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Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018

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Why OIG Did This Review

In 2010, OIG reported the first national incidence rate of patient harm events in hospitals—27 percent of hospitalized Medicare patients experienced harm in October 2008. During that month, hospital care associated with these events cost Medicare and patients an estimated $324 million in reimbursement, coinsurance, and deductible payments. Nearly half of these events were preventable.

OIG conducted a new study to update the national incidence rate of patient harm events among hospitalized Medicare patients in October 2018. This work included calculating a new rate of preventable events and updating the cost of patient harm to the Medicare program.

HHS leads national efforts to promote quality health care and prevent patient harm. Several agencies share this responsibility, including the Agency for Healthcare Research and Quality (AHRQ), which leads HHS's efforts to improve health care quality, and the Centers for Medicare & Medicaid Services (CMS), which is the Nation's largest health care payer and oversight entity.

Although HHS agencies have reported progress during the past decade toward improving patient safety, protecting the health and safety of HHS beneficiaries remains one of HHS's top management and performance challenges. An increased understanding of the prevalence and nature of patient harm will further assist efforts to reduce patient harm events and the factors contributing to these events.

Key Takeaway

One in four hospitalized Medicare patients experienced harm during October 2018. For nearly a quarter of these patients, harm events resulted in additional costs to Medicare. Physician-reviewers determined that 43 percent of the harm events could have been prevented if patients had been provided better care.

What OIG Found

Twenty-five percent of Medicare patients experienced patient harm during their hospital stays in October 2018. Patient harm includes adverse events and temporary harm events.

Twelve percent of patients experienced adverse events, which are events that led to longer hospital stays, permanent harm, life-saving intervention, or death. In addition to the patients who experienced adverse events, 13 percent of patients experienced temporary harm events, which required intervention but did not cause lasting harm, prolong hospital stays, or require life-sustaining measures. Temporary harm events were sometimes serious and could have caused further harm if providers had not promptly treated patients.

- ***Categories of Harm Events.*** The most common type of harm event was related to medication (43 percent), such as patients experiencing delirium or other changes in mental status. The remaining events related to patient care (23 percent), such as pressure injuries; to procedures and surgeries (22 percent), such as intraoperative hypotension; and to infections (11 percent), such as hospital-acquired respiratory infections.

- ***Preventability of Harm Events.*** Physician-reviewers determined that 43 percent of harm events were preventable, with preventable events commonly linked to substandard or inadequate care provided to the patient. (The overall harm rate would be 13 percent if we were to include only events that our physician-reviewers determined were preventable.) Reviewers determined that 56 percent of harm events were not preventable and occurred even though providers followed proper procedures. Events were determined not preventable for several reasons, including that the patients were found to be highly susceptible to the events because of their poor health status.

- ***CMS's Lists of Hospital-Acquired Conditions.*** CMS's two policies on hospital-acquired conditions (HACs) create payment incentives for harm prevention by reducing payment for certain HACs. However, because the policies use narrowly scoped lists of HACs and employ specific criteria for counting harm events, they have limited effectiveness in broadly promoting patient safety. The lists did not cover most of the harm events that patients in our study experienced. Of the harm events we identified, only 5 percent were on CMS's HAC Reduction Program list and only 2 percent were on CMS's Deficit Reduction Act HAC list.

How OIG Did This Review

We reviewed medical records for a random sample of 770 Medicare patients who were discharged from acute-care hospitals during October 2018. We conducted a two-stage medical record review to estimate a national incidence rate of adverse events and temporary harm events. Our review included all causes of patient harm regardless of whether the harm was preventable.

Stage 1: Nurses screened the records for possible patient harm events using a "trigger tool" method. A "trigger" is a clinical clue (e.g., documentation of a fall) that may indicate harm. From the Medicare claims data, nurses also reviewed present-on-admission indicators to identify harm that developed after the patient was admitted. We automatically referred records to Stage 2 when patients were readmitted within 30 days of discharge, regardless of whether the nurse identified harm (these include readmissions in October and November).

Stage 2: Physicians reviewed the records flagged during Stage 1 as containing possible harm events. Physician-reviewers identified harm events and assessed the severity of events, whether events were preventable, and factors that contributed to events.

We calculated the potential cost incurred by Medicare and patients as a result of these events. We also determined whether events were on CMS's lists of hospital-acquired conditions. Finally, we compared the results of this report to our 2010 report and explained the limitations of this comparison.

- ***Harm Events Resulting in Costs to Medicare.*** Nearly a quarter of Medicare patients who experienced harm events (23 percent), either preventable or nonpreventable, required treatment that led to additional Medicare costs. These events also potentially increased patient costs in the form of coinsurance and deductible payments. Costs were incurred during the sample hospital stay or for an additional hospital stay necessary to ameliorate the harm. Combined, we estimated the costs for all events to be in the hundreds of millions of dollars for October 2018.

What OIG Recommends and How the Agencies Responded

Given the scale and persistence of patient harm in hospitals in the decade since our last report, HHS leadership and agencies must work with urgency to reduce patient harm in hospitals. Although HHS agencies took steps to improve patient safety in hospitals, including implementing many of our prior recommendations, substantial efforts are still needed. We made seven recommendations and received concurrences from CMS and AHRQ on all:

- We made the following three recommendations to CMS: (1) update and broaden its lists of HACs to capture common, preventable, and high-cost harm events; (2) explore expanding the use of patient safety metrics in pilots and demonstrations for health care payment and service delivery, as appropriate; and (3) develop and release interpretive guidance to surveyors for assessing hospital compliance with requirements to track and monitor patient harm. In its response to our draft report, CMS provided details about ongoing and planned efforts to improve patient safety.

- We made the following four recommendations to AHRQ: (1) with support from HHS leadership, coordinate agency efforts to update agency-specific Quality Strategic Plans; (2) optimize use of the Quality and Safety Review System, including assessing the feasibility of automating data capture for national measurement and to facilitate local use; (3) develop an effective model to disseminate information on national clinical practice guidelines or best practices to improve patient safety; and (4) continue efforts to identify and develop new strategies to prevent common patient harm events in hospitals. After receiving AHRQ's comments, we revised our first recommendation to make the recommended actions clearer and we revised the second recommendation to acknowledge recent progress by AHRQ regarding its event surveillance system.

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BACKGROUND

Objectives

1. To estimate the incidence of adverse events and temporary harm events for hospitalized Medicare patients.
2. To assess the extent to which adverse events and temporary harm events were preventable, to identify contributing factors, and to estimate the associated costs to Medicare.

Patient Harm in Health Care

Patient harm refers collectively to adverse events and temporary harm events. An "adverse event" is defined as harm to a patient as a result of medical care or in a health care setting, including the failure to provide needed care. An adverse event indicates that care resulted in an undesirable clinical outcome—an outcome not caused by underlying disease—that prolonged the patient stay, caused permanent patient harm, required life-saving intervention, or contributed to death. We also identify "temporary harm events," which are events that resulted in patient harm and required medical intervention but did not prolong hospital stays, cause lasting harm, or require life-sustaining intervention. Adverse events are often more serious than temporary harm events, but temporary harm events can also be serious and lead to more severe consequences if left untreated. For example, if treated promptly, hypoglycemia (low blood glucose) is usually a temporary harm event, but it can become a life-threatening adverse event if left untreated.

Patient harm events may involve medical errors and general substandard care that result in harm, such as infections caused by using contaminated equipment. However, harm events do not always involve errors, negligence, or poor quality of care, and as a result they are not always preventable. For example, an allergic reaction might not have been preventable if it was unexpected. The Institute for Healthcare Improvement, a nonprofit advisory group dedicated to improving health and health care worldwide, states that "unpreventable events are only an innovation away from being preventable" and that including "all causes" of harm in research allows for better comparisons over time.[1] All-cause harm includes "any event during the care process that results in harm to a patient, regardless of the cause."[2]

Reducing the incidence of patient harm events in hospitals is fundamental to improving patient safety and quality of care. In the past few decades, there has been increased national attention devoted to identifying and preventing patient harm. In 2000, the Institute of Medicine helped launch the current patient safety movement with its report *To Err Is Human: Building a Safer Health System*.[3] The Institute (now

the National Academy of Medicine) cited two medical record reviews to identify adverse events. The studies found that between 2.9 and 3.7 percent of hospitalized patients experienced patient harm events and that these events caused "at least 44,000 and perhaps as many as 98,000 deaths in hospitals each year."[4, 5, 6]

OIG Studies on Adverse Events

Beginning in 2008, the Office of Inspector General (OIG) has released 17 reports regarding adverse events in hospitals and other health care settings.[7] The Tax Relief and Health Care Act of 2006 required that OIG report to Congress regarding the incidence of "never events" (i.e., a subset of adverse events that should never occur, such as surgery on the wrong patient) among Medicare patients. The Act also required OIG to examine the extent to which the Medicare program paid, denied payment, or recouped payment for services furnished in connection with such events; and to examine the processes that the Centers for Medicare & Medicaid Services (CMS) uses to identify such events and deny or recoup payment.[8] To meet the requirements of the Act, OIG published a study of adverse events in two counties and then published a study on the national incidence rate of adverse events in acute-care hospitals.[9, 10] Each OIG study on adverse events captured all causes of harm, as well as the preventability of patient harm events.

First National Study of Adverse Events. In 2010, OIG provided the first nationwide estimate of patient harm. In *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries* (the 2010 report), OIG found that 27 percent of hospitalized Medicare patients experienced adverse events and temporary harm events in October 2008. Forty-four percent of harm events were preventable, and care associated with events cost Medicare and patients an estimated $324 million in that single month.[11] For that same period, OIG estimated that adverse events contributed to approximately 15,000 deaths among hospitalized Medicare patients.[12]

Subsequent OIG Reports on Adverse Events. Subsequent OIG reports on adverse events have focused on incident reporting and incidence rates in different health care settings. In a 2012 followup report, OIG found that only 14 percent of patient harm events were reported to hospitals' incident reporting systems or other internal surveillance systems.[13] In a series of reports regarding the incidence of harm events in post-acute settings, OIG found that 32 percent of Medicare residents in skilled nursing facilities, 29 percent of Medicare patients in rehabilitation hospitals, and 46 percent of Medicare patients in long-term care hospitals experienced harm.[14, 15, 16]

Identifying Patient Harm Events From Medical Record Review

Each OIG study on the incidence of adverse events used a two-stage medical record review in which nurses screened inpatient medical records for potential patient harm events using a Global Trigger Tool (GTT), and physicians then reviewed the full records when nurses suspected harm events. The Institute for Healthcare Improvement (IHI) developed the original GTT to systematically screen records for

"triggers" (clinical clues) that may indicate patient harm. In OIG's reviews of adverse events, we used a modified version of this GTT.

A prior OIG study found that compared to other detection methods, the GTT identified a wider range of patient harm events.[17] In addition, some researchers consider medical record review by a physician to be the "gold standard" of adverse event detection because of the rich clinical information contained in medical records that can provide details about both the harm event and the circumstances, such as the patient's condition before and after the event.[18, 19]

Other researchers and organizations have also studied the incidence of adverse events. Studies from the academic literature have used variations of the GTT methodology, reviews of administrative data, and other methods to identify and estimate rates of adverse events in hospitals and other health care settings. Using these variations of the GTT method, researchers have found harm rates ranging from 9 to 33 percent in hospitals (see Exhibit 1).

Exhibit 1: Patient Safety in Hospitals—Selected Research Using the Global Trigger Tool

Study	Description	Harm Rate
Office of Inspector General[20] (2010)	OIG randomly selected a sample of 780 Medicare patients who had inpatient stays at Medicare-certified hospitals in October 2008. OIG identified 302 harm events (174 temporary harm events) using an OIG-modified version of the GTT.	27% of patients (13.5% had an adverse event)
Landrigan et al.[21] (2010)	Researchers randomly selected 2,341 adult patient admissions from 10 hospitals for admissions occurring between 2002 and 2007. They identified 588 events, including those present on admission (POA), across 423 patient admissions using the IHI GTT.	18% of patient admissions (including POA)
Classen et al.[22] (2011)	Researchers randomly selected 795 adult patient admissions from 3 hospitals during October 2004. They identified 393 harm events (354 events identified using the IHI GTT).	33% of patient admissions
Kirkendall et al.[23] (2012)	Researchers randomly selected 240 pediatric admissions from a hospital medical center in 2009. They identified 88 harm events (74 events were not POA) across 62 patients using the IHI GTT.	26% of patients (including POA)
Kennerly et al.[24] (2014)	Researchers randomly selected 9,017 adult patient encounters from 8 hospitals from a health care system between 2007 and 2011. They identified 3,430 harm events (2,129 events not POA) using the IHI GTT.	21% of admissions (33% of admissions including POA)
Adler et al.[25] (2018)	Researchers randomly selected 21,007 adult patient records from 24 hospitals in a large multistate health system from 2009 to 2012. They identified 5,397 patients who experienced harm (2,579 patients with adverse events and 2,818 patients with temporary harm events) using the IHI GTT.	26% of patients (12.3% had an adverse event)
Griffey et al.[26] (2018)	Researchers randomly selected 2,594 adult patient records from four emergency departments from 2016 to 2017. They identified 240 harm events (72 events involving patient harm and not POA) using an Emergency Department Trigger Tool.	9% of emergency department visits (including POA)
Stockwell et al.[27] (2018)	Researchers randomly selected 3,790 pediatric patient records from 16 hospitals from 2007 to 2012. They identified 414 adverse events (210 preventable adverse events) using the Global Assessment of Pediatric Patient Safety (GAPPS) Trigger Tool.	11% of patients* (including POA)

*The incidence rate of 11 percent was not specifically included in the article. We calculated 11 percent by using numbers presented in the article.

Classification of Patient Harm Events

Researchers, policymakers, and health care entities sometimes focus on different types of patient harm events. For example, government agencies and researchers study specific types of harm events, such as health care-associated infections (HAIs) and adverse drug events (ADEs). Researchers also distinguish events by their level of harm and preventability. Thus, entities tracking events may find different rates of patient harm depending on which list they use to identify and classify events.

The National Quality Forum List of Serious Reportable Events

One list that researchers and government agencies have used to track and classify patient harm events is the list of "serious reportable events" (SREs) developed by the National Quality Forum (NQF) to facilitate uniform and comparable public reporting. NQF is a public-private membership organization for health care quality measurement and reporting.[28] This list focuses on events that are serious, largely preventable, and often associated with injury or death. Several State reporting systems and quality improvement organizations use this list to track harm events in hospitals.[29] In the 2010 OIG report, OIG found that these types of events constitute a small percentage of adverse events, with less than 1 percent of Medicare patients experiencing events that were included on the NQF list. NQF last updated the list of SREs in 2011. (See Appendix A for the NQF's list of SREs.)

NCC MERP Levels of Patient Harm

Researchers and health care entities also adopt different standards for distinguishing degrees of harm and defining what constitutes a patient harm event. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) devised an index to categorize medication errors by the degree of harm and additional resources expended to treat the patient.[30] The NCC MERP Index ranks errors from A to I, with levels A through D constituting "near misses" in which the error did not result in patient harm, and levels E through I progressing from temporary harm (E) to contributing to death (I).

Although the NCC MERP Index was initially developed to categorize the effect of medication errors, researchers have modified the Index to measure and distinguish other types of harm events. For example, the IHI uses a modified version of the NCC MERP Index to measure the severity of harm events.[31] Building off IHI's version, OIG also uses a modified version of the NCC MERP Index in our adverse events work.[32] (See Exhibit 2 on page 13 for the OIG-modified version of the NCC MERP Index.)

HHS Efforts To Improve Quality and Safety in Hospitals

The Department of Health and Human Services (HHS) is tasked with leading the Nation in promoting quality health care and preventing patient harm. In 2011, pursuant to the Patient Protection and Affordable Care Act (ACA), HHS created a

National Strategy for Quality Improvement in Health Care (National Quality Strategy) with auxiliary, coordinated plans developed by each HHS agency.[33, 34] The first priority within the overarching National Quality Strategy is "making care safer by reducing harm caused in the delivery of care."[35] To achieve this end, HHS agencies use a series of levers to effect change, such as publicly reporting quality data for health care facilities, providing technical assistance to organizations, and implementing payment incentives, among others. As mandated by the ACA, HHS conducts annual progress reviews of the National Quality Strategy and sends these reports to Congress.[36]

HHS also developed targeted national action plans, in collaboration with other Federal departments and agencies, to reduce certain types of patient harm events. These plans include the HAI Action Plan and the ADE Action Plan.[37, 38] Led by HHS's Office of Disease Prevention and Health Promotion, these two action plans are related to HHS's Healthy People initiative.[39] These action plans include goals to reduce patient harm events. The ADE Action Plan called for a 10-percent reduction in ADEs related to three classes of drugs (anticoagulants, diabetes agents, and opioids) by 2020.[40] The HAI Action Plan called for reductions of 25 to 50 percent in various hospital-onset HAIs by 2020, as compared to 2015.[41] (The plan uses 5-year increments and at the time of this report, HHS had not yet released the 2020 data.)

Each agency within HHS contributes to the National Quality Strategy and the HAI and ADE action plans while pursuing agency-specific goals to improve quality and safety. Agencies contributing to these efforts include: the Agency for Healthcare Research and Quality (AHRQ), which leads efforts to improve health care quality; CMS, which is the Nation's largest health care payer and is the primary oversight entity of health care nationally; and the Centers for Disease Control and Prevention (CDC), which leads efforts to study and prevent HAIs and ADEs and manages the National Healthcare Safety Network (NHSN), the Nation's most widely used HAI surveillance system.[42] These agencies created agency-specific Quality Strategic Plans—last updated in 2016—aligned with the National Quality Strategy.[43] (See Appendix B for more information about other HHS agency-specific efforts to improve quality and safety in hospitals.)

CMS Oversight of Hospitals and Payment Policies To Reduce Patient Harm Events

CMS is the primary Federal regulatory body responsible for overseeing care and enforcing Federal requirements for care provided in hospitals under the Medicare and Medicaid programs.[44] CMS promotes patient safety by regulating and overseeing the care provided in hospitals and by using payment policies designed to reduce patient harm and improve quality of care.

CMS Oversight of Hospitals for Patient Health and Safety

As part of its role to protect patients from harm in hospitals, CMS oversees hospital compliance with a set of patient health and safety requirements known as the Medicare hospital Conditions of Participation (CoPs).[45] The CoPs set baseline standards for a range of hospital services and areas, including medical staff, infection control, nursing services, medical records, and pharmaceutical services. These standards are, in part, designed to minimize harm events. To verify compliance with the CoPs, three types of entities—CMS regional offices; State survey agencies; and Medicare-approved accreditation organizations, such as the Joint Commission—conduct onsite surveys of hospitals.[46]

One CoP requires hospitals to develop, implement, and maintain an effective, ongoing, hospitalwide, data-driven Quality Assessment and Performance Improvement (QAPI) program that focuses on indicators related to improving health outcomes and preventing and reducing medical errors.[47] To satisfy the QAPI CoP, hospitals must "track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms."[48] A QAPI program must include an ongoing effort that "shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors."[49] CMS provides interpretive guidance and survey procedures regarding the hospital CoPs in its State Operations Manual.[50]

CMS Payment Policies for Improving Patient Safety and Reducing Costs Associated With Hospital-Acquired Conditions

As mandated by Congress, CMS implemented, in fiscal years (FYs) 2009 and 2015, two payment policies focused on hospital-acquired conditions (HACs) under Medicare. These payment policies are designed to reduce payment to hospitals for certain HACs.[51] (See Appendix C for CMS's two lists of HACs and see Appendix B for additional CMS pay-for-performance programs focused on patient safety.)

Inpatient Prospective Payment System Payments. For most patient stays, Medicare pays eligible hospitals through the inpatient prospective payment system (IPPS), under which payment amounts are based on the average cost of care for patients with similar conditions.[52] In FY 2019, Medicare classified patient stays into 1 of 759 Medicare Severity–Diagnosis Related Groups (MS-DRGs) based on the diagnosis and procedure codes included on the Medicare claim, as well as on the patient's age, sex, and discharge status. Providers may submit up to 25 diagnosis codes and 25 procedure codes on a claim.[53] These MS-DRGs correlate to the payment that Medicare allows for the stay. In calendar year 2018, Medicare certified 3,334 short-stay acute-care hospitals.[54] In the same year, these hospitals served over 6 million Medicare patients, with Medicare program payments totaling $750 billion or a monthly average of about $63 billion.[55, 56] In addition to payments made by Medicare, patients are responsible for deductible and, in certain situations, coinsurance payments.

1. **Deficit Reduction Act (DRA) List.** The first CMS policy prevents hospitals from receiving increased payments resulting from HACs that develop during the hospital stay.[57] The DRA of 2005 required the Secretary of HHS to select diagnosis codes associated with at least two conditions for which hospitals would not receive higher Medicare payments.[58] The original DRA HAC list of FY 2009 was composed of 10 conditions, most of which included several diagnosis codes. Last updated in FY 2013, the list now consists of 14 conditions that CMS selected in collaboration with CDC using the following criteria:

   - conditions that are high-cost, high-volume, or both;
   - conditions that, when present as a secondary diagnosis, result in assignment of a case to a category that has a higher payment; and
   - conditions that could be reasonably prevented using readily available evidence-based guidelines.[59]

   As required by this payment policy, Medicare-certified hospitals assign one of five "present on admission" (POA) indicators to each diagnosis on a patient's claim to identify whether each diagnosis was present at the time of admission. For example, these indicators could include "Y" (POA), "N" (not POA), "U" (documentation insufficient to determine), "W" (clinically undetermined), or "1" (unreported or not used).[60] CMS then uses these indicators on claims to identify specific HACs (as defined above) and thereby deny higher payment in cases where such HAC diagnoses would have resulted in higher payment.[61]

   In examining the incidence of these harm events in the 2010 report, OIG found that the FY 2009 list of HACs represented a small percentage of harm events, with only about 1 percent of Medicare patients having experienced these events.

2. **Hospital-Acquired Condition Reduction Program (HACRP) List.** Another payment policy that hospitals are subject to is a Medicare pay-for-performance program that adjusts payments to hospitals with high rates of HACs relative to other hospitals.[62] The ACA established the HACRP, which CMS implemented beginning in FY 2015.[63] HACRP's metrics include five equally weighted HAI measures and one patient safety composite indicator to measure hospital performance.[64] These measures are based on administrative claims data and reporting of HAIs. The HACRP list was last updated in FY 2017. If a hospital performs in the lowest quartile of eligible hospitals, CMS reduces the hospital's payments by 1 percent of its annual Medicare inpatient fee-for-service payments. CMS uses the following criteria for selecting conditions for inclusion in the program:

   - conditions identified as HACs under the DRA or by the Secretary,
   - conditions that are high-cost or high-volume,
   - conditions that are easily preventable using evidence-based guidelines, and

- conditions that do not require additional system infrastructure for data submission and collection.[65, 66]

Non-IPPS Payments. CMS does not explicitly prohibit payment for HACs under Medicare managed care programs that are not paid through IPPS. Medicare coverage not paid under IPPS includes inpatient care services covered under Medicare managed care organizations (i.e., Medicare Advantage plans) and inpatient care services provided at hospitals excluded from IPPS, including hospitals in Maryland and some specialty hospitals nationwide, such as cancer treatment centers.[67] Payment under managed care is arranged through capitation (a fixed payment for each enrolled patient per time period) rather than fee-for-service (payments for each service).[68] CMS calculates capitated payments to managed care organizations using a risk-adjustment methodology.[69] In 2018, about one in three Medicare patients were covered under managed care and other non-IPPS programs.[70] Similar to IPPS patients, non-IPPS patients are responsible for deductible and, in certain situations, coinsurance payments.

CMS Models for Health Care Payment and Service Delivery. In addition to its broader oversight and payment functions, CMS also designs, tests, and manages new health care payment and service delivery payment models focused on improving quality of care and addressing the rising costs of health care. The Center for Medicare and Medicaid Innovation (CMS Innovation Center), authorized under the ACA, tests the effectiveness of these models at improving quality of care and reducing health care costs through pilots and demonstrations.[71, 72]

AHRQ Programs for Reducing Patient Harm in Hospitals

AHRQ contributes to reducing patient harm events in hospitals through a variety of programs and initiatives, particularly through research that generates evidence on how to deliver high-quality care; educational efforts to improve clinical practice; and data and analytics to track nationwide rates of patient harm.

Patient Safety Organization Program. As part of wider agency efforts to improve patient safety, AHRQ manages the patient safety organization (PSO) program authorized by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act).[73] This program allows hospitals to voluntarily report patient safety work product information to PSOs for learning and quality improvement.[74, 75] This information may include data about patient harm events and falls under Federal confidentiality and privilege protections. PSOs aggregate and analyze this information and offer expert feedback and advice to hospitals, physicians, and other health care providers to prevent patient harm events. In 2019, OIG found that over half of hospitals worked with a PSO, and most of these hospitals (97 percent) reported that they found the relationship with a PSO valuable.[76]

AHRQ Patient Safety Initiatives. AHRQ maintains a range of toolkits, educational materials, and trainings for providers to improve patient safety and quality of care.

