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ADVERSE EVENTS IN SKILLED NURSING FACILITIES: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES

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EXECUTIVE SUMMARY: Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries
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WHY WE DID THIS STUDY

From 2008–2012, we conducted a series of studies about hospital adverse events, defined as harm resulting from medical care. This work included a Congressionally mandated study to determine a national incidence rate for adverse events in hospitals. As part of this work, we developed methods to identify adverse events, determine the extent to which events are preventable, and measure the cost of events to the Medicare program. This study continues that work by evaluating post-acute care provided in skilled nursing facilities (SNF). SNF post-acute care is intended to help beneficiaries improve health and functioning following a hospitalization and is second only to hospital care among inpatient costs to Medicare. Although various health care stakeholders have in recent years paid substantial attention to patient safety in hospitals, less is known about resident safety in SNFs.

HOW WE DID THIS STUDY

This study estimates the national incidence rate, preventability, and cost of adverse events in SNFs by using a two-stage medical record review to identify events for a sample of 653 Medicare beneficiaries discharged from hospitals to SNFs for post-acute care. Sample beneficiaries had SNF stays of 35 days or less.

WHAT WE FOUND

An estimated 22 percent of Medicare beneficiaries experienced adverse events during their SNF stays. An additional 11 percent of Medicare beneficiaries experienced temporary harm events during their SNF stays. Physician reviewers determined that 59 percent of these adverse events and temporary harm events were clearly or likely preventable. They attributed much of the preventable harm to substandard treatment, inadequate resident monitoring, and failure or delay of necessary care. Over half of the residents who experienced harm returned to a hospital for treatment, with an estimated cost to Medicare of $208 million in August 2011. This equates to $2.8 billion spent on hospital treatment for harm caused in SNFs in FY 2011.

WHAT WE RECOMMEND

Because many of the events that we identified were preventable, our study confirms the need and opportunity for SNFs to significantly reduce the incidence of resident harm events. Therefore, we recommend that the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) raise awareness of nursing home safety and seek to reduce resident harm through methods used to promote hospital safety efforts. This would include collaborating to create and promote a list of potential nursing home events—including events we found that are not commonly associated with SNF care—to help nursing home staff better recognize harm. CMS should also instruct State agency surveyors to review nursing home practices for identifying and reducing adverse events. AHRQ and CMS concurred with our recommendations.

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OBJECTIVES

1. To estimate the national incidence of adverse and temporary harm events for Medicare beneficiaries admitted to skilled nursing facility (SNF) 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 costs associated with adverse and temporary harm events to the Medicare program.

BACKGROUND

The Office of Inspector General (OIG) conducted a series of studies about adverse events in hospitals from 2008–2012.[1] This work included a Congressionally mandated study of adverse event incidence within hospitals.[2, 3] OIG found that 27 percent of hospitalized Medicare beneficiaries experienced adverse and temporary harm events, nearly half of the events were preventable, and care associated with events cost the Medicare program an estimated $4.4 billion a year. OIG has identified a number of problems with the quality of care provided in nursing homes, including SNFs. These problems include inadequate discharge planning and lack of compliance with CMS standards regarding the use of atypical antipsychotic drugs.[4, 5] These problems pose risks to individuals and increase Medicare costs in the form of hospitalizations.

Medicare expenditures for SNF care have more than doubled in the last decade. Medicare paid $12 billion for SNF care in 2000 and $26 billion in 2010.[6, 7] In fiscal year (FY) 2011, Medicare paid $28.4 billion for SNF

[1] OIG released 11 reports regarding adverse events in hospitals during 2008-2012, including reports about the incidence of adverse events, methods for identifying adverse events, State reporting systems, and public disclosure of event information. All reports are available at http://oig.hhs.gov/reports-and-publications/oei/a.asp#adverse_care.

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

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

[4] OIG, *Skilled Nursing Facilities Often Fail To Meet Care Planning and Discharge Planning Requirements*, OEI-02-09-00201, February 2013.

[5] OIG, *Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs,* OEI-070800151, July 2012.

[6] U.S. Department of Health and Human Services (HHS), Office of the Actuary, National Health Statistics Group, SNF Utilization Chart, 2010, p. 50.

[7] Medicare Payment Advisory Committee (MedPAC), *Skilled Nursing Facility Services Payment System*, updated October 2011, p. 1.

services provided to 1.8 million beneficiaries.[8] Post-acute SNF stays—which we define for the purposes of this study as SNF stays that began within 1 day of discharge from a hospital and lasted 35 days or less—constitute 70 percent of all Medicare beneficiary stays in SNFs.[9]

Adverse Events

The term "adverse event" describes harm to a patient or resident as a result of medical care.[10] An adverse event indicates harm to the patient as a result of medical care, including the failure to provide needed care. Adverse events include medical errors but they may also include more general substandard care that results in patient or resident harm, such as infections caused by the use of contaminated equipment. However, adverse events do not always involve errors, negligence, or poor quality of care and are not always preventable.[11,12]

Post-Acute Care in SNFs

The Social Security Act (SSA) §1819(a) defines a "SNF" as a facility engaged primarily in providing skilled nursing care and rehabilitation services for residents who require such care because of injury, disability, or illness. Although the term "SNF" refers to a provider that meets the Medicare Part A coverage requirements described above, 90 percent of SNFs are dually certified as both SNFs and nursing homes (i.e., long-term care providers).[13] In 2011, about 20 percent of all hospitalized Medicare beneficiaries went to one of the 15,207 SNFs for post-acute care following their hospital stays.[14] Medicare Part A pays for up to 100 days of care in SNFs per benefit period.[15, 16] Medicare beneficiaries are eligible for SNF stays following a hospital stay of at least 3 days and when a medical

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[8] Centers for Medicare & Medicaid Services (CMS), 2011 CMS Statistics, Tables III.6 and IV.6a. Accessed at www.cms.gov/ResearchGenInfo/02_CMSStatistics.asp on April 9, 2012.

[9] OIG analysis of 2010 Medicare SNF claims, Standard Analytical File (SAF).

[10] See Appendix A for a definition of "adverse events" as well as a list of select clinical terms and conditions.

[11] R.M. Wachter, *Understanding Patient Safety*, McGraw-Hill, 2008, p. 17.

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

[13] MedPAC, *Report to the Congress: Medicare Payment Policy, Skilled Nursing Facility Services*, March 2013, p. 161.

[14] Ibid.

[15] A "benefit period" is a period of consecutive days during which medical benefits for covered services, with certain specified maximum limitations, are available to the beneficiary. CMS, *Medicare Benefit Policy Manual: Duration of Covered Inpatient Services*, Chapter 3.

[16] CMS, *Medicare Benefit Policy Manual: Coverage of Extended Care (SNF) Services Under Hospital Insurance*, Chapter 8.

professional verifies the need for nursing care and rehabilitation related to the hospitalization.[17]

In 2010, MedPAC described Medicare beneficiaries in SNFs as more likely than other Medicare beneficiaries to report poor health status, have multiple limitations in their activities of daily living, live in an institution, and be disabled.[18] Examples of SNF residents include those recovering from surgical procedures performed in hospitals (e.g., hip or knee replacements) or recovering from acute medical conditions (e.g., stroke, pneumonia).[19] Examples of care provided to SNF residents include the development, management, and evaluation of a resident care plan; physical therapy; administration of intravenous feedings; medication management; and wound care.

Medicare Payment to SNFs. Medicare payment to SNFs is determined by rate groups based on the level of care provided and is adjusted for geographic and resident population differences. Each of these 66 rate groups—referred to as "resource utilization groups," or "RUGs"—in 8 categories have weights for nursing and therapy care that are applied to the base rates.[20] Assignment to a rate group is based on the number of minutes of therapy that the resident requires, the need for certain services (such as respiratory therapy), the presence of certain conditions (such as dehydration), and an index based on the ability of the resident to independently perform four activities of daily living (i.e., eating, toileting, bed mobility, and transferring).[21]

Federal Oversight of Nursing Homes

CMS oversees nursing home compliance with Federal standards through State survey agencies, which monitor SNFs and enforce penalties for substandard quality of care.[22, 23] Surveys may include medical record review and audits of resident assessments or plans of care.[24] CMS enters into agreements with State survey agencies to conduct onsite surveys of

[17] Ibid.
[18] MedPAC, op. cit., p. 162-163.
[19] MedPAC, op. cit., p. 161.
[20] CMS, *Resident Assessment Instrument (RAI) Version 3.0 Manual (v. 1.07)*, ch. 6, § 6.3.
[21] Ibid, ch. 6, § 6.6.
[22] 42 CFR Part 488, Subparts E and F.
[23] CMS, *State Operations Manual*, Appendix PP, *Guidance to Surveyors for Long Term Care Facilities*, Tag F309.
[24] 42 CFR §§ 488.305(a) and 488.310(b).

each nursing home to certify compliance with Federal requirements.[25] When surveyors identify noncompliance with Federal requirements, CMS requires nursing homes to submit plans of correction and to correct the problems. If nursing homes do not correct the problems, CMS may take enforcement actions, including imposing civil monetary penalties and denying payment for new admissions of Medicare residents.[26]

CMS requirements regarding resident safety in nursing homes include both broad, facility-wide mandates (such as staff training) and requirements specific to certain practices (such as treatment of pressure ulcers). To establish and oversee quality and safety-related practices, CMS requires that nursing homes establish and maintain a Quality Assurance and Assessment (QAA) committee composed of a physician designated by the facility, director of nursing, and other staff members as determined by the facility.[27] Tasks of the QAA include identifying and addressing quality and safety problems. To evaluate nursing home quality and safety practices, CMS instructs surveyors to review QAA committee activities and interview committee members as a part of onsite reviews.[28] Noncompliance with the QAA requirements can result in surveyors' citing a deficiency specific to the QAA process.[29]

Additionally, CMS requires that Medicare- and Medicaid-certified nursing homes report alleged instances of mistreatment, neglect, or abuse to State survey agencies.[30] These instances are to include injuries of unknown source as well as misappropriation of resident property. When allegations of such instances are made, the nursing homes must take measures to prevent further potential abuse, investigate the allegations, and establish a corrective action plan if warranted.[31] Federal regulation defines abuse as "willful infliction of injury" and neglect as "failure to provide goods and services necessary to avoid harm."[32] Noncompliance with the reporting

[25] 42 CFR § 488.10 and CMS, *Survey and Certification: General Information*, April, 11, 2013. Accessed at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/index.html?redirect=/surveycertificationgeninfo/ on May 15, 2013.

[26] 42 CFR §§ 488.402(d), 488.408, and 488.417.

[27] 42 CFR §§ 483.75(o).

[28] CMS, *State Operations Manual*, Appendix PP, Guidance to Surveyors for Long Term Care Facilities, Tag F520.

[29] Ibid.

[30] 42 CFR §§ 483.13(c)(2).

[31] 42 CFR §§ 483.13(c)(3) and (4).

[32] 42 CFR §§ 488.301.

requirements results in a deficiency citation specific to the reporting process.[33]

Nursing Home Quality Measures. Medicare- and Medicaid-certified nursing homes routinely collect resident assessment data at specific intervals during a nursing home stay and maintain the assessment results in the Minimum Data Set (MDS).[34] CMS converts portions of the MDS data into 18 quality measures (QMs), which indicate how well nursing homes care for residents.[35] Examples of QMs include the percentage of residents who develop pressure ulcers, the percentage who develop urinary tract infections, and the percentage who experience falls with injury.[36] CMS provides QMs to SNFs for use in quality improvement efforts.

CMS publicly reports nursing home QMs through the Five-Star Quality Rating System and Nursing Home Compare. CMS gives each Medicare- and Medicaid-certified nursing home an overall rating between one and five stars. A rating of one star indicates that a nursing home is "much below average" in terms of quality, and a rating of five stars indicates that a nursing home is "much above average."[37] CMS bases the overall ratings on the nursing homes' performance in three areas: performance on inspection surveys (survey metric), QMs (quality metric), and staffing (staffing metric).

Adverse Event Lists and Reporting. To date, there is no Federal requirement that SNFs report adverse events beyond the requirements to report instances of mistreatment, neglect or abuse and the discrete potential events described in the QMs (e.g., pressure ulcers, falls). Additionally, there are no Federal standards that require States to operate adverse event reporting systems. To help define potential events for reporting, the National Quality Forum (NQF) issued guidance in 2011 expanding its list of hospital Serious Reportable Events (SRE) to SNFs

[33] CMS, *State Operations Manual*, Appendix PP, Guidance to Surveyors for Long Term Care Facilities, Tags F223-226.

[34] CMS, *RAI Version 3.0 Manual (v. 1.07)*, ch. 1, § 1.2, and ch. 2, § 2.6.

[35] RTI [Research Triangle Institute] International, *Nursing Home MDS 3.0 Quality Measures: Final Analytic Report* (Sept. 2012), §§ 1.1 and 1.2.

[36] RTI, *MDS 3.0 Quality Measures User's Manual* (v. 6.0). Accessed at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/MDS-30-QM-Users-Manual-V60.pdf on February 19, 2013.

[37] CMS, *Consumer Fact Sheet*, December 2008. Accessed at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/consumerfactsheet.pdf on October 4, 2013.

and other health care settings.[38] The NQF SRE list identifies adverse events that are "serious, largely preventable, and of concern to both the public and health care providers."[39] The 2011 updated SRE list includes 24 events applicable to SNF care. These 24 events largely represent only the most egregious potential events such as a patient death or serious injury associated with the use of contaminated drugs or devices.

Resident Safety in Nursing Homes

Previous studies of adverse events in nursing homes have focused largely on medication-related adverse events—which are a subset of all adverse events—among the entire nursing home population. A 2006 review of seven studies measuring the incidence of medication-related adverse events in nursing homes revealed that such events are common and that as many as half of the events could have been prevented.[40]

Research also indicates that patient and resident transfers between hospitals and nursing homes can pose problems for medically fragile individuals.[41] Many transitions from hospitals to post-acute care occur in a hurried manner and have limited prior planning, occur during nights and on weekends when nursing homes may have fewer and less experienced staff, involve clinicians who may not have a relationship with the residents, and happen too quickly for nursing home staff to respond well and in a timely manner.[42] Similarly, hospitalizations of nursing home residents increase the risk that residents will experience harm and other negative care outcomes.[43, 44] The impact on residents during hospitalizations can include disruption of their care plans and greater

[38] The NQF is a consensus-building organization focused on health care quality and funded in part by grants from HHS. "NQF Mandate and Call to Action," About NQF, updated January 2012. Accessed at http://www.qualityforum.org/About_NQF/About_NQF.aspx on March 23, 2012.

[39] NQF, "National Voluntary Consensus Standards for Serious Reportable Events in Healthcare," Press Release, August 2011.

[40] S.M. Handler, "Epidemiology of Medication-Related Adverse Events in Nursing Homes," *The American Journal of Geriatric Pharmacotherapy*, 4, 3, 2006, pp. 264-272.

[41] Congressional Research Service, "Medicare Hospital Readmissions: Issues, Policy Options and PPACA," Fact Sheet, September 21, 2010.

[42] E. Coleman and R.A. Berenson, "Lost in Transition: Challenges and Opportunities for Improving the Quality of Transitional Care," *American College of Physicians*, 141, 7, 2004, p. 533.

[43] Assistant Secretary for Planning and Evaluation (ASPE), *Hospitalizations of Nursing Home Residents: Background and Options*, June 2011, p. 1.

[44] J.G. Ouslander, "Reducing Potentially Avoidable Hospitalizations of Nursing Home Residents: Results of a Pilot Quality Improvement Project," *Journal of the American Medical Directors Association*, 10, 9, 2009, p. 645.

vulnerability for disorientation, stress, and adverse events.[45] Hospitalization rates are seen as a measure of nursing home quality and safety and have received attention from OIG and other stakeholders.[46, 47]

Federal Efforts To Improve the Quality of Post-Acute Care

In addition to CMS, other Federal agencies share responsibility for ensuring health care quality and safety in nursing homes. For example, the Agency for Healthcare Research and Quality (AHRQ) in HHS leads efforts related to research and learning. The Center for Quality Improvement and Patient Safety (CQuIPS) within AHRQ provides national leadership in improving health care safety. CQuIPS objectives are to develop a solid evidence base, design useful tools, and disseminate information for implementation to all health care facilities.[48] AHRQ is also required by statute to produce an annual report to Congress about health care quality.[49]

Patient Safety Organizations. AHRQ maintains responsibility for implementing and overseeing the certification process for Patient Safety Organizations (PSO) created by the Patient Safety and Quality Improvement Act of 2005 (PSQIA).[50] PSOs are intended to receive adverse event reports from health care facilities and then forward the information to a national database from which CQuIPS will analyze aggregated data. PSQIA also provides Federal privilege and confidentiality protections for information reported to PSOs.[51] These protections prohibit other entities from accessing adverse event reports, including State survey agencies, with providers facing possible penalties enforced by the HHS Office of Civil Rights. Officials at AHRQ and CMS indicated in interviews with OIG staff that the PSQIA confidentiality provision may be in conflict with CMS compliance requirements that allow surveyors access to facility QAA actions and reports.

