Department of Health and Human Services
Office of Inspector General
Office of Evaluation and Inspections

July 2025 | OEI-06-18-00401

Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer

REPORT HIGHLIGHTS

July 2025 | OEI-06-18-00401

Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer

Why OIG Did This Review

- Over nearly 20 years, OIG has identified persistently high patient harm rates nationwide in hospitals, nursing homes, and other health care settings.
- Key to improving patient safety is identifying, or capturing, patient harm events; investigating their cause; and making system-wide improvements to prevent future harm.
- For this report, we traced harm events identified in a 2022 report on the incidence of harm in hospitals to examine whether hospitals captured those events in their incident reporting or other surveillance systems and to understand what actions they took in response.

What OIG Found

Hospitals did not capture all OIG-identified patient harm events, nor investigate all harm events they did capture, limiting hospitals' ability to make improvements for patient safety.

Hospitals did not capture half of patient harm events that occurred among hospitalized Medicare patients. In many cases, staff did not consider these events to be harm or explained that it was not standard practice to capture them. This was often because hospitals applied narrow definitions of harm.

Of the patient harm events that hospitals captured, few were investigated, and even fewer led to hospitals making improvements for patient safety. Some of the improvement actions hospitals took in response to the harm events included training staff and enhancing monitoring for similar events.

What OIG Recommends

HHS leads national efforts to promote patient safety. Our findings demonstrate that more Federal leadership is needed to drive and sustain progress. We recommend that AHRQ and CMS work with Federal partners and other organizations to align harm event definitions and create a taxonomy of patient harm to drive a more comprehensive capture rate of harm events. We also recommend that CMS ensure that surveyors prioritize the Medicare Quality Assurance and Performance Improvement (QAPI) requirement to hold hospitals accountable for patient harm. The QAPI requirement is intended to ensure that hospitals deliver safe, quality care and prevent patient harm. Finally, we recommend that CMS instruct Quality Improvement Organizations to use information about harm events to assist hospitals in identifying weaknesses in their incident reporting or other surveillance systems. AHRQ and CMS concurred with the first recommendation directed to both agencies. For the two recommendations directed to CMS, the agency neither concurred nor nonconcurred with the second recommendation and concurred with the third recommendation.

TABLE OF CONTENTS

BACKGROUND **1**

FINDINGS **5**

Hospitals did not capture half of patient harm events in their incident reporting or other surveillance systems 5

Of the patient harm events that hospitals captured, few were investigated, and even fewer led to hospitals making improvements for patient safety 11

CONCLUSION AND RECOMMENDATIONS **13**

Work with Federal partners and other organizations to align harm event definitions and create a taxonomy of patient harm to drive a more comprehensive capture rate of harm events 13

Ensure that surveyors prioritize the Medicare QAPI requirement to hold hospitals accountable for patient harm 14

Instruct Quality Improvement Organizations to use information about harm events to assist hospitals in identifying weaknesses in their incident reporting or other surveillance systems 14

AGENCY COMMENTS AND OIG RESPONSE **16**

DETAILED METHODOLOGY **18**

APPENDICES **20**

Appendix A: Estimates, Confidence Intervals, and Key Statistics 20

Appendix B: Agency Comments 23

ENDNOTES **31**

BACKGROUND

OBJECTIVE

To determine the extent to which hospitals captured patient harm events in their incident reporting or other surveillance systems, and what patient safety improvement actions they took in response to the events.

OIG established the first national rate of harm among hospitalized Medicare patients in a report released in 2010, which found that more than one in four patients were harmed by the care they received.[1] Since that time, national attention toward identifying and preventing patient harm has increased, yet in a 2022 report, OIG found that patient harm events continued to be widespread.[2] Specifically, that report found that 25 percent of hospitalized Medicare patients experienced harm events during their stays in October 2018, and 43 percent of these could have been prevented if patients had received better care.

Reducing the rate of patient harm is a goal shared by hospitals across the country.[3] To reduce patient harm, hospitals seek to identify and capture harm events within their incident reporting and other surveillance systems. They use this information to understand the harm that occurs in their facilities and to guide their patient safety improvement activities. In 2012, OIG found that despite their efforts, hospitals were unaware of the majority of harm events that occurred in their facilities—hospitals failed to identify 86 percent of events.[4] For this report, we traced the harm events identified in our 2022 report to examine whether hospitals captured those events in their systems and to understand what actions they took in response.

OIG defines patient harm as any undesirable clinical outcome—not caused by underlying disease—that was the result of medical care or that occurred in a health care setting, including the failure to provide needed care. We include all patient harm in our definition, regardless of preventability, severity, or cause. Other researchers and government agencies may use different, more limited definitions of harm or track harm events designated by a predetermined list.