One initiative is AHRQ's Comprehensive Unit-based Safety Program (CUSP), which provides a method to help clinical teams make care safer by combining improved teamwork, clinical best practices, and the science of safety.[77] A number of projects have been designed using the CUSP method, including tools and resources developed under AHRQ's HAI program to prevent and reduce HAIs. This program funds work through grants and contracts to help clinicians prevent HAIs by improving how care is delivered to patients.[78]

In November 2021, AHRQ released *Strategies To Improve Patient Safety: Final Report to Congress*, as required by the Patient Safety Act.[79, 80] The report outlined strategies for reducing medical errors and increasing patient safety as well as measures to accelerate and encourage the health care community to adopt these strategies. The report built on AHRQ's series of reports, *Making Healthcare Safer*, which detail existing and emerging evidence-based patient safety practices for reducing certain patient harm events.[81] AHRQ reported in 2018 that it was working to identify additional models for disseminating and accessing evidence-based clinical practice guidelines.[82]

Public Reports on Nationwide Patient Harm. AHRQ publishes nationwide rates of HACs tracked through patient safety surveillance programs in its series of reports: *National Scorecard on Hospital-Acquired Conditions*.[83] AHRQ also publishes health care quality and health disparities data collected from multiple programs in its *National Healthcare Quality and Disparities Report* and via a public interface with selected patient safety data.[84] Since 2014, AHRQ has included progress reviews of the National Quality Strategy in these annual reports to Congress.[85]

CDC Programs and Initiatives Focused on Patient Safety

CDC operates surveillance systems that track certain types of harm events. CDC's surveillance focuses on HAIs tracked through NHSN and ADEs tracked through the National Electronic Injury Surveillance System-Cooperative Adverse Drug Events Surveillance System.[86, 87] In collaboration with the relevant HHS programs, CDC's National Center for Health Statistics monitors HHS's progress toward meeting the goals of HHS's Healthy People initiative and action plans to reduce the national incidence of HAIs and ADEs.[88] CDC publishes national HAI rates collected from NHSN in its *HAI Progress Reports* and on its Antibiotic Resistance & Patient Safety Portal (formerly the Patient Safety Atlas).[89]

CDC also provides guidance and conducts research in patient safety to inform clinical and infection control practices.[90] CDC works with States, local health departments, and academic medical center partners to develop strategies and resources to prevent HAIs.[91] AHRQ and CMS use CDC's data, guidelines, and other resources to carry out their patient safety programs and initiatives.

Progress in Reducing Patient Harm Events in Hospitals

In the decade since the release of OIG's 2010 report, HHS agencies have reported progress toward improving patient safety nationwide. This progress has involved reported reductions of specific kinds of patient harm events with cost savings, advances in patient safety practices within the health care community, and HHS agencies' implementation of OIG's prior recommendations.

Reported Reductions in Specific Types of Harm. Since 2010, several HHS agencies have reported progress in reducing particular types of patient harm events—HACs, HAIs, and ADEs. AHRQ reported significant declines in the rate of HACs, with a 17-percent reduction between 2010 and 2014 and a 13-percent reduction between 2014 and 2017.[92, 93] On the basis of these data, CMS reported that its HAC payment policies and initiatives have been successful in reducing HACs.[94] CDC also reported that the rates of most HAIs tracked by NHSN fell from 2006 to 2019.[95, 96] For example, the rate of *Clostridioides difficile* (*C. diff*) infections in acute-care hospitals fell by an estimated 7 percent from 2010 to 2015 and by 42 percent from 2015 to 2019, and central line-associated bloodstream infections (CLABSIs) fell by 40 percent from 2006 to 2015 and by 31 percent from 2015 to 2019.[97, 98]

Advances in Patient Safety Practices. HHS's focus on patient safety, in addition to substantial efforts by health care organizations and hospitals, has led to advances in hospital and clinical practices. Research has shown that these improved safety practices—such as medication barcoding, surgical checklists, and "bundles" of patient safety best practices—have helped reduce medical errors and substandard care.[99] Some harm events, such as CLABSIs, are now considered widely preventable if providers follow proper protocols.[100] This focus on safety in providing patient care is ongoing. In September 2020, the IHI's National Steering Committee for Patient Safety (formed in 2018) called for a comprehensive action plan to improve patient safety.[101] The committee included 27 organizations, including CMS, AHRQ, and the Joint Commission. The action plan made recommendations to leaders of health care organizations, including hospitals, to improve patient safety.

Prior OIG Recommendations. In the 2010 report, OIG recommended that CMS and AHRQ broaden patient safety efforts to include all types of adverse events; that both agencies enhance efforts to identify adverse events; and that CMS provide incentives to reduce the incidence of adverse events through its payment and oversight functions.[102] Both agencies implemented these recommendations through a series of actions, including a nationwide initiative focused on hospital safety and a new national surveillance system for monitoring patient harm.

- In 2011, CMS began its Partnership for Patients initiative, which was designed to decrease preventable HACs by 40 percent compared to 2010.[103] The initiative also expanded CMS's collection of health care quality data among participating hospitals. Prior reports indicate that this program, along with the new Medicare payment incentives, prompted a period of "concerted attention by hospitals throughout the country to reduce adverse events."[104] In 2016,

this initiative was integrated into the Quality Improvement Organization (QIO) program to sustain nationwide progress toward reducing patient harm.

- In December 2020, AHRQ deployed an expanded patient harm surveillance system to measure national rates of patient harm using information from patient medical records, the Quality and Safety Review System (QSRS). QSRS replaced a prior harm event surveillance system with the goal of automating the capture of data from medical records to reduce manual data entry, increasing the types of events detected to identify all causes of harm, improving harm estimates by standardizing event definitions, and facilitating use by individual hospitals and health systems as a method for facilities to identify and measure events.[105]

CMS also implemented an OIG recommendation to ensure that hospitals code claims accurately and completely to allow for identification of HACs that should reduce payment pursuant to the DRA HAC payment policy.[106] CMS reported to OIG that to promote proper hospital coding practices, it had established a process to provide coding advice to hospitals and had directed its contractors to examine issues related to coding accuracy of POA indicators and HACs. Although CMS has taken steps to implement OIG's recommendations, CMS has still not implemented prior recommendations for it to develop and release guidance to surveyors and accreditors in assessing hospital compliance to track and monitor patient harm in their facilities.[107]

Methodology

Scope

In this study, we revisited the national incidence rate of harm among hospitalized Medicare patients and largely replicated the methodology used in the 2010 study. We estimated the incidence of adverse events and temporary harm events experienced by Medicare patients during inpatient stays in Medicare-certified short-term acute-care hospitals during October 2018.[108] This assessment included all causes of patient harm, regardless of whether the harm was preventable. We did not include events that occurred in hospital outpatient settings, such as emergency departments, unless they resulted in a direct hospital admission, nor did we include events that occurred before or after the patient's hospital stay unless it resulted in a readmission.[109] We estimated the cost of these events to Medicare, and we treated claims paid through managed care and Maryland's payment system the same as those paid through IPPS, reporting those costs separately. We generalized our findings to Medicare patients discharged during October 2018 nationwide. The care provided to patients in this review occurred before the COVID-19 pandemic.

Sample Selection

We selected a simple random sample of Medicare patients from the National Claims History file. Of the 1,076,344 Medicare patients who were discharged from short-term acute-care hospitals during October 2018, we selected a sample of 800 patients. We excluded 30 patients from our analysis because their inpatient stay occurred in a hospital currently under OIG investigation for an unrelated matter or because the hospital was unable to provide complete medical records.[110] Our final sample consisted of 770 patients from 629 hospitals nationwide. Some patients had more than one hospital stay. The patients in our sample had a combined 834 eligible hospital admissions with discharges in October 2018 and an average length of stay of 4.9 days.[111]

Data Collection

We requested complete medical records, as well as abbreviated records (i.e., discharge summaries, emergency department summaries, and operative reports) for stays that occurred within 30 days after the last discharge for sampled patients' hospital stays. We reviewed the medical records for completeness and made additional requests for any missing components.

Medical Record Reviews

We conducted a two-stage medical record review using OIG-contracted reviewers to identify adverse events and temporary harm events experienced by hospitalized Medicare patients. (See the Medical Record Review Methodology for more information on identifying events and determining preventability and Appendix D for a glossary of selected clinical terms used to describe events.)

Stage 1: Nurse Screening. Registered nurses screened all 834 admissions using the OIG-modified GTT methodology to look for "triggers"—clinical clues—that indicated possible patient harm in the medical record. (See Appendix E for the trigger tool.) From the Medicare claims data, nurses also reviewed POA indicators of "N" (not POA) or "U" (documentation insufficient to determine) as additional clinical clues indicating possible patient harm. When nurses identified possible patient harm, they flagged the records for the second stage of review. When nurses did not identify possible harm, a quality assurance reviewer re-screened the records to verify the nurses' results. We automatically referred records for patients who were readmitted within 30 days of discharge (these include readmissions in October and November) to identify possible events that may have been missed by the screener.

Stage 2: Physician Review. Physicians reviewed the complete medical record for each of the 393 admissions flagged during Stage 1. Physicians either confirmed or refuted the presence of patient harm events using evidence in the record and independently identified any additional events. For each harm event, physician-reviewers determined whether events were preventable (i.e., events that could have

been avoided if the patients had been given better care). They assigned each event to one of five preventability determinations: clearly preventable, likely preventable, likely not preventable, clearly not preventable, or unable to determine. Physician-reviewers also assigned each event to one of five harm severity levels using an OIG-modified version of the NCC MERP Index. (See Exhibit 2 for a description of the severity levels used in this report.)

Exhibit 2: OIG-Modified Version of the NCC MERP Index for Categorizing Events

Event Type	Level	Description
Adverse Event	I	Harm occurred that may have contributed to or resulted in the patient's death.
	H	Harm occurred that required intervention to sustain the patient's life.
	G	Harm occurred that contributed to or resulted in permanent patient harm.
	F	Harm occurred that contributed to or resulted in prolonged facility stay, elevation in level of care, transfer to another facility, or subsequent admission.
Temporary Harm Event	E	Harm occurred that caused temporary harm that required intervention.

Source: Adapted from the NCC MERP Index for Categorizing Errors. Revised on February 20, 2001.

Medical Coder Reviews

Certified medical coders reviewed all patient harm events identified by the physicians to identify potential costs associated with these events. To do this, coders reviewed the medical records, physician findings, and the associated Medicare claims to identify diagnosis and procedure codes that would not have been included in the claim if the event(s) had not occurred. The coders then used the TruCode Encoder software to determine the revised MS-DRG for the hospital claims and the resulting payment amounts.[112] Coders also identified costs associated with patients' 30-day hospital readmissions related to harm events.

Data Analysis

We analyzed the results of medical record reviews and generated national estimates about adverse events and temporary harm events among Medicare patients with hospital stays in October 2018. (See Appendix F for point estimates, 95-percent confidence intervals, and statistical tests.)

Incidence Analysis. We estimated the national incidence rate of adverse events and temporary harm events as the percentage of patients who experienced at least one harm event during their hospital stays. We also generated separate estimates for

harm events that met the criteria for CMS's two lists of HACs. We projected these incidence rates to the population of Medicare patients discharged from hospitals during October 2018.

As an additional measure, we estimated two ratios of incidence density commonly used by hospitals and medical researchers: events per 1,000 patient days and events per 100 hospital admissions. (See Appendix G for incidence density estimates.)

Preventability Analysis. We estimated proportions for each preventability classification and analyzed contributing factors for each classification. We also conducted t-tests to identify statistically significant differences between preventable and not preventable harm events within clinical categories. We report the p-values associated with the mean differences to describe the statistical significance.

Medicare Cost Analysis. We estimated the cost to Medicare and patients for care provided in response to adverse events and temporary harm events in October 2018. For each claim, we calculated the MS-DRG and associated payment amount using information from the hospital's Medicare claim. We then recalculated the payment amount excluding diagnosis and procedure codes that coders determined were the direct result of any patient harm event experienced by the patient. Finally, we calculated the costs of patient harm events as the difference between these two amounts. These amounts do not include costs for care provided after discharge from the hospital, such as followup doctor visits. (See Appendix F for projected cost estimates and 95-percent confidence intervals.)

We presented Medicare claims that were paid under IPPS separately from those paid by managed care organizations, those paid by Maryland's all-payer system, and those exempt from IPPS. (We refer to these as non-IPPS claims.) We presented the estimated costs for these two groups separately because claims paid through IPPS use an MS-DRG-associated payment amount, but the non-IPPS claims use alternative payment methods. We used the MS-DRG-associated payment amount for both groups; therefore, the IPPS amount is an accurate representation of costs and the non-IPPS amount is an approximation of the costs.

Limitations

Our estimates, as with all medical record reviews, are subject to physician interpretation and clinical judgment. It is unlikely that the reviewers identified all patient harm events within our sample of Medicare patients. Medical record reviews also depend on available documentation and omitted information could lead reviewers to miss some events or assess the severity or preventability differently. Preventability determinations may also be affected by hindsight bias given the retrospective nature of medical reviews.

The sample size was insufficient to effectively compare the results of this report to the harm rates identified in the 2010 report. The sample size did not allow us to detect small differences between the rates or to conduct comparisons of individual

subgroups of events. Therefore, we do not include a comparison of the reports in our findings. We offer a discussion of this comparison that includes its limitations beginning on page 38.

The sample size was also insufficient to calculate the total dollar amounts of cost estimates with a high level of precision. Further, the cost estimates for patients who received care in Maryland or through a managed care organization may be less precise because we used IPPS payment rates as a proxy for other payment systems.

Finally, the Medicare population consists of patients who are either aged or disabled and may have more comorbidities than younger, healthier patients. The presence of comorbidities has been tied to a higher risk of patients experiencing harm events.[113] These patients may also require more complex treatments and, due to their underlying conditions, may be more susceptible to harm. Therefore, the findings of this review do not fully apply to the broader patient population.

Standards

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

FINDINGS

A quarter of hospitalized Medicare patients experienced harm during their hospital stays

Color Key
We use the following color scheme in the Findings for Exhibits and Patient Stories:

All Events

Adverse Events

Temporary Harm Events

Of the roughly 1 million Medicare patients discharged from hospitals in October 2018, about 1 in 4 (25 percent) experienced at least 1 adverse event or temporary harm event during their stays. This projects to almost 260,000 Medicare patients having experienced harm as a result of medical care received during hospital stays that ended in October 2018. (See Appendix F for confidence intervals associated with the point estimates.)

Medicare patients who experienced harm events were in two groups: 12 percent experienced adverse events, and an additional 13 percent experienced temporary harm events. Some patients (8 percent) experienced multiple unrelated adverse events or temporary harm events during their stays. Adverse events are often more serious than temporary harm events. However, some temporary harm events are also serious and could have developed into adverse events if hospital staff had not intervened. (See page 18 for more details about temporary harm events.) Exhibit 3 shows an overview of the rates of harm. (See Appendix H for a list of the harm events identified in our sample.)

Exhibit 3: Patient Harm Events at a Glance

All Events	Adverse Events*	Temporary Harm Events**
25% of patients	**12%** of patients	**13%** of patients
258,323 patients	**121,089** patients	**137,234** patients

Source: OIG analysis of hospital stays for 770 Medicare patients in October 2018.
* The rate and number of patients who experienced adverse events consists of patients who experienced at least one adverse event. Four percent of patients (41,708) counted in this group also experienced temporary harm events.[114]
** The rate and number of patients who experienced temporary harm events consists of patients who experienced at least one temporary harm event and no adverse events.

Twelve percent of hospitalized Medicare patients experienced adverse events during their stays

Twelve percent of Medicare patients experienced adverse events during their hospital stays. Adverse events fall under the four highest levels of harm (F through I) on the OIG-modified NCC MERP index. These are events that prolonged the hospital stay, led to permanent harm, required life-saving intervention, or resulted in or contributed to death. (See Exhibit 4 on the next page for the percentages of adverse events in

each harm level.) This projects to 121,089 Medicare patients having experienced at least 1 adverse event during the 1-month study period.

Exhibit 4: Adverse Events Classified as F Through I on OIG's Modified NCC MERP Index (n=115)

Level of Harm	Percentage of Adverse Events*
F Level *Resulted in a prolonged hospital stay, an elevation in the level of care, a transfer to another facility, or a subsequent admission*	**74%**
G Level *Contributed to or resulted in permanent patient harm*	**10%**
H Level *Required intervention to sustain the patient's life*	**7%**
I Level *Contributed to or resulted in patient death*	**10%**

Source: OIG analysis of hospital stays for 770 Medicare patients in October 2018.
* Column does not equal 100 percent due to rounding.

Most adverse events resulted in prolonged hospital stays, elevations in level of care, or subsequent admissions. Seventy-four percent of adverse events resulted in F-level harm. (This equates to 28 percent of all events when temporary harm events are included.) Over half of these events resulted in a longer hospital stay.[115] The remainder were classified at this level of harm because they resulted in a subsequent admission, elevated the patients' level of care, or resulted in the current admission. For example, seven patients in our sample experienced excessive bleeding that prolonged their hospital stays and three patients experienced hyperkalemia (elevated potassium) that resulted in a subsequent admission. Another two patients experienced respiratory failure that elevated their level of care to the intensive care unit (ICU) for monitoring and treatment.

Fewer adverse events contributed to permanent harm or required life-saving intervention. In addition to F-level harm, 10 percent of adverse events contributed to or resulted in permanent harm (G-level harm) and 7 percent required intervention to sustain the patient's life (H-level harm). Several of the events that resulted in permanent harm involved complications from major surgeries, such as strokes related to surgery that resulted in permanent cognitive and physical impairment. For example, one patient was unable to read and had partial loss of vision due to a stroke following surgery. Of the few adverse events that were H-level harms, hospital staff intervened after patients experienced life-threatening harm events. This included one patient whose heart stopped during surgery, thus requiring life-saving intervention.

Some Medicare patients experienced adverse events that contributed to their deaths. Ten percent of adverse events contributed to the patients' deaths (I-level harm). This translates to 1.4 percent of the roughly 1 million hospitalized Medicare patients—14,800 patients—during the 1-month study period.[116] (See page 27 for the preventability determinations for these adverse events.)

Although no single type of event was prominent within the sample as contributing to death, patients who died as a result of adverse events shared some commonalities. In our sample, most had multiple, complex comorbidities, including cancer, morbid obesity, dementia, kidney failure, or diabetes. Although the comorbidities were not directly related to the adverse events, they may have caused patients' health to be more fragile and increased the complexity of their care. For some patients, harm events may have hastened their deaths because they were already terminally ill or had a poor prognosis for survival. For example, one patient with metastatic lung cancer experienced excessive gastrointestinal bleeding from anticoagulants (blood thinners) that were being used to treat atrial fibrillation (irregular heartbeat). The bleeding led to other harms, including hypotension (low blood pressure), acute kidney injury, and ultimately death.

Within our sample, 11 patients experienced adverse events that contributed to their deaths. Of those patients, 7 experienced a series of related harm events—termed "cascade" events—that contributed to their deaths. Initial events progressed and triggered other related harm events that resulted in the patient's death. For example, one patient acquired a methicillin-susceptible *Staphylococcus aureus* (MSSA) infection during the hospital stay. The infection led to septic shock, which contributed to the patient's death. Another cascade event involved substandard treatment of sepsis with insufficient fluid administration and inadequate antibiotic treatment, which led to septic shock, respiratory failure, and the patient's death.

An additional 13 percent of hospitalized Medicare patients experienced temporary harm during their hospital stays

An additional 13 percent of Medicare patients experienced a temporary harm event during their hospital stays. (This 13 percent of patients added to the 12 percent of patients who experienced an adverse event forms the 25-percent patient harm rate. Four percent of patients experienced both an adverse event and a temporary harm event; they are represented among the 12 percent who experienced an adverse event.)[117] These temporary harm events required medical intervention but did not prolong stays, necessitate transfers to a higher level of care, require life-saving interventions, cause permanent harm, or contribute to death (i.e., E-level harm on the OIG-modified NCC MERP Index). This projects to 137,234 Medicare patients experiencing only temporary harm events during their hospital stays in the 1-month study period.

Although many cases of temporary harm represented minor occurrences, some temporary harm events could have developed into adverse events if hospital staff had

not intervened. For example, episodes of hypoglycemia (low blood glucose) can lead to coma and even death without prompt intervention.[118] All of the hypoglycemic events in our sample that were classified as temporary harm (12 events) occurred in patients receiving insulin, with blood glucose levels ranging from 34 to 67 milligrams per deciliter (mg/dL). The normal range for blood glucose is 80 to 130 mg/dL before a meal.[119] One of these events involved a diabetic patient whose blood glucose level fell to 50 mg/dL after staff gave the patient a high dose of fast-acting insulin (70 units per milliliter) prior to a meal. The patient experienced dizziness and staff took immediate steps to address the hypoglycemia by giving the patient orange juice and glucose tablets to raise the patient's blood glucose. They also adjusted subsequent insulin doses to prevent recurrence. If left untreated, this event could have resulted in life-threatening complications.

Medication-related harm events were the most common type of harm events

Medication was the most common clinical category for both adverse events and temporary harm events. Combined, 43 percent of patient harm events were related to medication. The remaining harm events related to patient care (23 percent), procedures or surgeries (22 percent), and infections (11 percent). (See Exhibit 5 for the percentage of events in each of the four clinical categories.)

Exhibit 5: Adverse Events and Temporary Harm Events by Clinical Category

Harm Event Categories	All Events (n=299)*	Adverse Events (n=115)	Temporary Harm Events (n=184)*
Medication	43%	41%	45%
Patient Care	23%	13%	29%
Procedure or Surgery	22%	28%	19%
Infection	11%	18%	7%
Total	100%	100%	100%

Source: OIG analysis of hospital stays for 770 Medicare patients in October 2018.
* Column does not equal 100 percent due to rounding.

Medication. Forty-three percent of patient harm events were related to medication. These events commonly involved patients who experienced delirium (confusion, disordered speech, and/or hallucinations) or other changes in mental status or patients who experienced hypotension. Many of the patients in our sample who experienced delirium or other changes in mental status were taking a combination of opioids. For example, one patient—who was admitted to the hospital with chest and back pain related to spinal compression—experienced delirium with difficulty

speaking after staff gave the patient several different opioids (fentanyl, hydrocodone, and oxycodone). Hospital staff intervened by adjusting the patient's medication.

Several patients experienced hypotension related to the use of opioids or antihypertensive medications. For example, one patient was admitted to the hospital for right knee arthroplasty (total knee replacement) and experienced hypotension and dizziness after receiving two doses of an opioid (oxycodone) within 1 hour. To resolve the hypotension, hospital staff stopped giving the patient the opioid and gave a substitute nonopioid drug for pain.

Other common types of medication-related harm events included acute kidney injuries or excessive bleeding. Acute kidney injuries were often related to the use of intravenous contrast agents, which enhance the visibility of the internal structure for imaging but can also pose a risk to the kidneys. Excessive bleeding was often related to anticoagulants, which are used to prevent blood clots but can also cause bleeding. (See Exhibit 6 for the top five types of harm events related to medication within the sample.)

Exhibit 6: Top Five Types of Harm Events Related to Medication Within the Sample

Medication-Related Harm Event Types	All Events (n=299)	Adverse Events (n=115)	Temporary Harm Events (n=184)
Delirium or other change in mental status	28	8	20
Hypotension	19	5	14
Acute kidney injury or insufficiency	18	8	10
Excessive bleeding	18	12	6
Hypoglycemia	13	1	12

Source: OIG analysis of hospital stays for 770 Medicare patients in October 2018.

PATIENT STORY 1: Excessive use of opioids led to severe hypotension

One medication-related adverse event involved a 67-year-old patient who was admitted for a right knee arthroplasty. Two days after the procedure, the patient received a total of four doses of an opioid (oxycodone, 5 milligrams each) for postoperative pain in the morning. The patient was also given one dose of another opioid (tramadol) following a short time interval the same morning. Staff gave the patient these opioids within less than 4 hours. Later that morning, the patient developed dizziness and hypotension (systolic blood pressure was less than 90 millimeters of mercury (mmHg)). To address the patient's hypotension and dizziness, the provider lowered the dosage and frequency of the opioid and observed the patient in the hospital for an additional day. Our physician-reviewers determined that the level of opioids given to the patient was excessive.

Patient Care. Twenty-three percent of harm events related to patient care. Patient care pertains to the daily care of patients, which is often performed by nurses. These events commonly involved patients who experienced pressure injuries. Pressure injuries ranged from unstageable to Stage 2 (on a scale increasing in severity from unstageable to Stage 4) and were identified on various parts of the body.[120] For example, one patient developed two Stage 2 sacral (lower spine) pressure injuries several days after being admitted for abdominal pain and frequent diarrhea. Another patient had a preexisting pressure injury on a hip that progressed from Stage 1 to Stage 2 during the hospital stay.

Other common patient care-related harm events included skin tears or falls or other traumas with injury. Skin tears, abrasions, and breakdowns occurred on different parts of the body, including the face, arm, and buttock. For example, after having blood drawn, one frail patient experienced a skin tear on the left hand with a blister and wound drainage. Another patient experienced two skin tears on the arm as the result of leaning directly against the bed rail. For that event, the hospital treated the skin tears and placed a pillow between the patient's arm and bed rail to prevent further injury. Falls or other traumas also occurred during hospital stays and resulted in injuries ranging from minor abrasions to more serious injuries to the head and hip. For example, one patient experienced a traumatic hematoma (an abnormal accumulation of blood inside the body) of the right knee after accidently hitting a bed rail. (See Exhibit 7 for the top five types of harm events related to patient care within the sample.)

Exhibit 7: Top Five Types of Harm Events Related to Patient Care Within the Sample

Patient Care-Related Harm Event Types	All Events (n=299)	Adverse Events (n=115)	Temporary Harm Events (n=184)
Pressure injury	22	2	20
Skin tear, abrasion, or breakdown	11	0	11
Fall or other trauma with injury	9	2	7
Fluid or electrolyte disorders	9	5	4
Intravenous catheter infiltration, burn, or phlebitis	9	0	9

Source: OIG analysis of hospital stays for 770 Medicare patients in October 2018.

Procedures and Surgeries. Physician-reviewers categorized 22 percent of harm events as being related to procedures or surgeries. These events often involved patients who experienced new episodes of hypotension as the result of a procedure or surgery. For hypotension events that were associated with anesthesia, we categorized these events as related to a surgery or procedure rather than related to medication. These instances of hypotension arose directly from the administration of

anesthesia that was required to perform the procedure or surgery. For example, one patient experienced hypotension during surgery to repair an inguinal (groin) hernia and another patient experienced hypotension during hip replacement surgery. Both instances were related to anesthesia and required sustained treatment with vasopressors (medicine to raise blood pressure).

Patients also experienced excessive bleeding as the result of a procedure or surgery. For example, one patient experienced serious bleeding after being given an anticoagulant (warfarin) following a colonoscopy to remove two polyps (small growths in the colon). As a result, providers were able to remove only one polyp and the patient had to be readmitted days later for a second procedure to safely remove the remaining polyp after the initial bleeding had ceased. (See Exhibit 8 for the top five types of harm events related to procedures and surgeries within the sample.)

Exhibit 8: Top Five Types of Harm Events Related to Procedures and Surgeries Within the Sample

Procedure and Surgery-Related Harm Event Types	All Events (n=299)	Adverse Events (n=115)	Temporary Harm Events (n=184)
Hypotension	15	2	13
Excessive bleeding	13	6	7
Embolisms (i.e., vascular and fat embolisms)	5	4	1
Cerebrovascular accident	5	5	0
Prolonged ileus	4	4	0

Source: OIG analysis of hospital stays for 770 Medicare patients in October 2018.