To facilitate reporting, AHRQ developed a set of event definitions and reporting tools—the Common Formats—which PSOs can choose to use

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[45] E. Hutt, "Precipitants of Emergency Room Visits and Acute Hospitalization in Short-Stay Medicare Nursing Home Residents," *Journal of the American Geriatrics Society*, 50, 2, 2002, 223–224.

[46] OIG, *Medicare Nursing Home Resident Hospitalization Rates Merit Additional Monitoring*, OEI-06-11-00040, November 2013.

[47] ASPE, op. cit., pp. 8–12.

[48] AHRQ, *Advancing Patient Safety: A Decade of Evidence, Design, and Implementation,* AHRQ Publication No. 09(10)-0084, November 2009.

[49] Public Health Service Act (PHSA), § 913, 42 U.S.C. § 299b-2.

[50] The Secretary of HHS delegated authority to AHRQ to certify entities as PSOs, as well as to fulfill other requirements of the PSQIA. P.L. 109-41 § 2, PHSA, § 924, 42 U.S.C. § 299b-24; 73 Fed. Reg. 70732 (Nov. 21, 2008).

[51] P.L. 109-41 § 2, PHSA, § 924, 42 U.S.C. § 299b-24.

and which contain data elements that AHRQ determined are important for a complete and useful adverse event report.[52] AHRQ designed the Common Formats for both the hospital and SNF settings.[53] The Patient Protection and Affordable Care Act (ACA) provides that, by January 1, 2015, health plans that participate in insurance exchanges may not contract with a hospital of 50 beds or more unless that hospital reports patient safety data to a PSO.[54] Currently, no such requirement exists for SNFs.

The ACA also mandated HHS to establish a national strategy for quality improvement in health care,[55] including patient and resident safety,[56] and increased funding to AHRQ for research grants to explore best practices.[57] As part of this strategy, CMS introduced in 2011 its Partnership for Patients, a public/private collaboration to improve health care quality and safety, specifically including transitions from acute to post-acute care.[58] HHS also developed the Measure Applications Partnership (MAP), a public/private partnership facilitated by NQF and designed to provide CMS and other agencies within HHS with input regarding health care performance measurement, in order to satisfy a mandate in the ACA to seek multi-stakeholder group input.[59] MAP recently released a draft set of core measure concepts to use in assessing post-acute care by facilities such as SNFs, identifying both care coordination and safety as two of six high-leverage priority areas.[60]

The ACA also requires nursing homes to develop and operate Quality Assurance and Performance Improvement (QAPI) programs.[61] In June 2013, CMS released guidance to nursing homes regarding developing and

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[52] AHRQ, *Common Formats for Patient Safety Data Collection and Event Reporting, Notice of Availability: Common Formats Version 1.0*, September 2, 2009.

[53] AHRQ, *Users Guide: AHRQ Common Formats for Skilled Nursing Facilities Version 0.1 Beta Release*, February 2011.

[54] P.L. 111-148 § 1311, (h)(1)(A), i-ii.

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

[56] ACA, § 3011, PHSA, § 399HH(a)(2)(B)(vii), 42 U.S.C. § 280j(a)(2)(B)(vii).

[57] ACA, § 3501, PHSA, §§ 933 and 934, 42 U.S.C. §§ 299b-33 and 299b-34.

[58] CMS, *Partnership for Patients: A Common Commitment*, April 2011. Accessed at http://www.healthcare.gov/compare/partnership-for-patients/about/index.html on March 7, 2012.

[59] ACA § 3014.

[60] NQF, *Input on Measures Under Consideration by HHS for 2012 Rulemaking: Final Report*, Measure Applications Partnership, February 2012, pp. 99-100.

[61] ACA, 6102, Social Security Act, § 1128I(c), 42 U.S.C. § 1320a-7j(c).

maintaining QAPI programs.[62] This guidance states that QAPI programs are to serve as comprehensive plans to both improve routine facility practices and to conduct periodic, targeted performance improvement projects. It further states that facilities are to continue working within the prior Federal requirements, relying on QAA committees to implement and oversee QAPI activities.[63] CMS provides QAPI tools for identifying and addressing quality and safety programs, such as guidance for developing a facility mission statement and establishing safety goals.[64]

CMS, in its 2012 Nursing Home Action Plan, described several initiatives intended to improve resident safety and quality in nursing homes.[65] These initiatives involve many of CMS' nursing home oversight and payment tools. Action Plan initiatives include multiple refinements to the existing survey and certification process, improvements in data reported through the Five-Star Quality Rating System, demonstration projects designed to test the effect of payment incentives on nursing home performance and quality, and plans to collaborate with Quality Improvement Organizations and State survey agencies.

Measuring Health Care Safety

Research and policy to improve health care safety and reduce adverse events often focus on identifying systemic problems that lead to harm and avoid labeling the event as an outcome of negligence or poor quality. As part of this effort to identify problems, researchers and health care entities may adopt different standards for distinguishing between degrees of harm in defining what constitutes an adverse event. Thus, entities tracking events may find different results depending on the tools used to identify and classify events. For example, the National Coordinating Council for Medication Errors Reporting and Prevention (NCC MERP) Index can be used to classify adverse events by level of harm. The NCC MERP Index was initially developed to categorize the effect of medication errors. The index includes categories for circumstances that presented a risk but did

[62] CMS, *QAPI at a Glance: A Step by Step Guide to Implementing QAPI in Your Nursing Home*. Accessed at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/QAPIAtaGlance.pdf on October 2, 2013.

[63] Ibid.

[64] CMS, Guide for Development Purpose, Guiding Principles, and Scope for QAPI, June 7, 2013. Accessed at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/QAPIPurpose.pdf on September 5, 2013.

[65] CMS, *2012 Nursing Home Action Plan*, 2012.

not cause harm ("near misses") and those that did cause harm.[66] Table 1 shows the NCC MERP Index for Categorizing Errors.

Table 1: The NCC MERP Index for Categorizing Errors

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

Source: 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.

Researchers have also used the NCC MERP index for measuring and distinguishing other types of adverse events. The Institute for Healthcare Improvement (IHI), a nonprofit organization that advises health care providers regarding health care quality, uses a modified version of the NCC MERP index to measure the degree of harm, regardless of whether the harm was the result of error.[67]

Identifying Adverse Events. Retrospective medical record review is often considered the most definitive method for detecting adverse events, because it can provide detail about both the adverse event and the circumstances, such as the patient's or resident's condition prior to and following the event.[68] Research indicates that identifying adverse events retrospectively is a complex and difficult task, requiring extensive clinical

[66] AHRQ designed an alternative harm scale for use with the Common Formats. According to AHRQ, the AHRQ Harm Scale differs from the NCC MERP harm scale in that it is intended to measure the harm experienced by the beneficiary after the harm is ameliorated. AHRQ, *Users Guide: Version 1.2 AHRQ Common Formats for Patient Safety Organizations,* 2013.

[67] F.A. Griffin and R.K. Resar, *IHI Global Trigger Tool for Measuring Adverse Events*, Institute for Healthcare Improvement Innovation Series, 2009, pp. 4–5.

[68] E.J. Thomas, D.M. Studdert, and T.A. Brennan, "The Reliability of Medical Record Review for Estimating Adverse Event Rates," *Annals of Internal Medicine*, 136, 11, 2002, pp. 812–816.

knowledge, adequate documentation, and subjective judgment on the part of the researcher.[69]

Medical record reviews can be costly, requiring hospitals to make records available and substantial effort by physicians or other clinicians to review them. To limit physician medical record reviews to identify adverse events, cases can be screened to identify potential events using other methods, such as nurse reviews of medical records and analysis of Medicare hospitalization claims. One such method, the IHI's Global Trigger Tool (GTT), uses a review of hospital inpatient medical records to identify "triggers" that could signal patient harm and indicate potential adverse events. A trigger could be a description of the harm or a reference that indicates potential harm, such as a return to surgery. The IHI GTT review is designed to be completed by nurse reviewers with the results then confirmed or refuted by a physician. Another example of a trigger tool is the Nursing Home Adverse Drug Event Trigger Tool.[70] Unlike the IHI GTT, which focuses on all aspects of patient care in the hospital setting (e.g., medication, surgery, patient care), the Nursing Home Adverse Drug Event Trigger Tool is focused on medication-related adverse events in the nursing home or other long-term care settings.

Determining Preventability. To provide additional context regarding adverse events, researchers have assessed whether events were preventable and described the factors contributing to the events. In a 2010 OIG report about adverse events in hospitals, physician reviewers determined that 44 percent of events were preventable.[71] A 2008 review of eight academic studies found a similar result, with an average of 44 percent of events judged preventable.[72] A 2010 study that examined the incidence of adverse events in 10 North Carolina hospitals described 63 percent of identified events as preventable.[73] Assessing preventability can provide greater understanding of the causes of events, which can be used to develop actionable solutions to the systemic problems that lead to events.

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

[70] S.M. Handler, "Detecting Adverse Drug Events Using a Nursing Home Specific Trigger Tool," *Annals of Longterm Care*, 18, 5, 2010, pp. 17-22.

[71] OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090, November 2010, p. 24.

[72] E.N. De Vries, "The Incidence and Nature of Hospital Adverse Events: A Systematic Review," *British Medical Journal – Quality and Safety in Health Care*, 17, 3, 2008: pp. 216–23.

[73] C.P. Landrigan, "Temporal trends in rates of patient harm resulting from medical care," *New England Journal of Medicine,* 363, 22, 2010: 2124–34.

METHODOLOGY

This report estimates the national incidence of adverse events that occurred in SNFs using a representative sample of Medicare SNF residents. Our study population includes all Medicare beneficiaries who had Medicare-paid SNF stays that met each of the following criteria:

- began within 1 day of a beneficiary's discharge from a hospital,
- had a length of stay of 35 days or less (rather than the maximum 100 days allowed by Medicare),[74] and
- ended in August 2011.

We included in the estimated national incidence rates all SNF resident harm events that occurred during the SNF stays, regardless of whether they were preventable. All SNF harm described in this report is attributable to the care provided in the SNF. Additionally, this report provides a physician assessment of the extent to which the identified events were preventable and an analysis of billing data to estimate the cost to the Medicare program for inpatient hospital stays and emergency room visits resulting from preventable and not preventable adverse events. This study largely follows the methodology used by OIG in the November 2010 report, which estimated the national incidence rate, preventability, and cost of adverse events in hospitals.[75]

Sample Selection and Profile

Using Medicare claims data from the National Claims History (NCH) file, we selected a simple random sample of 655 Medicare beneficiaries out of the 100,771 beneficiaries who had SNF stays that met our 3 sample criteria. We excluded 2 beneficiaries because the SNFs they resided in were under OIG investigation, which resulted in a review of 653 beneficiaries' SNF stays. Thirty-seven sample beneficiaries had more than 1 SNF stay during August (35 had 2 stays and 2 had 3 stays). Combined, reviewed sample beneficiaries had 692 SNF stays that ended in August 2011; the length of stay averaged 15.5 days.

The majority (70 percent) of sample beneficiaries entered SNFs following hospital stays described by CMS as medical, or nonsurgical, stays. The most frequent medical conditions treated in these stays were septicemia

[74] In consultation with CMS, physician reviewers and geriatrician consultants, we limited our study population to only those stays that were 35 days or less because it allowed for measurement of harm in the post-acute care period. Additionally, stays that ended on the 35th day or earlier constituted the majority—approximately 70 percent—of SNF stays in FY 2011.

[75] OIG, op. cit., pp. 8-11.

and urinary tract infections.[76] The remaining 30 percent of beneficiaries entered SNFs following surgical hospital stays (most often for hip or knee joint replacements).

Data Collection

We requested complete medical records for the sampled beneficiaries' SNF stays. We received 100 percent of the SNF records we requested.[77] As part of this request, we asked the SNFs to provide the discharge summaries and other key medical record documents from the hospital stays that preceded the post-acute stays. In cases when the SNFs were not able to provide the hospital records, we requested the records directly from the hospitals. We also requested discharge summaries and other key medical record documents for any hospital stay that occurred during the SNF stay or within 14 days of a beneficiary's discharge from the SNF stay.

In addition to collecting the medical record documentation, we collected billing data for the SNF stays and any associated hospital stays. We collected MDS assessment data associated with the sampled beneficiaries' Part A SNF stays. We collected hospital inpatient and outpatient claim data associated with sample beneficiaries' qualifying inpatient stays—as well as for any subsequent inpatient or emergency room visits—from the National Claims History file.

Identification of Adverse and Temporary Harm Events. We conducted a two-stage medical record review to identify adverse and temporary harm events.[78] The first stage was a screening process designed to identify sample beneficiaries who may have experienced an adverse or temporary harm event during their stay(s). We asked one nurse practitioner and four nurses (referred to as "screeners") with IHI GTT or SNF experience to review the medical records and administrative data associated with the sample beneficiaries' SNF stays and hospital stays. They reviewed the medical records and administrative data of the hospital stays for evidence of harm that occurred during the SNF stays. They used the OIG-developed SNF trigger tool to facilitate and standardize their individual reviews of the SNF records.[79] The contracted screeners reviewed the records independently and each record was reviewed by one screener. Prior to beginning their reviews,

[76] Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

[77] We did not request records for the two stays that occurred in SNFs under OIG investigation.

[78] See Appendix B for an expanded description of the methodology used to identify adverse and temporary harm events.

[79] See Appendix C for description of the development process and a list of SNF Trigger Tool triggers.

we provided training to all screeners on the use of the SNF Trigger Tool. The screeners "flagged" the records of 262 beneficiaries for the second stage of the review. In addition, we randomly selected 100 beneficiaries from 391 beneficiaries who were not flagged during the screener review to determine a screener false-negative rate (i.e., the rate at which the screeners incorrectly determined that a beneficiary did not experience an adverse or temporary harm event). See Appendix B for a detailed description of these additional reviews.

The second stage of the medical record review consisted of reviews by five contracted physicians of the medical records of the 262 beneficiaries flagged by the screening process and the records of the 100 beneficiaries selected for the screener false-negative rate review. The physicians reviewed the records independently and each record was reviewed by one physician reviewer. To describe the harm caused by the events, the reviewers used a modified version of the NCC MERP harm scale:

- F level—Harm occurred that prolonged the SNF stay or led to a transfer to a different SNF or other post-acute facility and/or hospitalization (i.e., admission to a hospital observation unit, emergency department, or inpatient care).
- G level—Harm occurred that contributed to or resulted in permanent resident harm.
- H level—Harm occurred that required intervention to sustain the resident's life.
- I Level—Harm occurred that may have contributed to or resulted in resident death.

The physician panel included four physicians who participated in the 2011 OIG study of hospital events (specialists in cardiology, infectious disease, internal medicine, and orthopedics) and one geriatrician with experience as a Medical Director in SNFs. To ensure consistency across physician reviewers, we facilitated weekly conference calls during which physician reviewers discussed cases that either were complex or had possible implications for other cases. Additionally, a contracted geriatric psychiatrist provided a secondary review of select events that involved psychotropic medications, including falls associated with medications.

Data Analysis

We performed analysis and generated estimates about adverse and temporary harm events in three categories: national incidence of events, preventability of events, and Medicare cost associated with events. We included the results of the screener false-negative rate review in all of our analyses using

appropriate methodology. For estimates and corresponding 95-percent confidence intervals, see Appendix D.

Adverse Event Incidence Analysis. We calculated the estimated national adverse event incidence rate as the percentage of Medicare SNF residents who experienced at least one adverse event. We defined adverse events as events that resulted in one of the four most serious categories on a modified version of the NCC MERP index described above (classified on the index as F-I). We projected incidence rates to the population of Medicare beneficiaries who had SNF stays that began within 1 day of a beneficiary's discharge from a hospital, had a length of stay of 35 days or less, and ended in August 2011.

The overall adverse event incidence rate does not include events that physician reviewers identified as temporary harm events, defined as events that required intervention but did not cause lasting harm (classified as E level harm on the NCC MERP index). We excluded these temporary harm events from our overall rate because we determined, in consultation with physician reviewers, that the effect of these events was not comparable to those of the more serious events (i.e., F level through I level events). We calculated a separate incidence rate for Medicare SNF residents who experienced only temporary harm events.

For beneficiaries in our sample, we also calculated 2 ratios of adverse event incidence density: events per 1,000 resident days and events per 100 SNF admissions. These measures are commonly used by providers and medical professionals.[80] For the resulting metrics and an explanation of the methods used, see Appendix E.