HHS Role in Promoting Patient Safety

The U.S. Department of Health and Human Services (HHS) leads nationwide efforts to promote high-quality health care and prevent patient harm. Several HHS agencies share this responsibility, and most central to this role are the following:

Centers for Medicare & Medicaid Services (CMS). CMS is the Nation's largest health care payer and oversight entity. CMS assesses hospital compliance with Federal requirements, aligns payment with quality under its pay-for-performance programs,

and utilizes its Quality Improvement Organization (QIO) program to assist hospitals in improving patient safety.[5] QIOs provide hospitals with data on quality improvement projects, offer technical assistance, address Medicare patient complaints, and conduct case reviews of care provided.[6, 7] If a patient harm event is brought to the attention of a QIO via a complaint or other data, the QIO will conduct a case review and notify the hospital to participate in an investigation of the event.

Agency for Healthcare Research and Quality (AHRQ). AHRQ leads efforts to improve health care quality with research, education, data, and oversight of the Patient Safety Organization (PSO) program.[8, 9] PSOs collect and analyze information reported voluntarily by health care providers to help improve patient safety and quality of care.[10] Pursuant to the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), this information is considered confidential and privileged information that is protected from disclosure.[11] AHRQ also manages the Quality and Safety Review System, in collaboration with CMS, to track 43 types of harm events identified from medical records collected from Medicare-certified hospitals (including those that participate with QIOs).[12] AHRQ uses a set of standardized definitions called the Common Formats to track events.[13]

HHS Office of Strategy. In March 2025, HHS announced that AHRQ will merge with the Assistant Secretary for Planning and Evaluation (ASPE) to create the HHS Office of Strategy "to enhance research that informs the Secretary's policies and improves the effectiveness of Federal health programs."[14] This report refers to AHRQ prior to the restructuring, and our recommendations are directed to AHRQ until the creation of the Office of Strategy is completed.

Federal Requirements to Track Harm Events

As a Condition of Participation (CoP) in the Medicare program, hospitals must develop and maintain a Quality Assessment and Performance Improvement (QAPI) program. To satisfy QAPI requirements, hospitals must "track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital."[15]

To determine compliance with the Medicare CoPs, CMS delegates responsibility to State survey agencies and accreditation organizations to conduct periodic onsite surveys of hospitals.[16, 17] In fiscal year 2019, surveyors cited hospitals for non-compliance with QAPI 465 times, and 103 of these deficiencies related to failure to track and monitor patient harm events.[18] In fiscal years 2022 and 2023, QAPI deficiencies were the third most frequently cited of the 24 CoPs for hospitals.[19]

In response to an OIG recommendation, CMS in 2023 released new interpretive guidance for surveyors on how to assess hospital compliance with QAPI, including how to track and monitor patient harm events.[20, 21] The new guidance addresses procedures for assessing hospital compliance for (1) ensuring that hospital governing bodies are providing oversight of QAPI programs; (2) analyzing the causes of harm

events; (3) implementing preventive measures to address the causes of patient harm; and (4) ensuring continuous and hospital-wide implementation of a QAPI program.

Patient Safety Initiatives and Efforts

There are a number of ongoing national efforts by government, health care providers, and other groups aimed at reducing patient harm. CMS finalized new patient safety measures in August 2024 to incentivize and promote safety in hospitals.[22] AHRQ launched the National Action Alliance for Patient and Workforce Safety in 2024 to convene leaders from HHS, health care systems, and others to recommit to patient safety.[23, 24] Other efforts include a report from the President's Council of Advisors on Science and Technology (PCAST).[25] Additionally, advances in clinical practice and technology in recent years may better position hospitals to capture harm events.[26]

Related Work

Since 2008, OIG has released 20 reports on adverse events in hospitals and other health care settings. Earlier work found high rates of harm in hospitals and post-acute care facilities including nursing homes, inpatient rehabilitation facilities, and long-term care hospitals.[27] In a memorandum report that serves as a companion to this report, we found that few harm events that hospitals captured were required to be reported externally per CMS and State requirements; however, hospitals failed to report all of those events.[28] Other related work includes an examination of key insights, challenges, and opportunities for improvement for the PSO program.[29]

Methodology

For this study, we traced 299 harm events experienced by a nationally representative sample of 770 Medicare patients discharged in October 2018. OIG identified these events through comprehensive medical record reviews. For more information about these harm events, see *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400).

After the release of our report in 2022, we administered a survey in 2023 to the 172 hospitals at which the harm events occurred. The purpose of the survey was to determine the extent to which the hospitals captured and responded to those events. We received responses from 154 hospitals that provided information for 266 of the 299 harm events. We used these responses to estimate a national rate at which harm events experienced by hospitalized Medicare patients were captured by hospitals' incident reporting and other surveillance systems. We conducted Chi-square tests for independence to identify statistically significant differences in rates of harm events captured by hospitals and harm event characteristics. (See Appendix A for point estimates, associated 95-percent confidence intervals, and statistical test results.) We also interviewed CMS and AHRQ on topics such as

Medicare requirements. See Detailed Methodology on page 18 for more information about our methods.