PATIENT STORY 2: Postoperative bleeding led to other complications

One surgery-related adverse event involved a 46-year-old patient who was morbidly obese and had end-stage kidney disease, hypertension (elevated blood pressure), and diabetes. The patient was admitted for a gastric sleeve resection (a procedure to remove part of the stomach) for weight loss. A day after the operation, the patient developed hypotension and delirium. The hospital staff subsequently identified bleeding from the patient's surgical wound, which resulted in hemorrhagic shock. The hospital then transferred the patient to the ICU where a central line was placed for rapid infusion of vasopressors to manage the patient's blood pressure. A scan of the patient's abdomen revealed a large hematoma at the surgical site. The shock led to severe acidosis and hyperkalemia and the patient required dialysis. To compensate for the bleeding, providers gave the patient a total of 4 units of blood, transfused over 2 days until the bleeding resolved. Our physician-reviewers determined that a proper surgical technique would have likely prevented this event.

Infections. Physician-reviewers categorized 11 percent of harm events as being related to infections. These harm events commonly involved patients who experienced respiratory infections. In our sample, most of the respiratory infections were related to two types of pneumonia: ventilator-associated pneumonia and aspiration pneumonia. For example, one patient was admitted to the hospital for a stroke resulting in dysphagia (difficulty swallowing). The patient received tube feedings that led to aspiration pneumonia after the patient inhaled the feedings. Other common infections included surgical site infections, thrush, sepsis, and *C. diff* infections. (See Exhibit 9 for the top five types of harm events related to infections within the sample.)

Exhibit 9: Top Five Types of Harm Events Related to Infections Within the Sample

Infection-Related Harm Event Types	All Events (n=299)	Adverse Events (n=115)	Temporary Harm Events (n=184)
Respiratory infection	8	6	2
Surgical site infection	6	6	0
Thrush	5	0	5
Sepsis	4	4	0
C. diff infection	3	3	0

Source: OIG analysis of hospital stays for 770 Medicare patients in October 2018.

PATIENT STORY 3: An infected hip implant required readmission for surgery

One infection-related adverse event involved a 69-year-old patient who was hospitalized for a fall and required hip replacement surgery with placement of a prosthesis (implant). While the patient was being seen during a followup appointment at an outpatient clinic 10 days after discharge from the hospital, the provider found purulent drainage (pus) at the patient's surgical site indicating an infection. The wound culture tested positive for methicillin-resistant *Staphylococcus aureus* (MRSA). After the provider identified the infection, the patient was given antibiotics. The patient was then readmitted to the hospital 5 days later for additional surgery to clean the wound and replace the infected implant. The patient was discharged after 7 days of recovery. Our physician-reviewers determined that this event was likely preventable.

Physician-reviewers determined that 43 percent of adverse events and temporary harm events were preventable

The incidence rates for adverse events and temporary harm events include all events regardless of preventability, but physician-reviewers also assessed whether each event could have been prevented. They determined that 43 percent of adverse events and temporary harm events were preventable, and that 56 percent were not preventable. Physician-reviewers were unable to determine preventability for the remaining three events within the sample because of incomplete documentation or complexities in the patients' conditions.[121] Exhibit 10 shows the percentages of events within each preventability assessment.

Exhibit 10: Adverse Events and Temporary Harm Events by Preventability Determination

Preventability Assessment*	All Events (n=299)	Adverse Events (n=115)	Temporary Harm Events (n=184)
Preventable *Harm could have been avoided through improved assessment or alternative actions*	43%	45%	41%
Not Preventable *Harm could not have been avoided given the complexity of the patient's condition or care required*	56%	53%	58%

Source: OIG analysis of hospital stays for 770 Medicare patients in October 2018.
* We cannot reliably project the proportion of harm events where preventability was unable to be determined.

If we included only preventable events in the estimated incidence rate of harm among Medicare patients, the overall harm rate would be 13 percent (rather than 25 percent), the rate of adverse events would be 6 percent (rather than 12 percent), and the rate of additional patients experiencing temporary harm events would be 7 percent (rather than 13 percent).

Events related to procedures or surgeries were more likely to be determined by our physician-reviewers to be not preventable.[122] However, we did not find statistically significant differences in the preventability determinations for medication or patient care-related events.[123] Because of the small number of events, we were not able to determine the difference in preventability for infection-related events. In our sample, physician-reviewers indicated that most of the procedure-related and surgery-related events that were not preventable occurred even though providers followed proper preparation and procedures. Many of these patients were also in poor health, which made them more susceptible to the events. For example, one particularly frail patient, who had multiple medical problems and was in declining health prior to admission, experienced gastrointestinal bleeding after undergoing surgery to remove the gallbladder. Given the patient's poor health and complex diagnosis (the patient had

ampullary stenosis, a bile duct obstruction), our physician-reviewers determined that the bleeding was likely not preventable. Exhibit 11 shows the percentages of preventable and not preventable harm events within each clinical category.

Exhibit 11: Preventable and Not Preventable Adverse and Temporary Harm Events Within Each Clinical Category

Clinical Category	Preventable Events	Not Preventable Events
Medication (n=130)*	**42%**	**57%**
Patient Care (n=69)	**52%**	**48%**
Procedure or Surgery (n=67)*	**25%**	**72%**
Infection (n=33)**	**--**	**--**

Source: OIG analysis of hospital stays for 770 Medicare patients in October 2018.
Note: The 95-percent confidence intervals for patient care and procedure or surgery preventability estimates exceed 10-percent absolute precision.
* Row does not sum to 100 percent because reviewers were unable to determine the preventability for 1 or more events.
** We are unable to reliably project the proportion of infection-related events due to the small sample size.

Similarities in Preventability Assessments. Within the clinical categories, physician-reviewers often gave the same preventability assessment for events with similar characteristics. For example, they assessed 15 of 18 excessive bleeding events related to medication as not preventable because the patients received appropriate care, but poor health or comorbidities made them susceptible to a bleeding event or made them difficult to treat. For the remaining three events, physician-reviewers determined that two were preventable and one was unable to be determined. One of the preventable excessive bleeding events involved a patient who was admitted with jaundice and diagnosed with autoimmune hepatitis (a condition where the body attacks the liver), which can lead to internal bleeding. The patient was prescribed an anticoagulant to prevent blood from clotting and resulting in melena (black, tarry stools associated with upper gastrointestinal bleeding).

Differences in Preventability Assessments. In other cases, preventability determinations for similar events differed based on the patients' health and whether providers took preventative measures. For example, physician-reviewers often described pressure injuries as preventable when patients at risk for pressure injuries did not receive proper preventative care. One high-risk patient, who was immobile and had chronic diarrhea, was admitted to the hospital with fever and sepsis. While in the hospital, the patient was not turned regularly in bed and developed two pressure injuries in different locations (the sacrum and elbow). Physician-reviewers described pressure injuries as not preventable when they found evidence that the patient received proper preventative care but still developed pressure injuries because of comorbidities that increased the patient's risk. Another patient with dementia and

numerous preexisting pressure injuries was admitted for pneumonia and sepsis. During the hospital stay, the patient was on a strict turning schedule but did not always cooperate because of their dementia. This led to a new pressure injury over the patient's coccyx (tailbone) that our physician-reviewers determined was likely not preventable.

Preventable events were commonly linked to substandard or inadequate care provided to the patient

Based on their clinical judgment, physician-reviewers selected one or more rationales to support each preventability determination. These contributing factors are not necessarily mutually exclusive, and our physician-reviewers often identified multiple factors as having contributed to preventable events. Among preventable events, physician-reviewers determined that 33 percent involved patients receiving substandard treatment or therapeutic care and 31 percent involved patients receiving substandard or inadequate preventative care. In one such case, a patient became unresponsive after receiving multiple medications post-surgery for an ankle fracture, including three opioids (hydrocodone, fentanyl, and morphine). After reviving the patient, hospital staff discontinued the opioids. Our physician-reviewers determined that this event likely could have been prevented by using a less aggressive pain management regimen after surgery. (See Appendix F, Exhibit F-3 for a complete list of the rationales cited by physician-reviewers for preventable events.)

PATIENT STORY 4: A delay in surgery led to a cascade of preventable harm events, additional treatment, and contributed to the patient's death.

One preventable adverse event involved an 89-year-old patient who had a recent stroke and a history of chronic obstructive pulmonary disease. The patient was hospitalized for sepsis after complaining of abdominal pain and nausea. Providers determined that the patient required surgery to remove dead tissue that they found in the patient's small intestine. However, providers unnecessarily delayed surgery for 5 days while the patient continued to deteriorate. This delay led to a cascade of harms that included worsening of the small intestine, contamination of the abdomen with pus, septic shock with an associated kidney injury, and delirium. These conditions required additional surgeries and intubation, ultimately resulting in the patient's death. Our physician-reviewers determined that this event was likely preventable because of the delay in care that our reviewer determined was an error related to medical judgment and patient management.

Events that were not preventable commonly occurred despite providers following proper preparation and procedures

Among events that were not preventable, physician-reviewers determined that over half (51 percent) occurred despite providers following proper preparation and procedures and 36 percent occurred because patients were highly susceptible to the events due to poor health status. As with preventable events, these rationales are not

mutually exclusive, and physician-reviewers often cited multiple reasons for events being not preventable. Examples of events occurring despite providers following proper preparation and procedures included acute kidney injuries and new episodes of hypotension resulting from necessary medications. For example, one patient experienced an unexpected new episode of hypotension while on a medication required during surgery to repair a fractured humerus (arm bone). Physicians determined that this event was not preventable because the patient needed the medication during the surgery, so providers had followed proper preparation and procedures. (See Appendix F, Exhibit F-3 for a complete list of the rationales cited by physician-reviewers for events that were not preventable.)

PATIENT STORY 5: Complications associated with chemotherapy for a stem cell transplant that were considered not preventable

A 76-year-old patient with non-Hodgkin's lymphoma (cancer of the immune system) was admitted for chemotherapy and a stem cell transplant and experienced multiple harm events that were not preventable. While receiving chemotherapy medication (cytarabine and etoposide) prior to the transplant, the patient developed a medication-induced toxic skin rash with peeling over the torso and upper extremities that lasted several days. The patient also experienced episodes of diarrhea due to the chemotherapy medication. The last harm event was a respiratory infection, neutropenic (low white blood cell count) pneumonia, that developed about a week into the stay. Our physician-reviewers determined that these events were likely not preventable because these are known complications associated with chemotherapy that are difficult to prevent and providers followed proper preparation and procedures.

In our sample, 7 of the 11 adverse events that contributed to or resulted in death were preventable

Our physician-reviewers determined that 7 of the 11 events that contributed to or resulted in death were preventable. Reviewers indicated that preventable events involved substandard treatment or therapeutic care, inadequate patient monitoring, inadequate care plans, inadequate admission assessments, and provider errors. For example, one patient was administered total parenteral nutrition against the recommendation of a nutritionist leading to pulmonary edema (fluid in the lungs) and refeeding syndrome (a dangerous shift in fluids and electrolytes), which ultimately hastened the patient's death. Another patient experienced severe bradycardia (slow heart rate) as the result of poorly managed hyperkalemia while being transported to a different floor within the hospital for an x-ray and required emergency assistance. The emergency response team was unable to locate the patient, who suffered cardiac arrest and died.

Physician-reviewers determined that the remaining four events that contributed to or resulted in death were not preventable. Poor health status and complex diagnoses contributed to events not being preventable. Two of these events also occurred even though providers followed proper preparation and procedures. For example, one patient was admitted for surgery to remove a large necrotized (dead) part of the

colon. The patient received appropriate care, but excessive bleeding and anemia following the surgery contributed to the patient's death.

CMS's two policies on hospital-acquired conditions create payment incentives for harm prevention but do not apply to the vast majority of harm events that patients experienced

CMS's two HAC policies (HACRP and DRA HAC) do not apply to the vast majority of harm events that patients experienced. These programs create incentives for harm prevention by reducing payments to hospitals for HACs from two separate lists. Despite CMS's reported success in reducing HACs, both lists are narrow in scope and employ specific criteria for inclusion of events, limiting the effectiveness of these programs in addressing patient safety broadly. (See Appendix H for the harm events that were included on these lists and Appendix A for the NQF list.)

Hospital-Acquired Condition Reduction Program (HACRP). CMS established the HACRP list in FY 2015 as a pay-for-performance program that adjusts payments to hospitals with high rates of HACs relative to other hospitals. Under this program, CMS reduces hospital payments based on metrics identified through administrative claims data and reporting of hospital-acquired infections. The HACRP list incorporates only 15 types of harm events as having implications for a hospital, and few of the harm events we found were affected by this program.

We found that 5 percent of harm events experienced by Medicare patients were on the HACRP list. These events included hospital-acquired infections, sepsis, a fall with a hip fracture, a pulmonary embolism (lung artery blockage caused by a blood clot), and hemorrhage (bleeding). In our sample, infections were the most common type of event that qualified for the HACRP list. These included surgical site infections, a CLABSI, a MRSA infection, a *C. diff* infection, and catheter-associated urinary tract infections (CAUTIs).

In addition to designating a small number of event types under the HACRP list, CMS uses narrow criteria that further limit its ability to capture harm events. For example, with surgical site infections, HACRP counts only infections associated with procedures involving the colon or an abdominal hysterectomy (a surgery to remove all or part of the uterus). Although we did identify surgical site infections that met these criteria, some infections did not, including one that occurred after a laminectomy (back surgery).

Deficit Reduction Act Hospital-Acquired Conditions (DRA HAC). CMS established the DRA HAC list to comply with the DRA of 2005 to prevent hospitals from receiving increased payment resulting from certain HACs that develop during the hospital stay. CMS uses POA indicators assigned by hospitals to each claim to identify certain HACs that developed during the stay. The DRA HAC list, which overlaps with the HACRP list, includes only 14 types of events and few of the harm events we observed were affected by the policy. We found that 2 percent of harm events experienced by

Medicare patients were on CMS's DRA HAC list. These events involved a fall resulting in hip fracture; a trauma resulting in rib fracture; two CAUTIs; and a CLABSI, which is a type of vascular catheter-associated infection.

For the few events on the DRA HAC list, hospitals did not always include the diagnosis codes on claims that CMS uses to identify these events. Only one of the five HACs identified in our sample was included in the associated Medicare claim. As a result, the remaining four HACs were not identifiable through analysis of the claims data that CMS uses to implement the DRA HAC payment policy. For example, we found that hospitals coded the two CAUTIs with a less specific diagnosis that would not be detected by the policy. Hospitals omitting the specific codes CMS monitors for this policy may limit its awareness of the HACs occurring in Medicare-certified hospitals. Since our review, CMS has taken additional steps to flag claims with unspecified code types (e.g., unspecified site or etiology) and to educate providers about more specific codes that may be available.[124] Additionally, new ICD-10-CM Official Guidelines for Coding and Reporting FY 2022 were released with language requiring providers to code to the highest level of specificity for diagnoses and procedures.[125]

CMS's narrow criteria for specific harm event types on the DRA HAC list also limited the agency's ability to capture harm events. For example, like the HACRP, the DRA HAC list also narrowly defines surgical site infections. As a result, none of the surgical site infections we identified met the DRA HAC criteria because it applies only to infections following a limited set of procedures. For example, one event that did not qualify was an infection following an orthopedic procedure involving the hip because the procedure did not involve the spine, neck, shoulder, or elbow.

Nearly a quarter of patients who experienced harm events required treatment that led to additional Medicare costs

Combining both Medicare IPPS patients (i.e., patients whose hospital care was paid directly by Medicare according to a diagnosis related group) and non-IPPS patients (i.e., patients whose care was paid through another arrangement, such as a managed care organization), 23 percent of patients who experienced a patient harm event, either a preventable or nonpreventable, required treatment that led to additional Medicare costs. The events also potentially increased patient costs in the form of coinsurance and deductible payments.[126] These costs were incurred either during the patient's hospital stay or for an additional stay necessary to ameliorate the harm. Because of the variability of these costs and the small number of sampled patients with events that resulted in additional costs, we could not estimate the total dollar amount with a high level of precision. Below, we provide the estimated costs for both IPPS and non-IPPS patients, as well as the associated 95-percent confidence intervals. The cost of events was substantial for some patients with individual amounts over $40,000. Combined, we estimated the costs for all events to be in the hundreds of millions of dollars for October 2018.

PATIENT STORY 6: An increase in potential Medicare payment due to complications from a heart valve replacement procedure

One harm event that increased the allowable Medicare payment of a hospital stay involved an 81-year-old patient admitted for a transcatheter aortic valve replacement (heart valve replacement). During the procedure, the patient experienced a likely preventable adverse event involving a prolonged period (around 1 hour) of hypotension while under sedation. This led to pulseless electrical activity (a state where the pulse cannot be felt). Staff intervened with cardiopulmonary resuscitation, vasopressors, and insertion of a heart pump. Although staff successfully revived the patient, the patient experienced acute encephalopathy (altered brain function) as a result of the initial harm. We found that the hypotension-related event potentially increased the Medicare payment by $48,000 (from about $63,000 to just over $111,000).

IPPS Costs. Two-thirds of patients received care that was paid under the Medicare IPPS. We found that 20 percent of patients covered by IPPS who experienced harm events incurred additional costs to the Medicare program and potentially to the patients themselves as a result.[127] In one case, a patient experienced a stroke following an outpatient angioplasty that resulted in an unplanned hospital admission. The additional hospital stay needed to treat the stroke cost Medicare $44,000.

We estimated that Medicare spent $520 million on IPPS costs associated with patient harm events during October 2018.[128] The 95-percent confidence interval for this estimate spans $223 million to $818 million. This correlates to between 2 and 8 percent of Medicare IPPS expenditures for October 2018.

Non-IPPS Costs. The remaining one-third of patients received care that was paid under managed care plans or other non-IPPS payment systems.[129] We found that 28 percent of non-IPPS patients who experienced harm events incurred additional costs to the Medicare program and potentially to the patients themselves as a result. In one case, a non-IPPS patient incurred an additional $28,000 during the sampled hospital stay because the patient experienced respiratory failure due to anesthesia, which required the hospital to transfer the patient to the ICU with ventilator support.

Using the IPPS payment rates as a proxy for the payments associated with non-IPPS patients, we estimated that Medicare spent $281 million on hospital costs associated with harm events for non-IPPS patients during October 2018.[130] The 95-percent confidence interval for this estimate spans $124 million to $439 million.

Additional Costs. In addition to the Medicare costs associated with hospital care in October 2018 and readmissions within 30 days, some patients likely required followup care on an outpatient basis or even hospital readmissions after our study period. These additional costs are not reflected in our estimates. This additional care may include physician office visits, medication, and rehabilitation services during and after our study period. Further, some patients may not regain the full functional status they had prior to the harm events, leaving them at greater risk for poor health outcomes in the future, with their associated costs, and lost wages for them and their caregivers.

CONCLUSION AND RECOMMENDATIONS

In the decade since OIG reported the first national incidence rate of patient harm among hospitalized Medicare patients and more than 20 years since the publication of the Institute of Medicine report *To Err Is Human: Building a Safer Healthcare System*, increased national attention has been devoted to patient safety. HHS and health care organizations across the Nation have since taken steps to improve patient safety with advances in hospital practices, both in patient safety and clinical practice. The nationwide patient safety movement has also experienced increased Federal involvement in tracking and reducing preventable patient harm.

As the Federal Government's principal Department for protecting the health of Americans, HHS is uniquely positioned to lead national efforts to reduce patient harm events in hospitals. A number of agencies within HHS share responsibility for addressing patient harm, including AHRQ, which leads HHS efforts to improve health care quality and CMS, which is the Nation's largest health care payer and oversight entity. In addressing the recommendations in OIG's 2010 report, and as part of wider patient safety efforts, both agencies launched new programs and initiatives designed to better track, reduce, and contain the costs associated with treating harm events.

Addressing patient harm and promoting patient safety takes on added urgency in light of the ongoing pandemic and its effects on hospital operations.[131] Despite substantial action by HHS agencies and success in reducing certain types of events, patient harm remains pervasive, is often preventable, and continues to cost the Medicare program and patients. We found that an estimated 25 percent (about 1 in 4) of Medicare patients experienced patient harm events during their hospital stays in October 2018, and that 43 percent of events could have been prevented if patients had received better care. Nearly a quarter of patients who experienced harm events incurred additional Medicare costs and patient costs as a result. Given our findings, HHS leadership and agencies must work with urgency to address these persistent harm rates and promote patient safety in hospitals.

We recommend that CMS:

Update and broaden its lists of hospital-acquired conditions to capture common, preventable, and high-cost harm events

CMS should look for opportunities to broaden or expand its lists of hospital-acquired conditions, particularly the DRA HAC or HACRP list. As the largest health care payer in the Nation, CMS is uniquely positioned to align payment with quality by ensuring that coverage and payment are available to support only appropriate clinical practices. Although CMS reported success in reducing HACs through the DRA HAC

and HACRP programs, we found that these lists addressed few of the harm events that Medicare patients experienced.

CMS should update one or both of its lists of HACs to include additional harm events. Although CMS annually considers new measures for its quality improvement programs, CMS last added measures to the DRA HAC list in FY 2013 and the HACRP list in FY 2017. If adopted, the current measures under consideration may further incentivize hospitals to improve patient safety. We encourage CMS to continue studying other types of harm events that may be good candidates for one of the HAC lists and working with HHS agencies, such as AHRQ and CDC, to identify other conditions that would be appropriate to include in its lists of HACs.

Explore expanding the use of patient safety metrics in pilots and demonstrations for health care payment and service delivery, as appropriate

As part of broader efforts to connect payment to quality of care, CMS should explore ways to expand the use of patient safety metrics with existing or new pilots and demonstrations for health care payment and service delivery. An important component in this effort is the CMS Innovation Center—authorized under the ACA—which focuses on designing, testing, and implementing new health care payment and service delivery models to improve quality of care and address rising health care costs. The CMS Innovation Center independently evaluates these models through pilots and demonstrations for impact on both expenditures and quality of care to determine whether to maintain and expand them.

In refining and developing these new methods for health care payment and service delivery, CMS should consider new options for using patient safety metrics to evaluate the effectiveness of its models. This could include assessing reductions in the incidence of preventable patient harm events to measure model effectiveness. The CMS Innovation Center could leverage harm event surveillance programs to monitor rates of different types of harm in participating hospitals and factor in the cost savings from reductions in these harm events. This approach could bolster CMS's efforts to identify effective demonstrations and pilots that promote quality of care while reducing costs to Medicare.

As OIG previously recommended, develop and release interpretive guidance to surveyors for assessing hospital compliance with requirements to track and monitor patient harm events

Our findings lend new urgency to OIG's prior recommendation that CMS provide interpretive guidance to surveyors for assessing hospital compliance with QAPI requirements to track and monitor patient harm.[132] The QAPI Condition of Participation for Medicare requires that hospitals have a program to track adverse events and to demonstrate quality improvement. In 2019, CMS reported to OIG that it had developed this interpretive guidance and was engaged in the rulemaking process to finalize its release but has not yet released the guidance. This recommendation supersedes OIG's prior recommendation on this issue.

We recommend that AHRQ:

With support from HHS leadership, coordinate agency efforts to update agency-specific Quality Strategic Plans

In the years since HHS created its National Quality Strategy to improve health care, and subsequent national action plans to reduce patient harm events, protecting the health and safety of Medicare patients remains a top management challenge. Although HHS agencies have reported reductions in certain types of harm events, the overall rate of harm demonstrates a strong need for further action.

With support from HHS leadership, AHRQ should coordinate agency efforts to update agency-specific Quality Strategic Plans and ensure alignment with the priorities of the National Quality Strategy. These Quality Strategic Plans have not been updated on AHRQ's website since 2016. AHRQ could assist the agencies in a number of ways, for example by providing a common framework for agencies to assess their plans and patient safety initiatives, facilitating communication among the agencies about the plans, and providing guidance and technical assistance to agencies as needed. AHRQ's role in supporting quality and safety planning throughout HHS would promote information-sharing and a coordinated approach to patient safety among HHS operating divisions.

Optimize use of the Quality and Safety Review System (QSRS), including assessing the feasibility of automating data capture for national measurement and to facilitate local use

In its response to the draft report, AHRQ reported that it is currently using QSRS to measure rates of patient harm at the national level but has not yet fully deployed the

system's planned functionality. AHRQ has not yet reported data from the new system. QSRS still requires manual data entry, which individual hospitals and health systems reported to AHRQ is a significant barrier to use. AHRQ reported to OIG that it is assessing the feasibility of automating the capture of data from medical records which would help facilitate use by individual hospitals and health systems. Automating data capture would likely also enable AHRQ to be more efficient in its measurement of national data.

AHRQ should continue to optimize use of QSRS, including completing its feasibility assessment of automating data capture. AHRQ should also review the events we identified in this study and consider whether it should add additional types of harm events to the system. We encourage AHRQ to share data from QSRS with CMS to help expand its lists of HACs and with other agencies, such as CDC, to inform and coordinate patient safety activities.

Develop an effective model to disseminate information on national clinical practice guidelines or best practices to improve patient safety

Our findings suggest that educating providers on national clinical practice guidelines or best practices could help reduce preventable patient harm events such as pressure injuries. Given these benefits, AHRQ should develop an effective model to disseminate information on these guidelines and best practices to improve patient safety. Despite an agency effort to identify new models for disseminating and accessing evidence-based clinical practice guidelines, AHRQ has not released information on the status of this initiative. AHRQ could consider tailoring the scope of a new model to focus on patient safety best practices, including topics related to reducing some of the types of patient harm events we identified. AHRQ could also solicit input from stakeholders, such as medical specialty societies, to compile evidence-based practices for harm reduction and leverage its *Making Healthcare Safer* series of reports to promote these practices. Using these resources, AHRQ should establish a new method to share evidence on effective clinical practices to make such information readily discoverable, accessible, and useable to frontline health care practitioners to improve patient safety.