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

Medicare Cost Analysis. We estimated the cost to Medicare resulting from inpatient hospital stays and emergency room visits. To determine how much Medicare paid for services associated with events, we asked physician reviewers to indicate whether the SNF residents were hospitalized because

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

of identified adverse events. To assist them in their determinations, we provided the physicians with summaries of the hospital claims associated with each sample beneficiary. These summaries provided information on the hospitalizations that occurred during the SNF stays or within 14 days of the sample beneficiaries' discharges from the SNFs and the diagnoses codes associated with the hospitalizations.

Using hospital claims data from the NCH file and the results of the physicians' medical record reviews, we identified the inpatient hospital stay or emergency room visit claims associated with the sample beneficiaries' adverse events. We did this by matching the discharge date of the SNF stay with the admission date of the hospital stay or emergency room visit.[81] We attributed the entire cost of the inpatient hospital stay or emergency room visit to the adverse event. We summed the reimbursements paid by Medicare for the hospital and emergency room claims to determine the total Medicare paid for the hospitalizations.

Limitations

The methodology presents three specific limitations. First, it is unlikely that the study identified all adverse and temporary harm events within the sample of SNF residents. To the extent that the study did not identify an event, it was likely because documentation in the medical records was incomplete. Second, cost estimates do not include all costs of care associated with events, including additional SNF stays caused by events but occurring after our sample period, additional care beyond the hospitalizations (such as physician office visits), and changes in Medicare RUG payments. Third, our sampling methodology limits our findings to beneficiaries who had SNF stays that ended in August 2011, began within 1 day of the beneficiaries' discharges from hospitals, and were 35 days or less.

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.

[81] We were not able to match one physician-identified hospitalization with a Medicare claim for an inpatient hospital stay or an emergency room visit. We included this transfer in our transfer rate but imputed the cost as zero dollars.

FINDINGS

An estimated 22 percent of Medicare SNF residents experienced adverse events during their SNF stays

Approximately one in five Medicare beneficiaries who had post-acute SNF stays that were 35 days or less and that ended in August 2011 experienced at least one adverse event during their stays (22 percent).[82] For this study, an adverse event is as an event that resulted in harm equivalent to the four most serious categories (F-I) on our modified NCC MERP index (prolonged SNF stay or transfer to hospital, permanent harm, life-sustaining intervention, or death). We estimate that 21,777 post-acute Medicare SNF residents experienced at least 1 adverse event during stays that ended in August 2011. A small portion of residents experienced more than one adverse event (2.6 percent), with a few of these residents experiencing as many as three events during a single SNF stay.

The majority (79 percent) of the adverse events experienced by the Medicare SNF residents caused F level harm (see Table 2). These events either extended the beneficiaries' stays in the SNFs or resulted in transfers from the SNFs to hospitals for acute level care, including both emergency department visits and inpatient admissions. Of the remaining events, 14 percent required a life-sustaining intervention and 6 percent contributed to the residents' deaths.

Table 2: Adverse Events Classified as F-I on OIG's Modified NCC MERP Index for Categorizing Adverse Events by Level of Harm

Level of Harm	Percentage of Adverse Events
F level: Resulted in prolonged SNF stay, transfer to a different SNF or other post-acute facility, and/or hospitalization (i.e., admission to inpatient care, hospital observation unit, or emergency department)	79%
G level: Contributed to or resulted in permanent resident harm*	--
H level: Required intervention to sustain the resident's life	14%
I level: Contributed to or resulted in resident death	6%

See Appendix D for confidence intervals.
*We are unable to reliably project the weighted point estimate for adverse events classified as G Level harm because of the small number of sample occurrences.
Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

We classified the adverse events into three clinical categories: events related to medication (37 percent), events related to ongoing resident care (37 percent), and events related to infections (26 percent). Table 3 lists the adverse events within these three categories. See Appendix F for a list of

[82] For this study, we define "post-acute SNF stays" as SNF stays that were paid for by Medicare Part A under the SNF benefit, began within 1 day of beneficiaries' discharge from hospitals, had lengths of stay of 35 days or less, and ended in August 2011.

the 148 events with detailed descriptions and level of harm. While some events (such as pressure ulcers and hypoglycemia) have long been of concern to post-acute caregivers, we found other events (such as severe gastrointestinal bleeding due to anticoagulant overdose) not commonly associated with nursing homes.

Table 3: Adverse Events Identified Among Medicare SNF Residents by Category

Types of Adverse Events	Percentage*
Events Related to Medication	**37%**
• Medication-induced delirium or other change in mental status	*12%*
• Excessive bleeding due to medication	*5%*
• Fall or other trauma with injury secondary to effects of medication	*4%*
• Constipation, obstipation, and ileus related to medication	*4%*
• Other medication events	*14%*
Events Related to Resident Care	**37%**
• Fall or other trauma with injury related to resident care	*6%*
• Exacerbations of preexisting conditions resulting from an omission of care	*6%*
• Acute kidney injury or insufficiency secondary to fluid maintenance	*5%*
• Fluid and other electrolyte disorders (e.g., inadequate management of fluid)	*4%*
• Venous thromboembolism, deep vein thrombosis (DVT), or pulmonary embolism (PE) related to resident monitoring	*4%*
• Other resident care events	*14%*
Events Related to Infections	**26%**
• Aspiration pneumonia and other respiratory infections	*10%*
• Surgical site infection (SSI) associated with wound care	*5%*
• Urinary tract infection associated with catheter (CAUTI)	*3%*
• *Clostridium difficile* infection	*3%*
• Other infection events	*5%*
Total	**100%**

*The percentages for conditions listed within the clinical categories do not sum to 100 percent because of rounding.
See Appendix D for percentage estimates and confidence intervals.
See Appendix F for a complete listing of all adverse events identified by the reviewers.
Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

Within the sample, physician reviewers categorized some seemingly similar events in different clinical categories because the events or factors that led to the harm differed. This was most evident in the categorization of resident fall events; physician reviewers categorized about half of sample fall events as medication events and the other half as resident care events. The fall events categorized as medication events demonstrated clear evidence in the medical record that medication was the primary cause of the fall, because of delirium and hallucinations caused by psychotropic and other medications. Physician reviewers categorized the remaining fall events as resident care events because the falls and accompanying harm were the result of inadequate resident care (e.g., SNF staff did not adequately monitor residents who were known fall risks) rather than the effects of medication.

The use of multiple medications often complicated the determination of the primary cause of events, particularly when the primary cause was related to another medication. For example, in one case our consulting geriatric psychiatrist determined that the overuse of anti-anxiety medication might have masked symptoms of hypoglycemia and resulted in a delayed diagnosis.

An estimated 1.5 percent of Medicare SNF residents experienced events that contributed to their deaths

This rate projects to an estimated 1,538 SNF residents who experienced adverse events that contributed to their deaths during the study month. Within the sample, events that contributed to deaths represented a wide range of adverse events from each of the three clinical categories. Resident care events that contributed to death included blood clots, such as deep vein thrombosis (DVT); fluid imbalances; and acute renal insufficiency. Medication events included excessive bleeding due to anticoagulants and acute hypoglycemia. Most of these residents died at hospitals rather than in the SNFs where the harm occurred, having been transferred back to the hospitals for higher level treatment as a result of the event. Some of these residents were admitted to hospitals, but others died in emergency departments because of the acute nature of their adverse events, such as cardiac arrest or excessive bleeding.

Although no single type of event was prominent within the sample as contributing to death, residents who died as a result of events shared commonalities. Most had multiple, complex co-morbidities that physician reviewers determined made their care more challenging, weakened their conditions, or both. For example, one resident who died from a PE had a range of other chronic and acute conditions, including a serious infection, chronic heart and kidney diseases, a history of blood clots, and dementia. Other residents who died had previously experienced multiple instances of the types of events that ultimately contributed to their deaths. For example, one resident who died of aspiration had suffered multiple prior strokes that likely hampered swallowing ability.

In the case of some resident deaths, physician reviewers found evidence in the medical record that the deaths may have been expected by caregivers, the residents, or family. In one such case, the medical record for the resident's prior hospitalization showed that the hospital physician stopped medical intervention and suggested that the resident seek palliative care at the SNF. In another case of an elderly resident, the SNF medical record indicated that the resident's family requested palliative care shortly before the resident died of cardiac arrest. Most commonly, though, death during the SNF stay was likely not an expected outcome, as in the case of a

resident who died of cardiac arrest following progressive kidney failure that was not detected until the resident was awaiting discharge from the SNF.

An estimated 4 percent of Medicare SNF residents experienced at least one "cascade" adverse event, wherein multiple, related events occurred in succession

This rate projects to an estimated 3,986 residents who experienced cascade events during the study month. A "cascade event" is defined as an event that included a series of multiple, related events. We counted cascade events as single events. Within the sample, medication often played a secondary role in the cascading harm. For example, in one sample cascade event, a resident with multiple comorbidities, including neurological disorders (e.g., tremors, rigidity), and chronic kidney insufficiency developed significant gastrointestinal bleeding from excessive anticoagulation. The internal bleeding resulted in hematemesis (vomiting blood), which ultimately caused a fatal aspiration. Also within the sample, a number of cascade events began with inadequate resident hydration. In at least one sample case, a resident experienced significant dehydration followed by an electrolyte imbalance and damage to the kidneys because SNF staff did not actively monitor and manage the resident's fluid intake.

An additional 11 percent of Medicare SNF residents experienced events during their SNFs stays that resulted in temporary harm

Another 11 percent of Medicare SNF residents experienced events classified as E level harm on the NCC MERP index (defined as resident harm events that required medical intervention but did not cause lasting harm). We estimate that 10,742 post-acute Medicare SNF residents experienced at least 1 temporary harm event during the study month. Of these beneficiaries, an estimated 2,154 had more than 1 unrelated event. Additionally, 21 percent of beneficiaries who experienced adverse events also had temporary harm events during their stays.

As with adverse events, temporary harm events represented a wide array of conditions from the three clinical categories (see Table 4). Table F-2 in Appendix F contains a list of the 113 temporary harm events identified in the sample and provides detailed descriptions.

Table 4: Temporary Harm Events Identified Among SNF Residents by Category

Types of Temporary Harm Events	Percentage*
Events Related to Medication	**43%**
• Hypoglycemic episodes (e.g., low or significant drop in blood glucose)	*16%*
• Fall or other trauma with injury associated with medication	*9%*
• Medication-induced delirium or other change in mental status	*7%*
• Thrush and other nonsurgical infections related to medication	*4%*
• Allergic reactions to medications (e.g., rash, itching)	*3%*
• Other medication events	*3%*
Events Related to Resident Care	**40%**
• Pressure ulcers	*19%*
• Fall or other trauma with injury associated with resident care	*8%*
• Skin tear, abrasion, or breakdown	*7%*
• Other resident care events	*6%*
Events Related to Infections	**17%**
• CAUTI	*5%*
• SSI associated with wound care	*5%*
• Other infection events	*7%*
Total	**100%**

*The percentages for conditions listed within the clinical categories do not sum to 100 percent because of rounding.
See Appendix D for percentage estimates and confidence intervals.
See Appendix F for a complete listing of all temporary harm events identified by the reviewers.
Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

Although many cases of temporary harm within the sample represented instances of fairly minor harm to the residents, other temporary harm events caused harm that was significant for the residents. We did not classify these events as adverse events because they did not require transfer to a hospital or prolong the SNF stays. Additionally, physician reviewers indicated that many sample temporary harm events could have developed into more serious events if SNF staff had not provided a timely intervention. For example, infection events such as *Clostridium difficile* and CAUTIs can quickly escalate from infections to serious, life-threatening infections if not diagnosed and treated quickly.[83, 84]

[83] L.A. Mermel, "Reducing *Clostridium difficile* incidence, colectomies, and mortality in the hospital setting: a successful multidisciplinary approach," *Joint Commission Journal of Quality and Patient Safety,* 39, 7, 2013: pp. 298-305.
[84] Centers for Disease Control and Prevention (CDC), *Inpatient Care of Septicemia or Sepsis: A Challenge for Patients and Hospitals*, National Center for Health Statistics Data Brief, 2011.

Physician reviewers determined that 59 percent of adverse events and temporary harm events were clearly or likely preventable

Physician reviewers assessed the extent to which events were preventable on the basis of information in the medical records, their clinical experience with similar circumstances, research literature about specific events, and group discussion to reach consensus. Combining adverse events and temporary harm events, physicians determined that 59 percent were preventable and 37 percent were not preventable. For the remaining 4 percent, physicians were unable to make determinations because of incomplete documentation in the medical records or extreme complexities in the residents' conditions or in the care provided. Table 5 provides the percentage of events by preventability assessment for adverse events, temporary harm events, and both groups of events combined.

Table 5: Adverse and Temporary Harm Events by Preventability Determination

Preventability Assessment	Percentage of Adverse Events	Percentage of Temporary Harm Events	**Percentage of All Events**
Preventable—Harm could have been avoided through improved assessment or alternative actions	69%	46%	**59%**
Clearly preventable	*18%*	*6%*	*13%*
Likely preventable	*50%*	*40%*	*46%*
Not preventable—Harm could not have been avoided given the complexity of the resident's condition or care required	29%	47%	**37%**
Clearly not preventable	*11%*	*12%*	*11%*
Likely not preventable	*18%*	*35%*	*26%*
Unable To Determine Preventability*	3%	--	**4.2%**

*We are unable to reliably project the weighted point estimate for temporary harm events classified as "Unable to Determine" because of the small number of sample occurrences.
Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

Physicians determined that a larger percentage of adverse events was preventable (69 percent) than temporary harm events (46 percent).[85] If we were to include only preventable events in the estimated incidence rate of adverse events among Medicare beneficiaries, the adverse event rate would be 15 percent (rather than 22 percent) and the rate of additional beneficiaries experiencing temporary harm events would be 5 percent (rather than 11 percent). Physician reviewers determined that 66 percent of medication events were preventable, 57 percent of resident care events

[85] The ratio of preventable adverse events to adverse events was statistically higher than the ratio of preventable temporary harm events to temporary harm events at the 95-percent confidence level.

were preventable, and 52 percent of infection events were preventable. Table 6 provides the percentage of preventable events by clinical category.

Table 6: Percentage of Preventable Adverse and Temporary Harm Events by Clinical Category

Types of Adverse and Temporary Harm Events	Percentage of Preventable Adverse and Temporary Harm Events (n = 155)
Events Related to Medication	66%
Events Related to Resident Care	57%
Events Related to Infections	52%

Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

Within the clinical categories, physician reviewers often gave the same preventability assessment to events with similar circumstances. In making preventability determinations for specific cases, physicians factored in both the residents' condition and the adequacy of SNF monitoring and interventions. For example, all cases of hypotension in the sample were considered preventable because all the residents developed the condition because of insufficient monitoring. Similarly, all allergic reactions identified in the sample were considered not preventable because the residents' medical records lacked historical information about allergies.

In other cases, similar events had different preventability determinations, often because of variation in the health of SNF residents involved. For example, reviewers described pressure ulcers as preventable when the resident was generally healthy and able to comply with pressure ulcer precautions (e.g., frequent rotation of the resident) but received inadequate evidence-based pressure ulcer precautions. They described pressure ulcers as not preventable when they found evidence that the resident received evidence-based preventative pressure ulcer care but developed the ulcers because of comorbidities that greatly increased their risk of developing pressure ulcers. Physician reviewers reported that these comorbidities made it difficult for SNF staff to provide the type of care typically used to prevent such ulcers. As another example, among sample cases of aspiration pneumonia, physicians determined preventability on the basis of resident conditions that may not respond well to treatments, such as chronic dysphagia (difficulty in swallowing). Among hypoglycemic episodes, physicians determined similar cases as preventable on the basis of factors such as the residents' past experience with wide variance in blood glucose levels and staff use of appropriate insulin dosing regimens.

Factors that contributed to preventable adverse and temporary harm events included substandard treatment, inadequate resident monitoring, and failing to provide treatments

Physician reviewers selected one or more rationales to support each preventability determination from a list developed by the physician panel. To make these selections, physicians gleaned information from medical records, such as staff actions, environmental factors, and resident condition unrelated to the event. Among preventable events, 37 percent involved inadequate monitoring of the residents and 25 percent involved failure to provide necessary treatments. One sample resident suffered an undiagnosed pneumothorax (collapsed lung) because of SNF staff failure to recognize symptoms of shoulder pain and shortness of breath. The resident later had two additional events, a reaction to medication and a blood clot, both requiring transfer to a hospital. Table 7 provides preventability rationales for events within the preventable and not preventable assessment categories.