Limitations

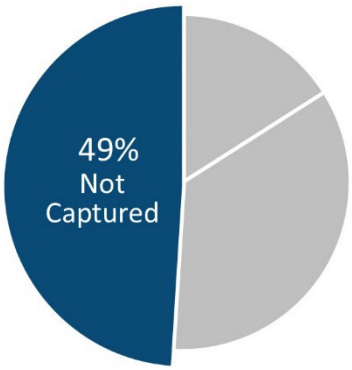
Some respondent hospitals declined to report in the survey whether they captured specific patient harm events, claiming that certain information was confidential pursuant to the Patient Safety Act. These omissions could have resulted in underestimation of the rate at which hospitals captured harm events. Further, we did not independently verify survey responses from hospitals.

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

Hospitals did not capture half of patient harm events in their incident reporting or other surveillance systems



Hospitals miss opportunities to learn from and reduce harm when their incident reporting or other systems fail to capture harm events. Our review found that these systems did not capture 49 percent of harm events that occurred among hospitalized Medicare patients in October 2018.[30, 31] Missed events were absent from all of the hospital's incident reporting and surveillance systems regardless of whether the hospitals were aware of the events. (We use the term "missed" to refer to events not captured for any reason.) For comparison, in 2012, we found that hospitals did not capture 86 percent of events.[32] Although we were unable to conduct a statistical comparison to our prior work, this difference suggests that hospitals may have improved their capture of patient harm during the past decade.[33] Yet, the reasons why hospitals did not capture events, as well as the types of events missed, highlight gaps in hospitals' efforts to identify, learn from, and reduce patient harm.

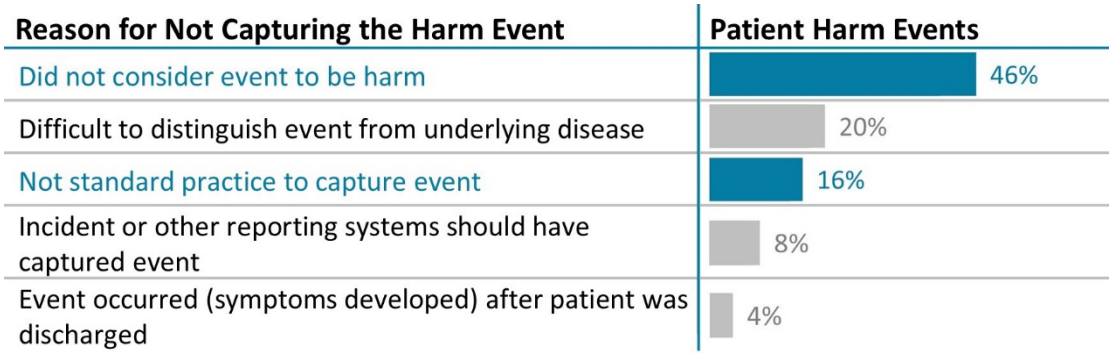
When hospitals missed patient harm events, it was often because staff did not consider them to be harm or, as staff explained, it was not standard practice to capture them

Hospitals did not capture many of the harm events in their incident or other reporting systems, largely because they used narrow definitions of patient harm. Hospital staff did not consider 46 percent of missed events to be harm. They considered these events as part of the normal course of patient care, such as known complications and side effects from treatment. Another reason hospital staff reported that they did not capture these events was because it was not standard practice to capture them as they did not meet the hospitals' criteria for capturing (16 percent). For example, reporting policies at several of these hospitals require staff to only report harm events that result in serious injury or death, or events tracked on a specific list of harms by external entities such as CMS, accreditation organizations, or States which often include a limited list of patient harm events.[34]

In addition to narrow definitions of patient harm, hospital staff reported not capturing harm events because they were difficult to distinguish from the patient's underlying disease (20 percent) or because the event occurred after the hospital discharged the patient (4 percent). For 8 percent of the missed harm events, hospital

staff acknowledged that their systems should have captured those missed events. See Exhibit 1 below for the list of reasons why harm events were not captured.

Exhibit 1: The most common reasons hospitals did not capture patient harm events were related to narrow definitions of patient harm (*n*=130)



Source: OIG analysis of survey data, 2024.
Note: Hospitals could provide more than one reason for not capturing harm events. Only the top five reasons are listed in this exhibit; therefore, the percentages do not add up to 100 percent. See Exhibit A-2 in Appendix A for the associated confidence intervals and corresponding percentages.

The lack of a nationwide definition of patient harm may impede hospitals' efforts to capture the full scope of harm events that occur in their facilities. In interviews, CMS officials acknowledged that the absence of a clear and standard definition of patient harm may thwart efforts to capture harm events across hospitals. Although the Medicare QAPI CoP requires hospitals to track, measure, and analyze the causes of harm events, it is not prescriptive about the types of events hospitals should capture.[35] Instead, CMS officials explained, hospitals should develop their own criteria for identifying and tracking harm events. CMS's QAPI guidance further states that hospitals should track data (including harm events) based on high-risk, high-volume, or problem-prone areas.[36] However, hospital reporting policies in our sample often referenced or relied on different lists of serious harm events tracked by CMS, States, accreditation organizations, and other entities. As a result, definitions of harm events vary widely across hospitals. This means that a harm event reportable at one hospital may not be considered reportable in another hospital, which undermines reliable measurement of the extent of patient harm across hospitals.