Continue efforts to identify and develop new strategies to prevent common patient harm events in hospitals

AHRQ should continue to invest in new research, tools, and projects to provide a mechanism to improve quality of care by developing evidence-based approaches to reduce all causes of patient harm. These efforts could culminate in effective strategies to prevent some of the types of patient harm events that we identified such as new episodes of hypotension related to medications like opioids and anesthesia.

AHRQ should use the insights from our evaluation to inform and bolster patient safety research. This could include new toolkits and resources for providers to address the most common harm events identified in this report. AHRQ should then assess the impact of these new tools with implementation projects and impact case studies. As advances in medicine and technology continue, AHRQ should focus on ensuring that patient safety efforts remain abreast of these advances and work with urgency to help guide national efforts to improve our understanding of the extent and causes of patient harm in hospitals. To help accomplish this, AHRQ should actively and continually coordinate with stakeholders, including providers, accreditors, researchers, and States, to combat patient harm in hospitals.

AGENCY COMMENTS AND OIG RESPONSE

CMS and AHRQ concurred with our recommendations. CMS concurred with three recommendations and AHRQ concurred with four recommendations. OIG appreciates the efforts of CMS, AHRQ, and other HHS agencies to improve patient safety and promote quality of care. Their comments are summarized below and for the full text of their comments, see Appendix I on page 90.

CMS Comments and OIG Response

CMS stated that preventable adverse and temporary harm events are unacceptable and reported ongoing efforts to improve patient safety. CMS also described evidence of specific improvements in patient safety during the past decade resulting from these efforts, including reducing the incidence of several HACs, such as adverse drug events and injuries from falls.

CMS described several programs and policies it uses to achieve its quality of care goals: (1) establishing and enforcing minimum standards for care through the CoPs, including the QAPI CoP which requires hospitals to monitor adverse events and develop improvement plans; (2) implementing a range of quality reporting and value-based purchasing programs; and (3) managing the QIO program, which is dedicated to improving health care quality for Medicare beneficiaries and has a focus on engaging hospitals to implement best practices and improve patient safety.

In its response to the draft report, CMS also commented on OIG's sample size and on comparing the results from this study to those of the 2010 OIG report. Regarding the sample size, OIG selected the number of sampled patients to allow for national projections at the 95-percent confidence interval (see Appendix F). Regarding the comparison between reports, there are important limitations to comparing the results of this study with the prior study and therefore we did not include a comparison in our report findings. We offer a discussion of the comparison that includes its limitations beginning on page 38.

Recommendation 1: CMS concurred with the recommendation to update and broaden its lists of HACs to capture common, preventable, and high-cost harm events. CMS reported that it is considering new measures for inclusion in several CMS payment programs, including HACRP, through the annual pre-rulemaking measure selection process and subsequent rulemaking. CMS added two new measures for reporting to the Hospital Inpatient Quality Reporting Program beginning in 2023 (i.e., measures for reporting glycemic management).

Recommendation 2: CMS concurred with the recommendation to explore expanding the use of patient safety metrics in pilots and demonstrations for health care payment and service delivery, as appropriate. CMS provided two examples of models that

incorporate patient safety measures and reported that it will continue to consider new opportunities to include patient safety metrics in pilots, demonstrations, and models.

Recommendation 3: CMS concurred with the recommendation to develop and release interpretive guidance to surveyors for assessing hospital compliance with QAPI requirements to track and monitor patient harm events. In 2010, CMS concurred with a version of this recommendation. CMS reported that it is still considering the best option for updating the interpretive guidance and cited evidence that surveyors are conducting such assessments without formal guidance.

AHRQ Comments and OIG Response

AHRQ stated that it appreciates the focus the report gives to its role in promoting patient safety and reducing patient harm.

Recommendation 4: AHRQ concurred with the recommendation to coordinate agency efforts to update agency-specific Quality Strategic Plans, ensuring alignment with the priorities of HHS's National Quality Strategy. After receiving AHRQ's comments, we clarified how AHRQ might implement the recommendation, including assisting agencies in performing their own assessments as they update their Quality Strategic Plans. We anticipate that AHRQ may provide a framework for agencies to conduct their individual assessments and that it will act as the coordinating agency for these efforts across the Department.

Recommendation 5: AHRQ generally concurred with the recommendation as originally written but explained that QSRS has been fully deployed at the national level and that it is currently assessing the feasibility of automating the capture of data from medical records. In response, we revised the recommendation to reflect the current status of the system. We now recommend that AHRQ should optimize use of QSRS, including assessing the feasibility of automating data capture for national measurement and to facilitate local use. AHRQ has since concurred with this revised recommendation.

Recommendation 6: AHRQ concurred with the recommendation to develop an effective model to disseminate information on national clinical practice guidelines or best practices to improve patient safety. AHRQ reported that it will explore working with the National Steering Committee for Patient Safety, and other similar groups, to achieve this shared objective.

Recommendation 7: AHRQ concurred with the recommendation to continue efforts to identify and develop new strategies to prevent common patient harm events in hospitals. AHRQ reported that it will continue to invest in new research, tools, and projects consistent with its mission to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable; and will work within HHS and with other partners to make sure that the evidence is understood and used.

COMPARISON TO THE 2010 REPORT

Patient harm events are common and often preventable, similar to OIG's findings in the 2010 report

Our findings suggest that patient harm events continue to be widespread among Medicare patients in hospitals since the publication of our 2010 report, with an estimated 27 percent of Medicare patients experiencing harm in 2008 and an estimated 25 percent of Medicare patients experiencing harm in 2018. We conducted both studies using a similar sample size and the same general methodology. When comparing the results, we did not detect a statistically significant difference in the rates of patient harm, severity of harm events, or preventability of harm events over time, but due to sample size constraints, our ability to identify small statistical differences between those rates, or within specific types of harm, is limited.[133] Changes in the Medicare population and slight changes in the study methodology (described below) also limit the appropriateness of a comparison. Notably, reports by AHRQ and CDC indicate success in reducing specific types of harm.[134] Exhibit 12 shows the patient harm event estimates and preventability for both reports, and below we explain the differences between the two studies.

Exhibit 12: Patient Harm Event Estimates in 2008 and 2018

Incidence of Patient Harm	2008	2018
Patients Who Experienced Harm Events	**(n=780)**	**(n=770)**
Adverse event or temporary harm event	27%	25%
Adverse event	13%	12%
Temporary harm event*	13%	13%
Severity Level of Harm Events	**(n=302)**	**(n=299)**
Adverse events	42%	38%
Temporary harm events	58%	62%
Preventability of Harm Events	**(n=302)**	**(n=299)**
Preventable events	44%	43%
Not preventable events	51%	56%

Sources: OIG analysis of hospital stays for 770 Medicare patients in October 2018 and 780 Medicare patients in October 2008 (OEI-06-09-00090).
Note: Our definition of adverse events in the 2010 report included all harm events identified on the HAC and NQF lists.
* The rate of patients who experienced temporary harm events is composed of patients who experienced at least one temporary harm event and no adverse events.

Medicare data indicates that patients have higher rates of some chronic diseases since the 2010 report

To provide more context to the comparison between the two reports, we examined the proportion of Medicare patients with chronic diseases using CMS statistics from 2008 compared to 2018 (the years of data collection for both reports). (We did not assess the incidence of chronic diseases for our specific sample of patients.) Research indicates that the prevalence of comorbidities is rising in the Medicare population, and that Medicare patients are being treated for more clinically complex conditions and diagnoses than in the past.[135] Comorbidities have been tied to a higher risk of patient harm events.[136] For example, patients with chronic kidney disease may be at greater risk for harm such as acute kidney injury or insufficiency.[137] As a result, harm rates may be affected, in part, by the complexity of care required to treat a patient population with more comorbidities.

The data showed that Medicare patients tended to have more chronic diseases in 2018 than in 2008 with higher rates of comorbidities for 15 of the 21 conditions tracked by CMS.[138] According to CMS program statistics, Medicare patients had higher rates of chronic kidney disease, hyperlipidemia (elevated cholesterol), and hypertension, among others.[139] Conversely, some rates were lower for certain diseases and conditions such as ischemic heart disease and heart failure. Exhibit 13 shows selected rates of chronic diseases with some of the greatest changes among Medicare patients between 2008 and 2018.

Exhibit 13: Differences in Rates of Selected Chronic Diseases and Conditions Between 2008 and 2018 in the Medicare Patient Population

Chronic Disease or Condition	Percentage of Medicare Patients in 2008	Percentage of Medicare Patients in 2018	Difference in Rates 2008 vs 2018
Chronic kidney disease	12.3%	24.5%	+12.2%
Hyperlipidemia	41.9%	47.7%	+5.8%
Hypertension	54.9%	57.2%	+2.3%
Heart failure	16.3%	14.0%	-2.3%
Ischemic heart disease	31.0%	26.8%	-4.2%

Source: OIG analysis of CMS, "Chronic Conditions." Accessed at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main on January 28, 2021.
Note: These data include only Medicare fee-for-service patients and exclude patients enrolled in Medicare Advantage.

Changes in review process from the 2010 report

We largely replicated the methodology we used for the 2010 report, adjusting the screening process slightly—we updated the trigger tool and allowed nurses to review present-on-admission indicators as part of their review. We also expanded and

revised the clinical guidance document for reviewers to incorporate updated clinical guidance and practices. The guidance document was built on more than a decade of OIG research and experience studying adverse events.

Over time, our definitions of certain types of harm events have evolved. We now include a broader range of events resulting from omissions of care, and we updated our definition of sepsis, acute kidney injuries, and other events to be consistent with newer guidelines.[140, 141, 142, 143] We also improved our use of clinical thresholds (e.g., laboratory results or blood pressure readings) for determining harm. The same information was used to identify harm events in the prior study, but the decisions were based on group consensus about harm instead of a threshold. For example, we adopted specific guidelines, based on the patient's mean arterial blood pressure, for determining the point at which intraoperative hypotension associated with anesthesia is counted as a harm event or requires a consensus discussion.[144]

In addition to these changes to our review, some event types are now associated with different clinical categories. For example, we now consider aspiration events that lead to pneumonia as related to infection rather than patient care and now include intravenous volume overload under fluid and electrolyte disorders.

MEDICAL RECORD REVIEW METHODOLOGY

We conducted a two-stage medical record review using OIG-contracted reviewers to identify adverse events and temporary harm events experienced by hospitalized Medicare patients during October 2018. We also conducted quality assurance activities to ensure consistency and accuracy of results.

Stage 1: Nurse Screening

In the first stage, registered nurses screened all 834 admissions using the OIG-modified GTT methodology to look for "triggers" that indicated possible patient harm in the medical record. A trigger is a clinical clue (e.g., a laboratory test showing low blood glucose, or a patient care event such as a fall) that required the nurse-screener to explore the medical record to determine whether adverse or temporary harm events likely occurred. A trigger could be the harm itself, such as a pressure injury, or a reference that indicates possible harm, such as a transfer to a higher level of care. The GTT included triggers in four categories: patient care, intensive care, medication, and procedures/surgery. (See Appendix E for a list of the triggers used to identify events.)

From the Medicare claims data, nurses also reviewed POA indicators of "N" (not POA) or "U" (documentation insufficient to determine) as additional clinical clues for possible patient harm. As part of Medicare payment policies required under the DRA, CMS requires hospitals to include POA indicator codes on claims to discern whether each diagnosis was present at the time of admission.

When nurses identified possible patient harm events during the hospital stays, they flagged them for the second stage of review. For each possible event, the nurse-screeners recorded a description of the event, the level of harm, and the relevant evidence in the medical record. The flagged records could include more than one possible harm event. When nurses did not identify possible patient harm, a quality assurance reviewer re-screened the records to verify the nurses' results. In total, nurses and quality assurance reviewers flagged 244 admissions (220 from nurse review and 24 from quality assurance review). We automatically referred 149 admissions (among those not already flagged by a nurse) for patients who were readmitted within 30 days of discharge (these include readmissions in October and November 2018).

Stage 2: Physician Review

In the second stage, physicians reviewed the complete medical record for each of the 393 admissions flagged during Stage 1. Physicians either confirmed or refuted the presence of patient harm events using evidence in the record and independently

identified any additional events. For each harm event, physician-reviewers used their clinical expertise and followed a structured protocol requiring them to assess the following:

Clinical Category. Physician-reviewers classified each event under one of four clinical categories: medication, infection, patient care, and surgery or procedure. Medication-related events were those that involved adverse reactions to medication. Infection-related events included health care-associated infections acquired during the hospital stay. Patient care-related events included harm occurring during the daily care of patients and were not related to the other clinical categories. Surgery or procedure-related events included harm or complications attributed to the surgery or procedure and adverse reactions to medications (e.g., anesthesia) required during the operation.

Harm Event Lists. Physician-reviewers determined whether each event qualified as an event on CMS's lists of HACs or NQF's list of SREs (events could qualify for more than one list). For the NQF list, we re-reviewed each event to confirm whether it qualified for the list. For the CMS DRA HAC list, we confirmed whether each event met the criteria for this list based on the claims data and checked if hospitals did not code for diagnoses and procedures related to the harm event. For the CMS HACRP list, we requested that AHRQ review each admission's claims data to detect HACs using its patient safety indicators software and we had an NHSN specialist confirm the HAIs on this list. We then independently confirmed whether events fell on this list from these reviews.

Preventability. Physicians assigned each event to one of five preventability determinations and identified one or more factors that contributed to each event. (See the preventability scale in Exhibit 14.) Physicians also explained their rationale for each harm event determination based on a list of 24 contributing factors gleaned from prior research and experience in OIG studies of adverse events.[145]

Exhibit 14: Preventability Scale and Descriptions

Preventability Determination	Description
Clearly preventable	Patient harm could definitely have been avoided through improved assessment or alternative actions.
Likely preventable	Patient harm could have been avoided through improved assessment or alternative actions.
Likely not preventable	Patient harm could not have been avoided given the complexity of the patient's condition or the care required.
Clearly not preventable	Patient harm could definitely not have been avoided given the complexity of the patient's condition or the care required.
Unable to determine	Physicians were unable to determine preventability because of incomplete documentation or case complexity.

Contributing factors varied depending on the circumstances of each event. For example, preventable events may be related to substandard treatment, medical error, and inadequate monitoring depending on the factors involved. Events that are not preventable may be related to a patient's diagnosis or treatment being unusual or complex and thereby making care difficult, or a patient being highly susceptible to harm because of poor health. These factors are not necessarily exclusive of each other and their definitions are often subjective. For example, substandard care generally refers to the failure to adhere to professional standards of practice in the delivery of care, but practitioners may not always agree on what this includes, and their determination depends on the strength of the evidence available to substantiate whether a patient received substandard care.

As a result, preventability determinations are necessarily subjective and required the physicians to use clinical experience and judgment. Physicians based decisions on the circumstances of the specific case and also considered accepted standards of care; the expected frequency of certain events; guidance developed during the review process; and group discussion of the patients and events. Physicians were allowed to choose multiple contributing factors for the rationale behind their determinations.

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* into the larger categories of *preventable* or *not preventable*.

The physician-reviewers represented a variety of specializations and experience, including a hospitalist and cardiology, infectious disease, internal medicine, orthopedics, neurology, rehabilitation, intensive care, emergency medicine, and pulmonology. Three of the six had served as physician-reviewers in prior OIG studies of adverse events. In addition to our physician-reviewers, a seventh physician, also contracted by OIG, was our lead physician, having extensive experience with OIG's prior adverse event studies and the GTT methodology. The lead physician was involved in training physicians in reviewing records and engaging in quality assurance reviews of physicians' reviews.

Severity of Event. As in prior OIG studies, physician-reviewers assigned each event to one of five levels of harm using an OIG-modified version of the NCC MERP Index. We separately identify "temporary harm events" (level E on the index) because the effect of these events was typically not comparable to the more severe "adverse events" (levels F through I on the index). In addition, we use the term "patient harm events" as a combination of both adverse events and temporary harm events because both types represent harm resulting from medical care. (See Exhibit 2 on page 13.)

Medical Coder Reviews

Certified medical coders reviewed all patient harm events identified by the physicians to identify potential costs incurred to Medicare because of these events. To do this, coders reviewed the medical records, physician findings, and the associated Medicare

claims to identify diagnosis and procedure codes that would not have been included in the claim if the event(s) had not occurred. The coders then used the TruCode Encoder software to determine the revised MS-DRG for the hospital claims and the resulting payment amounts.[146] To simplify the review process, coders treated claims paid through managed care or Maryland's payment system the same as IPPS claims.

Efforts To Improve Consistency and Quality of Reviews

To promote consistency and accuracy across reviews, we issued a study-specific guidance document for improved decision making, we provided training to all clinician reviewers and certified medical coders, we facilitated consensus calls with the physician-reviewers, and we conducted quality assurance reviews of nurse reviews, physician reviews, and coder reviews.

Guidance Document. We provided reviewers with a guidance document that included event definitions, considerations for specific types of events, and a list of frequently asked questions. We created the guidance document to align with clinical research literature, professional and government guidelines (such as evidence-based practices), and decisions made in prior OIG studies; and consultations with subject-matter experts. The document also provides instructions that are applicable to a wide range of events, including how to assess event timing, underlying disease, related events, and recurring events:

- **Present on admission (POA)**—We excluded events that occurred before the patient entered the hospital or that were attributable to care provided prior to admission.
- **Underlying disease**—We excluded events that were part of the underlying disease process unless there was an omission of care resulting in an exacerbation of the underlying disease.
- **Related events**—When an initial event caused a series of related and dependent events, we combined the events into a "cascade" event and counted it as a single event.
- **Multiple similar events**—When a patient experienced multiple similar events during a hospital stay (e.g., multiple episodes of hypoglycemia), we counted these as separate events with some exceptions. We collapsed multiple hypoglycemic events within 24 hours into a single event and counted recurrences after 24 hours as separate events. We collapsed multiple pressure injuries into a single event when the pressure injury was: (1) at the same anatomical site and (2) occurred within 24 hours of the initial pressure injury. We counted pressure injuries at different anatomical sites as separate events even if they occurred within 24 hours of one another.

Trainings. We conducted several training sessions for each reviewer type (nurses, physicians, and coders) to train them on our study protocols and practices, harm identification techniques, use of the database, and our guidance document. Prior to

beginning reviews, each reviewer performed pre-test reviews and received feedback on the results of those reviews.

Consensus Calls. We facilitated 10 conference calls to further promote consistency across physician-reviewers. During these calls, physician-reviewers discussed events that were complex, difficult to assess, involved issues outside their area of expertise, or had possible implications for other cases. Patient harm events were directly taken to consensus calls when events were determined to have contributed to or resulted in death; events in which the reviewer was unable to provide a preventability assessment (i.e., unable to determine); and for cases with a series of related harm events (termed "cascade"). Physicians were also encouraged to bring cases to group discussion at their discretion. Some cases were also discussed between physician-reviewers and the lead physician. We documented the discussions and conclusions made during these weekly calls to further promote consistency.

Quality Assurance Reviews. Our clinicians and coders conducted quality assurance reviews for each type of review to gauge accuracy and adherence to the protocols throughout the study. We selected admissions for these quality assurance reviews based on prior experience and data anomalies identified during preliminary analysis. The quality assurance reviews for the GTT screening included all admissions not referred to a physician-reviewer; 29 admissions that received physician review; and 113 admissions that received coding review. In addition to these quality assurance reviews, we also referred certain health care-associated infections to an infection prevention nurse specialist (with expertise in NHSN guidelines) to assess physician-reviewer determinations of these type of events. We also conducted extensive checks of the events for consistency in preventability determinations and event categorization; reassessed whether events qualified under CMS's HAC lists and NQF's SRE list; and identified and reassessed outlier cases.

APPENDIX A

National Quality Forum List of Serious Reportable Events

The NQF list of SREs is separated into seven categories. The term "serious" describes loss of a body part, disability, or loss of bodily function lasting more than 7 days or that is still present at time of discharge from an inpatient health care facility or, when referring to other than an adverse event, an event whose occurrence is not trivial.[147] The list was last updated in 2011 and reflected several changes from the prior version, including the retirement of three care-management events and the addition of four new events.[148] Exhibit A-1, on the next page, shows the NQF SRE list that we used for this report's analysis.

Patient Harm Events on the NQF List

One harm event within our sample was on NQF's list of SREs. This event involved a patient who was hospitalized for hip replacement surgery. The patient was left unattended following surgery and fell in the bathroom, which resulted in a new fracture requiring additional surgery. Our physician-reviewers determined that this event was clearly preventable because the patient was at high risk for a fall and should not have been left unattended in the bathroom.

The rest of the events that we identified were not on NQF's list of SREs because this list focuses primarily on a small number of events that result in serious injury or death. Although we identified events that were similar in type, these events did not result in disability or death, and thus did not qualify for this list. For example, we identified several patients who were injured as a result of a fall in a hospital. However, none of these falls resulted in serious injury or death, except for the hip fracture we identified. NQF also adds other restrictions to certain event types, such as with pressure injuries. Although we identified 22 pressure injuries, none of these pressure injuries qualified because NQF includes only severe pressure injuries (Stage 3, Stage 4, and unstageable) for reporting on the NQF list.

Exhibit A-1: The NQF List of Serious Reportable Events

Surgical or Invasive Procedure Events

A. Surgery or other invasive procedure performed on the wrong site
B. Surgery or other invasive procedure performed on the wrong patient
C. Wrong surgical or other invasive procedure performed on a patient
D. Unintended retention of a foreign object in a patient after surgery or other invasive procedures performed
E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient[149]

Product or Device Events

A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the health care setting
B. Patient death or serious injury associated with use or function of a device in patient care, in which the device is used or functions other than as intended
C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care setting

Patient Protection Events

A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
B. Patient death or serious injury associated with patient elopement (disappearance)
C. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a health care setting

Care Management Events

A. Patient death or serious injury associated with a medication error
B. Patient death or serious injury associated with unsafe administration of blood products
C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting
D. Death or serious injury associated with neonate associated with labor or delivery in a low-risk pregnancy
E. Patient death or serious injury associated with a fall while being cared for in a health care setting
F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a health care setting
G. Artificial insemination with the wrong donor sperm or wrong egg
H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

Environmental Events

A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a health care setting
B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances
C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a health care setting

Continued From Previous Page

D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a health care setting

Radiologic Events

A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the magnetic resonance imaging (MRI) area

Potential Criminal Events

A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
B. Abduction of a patient/resident of any age
C. Sexual abuse/assault on a patient or staff member within or on the grounds of a health care setting
D. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care setting

Source: NQF, *List of Serious Reportable Events*. Accessed at https://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx on April 22, 2021.

APPENDIX B

HHS Agency Efforts To Improve Quality and Safety in Hospitals

HHS is tasked with leading the Nation in promoting quality health care and preventing patient harm. As such, each agency within HHS contributes to the National Quality Strategy and the HAI and ADE action plans while pursuing their own goals to improve quality and safety. The roles of CMS, AHRQ, and CDC are described on pages 5 to 11. Additional information about these agencies efforts to reduce patient harm and improve quality and safety is below.

CMS Programs To Track and Prevent Adverse Events

CMS Pay-for-Performance Programs. CMS has multiple programs and initiatives beyond the DRA HAC payment provision and HACRP's payment adjustments. These other efforts include the Hospital Readmissions Reduction Program (HRRP) and the Hospital Value-Based Purchasing (HVBP) program, both authorized under the ACA.[150] HRRP reduces payments to hospitals with a high number of readmissions for six conditions and procedures.[151] HVBP rewards high-quality care with financial incentives. This program measures hospital performance on six outcomes, including patient safety, and those with the highest scores and most improvement receive a payment adjustment on each claim as an incentive to deliver safer care.[152] These programs build on CMS's agency-specific national quality strategy, released in 2016, which focused on leveraging CMS's unique authorities to improve quality of care and patient safety nationwide.[153]

CMS Data Collection of Quality Measures. To track harm events, CMS collects data on quality measures from care provided in hospitals and other health care facilities. CMS highlighted patient safety as a quality measurement priority in its triennial *National Impact Assessment of CMS Quality Measures* report to address gaps and inform future measurement development.[154] CMS promotes transparency of quality measurement data collected from the Hospital Inpatient Quality Reporting Program through its consumer-oriented Care Compare website (formerly on Hospital Compare).[155, 156] Care Compare aggregates information on patient outcomes, including HAIs and other complications, and the provision of care in U.S. hospitals and other health care facilities, such as the use of recommended practices and patient survey results.[157] It is intended as a tool for consumers to make informed health care decisions and to support efforts to improve quality of care.

CMS also manages electronic clinical quality measures (eCQMs), such as certain patient safety metrics, under the Hospital Inpatient Quality Reporting Program and the Promoting Interoperability Programs (formerly the Medicare and Medicaid Electronic Health Record Incentive Programs).[158] Under these programs, providers are

required to demonstrate meaningful use of certified electronic health record technology, including the reporting of eCQMs.[159]

CMS Quality Improvement Initiatives. CMS maintains numerous initiatives aimed at improving quality of care. The CMS Innovation Center, authorized under the ACA, focuses on designing, implementing, and testing new health care payment and service delivery models to improve quality of care and address rising health care costs.[160] CMS also funds contracts to create support networks that spread best practices and prevent adverse events. CMS-funded Quality Improvement Organizations (QIOs) bring together patients, providers, and communities into Quality Improvement Networks to spread best practices for better care, including preventing adverse events.