Table 7: Adverse and Temporary Harm Events by Preventability Rationales

Adverse and Temporary Harm Preventability Rationale	Percentage*
Preventable Events	
Appropriate treatment was provided in a substandard way	56%
The resident's progress was not adequately monitored	37%
Necessary treatment was not provided	25%
Error was related to medical judgment, skill, or resident management	14%
Resident care plan was inadequate	11%
Care plan was incomplete or not sufficient in describing resident's condition	7%
The resident's health status was not adequately assessed	4%
Not Preventable Events	
Resident was highly susceptible to event because of health status	59%
Event occurred despite proper assessment and procedures followed	32%
Resident's diagnosis was unusual or complex, making care difficult	27%
Care provider could not have anticipated event given information available	20%

*Percentages do not add to 100 because physician reviewers often selected more than one rationale.
See Appendix D for confidence intervals.
Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

Not preventable events involved residents who were highly susceptible or otherwise at risk for experiencing harm despite efforts by staff to avoid harm

In these cases, physicians determined that the care provided was sufficient and appropriate and that there was no evidence of errors or other problems. In some of these cases, necessary treatment resulted in harmful side effects. For example, one elderly resident in our sample experienced delirium from needed pain medications given following surgery and

another experienced gastrointestinal bleeding from anticoagulants prescribed for a heart condition. In other cases, resident care decisions made in the prior hospitalization resulted in harm during the SNF stay. In one case, a resident developed a full body rash several days into the stay that was an allergic reaction to an antibiotic that had been prescribed in the preceding hospitalization and was continued in the SNF. In other cases of not preventable adverse events, the SNF residents or families contributed to the events by not complying with staff recommendations. For example, one sample resident with Alzheimer's-related dementia fractured his hip while attempting to stand without assistance and another resident pulled out his feeding tube, ultimately causing an infection at the insertion site.

For 59 percent of the not preventable events, physician reviewers found that residents' comorbidities or health status made them highly susceptible to the events. Within our sample, aspiration pneumonia events were a prominent example. Many of the sample beneficiaries who experienced these events were highly susceptible to aspiration because they had comorbidities that made it difficult for them to swallow. In one such case, a resident with significant difficulty swallowing because of neurological disorders (tremors, rigidity) aspirated despite a thorough evaluation and with aspiration precautions in place (substituting liquid food for solid).[86]

Over half of the residents who experienced harm went to a hospital for treatment, with an estimated cost to Medicare of $208 million in August 2011

Adverse events that occurred in post-acute SNF stays of less than 36 days ending in August 2011 resulted in an estimated 20,393 resident transfers to hospitals and an estimated $208 million in Medicare expenditures for these hospitalizations.[87] Of the estimated $208 million spent on all hospitalizations, $136 million was spent on hospitalizations associated with preventable events. The estimate of $208 million spent on care associated with all adverse events equates to 2 percent of the $10.2 billion that Medicare spent on inpatient hospital stays in August 2011.[88]

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[86] The study methodology did not include an analysis of end-of-life care issues, such as instructions from residents and families to not resuscitate residents in the event of a poor condition. However, when these factors were present in the medical record, physician reviewers considered them in determining preventability. For example, when the SNF record included a signed order to provide only palliative care or included notes regarding a discussion of such care with the resident or family, physician reviewers weighed that obligation against any inadequacies in the provision of care leading up to the harm event.

[87] For this study, we define "hospitalization" as any transfer to a hospital for an inpatient admission, emergency department visit, or observation unit stay.

[88] The August 2011 Medicare inpatient cost figure is from OIG analysis of August 2011 Medicare hospital claims, NCH file.

Assuming that the rate of Medicare spending on hospitalizations due to adverse events in SNFs remained constant throughout the year, 2 percent of the $140 billion Medicare inpatient expenditures equates to $2.8 billion spent in FY 2011 on hospitalizations associated with preventable and not preventable adverse events that occurred in SNFs.[89]

Of the estimated 32,519 Medicare SNF residents who experienced at least 1 adverse or temporary harm event, an estimated 19,470 (60 percent) were hospitalized at least once as a result of the events. The hospitalized residents constitute 19 percent of all Medicare beneficiaries in SNF stays that were 35 days or less and that ended in August 2011.[90] Because some SNF residents were hospitalized more than once, the total number of hospitalizations resulting from adverse events was 20,393. Within our sample, infection-related events resulted in the fewest hospitalizations among the three clinical categories but incurred the highest cost per hospitalization (see Table 8).

Table 8: Costs of Hospitalizations Associated With Adverse Events

Hospitalization Type	Estimated Number of Hospitalizations	Estimated Average Costs	Estimated Total Spending
Hospitalizations for medication events	7,203	$8,372	$57,729,935
Hospitalizations for resident care events	7,511	$8,967	$67,350,098
Hospitalizations for infections events	5,679	$14,599	$82,899,180
Hospitalizations Associated With All Events	**20,393**	**$10,276**	**$207,979,213**

Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

Within the sample, certain types of events frequently led to hospitalizations. For example, all sample aspiration pneumonia events led to hospitalization. For most of these sample events, the medical records indicated that SNF staff hospitalized the residents because the care needed to ameliorate the respiratory distress caused by the aspiration exceeded the level of care they could provide.

The full costs associated with these events are likely greater than our estimate. Our cost estimate is a projection of reimbursements paid by Medicare Part A for the hospitalizations associated with the identified adverse events and by Medicare Part B for emergency room visits. It does

[89] The annual cost estimate of $2.8 billion is 2 percent of the $140 billion Medicare inpatient costs for FY 2011, which assumes the same proportion of costs for adverse events for the other 11 months that we found in August 2011. Annual Medicare inpatient cost figure is from CMS, *2011 CMS Statistics Book*, Table III.6, Office of Research, Development, and Information, CMS Pub. No. 03504, June 2011, p. 30.

[90] The remaining Medicare SNF residents either did not experience adverse events or temporary harm events, experienced events that did not lead to hospitalization, were hospitalized for other reasons, or died during their SNF stays.

not include any other costs paid by Medicare or by other payers—including beneficiaries—for medical care needed as a result of the adverse events or temporary harm events.

CONCLUSION AND RECOMMENDATIONS

The ACA mandated HHS to establish and follow a national strategy for quality improvement in health care, including patient and resident safety. Post-acute care in SNFs is intended to help beneficiaries improve health and functioning following a hospitalization and is second only to hospital care among inpatient costs to Medicare. While health care stakeholders have in recent years given substantial attention to patient safety in hospitals, less is known about resident safety in SNFs.

Replicating the methods we used in the 2010 OIG study of hospital adverse events, this report provides the first national incidence rate of adverse events in SNFs. Twenty-two percent of Medicare beneficiaries experienced adverse events during their SNF stays, resulting in prolonged SNFs stays or hospitalizations, permanent harm, life-sustaining intervention, or death. An additional 11 percent experienced temporary harm events. This 32-percent total harm rate is similar to what OIG found in its 2010 hospital report, which stated that 27 percent of Medicare beneficiaries had experienced adverse and temporary harm events during their hospital stays. Also, 59 percent of events in SNFs were preventable, and hospitalizations necessitated by the events increased costs to Medicare by an estimated $208 million in a single month, suggesting potential savings from reducing the incidence of adverse events that occur in SNFs.

Because more than half of the adverse events that we identified were preventable, our study confirms the need and opportunity for SNFs to significantly reduce the incidence of events. This reduction in events and improved safety for post-acute residents would require a coordinated response to include both providers and overseers. A number of agencies within HHS share responsibility for addressing this issue, most prominently AHRQ as a coordinating body for efforts to improve health care quality and CMS as the Nation's largest health care payer and an oversight entity.

Therefore, we recommend the following:

AHRQ and CMS should raise awareness of adverse events in post-acute care and seek to reduce harm to nursing home residents through methods used to promote hospital safety

In response to recent OIG recommendations to reduce adverse events in hospitals, AHRQ and CMS are collaborating to create a list of potentially reportable adverse events for hospital staff education and facility measurement. CMS also developed hospital surveyor training to assist hospital overseers in assessing safety practices, and AHRQ has refined the process for submitting event reports to PSOs. Broadening these and other patient safety improvement efforts to include the nursing home environment would ensure that safe care practices promoted in acute care hospitals extend to the critical period of post-acute recovery.[91] Agency response to this recommendation should include the following:

- ***AHRQ and CMS should collaborate to create and promote a list of potential nursing home events***

  Staff identification of resident harm is critical to the success of resident safety efforts, giving them the opportunity to correct problems and reduce harm as well as to report problems contributing to events. Our physician review of medical records found that many events were the result of failure by SNF staff to monitor residents or staff delay in providing necessary medical care. AHRQ and CMS should ensure that nursing home staff are able to identify resident harm events to prevent harm or worsening. Additionally, we found events not commonly associated with nursing homes that therefore may not have been included in staff training efforts.

  To inform nursing homes about the range of potential adverse events, AHRQ and CMS should collaborate to create and promote a list of potentially reportable events for nursing homes. The list would educate SNF staff about the full range of resident harm. The list should go beyond the conventional SNF care issues and include a comprehensive range of possible resident harm. Events could include those identified in this report and by other researchers, recognizing the unique challenges of the SNF setting rather than duplicating lists of hospital events. AHRQ and CMS should be clear that they do not require external nursing home reporting of these events, but provide the list to broaden and improve staff understanding.

[91] We specify that these efforts should be directed to all nursing homes rather than only to post-acute care in SNFs, given that AHRQ and CMS guidance and CMS oversight authority extend to all nursing home stays.

- ***CMS should include potential events and information about resident harm in its quality guidance to nursing homes***
  Under the ACA, nursing homes must develop QAPI programs to address quality problems and improve facility performance. In 2013, CMS began to provide new guidance to nursing homes to encourage effective QAPI development and implementation. The initial guidance, released in July 2013, focused on core elements needed to improve practices, such as goal-setting. CMS has indicated that subsequent materials to be released in 2014 will provide information specific to clinical care and resident safety. CMS should ensure that the guidance includes elements similar to what it has promulgated to hospitals, including a definition of "adverse events," a list of potential adverse events for staff education on the range of harm that residents can experience, strategies for detecting and measuring adverse events, and best practices for improving staff recognition and reporting of adverse events. Issuing similar guidance to both hospitals and nursing homes may improve communication and collaboration regarding shared safety concerns and care transitions as prescribed in the ACA.

- ***AHRQ and CMS should encourage nursing homes to report adverse events to Patient Safety Organizations***
  Nursing home reporting to PSOs would enable the post-acute community to gain from the structure already in place for the hospital community. Routine reporting by nursing homes could help establish the process of event identification within facilities, and the resulting PSO analysis of nursing home events would provide much-needed information that would be useful in quality and safety improvement efforts. Analysis of events across facilities assists providers in directing resources to the areas of greatest need, setting clear goals for improvement, assessing the effectiveness of specific strategies, holding nursing homes accountable, and gauging progress in reducing incidence.

  Encouraging nursing home reporting to PSOs will require efforts on the part of both agencies to adapt processes to the nursing home setting and to reduce barriers to reporting. AHRQ has designed PSO reporting formats for the nursing home setting, and a number of PSOs accept adverse event reports from post-acute care providers. AHRQ and CMS should build on these initial steps by conducting outreach to nursing homes about event reporting, promoting the reporting of adverse events by nursing homes to PSOs, and gaining knowledge about the nature and type of information and assistance that would be most helpful to nursing homes. AHRQ and CMS should also collaborate to resolve any barriers to nursing home reporting due to

possible conflicts between QAPI provisions that require nursing homes to share event information with State agency surveyors and PSO provisions that require confidentiality of reported information.

CMS should instruct nursing home surveyors to review facility practices for identifying and reducing adverse events

Federal requirements regarding resident safety in SNFs include both broad, facilitywide mandates, as well as requirements specific to certain practices. These requirements are tied largely to nursing home QAPI programs and governed by the facilities' QAA committees. CMS should instruct State survey agencies to include an assessment of adverse event identification and reduction in their evaluations of QAPI and QAA compliance and link related deficiencies specifically to resident safety practices. This link would provide an incentive to nursing homes to develop strategies to reduce adverse events. To facilitate State agency assessment of QAPI programs, QAA committee activities, and other nursing home activities related to adverse events, we recommend that this guidance include information about how surveyors should assess nursing home adverse event collection efforts and should include the list of potentially reportable events to be developed by AHRQ and CMS.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

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

AHRQ. AHRQ concurred with our recommendations. AHRQ stated that the information presented in the report will help improve the care provided to an "especially vulnerable patient population."

In response to our sub-recommendation that AHRQ and CMS collaborate to create and promote a list of potential nursing home events, AHRQ stated that it will use information about the 261 events identified in our report as it develops the next version of the Common Formats.

In response to our sub-recommendation that AHRQ and CMS encourage nursing homes to report adverse events to PSOs, AHRQ stated that it will increase its emphasis on this organizational priority. In particular, AHRQ will conduct outreach to organizations representing nursing homes to increase awareness of PSOs. AHRQ also noted that it is working with CMS on the 11th Scope of Work for Quality Improvement Organizations, specifically to resolve issues related to nursing home event reporting.

CMS. CMS concurred with our recommendations. CMS stated that it recognizes the importance of identifying adverse events among nursing home residents as a way to improve resident quality of life and medical

care. In its comments, CMS provided details about current activities and future plans to improve nursing home resident safety.

In response to our recommendation that AHRQ and CMS raise awareness of adverse events in post-acute care and seek to reduce harm to nursing home residents through methods used to promote hospital safety, CMS agreed that helping nursing homes better understand what constitutes an adverse event could reduce preventable harm. CMS also agreed that it would be instructive to review methods used by hospitals to reduce adverse events. CMS indicated that activities underway to establish specific QAPI requirements for nursing homes may raise awareness of adverse events. These activities include CMS development of technical guidance on QAPI and release of the guidance to nursing homes.

In response to our sub-recommendation that AHRQ and CMS collaborate to create and promote a list of potential nursing home events, CMS stated that it will work with AHRQ to develop a common definition and description of adverse events. CMS also stated that it intends to use the results of the OIG's review to build a list of potential adverse events.

In response to our sub-recommendation that CMS include potential events and information about resident harm in its quality guidance to nursing homes, CMS stated that it will include guidance on adverse events and a list of potential events in its QAPI technical assistance and make this available through the nursing home QAPI Web page.

In response to our sub-recommendation that AHRQ and CMS encourage nursing homes to report to PSOs, CMS concurred conditionally. CMS stated that while it believes PSOs can help nursing homes improve their performance improvement capabilities, it is concerned that the confidentiality and privilege protections outlined in the legislation that created the PSOs—the Patient Safety and Quality Improvement Act of 2005—could make it difficult for surveyors to adequately assess nursing home QAPI programs. Therefore, CMS stated that in implementing the sub-recommendation, it would work with AHRQ to ensure preservation of both the survey and certification function and the confidentiality and privilege protections afforded by PSOs.

In response to our recommendation that CMS instruct nursing home surveyors to review facility practices for identifying and reducing adverse events, CMS stated that activities underway to establish QAPI requirements for nursing homes will include guidance for surveyors on how to evaluate nursing home efforts to identify and reduce adverse events.

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

APPENDIX A

Glossary of Select Medical Terms[92]

Adverse event—Harm to a patient or resident as a result of medical care or in a health care setting. For purposes of calculating an incidence rate for this study, we defined "adverse events" as events that resulted in one of the four most serious categories on our modified version of the NCC MERP Patient Harm Index (classified on the index as F-I): prolonged SNF stay or hospitalizations (including emergency room visit), permanent harm, life-sustaining intervention, or death.

Anticoagulant—A drug that hinders blood coagulation, typically used to prevent or treat blood clots.

Aspiration—Accidental inhalation of foreign material into the lungs, such as food and/or gastric contents.

Aspiration pneumonia—An infectious process caused by the inhalation of oropharyngeal secretions (food, liquid, or gastric contents) that are colonized by pathogenic bacteria.

Blood clot—A coagulated mass that can occlude an artery or vein.

Comorbidity—The presence or effect of one or more diseases or disorders in addition to a primary disease or disorder.

Chronic kidney insufficiency—Slow loss of kidney function over time.

Deep vein thrombosis or DVT—A condition marked by the formation of a thrombus (blood clot) within a deep vein (as of the leg or pelvis) that is potentially life threatening if dislodgment of the thrombus results in pulmonary embolism blocking the pulmonary (lung) artery.

Fluid and electrolyte balance—Minerals in the body that have an electric charge and are in body fluids, such as Sodium (Na+) and Potassium (K+). Maintaining the right balance of electrolytes helps maintain normal biochemical and physiological functions.

Gastrointestinal (GI) bleeding—Bleeding from one or more areas of the digestive or GI tract.

Hypertension—Abnormally high arterial blood pressure that typically results in a thickening of arterial walls and is a risk factor for various

[92] Clinical definitions adapted from the National Institutes of Health, U.S. National Library of Medicine, *Medline Plus Medical Dictionary*. Accessed at http://www.nlm.nih.gov on May 5, 2013.

pathological conditions or events (such as heart attack, heart failure, stroke, end-stage renal disease, or retinal hemorrhage).