Hospitals appeared no more likely to capture adverse events than temporary harm events, raising concerns that hospitals are missing the most serious events

We found that hospitals captured similar percentages of adverse events and temporary harm events, which means that hospitals may not be focusing on the most serious types of harm events.[37] OIG's prior reports distinguish between "adverse events" and "temporary harm events" on the basis of the severity of the impact to the patient.[38] Hospitals captured 40 percent of adverse events, which are harm

events that resulted in extended hospital stays or more serious health outcomes.[39] Similarly, hospitals captured 43 percent of the harms that we categorized as temporary harm events, which include events in which the harm was quickly ameliorated and did not prolong the patient's hospital stay.

Furthermore, hospitals may be missing information about some of the most serious adverse events, which could impact their ability to mitigate risks for future patients. Our review found that hospitals did not capture several of the most serious types of adverse events: those that contributed to permanent injury, required life-sustaining intervention, or resulted in death. Of the 23 sample events in this group, hospitals missed 9 events, including 4 that involved patient deaths.

Hospitals may be more likely to miss patient harm events resulting from surgeries or procedures, indicating the need for greater attention to these types of events

Our review found that hospitals' incident reporting and surveillance systems may be more likely to miss surgery and procedure-related harm events compared to other types of harm events.[40] Hospitals failed to capture 73 percent of surgery or procedure-related harm events, compared to 54 percent of other types of harm events (i.e., medication, patient care, and infection-related events). See Exhibit 2 for the proportion of missed harm events by clinical category.

Exhibit 2: Surgery and procedure-related harm events were more likely to be missed by hospitals

Source: OIG analysis of survey data, 2024. For sample size and confidence intervals, see Exhibit A-5 in Appendix A.
Note: The 95-percent confidence interval for the surgery/procedure-related harm event estimate slightly exceeds 10-percent absolute precision.

In our sample, 37 missed harm events were related to surgeries or procedures. For example, one of these serious events included a stroke experienced by a patient following a hip replacement that resulted in permanent harm with impaired vision and speaking. The most common reason staff missed these events was because they did not consider the events to be harm (17 harm events), followed by staff not considering the event standard practice to capture (7 events) and difficulty distinguishing the event from underlying disease (5 events).[41] Among the events that were not standard practice to capture, hospital staff explained, five events were known complications and two events were considered non-preventable,

characteristics which meant that such events were not normally reported at these specific hospitals.

Teaching hospitals may be more likely to miss patient harm events, possibly due to a higher complexity of care

We found that teaching hospitals did not capture 62 percent of harm events compared to 46 percent of events not captured by non-teaching hospitals.[42] Teaching hospitals are institutions that often work with medical schools and other programs to train physicians and other medical professionals. Research suggests that harm events occur more frequently in teaching hospitals, which may be due to the higher level of care provided in those facilities and the complex environment associated with medical training.[43] The higher rates of missed events in teaching hospitals suggests a failure in hospitals' ability to identify, capture, and prevent harm in complex care environments. See Exhibit 3 for differences in rates of missed events by teaching hospital status.

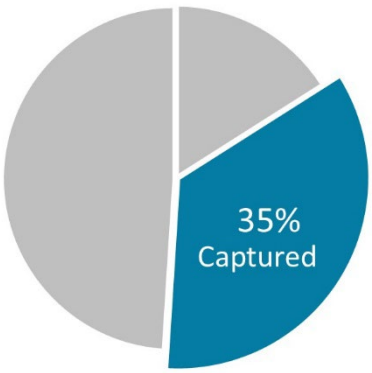
Exhibit 3: Harm events that occurred in teaching hospitals were more likely to be missed

Type of Hospital	Missed Events
Teaching hospitals	62%
Non-teaching hospitals	46%

Source: OIG analysis of survey data, 2024. For sample size and confidence intervals, see Exhibit A-5 in Appendix A.
Note: The 95-percent confidence interval for the non-teaching hospital estimate slightly exceeds 10-percent absolute precision.

About one-third of patient harm events were captured by hospitals, most commonly through medical record reviews

When hospitals capture harm events in their systems, they can use the information to monitor trends, identify systemic patient safety problems, and prevent recurrence. We found that hospitals captured 35 percent of harm events using a variety of methods. Hospitals may have captured additional events that they chose not to report to us due to their non-disclosure of certain information (see information on Patient Safety Act on page 10).



The most common method used by hospitals to capture harm events—medical record reviews—is difficult to implement consistently,

which can pose a challenge to hospital efforts to effectively capture harm events. Medical record reviews, such as clinical peer reviews and mortality reviews, can be more thorough than other methods for capturing harm events, but medical record reviews are more resource-intensive. Hospitals often conduct these reviews in tandem with or as an additional step to other capture methods.