AHRQ Programs To Track and Prevent Adverse Events

AHRQ Tools To Track Harm Events. AHRQ maintains tools to help hospitals track harm events and learn from these events. AHRQ makes available free Patient Safety Indicators software that hospitals can use with their existing administrative data to track potential adverse events and other complications.[161] AHRQ also developed common definitions (known as the Common Formats) for PSOs working with hospitals and other providers.[162] The AHRQ Common Formats make it possible to collect, aggregate, and analyze uniformly structured information about patient safety events for local, regional, and national learning. The AHRQ Common Formats are available in the public domain to encourage their widespread adoption, but the privilege and confidentiality protections available under the Patient Safety Act only apply to information created as patient safety work product by providers working with federally listed PSOs.[163, 164] AHRQ also maintains a Network of Patient Safety Databases under the PSO program to enable learning on a national scale about the causes of harm events.[165]

AHRQ Patient Safety Resources. AHRQ works to improve the quality and safety of the health care system through research and implementation of evidence-based practices. AHRQ provides resources such as strategies and tools to reduce specific types of adverse events. These resources include a range of toolkits, education, and trainings for providers to improve patient safety such as the CUSP method and HAI resources and toolkits.[166] Until 2018, AHRQ managed the National Guideline Clearinghouse, which was a public resource website for summaries on evidence-based clinical practice guidelines.[167] Another program, the National Quality Measures Clearinghouse, is no longer managed by AHRQ. Instead, these measures are provided by CMS's Measure Inventory Tool, which provides information on measures that CMS uses to promote health care quality.[168] AHRQ also publishes a series of reports, *Making Healthcare Safer*, that detail existing and emerging evidence-based patient safety practices for reducing certain patient harm events.[169]

CDC Programs To Track and Prevent Adverse Events

CDC HAI Surveillance Initiatives. CDC has several surveillance initiatives to track and prevent HAIs. NHSN is a HAI surveillance system with more than 25,000 participating medical facilities, including hospitals. NHSN provides real-time data to these facilities, enabling them to track medical events such as HAIs and blood safety errors, and assists with State and Federal reporting mandates.[170] CDC also monitors HAIs through its Emerging Infections Program's Healthcare-Associated Infections–Community Interface—a collaboration with a network of State health departments and their academic medical center partners.[171] This program provides population-based data and detailed patient-level information to evaluate the epidemiology and public health impact of HAIs and antimicrobial resistance.

CDC Quality Improvement Initiatives. CDC has several initiatives focused on preventing HAIs and improving quality of care nationwide, including providing support to HAI programs in all State and several large local health departments to detect, prevent, respond to, and contain HAIs and antimicrobial pathogens.[172] CDC has developed resources and strategies to prevent HAIs such as the Targeted Assessment for Prevention (TAP) Strategy as a framework for quality improvement.[173] CDC also manages the Prevention Epicenters Program, a network of academic centers with which CDC performs collaborative research on the epidemiology and prevention of HAIs.[174] In addition, in 2011 CDC formed the Safety and Healthcare Epidemiology Prevention Research Development program, which provides a mechanism for developing and implementing HAI prevention research on a contractual basis.[175] Finally, CDC's Modeling Infectious Diseases in Healthcare Network supports research that models the spread of HAIs and antibiotic resistant infections and it includes six centers that collaborate to study the transmission of health care-associated pathogens and evaluate the effect of prevention measures.[176]

APPENDIX C

CMS Lists of Hospital-Acquired Conditions

The Centers for Medicare & Medicaid Services (CMS) maintains two lists of hospital-acquired conditions (HACs), one related to the Deficit Reduction Act of 2005 (DRA) and another related to the Hospital-Acquired Conditions Reduction Program (HACRP).

The DRA list of HACs includes 14 conditions. The original list, issued in fiscal year (FY) 2009, had 10 conditions. The list was last updated in FY 2013, at which time CMS added two new conditions. In a prior update, CMS separated surgical site infections into three conditions. Exhibit C-1 shows the current DRA list of HACs used for this report's analysis.

The HACRP list of HACs consists of 2 types of measures: a composite measure consisting of 10 patient safety indicators (PSIs) collected by the Agency for Healthcare Research and Quality (AHRQ), and 5 health care-associated infections (HAIs) collected by the National Healthcare Safety Network (NHSN). CMS's PSI composite is based on a pooled measure of 10 weighted PSIs. CMS has recalibrated the PSI and HAI measures for Medicare fee-for-service claims and the acute-care hospital setting. The list was last updated in FY 2017. Exhibit C-2 shows the current HACRP list of HACs used for this report's analysis.

Exhibit C-1: The DRA HAC List

Hospital-Acquired Condition
1. Foreign object retained after surgery
2. Air embolism
3. Blood incompatibility
4. Pressure ulcers Stages 3 and 4
5. Falls and trauma A. Fractures B. Dislocations C. Intracranial injuries D. Crushing injuries E. Burn F. Other injuries

6. Manifestations of poor glycemic control A. Diabetic ketoacidosis B. Nonketotic hyperosmolar coma C. Hypoglycemic coma D. Secondary diabetes with ketoacidosis E. Secondary diabetes with hyperosmolarity
7. Catheter-associated urinary tract infection
8. Vascular catheter-associated infection
9. Surgical site infection, mediastinitis, following coronary artery bypass graft
10. Surgical site infection following certain bariatric surgical procedures for obesity A. Laparoscopic gastric bypass B. Gastroenterostomy C. Laparoscopic gastric restrictive surgery
11. Surgical site infection following certain orthopedic procedures involving the: A. Spine B. Neck C. Shoulder D. Elbow
12. Surgical site infection following cardiac implantable electronic device
13. Deep vein thrombosis/pulmonary embolism following certain orthopedic procedures: A. Total knee replacement B. Hip replacement
14. Iatrogenic pneumothorax with venous catheterization

Source: CMS, "Hospital Acquired Conditions." Accessed at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions on April 30, 2021.

Exhibit C-2: The HACRP List of HACs

CMS Patient Safety Indicator Composite	
PSI 03	Pressure ulcer rate
PSI 06	Iatrogenic pneumothorax rate
PSI 08	In-hospital fall with hip fracture rate
PSI 09	Perioperative hemorrhage or hematoma rate
PSI 10	Postoperative acute kidney injury requiring dialysis
PSI 11	Postoperative respiratory failure rate

PSI 12	Perioperative pulmonary embolism or deep vein thrombosis rate
PSI 13	Postoperative sepsis rate
PSI 14	Postoperative wound dehiscence rate
PSI 15	Unrecognized abdominopelvic accidental puncture/laceration rate
NHSN Healthcare-Associated Infections	
CLABSI	Central line-associated bloodstream infection
CAUTI	Catheter-associated urinary tract infection
SSI	Surgical site infection (colon and hysterectomy)
MRSA	Methicillin-resistant *Staphylococcus aureus* bacteremia
C. diff	*Clostridioides difficile* infection

Source: CMS, "Hospital-Acquired Condition (HAC) Reduction Program," last modified in July 2018. Accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HAC/Hospital-Acquired-Conditions.html on April 22, 2021.

APPENDIX D

Glossary of Selected Terms

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

Acute encephalopathy—An acute or subacute global, functional alteration of the mental status due to systemic factors.

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

Acute renal insufficiency—Poor functioning of the kidneys because of reduced blood flow to them. May progress to acute kidney failure.

Adverse event—Harm to a patient as a result of medical care or in a health care setting, including the failure to provide needed care. (Adverse events are Levels F through I on the OIG-modified NCC MERP Index.)

Ampullary stenosis—The narrowing of the ampulla of Vater (the small opening that enters into the first portion of the small intestine, known as the duodenum), which can lead to a bile duct blockage.

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

Anesthesia—Medicines used to prevent pain during surgery and other procedures. Local anesthesia numbs a small part of the body. Regional or epidural anesthesia numbs larger areas of the body such as an arm or leg, or below the waist. General anesthesia affects the whole body.

Angioplasty—A procedure used to open clogged heart arteries.

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

Arthroplasty—A surgical procedure to restore the function of a joint.

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

Aspiration—Accidental inhalation of foreign material into the lungs.

Atrial fibrillation—A quivering or irregular heartbeat that can lead to blood clots, stroke, heart failure, or other heart-related complications.

Autoimmune hepatitis—A disease in which the immune system attacks the liver.

Bradycardia—A slower than normal heart rate.

Cascade—A chain of events initiated by an unexpected result or other incident that may result in patient harm.

Catheter-associated urinary tract infection (CAUTI)—An infection involving any part of the urinary system, including urethra, bladder, ureters, and kidney, that is associated with a urinary catheter, which is a tube inserted into the bladder through the urethra to drain urine.

Central line-associated bloodstream infection (CLABSI)—A serious infection that occurs when germs (usually bacteria or viruses) enter the bloodstream through the central line. This is a type of vascular catheter-associated infection.

***Clostridioides difficile* (*C. diff*)**—A bacterium that can cause symptoms ranging from diarrhea to life-threatening inflammation of the colon.

Colonoscopy—An exam used to detect changes or abnormalities in the large intestine (colon) and rectum.

Comorbidity—When more than one disease or condition is present in the same person at the same time. Conditions described as comorbidities are often chronic or long-term conditions.

Delirium—A mental disturbance characterized by acute confusion, disordered speech, and/or hallucinations.

Dementia—A group of symptoms affecting memory, thinking, and social abilities severely enough to interfere with daily life.

Dysphagia—The condition of having difficulty swallowing.

Fluid and electrolyte balance—Electrolytes are minerals in the body, such as sodium and potassium, that have an electric charge and are in body fluids. Maintaining the right balance of electrolytes helps maintain normal biochemical and physiologic functions.

Gastric sleeve resection—A type of bariatric surgery used to permanently reduce the size of the stomach.

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

Hematoma—A pool of clotted or partially clotted blood in an organ, tissue, or body space, usually caused by a broken blood vessel.

Hernia—When an internal organ pushes through a weak spot in the muscle or tissue.

Hyperkalemia—The condition of having elevated potassium levels in the blood.

Hypertension—The condition of having abnormally high blood pressure.

Hypoglycemia—The condition of having abnormally low level of blood sugar (glucose).

Hypotension—The condition of having abnormally low blood pressure.

Hysterectomy—A surgery to remove all or part of the uterus.

Ileus—A lack of normal muscle contractions of the intestines, marked by bloating, cramps, nausea, vomiting, and severe constipation.

Intensive care unit (ICU)—A specialized hospital or hospital department that provides critical care and life support for acutely ill and injured patients.

Intravenous contrast agents—Iodine and gadolinium-based substances that are injected into a vein and are used to improve pictures of the inside of the body produced by x-rays, computed tomography, and magnetic resonance imaging.

Intravenous infiltration—A situation in which fluids administered by entering a vein accidentally enter the surrounding tissue.

Laminectomy—A type of surgery in which a surgeon removes part or all of the vertebral bone.

Methicillin-resistant *Staphylococcus aureus* (MRSA)—A type of staph bacteria that is resistant to several antibiotics used to treat ordinary staph infections.

Methicillin-susceptible *Staphylococcus aureus* (MSSA)—A type of staph bacteria that responds well to antibiotics used to treat staph infections.

Naloxone—A life-saving drug that can reverse the effects of an opioid overdose when administered in time.

Opioid—A class of drugs most often prescribed to treat moderate to severe pain, notable for their addictive potential.

Patient harm event—Any harm to a patient as a result of medical care. This term encompasses both adverse events (Levels F through I on the OIG-modified NCC MERP Index) and temporary harm events (Level E on this index).

Pneumonia—An infection that inflames the air sacs in one or both lungs.

Pneumothorax—A collapsed lung that occurs when air leaks into the space between the lung and chest wall.

Pressure injury—Ulceration of tissue deprived of adequate blood supply by prolonged pressure, also called decubitus ulcer or bedsore. Pressure injuries are classified into four stages: Stage 1 is intact skin with nonblanchable redness; Stage 2 is a shallow ulcer or blister indicating damage to the epidermis; Stage 3 is damage extending through all layers of the skin; and Stage 4 is damage through all the layers of the skin and underlying muscle, tendons, or bone. Unstageable pressure injuries are when the extent of the tissue damage cannot be confirmed because it is obscured

by slough or eschar. Deep tissue pressure injuries are persistent nonblanchable deep red, maroon, or purple discoloration of the skin revealing a dark wound or blood-filled blister.[177]

Pulmonary edema—Abnormal accumulation of fluid in the lungs.

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

Pulseless electrical activity—A condition characterized by unresponsiveness and impalpable (unable to be felt) pulse in the presence of sufficient electrical discharge.

Refeeding syndrome—The potentially fatal shifts in fluids and electrolytes that may occur in malnourished patients receiving artificial refeeding.

Sepsis—A life-threatening organ dysfunction caused by a dysregulated host response to infection.

Septic shock—A subset of sepsis with circulatory and cellular/metabolic dysfunction associated with a higher risk of mortality.

Temporary harm—Harm to a patient that required intervention but did not cause lasting harm or prolong the hospital stay. Classified as Level E on the OIG-modified NCC MERP Index.

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

Total parenteral nutrition—A method of feeding that bypasses the gastrointestinal tract.

Transcatheter aortic valve replacement—A minimally invasive procedure to replace a narrowed aortic valve that fails to open properly.

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

Vascular catheter-associated infection—An infection associated with a catheter used for vascular access and placement.

Vasopressors—A group of medications that tighten blood vessels and raise blood pressure.

Ventilator-associated pneumonia—A lung infection that develops in a person who is on a ventilator. A ventilator is a machine that is used to help a patient breathe by giving oxygen through a tube placed in a patient's mouth or nose, or through a hole in the front of the neck. An infection may occur if germs enter through the tube and get into the patient's lungs.

APPENDIX E

Trigger Tool Used To Screen for Patient Harm Events

OIG and its contracted clinical consultants developed an OIG-modified trigger tool to screen for patient harm events specific to acute-care hospital stays based on the Institute for Healthcare Improvement's (IHI's) global trigger tool (GTT). The 2010 OIG report on adverse events used this as a method to screen records for harm events. For this study, we modified the trigger tool by reviewing and selecting triggers from the IHI GTT and from triggers that were included in prior OIG studies of adverse events. See Exhibit E-1 for the list of triggers used by clinicians to screen medical records for potential patient harm events.

Exhibit E-1: OIG-Modified Trigger Tool Worksheet

Care Triggers	
C1	Acute mental status change
C2	Transfusion or use of blood products
C3	Code/arrest/rapid response team
C4	Acute dialysis
C5	Positive culture (e.g., blood, urine, stool)
C6	Studies for emboli, pulmonary embolism (PE) or deep vein thrombosis (DVT) such as D-Dimer, computerized tomography (CT) pulmonary angiogram (CTPA), or lung ventilation-perfusion scan
C7	Abrupt or significant decrease in hemoglobin or hematocrit
C8	Patient fall or other trauma
C9	Pressure injury/skin breakdown from medical device
C10	Readmission within 30 days
C11	Restraint use
C12	Hospital-acquired infections
C13	In-hospital stroke/transient ischemic attack (TIA)
C14	Transfer to higher level of care
C15	Any procedure complication
C16	Urinary retention
C17	Aspiration
C18	Care – other

Medication Triggers	
M1	*Clostridioides difficile* positive stool test
M2	Partial thromboplastin time greater than (>) 100 seconds
M3	International normalized ratio (INR) greater than (>) 6
M4	Glucose less than (<) 50 mg/dL
M5	Rising blood urea nitrogen (BUN) or serum creatinine greater than (>) 2 times baseline
M6	Vitamin K, Factor Xa reversal agents (andexanet alfa, idarucizumab administration)
M7	Diphenhydramine use
M8	Flumazenil use
M9	Naloxone use
M10	Anti-emetic use
M11	Abrupt decrease in blood pressure
M12	Abrupt medication stop
M13	Sodium polystyrene (kayexalate administration) or potassium greater than or equal to (≥) 6 mEq/L
M14	Abnormal drug levels
M15	Medication – other
Surgical Triggers	
S1	Unplanned return to surgery
S2	Unplanned change in procedure
S3	Unplanned admission to intensive care post-operation
S4	Intubation/reintubation/bilevel positive airway pressure (BiPAP) in post anesthesia care unit (PACU)
S5	Unplanned x-ray/CT scan/magnetic resonance imaging (MRI) or other imaging intraoperatively or in PACU
S6	Intraoperative or postoperative death
S7	Mechanical ventilation greater than (>) 24 hours postoperatively
S8	Intra-operative epinephrine, norepinephrine, naloxone, or flumazenil
S9	Abnormal postoperative troponin level, including sensitive or highly sensitive troponin I or troponin T
S10	Injury, unplanned repair or removal of organ
S11	Operative complication – other
Intensive Care Unit Triggers	
I1	Hospital-acquired pneumonia onset
I2	Readmission or unplanned admission to intensive care
I3	In-unit procedure
I4	Intubation/reintubation
I5	Intensive care unit—other

APPENDIX F

Estimates, Confidence Intervals, and Key Statistics

The estimates included in this report are based on a sample of 770 Medicare patients discharged from short-term acute-care hospitals in October 2018. The resulting incidence rates were projected to the population of 1,076,344. Below, we present the corresponding 95-percent confidence intervals. Exhibit F-1 provides patient-level estimates, Exhibit F-2 provides event-level estimates, Exhibit F-3 provides the estimates of preventability rationales assigned to events by physician-reviewers, Exhibit F-4 provides the estimates and statistical test results for the preventability analysis, Exhibit F-5 provides estimates of Medicare costs associated with harm events, and Exhibit F-6 provides estimates of patients who experienced harm events with associated Medicare costs by IPPS status.

Exhibit F-1: Patient-Level Estimates, Confidence Intervals, and Key Statistics (n=770)

Estimate Description	Number of Patients in Sample	Estimated Percentage of Patients	95-Percent Confidence Interval		Estimated Number of Patients	95-Percent Confidence Interval	
			Lower Bound	Upper Bound		Lower Bound	Upper Bound
Patients Who Experienced Adverse Events and/or Temporary Harm Events							
At least one adverse event or temporary harm event	192	24.94%	22.00%	28.12%	258,323	226,412	290,233
More than one adverse event or temporary harm event	64	8.31%	6.56%	10.49%	86,108	65,837	106,378
An adverse event and temporary harm event*	31	4.03%	2.84%	5.67%	41,708	27,288	56,129
A preventable adverse event or temporary harm event	102	13.25%	11.03%	15.83%	137,234	112,313	162,155
Patients Who Experienced Adverse Events							
At least one adverse event	90	11.69%	9.60%	14.16%	121,089	97,479	144,698
More than one adverse event*	18	2.34%	1.48%	3.68%	24,218	13,137	35,299
Adverse event only	59	7.66%	5.98%	9.77%	79,380	59,852	98,909
A preventable adverse event	49	6.36%	4.84%	8.33%	65,926	48,010	83,842
A preventable adverse event only*	39	5.06%	3.72%	6.86%	52,472	36,382	68,562
An adverse event that contributed to or resulted in death (I-level harm)*	11	1.43%	0.79%	2.56%	14,800	6,099	23,501

Estimate Description	Number of Patients in Sample	Estimated Percentage of Patients	95-Percent Confidence Interval		Estimated Number of Patients	95-Percent Confidence Interval	
			Lower Bound	Upper Bound		Lower Bound	Upper Bound
Patients Who Experienced Temporary Harm Events							
At least one temporary harm event	133	17.27%	14.76%	20.11%	178,942	151,124	206,760
More than one temporary harm event*	37	4.81%	3.50%	6.57%	49,781	34,088	65,474
Temporary harm only	102	13.25%	11.03%	15.83%	137,234	112,313	162,155
A preventable temporary harm event	63	8.18%	6.44%	10.34%	84,762	64,637	104,887
A preventable temporary harm only	53	6.88%	5.29%	8.91%	71,308	52,724	89,891

Source: Office of Inspector General analysis of hospital stays for 770 Medicare patients in October 2018.
* The 95-percent confidence intervals for projected number of patients exceed 30-percent relative precision.

Exhibit F-2: Event-Level Estimates, Confidence Intervals, and Key Statistics

Estimate Description	Number in Sample	Percentage Estimate	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Adverse Events and/or Temporary Harm Events (n=299)				
Adverse events	115	38.46%	32.63%	44.29%
Temporary harm events	184	61.54%	55.71%	67.37%
Preventability of Events				
Preventable events	128	42.81%	36.99%	48.63%
Clearly preventable events	14	4.68%	2.26%	7.11%
Likely preventable events	114	38.13%	32.49%	43.77%
Not preventable events	168	56.19%	50.33%	62.04%
Clearly not preventable events	9	3.01%	1.08%	4.94%
Likely not preventable events	159	53.18%	47.52%	58.84%
Unable to determine preventability of events**	3	--	--	--
Clinical Category of Events				
Medication-related events	130	43.48%	37.80%	49.15%
Patient care-related events	69	23.08%	18.09%	28.07%
Surgery/Procedure-related events	67	22.41%	17.16%	27.65%
Infection-related events	33	11.04%	7.38%	14.69%
F-level harm—Prolonged hospital stay	85	28.43%	22.88%	33.98%
Event on NQF SRE list**	1	--	--	--
Event on DRA HAC list	5	1.67%	0.27%	3.08%
Event on HACRP-HAC list	14	4.68%	2.08%	7.29%

Estimate Description	Number in Sample	Percentage Estimate	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Adverse Events and/or Temporary Harm Events within Each Clinical Category				
Medication (n=130)				
Preventable medication-related events	55	42.31%	33.55%	51.07%
Not preventable medication-related events	74	56.92%	48.14%	65.70%
Patient Care (n=69)				
Preventable patient care-related events*	36	52.17%	41.49%	62.86%
Not preventable patient care-related events*	33	47.83%	37.14%	58.51%
Surgery/Procedure (n=67)				
Preventable surgery/procedure-related events*	17	25.37%	14.83%	35.91%
Not preventable surgery/procedure-related events*	48	71.64%	60.20%	83.09%
Infection (n=33)				
Preventable infection-related events***	20	--	--	--
Not preventable infection-related events***	13	--	--	--
Adverse Events (n=115)				
Preventability of Adverse Events				
Preventable adverse events	52	45.22%	36.33%	54.11%
Not preventable adverse events	61	53.04%	43.91%	62.17%
Unable to determine preventability of adverse events**	2	--	--	--
Clinical Category of Adverse Events				
Medication-related adverse events	47	40.87%	31.38%	50.36%
Patient care-related adverse events	15	13.04%	6.78%	19.31%
Surgery/Procedure-related adverse events	32	27.83%	19.53%	36.12%
Infection-related adverse events	21	18.26%	11.50%	25.02%
Harm Level of Events				
F-level harm—Prolonged hospital stay	85	73.91%	65.97%	81.85%
G-level harm—Permanent patient harm	11	9.57%	3.94%	15.19%
H-level harm—Life-saving intervention required	8	6.96%	2.32%	11.59%
I-level harm—Contributing to or resulting in death	11	9.57%	4.11%	15.02%
F-Level Harm Results (n=85)				
Prolonged the patients' stay*	51	60.00%	49.11%	70.89%
Elevated the patients' level of care	13	15.29%	7.91%	22.67%
Resulted in a subsequent admission*	18	21.18%	10.86%	31.49%

Estimate Description	Number in Sample	Percentage Estimate	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Other**	3	--	--	--
Temporary Harm Events (n=184)				
Preventability of Temporary Harm Events				
Preventable temporary harm events	76	41.30%	34.03%	48.58%
Not preventable temporary harm events	107	58.15%	50.87%	65.44%
Unable to determine preventability of temporary harm events**	1	--	--	--
Clinical Category of Temporary Harm Events				
Medication-related temporary harm events	83	45.11%	37.61%	52.61%
Patient care-related temporary harm events	54	29.35%	22.25%	36.45%
Surgery/Procedure-related temporary harm events	35	19.02%	12.84%	25.20%
Infection-related temporary harm events	12	6.52%	2.71%	10.34%

Source: Office of Inspector General analysis of hospital stays for 770 Medicare patients in October 2018.
* The 95-percent confidence intervals for projected proportion of harm events exceed 10-percent absolute precision.
** We are unable to reliably project the proportion for this item because of the small number of sample occurrences.
*** We are unable to reliably project the proportion for this item because of the small sample size.

Exhibit F-3: Physician Rationale Event-level Estimates, Confidence Intervals, and Key Statistics

Estimate Description	Number in Sample	Percentage Estimate	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Adverse Events and/or Temporary Harm Events				
Physician Rationale for Preventable Events (n=128)				
Inadequate admission assessment of the patient	8	6.25%	2.02%	10.48%
Inadequate care plan used to treat the patient	24	18.75%	11.38%	26.12%
Inadequate monitoring of the patient	10	7.81%	2.46%	13.17%
Patient received substandard or inadequate preventative care	40	31.25%	22.12%	40.38%
Patient received substandard treatment or therapeutic care	42	32.81%	24.17%	41.46%
Necessary treatment was not provided to patient	5	3.91%	0.59%	7.22%
Provider made an error related to medical judgment, skill, or patient management	26	20.31%	12.61%	28.02%
Poor communication between caregivers*	1	--	--	--
Event rarely happens when proper precautions and procedures are followed*	1	--	--	--
Other factor contributing to preventable event*	3	--	--	--

Estimate Description	Number in Sample	Percentage Estimate	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Physician Rationale for Not Preventable Events (n=168)				
Event occurred even though providers followed proper preparation and procedures	86	51.19%	43.38%	59.00%
Provider could not have anticipated this event with the information available at the time	15	8.93%	4.59%	13.26%
Patient's diagnosis was unusual or complex, making care difficult	19	11.31%	6.51%	16.11%
Patient's treatment was unusual or complex, making care difficult	13	7.74%	2.69%	12.79%
Patient was highly susceptible to this type of event due to poor health status	60	35.71%	27.89%	43.53%
Harm was foreseeable but was considered acceptable given alternatives	19	11.31%	6.64%	15.98%
Other factor contributing to not preventable event*	1	--	--	--

Source: Office of Inspector General analysis of hospital stays for 770 Medicare patients in October 2018.
Note: Physician-reviewers often choose more than one contributing factor for an event.
* We are unable to reliably project the proportion for this item because of the small number of sample occurrences.

Exhibit F-4: Estimates and Statistical Test Results for Preventability Subanalysis

Estimate Description	Number in Sample	Percentage Estimate	95-Percent Confidence Interval		P-Value for Difference in Proportions
			Lower Bound	Upper Bound	
Statistical Test for Relationship Among Preventability Determinations by Clinical Category					
Medication (n=130)					
Preventable medication-related events	55	42.31%	33.55%	51.07%	0.1011
Not preventable medication-related events	74	56.92%	48.14%	65.70%	
Patient Care (n=69)					
Preventable patient care-related events**	36	52.17%	41.49%	62.86%	0.6897
Not preventable patient care-related events**	33	47.83%	37.14%	58.51%	
Surgery/Procedure (n=67)					
Preventable surgery/ procedure-related events**	17	25.37%	14.83%	35.91%	<0.0001*
Not preventable surgery/ procedure-related events**	48	71.64%	60.20%	83.09%	

Estimate Description	Number in Sample	Percentage Estimate	95-Percent Confidence Interval		P-Value for Difference in Proportions
			Lower Bound	Upper Bound	
Infection (n=33)					
Preventable infection-related events***	20	--	--	--	--
Not preventable infection-related events***	13	--	--	--	

Source: Office of Inspector General analysis of hospital stays for 770 Medicare patients in October 2018.
Note: We conducted t-tests to identify statistically significant differences between preventable and not preventable harm events within clinical categories.
* P-values are statistically significant at the 95-percent confidence level.
** The 95-percent confidence intervals for projected proportions exceed 10-percent absolute precision.
*** We are unable to reliably project the proportion for this item because of the small sample size.