Hypoglycemia—An abnormal decrease in blood sugar in the blood.

Hypotension—Abnormally low blood pressure.

Ileostomy—The bottom of the small intestine (ileum) attached to the stoma; bypasses the colon, rectum, and anus.

Ileus—Hypomotility of the gastrointestinal tract in the absence of mechanical bowel obstruction; specifically, a condition that is commonly marked by a painful distended abdomen, vomiting, toxemia, and dehydration when intestinal contents back up.

Ketoacidosis—A condition in which the body cannot use sugar (glucose) for energy because there is no insulin or not enough insulin; fat is used for energy instead. During ketoacidosis, ketones build up in the blood and urine. In high levels, ketones are poisonous and potentially life threatening.

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

Sepsis—A systemic response typically to a serious, usually localized, infection (in the urinary tract or lungs), especially of bacterial origin.

Septicemia—Presence of virulent microorganisms, such as bacteria, virus, or fungi from an infection accompanied by acute systemic illness.

Temporary harm event—Patient or resident harm event that required intervention but did not cause lasting harm, a prolongation of medical stay, or death or require a life-sustaining intervention; classified as E level of harm on the NCC MERP index.

Thrush—Yeast infection that causes white patches in mouth, in the GI tract, and in other mucocutaneous junctions.

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

APPENDIX B

Methodology for Identifying Events and Determining Preventability

We conducted a two-stage medical record review to identify adverse and temporary harm events. In the first stage, a nurse practitioner and four registered nurses (referred to as "screeners") identified sample beneficiaries who were likely to have experienced adverse and temporary harm events during their SNF stays. In the second stage, physicians identified adverse and temporary harm events in the records of the subset of beneficiaries who were determined by the screeners as likely to have experienced adverse or temporary harm events and in the records of those selected as part of an assessment of the screener efficacy.

Screening for Beneficiaries Who Likely Experienced Harm Events. To identify beneficiaries who were likely to have experienced adverse and temporary harm events during their SNF stays, contracted screeners reviewed the following: complete medical records from the SNF stays; resident assessment data (i.e., Minimum Data Set) collected during the SNF stay; discharge summaries, lab results, and other key documents from the medical records of the hospital stays that preceded the SNF stays; discharge summaries, lab results, and other key documents from the medical records of the hospital stays or emergency room visits that occurred during the SNF stays or within 14 days of the SNF discharge dates; and administrative and billing data from the preceding and subsequent hospital stays. From the SNF resident assessment data, we extracted information about each resident's health status during the stays, any chronic illnesses, rehabilitation progress, and possible medical concerns (e.g., risk of falling, developing a pressure ulcer). From hospital claims data, we extracted administrative data (e.g., admission and discharge dates), diagnosis and procedure codes, and information on the reimbursements paid by Medicare for the hospital stays. The screeners reviewed the documents and data from the preceding and subsequent hospital stays to look for evidence of events that occurred during the SNF stays. A beneficiary was considered likely to have experienced an adverse or temporary harm event if the screeners found at least one potential event during any of the beneficiary's hospital stays. Of the 653 beneficiaries in the sample, the screeners "flagged" 262 beneficiaries' (40 percent) records for physician review.

To standardize their review, we required the screeners to use an OIG-developed protocol—the SNF Trigger Tool—to identify triggers in the medical record. These triggers are indicators of possible adverse and temporary harm events. If the screeners found a trigger, they explored the

record further to determine whether events occurred and, if so, documented the level of harm.

The screening process enabled us to reduce the number of cases requiring second-level review of the full medical records by a physician. The physician reviewers indicated that the results of the screening methods helped them to readily identify potential adverse and temporary harm events for consideration.

Determining a Screener False-Negative Rate. In addition to reviewing the records associated with the 262 beneficiaries flagged by the screeners, the physicians also reviewed the records of 100 beneficiaries randomly selected from 391 beneficiaries who were not flagged by the screeners. The physicians reviewed these records to determine the rate at which the screeners failed to identify beneficiaries who likely experienced adverse or temporary harm events. The physician reviewers found harm events not otherwise found by the screeners in 7 of the 100 randomly selected beneficiaries' records. These events are noted in Appendix F.

Physician Identification of Events Within SNF Records. Five contracted physicians independently reviewed the medical records of the 362 beneficiaries flagged by either the screening method or selected as part of the screener false-negative rate review. The physician reviewers represented a variety of specializations and experience: 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 five had many years of clinical experience, and four had prior experience in detecting adverse and temporary harm events in retrospective medical record review. Four of the five served as physician reviewers for a 2010 OIG study of adverse events in hospitals.

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

Over 20 weeks, the physician reviewers examined the records of the 362 beneficiaries. Each case was reviewed by one physician. Physician reviewers used a structured medical review protocol that required them to describe each adverse event, list the parts of the medical record that contained evidence of the 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. The modified version of the NCC MERP index is in Table B-1.

Table B-1: Modified Version of the NCC MERP Index for Categorizing Errors Used in the OIG study of Adverse Events in SNFs

Level	Description	Category
E	Harm occurred that caused temporary harm that required intervention.	Temporary Harm Event
F	Harm occurred that prolonged the SNF stay and led to a transfer to a different SNF or other post-acute facility and/or hospitalization (i.e., admission to a hospital observation unit, an emergency department, or inpatient care).	Adverse Event
G	Harm occurred that contributed to or resulted in permanent resident harm.	
H	Harm occurred that required intervention to sustain the resident's life.	
I	Harm occurred that may have contributed to or resulted in resident death.	

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.

We recorded all harm events identified by the physician reviewers as occurring during the SNF stays and attributable to SNF care. We excluded all harm events that occurred before the beneficiary entered the SNF and all events attributable to the care provided in the preceding hospitalization. When an initial event caused a series of related and dependent events, we collapsed the events into a "cascade event" and counted it as a single event.[93] When a resident 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 reoccurred within 7 days of the first event and occurred under the same circumstances. We counted them as separate events if the second event reoccurred more than 7 days after the first event or the circumstances that led to the event were substantially different.

Determining Preventability for Each Event. The 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:

- Clearly Preventable—Resident harm could definitely have been avoided through improved assessment or alternative actions.
- Likely Preventable—Resident harm could have been avoided through improved assessment or alternative actions.
- Likely Not Preventable—Resident harm could not have been avoided given the complexity of the resident's condition or the care required.
- Clearly Not Preventable—Resident harm could definitely not have been avoided given the complexity of the resident's condition or the care required.

[93] On the basis of OIG interviews with IHI staff, a "cascade event" is defined as an initial event that causes a series of related events for the same patient and results in collapsing these into a single event.

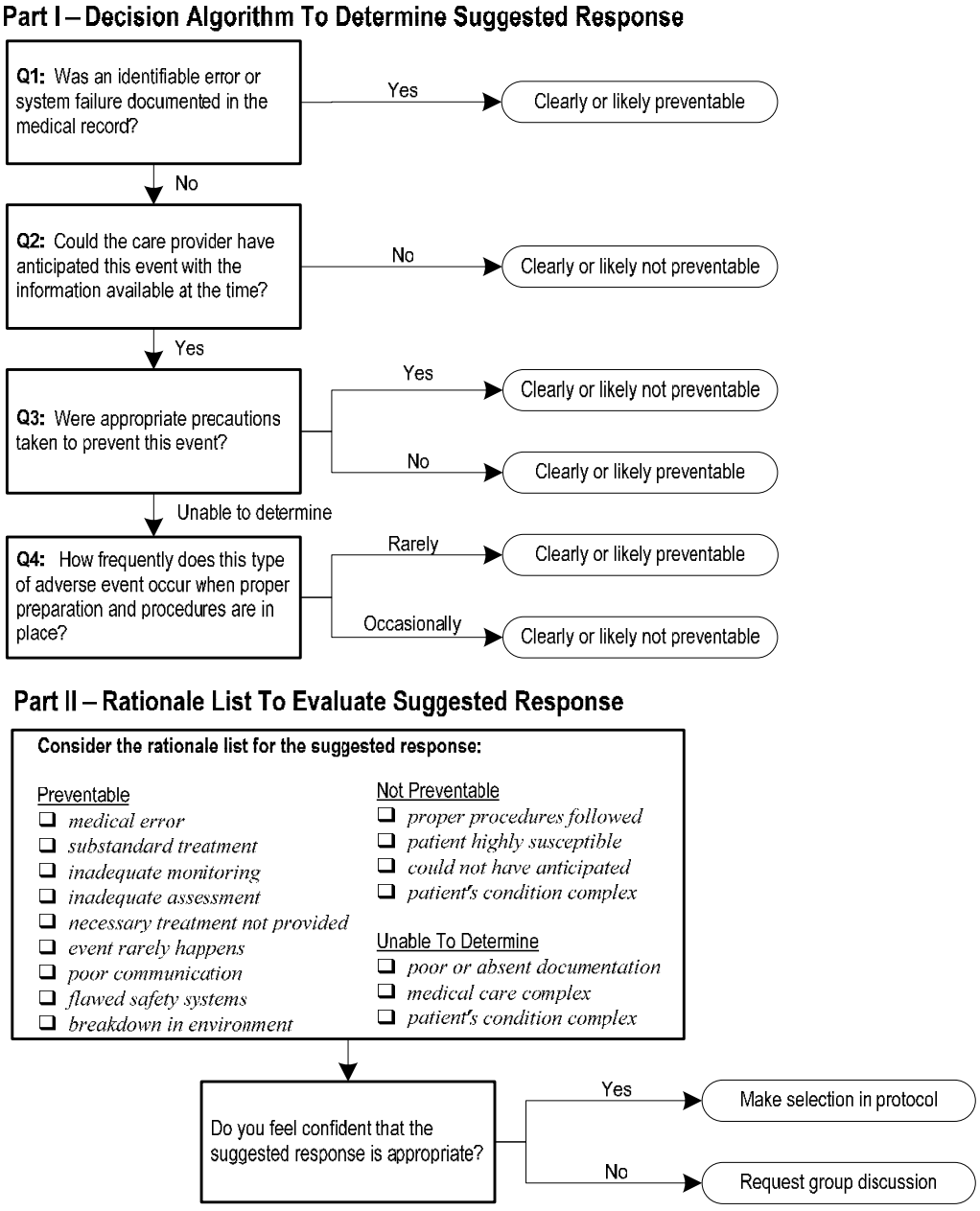
- Unable To Determine—Physicians were unable to determine preventability because of incomplete documentation or case complexity.

Assessing an event as *clearly* preventable or *clearly not* preventable required a greater degree of certainty on the part of the reviewer. The expanded scale enabled physicians to make more precise determinations, while our primary statistics collapse *clearly* and *likely*. Physician reviewers used a uniform method to improve consistency in making preventability determinations. We worked with the reviewers to develop a decision algorithm during practice reviews consisting of a series of questions that led the reviewers to a suggested response. Questions addressed issues such as whether there was a medical error, whether the event could have been anticipated, and how frequently the event occurred given proper care. Physicians did not automatically accept the suggested response, but determined whether it was appropriate in the particular case. Figure B-1 on the next page illustrates the review process for determining preventability.

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 resident's condition. Physicians also used information about accepted standards of care, the frequency with which certain events occurred despite appropriate assessment and care, the physicians' individual clinical experiences, guidance developed during the review process, and group discussion of cases. Using a list of contributing factors gleaned from prior research 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.

The list of contributing factors included broad concepts from the decision algorithm, such as errors, but also more nuanced factors, such as whether the resident was monitored or was susceptible to the event. To identify the factors that contributed to the events and assess preventability, physicians relied on information provided in the medical record about the residents' conditions and actions of health care providers, supplemented by their own clinical expertise. Physician reviewers used published research and policy guidance regarding evidence-based guidelines and associated standards of care.

Figure B-1: Physician Review Process for Determining Preventability



Consistency Discussions and Review. Throughout our medical records review, we facilitated 17 conference calls during which the physician reviewers discussed the review protocol and sample cases that either were complex or had possible implications for other cases. The goal of these calls was to reach consensus on difficult and complex cases and to establish consistency between reviewers. On the calls, the physicians solicited the opinions of the other panelists and used the conclusions of their discussions to make determinations on difficult cases. We required that physicians

discuss all *clearly preventable* determinations and events that potentially contributed to a resident's death during the weekly conference calls, 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 a specialization of another physician. We documented the discussions and conclusions made during these weekly calls, continually revising a written physician guidance document to further promote consistency. The physicians 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 C

Development and Description of the SNF Trigger Tool

In preparation for this study, OIG built a trigger tool for screening SNF medical records. We refer to this tool as the "SNF Trigger Tool." For studies of adverse events in hospitals in 2008 and 2010, OIG used a modified version of the IHI's GTT. The IHI GTT is a 20-minute review of medical records that identifies "triggers" signaling possible resident harm and then identifies adverse and temporary harm events on the basis of evidence in the records. A trigger could be a description of the harm itself or a reference that indicates harm occurred (such as a return to surgery). The IHI GTT is to be completed by nurses. The results are then to be confirmed or refuted by a physician. The IHI GTT is designed to be specific to acute care medical records.

OIG developed a SNF Trigger Tool to apply the concept of the acute care IHI GTT to post-acute SNF care. OIG staff and contracted physicians developed the instrument in consultation with experts in trigger tool development, geriatricians, a geriatric pharmacist, and nurses employed in SNFs. The development process included reviewing triggers against findings of published research, clinical expertise, and two rounds of practice SNF record reviews. The development team used a seven-step modified Delphi Method to identify and refine SNF triggers (see Table C-1).[94] The Delphi method facilitates group decision making by prioritizing key issues for discussion and consensus.

Table C-1: OIG Modified Delphi Method for SNF Trigger Tool Development

Step Number	Step Name	Step Description
1	Facilitator	Facilitator serves as a moderator throughout all rounds.
2	Panel	Convene panel of experts in the SNF setting.
3	List	Create preliminary list of SNF triggers.
4	Survey	Respond to triggers with five-point scale and comment section to select level of agreement that the trigger would lead to harm.
5	Analysis	Compile responses for each trigger by clustering into Agree, Neutral, and Disagree. A mean was calculated for each of the groups.
6	Feedback	Calculate de-identified feedback and discuss.
7	Modifications	Modify SNF trigger list according to discussion.

Source: SNF Trigger Tool development process.

The resulting SNF Trigger Tool worksheet includes 49 triggers that the nurses used to screen cases for physician review (see Table C-2). The worksheet divides triggers into three clinical categories: resident care, medication, and procedures.

[94] B.B. Brown, *Delphi Process: A Methodology Used for the Elicitation of Opinions of Experts*, RAND Corporation, September 1968.

Table C-2: SNF Trigger Tool Worksheet

Care Module Triggers		Medication Module Triggers	
C1	Acute mental status change	M1	Abnormal electrolytes
C2	Aspiration	M2	Abrupt medication stop
C3	Call to physician or family members	M3	Anti-emetic use
C4	Code or Emergency Medical Services (EMS)	M4	Diphenhydramine (Benadryl) use
C5	Death	M5	Elevated INR
C6	Drop in hemoglobin/hematocrit	M6	Epinephrine use
C7	Studies for emboli: PE or DVT	M7	Glucose <50, Glucagon or Dextrose supplement
C8	Fall	M8	Abrupt onset hypotension
C9	Family complaint	M9	Naloxone (Narcan) use
C10	Any infection	M10	Sodium Polystyrene (Kayexalate administration)
C11	New or increased diuretics	M11	Abnormal drug levels
C12	High or low body temperature	M12	Thrombocytopenia
C13	In (SNF) stroke or TIA	M13	Total WBC < 3000
C14	New onset of incontinence	M14	Vitamin K administration (Aqua-Mephyton)
C15	Insertion or use of urinary catheter	M15	Antibiotics started in SNF
C16	Significant Change in Status Assessment in MDS (SCSA)	M16	Increasing pain medication needs
C17	Resident incident or accident	M17	Administration of parenteral fluid
C18	Pressure ulcer	M18	Rising ALT/AST liver function test
C19	ED visit	M19	Medication-Other
C20	Transfer to acute care hospital or observation (OBS) unit	**Procedure Module Triggers**	
C21	Restraint use		
C22	Rising serum creatinine	P1	Postoperative/post-procedure complication
C23	Urinary retention	P2	Procedure reintubation/BiPAP/new CPAP
C24	New onset diarrhea	P3	Procedure-Other
C25	Prolonged constipation	--	--
C26	Diagnostic radiology or imaging studies	--	--
C27	Care-Other	--	--

Source: OIG, Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries (OEI-06-11-00370)

APPENDIX D

Estimates, Confidence Intervals, and Key Statistics

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

	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	653	21.7%	18.3%	25.4%	21,777	18,213	25,342
Experienced at least two adverse events	653	2.6%	1.6%	4.1%	2,615	1,407	3,824
Experienced at least one temporary harm event and didn't experience an adverse event	653	10.7%	8.3%	13.7%	10,742	8,073	13,410
Experienced at least one adverse event or at least one temporary harm event	653	32.4%	28.7%	36.2%	32,519	28,746	36,292
Experienced only preventable adverse events	653	15.4%	12.4%	19.0%	15,483	12,212	18,755
Experienced only preventable temporary harm events and no adverse events	653	4.9%	3.5%	6.8%	4,923	3,317	6,530
Experienced adverse events that contributed to death	653	1.5%	0.8%	2.8%	1,538	598	2,479
Experienced transfer to a hospital because of an adverse event	653	19.4%	16.1%	23.1%	19,470	15,930	23,010
Experienced a cascade adverse event	653	4.0%	2.5%	6.2%	3,986	2,183	5,789
Beneficiaries Who Experienced at Least One Adverse Event or One Temporary Harm Event							
Experienced at least one hospitalization that was the result of an adverse event or a temporary harm event	191	59.9%	52.0%	67.3%	19,470	15,930	23,010
Beneficiaries Who Experienced at Least One Adverse Event							
Experienced temporary harm in addition to adverse events	127	21.2%	15.0%	29.1%	4,615	3,053	6,178
Beneficiaries Who Experienced Temporary Harm Events and No Adverse Events							
Experienced multiple temporary harm events and no adverse events	64	20.1%	12.0%	31.6%	2,154	1,050	3,257

Source: OIG analysis of SNF stays and Medicare claims for 653 Medicare beneficiaries discharged in August 2011.