The next most common methods for capturing harm were real-time patient monitoring systems such as electronic trigger tools and incident reporting systems, both of which generally require less time and resources to capture harm events. However, these systems may also have their own disadvantages given they often focus on a prescribed list of harm events and can be costly for hospitals to implement. See Exhibit 4 on the next page for the methods hospitals reported using to capture harm events.

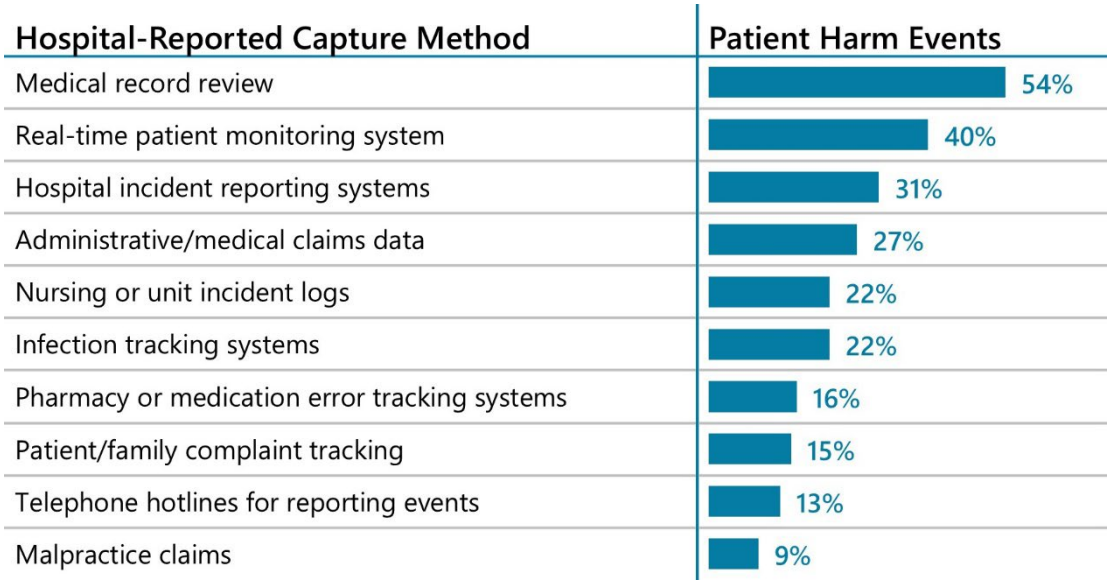
Common Methods for Capturing Harm Events

Medical record review is a manual examination of a patient's medical records to evaluate the care provided, including identifying errors and substandard care.

Real-time patient monitoring systems include automated alerts and tools, using electronic health information at the bedside or recorded in medical records, to identify patients who experienced harm events in real time (e.g., sepsis monitoring).

Hospital incident reporting systems gather and store information on patient safety incidents and other concerns, which can be used to monitor trends and trigger an investigation or other followup activities. All hospitals in our sample stated that they have an incident reporting system.

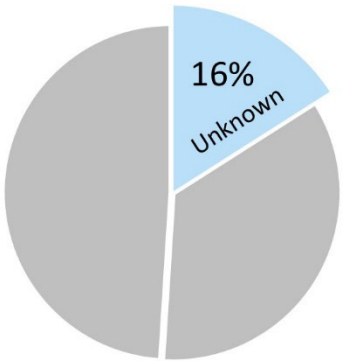
Exhibit 4: Medical record review was the most common method used to capture harm events (*n*=94)



Source: OIG analysis of survey data, 2024. Some hospitals categorized some of these systems as protected under the Patient Safety Act. Thus, they did not report any harm events that might have been captured in those systems, which could alter these percentages.
Note: The percentages of these systems do not add up to 100 percent because events could be captured through more than one method. "Other" responses totaled to 13 percent of responses. See Exhibit A-3 in Appendix A for the complete list of capture methods and corresponding percentages.

We note that the capture methods with lower percentages are not necessarily less effective than those with higher percentages. Several of these are type-specific systems that are not intended to capture all types of harm events. For example, patient falls would not be captured by infection tracking systems.

For the remaining 16 percent of patient harm events, we do not know whether hospitals captured them in their incident reporting systems



Among the 159 hospitals associated with our sample, 114 hospitals reported that they participated with a PSO. For hospitals that work with PSOs, information that meets the statutory definition of "patient safety work product" is afforded certain confidentiality and privilege protections.[44] Patient safety work product includes information that hospitals collect in a "patient safety evaluation system," or PSES (defined in the Patient Safety Act), for reporting to a PSO, but does not include information that is collected and maintained in a separate system, including information that is duplicative of information in a PSES.[45] The majority of PSO-participating hospitals in our sample did not consider the

information we requested to be protected, but 28 hospitals responded that at least some of the information we requested was protected.[46] For these cases, we did not take additional steps to determine whether the events were captured. Thus, we do not know whether the 16 percent of harm events that occurred at these 28 hospitals were captured by the hospitals.