Exhibit F-5: Estimates and Confidence Intervals for Analysis of Medicare Costs and Patient Costs Associated with Adverse Events and Temporary Harm Events

Estimate Description	Number of Patients in Sample with Cost Implications	Projected Number of Patients with Cost Implications	Projected Cost Estimate	95-Percent Confidence Interval	
				Lower Bound	Upper Bound
Estimated Medicare and Patient Costs for Associated Harm Events					
Costs associated with harm events for IPPS patients	25	33,636*	$520,352,452	$223,083,937	$817,620,968
Costs associated with harm events for non-IPPS patients	19	25,563**	$281,381,118	$123,834,314	$438,927,922

Source: Office of Inspector General analysis of hospital stays for 770 Medicare patients in October 2018.
Note: Confidence intervals for projected numbers exceed 30-percent relative precision.
* The 95-percent confidence interval for this estimate spans 20,635 to 46,636.
** The 95-percent confidence interval for this estimate spans 14,186 to 36,940.

Exhibit F-6: Estimates and Confidence Intervals of Patients Who Experienced Adverse and Temporary Harm Events with Associated Medicare Costs and Patient Costs, by IPPS Status

Estimate Description	Number of Patients in Sample	Percentage Estimate	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
IPPS and Non-IPPS Payment Systems (n=770)				
IPPS patients	508	65.97%	62.55%	69.24%
Non-IPPS patient	262	34.03%	30.76%	37.45%
Adverse Events and/or Temporary Harm Events with Cost Implications				
Patients with harm events (n=192) and cost implications	44	22.92%	17.51%	29.40%
IPPS patients with harm events (n=123) and cost implications	25	20.33%	14.11%	28.37%
Non-IPPS patients with harm events (n=69) and cost implications	19	27.54%	18.29%	39.21%

Source: Office of Inspector General analysis of hospital stays for 770 Medicare patients in October 2018.

APPENDIX G

Rates of Patient Harm Events by Patient Days and Hospital Admissions

Hospitals and researchers commonly measure patient harm events by incidence density, which accounts for the period during which patients are observed. For example, incidence density is often used in measuring hospital-acquired infections because risk can increase as the length of stay increases.[178] IHI, a nonprofit advisory group to hospitals that promotes quality of care, cites advantages to using incidence density metrics over standard incidence rates that measure the number of events per patient.[179] IHI reports that measuring total events by patient days or hospital admissions enables hospitals to count multiple events experienced by the same patient. As a result of these benefits, since the 2010 report, OIG has estimated the incidence density of patient harm across health care settings.

We found that in October 2018, hospitalized Medicare patients experienced 72.5 harm events per every 1,000 days and 35.9 events per every 100 admissions. We calculated patient days by subtracting the admission date for each hospital stay from its discharge date. The sample of 770 Medicare patients included 834 total eligible hospital stays (admissions) and a total of 4,119 days in the hospital (patient days). Exhibit G-1 provides the estimated ratios for adverse and temporary harm events per 1,000 patient days and per 100 admissions.

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

Category	Per 1,000 Patient Days (n=770)	95-Percent Confidence Interval		Per 100 Admissions (n=834)	95-Percent Confidence Interval	
		Lower Bound	Upper Bound		Lower Bound	Upper Bound
Adverse events and/or temporary harm events	72.5	63.2	81.8	35.9	30.3	41.4
Adverse events	27.9	22.5	33.2	13.8	10.8	16.8
Temporary harm events	44.6	37.3	52.0	22.1	18.1	26.0

Source: OIG analysis of hospital stays for 770 Medicare patients in October 2018.

APPENDIX H

Patient Harm Events Identified in the Sample

Exhibit H-1 contains information about adverse events in our sample and Exhibit H-2 contains information about temporary harm events (E-level harm events) in our sample. Within the exhibit tables we include each harm event's description, harm level, preventability, and whether the event was on one or more of the NQF, DRA HAC, or HACRP lists of events. Events are grouped based on the broad clinical categories of medication, patient care, infection, and procedure or surgery. Within each group similar types of harm events are grouped together, and these are ordered by descending frequency in our sample. Harm levels are labeled as E through I, in accordance with the OIG-modified NCC MERP Index. Preventability determinations are labeled as CP (clearly preventable), LP (likely preventable), LNP (likely not preventable), CNP (clearly not preventable), and UTD (unable to determine).

Exhibit H-1: Adverse Events by Clinical Category, Harm Level, Preventability, and Harm Event List (n=115)

	Harm Level	Preventability Determination	Event List
Adverse Events Related to Medication (47)			
Excessive bleeding (12)			
1. Cascade with excessive bleeding while on anticoagulant medication (enoxaparin) prophylaxis for atrial fibrillation leading to hypotension leading to acute kidney injury and ultimately request for comfort care and contributing to death	I	LNP	
2. Cascade with lower gastrointestinal bleeding (melena) due to anticoagulant medication (heparin) leading to hypotension requiring endoscopy, discontinuation of anticoagulant medication, transfusion, and intravenous fluids	F	LNP	
3. Cascade with overdiuresis leading to failure to recognize anemia due to bleeding gastric ulcer upon admission while on high dose anticoagulant (enoxaparin) and antiplatelet (clopidogrel, aspirin) medications requiring esophagogastroduodenoscopy with gastric clipping associated with hypotension, respiratory failure, intubation, and acute kidney injury	F	LP	
4. Cascade with subarachnoid hemorrhage with residual aphasia and likely exacerbation of postoperative seizures, while on anticoagulant (enoxaparin, warfarin) and antiplatelet (aspirin) medications given status post cerebral/carotid artery aneurysm repair during prior admission, leading to uncal (brain) herniation requiring readmission to the intensive care unit and urgent craniotomy	G	LNP	

	Harm Level	Preventability Determination	Event List
5. Excessive bleeding while on anticoagulant medications (heparin, enoxaparin, aspirin) for treatment of atrial fibrillation requiring 10 blood transfusions	F	LNP	
6. Gastrointestinal bleeding while on anticoagulant (apixaban) and antiplatelet (aspirin) medications leading to anemia requiring readmission, transfusion, discontinuation of anticoagulant and antiplatelet medications	F	LNP	
7. Gastrointestinal bleeding while on anticoagulant (heparin) and antiplatelet (clopidogrel, aspirin) medications during cardiac catheterization requiring discontinuation of anticoagulant and antiplatelet medications	F	LNP	
8. Gastrointestinal bleeding while on anticoagulant medication (heparin) requiring discontinuation of anticoagulant medication, transfusion, and esophagogastroduodenoscopy prolonging length of stay	F	LNP	
9. Gross hematuria while on anticoagulant (apixaban) and antiplatelet (aspirin) medications requiring bladder fulguration and clot evacuation, holding medications, and giving desmopressin (DDAVP)	F	LNP	
10. Hematuria while on anticoagulant medications (warfarin, enoxaparin) with elevated blood clotting test (international normalized ratio 7.9) requiring holding one anticoagulant medication and giving Vitamin K	F	LNP	
11. Hemorrhagic conversion of stroke following administration of tissue of thrombolytic agent (tissue plasminogen activator)	G	UTD	
12. Postoperative (hemicolectomy) bleeding from incision site while on anticoagulant medications (enoxaparin, warfarin) for suspected venous-thromboembolism requiring surgical intervention to stop bleeding	F	LNP	
Acute kidney injury or insufficiency (8)			
1. Acute kidney injury due to a nonsteroidal anti-inflammatory medication (ketorolac) resulting in readmission	F	LP	
2. Acute kidney injury on chronic kidney disease due to decreased fluid intake and diuretics (torsemide, spironolactone)	F	LNP	
3. Acute kidney injury on chronic kidney disease due to overdiuresis (metolazone, spironolactone, torsemide) resulting in readmission	F	LP	
4. Acute tubular necrosis due to nonsteroidal anti-inflammatory medications (ibuprofen, ketorolac) with delayed recognition of renal insufficiency on admission	F	LP	
5. Cascade with acute kidney injury and hyperkalemia (requiring treatment) due to postoperative hypotension and diuretic (furosemide) given for fluid overload	F	LNP	
6. Cascade with hypotension due to the antiarrhythmic medication (diltiazem) leading to acute kidney injury	F	LNP	
7. Contrast-induced (required for cardiac catheterization) acute kidney injury due to intravenous contrast agent	F	CNP	

	Harm Level	Preventability Determination	Event List
8. Contrast-induced acute kidney injury (following computed tomography scan) requiring readmission	F	LNP	
Delirium or other change in mental status (8)			
1. Cascade after placement of watchman device with acute encephalopathy and possible serotonin syndrome due to opioid pain medications (fentanyl, other opioids) leading to elbow skin tear	F	LNP	
2. Delirium due to patient-controlled analgesia (hydromorphone) requiring discontinuation of medication and starting atypical antipsychotic medication (quetiapine)	F	LP	
3. Delirium while on antiseizure medication (levetiracetam) requiring discontinuation of antiseizure medication and administration of antipsychotic (haloperidol) and benzodiazepine antianxiety (lorazepam) medications	F	LNP	
4. Hypoactive delirium requiring discontinuation of atypical antipsychotic medication (quetiapine)	F	LNP	
5. Lethargy due to opioid pain medications (morphine, meperidine, oxycodone) and antihistamine (phenothiazine) prolonging hospital stay	F	LP	
6. Post-cardiac catheterization psychosis while on multiple medications including benzodiazepine antianxiety (midazolam) and opioid pain (fentanyl) medications requiring an inpatient admission	F	LNP	
7. Prolonged acute respiratory failure and lethargy due a failure to provide adequate intravenous naloxone in a patient admitted to the emergency department with a long-acting opioid pain medication (methadone) overdose	F	CP	
8. Unresponsiveness post ankle fracture surgery due to polypharmaceuticals (including multiple opioid pain [hydrocodone, fentanyl, morphine], anticholinergic [oxybutynin] and benzodiazepine antianxiety [lorazepam] medications) requiring naloxone, discontinuation of opioid pain medications, and intravenous antiseizure medication (levetiracetam)	H	LP	
Hypotension (5)			
1. Cascade with symptomatic hypotension (blood pressure of 51/29 mmHg) due to local anesthetic (lidocaine) progressing to unresponsiveness requiring rapid response team, intravenous fluids, and discontinuation of lidocaine and hallucinations after event	H	LNP	
2. Dizziness due to hypotension (blood pressure of 76/51 mmHg) secondary to multiple doses of opioid pain medication (oxycodone) to manage postoperative pain requiring adjustment of medication	F	CP	

	Harm Level	Preventability Determination	Event List
3. Hypotension (blood pressure of 80/60s mmHg) due to antihypertensive medication (metoprolol) excessive dose at time of discharge resulting in readmission and adjustment of medication	F	CP	
4. Hypotension (blood pressure of 82/38 mmHg) with syncope following administration of antihypertensive medication (labetalol) prior to discharge resulting in syncope in car and a return to hospital bed requiring adjustment of medication and intravenous fluids	F	LP	
5. Hypotension (mean arterial pressure of 45 mmHg) due to antihypertensive medication (beta blocker) and possibly anemia requiring rapid response team, move to intensive care unit, and intravenous fluids	F	LNP	
Respiratory failure (4)			
1. Cascade with amiodarone-induced pulmonary toxicity leading to respiratory failure and hypotension requiring reintubation	F	LNP	
2. Cascade with delirium due to opioid pain medication (fentanyl) withdrawal leading to continuation of opioid pain medication prolonging respiratory failure and intubation	F	LNP	
3. Cascade with type two respiratory failure (oxygen desaturation 80s) due to opioid pain medication (fentanyl) leading to significant hypotension and patient becoming unresponsive requiring reintubation	H	LP	
4. Postprocedure (cranial clipping) respiratory failure requiring prolonged two-day intubation related to sedation in patient with renal failure	F	LNP	
Fluid, electrolyte, and metabolic disorders (3)			
1. Fluid overload while on total parenteral nutrition (TPN) requiring discontinuation of TPN, diuretic (furosemide), and contributing to death	I	CP	
2. Hyperkalemia (potassium of 6.1) due to diuretic (spironolactone) resulting in a readmission treated with a potassium-removing agent (sodium polystyrene sulfonate) and holding medication	F	LNP	
3. Hyperkalemia (potassium of 7.5) due to diuretics (metolazone, spironolactone, torsemide) and potassium supplements requiring readmission, discontinuation of medications and treatment	F	LP	
Cardiac dysrhythmia (2)			
1. Rapid onset pulmonary edema related to inadequate atrial fibrillation management requiring conversion to normal sinus rhythm	F	LP	
2. Severe asymptomatic bradycardia (heart rate in 30s) secondary to antihypertensive medications (clonidine, beta blockers) requiring discontinuation of antihypertensive medications and monitoring at higher level of care	F	LP	

	Harm Level	Preventability Determination	Event List
Venous thromboembolism (2)			
1. Left lower extremity deep vein thrombosis while on anticoagulant medication (heparin) requiring transition to different anticoagulant medication (apixaban)	F	LNP	
2. Pulmonary embolism with delay in recognition without a computed tomography scan on admission in a patient with pneumonia, hemoptysis, and an inferior vena filter initially placed on low dose intravenous drip of anticoagulant medication (heparin) with transition to different anticoagulant medication (apixaban)	F	LP	
Hypoglycemia (1)			
1. Hypoglycemia (blood glucose of 33 mg/dL, 30 mg/dL) with unresponsiveness requiring treatment with glucose by emergency medical services, received and treated in emergency department with subsequent admission	H	LP	
Urinary retention (1)			
1. Postoperative (cerebral/carotid artery aneurysm repair) urinary retention due to anesthesia and preexisting benign prostatic hypertrophy requiring urinary catheterization	F	CNP	
Vascular skin injury (1)			
1. Bilateral heels and toes red/purple/maroon discoloration while on vasopressor (norepinephrine)	G	LNP	
Adverse Events Related to Procedure or Surgery (32)			
Excessive bleeding (6)			
1. Cascade with surgical site bleed (hemorrhage) following bariatric sleeve gastrectomy leading to shock, requiring vasopressors, further leading to severe acidosis and hyperkalemia requiring emergent hemodialysis	F	LP	
2. Postoperative bleeding at colostomy site with significant anemia requiring transfusion and contributing to death	I	LNP	HACRP
3. Postoperative hernia repair with lysis of adhesions complicated by enterotomies (small intestinal serosal tears and lacerations) requiring small bowel resection	G	LNP	
4. Postprocedure (biliary stent placement) complication requiring hepatic embolization and transfusion with a readmission for presumed abscess	F	LNP	
5. Postprocedure (endoscopic biliary stent with percutaneous drain) gastrointestinal bleeding requiring hepatic artery embolization with microcoils and requiring readmission	F	LNP	
6. Postprocedure bleeding following removal of one of two colon polyps while on anticoagulant medication (warfarin) requiring readmission and removal of second polyp	F	LP	

	Harm Level	Preventability Determination	Event List
Cerebrovascular accident (5)			
1. Cerebral hemorrhage due to anticoagulant (heparin) and anti-platelet (clopidogrel) medications associated with percutaneous coronary intervention of right coronary artery and balloon of left anterior descending stent contributing to death	I	LNP	
2. Postoperative (atrial valve replacement) acute cerebrovascular accident leading to readmission	G	LP	
3. Postoperative (cerebral/carotid artery aneurysm repair) complicated by cerebrovascular accident	G	LNP	
4. Postoperative (hip replacement) complicated by a left occipital lobe infarction	G	LNP	
5. Postprocedure (angioplasty with stenting of bilateral iliac and femoral arteries) complicated by cerebrovascular accident requiring thrombolytic tissue plasminogen activator and stenting of left internal carotid artery	H	LP	
Embolisms (i.e., vascular and fat embolisms) (4)			
1. Cascade with failure to recognize atrial thrombus prior to valve replacement and coronary artery bypass graft resulting in prolonged surgery following discovery with interruption of blood supply leading to shock liver injury (aspartate aminotransferase = 12,948, alanine transaminase = 3927), renal injury (serum creatinine = 4.08), and contributing to death	I	LP	
2. Cascade with postoperative (lung transplant) atrial fibrillation leading to embolism with colon ischemia and ileus requiring hemicolectomy with resultant septic shock (hypotension) leading to acute kidney injury	G	LNP	HACRP
3. Postoperative (open reduction internal fixation humerus [arm] fracture) complicated by incomplete occlusive thrombus of the right common femoral (leg) vein requiring anticoagulant medication (heparin) and inferior vena cava filter	F	LNP	
4. Postoperative hip prosthesis revision complicated by hypoxemia, hypotension, and delirium likely due to fat emboli	F	LNP	
Prolonged ileus (4)			
1. Postoperative (lumbar fusion) ileus requiring holding opioid pain medication (hydromorphone), administered an enema and opioid receptor antagonist (methylnaltrexone bromide) for opioid-induced constipation	F	LP	
2. Postoperative (resection rectum) ileus with abdominal distention leading to prolongation of hospital stay	F	LNP	
3. Postoperative colectomy (resection colon) ileus day 4 requiring nasogastric tube with prolongation of hospital stay	F	LNP	
4. Prolonged postoperative (cholecystectomy [gall bladder removal]) ileus with nausea and vomiting and abdominal distension requiring treatment with intravenous ondansetron and extending the hospital stay	F	LNP	

	Harm Level	Preventability Determination	Event List
Cardiac dysrhythmia (2)			
1. Intraoperative (left craniotomy [aneurysm repair]) complicated by pulseless ventricular tachycardia requiring vasopressor (epinephrine)	H	LNP	
2. Postoperative (coronary artery bypass graft) atrial fibrillation with rapid ventricular response	F	LNP	
Hypotension (2)			
1. Postoperative hypotension (blood pressure of 82/35 mmHg, mean arterial pressure of 51 mmHg) with possible bleeding after ambulatory surgery for open reduction internal fixation of left humerus treated with fluids and admitted for observation due to underlying thrombocytopenia and liver disease	F	LNP	
2. Sustained postprocedure (internal carotid artery stent and angioplasty) hypotension (blood pressure of 89/29 mmHg, mean arterial pressure of 45 mmHg) requiring vasopressor therapy (dopamine)	F	LNP	
Postoperative seroma/infection (other than infections above) (2)			
1. Postoperative (lumbar fusion) wound seroma requiring readmission for incision and drainage	F	UTD	
2. Postoperative (small bowel resection) surgical site abscess requiring readmission for drainage and antibiotics	F	LNP	
Respiratory issues (other than infections) (2)			
1. Postoperative (laminectomy with tumor resection) respiratory failure due to anesthesia and pain medications resulting in remaining intubated with bilevel positive airway pressure and transfer to intensive care unit	F	LNP	
2. Postoperative (mitral and aortic valve replacement) oxygen desaturation due to perioperative fluid overload requiring intravenous diuretic (furosemide) and discontinuation of intravenous fluids	F	LNP	
Acute kidney injury or insufficiency (1)			
1. Cascade with postoperative vomiting (five times in less than 24-hour period) and dehydration (no intravenous fluids given) leading to acute kidney injury and requiring readmission	F	LP	
Nausea and vomiting (1)			
1. Postoperative (bariatric surgery) vomiting (two episodes) and nausea for three days requiring prolonged intravenous antiemetic medication (ondansetron) and hospital stay	F	LNP	
Pneumothorax (1)			
1. Postprocedure (outpatient lung biopsy) pneumothorax (lung collapse) requiring chest tube and hospital admission	F	CNP	

	Harm Level	Preventability Determination	Event List
Surgery or procedure-related cardiac event (1)			
1. Cascade with prolonged hypotension during transcatheter aortic valve replacement leading to pulseless electrical activity requiring cardiopulmonary resuscitation, vasopressor medication, heart pump insertion, and fluid resuscitation resulting in diagnosis of global cerebral hypoperfusion with possible hippocampus stroke	G	LP	
Urinary incontinence (1)			
1. Postoperative (prostatectomy) bladder leakage requiring readmission	F	LP	
Adverse Events Related to Infection (21)			
Respiratory infection (6)			
1. Cascade with aspiration of high-volume tube feedings leading to aspiration pneumonia, respiratory failure, sepsis, and cardiac arrest requiring intubation with mechanical ventilation and contributing to death	I	LP	
2. Cascade with chemotherapy-induced severe neutropenia leading to acute rhinovirus respiratory infection	F	LNP	
3. Cascade with CDC-defined ventilator-associated (*Klebsiella oxytoca*) pneumonia with secondary bacteremia leading to septic shock	F	LP	
4. Failure to recognize pneumonia during first admission resulting in readmission	F	LP	
5. Postoperative (hemicolectomy) right lower lobe pneumonia	F	LNP	
6. CDC-defined ventilator-associated pneumonia	F	LP	
Surgical site infection (6)			
1. Cascade with infected (MRSA) hip prosthesis leading to hypotension requiring readmission for revision	F	LP	HACRP
2. Cascade with surgical wound dehiscence following total hysterectomy leading to readmission, ventral hernia and partial small bowel obstruction requiring surgical repair	F	LP	HACRP
3. Postoperative (laminectomy) surgical site infection with dehiscence requiring computed tomography-drainage, washout and drainage procedure, debridement of skin, subcutaneous tissue, and fascia, placement of wound vacuum pump, peripherally inserted central catheter, and two readmissions	F	LP	
4. Postoperative colon cancer resection abdominal wall cellulitis requiring readmission	F	LNP	HACRP
5. Postoperative persistent serious wound drainage (likely infection) treated with wound vacuum pump and antibiotic (trimethoprim-sulfamethoxazole)	F	LNP	
6. Postoperative wound dehiscence with intraabdominal infection due to anastomotic leak requiring intestinal revision	G	LNP	HACRP

	Harm Level	Preventability Determination	Event List
Sepsis (4)			
1. Cascade with central line-associated bloodstream infection/catheter-associated urinary tract infection (CLABSI/CAUTI) MSSA bacteremia leading to septic shock and contributing to death	I	LNP	
2. Cascade with omission of empiric antibiotics on admission for underlying small bowel obstruction and micro-aspiration, septic shock, and respiratory failure requiring mechanical ventilation and vasopressor medication	F	LP	
3. Cascade with substandard treatment of sepsis with insufficient fluid administration and inappropriate antibiotic coverage leading to septic shock, respiratory failure, and contributing to death	I	LP	
4. Failure to treat urinary tract infection during first admission resulting in readmission due to sepsis with infectious encephalopathy	F	CP	
Clostridioides difficile (C. diff) infection (3)			
1. Cascade with *C. diff* infection leading to septic shock requiring intensive care unit admission and treatment with vasopressor medication (vasopressin)	F	LP	HACRP
2. *C. diff* infection	F	LP	HACRP
3. *C. diff* infection	F	LP	HACRP
Central line-associated bloodstream infection (CLABSI) (1)			
1. *Staphylococcus epidermidis* primary bacteremia and *Klebsiella oxytoca* secondary bacteremia (CLABSI) requiring line change	F	LP	DRA, HACRP
Intraabdominal infection with delayed treatment (1)			
1. Cascade with five-day delay of surgery for patient admitted with sepsis and abdominal symptoms leading to worsening of necrotic small intestine, purulent gross contamination of abdomen, septic shock with associated acute kidney injury, and hypoactive delirium treated with multiple surgeries and intubation and contributing to death	I	LP	
Adverse Events Related to Patient Care (15)			
Fluid and electrolyte disorders (5)			
1. Cascade with substandard intervention for hyperkalemia (6.4) leading to severe bradycardia (30s) per telemetry with inadequate emergency response due to difficulty locating patient leading to cardiac arrest and contributing to death	I	CP	
2. Cascade with volume overload due to fluid resuscitation for pneumonia with sepsis leading to acute respiratory distress requiring diuretics (furosemide) and thoracentesis	F	LP	
3. Fluid overload due to volume resuscitation for suspected sepsis requiring diuretics (furosemide, spironolactone) and thoracentesis	F	LNP	

	Harm Level	Preventability Determination	Event List
4. Inadequate management of potassium during first admission leading to readmission due to hyperkalemia (potassium = 6.2) requiring sodium polystyrene (kayexalate)	F	LP	
5. Pulmonary edema shortly after the placement of the dialysis catheter	H	LNP	
Acute myocardial infarction – delayed diagnosis (3)			
1. Cascade with delayed diagnosis of Type 2 myocardial infarction leading to hypotension, congestive heart failure, and episode of delirium	G	LP	
2. Delayed recognition of acute inferior myocardial infarction led to a two-day delay with cardiac arrest during catheterization, a failed attempt to resuscitate the patient, and contributing to death	I	CP	
3. Delayed recognition of Type 2 myocardial infarction with pulmonary edema resulting in cardiac arrest requiring resuscitation, intubation, and right jugular catheter	H	CP	
Respiratory issues (other than infections) (3)			
1. Acute on chronic respiratory failure with hypoxia/hypercapnia in obesity hypoventilation syndrome patient not on continuous positive airway pressure on admission requiring transfer to intensive care unit	F	LP	
2. Large aspiration of liquid requiring suctioning after intubation	F	LNP	
3. Multiple episodes of food and tube feeding aspirations related to intravenous opioid pain medication (morphine) and history of cerebrovascular accident treated with percutaneous esophagogastrostomy tube	F	LNP	
Fall or other trauma with injury (2)			
1. Cascade with fall following elective hip replacement resulting in new fracture with excessive bleeding and need for revision surgery	F	CP	NQF, DRA, HACRP
2. Traumatic hematoma to right knee following a bed rail injury	F	LNP	
Pressure injury (2)			
1. Deep tissue pressure injury left heel	F	LP	
2. Deep tissue pressure injury of bilateral buttocks	F	LP	

Source: Office of Inspector General analysis of hospital stays for 770 Medicare patients in October 2018.