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

	Sample Size (n)	Percentage	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
OIG's Modified NCC MERP Index for Categorizing Adverse Events by Level of Harm				
Harm F	148	78.5%	70.8%	86.3%
Harm G*	148	--	--	--
Harm H	148	13.5%	6.6%	20.4%
Harm I	148	6.2%	2.4%	9.9%
Clinical Category for All Adverse Events				
Medication adverse events	148	37.4%	28.0%	46.8%
Resident care adverse events	148	36.8%	27.6%	46.0%
Infection adverse events	148	25.8%	18.0%	33.6%
Adverse Events Related to Medication				
Delirium or other change in mental status, e.g., over-sedation	148	11.6%	4.2%	18.9%
Excessive bleeding	148	4.9%	1.2%	8.7%
Fall or other trauma with injury	148	3.7%	0.8%	6.6%
Constipation, obstipation, and ileus	148	3.7%	0.8%	6.6%
Other medication-related adverse events	148	13.5%	7.1%	20.0%
Adverse Events Related to Resident Care				
Fall or other trauma with injury related to resident care	148	5.5%	2.0%	9.1%
Exacerbations of preexisting conditions resulting from an omission of care	148	5.5%	0.3%	10.7%
Acute kidney injury or insufficiency secondary to fluid maintenance	148	4.9%	1.2%	8.7%
Fluid and other electrolyte disorders (e.g., inadequate management of fluid)	148	3.7%	0.8%	6.6%
Venous thromboembolism, DVT, or PE related to resident monitoring	148	3.7%	0.3%	7.0%
Other resident care events	148	13.5%	6.8%	20.1%
Adverse Events Related to Infections				
Aspiration pneumonia and other respiratory infections	148	9.8%	3.8%	15.8%
SSI associated with wound care	148	4.9%	1.6%	8.3%
CAUTI	148	3.1%	0.4%	5.7%
Clostridium difficile infection	148	3.1%	0.4%	5.7%
Other infection-related adverse events	148	4.9%	1.5%	8.3%
Clinical Category for All Temporary Harm Events				
Medication temporary harm events	113	42.8%	33.5%	52.2%
Resident care temporary harm events	113	40.3%	30.9%	49.7%
Infection temporary harm events	113	16.8%	10.0%	23.7%

Continued on next page.

*We are unable to reliably project the weighted point estimate for adverse events classified as G Level harm because of the small number of sample occurrences.

Source: OIG analysis of SNF stays and Medicare claims for 653 Medicare beneficiaries discharged in August 2011.

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

	Sample Size (n)	Percentage	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Temporary Harm Events Related to Medication				
Hypoglycemic episodes (e.g., low or significant drop in blood glucose)	113	16.0%	9.3%	22.7%
Fall or other trauma with injury associated with medication	113	9.2%	1.9%	16.5%
Medication-induced delirium or other change in mental status	113	6.7%	2.3%	11.1%
Thrush and other nonsurgical infections related to medication	113	4.2%	0.6%	7.8%
Allergic reactions to medications (e.g., rash, itching)	113	3.4%	0.1%	6.7%
Other temporary harm events related to medication	113	3.4%	0.1%	6.6%
Temporary Harm Events Related to Resident Care				
Pressure ulcers	113	19.3%	10.8%	27.8%
Fall or other trauma with injury associated with resident care	113	8.4%	3.4%	13.5%
Skin tear, abrasion, or breakdown	113	6.7%	2.2%	11.3%
Other resident care events	113	5.9%	1.7%	10.1%
Temporary Harm Events Related to Infections				
CAUTI	113	5.0%	1.1%	9.0%
SSI associated with wound care	113	5.0%	1.1%	9.0%
Other temporary harm events related to infections	113	6.7%	1.8%	11.7%
Preventability Classification for All Adverse Events and Temporary Harm Events				
▪ **Preventable events**	261	59.2%	52.7%	65.8%
o Clearly preventable events	261	13.1%	8.2%	18.0%
o Likely preventable events	261	46.1%	39.4%	52.8%
▪ **Not preventable events**	261	36.5%	30.2%	42.8%
o Clearly not preventable events	261	11.0%	7.3%	14.7%
o Likely not preventable events	261	25.5%	19.7%	31.3%
▪ **Unable to determine**	261	4.2%	0.9%	7.5%
Preventability Classification for Adverse Events				
▪ **Preventable adverse events**	148	68.7%	60.7%	76.6%
o Clearly preventable adverse events	148	18.3%	10.7%	26.0%
o Likely preventable adverse events	148	50.3%	41.5%	59.2%
▪ **Not preventable adverse events**	148	28.9%	21.1%	36.6%
o Clearly not preventable adverse events	148	10.5%	5.5%	15.4%
o Likely not preventable adverse events	148	18.4%	11.4%	25.4%
▪ **Unable to determine adverse events**	148	2.5%	0.05%	4.9%

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Source: OIG analysis of SNF stays and Medicare claims for 653 Medicare beneficiaries discharged in August 2011.

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

	Sample Size (n)	Percentage	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Preventability Classification for Temporary Harm Events				
▪ **Preventable temporary harm events**	113	46.3%	36.3%	56.3%
o Clearly preventable temporary harm events	113	5.9%	1.7%	10.1%
o Likely preventable temporary harm events	113	40.4%	30.5%	50.3%
▪ **Not preventable temporary harm events**	113	47.1%	36.9%	57.2%
o Clearly not preventable temporary harm events	113	11.8%	6.0%	17.6%
o Likely not preventable temporary harm events	113	35.3%	25.3%	45.3%
▪ **Unable to determine temporary harm events***	113	--	--	--
Preventable Adverse and Temporary Harm Events Within Each Clinical Category				
Medication adverse and temporary harm events	103	66.1%	56.0%	76.1%
Resident care adverse and temporary harm events	99	56.5%	46.0%	66.9%
Infection adverse and temporary harm events	59	51.7%	37.6%	65.7%
Physician Rationale for All Preventable Events				
Appropriate treatment was provided in a substandard way	155	55.7%	46.9%	64.5%
Resident's progress was not adequately monitored	155	36.5%	28.2%	44.8%
Necessary treatments were not provided	155	24.5%	16.5%	32.4%
Error related to medical judgment, skill, or resident management occurred	155	14.3%	8.1%	20.6%
Resident care plan was inadequate	155	11.3%	5.4%	17.3%
Care plan was incomplete or not sufficient in describing resident condition or care	155	7.2%	3.3%	11.1%
Resident's health status was not adequately assessed	155	4.2%	1.2%	7.2%
Physician Rationale for All Not Preventable Events				
Resident was highly susceptible to event because of health status	97	59.2%	48.0%	70.5%
Event occurred despite proper assessment and procedures followed	97	31.9%	21.1%	42.8%
Resident's diagnosis was unusual or complex, making care difficult	97	27.1%	16.5%	37.8%
Care provider could not have anticipated event given information available	97	20.4%	12.2%	28.6%

*We are unable to reliably project the weighted point estimate for adverse events classified as G Level harm because of the small number of sample occurrences.
Source: OIG analysis of SNF stays and Medicare claims for 653 Medicare beneficiaries discharged in August 2011.

Table D-3: Point Estimates and Confidence Intervals for Total and Average Additional Medicare Costs Associated With Adverse Events

Estimate Description	Sample Size (n)	Total Cost	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Costs Associated With Adverse Events in SNFs				
Increased cost because of hospitalizations from adverse events that occurred during SNF stay	148	$207,979,213	$150,589,933	$265,368,492
Costs Associated With Preventable Adverse Events in SNFs				
Increased cost because of hospitalizations from preventable adverse events that occurred during SNF stay	100	$135,548,133	$84,361,921	$186,734,346

Source: OIG analysis of SNF stays and Medicare claims for 653 Medicare beneficiaries discharged in August 2011.

Table D-4: Projections and Confidence Intervals for Total and Average Additional Medicare Costs Associated With Adverse Events Within the Clinical Categories

Category of Adverse Events	Frequency	95-Percent Confidence Interval		Total Cost	95-Percent Confidence Interval		Mean Cost	95-Percent Confidence Interval	
		Lower Bound	Upper Bound		Lower Bound	Upper Bound		Lower Bound	Upper Bound
Hospitalizations and costs associated with medication events	7,203	4,716	9,691	$57,729,935	$29,686,945	$85,772,925	$8,372	$5,418	$11,326
Hospitalizations and costs associated with resident care events	7,511	4,998	10,024	$67,350,098	$39,029,148	$95,671,047	$8,967	$7,064	$10,870
Hospitalizations and costs associated with infections	5,679	3,621	7,736	$82,899,180	$38,018,755	$127,779,605	$14,599	$9,386	$19,811
Hospitalizations and costs associated with all events in SNFs	20,393	16,688	24,097	$207,979,213	$150,589,933	$265,368,492	$10,276	$8,241	$12,312

Source: OIG analysis of SNF stays and Medicare claims for 653 Medicare beneficiaries discharged in August 2011.

APPENDIX E

Rates of Adverse Events and Temporary Harm Events in SNFs by Resident Days and SNF Admissions

Health care facilities, particularly hospitals, commonly measure adverse events by incidence density, which takes into account the period during which residents are observed. For example, incidence density is often used in measuring hospital-acquired infections because risk can increase with the length of exposure to the health care environment.[95] 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 resident.[96] IHI reports that measuring total events by resident days or hospital admissions enables hospitals to count multiple events experienced by the same beneficiary.

The sample of 653 Medicare beneficiaries discharged during August 2011 included 692 total SNF stays (admissions) and a total of 10,759 days in the SNF (resident days). We calculated resident days by subtracting the admission date for each SNF stay from its discharge date. Table E-1 provides ratios for adverse events and temporary harm events in the sample per 1,000 resident days and per 100 admissions.

Table E-1: Rates of Adverse and Temporary Harm Events in the Sample by Resident Days and SNF Admissions

Category	Per 1,000 Resident Days	Per 100 Admissions
Adverse events	14	21
Temporary harm events	11	16
Adverse and temporary harm events combined	**24**	**38**

Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

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

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

APPENDIX F

Adverse Events and Temporary Harm Events

Tables F-1 and F-2 contain information about adverse events and temporary harm events identified in the sample, including description, harm level, and preventability. Table F-1 contains information about adverse events (148 adverse events).[97] Table F-2 contains information about temporary harm events (113 events).

Table F-1: Adverse Events by Clinical Category, Harm Level, and Preventability (n=148)

Adverse Event	Harm Level	Preventability
Events Related to Medication (55)		
Medication-induced delirium or other change in mental status (13)		
1. Delirium and agitation secondary to psychotropic and pain medications resulting in hospitalization	F	CNP
2. Delirium, hallucinations, and respiratory failure secondary to pain and anti-anxiety medications (opioids and benzodiazepines) resulting in hospitalization	F	CP
3. Confusion, delusions, and continuing episodes of disorientation secondary to pain medication (opioids and benzodiazepines) resulting in hospitalization	F	LNP
4. Delirium, disorientation, and hallucinations secondary to inappropriately prescribed anti-anxiety medication (lorazepam) and other medications (acetaminophen and hydrocodone, cyclobenzaprine Hcl)	F	LP
5. Cascade in which disorientation and hallucinations due to multiple medications (acetaminophen, hydrocodone, cyclobenzaprine Hcl, and lorazepam) led to a fall with resultant skin tear and rib fracture, which led to pneumonia resulting in hospitalization	F	CP
6. Acute change in mental status due to inadequate hydration therapy that was exacerbated by multiple medications	F	CP
7. Acute change in mental status secondary to medication	F	LNP
8. Cascade event in which confusion and somnolence secondary to medications led to dehydration because of decreased fluid intake	F	LP
9. Delirium secondary to multiple pain medications (opioids) resulting in hospitalization	F	LP
10. Delirium secondary to psychiatric medications (hydrocodone)	F	LP
11. Confusion secondary to beta blocker (metoprolol) with sinus bradycardia	F	LP
12. Episode of unresponsiveness secondary to psychiatric medication (lithium)*	F	CP
13. Lethargy and altered mental status secondary to medication*	F	LP

*Event identified during screener false-negative rate review.
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[97] The harm level is classified according to the modified version of the NCC MERP Index for Categorizing Errors (E–I). Preventability determination is reflective of the physician review index: CP = clearly preventable, LP = likely preventable, LNP = likely not preventable, CNP = clearly not preventable, and UTD = unable to determine.

Table F-1: Adverse Events by Clinical Category, Harm Level, and Preventability (n=148) (Continued)

Adverse Event	Harm Level	Preventability
Events Related to Medication (55) (continued)		
Excessive bleeding due to medication (8)		
1. Cascade event in which hematemesis (gastrointestinal bleeding) from an anticoagulant (warfarin) led to aspiration, which resulted in death	I	LP
2. Epistaxis (significant bleeding through nose) due to anticoagulant (warfarin) resulting in hospitalization	H	CP
3. Gastrointestinal bleeding due to anticoagulation treatment (aspirin) resulting in hospitalization	F	LNP
4. Cascade event in which hemoptysis (coughing up blood) associated with anticoagulant led to aspiration, cardiac arrest, anoxic encephalopathy and contributed to resident's death	I	LNP
5. Cascade event in which anticoagulant (warfarin) toxicity led to hematemesis (gastrointestinal bleeding) with resultant hypotension and kidney insufficiency resulting in hospitalization	H	LNP
6. Coumadin toxicity led to gastrointestinal bleeding resulting in hospitalization	F	LP
7. Anticoagulant overdose led to hematemesis and subdural hematoma	H	CP
8. Gastrointestinal bleeding secondary to anticoagulants resulting in hospitalization	F	CNP
Fall or other trauma with injury secondary to the effects of medication (6)		
1. Fall associated with atypical antipsychotic (quetiapine) led to right hip fracture resulting in hospitalization	G	LNP
2. Fall associated with inappropriately prescribed atypical antipsychotic (quetiapine) resulting in femur fracture resulting in hospitalization	F	LP
3. Fall associated with appropriately prescribed antipsychotic medication (haloperidol decanoate) resulting in injury to hand	F	CNP
4. Fall associated with appropriately prescribed atypical antipsychotic (olanzapine) and antidepressant (escitalopram) that caused a hip fracture resulting in hospitalization	F	LNP
5. Fall associated with inappropriately prescribed opiates for pain (hydromorphone, hydrocodone/APAP, tramadol) resulting in rib fracture	F	LP
6. Fall associated with inappropriately prescribed antipsychotics (haloperidol decanoate and risperidone) resulting in hematoma	F	LP
Constipation, obstipation, and ileus related to medication (6)		
1. Inadequate bowel care led to significant constipation secondary to opiates resulting in hospitalization	F	LP
2. Severe constipation due to pain medications (opioids)	F	LP
3. Significant ileus secondary to narcotics resulting in hospitalization	F	CNP
4. Significant constipation secondary to opiates resulting in hospitalization	F	LNP
5. Significant ileus secondary to opiates and inadequate bowel care resulting in hospitalization	F	LP
6. Abdominal distention with ileus secondary to opiates	F	LP
Hypoglycemic events related to medication (5)		
1. Hypoglycemic episode characterized by blood glucose of 31	H	LP
2. Hypoglycemic episode characterized by blood glucose of 34	H	LP
3. Hypoglycemic episode characterized by blood glucose of 32	H	LP
4. Hypoglycemic episode characterized by blood glucose of 38 resulting in hospitalization and contributing to the resident's death	I	LP
5. Hypoglycemic episode characterized by a blood glucose of 20 resulting in hospitalization and contributing to the resident's death	I	LP

Continued on next page.