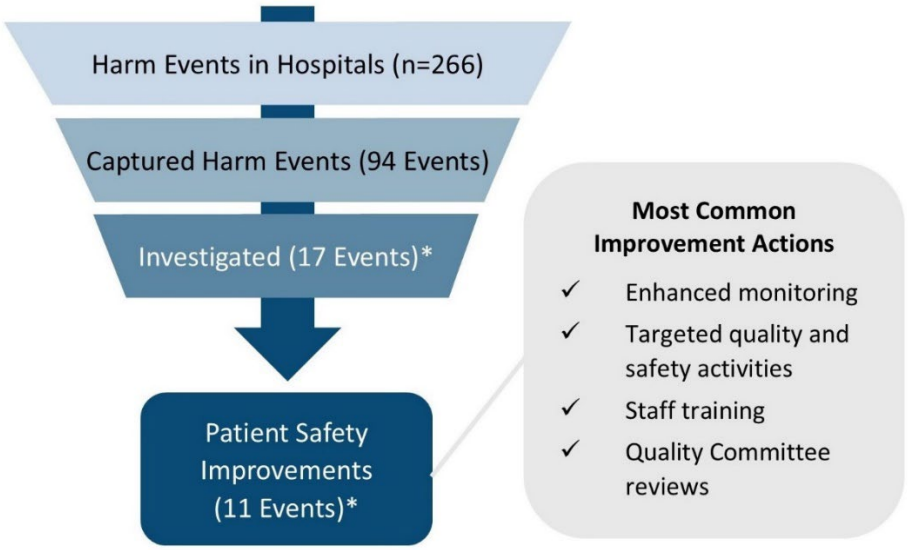
Of the patient harm events that hospitals captured, few were investigated, and even fewer led to hospitals making improvements for patient safety

In our sample, hospitals investigated few of the harm events they captured (17 of 48 events for which we had information), limiting opportunities for hospitals to make patient safety improvements to reduce the risk of future harm.[47] Investigations allow hospitals to identify system breakdowns, negligence, or errors that may have contributed to the event. Further, not all of the events that hospitals investigated led to patient safety improvements. Specifically, only 11 of the 17 captured harm events investigated by hospitals in our sample resulted in any type of patient safety improvement or process change. (See Exhibit 5 on the next page.)

When hospitals opted not to conduct investigations, they cited reasons similar to those for not capturing events—they believed that the harm events were not preventable; the cause was immediately known and remediated; or they considered the harm events to be known complications, side effects, or risks of treatment and therefore understood and even expected.[48] When hospitals did conduct investigations, hospital staff reported, they often involved a combination of tools such as medical record reviews; interviews of staff and clinicians; and reviews of policies and protocols to identify safety gaps and areas for improvement.

For the investigated harm events that led to improvements in patient safety, hospitals reported taking a variety of actions to mitigate and prevent recurrence of such events. These actions included enhancing monitoring for similar events; implementing targeted quality and safety activities; and training staff. In some cases, certain types of harm events, such as minor injuries, may not have warranted actions to improve patient safety. However, because so few harm events were investigated, fewer events led to any safety improvements.

Exhibit 5: Few harm events resulted in patient safety improvements in hospitals



Source: OIG analysis of survey data, 2024. These data represent the 266 harm events in our sample. See Exhibits A-1 and A-3 in Appendix A for the corresponding numbers.
*This number is out of 48 captured harm events for which we had information. We excluded captured harm events where hospitals did not disclose information due to their participation with a PSO.

Even when hospitals did investigate events, hospital leadership may not have elevated information about the events to the Governing Board. Pursuant to Medicare CoPs, Governing Boards are expected to ensure that medical staff are accountable for the quality of care provided to patients.[49] However, as a general practice, many hospitals reported, it takes more than a month for staff to notify all of their Governing Board members about serious harm events (51 of 159 hospitals) or they never notify the full board (29 of 159 hospitals).[50] As a result, Governing Boards may not have the information needed to address patient safety issues in hospitals.

Hospitals voluntarily disclosed 36 percent of captured harm events to patients or their families. Although it is not required by Federal law, we found that hospitals disclosed one-third (36 percent) of the captured harm events to patients or their families. Disclosing harm events to patients is considered a best practice that can increase accountability and improve investigations when patient perspectives are included.[51, 52] It can also improve the care experience and support patients' engagement in the decision-making about their care.[53] For the remaining 64 percent of the captured harm events, hospitals reported that they either did not disclose the events (21 percent) or did not have documentation to confirm whether they disclosed the events (43 percent).

CONCLUSION AND RECOMMENDATIONS

Over the last decade, investments in patient safety by HHS, health care providers, and other groups have likely contributed to progress in hospitals capturing patient harm events within their incident reporting and other surveillance systems. Hospitals captured 35 percent of harm events in their systems compared to 14 percent in 2012. Yet, our study shows that hospitals miss many harm events, which calls for further action to improve hospital identification and investigation of patient harm. Although we cannot expect hospitals to capture every harm event that occurs, narrow definitions of harm or decisions about what should be captured limit hospitals' ability to comprehensively identify harm. In addition, our findings show that many harm events that are known to hospitals may not be investigated, creating a knowledge gap that may contribute to the persistence of patient harm in hospitals. As a result, many hospitals are navigating a landscape of uncertainty about the harm that is occurring within their facilities and how to effectively respond to such events.