Exhibit H-2: Temporary Harm Events (E-level harm) by Clinical Category, Preventability, and Harm Event List (n=184)

Clinical Category	Harm Level	Preventability Determination	Event List
Temporary Harm Events Related to Medication (83)			
Delirium or other change in mental status (20)			
1. Acute toxic encephalopathy while on opioid pain medication (fentanyl) leading to discontinuation of medication with naloxone administration	E	LP	
2. Change in mental status resulting in discontinuing benzodiazepine antianxiety medication (temazepam) and prescribing atypical antipsychotic medication (risperidone)	E	LP	
3. Confusion due to anticholinergic (scopolamine) and opioid agonist pain (tramadol) medications requiring discontinuation of medications and femoral nerve block	E	CNP	
4. Confusion due to toxic metabolic encephalopathy associated with age, anesthesia, and health status	E	LNP	
5. Delirium due to opioid pain medications (fentanyl, hydromorphone) requiring medication adjustment	E	LNP	
6. Delirium while on benzodiazepine antianxiety medication (lorazepam) requiring antipsychotic medications (haloperidol, quetiapine)	E	LNP	
7. Delirium while on opioid pain medication (hydrocodone) requiring discontinuation of medication	E	LNP	
8. Delirium while on opioid pain medications (fentanyl, hydrocodone, oxycodone) requiring medication adjustment	E	LP	
9. Hallucinations while on opioid pain medication (oxycodone) requiring discontinuation and changing of medication	E	LP	
10. Increased depression and irritability due to serotonin-norepinephrine reuptake inhibitor antidepressant (desvenlafaxine succinate) requiring discontinuation of medication	E	LNP	
11. Lethargy due to benzodiazepine antianxiety (lorazepam) and opioid pain (hydrocodone) medications requiring dose adjustment	E	LNP	
12. Lethargy due to increase of atypical antipsychotic medication (quetiapine) requiring adjustment of medication	E	LP	
13. Mild metabolic encephalopathy (change in mental status) due to anesthesia	E	LNP	
14. Multiple episodes of oversedation while on opioid pain medications (fentanyl, morphine) requiring medication adjustment	E	LP	
15. New onset delirium while on hypnotic medication (zolpidem) requiring discontinuation of medication	E	LP	
16. Oversedation and confusion while on multiple opioid pain medications (oxycodone, morphine, hydromorphone, fentanyl)	E	LP	

Clinical Category	Harm Level	Preventability Determination	Event List
17. Oversedation due to antipsychotic (haloperidol, olanzapine) and benzodiazepine antianxiety (lorazepam) medications requiring discontinuation of medications	E	LNP	
18. Somnolence and inability to follow commands while on benzodiazepine antianxiety medication (lorazepam) in combination with anticonvulsants (valproic acid, levetiracetam)	E	LP	
19. Somnolence while on benzodiazepine antianxiety (lorazepam) and opioid pain (morphine and hydrocodone) medications resulting in discontinuing benzodiazepine antianxiety medication	E	LP	
20. Visual hallucinations due to multiple medications (anti-nausea [scopolamine], antiseizure [gabapentin], and opioid pain [tramadol, fentanyl, hydrocodone, oxycodone] medications) resulting in discontinuation of medications	E	LP	
Hypotension (14)			
1. Hypotension (blood pressure of 90/47 mmHg mean arterial pressure of 61 mmHg) related to opioid pain medications (fentanyl, oxycodone-acetaminophen, hydromorphone) requiring fluids	E	LNP	
2. Hypotension (blood pressure of 151/89 mmHg to 90/54 mmHg) due to topical vasodilator medication (nitroglycerin) requiring discontinuation of medication	E	LP	
3. Hypotension (blood pressure of 77/64 mmHg) due to intravenous antihypertensive medication (esmolol) continuing at the same dosage while adding an oral antihypertensive medication (metoprolol) leading to confusion and unresponsiveness to verbal and painful stimuli while consciousnesses remained intact requiring medication discontinuation	E	LP	
4. Hypotension (blood pressure of 78/50 mmHg) due to continuation of home antihypertensive medications (metoprolol, triamterene) in a patient with an admission systolic blood pressure in low 100s mmHg requiring adjustment of antihypertensive medications and administration of intravenous fluids	E	LP	
5. Hypotension (blood pressure of 80/45 mmHg) due to antihypertensive medications (metoprolol, triamterene) requiring medication adjustment and intravenous fluids	E	LP	
6. Hypotension (blood pressure of 83/48 mmHg) with mean arterial pressure in 50s mmHg requiring vasopressor (norepinephrine)	E	LNP	
7. Hypotension (blood pressure of 84/64 mmHg) due to oral calcium-channel blocker antihypertensive medication (diltiazem) requiring adjustment of medication	E	LP	
8. Hypotension (blood pressure of 86/45 mmHg) due to inappropriate continuation of home antihypertensive medication (prazosin) in the hospital requiring discontinuation of medication and intravenous fluids	E	CP	

Clinical Category	Harm Level	Preventability Determination	Event List
9. Hypotension (blood pressure of 89/41 mmHg) due to opioid pain medications (hydromorphone, hydrocodone) requiring intravenous fluid bolus and holding antihypertensive medications	E	LP	
10. Hypotension (blood pressure of 89/41 mmHg) with dizziness due to two doses of opioid pain medication (oxycodone) within 1 hour requiring discontinuation of medication	E	LP	
11. Hypotension (systolic blood pressure dropped from above 200 mmHg to 70s mmHg) due to benzodiazepine antianxiety medication (lorazepam) requiring intravenous fluids	E	LNP	
12. Orthostatic hypotension (systolic blood pressure 130s mmHg to 60s mmHg) with symptoms persisting due to volume depletion and polypharmacy, including anticonvulsant (gabapentin) and antihypertensive medication (metoprolol)	E	LP	
13. Prolonged hypotension (blood pressure of 83/48 mmHg, mean arterial pressure of 50s mmHg) related to anesthetic (propofol), opioid pain medication (fentanyl), and benzodiazepine sedative medication (midazolam) while on mechanical ventilation requiring medication adjustment and intravenous fluids	E	LP	
14. Symptomatic hypotension (precipitous drop of blood pressure of 189/69 mmHg to 126/54 mmHg and mean arterial pressure from 112 mmHg to 80 mmHg) due to antihypertensive vasodilator medication (hydralazine) requiring discontinuation of medication	E	LNP	
Hypoglycemia (12)			
1. Hypoglycemia (blood glucose of 34 mg/dL) due to insulin with drowsiness treated with apple juice, crackers, and adjustment of insulin	E	LP	
2. Hypoglycemia (blood glucose of 37 mg/dL, twice within 2-1/2 hours) due to receiving insulin drip while on mechanical ventilation requiring treatment with intravenous dextrose and discontinuation of insulin drip	E	CP	
3. Hypoglycemia (blood glucose of 40 mg/dL) due to insulin requiring glucose and insulin adjustment	E	LP	
4. Hypoglycemia (blood glucose of 41 mg/dL) due to insulin requiring glucose and insulin adjustment	E	LNP	
5. Hypoglycemia (blood glucose of 44 mg/dL) due to insulin requiring dextrose infusion and adjustment of insulin dose	E	CP	
6. Hypoglycemia (blood glucose of 48 mg/dL) due to insulin	E	LNP	
7. Hypoglycemia (blood glucose of 48 mg/dL) requiring dextrose (D50W)	E	LNP	
8. Hypoglycemia (blood glucose of 49 mg/dL, 46 mg/dL) treated with intravenous dextrose (D50W)	E	LNP	
9. Hypoglycemia (blood glucose of 49 mg/dL) managed with orange juice	E	LNP	
10. Hypoglycemia (blood glucose of 49 mg/dL) due to insulin treated with intravenous dextrose (D50W)	E	LP	

Clinical Category	Harm Level	Preventability Determination	Event List
11. Hypoglycemia (blood glucose of 50 mg/dL) with dizziness due to insulin treated with orange juice, glucose tablet, and insulin adjustment	E	CP	
12. Hypoglycemia (blood glucose of 67 mg/dL) due to insulin with dizziness following blood glucose of 231 mg/dL and 173 mg/dL requiring orange juice, snack, and discontinuation of insulin	E	LP	
Acute kidney injury or insufficiency (10)			
1. Acute kidney injury due to acute tubular necrosis, pre-renal events, and multiple medications	E	LNP	
2. Acute kidney injury due to antibiotic (vancomycin) requiring adjustment of dose	E	CNP	
3. Acute kidney injury due to diuretics (furosemide, spironolactone)	E	LP	
4. Acute kidney injury due to intravenous diuretic (furosemide)	E	LNP	
5. Acute kidney injury on chronic kidney disease due to diuretic (furosemide)	E	LNP	
6. Contrast-induced acute kidney injury and in combination with the intravenous diuretic (furosemide)	E	LNP	
7. Contrast-induced acute kidney injury	E	LNP	
8. Contrast-induced acute kidney injury following multiple computed tomography scans	E	LNP	
9. Contrast-induced acute kidney injury on chronic disease	E	LNP	
10. Contrast-induced acute kidney injury on chronic kidney disease requiring intravenous fluid and discontinuation of diuretics	E	LNP	
Excessive bleeding (6)			
1. Gastrointestinal bleeding while on anticoagulant medication (apixaban)	E	LNP	
2. Gross hematuria and clotting of urinary catheter while on anticoagulant medication (apixaban) requiring discontinuation of anticoagulant medication and new catheter	E	LNP	
3. Lower gastrointestinal bleed (melena) while on anticoagulant medication (heparin) requiring discontinuation	E	LP	
4. Postoperative coronary artery bypass graft day 3 bleeding while on anticoagulant medication (enoxaparin) requiring pressure and transfusion	E	LNP	
5. Retroperitoneal and upper arm hematoma while on thrombolytic agent (tissue plasminogen activator) requiring cryoprecipitate	E	LNP	
6. Significant anemia while on anticoagulant medication (enoxaparin) requiring transfusion	E	LNP	
Allergic reaction/hypersensitivity reaction (5)			
1. Chemotherapy-induced toxic skin rash	E	LNP	
2. Generalized pruritus due to opioid pain medication (intravenous morphine) treated with antihistamine (hydroxyzine) and discontinuation of opioid pain medication	E	CNP	

Clinical Category	Harm Level	Preventability Determination	Event List
3. Rash on chest following administration of rocuronium requiring treatment with antihistamine medication (diphenhydramine) and histamine (H-2) receptor agonist (famotidine)	E	LNP	
4. Rash with pruritis at peripheral intravenous site requiring removal of the line and treatment with ice	E	LNP	
5. Skin rash due to opioid pain medication (fentanyl) treated with antihistamine (diphenhydramine), steroids, histamine (H-2) receptor agonist, epinephrine, and discontinuation of opioid pain medication	E	CNP	
Noninfectious diarrhea (5)			
1. Chemotherapy-induced proctocolitis of rectum, sigmoid, and descending colon due to translocation of gut microflora	E	LNP	
2. Diarrhea after receiving multiple laxatives (bisacodyl, polyethylene glycol, sennosides-docusate) resulting in the patient refusing laxatives and resolution of diarrhea	E	LNP	
3. Diarrhea due to antibiotic (cefpodoxime) resulting in discontinuation	E	LNP	
4. Diarrhea due to laxatives (magnesium sulfate, sorbitol, senna) given for postoperative constipation requiring laxatives to be held	E	LNP	
5. Diarrhea while on multiple antibiotics (azithromycin, ceftriaxone, metronidazole, levofloxacin, meropenem, vancomycin, cefdinir) requiring antidiarrhea medication (loperamide) and probiotic	E	LNP	
Cardiac dysrhythmia (4)			
1. Complete heart block exacerbated by antihypertensive medication (clonidine) requiring discontinuation of medication	E	LP	
2. Presyncope manifested by weakness with bradycardia related to antihypertensive medication (beta blocker) requiring discontinuation of medication	E	LNP	
3. Prolonged cardiac pauses requiring discontinuation of antiarrhythmic medication (digoxin) and administration of intravenous fluids	E	LP	
4. Severe bradycardia due to calcium channel blocker (diltiazem) requiring discontinuation	E	LNP	
Prolonged constipation, obstipation, and ileus (3)			
1. Functional ileus with symptoms of nausea, vomiting, and anorexia likely due to anesthesia and opioid pain medications (hydromorphone, hydrocodone) treated with an antiemetic medication (ondansetron) and bowel rest	E	LP	
2. Prolonged symptomatic postoperative constipation due to a combination of surgery, sedation, and immobility requiring laxatives, enema, and a dopamine antagonist medication (metoclopramide)	E	LNP	
3. Prolonged, symptomatic constipation related to inadequate preventative regimen and requiring laxative (polyethylene glycol)	E	LP	

Clinical Category	Harm Level	Preventability Determination	Event List
Urinary retention (2)			
1. Acute urinary retention in a patient with benign prostatic hypertrophy after receiving nebulized bronchodilator (ipratropium) requiring discontinuation and urinary catheterization	E	LP	
2. Urinary retention likely due to opioid pain medication (fentanyl) treated with straight urinary catheterization	E	LP	
Fluid, electrolyte, and metabolic disorders (1)			
1. Acute gout due to diuretics requiring colchicine	E	LNP	
Seizure (1)			
1. Generalized seizure due to holding antiseizure medication (levetiracetam) because of aspiration requiring restarting medication with intravenous benzodiazepine antianxiety medication (lorazepam)	E	LP	
Temporary Harm Events Related to Patient Care (54)			
Pressure injury (20)			
1. Deep tissue pressure injury buttocks requiring specialty mattress	E	LP	
2. Multiple sacral deep tissue pressure injuries which progressed from admission Stage 1 pressure injury	E	LNP	
3. Penile Texas urinary catheter pressure injury	E	LP	
4. Progression from Stage 1 to Stage 2 pressure injury right hip	E	LP	
5. Progression of Stage 1 to Stage 2 sacral pressure injury while using specialty mattress	E	LNP	
6. Progression Stage 1 to Stage 2 coccyx pressure injury	E	LNP	
7. Progression Stage 1 to Stage 2 coccyx pressure injury	E	LNP	
8. Stage 1 bilateral elbows pressure injuries	E	LP	
9. Stage 1 coccyx pressure injury	E	LP	
10. Stage 1 elbow pressure injury	E	LP	
11. Stage 1 sacral pressure injury	E	LNP	
12. Stage 1 sacral pressure injury	E	LP	
13. Stage 1 sacral pressure injury in a patient with pre-admission *C. diff* diarrhea	E	LP	
14. Stage 2 bilateral ankle pressure injuries	E	LP	
15. Stage 2 bilateral buttocks pressure ulcers	E	LP	
16. Stage 2 coccyx pressure injury	E	LNP	
17. Stage 2 coccyx/sacrum pressure injury	E	LP	
18. Stage 2 right buttock pressure injury	E	LP	
19. Stage 2 sacral pressure injury	E	LNP	

Clinical Category	Harm Level	Preventability Determination	Event List
20. Stage 2 sacral pressure injury	E	LP	
Skin tear, abrasion, breakdown, or inflammation (11)			
1. Incontinence-associated dermatitis treated with a moisture barrier	E	LNP	
2. Inframammary (beneath breast) skin rash with ecchymosis	E	LP	
3. Mechanical trauma to bilateral buttocks related to repositioning in a debilitated patient resulting in skin tear with blistering	E	LNP	
4. Moisture dermatitis perineal and buttock area treated with moisture barrier and nystatin cream	E	LNP	
5. Penile excoriation due to urinary catheter requiring discontinuation of catheter and symptomatic treatment	E	LP	
6. Perineal dermatitis due to urinary and fecal incontinence	E	LNP	
7. Skin tear at intravenous site right forearm requiring dressing and continued skin care	E	LP	
8. Skin tear in gluteal fold in a patient with diarrhea treated with skin barrier cream	E	LNP	
9. Skin tear with blister and serosanguinous drainage of left hand at blood draw site requiring dressing	E	LNP	
10. Skin tears bilateral upper extremities requiring hydration, nonadhesive dressings, and positioning	E	LP	
11. Skin wound of left cheek due to endotracheal tube anchoring tape treated with nonadhesive tape dressing	E	LP	
Intravenous (IV) catheter infiltration/burn/phlebitis (9)			
1. Acute right upper extremity (proximal and mid right cephalic vein) occlusive thrombus at the IV site treated with anticoagulant medications (apixaban, heparin)	E	LNP	
2. Extravasation of computed tomography scan contrast into left arm requiring an ice pack	E	LP	
3. Infiltration of peripheral line IV site leading to arm swelling requiring elevation of the arm, replacement of the line, and local measures for comfort	E	LNP	
4. IV infiltrate right arm with swelling and blistering requiring discontinuation of IV and dressings	E	LP	
5. IV infiltrate with pain and swelling of right forearm requiring discontinuing and changing IV to other forearm, elevation, and compresses	E	LNP	
6. IV site infiltration with significant right arm swelling and discoloration requiring removal of IV, elevation, and cold compress	E	LNP	
7. IV infiltrate of cardiac medication (dopamine) with pain, swelling, redness, and soreness to the left upper extremity requiring discontinuation of medication and treatment with IV phentolamine mesylate to avoid necrosis	E	LNP	
8. Several small areas of skin breakdown at IV site requiring dressing and site change	E	LNP	

Clinical Category	Harm Level	Preventability Determination	Event List
9. Superficial vein thrombophlebitis at left upper extremity IV site with removal and replacement of IV	E	LP	
Fall or other trauma with injury (7)			
1. Cascade with overdosage of antiseizure medication (carbamazepine) causing dizziness leading to a fall with facial injury	E	CP	
2. Cascade with rib fractures due to cardiopulmonary resuscitation leading to traumatic pneumothorax and subcutaneous emphysema while on mechanical ventilation requiring chest tube	E	LNP	DRA
3. Fall while on opioid pain medication (oxycodone) resulting in abrasion and hematoma to right knee	E	LNP	
4. Fall while on opioid pain medication (oxycodone) resulting in pelvic pain	E	LP	
5. Fall with abrasion right shoulder	E	LNP	
6. Fall with ankle pain requiring opioid pain medication (oxycodone)	E	LNP	
7. Fall with injury to forehead with altered mental status and left peri-orbital ecchymosis	E	LP	
Fluid and electrolyte disorders (4)			
1. Acute pulmonary edema due to intravenous fluid overload requiring intravenous furosemide	E	LP	
2. Cascade with fluid overload leading to demand cardiac ischemia evidenced by increased troponin	E	LNP	
3. Fluid overload due to blood transfusion for anemia requiring intravenous furosemide	E	LNP	
4. Nonsustained ventricular tachycardia with electrolyte imbalance requiring increase in antihypertensive medication (carvedilol)	E	LNP	
Excessive bleeding (1)			
1. Hematuria due to urethral trauma during a urinary catheter removal	E	LNP	
Noninfectious conjunctivitis (1)			
1. Conjunctivitis with blistering (chemosis) result of inadequate preventative care in a patient with the inability to close eyelids while on ventilator	E	LP	
Respiratory issues (other than infections) (1)			
1. Decreased oxygen saturation level (59 percent on room air) due to patient with known chronic obstructive pulmonary disease removing their oxygen supplementation	E	LNP	
Temporary Harm Events Related to Procedure or Surgery (35)			
Hypotension (13)			
1. Cascade with hypotension following liver abscess biopsy/aspiration leading to change in mental status treated with intravenous fluids bolus	E	LNP	

Clinical Category	Harm Level	Preventability Determination	Event List
2. Hypotension (blood pressure of 63/30 mmHg, mean arterial pressure of 41 mmHg) and likely bradycardia (low heart rate of 49) related to sedating medication (dexmedetomidine) during trans-catheter aortic valve replacement requiring vasopressor (epinephrine)	E	LNP	
3. Hypotension (blood pressure of 82/44 mmHg, mean arterial pressure of 57 mmHg) related to epidural requiring dose adjustments and increased monitoring	E	LNP	
4. Intraoperative (colectomy) hypotension (blood pressure of 80s/50s mmHg, mean arterial pressure of 45 mmHg) requiring vasopressors (phenylephrine, ephedrine), and intravenous fluids	E	LNP	
5. Intraoperative (inguinal hernia repair) hypotension (blood pressure of 75/52 mmHg, mean arterial pressure of 52 mmHg) while on anesthesia medications (propofol, sevoflurane, midazolam, rocuronium) requiring vasopressor (phenylephrine)	E	LNP	
6. Intraoperative (knee arthroplasty) hypotension (blood pressure of 60/48 mmHg) due to excessive dose of induction agent (propofol) requiring treatment with vasopressors (ephedrine, phenylephrine)	E	LP	
7. Intraoperative (shoulder arthroplasty) prolonged hypotension (blood pressure of 71/46 mmHg, mean arterial pressure of 49 mmHg) requiring vasopressor (phenylephrine)	E	LNP	
8. Intraoperative hypotension (blood pressure of 86/44 mmHg) after receiving benzodiazepine sedative (midazolam) and opioid pain (fentanyl) medications requiring vasopressor (phenylephrine) and intravenous fluids	E	LNP	
9. Multiple hypotensive readings intraoperatively (blood pressure of 66/48–85/62 mmHg) and 6 hours postoperatively (blood pressure of 78/50 mmHg) while on benzodiazepine sedative medication (midazolam) in occupational therapy with significant lightheadedness	E	LNP	
10. Postoperative (coronary artery bypass graft) hypotension (blood pressure of 73/37 mmHg, mean arterial pressure of 49 mmHg) requiring vasopressor and intravenous fluids	E	CNP	
11. Postoperative (lumbar decompression) hypotension (blood pressure of 86/46 mmHg) with lightheadedness requiring intravenous fluids	E	LNP	
12. Postoperative hypotension (mean arterial pressure of 76 mmHg to 47 mmHg) lasting 30 minutes following Hickman Catheter placement requiring intravenous fluids	E	LP	
13. Prolonged intraoperative (total hip replacement) hypotension (blood pressure of 90s/70s mmHg) requiring vasopressor agent (epinephrine) and intravenous fluids	E	UTD	

Clinical Category	Harm Level	Preventability Determination	Event List
Excessive bleeding (7)			
1. Bleeding at Jackson-Pratt surgical drain site with patient cold, clammy, and lightheaded and blood pressure of 97/71 mmHg, requiring intravenous fluid bolus and drain removal	E	LP	
2. Bleeding due to laceration of lip into oropharynx from bite block inserted during endoscopic retrograde cholangiopancreatography while on subcutaneous anticoagulant medication (heparin)	E	LP	
3. Excess bleeding at transcatheter aortic valve replacement catheter site requiring manual pressure	E	LNP	
4. Excessive bleeding from femoral line leading to acute anemia requiring pressure dressing, transfusion, and removal of femoral line	E	LP	
5. Postoperative (mitral valve repair) anemia while on anticoagulant (heparin) and antiplatelet (aspirin) medications and requiring a transfusion	E	LNP	
6. Postoperative (proctectomy, colostomy) anemia while on preoperative anticoagulant medication (heparin) requiring transfusion	E	LP	
7. Postprocedure (percutaneous endoscopic gastrostomy [PEG] tube) bleeding requiring surgical consultation and extra gauze packing	E	LNP	
Blood transfusion reaction (2)			
1. Blood transfusion reaction treated with diphenhydramine	E	LNP	
2. Blood transfusion reaction without diphenhydramine pre-medication with history of prior reaction	E	LP	
Cardiac dysrhythmia (2)			
1. Postoperative (mitral valve repair) arrhythmia (atrial fibrillation) requiring treatment with antiarrhythmic medication (amiodarone)	E	LNP	
2. Postoperative (mitral valve repair, aortic valve replacement) atrial fibrillation requiring antiarrhythmic medication (amiodarone) and temporary cardiac pacing	E	LNP	
Extremity weakness due to regional anesthesia (2)			
1. Quadriceps (leg) muscle weakness and numbness due to partial block of femoral nerve from fascia iliaca block requiring leg immobilizer	E	LNP	
2. Supratherapeutic effect of continuous epidural infusion resulting in inability to lift left leg and requiring decrease of epidural rate	E	LNP	
Pneumothorax (2)			
1. Postoperative (upper lung lobectomy) complicated by pneumothorax (collapsed lung) with air leak requiring Heimlich valve insertion	E	LNP	
2. Postprocedure (thoracentesis) small left apical pneumothorax (9mm) requiring monitoring	E	LNP	

Clinical Category	Harm Level	Preventability Determination	Event List
Surgery or procedure-related trauma (other than above) (2)			
1. Intraoperative (knee arthrodesis [fusion]) fracture of distal tibia requiring modification of implanted device (rod) and boot orthosis	E	LNP	
2. Postcardioversion burn on chest with swelling and redness requiring monitoring	E	LNP	
Embolisms (i.e., vascular and fat embolisms) (1)			
1. Postoperative (bladder fulguration) in patient with advanced bladder cancer and gross hematuria complicated by pulmonary emboli requiring inferior vena cava filter	E	CNP	HACRP
Nausea and vomiting (1)			
1. Postoperative (abdominal hysterectomy) nausea and vomiting lasting 2 days while on multiple pain medications requiring antiemetic medications (ondansetron, prochlorperazine)	E	LP	
Respiratory issues (other than infections) (1)			
1. Postoperative abdominal aneurysm repair atelectasis resulting in oxygen desaturation (81 percent) requiring diuretic (furosemide)	E	LNP	
Seizure (1)			
1. Postoperative (complex aneurysm repair via craniotomy) seizure while on postoperative seizure prophylaxis requiring additional seizure medication and electroencephalogram monitoring	E	LNP	
Urinary incontinence (1)			
1. Dislodgment of ureteral stent resulting in leakage of urine with subsequent removal of stent	E	LNP	
Temporary Harm Events Related to Infection (12)			
Thrush (5)			
1. Hoarseness/dysphagia related to delay in recognition and treatment of thrush	E	LP	
2. Oral thrush while on antibiotics	E	LP	
3. Oral thrush while on antibiotics and steroids	E	LNP	
4. Oral thrush while on multiple antibiotics	E	LNP	
5. Oral thrush while on prednisone	E	LNP	
Soft tissue or other nonsurgical infection (3)			
1. Acute cellulitis on chronic sacral osteomyelitis due to fecal contamination	E	LNP	
2. Balanitis with penile pain associated with a three-way catheter for bladder irrigation	E	LP	
3. Fungal infection groin and buttocks	E	LNP	
Catheter-associated urinary tract infection (CAUTI) (2)			
1. Cascade with CDC-defined CAUTI leading to hypotension and catheter replacement	E	LP	DRA, HACRP

Clinical Category	Harm Level	Preventability Determination	Event List
2. CDC-defined CAUTI	E	LP	DRA, HACRP
Respiratory infection (2)			
1. Aspiration pneumonia	E	LNP	
2. Aspiration pneumonia due to tube feedings in a patient with a history of dysphagia due to a cerebrovascular accident	E	LNP	

Source: Office of Inspector General analysis of hospital stays for 770 Medicare patients in October 2018.