Table F-1: Adverse Events by Clinical Category, Harm Level, and Preventability (n=148) (Continued)

Adverse Event	Harm Level	Preventability
Events Related to Medication (55) (continued)		
Medication-induced allergic reaction (4)		
1. Cascade event in which antibiotics (levofloxacin) given for an infected incision site caused an unanticipated allergic reaction characterized by pruritic rash over most of resident's body	F	CNP
2. Rash secondary to anticoagulant	F	CNP
3. Rash secondary to antibiotic	F	CNP
4. Rash secondary to antibiotics	F	CNP
Ketoacidosis, hyperosmolar coma, and other complications of diabetes related to insulin management (3)		
1. Failure to provide adequate insulin care led to diabetic ketoacidosis resulting in hospitalization	F	CP
2. Cascade event in which hyperosmolar diabetic coma characterized by somnolence and vomiting led to aspiration resulting in hospitalization and contributing to the resident's death	I	CNP
3. Diabetic ketoacidosis due to insufficient administration of insulin resulting in hospitalization	F	LP
Anemia and other blood count problems secondary to medication (2)		
1. Cascade event in which provision of antibiotics led to pancytopenia, angina, and pneumonia resulting in hospitalization	F	LP
2. Anemia due to inadequate administration of epoetin alfa (anemia medication) in resident with chronic kidney failure resulting in hospitalization	F	LP
Hypotension secondary to medication (2)		
1. Syncope with atrial fibrillation and hypotension secondary to overdose of levothyroxine and liothyronine resulting in hospitalization	F	LP
2. Hypotension secondary to ACE inhibitor resulting in hospitalization	F	LP
Nausea and vomiting secondary to medication (2)		
1. Digoxin toxicity led to nausea	F	LP
2. Nausea and vomiting secondary to antibiotic	F	LP
Other medication events (4)		
1. Acute kidney injury due to inadequate diuretic therapy characterized by hyperkalemia resulting in hospitalization	H	LP
2. Stroke because of a failure to provide anticoagulants resulting in hospitalization	G	LP
3. Hyperkalemia and severe dehydration due to ACE inhibitor (lisinopril) resulting in hospitalization	H	CP
4. Seizure secondary to inadequate monitoring of antiepileptic medication resulting in hospitalization	F	CP
Events Related to Resident Care (54)		
Fall or other trauma with injury related to resident care (9)		
1. Fall resulting in chest hematoma	F	LP
2. Fall with injury resulting in hospitalization	F	LNP
3. Fall with large hematoma on head resulting in hospitalization	F	LP
4. Fall with nasal fracture resulting in hospitalization	F	LNP
5. Fall with injury resulting in hospitalization	F	LNP
6. Fall resulting in effusion and hematoma on knee resulting in hospitalization	F	LNP
7. Fall resulting in multiple skin tears	F	LP
8. Fall resulting in hematoma on head resulting in hospitalization	F	LNP
9. Ankle fracture due to unwitnessed trauma in SNF	F	UTD

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Table F-1: Adverse Events by Clinical Category, Harm Level, and Preventability (n=148) (Continued)

Adverse Event	Harm Level	Preventability
Events Related to Resident Care (54) (continued)		
Dehydration and related electrolyte disorders associated with resident care (8)		
1. Cascade event in which substandard monitoring of resident with known obstructive kidney disease resulted in progressive kidney failure, hyperkalemia (electrolyte abnormality characterized by high potassium), and cardiac arrest, which contributed to the resident's death	I	CP
2. Cascade event in which failure to adequately hydrate resident with dysphagia led to hypovolemia, hypernatremia (electrolyte abnormality characterized by high sodium), hypotension, paroxysmal atrial tachycardia, need for cardioversion, non-STEMI myocardial infarction, and acute kidney injury resulting in hospitalization	H	CP
3. Cascade event in which failure to recognize postoperative delirium led to poor oral intake, hyperkalemia, and hypernatremia resulting in hospitalization	F	LP
4. Severe hypernatremia due to inadequate hydration resulting in hospitalization	F	LNP
5. Hyponatremia with increased lethargy and change in mental status due to free-water gastrostomy tube flushes resulting in hospitalization	F	LP
6. Change in mental status due to electrolyte disorder caused by multiple free water gastrostomy tube flushes in a resident with a recent history of syndrome of inappropriate antidiuretic hormone secretion (SIADH)	F	LP
7. Cascade event in which insufficient monitoring of ileostomy led to leaking, excoriation around insertion site, significant dehydration, acute kidney injury, and high potassium	H	LP
8. Significant dehydration due to inadequate hydration resulting in hospitalization	F	LP
Acute kidney injury or insufficiency secondary to fluid maintenance (6)		
1. Cascade in which acute kidney injury due to inadequate hydration led to high potassium and uremia characterized by significant lethargy resulting in hospitalization	F	LP
2. Acute kidney injury characterized by severe hyperkalemia due to inadequate monitoring of electrolytes and serum creatinine resulting in hospitalization	H	LP
3. Acute kidney insufficiency and confusion due to inadequate hydration therapy resulting in hospitalization	F	LP
4. Acute kidney injury due to poor monitoring of hydration and inadequate diuretic therapy complicated by antipsychotics used to treat associated delirium	F	LP
5. Cascade event in which inadequate hydration led to acute kidney insufficiency, hypotension, and obtundation	F	LP
6. Acute kidney injury due to progressive dehydration resulting in hospitalization and contributing to the resident's death	I	LP
Venous thromboembolism, DVT, or PE related to resident monitoring (6)		
1. DVT due to insufficient DVT prophylaxis resulting in hospitalization and a PE that contributed to the resident's death	I	UTD
2. PE due to inadequate resident monitoring that resulted in a hospitalization and contributed to the resident's death	I	CP
3. Delay in recognition of pneumothorax resulting in hospitalization	F	LP
4. DVT and pulmonary embolism due to inadequate monitoring resulting in hospitalization	F	CNP
5. DVT due to a failure to provide adequate DVT monitoring and prophylaxis resulting in hospitalization	F	LP
6. Significant DVT due to failure to provide sufficient DVT monitoring and prophylaxis resulting in hospitalization	F	LNP

Continued on next page.

Table F-1: Adverse Events by Clinical Category, Harm Level, and Preventability (n=148) (Continued)

Adverse Event	Harm Level	Preventability
Events Related to Resident Care (54) (continued)		
Exacerbations of preexisting conditions resulting from an omission of care (6)		
1. Suicide attempt by resident at risk for suicide characterized by self-inflicted cuts on wrists resulting in hospitalization due to inadequate compliance with a care plan that was not sufficient for the resident	F	LP
2. Failure to properly assess resident in SNF and in preceding hospital stay, which led to delay in recognizing hip fracture resulting in hospitalization	F	CP
3. Jaundice, low hemoglobin, and lethargy due to a delay in recognition of acquired autoimmune hemolytic anemia resulting in hospitalization	F	CNP
4. Hydronephrosis due to delay in needed post-hospital followup care for resident with significant urinary tract obstruction	F	LP
5. Failure to provide appropriate intervention for increasing hypothyroidism and monitoring of increasing heart failure, which led to episode of exacerbated heart failure resulting in hospitalization	F	LP
6. Reduction in diuretics and failure to adequately monitor increased weight gain (anasarca) associated with congestive heart failure and cirrhosis resulting in hospitalization and contributing to the resident's death*	H	LP
Respiratory issues (other than infections below) (4)		
1. Hypoxia and respiratory distress due to insufficient pulmonary suction resulting in hospitalization	H	CP
2. Delay in diagnosis of pneumothorax and inadequate monitoring, which led to significant worsening of condition characterized by difficulty breathing resulting in hospitalization	H	LP
3. Failure to provide adequate tracheostomy care resulted in acute respiratory failure	H	LNP
4. Cascade event in which delay in treatment for pleural effusion led to worsening of hypoxia (inadequate oxygen in blood) resulting in hospitalization for chest tube, drainage, and intubation*	F	CP
Excessive bleeding related to resident care (3)		
1. Excessive bleeding from infection site resulting in hospitalization	F	LP
2. Excessive bleeding around wound vacuum pump site resulting in hospitalization	F	LNP
3. Hematuria secondary to Foley catheter resulting in hospitalization	F	UTD
Displacement of feeding tubes related to resident monitoring (2)		
1. Feeding tube displacement due to lack of monitoring resulting in hospitalization	F	LP
2. Feeding tube displacement due to lack of monitoring resulting in hospitalization	F	LP
Hypotension related to resident care (2)		
1. Cascade event in which dehydration due to inadequate monitoring led to hypotension, sinus tachycardia, and atrial fibrillation resulting in hospitalization	F	LP
2. Hypotension and hematuria due to inadequate monitoring of Foley catheter resulting in hospitalization	F	CP
Stage III or IV pressure ulcers (2)		
1. Stage III pressure ulcer on sacrum and stage II pressure ulcer on buttocks	F	CP
2. Stage III pressure ulcer on heel	G	LP
Other resident care events (6)		
1. Clogged arteriovenous shunt (dialysis access device) due to excessive blood clotting	F	LP
2. Significant constipation resulting in hospitalization	F	LNP
3. Cascade event in which failure to provide adequate skin care caused a skin friction abrasion that progressed to a stage II pressure ulcer and developed cellulitis resulting in hospitalization	F	LP
4. Omission of care, which led to progressive weakness and decreased bowel and overall functional status resulting in hospitalization	F	CP
5. Substandard urinary catheter care, which led to urinary retention resulting in hospitalization	F	LP
6. Cascade event in which pulmonary fluid overload led to decreased oxygenation, respiratory failure, atrial flutter, and significant lethargy resulting in hospitalization	H	LP

*Event identified during screener false-negative rate review.

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Table F-1: Adverse Events by Clinical Category, Harm Level, and Preventability (n=148) (Continued)

Adverse Event	Harm Level	Preventability
Events Related to Infections (39)		
Aspiration pneumonia and other respiratory infections (13)		
1. Aspiration pneumonia due to inadequate aspiration precautions and monitoring of resident with history of dysphagia	F	CNP
2. Aspiration pneumonia due to failure to monitor resulting in hospitalization	F	LP
3. Cascade event in which dysphagia and vomiting led to aspiration pneumonia, associated with hyperglycemia (with diabetic ketoacidosis or hyperosmolar coma) and hyponatremia, resulting in hospitalization	F	CNP
4. Several episodes of emesis, which led to aspiration pneumonia resulting in hospitalization	F	CNP
5. Aspiration pneumonia resulting in hospitalization	F	LP
6. Aspiration pneumonia resulting in hospitalization	F	LNP
7. Cascade event in which aspiration pneumonitis led to respiratory failure resulting in hospitalization	H	LP
8. Aspiration pneumonitis resulting in hospitalization	F	CNP
9. Aspiration pneumonia characterized by tachypnea, dyspnea, and chest congestion resulting in hospitalization and contributing to the resident's death	I	CNP
10. Emesis associated with lung infiltrate resulting in hospitalization	F	CNP
11. Recurrence of pneumonia due to incomplete treatment of prior pneumonia resulting in hospitalization	F	UTD
12. Cascade event in which aspiration pneumonitis led to respiratory failure, which exacerbated resident's COPD resulting in hospitalization for needed BIPAP treatment	H	CP
13. Aspiration pneumonia resulting in hospitalization*	F	LNP
SSI attributable to wound care (8)		
1. Superficial infection around surgical incision site on lower back	F	LP
2. Superficial infection around surgical incision site for recent knee arthroplasty	F	LP
3. Superficial infection around surgical incision site on hip	F	LP
4. Superficial infection around surgical incision site on leg resulting in hospitalization	F	LP
5. Superficial infection around surgical incision site for recent toe resection resulting in hospitalization	F	LP
6. Cellulitis at surgical site resulting in hospitalization	F	LP
7. Cellulitis at PEG tube placement site resulting in hospitalization	F	LNP
8. Cellulitis at site of skin graft resulting in hospitalization	F	LNP
CAUTI (5)		
1. Urinary tract infection associated with urinary catheter resulting in hospitalization	F	LP
2. Cascade in which a partial obstruction due to Foley catheter placement led to a urinary tract infection.	F	LP
3. Urinary tract infection associated with urinary catheter	F	LP
4. Urinary tract infection associated with urinary catheter characterized by acute change in mental status resulting in hospitalization	F	CP
5. Cascade event in which urosepsis led to dehydration, hypotension and paroxysmal supraventricular tachycardia	F	LNP
***Clostridium difficile* infection (5)**		
1. *Clostridium difficile* infection resulting in hospitalization	F	LP
2. *Clostridium difficile* infection	F	LP
3. *Clostridium difficile* infection associated with significant weight loss resulting in hospitalization	F	CP
4. *Clostridium difficile* infection resulting in hospitalization	F	LNP
5. *Clostridium difficile* infection resulting in hospitalization	F	LP

*Event identified during screener false-negative rate review.
Continued on next page.

Table F-1: Adverse Events by Clinical Category, Harm Level, and Preventability (n=148)

Adverse Event (Continued)	Harm Level	Preventability
Events Related to Infections (39) (continued)		
Sepsis (3)		
1. Urinary tract infection associated with urinary catheter characterized by acute change in mental status and somnolence resulting in hospitalization	F	CP
2. Sepsis due to progression of inadequately treated pneumonia resulting in hospitalization	H	CP
3. Failure to provide adequate care for urinary tract infection, which led to sepsis resulting in hospitalization	F	LNP
Vascular-catheter associated infection, e.g., PICC line, central line (3)		
1. Port site infection resulting in hospitalization	F	LP
2. Infection (MRSA) around dialysis insertion site resulting in hospitalization	F	LNP
3. Cascade event involving DVT and catheter-associated central line infection	F	LP
Soft tissue or other nonsurgical infection (2)		
1. Cellulitis on legs resulting in hospitalization	F	LNP
2. Progressive infection characterized by rash, sloughing, and necrosis resulting in hospitalization	F	CP

Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

Table F-2: Temporary Harm Events by Clinical Category and Preventability (n=113)

Temporary Harm Event	Preventability
Events Related to Medication (48)	
Hypoglycemic episodes (e.g., low or significant drop in blood glucose) (19)	
1. Multiple hypoglycemic episodes characterized by lowest blood glucose of 24	CP
2. Hypoglycemic episode characterized by blood glucose of 32	LP
3. Multiple hypoglycemic episodes characterized by lowest blood glucose of 35	CP
4. Multiple hypoglycemic episodes characterized by blood glucose of 55 and unresponsiveness	CP
5. Hypoglycemic episode characterized by blood glucose of 43	LP
6. Hypoglycemic episode characterized by blood glucose of 59 and lethargy	LP
7. Hypoglycemic episode characterized by blood glucose of 39	LNP
8. Hypoglycemic episode characterized by blood glucose of 49	LP
9. Hypoglycemic episode characterized by blood glucose of 49 and diaphoresis (excessive sweating)	LNP
10. Multiple hypoglycemic episodes characterized by lowest blood glucose of 66 and diaphoresis	CP
11. Hypoglycemic episode characterized by significant drop in blood glucose from baseline	LP
12. Hypoglycemic episode characterized by shaking and heart palpitations	LP
13. Hypoglycemic episode characterized by blood glucose of 48	LP
14. Hypoglycemic episode characterized by a significant drop in blood glucose	LP
15. Cascade event in which hypoglycemic episode characterized by blood glucose of 53 resulted in fall	LP
16. Hypoglycemic episode characterized by symptoms and blood glucose of 57	CNP
17. Multiple hypoglycemic episodes characterized by blood glucose of 54 and 48	LP
18. Hypoglycemic episodes characterized by significant drop in blood glucose and trembling	LP
19. Multiple hypoglycemic episodes characterized by lowest blood glucose of 20	CP
Medication-induced delirium or other change in mental status (8)	
1. Delirium secondary to pain medication (hydrocodone)	LP
2. Delirium and hallucinations due to pain medication (opioid)	LP
3. Delirium and hallucinations secondary to polypharmacy	LP
4. Delirium secondary to pain medication (opioid), which caused resident to pull IV tube	LP
5. Confusion and anxiety secondary to pain medication (oxycodone)	LP
6. Lightheadness and vertigo due to pain medication (opioids)	LNP
7. Confusion secondary to pain medication (opioids)	LP
8. Episode of diaphoresis and dizziness due to pain medication (oxycodone and paracetamol)	CNP
Fall or other trauma with injury associated with medication (8)	
1. Fall associated with inappropriately prescribed anti-anxiety medication (clonazepam) resulting in injury to head	LP
2. Fall associated with appropriately prescribed anti-anxiety medication (lorazepam) resulting in abrasions	LNP
3. Fall associated with anti-anxiety medications (lorazepam and escitalopram) and inappropriately prescribed atypical antipsychotropic medication (risperidone) resulting in abrasion	LP
4. Multiple falls associated with inappropriately prescribed antidepressant (fluoxetine) and anti-anxiety medications (selective serotonin reuptake inhibitor and lorazepam) resulting in skin tears and abrasions	LP
5. Fall associated with poor diabetes management (multiple episodes of hypoglycemia and hyperglycemia) resulting in abrasions	LP
6. Fall associated with inappropriately prescribed anticholinergic (amitriptyline and perphenazine) resulting in skin tear on forearm	LP
7. Delirium and disorientation secondary to opiates for pain (oxycodone) resulting in multiple falls without injury*	LNP
8. Fall associated with psychotropic medications (alprazolam and risperidone) resulting in abrasions	LP

* Event identified during screener false-negative rate review.