In response to our prior work, HHS agencies took a number of actions to help hospitals improve patient safety, but our study shows that additional actions are needed. Therefore, to address our findings, AHRQ and CMS—in collaboration with Federal leadership, industry, and patient safety groups—should take additional steps to reinforce ongoing efforts to increase hospitals' effectiveness in capturing harm events and improving patient safety.

We recommend that AHRQ and CMS:

Work with Federal partners and other organizations to align harm event definitions and create a taxonomy of patient harm to drive a more comprehensive capture rate of harm events

To increase hospital identification of patient harm events, AHRQ and CMS should lead a national effort to align definitions across the health care industry and create a robust taxonomy of patient harm in partnership with relevant Federal partners and other organizations (e.g., health care systems, accreditors, payors, and patient safety advocates). In addition to serious events already tracked by existing programs, this new taxonomy could include the most common types of patient harm events classified by prevalence, clinical category, preventability, severity, and other characteristics. By aligning these definitions, AHRQ and CMS would be supporting hospitals' efforts to capture harm and would facilitate greater communication about the incidence of harm and safety practices within facilities and across the medical community.

AHRQ and CMS could use existing partnerships such as the National Action Alliance for Patient and Workforce Safety or other ongoing initiatives to convene Federal

partners and other organizations to launch this initiative. AHRQ could expand upon the Common Formats for harm event surveillance in hospitals as a foundation for this comprehensive taxonomy of harm events. Both agencies should also periodically update this taxonomy of harm events to streamline and harmonize event definitions across health care organizations as needed.

We further recommend that CMS:

Ensure that surveyors prioritize the Medicare QAPI requirement to hold hospitals accountable for patient harm

In response to a prior OIG recommendation, CMS released in 2023 new interpretive guidance for surveyors regarding how to assess hospital compliance with the Medicare QAPI requirement. This guidance includes information about methods to track and monitor patient harm events. The new guidance provides an essential tool for surveyors to help focus on hospitals' efforts to improve quality and sustain such efforts over time. Our findings of hospitals' failure to capture patient harm events and appropriately respond to such events raise concerns that hospitals may not be fully complying with the QAPI requirement, and surveyors may not be effectively assessing hospitals' QAPI programs.

Although our data on harm events predate the new interpretive guidance, we recommend that CMS take steps to ensure that surveyors prioritize the QAPI requirement in their assessment of hospitals, holding hospitals accountable for adhering to the requirement. CMS should urge surveyors to adopt the new guidance and to use it to thoroughly assess hospitals' QAPI programs. CMS could share our findings to alert surveyors of potential weaknesses in the QAPI programs. CMS could also leverage its oversight of the survey process to ensure that surveyors are effectively assessing hospital compliance with the QAPI requirement. As it launches these efforts, CMS should continue to explore additional ways to track and analyze hospital deficiencies for egregious patient harm or patterns of serious patient harm.

Instruct Quality Improvement Organizations to use information about harm events to assist hospitals in identifying weaknesses in their incident reporting or other surveillance systems

CMS has a framework for Quality Improvement Organizations (QIOs) to assist hospitals in the investigation of patient harm events identified through the Quality and Safety Review System, Medicare patient complaints, and other sources. CMS should reinforce this framework by providing further guidance to QIOs to routinely determine whether hospitals captured these events in their incident reporting or other surveillance systems, and if not, seek to identify and address potential

weaknesses in their incident reporting systems. The guidance should also direct QIOs to assess whether hospitals investigated the captured events and escalated them to hospital Governing Boards, when appropriate. This could help hospitals identify and mitigate barriers to making quality and safety improvements within their own systems.

AGENCY COMMENTS AND OIG RESPONSE

AHRQ and CMS concurred with our first recommendation to work with Federal partners and other organizations to align harm event definitions and create a taxonomy of patient harm to drive a more comprehensive capture rate of harm events. Both agencies reported ongoing and planned efforts to address the recommendation. AHRQ described working alongside CMS on the National Quality Forum's "Focus on HARM" initiative, a public-private partnership tasked with updating the Serious Reportable Events list to reflect current harm events and harmonize reporting of such events. AHRQ also stated that it has plans to review the Common Formats and its Patient Safety Indicators to determine whether updates are needed to align with the "Focus on HARM" initiative. AHRQ explained that this effort will include an independent review as well as input from the public, Federal partners, and PSOs. CMS also described collaborating with AHRQ on a number of efforts, including the National Action Alliance for Patient and Workforce Safety led by AHRQ and the launch of AHRQ's National Healthcare Safety Dashboard. CMS stated that it will continue to participate in these efforts and emphasized that aligning and prioritizing quality efforts across agencies will amplify the impact.