APPENDIX I

Agency Comments: Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: February 25, 2022

TO: Christi A. Grimm
Principal Deputy Inspector General
Office of Inspector General

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare &

SUBJECT: Office of Inspector General (OIG) Draft Report: Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018, OEI-06-18-00400

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the OIG draft report on Medicare patients who experienced adverse and temporary harm events as a result of medical care, including failure to provide needed care, in hospitals. CMS serves the public as a trusted partner and steward and is dedicated to improving health outcomes. Preventable adverse and temporary harm events are unacceptable and CMS strives to hold providers and health care systems accountable for preventable health care harm through multiple levers, including survey requirements, quality reporting and value-based purchasing, and innovative quality improvement programs.

As described below, sustained efforts are underway to improve patient safety in hospitals through the reduction of preventable harm events, and progress has been made in several areas. However, more work needs to be done to protect patients from these events. While OIG's review did not look at care provided to patients during the current COVID-19 public health emergency (COVID-19 PHE), CMS agrees with OIG that addressing patient harm and promoting patient safety takes on added urgency in light of the ongoing pandemic and its effects on hospital operations. In addition to its sustained efforts to improve overall quality of care in hospitals, CMS has remained vigilant in assessing the health care needs of the American population and

health care providers during the COVID-19 PHE and continues to evaluate flexibilities and their effect on patient safety in health care settings.

Health care professionals, such as physicians, nurses, pharmacists, and other allied health professionals qualified in the clinical practice of medicine, work together with hospitals to care for patients to ensure the quality and value of clinical care. Medicare patients are often frail and living with multiple complex clinical conditions. Unfortunately, not every adverse or temporary harm event is preventable. As OIG noted in the report, their reviewers determined that 56 percent of harm events studied were not preventable and occurred even though providers followed proper preparation and procedures. OIG noted that events were determined not preventable for several reasons, including that the Medicare patients were found to be highly susceptible to the event due to poor health status. However, CMS appreciates OIG's distinction in their reporting to provide more insight into whether an event is preventable.

It is important to note the limitations of the report. As OIG explains, the preventability of certain adverse events may be overstated based on the retrospective nature of medical review. In addition, the prevalence of comorbidities is rising in the Medicare population, and Medicare patients are being treated for more clinically complex conditions and diagnoses than in the past. Comorbidities put patients at a higher risk for the occurrence of adverse events and often factor into the preventability of an event. OIG noted that CMS data showed that Medicare patients tended to have more chronic diseases in 2018 than in 2008 with higher rates of comorbidities for 15 of the 21 conditions tracked by CMS. This is an important distinction when comparing OIG's prior adverse event review and this current review. As these reports selected patients using a simple random sampling without adjustment, changes in the Medicare population do not appear to have been accounted for, which can impair efforts to make a meaningful comparison to their previous work or identify the effects of improvements in patient safety.

While CMS and Agency for Healthcare Research and Quality (AHRQ) data have shown improvements in patient safety in hospitals, we also know that improvements in detection and surveillance of adverse events have occurred during this time period. Due to increased detection, it is expected that the number of these events will increase before subsequently decreasing due to better care management.

Overall, due to sustained efforts by health care professionals and hospitals, the data demonstrates significant improvements in patient safety have occurred over the past decade. Data released by AHRQ showed national efforts to reduce hospital-acquired conditions (HACs), such as adverse drug events and injuries from falls, helped prevent an estimated 20,700 deaths and generated $7.7 billion in Medicare cost savings in 2015-2017 compared to what would have been expected based on HACs in 2014. Based on the HAC reductions seen in 2015, 2016, and 2017, compared with 2014, AHRQ estimates a total of 910,000 fewer HACs occurred between 2015 and 2017. This is an overall rate reduction of HACs of 13 percent from 2014 to 2017. These gains in safety among hospital patients echoed earlier successes, including 2.1 million HACs avoided between 2010 and 2014. HACs overall dropped 17 percent from 2010 to 2014, saving an estimated $19.9 billion in health care costs and preventing an estimated 87,000 deaths.[1]

[1] AHRQ, *AHRQ National Scorecard on Hospital-Acquired Conditions Final Results for 2014 Through 2017*, https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/pfp/Updated-hacreportFInal2017data.pdf

For the AHRQ data described above, depending on the year, the sample size varied from approximately 18,000 to 28,000 patient charts reflecting care delivered in approximately 800 to 1,600 hospitals. The OIG's sample size for this report was 770 Medicare patients from 629 hospitals, which represents 0.07 percent of Medicare patients who were discharged from short-term acute-care hospitals during October 2018. Given this small sample size and high variability in adverse events across patients and hospitals, the extrapolation of the OIG's findings to a national population may have limited reliability. Further, as the OIG notes, this sample size was insufficient to effectively compare the results within their current report to the harm rates identified in their 2010 report, which looked at 2008 data.

In its continuing efforts to improve the measurement and reporting of adverse events and to address prevention of the underlying causes, CMS uses a number of policy levers to achieve quality of care goals, including the reduction of preventable adverse and temporary harm events, as outlined in the CMS Quality Strategy.[2] First, CMS sets standards for providers that support patient safety and quality improvement, known as the Conditions of Participation (CoPs), and surveys providers against these standards. CMS provides guidance to state survey agencies and accreditation organizations for conducting hospital surveys to verify compliance with the CoPs. While many of the CoPs have an impact on patient safety and quality, the Quality Assessment and Performance Improvement (QAPI) CoP focuses specifically on standards for facilities to improve quality and safety. As part of this CoP, hospitals must track adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning through the hospital.

Second, as required by law, CMS also administers a number of quality reporting and value-based purchasing programs, which measure a hospital's quality of care, including hospital-associated infections (HAIs) and other adverse events. CMS provides payment incentives based on those measures, publicly reports performance measures, and includes many of the measures in Hospital Star Ratings. CMS collects quality data from hospitals paid under the Inpatient Prospective Payment System, with the goal of driving quality improvement through measurement, payment incentives, and transparency by publicly displaying data on the Care Compare website to help consumers make more informed decisions about their health care.

The Hospital Inpatient Quality Reporting (IQR) program requires hospitals to report specified quality measures, and hospitals that do not satisfactorily report the measures are subject to a payment reduction equal to one-quarter of the hospital update.[3] In addition, selected patient safety measures are used for hospital programs that make payments based on the quality and efficiency of care, including the Hospital Value-Based Purchasing (VBP) Program, the Hospital-Acquired Condition Reduction Program (HACRP), and Hospital Readmissions Reduction Program. These programs include measures that address avoidable adverse events, such as HAI measures (central line-associated bloodstream infections, catheter associated urinary tract infections, surgical site infection from colon surgery or abdominal hysterectomy, methicillin-resistant Staphylococcus Aureus blood laboratory-identified events, Clostridium difficile laboratory-identified events) and a measure on the death rate among surgical inpatients with serious treatable complications. These measures are also publicly reported on the Care Compare

[2] CMS, *CMS Quality Strategy*, 2016, https://www.ahrq.gov/sites/default/files/wysiwyg/workingforquality/2016-cms-agency-specific-plan.pdf

[3] Section 1886(b)(3)(B)(viii) of the Act

website and contribute to Hospital Star Ratings.[4] Data from the HAI measures listed above are used in both the Hospital VBP Program and HACRP.

CMS is statutorily limited in the payment adjustments that can be made under the quality reporting and value-based purchasing programs. As noted above, the reduction for failing to report to the Hospital IQR program is one-quarter of the hospital update. The Hospital VBP program reduces hospital payments by two percent in order to create a funding pool that is redistributed to hospitals based on a Total Performance Score.[5] The HACRP reduces hospital payments by one percent for those hospitals that fall in the bottom quartile based on their performance on HAC measures.[6]

CMS is constantly working to ensure that CMS programs have sufficient measures to identify and report on adverse and temporary harm events and through the Meaningful Measures initiative, CMS has ensured that patient safety is a prominent theme in the measure areas. CMS regularly evaluates whether new measures should be added to its quality reporting and value-based purchasing programs. This process occurs yearly and starts with CMS soliciting new measures and noting priority areas for the agency. CMS highlighted patient safety as a CMS quality measurement priority in the triennial 2021 National Impact Assessment of CMS Quality Measures Report,[7] in which CMS identified and analyzed patient safety measure performance trends. During the pre-rulemaking process, CMS releases the Measures Under Consideration list no later than December 1st, and multi-stakeholder groups provide recommendations on the list no later than February 1st. The pre-rulemaking process provides CMS with a vehicle to hear from stakeholders for early consideration of measures. CMS then considers any feedback on the new measures and selects measures to propose in the Federal Register, allowing comment before a final rule is issued. For example, CMS finalized two new medication-related adverse event electronic clinical quality measures (eCQMs) for reporting glycemic management, which were recommended in the pre-rulemaking process, into the Hospital IQR Program beginning with the calendar year 2023 reporting period.[8] For the 2021 measure development cycle, CMS noted areas of need and priorities for measures addressing causes of hospital harm and adverse drug events, among other areas.[9] The current list of Measures Under Consideration includes new and updated measures on healthcare-associated clostridioides difficile infection outcomes, hospital-onset bacteremia and fungemia outcomes, opioid-related adverse events, and severe obstetric complications.[10]

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[4] CMS, *Hospital Compare Overall Ratings Data Collection Periods*, April 2021, https://qualitynet.cms.gov/inpatient/public-reporting/overall-ratings/data-collection

[5] Section 1886(o)(7)(C)(v) of the Act

[6] Section 1886(p)(1) of the Act

[7] CMS, *2021 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Report*, June 2021, https://www.cms.gov/files/document/2021-national-impact-assessment-report.pdf.

[8] CMS, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program, (86 FR 44774), August 13, 2021.

[9] CMS, *Program-Specific Measure Needs and Priorities 2021 Measures Under Consideration List*, March, 24, 2021, https://www.cms.gov/files/document/2021-muc-list-program-specific-measure-needs-and-priorities.pdf.

[10] CMS, *List of Measures Under Consideration for December 1, 2021*, https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.

Finally, CMS had success focusing the attention of health care professionals and hospitals through the Partnership for Patients (PfP) initiative which was a public-private partnership working to improve the quality, safety and affordability of health care for Medicare, Medicaid and CHIP beneficiaries, and by extension, all Americans. Subsequently, in 2016, CMS awarded 16 national, regional, or state hospital associations and health system organizations to serve as Hospital Improvement Innovation Networks. These awards integrated the PfP networks into the Quality Improvement Organization (QIO) program, one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries and an integral part of CMS's Quality Strategy. This integration maximized the strengths of the QIO program and the PfP to sustain and expand national reductions in patient harm and 30-day readmissions for the Medicare program.[11] With the current QIO contract cycle, launched in 2019, the QIO program again refocused hospital patient safety efforts as the Hospital Quality Improvement Contractor program to further increase these efforts. An essential element of this work is a commitment to improving health equity, and organizations will give specific attention to identifying and reducing health care disparities. This program continues to engage the hospital, provider and broader caregiver communities to quickly implement well-tested and measured best practices to improve patient safety and the quality of care in the Medicare program.

In summary, while sustained efforts are underway to improve patient safety in hospitals and progress has been made in several areas over the last decade, more work needs to be done to protect patients from these events. In addition to CMS's efforts, CMS looks forward to continued focus on this area from health professionals, hospitals, and the OIG.

The OIG's recommendations and CMS's responses are below.

OIG Recommendation

Update and broaden its hospital-acquired conditions lists to capture common, preventable, and high-cost harm events.

CMS Response

CMS concurs with this recommendation. As noted above, several hospital programs to promote quality and safety have been created in the past decade.

Under the Deficit Reduction Act Hospital Acquired Conditions (DRA HAC) program, the hospital-acquired conditions (HAC) list is reviewed to determine if any of the newly created diagnosis or procedure codes should be added to the existing HAC categories. Under the DRA HAC provision, Medicare no longer assigns an inpatient hospital discharge to a higher paying Medicare Severity-Diagnosis Related Group (MS-DRG) if a selected HAC was not present on admission. That is, the case will be paid as though the secondary diagnosis was not present. Any additional updates, such as consideration for a new candidate condition to the current list of HAC categories, would require notice and comment rulemaking. Separately, CMS considers updates to the HAC list through the annual pre-rulemaking measure selection process and through subsequent rulemaking related to the HAC Reporting Program (HACRP) set out at section 1886(p) of the Act.

[11] CMS, Partnership for Patients and the Hospital Improvement Innovation Networks:
CMS, *Continuing Forward Momentum on Reducing Patient Harm*, September 29, 2016, https://www.cms.gov/newsroom/fact-sheets/partnership-patients-and-hospital-improvement-innovation-networks-continuing-forward-momentum.

The HACRP was implemented in fiscal year (FY) 2015 and includes several patient safety measures. CMS finalized two new medication-related adverse event electronic clinical quality measures for reporting glycemic management into the Hospital Inpatient Quality Reporting Program (IQR) beginning with the calendar year 2023 reporting period.[12] For the 2021 measure development cycle, CMS noted areas of need and priorities for measures addressing causes of hospital harm and adverse drug events, among other areas.[13] The current list of Measures Under Consideration includes new and updated measures on healthcare-associated clostridioides difficile infection outcomes, hospital-onset bacteremia and fungemia outcomes, opioid-related adverse events, and severe obstetric complications for several of CMS's payment programs, including the HACRP and the Hospital IQR Program.[14] CMS is in the process of evaluating additional digital safety measures while identifying ways to more closely align to Centers for Disease Control and Prevention and Agency for Healthcare Research and Quality safety metrics for consideration of future adoption into one or more quality reporting programs.

CMS must follow statutory requirements for programs when considering updates to its measure lists. Even as the list of HAC measures continues to expand, CMS is statutorily limited in the payment adjustments that can be made under its pay-for-reporting and value-based purchasing programs. For example, the HACRP is limited to a one percent payment reduction for those hospitals in the worst-performing quartile, and the Hospital Value-Based Purchasing program can reduce hospital payments by a maximum of two percent in response to poor performance or increase payments for good performance. Some measures, such as those regarding hospital-associated infections, are included in both programs and can therefore have a greater payment impact. However, the structure of the HACRP is such that only the worst 25 percent of performers receive the one percent reduction each year. Hospitals that routinely are in the top three quarters of performance do not have a financial incentive through the HACRP to improve more.

OIG Recommendation

Explore expanding the use of patient safety metrics in pilots and demonstrations for health care payment and service delivery as appropriate.

CMS Response

CMS concurs with this recommendation. The CMS Center for Medicare and Medicaid Innovation (CMS Innovation Center) tests innovative service and delivery models to reduce program expenditures and improve quality for Medicare and Medicaid beneficiaries. While all models are intended to maintain or enhance patient safety, two models currently being tested specifically address hospital patient safety, the Bundled Payments for Care Improvement Advanced (BPCI Advanced) model and the Maryland Total Cost of Care model. The BPCI

[12] CMS, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program, (86 FR 45382), August 2, 2021

[13] CMS, *Program-Specific Measure Needs and Priorities 2021 Measures Under Consideration List*, March, 24, 2021, https://www.cms.gov/files/document/2021-muc-list-program-specific-measure-needs-and-priorities.pdf

[14] CMS, *List of Measures Under Consideration for December 1, 2021*, https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf

Advanced model[15] tests payment for clinical episodes for Medicare beneficiaries while using some of the same patient safety measures that are in CMS's statutorily mandated inpatient programs. Similarly, the Maryland Total Cost of Care model[16] includes similar patient safety measures as those in CMS's inpatient programs to further incentivize quality improvement and reduce patient safety events in support of its aim to reduce total cost of care. CMS will continue to consider new opportunities to include patient safety metrics in pilots, demonstrations, and models for health care payment and service delivery.

OIG Recommendation

As OIG previously recommended, develop and release interpretive guidance to surveyors for assessing hospital compliance with requirements to track and monitor patient harm events.

CMS Response

CMS continues to concur with this recommendation. CMS requires that providers have internal quality assessment and performance improvement (QAPI) programs in place and that such programs include the practiced capability to track adverse patient events, analyze their causes, and implement preventive actions and mechanisms. While CMS is considering how best to update the State Operations Manual with interpretive guidance for surveyors to ensure consistency when assessing QAPI systems, surveyors already assess hospital compliance with these requirements as laid out in the hospital Conditions of Participation (CoPs). For example, surveyors cited hospitals for non-compliance with QAPI, generally, 465 times in fiscal year (FY) 2019 (the last year prior to the COVID-19 PHE where comparable data exists). Specific to the requirement to track and monitor patient harm events, hospitals were cited 103 times in FY 2019 for failure to comply. In FY 2019, QAPI and the patient safety tracking and monitoring requirement were the 15th and 16th top cited deficiencies for hospitals out of 405 total deficiency tags. Of note, roughly 80 percent of hospitals are deemed and surveyed by accrediting organizations that are required to effectively evaluate a facility using accreditation standards which meet or exceed the CoPs. CMS intends to continue to hold hospitals accountable for their compliance with the CoPs while updating guidance to surveyors.

[15] CMS, *BPCI Advanced*, https://innovation.cms.gov/innovation-models/bpci-advanced
[16] CMS, *Maryland Total Cost of Care Model*, https://innovation.cms.gov/innovation-models/md-tccm

Agency Comments: Agency for Healthcare Research and Quality

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

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To: Christi A. Grimm
Principal Deputy Performing Duties of the Inspector General
Department of Health and Human Services

From: David Meyers, M.D. DSM
Deputy Director, Agency for Healthcare Research and Quality

Date: March 18, 2022

Subject: *OIG Draft Report: Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018, OEI-06-18-00400*

Thank you for the opportunity to review the draft report entitled *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018, OEI-06-18-00400*, and for you and the OIG team's ongoing dedication and support for improving patient safety and healthcare quality.

AHRQ provides the following specific responses to each of the OIG's recommendations:

1. Recommendation #1: *With support from HHS leadership, reassess patient safety efforts across the Department by ensuring that agencies update quality strategic plans, identify weaknesses, and address gaps in these efforts.*

   AHRQ concurs with this recommendation.

   AHRQ appreciates the focus the report gives to the Agency's role in promoting patient safety and reducing patient harms. AHRQ's mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used. The Agency, within its current capacity, supports HHS efforts to coordinate patient safety activities across the Department and works collaboratively with other agencies to achieve the Department's goals and objectives. With specific direction and engagement by the HHS Secretary, AHRQ stands ready to begin implementation of this recommendation in a manner determined to be feasible by HHS. One clear prerequisite would be an assessment of the additional resources and infrastructure development required for AHRQ to become sufficiently resourced to assess patient safety efforts across the Department and ensure

that all HHS agencies, including the Centers for Medicare and Medicaid Services and the Centers for Disease Control, update and implement their quality strategic plans.

2. Recommendation #2: *Optimize use of QSRS, including assessing the feasibility of automated data capture for national measurement and to facilitate local use.*

   AHRQ concurs with this recommendation.

   Regarding QSRS use for national measurement, AHRQ will continue to implement QSRS to measure a national rate of hospital-acquired adverse events among hospital patients covered by Medicare and to create a baseline to assess the impact of national patient safety initiatives. AHRQ will assess the feasibility of incorporating automatic data capture into the system and will review the event types identified in OIG's report for potential inclusion into the system. AHRQ will also continue to share data from QSRS, as it is available, with CMS in accordance with AHRQ's Memorandum of Understanding with CMS and will consider ways to share data with other agencies, such as CDC, as appropriate. Additionally, AHRQ will continue to explore the best application of the QSRS measures (i.e., the event descriptions and algorithms) and underlying Common Formats for Surveillance at the local level.

3. Recommendation #3: *Develop an effective model to disseminate information on national clinical practice guidelines or best practices to improve patient safety*

   AHRQ concurs with this recommendation.

   AHRQ appreciates that OIG is highlighting the critical importance of using evidence-based strategies to improve patient safety. AHRQ currently employs a number of approaches to disseminating evidence-based patient safety improvement resources that are readily discoverable, accessible, and usable. These approaches are continually evolving as new patient safety issues, new evidence, and new strategies emerge. AHRQ concurs with the recommendation to develop new approaches to disseminating information about evidence-based patient safety practices. For example, AHRQ will explore working with the National Steering Committee for Patient Safety, and other similar groups, to achieve this shared objective. The approach will be developed in concert with recognized patient safety principles, such as those set forth in *Safer Together: A National Action Plan to Advance Patient Safety*. [National Steering Committee for Patient Safety. *Safer Together: A National Action Plan to Advance Patient Safety.* Boston, Massachusetts: Institute for Healthcare Improvement. (http://www.ihi.org/SafetyActionPlan).]

4. Recommendation #4: *Continue efforts to identify and develop new strategies to prevent common patient harm events in hospitals*

   AHRQ concurs with this recommendation.

   AHRQ will continue to invest in new research, tools, and projects consistent with its mission to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within HHS and with other partners to make sure

that the evidence is understood and used. In determining its research and program priorities, AHRQ will consider this OIG evaluation along with the continually evolving evidence base, statutory requirements, national priorities, Departmental goals, and input from a variety of other sources, including the National Advisory Council for Healthcare Research and Quality.

Although the Agency's mission to improve patient safety and quality spans all health care settings and patient populations, the following are examples of AHRQ portfolios and projects that can inform and/or be deployed in improvement work to address adverse events that occur in acute care hospitals:

- **Diagnostic Safety**: Diagnostic safety improvement is a critical patient safety issue that is relevant to preventing patient harm in all settings. AHRQ is supporting diagnostic safety research, has developed several tools and resources to support diagnostic safety improvement efforts, and has others under development. For example, in March 2022, AHRQ plans to release a new TeamSTEPPS® module for Diagnosis Improvement, which aims to raise diagnostic safety awareness and provide assessment and training tools to support local efforts to improve communication among all members of the care team, including non-clinicians and patients and their families. AHRQ also plans to release a new Common Formats for Event Reporting-Diagnostic Safety in 2022.

- **Patient Safety Learning Laboratories**: AHRQ-funded Patient Safety Learning Laboratories conduct research that facilitates collaboration between the health care disciplines and those such as architecture, design, and engineering to develop new and innovative patient safety approaches. The Patient Safety Learning Laboratories demonstrate AHRQ's focus on remaining abreast of advances in safety science and encouraging evidence development that can inform more effective patient safety improvement efforts. Such transdisciplinary approaches show promise in generating innovative strategies that have the potential to alter the status quo and shape a safer future rather than simply layering new toolkits on top of existing systems that may require foundational change.

- **AHRQ Safety Program for Improving Surgical Care and Recovery (ISCR)**: AHRQ contracted with the Johns Hopkins University Armstrong Institute for Patient Safety and Quality and its partners, including the American College of Surgeons, the University of California San Francisco, Westat, and the Johns Hopkins Applied Physics Lab to conduct and evaluate the ISCR. The project focuses on helping hospitals implement evidence-based enhanced recovery pathways that include preoperative, intraoperative, and postoperative practices that can decrease complications and accelerate recovery. In order to facilitate broader adoption of these evidence-based practices among U.S. hospitals, this AHRQ project uses the Comprehensive Unit-based Safety Program approach known as CUSP, a combination of clinical and cultural (i.e., technical and adaptive) intervention components. Adaptive elements include promoting leadership and frontline staff engagement; improvement in safety culture; close teamwork among surgeons, anesthesia providers, and nurses; and enhancing patient communication and engagement. Tools and resources used, and lessons learned by the hospitals

participating in this project, will be compiled into a toolkit that AHRQ will make publicly available. The final report and toolkit are expected to be available some time in 2023.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

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

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ABOUT THE OFFICE OF INSPECTOR GENERAL

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

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

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

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[108] In our incidence rate calculations, we include patients enrolled in Medicare managed care programs (i.e., Medicare Advantage plans) and in the State of Maryland who are not covered under the traditional fee-for-service payment model.

[109] Patient harm events that occurred during the initial hospital stay (index stay) and that resulted in or contributed to a patient's 30-day readmission were attributed to the index stay. Harm events that subsequently occurred during readmissions were not included in the analysis unless those events were related to the first event (i.e., part of a cascade event), thus counting as one event across admissions and attributable to the index stay.

[110] In our sample, we had one patient with both an eligible and ineligible hospital admission. We included the patient in our sample and attributed any harm events to the patient's eligible admission.

[111] The average length of stay of 4.9 days includes the day of discharge.

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[114] The 95-percent confidence interval for the number of patients who experienced an adverse event and temporary harm event spans 27,288 to 56,129, which exceeds 30-percent relative precision.

[115] The 95-percent confidence interval for the percentage of F-level events that resulted in a longer hospital stay spans 49 to 71 percent, which exceeds 10-percent absolute precision.

[116] The 95-percent confidence interval for the number of patients who experienced an event that contributed to or resulted in death (I-level harm) spans 6,099 to 23,501, which exceeds 30-percent relative precision.

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[121] We cannot reliably project the proportion of harm events that were unable to determine.

[122] The difference between the procedure or surgery preventability rates was statistically significant at the 95-percent confidence level (p=<0.0001).

[123] The differences between the preventability rates for medication (p=0.1011) and patient care (p=0.6897) events were not statistically significant at the 95-percent confidence level.

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[126] The patients who were harmed and incurred additional costs (23 percent) includes non-IPPS patients for which additional Medicare costs were calculated as a proxy measure.

[127] One reason that more events did not affect payment is that Medicare bases IPPS payment on a standardized code typically driven by the patient's primary diagnosis and not the individual components of care. As a result, only events that have a profound effect on the care provided will incur additional costs.

[128] The relative precision for the point estimate of $520 million in IPPS payments is 57 percent, indicating a high degree of uncertainty in the point estimate.

[129] "Other non-IPPS payment systems" includes all hospitals serving Medicare patients in the State of Maryland and IPPS-Exempt Cancer Hospitals.

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