Continued on next page.

Table F-2: Temporary Harm Events by Clinical Category and Preventability (n=113) (Continued)

Temporary Harm Event	Preventability
Events Related to Medication (48) continued	
Thrush and other nonsurgical infections related to medication (5)	
1. Oral thrush secondary to antibiotics	CNP
2. Candida vaginitis secondary to antibiotics	CNP
3. Oral and pharyngeal thrush secondary to antibiotic	CNP
4. Pharyngeal thrush secondary to antibiotic	CNP
5. Candida vaginitis and oral thrush secondary to antibiotics	LNP
Allergic reactions to medications (e.g., rash, itching) (4)	
1. Allergic reaction to medication (fluroquinolone antibiotic) characterized by itching	CNP
2. Rash in groin area due to immunosuppressant (methotrexate)	LNP
3. Skin rash on abdomen and legs associated with medication	CNP
4. Pruritus associated with narcotics	CNP
Constipation, obstipation, and ileus (2)	
1. Significant constipation secondary to pain medication (opioids)	LNP
2. Significant constipation secondary to pain medication (opioids) and inadequate bowel care	LP
Other medication events (2)	
1. Seizure in resident with history of seizures during period of inadequate levels of anti-epileptic (phenytoin)	LNP
2. Significant and unanticipated diarrhea secondary to laxative	LP
Events Related to Resident Care (45)	
Pressure ulcers (20)	
1. Stage I pressure ulcer	UTD
2. Progression of stage I pressure ulcer to stage II pressure ulcer	LP
3. Stage I pressure ulcers on heels	LP
4. Progression of stage I pressure ulcer to a stage II pressure ulcer	LNP
5. Stage I pressure ulcers on buttocks and heel	LP
6. Stage II pressure ulcer on buttocks	LP
7. Stage I pressure ulcer on coccyx	LP
8. Stage I pressure ulcer	LP
9. Stage II pressure ulcers on thigh and stage I pressure ulcers on buttock and coccyx	LNP
10. Progression of stage I pressure ulcers on coccyx and heels to stage II ulcers	LNP
11. Progression of pressure ulcer on buttocks from stage I to stage II	LNP
12. Stage I pressure ulcer on heel	LNP
13. Stage I pressure ulcer on heel	LNP
14. Progression of stage I pressure ulcer to stage II	LP
15. Multiple stage I pressure ulcers on heels, elbow, scapula, and toe	CNP
16. Stage II pressure ulcer on heel	CP
17. Stage I pressure ulcer on coccyx*	UTD
18. Unstagable pressure ulcer on left heel	LNP
19. Unstagable pressure ulcer on right heel	LP
20. Stage III pressure ulcer on hand	LNP

* Event identified during screener false-negative rate review.

Continued on next page.

Table F-2: Temporary Harm Events by Clinical Category and Preventability (n=113) (Continued)

Temporary Harm Event	Preventability
Events Related to Resident Care (45) continued	
Fall or other trauma with injury associated with resident care (10)	
1. Fall resulting in skin tear	LP
2. Fall with injury to head	LP
3. Fall with skin tear	LNP
4. Trauma while in bed characterized by abrasions on temple and elbow	LNP
5. Fall resulting in abrasions on face and elbow	LNP
6. Fall resulting in elbow fracture	LNP
7. Multiple falls resulting in skin tear on hand and elbow	LNP
8. Fall resulting in multiple skin tears on appendages and bruising on head	LNP
9. Fall from motorized wheelchair resulting in multiple scrapes and abrasions	CNP
10. Fall resulting in hematoma on head	LNP
Skin tear, abrasion, or breakdown (8)	
1. Skin tears on arm and leg	LNP
2. Skin tear on leg	LNP
3. Multiple skin breakdowns above the coccyx	LNP
4. Skin tear on elbow	CNP
5. Pressure wound on leg associated with cast	LP
6. Abrasion on forearm caused by collision with railing	LNP
7. Skin tear on right forearm	LNP
8. Multiple skin excoriations	UTD
Other resident care events (7)	
1. Acute urinary retention	LNP
2. Multiple day delay in appropriate treatment of excessive swelling in a resident recovering from a hip fracture, which resulted in difficulty breathing	LP
3. Hypotension due to inadequate hydration therapy	LP
4. Failure to monitor resident, which led to dislodged enteral feeding tube requiring multiple replacement attempts	LNP
5. Cascade event in which inadequate monitoring led to severe dehydration with associated confusion leading to falls with minor injuries	LP
6. Blistering caused by medical tape	LP
7. Acute kidney injury secondary to inadequate monitoring of urinary retention	LNP
Events Related to Infections (20)	
CAUTI (6)	
1. Multiple catheter associated urinary tract infections secondary to multiple catheterizations.	LP
2. Recurrent urinary tract infections associated with urinary catheter	LP
3. Urinary tract infection associated with urinary catheter	LP
4. Urinary tract infection associated with urinary catheter	CP
5. Urinary tract infection associated with urinary catheter	LNP
6. Urinary tract infection associated with urinary catheter	LP

Continued on next page.

Table F-2: Temporary Harm Events by Clinical Category and Preventability (n=113)

Temporary Harm Event	Preventability
Events Related to Infections (20) continued	
SSI attributable to wound care (6)	
1. Superficial infection at surgical incision site	LNP
2. Superficial infection at surgical incision site	LNP
3. Cellulitis at surgical site	LP
4. Cellulitis at surgical site	LP
5. Superficial infection at surgical incision site for a lower leg fracture	LP
6. Superficial infection at surgical incision site for recent knee replacement	UTD
Soft tissue or other nonsurgical infection (4)	
7. Conjunctivitis on eye	LNP
8. Fungal skin infection on abdomen	LNP
9. Blepharitis (swelling of the eyelids)	LNP
10. Bacterial conjunctivitis	UTD
***Clostridium difficile* infection (2)**	
11. *Clostridium difficile* infection following treatment with broad spectrum antibiotic	CNP
12. *Clostridium difficile* infection	LP
Other infections (2)	
13. Sepsis resulting from urinary tract infection	LNP
14. Aspiration pneumonia	CNP

Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

APPENDIX G

Agency Comments: AHRQ

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

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

To: Inspector General, Department of Health and Human Services

From: Director

JAN 2 4 2014

Subject: OEI Inspection Number OEI-06-11-00370

Thank you for the opportunity to review draft report entitled, Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries (# OEI-06-11-00370)

We have specific responses to two recommendations.

1. Recommendation: **AHRQ and CMS should collaborate to create and promote a list of potential nursing home events**. AHRQ concurs with this recommendation and believes that it would be useful to perform a special review of the 261 events identified in the report to determine how they "map" with respect to the current AHRQ Common Formats (Formats) for Nursing Homes. Attached is a list of the 27 event types that your report identifies and that will be considered, based on combining the categories and counts of events from your adverse event list and temporary harm event list. If it makes conceptual sense to do so, event types that do not map readily to the existing Formats can be added as separate events in the next Formats update. (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 the next Formats update is released, the OIG report on SNFs 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. For example, "Surgical Site Infections (SSI) attributable to wound care" may not always be distinguishable from SSI overall, as the cause of many SSIs is unclear. Some SSIs, with or without excellent care in a Skilled Nursing Facility, may be due to contamination or other events that occurred during the procedure when the patient's surgical wound was open in the operating room, or other peri-operative steps, such as the timely administration of pre-op antibiotics.

2. Recommendation: **AHRQ and CMS should encourage nursing homes to report adverse events to Patient Safety Organizations**. AHRQ concurs with this recommendation. This recommendation is directly in line with pre-existing priorities, and based on OIG recommendations, we will increase emphasis on this objective. In particular, we will include a session on reporting adverse events from nursing homes in this year's or next year's annual PSO meeting, and we will take steps to reach out to organizations representing nursing homes to increase awareness of the opportunity to work with PSOs to improve patient safety. The OIG report should be quite valuable in the latter effort, as it sheds new light on the high rate of adverse events in nursing home and on their consequences, including deaths.

Also related to this recommendation, AHRQ is now working with CMS on their 11th Scope of Work for QIOs, and in particular we are working to resolve issues and to communicate guidance related to nursing home reporting of adverse events.

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 hospitalized 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. Bill Munier, Director, Center for Quality Improvement and Patient Safety at William.munier@ahrq.hhs.gov or 301-427-1921

/S/

Richard Kronick, Ph.D.

Attachment

Skilled Nursing Facility (SNF) Event-Type List: Adverse Events and Temporary Harm Events based on OIG Report # OEI-06-11-00370

The numbers of adverse events or temporary harm events, seen in the OIG's analysis of about 600 SNF patient charts, are included in parentheses.

Events Related to Medication

1. Medication-induced delirium or other change in mental status (21)
2. Excessive bleeding due to medication (8)
3. Fall or other trauma with injury secondary to the effects of medication (14)
4. Constipation, obstipation, and ileus related to medication (8)
5. Hypoglycemic events related to medication (24)
6. Medication-induced allergic reaction (8)
7. Ketoacidosis, hyperosmolar coma, and other complications of diabetes related to insulin management (3)
8. Anemia and other blood count problems secondary to medication (2)
9. Hypotension secondary to medication (2)
10. Thrush and other nonsurgical infections related to medication (5)

Events Related to Resident Care

11. Fall or other trauma with injury related to resident care (19)
12. Dehydration and related electrolyte disorders associated with resident care (8)
13. Acute kidney injury or insufficiency secondary to fluid maintenance (6)
14. Venous thromboembolism, DVT, or pulmonary embolism related to resident monitoring (6)
15. Exacerbations of preexisting conditions resulting from an omission of care (6)
16. Respiratory issues (other than infections below) (4)
17. Excessive bleeding related to resident care (3)
18. Displacement of feeding tubes related to resident monitoring (2)
19. Stage III or IV pressure ulcers (22)
20. Skin tear, abrasion, or breakdown (8)

Events Related to Infections

21. Aspiration pneumonia and other respiratory infections (13)
22. SSI attributable to wound care (14)
23. CAUTI (11)
24. Clostridium difficile infection (7)
25. Sepsis (3)
26. Vascular-catheter associated infection, e.g., PICC line, central line (3)
27. Soft tissue or other nonsurgical infection (6)

Agency Comments: CMS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: DEC 2 3 2013

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries" (OEI-06-11-00370)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the above subject OIG draft report. This is another study in a series of remarkable OIG reports on adverse events. Through a significant investment in original research generating new information not otherwise available, each such report has made important contributions to our understanding of the nature and prevalence of adverse events in hospitals and nursing homes. OIG objectives for this report were to—(1) Estimate the national incidence of adverse and temporary harm events for Medicare beneficiaries in skilled nursing facility (SNF) post-acute care; (2) Assess the extent to which adverse and temporary harm events were preventable and identify factors contributing to these events; and (3) Estimate the costs associated with adverse and temporary harm events to the Medicare program.

CMS fully concurs with OIG on the importance of identifying avoidable adverse events among nursing home residents and improving the quality of life and care for nursing home residents. OIG recommendations and CMS responses to those recommendations are discussed below.

OIG Recommendation

The OIG recommends that AHRQ and CMS should raise awareness of adverse events in post-acute care and seek to reduce harm to nursing home residents through methods used to promote hospital safety.

CMS Response

The CMS concurs with this recommendation. We agree that helping nursing homes to have a better understanding of adverse events and an awareness of the preventable events that often lead to resident harm could reduce preventable injury and harm to residents. We also agree that reviewing those methods for promoting hospital safety would be valuable in the development of nursing home information. Section 6102 (c) of the *Affordable Care Act* also established specific requirements for nursing homes to develop Quality Assessment and Performance Improvement (QAPI) activities, and required CMS to develop technical assistance materials in advance of a new QAPI regulation to help establish standards and distribute best practices for meeting these standards. CMS launched the nursing home QAPI website in summer of 2013

(http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/NHQAPI.html) which included a variety of technical assistance materials to help raise the awareness of QAPI processes such as identification and analysis of adverse events. We will continue to release additional tools and training materials throughout the coming year to help nursing homes identify and analyze adverse events and take action that prevents their recurrence.

OIG Recommendation

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

CMS Response

The CMS concurs with this recommendation. CMS will collaborate with AHRQ on developing a common definition and description of adverse events and other potential nursing home events to help nursing home staff better recognize harm. A definition of adverse events and listing of potential events will be included in future QAPI technical assistance training materials and other tools and resources to be rolled out on the nursing home QAPI webpage. We understand that the OIG also identified a list of potential nursing home events in conducting the analysis for this report. We would appreciate any background materials OIG would like to share regarding this information.

OIG Recommendation

The OIG recommends that CMS should include potential events and information about resident harm in its quality guidance to nursing homes.

CMS Response

The CMS concurs with this recommendation. CMS agrees with this recommendation and will include guidance on adverse events and potential events in its QAPI technical assistance, tools and resources to be posted at the nursing home QAPI webpage.

OIG Recommendation

The OIG recommends that AHRQ and CMS should encourage nursing homes to report adverse events to Patient Safety Organizations.

CMS Response

The CMS conditionally concurs with this recommendation. The Affordable Care Act sets forth the expectation that every nursing home have an effectively functioning, internal quality assessment and performance improvement system. CMS believes that the Patient Safety Organizations (PSOs) can offer added value to the extent that they can augment, rather than strive to substitute, for such internal facility capability. In such an augmentative capacity the PSOs can provide a valuable opportunity to improve the quality and safety of U.S. health care

delivery. The PSOs can create a vehicle for clinicians and health care organizations to voluntarily report and share quality and patient safety information, analyze such information, and provide valuable insights to each participating nursing home. We would therefore encourage nursing homes to utilize PSOs to take advantages of this opportunity.

As OIG identifies in its report, there are challenges in fully utilizing the PSO framework, and in the ability of facilities to demonstrate compliance with CMS Conditions of Participation and other requirements. For example, we have encountered issues with health care organizations that choose to submit some or all of their entire quality assurance and improvement system to the PSO, and then indicate that they are consequently unable to demonstrate their compliance to the surveyors with the Medicare Conditions/Requirements for Participation without disclosing information that they consider to be protected. Such a challenge is particularly evident in demonstrating compliance with the QAPI requirements, but is not limited to the QAPI arena. For example, a facility that has interpreted "patient safety work product" to include the entire internal facility incident reporting system would be challenged to demonstrate that it has identified, tracked, and investigated adverse events. Further, CMS ability to implement the OIG's recommendation that CMS strengthen assessment of facility adverse event identification and reduction (#5, below), would be impossible if surveyors did not examine the internal incident reporting system.

We appreciate that the Patient Safety and Quality Improvement Act of 2005 makes it clear that information required for health care oversight is not a patient safety work product. Nonetheless, we recognize the value in providers having protections to analyze adverse events in a protected environment. CMS and AHRQ are therefore working to reconcile the values of accountability and PSO participation. CMS will also work to clarify Medicare's requirements and identify options that might help to harmonize the values of accountability and quality improvement processes of the PSOs. CMS' encouragement of nursing home participation in the PSOs would be set within the context of preserving the survey & certification functions to ensure accountability and remediation of identified problems, and the confidentiality and privilege protections afforded to providers through participation with the PSOs.

OIG Recommendation

The OIG recommends that CMS should instruct nursing home surveyors to review facility practices for identifying and reducing adverse events.

CMS Response

The CMS concurs with this recommendation. As described above, CMS is currently in the rulemaking process related to the QAPI requirements. Following finalization of the QAPI regulation, we will develop surveyor guidance to review facility practices for identifying and reducing adverse events.

The CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

ACKNOWLEDGMENTS

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

Jeremy Moore served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Dallas regional office who contributed to the report include Maria Balderas and Nathan Dong. Central office staff who provided support include Heather Barton, Mandy Waltz Brooks, Kevin Farber, Althea Hosein, Sandy Khoury, Berivan Demir Neubert, and Diane Reinke.

Office of Inspector General

http://oig.hhs.gov

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