSI) (3)	
1. Superficial infection that developed on existing wound site	LP
2. Surgical site infection at site of hip surgery	LP
3. Cellulitis on left leg	LNP
Catheter-associated urinary tract infection (2)	
1. Catheter-associated urinary tract infection (*Citrobacter freundii*)	LNP
2. Catheter-associated urinary tract infection	LNP
Other (3)	
1. *Clostridium difficile* infection secondary to antibiotics	LNP
2. Scabies (pruritic bumps on back and hand)	LNP
3. Vaginal *candidiasis*	LNP

Source: OIG analysis of rehab hospital stays for 417 Medicare beneficiaries discharged in March 2012.

APPENDIX F

Agency Comments: Centers for Medicare and Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

APR 14 2016

200 Independence Avenue SW
Washington, DC 20201

To: Daniel R. Levinson
Inspector General
Office of Inspector General

From: Andrew Slavitt
Administrator
Centers for Medicare & Medicaid Services

Subject: Office of Inspector Draft Report: "Adverse Events in Rehabilitation Hospitals: National Incidence Among Medicare Beneficiaries" (OEI-06-14-00110)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the OIG draft report on adverse events in rehabilitation hospitals. CMS is committed to identifying adverse events in rehabilitation hospitals and other healthcare settings and improving the quality of care for patients.

As the OIG mentioned, CMS oversees rehabilitation hospitals' compliance with a set of minimum Federal quality and safety standards known as the Conditions of Participation (CoPs). CMS provides guidance to State survey and certification agencies for conducting hospital surveys on behalf of CMS, including guidance specific to the rehabilitation setting, to verify compliance with CoPs. While many of the CoPs have an impact on quality, the Quality Assessment and Performance Improvement (QAPI) focuses specifically on standards for facilities to improve quality and safety. As part of the QAPI CoP, rehabilitation hospitals must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning through the hospital.

As part of efforts to improve the quality of care in rehabilitation facilities, the Affordable Care Act (ACA) established the quality reporting program for inpatient rehabilitation facilities (IRFs), which requires providers to submit data on quality measures specified by the Secretary, which include measures addressing avoidable adverse events. As part of the IRF Quality Reporting Program (QRP), CMS has developed and adopted several quality measures aimed at addressing adverse events in IRFs and is required to reduce IRF payments by two percent in a given year if an IRF does not satisfactorily report the measure data. In addition, the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) included new reporting requirements for post-acute care providers, including IRFs, such as reporting data quality, resource use and other measures that focus on falls with injury, pressure ulcers, functional status, and other quality issues.

CMS strives to align quality improvement efforts across programs in order to improve the measurement and reporting of adverse events. CMS will continue to work with federal and other partners to identify and address adverse events.

OIG Recommendation

The OIG recommends that the Agency for Healthcare Research and Quality (AHRQ) and CMS should raise awareness of adverse events in rehabilitation hospitals and work to reduce harm in patients.

CMS Response

CMS concurs with this recommendation. CMS is committed to identifying adverse events in rehabilitation hospitals and other healthcare settings and improving the quality of care for patients. As such, CMS has provided guidance to state survey agencies on Federal requirements of hospitals to track adverse events and shared AHRQ tools to help with such tracking. CMS will continue its work with AHRQ and other partners to identify and address adverse events.

OIG Sub Recommendation

The OIG recommends that AHRQ and CMS should collaborate to create and promote a list of potential rehabilitation hospital events.

CMS Response

CMS concurs with this recommendation. CMS will work with AHRQ to create and promote a list of potential rehabilitation hospital events, similar to its efforts for other patient settings.

OIG Sub Recommendation

The OIG recommends that CMS should include information about potential events and patient harm in its quality guidance to rehabilitation hospitals.

CMS Response

CMS concurs with this recommendation. To participate in Medicare, rehabilitation hospitals must comply with the CoPs for hospitals, including the QAPI CoP. CMS provides guidance for surveyors assessing facility efforts to improve patient safety under the QAPI CoP and will look into expanding the current QAPI guidance to include quality guidance specifically on rehabilitation hospitals. In addition, through the IRF QRP, CMS currently provides training on recognition and reporting of quality measures specific to rehabilitation hospitals as well as provides reports on measure performance consistent with the requirements set forth by the IMPACT Act. CMS will also look into using the Quality Improvement Organization (QIO) Program to assist with quality improvement efforts in rehabilitation hospitals.

Agency Comments: Agency for Healthcare Research and Quality

To: Daniel R. Levinson
Inspector General,
Department of Health and Human Services

From: Dr. Sharon Arnold
Acting Director
Agency for Healthcare Research and Quality

Subject: OIG Draft Report: Adverse Events in Rehabilitation Hospitals: National Incidence Among Medicare Beneficiaries, OEI Inspection Number OEI-06-14-00110

Thank you for the opportunity to review draft report entitled, Adverse Events in Rehabilitation Hospitals: National Incidence Among Medicare Beneficiaries," (OEI-06-14-00110).

We have specific responses to the recommendation.

1. Recommendation: **AHRQ and CMS should collaborate to create and promote a list of potential rehab hospital events.** AHRQ concurs with this recommendation and will work with CMS to collaborate as we have in identifying adverse events for the hospital and skilled nursing facilities. AHRQ believes that it would be useful to perform a special review of the events identified in Appendix E of the report to determine how they "map" with respect to the current AHRQ Common Formats (Formats) for Hospitals. If it makes conceptual sense to do so, event types that do not map readily to the existing Formats (e.g., known side effects of medications or treatments such as nausea, headache, and constipation) can be added as separate events in a future Formats update. At this time AHRQ does not anticipate a need for a Formats version dedicated solely to rehabilitation hospitals. (The existing Formats allow collection of data on all event types, with an "other" category for events that occur infrequently. New definitions can be created to address specific event types, if warranted.) When a Formats update is released, the OIG report on rehabilitation hospitals can be cited as one of the sources and reasons for the inclusion of any new event types. Please note that "mapping" of some event sub-types may not be possible. In this case, they may be captured with the "other" category.

We look forward to following up with you regarding our activities related to the above recommendations, as well as to collaborating as appropriate with our colleagues at CMS.
We believe that your previous reports on adverse events in Medicare patients have provided valuable information to the public and to Federal and private-sector healthcare leaders. This report promises to do the same by addressing a new and especially vulnerable patient population.

If you or your staff has any questions, please feel free to contact Dr. Jeff Brady, Director, Center for Quality Improvement and Patient Safety at Jeff.Brady@ahrq.hhs.gov or 301-427-1322.

Sharon Arnold, Ph.D.
Sharon B. Arnold, PhD

Attachment

ACKNOWLEDGMENTS

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

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