CMS neither concurred nor nonconcurred with our second recommendation to ensure that surveyors prioritize the Medicare QAPI requirement to hold hospitals accountable for patient harm. CMS noted that it issued guidance in 2023 to provide clarification of the QAPI requirement, which surveyors can use to assess hospital compliance and hospitals can use as a resource to strengthen their QAPI programs. According to CMS, QAPI CoP deficiencies were the third most frequently cited of the 24 CoPs for Medicare-certified hospitals in fiscal year 2025. CMS asserted that these data show that surveyors are thoroughly assessing hospitals' QAPI programs and citing them for deficiencies where applicable. CMS also stated that the CoP requirements are intentionally broad to allow hospitals flexibility to meet the specific needs of their facility and patient population. As such, surveyors must rely on the hospital's identified priorities to determine compliance with the QAPI CoP.

While OIG appreciates CMS's continued efforts to ensure that hospitals meet the Medicare CoPs, we believe that more action is needed to ensure that surveyors prioritize assessing hospitals' compliance with the QAPI requirement. We acknowledge that the harm events identified in this report predate CMS's 2023 QAPI guidance. However, it is important to note that we collected hospitals' survey responses regarding those harm events, as well as their policies and practices, in 2023. As our findings show, hospitals did not capture half of harm events that occurred in their facilities, and few were investigated and resulted in patient safety improvements following the events, suggesting that further action is warranted.

CMS concurred with our third recommendation to instruct QIOs to use information about harm events to assist hospitals in identifying weaknesses in their incident

reporting or other surveillance systems. CMS stated that it supports technical assistance to improve patient safety in hospitals through the QIO program and that it directs QIOs to assess whether hospitals appropriately investigated and escalated patient harm events. CMS noted that it will further promote this work by requiring QIOs to address executive-level governance of hospitals' quality and safety programs, which we identified as a vulnerability.

OIG supports AHRQ's and CMS's actions and believes that the agencies' ongoing and planned efforts will help address the issues raised in this report and advance patient safety. For the full text of AHRQ's and CMS's comments, see Appendix B.

DETAILED METHODOLOGY

This study examined whether hospitals captured harm events experienced by hospitalized Medicare patients who were discharged from their stays in October 2018. For the purposes of this report, "captured" means that hospital staff identified and reported the event using at least one of the following systems or methods: incident reporting systems; medical review process; or any other system the hospital had in place to monitor harm events and quality of care. We use the term "missed" to refer to events not captured for any reason. We surveyed hospitals to learn whether previously identified events were captured and what the hospital did in response, including whether hospitals investigated the events, disclosed them, and reported them to external entities. These proportions are estimates of harm events experienced by hospitalized Medicare patients nationwide during the month reviewed, unless otherwise noted as the number of events in our sample.

Sample Selection

The original sample consisted of 299 harm events identified by a medical record review from our national incidence study, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400). In that study, we randomly selected 770 patients from all Medicare patients discharged from hospitals in October 2018. The medical record review revealed that 192 of the patients experienced at least one harm event for a combined total of 299 harm events across 179 hospitals (some patients experienced more than one harm event).

This review is based on the 290 harm events that occurred in 172 hospitals. We excluded nine harm events from our sample—six events were ineligible because the hospitals that provided the care were no longer in operation in 2023 or no longer providing inpatient care, and three events were excluded because the hospitals were under investigation by OIG at the time of our data collection.

Data Collection and Analysis

Survey. We administered an electronic survey to administrators and risk management staff at the selected hospitals who were familiar with their hospital's incident reporting or other surveillance systems and quality improvement activities. The survey included two sections designed to gather information about general practices and how the hospitals responded to the specific harm events we had previously identified. The first section asked about the hospitals' policies and standard practices for responding to harm events. It also collected contextual information, such as the number of hospital beds. For the second section, we asked hospitals to review documentation within their incident reporting and surveillance systems; medical records; and quality improvement programs to research the previously identified harm events. The questions focused on hospitals' response to

the specific harm events in our sample, including whether and how harm events were captured, investigated, disclosed, and reported to external entities.

Our final sample included 172 hospitals representing 290 harm events, and we received responses from 154 hospitals representing 266 harm events. These 266 harm events affected 164 patients. The overall response rate was 92 percent for our unit of analysis, which is harm events. In addition, some hospitals provided incomplete responses and answered questions in only one section of the survey. A total of 159 hospitals completed section one. As a result, we provide some estimates for a sample of 270 harm events. Hospitals that responded were spread across 40 States and the District of Columbia.

We had several sources of non-response concerning 24 of the harm events. These included refusal to participate in the survey (15 harm events); lack of response despite multiple attempts to contact (4 harm events); and inability to locate the necessary records (5 harm events).

We estimated the proportion of harm events that were captured, not captured, and protected from disclosure and estimated 95-percent intervals for these proportions. We also estimated additional measures within each of these groups, such as the percentage of captured events that were investigated, disclosed to patients, and reported to external entities. For each of these groups, we examined survey responses to understand reasons for actions taken or not taken in response to harm events. A few hospitals reported that at least one of their incident reporting or surveillance systems included protected information; we did not collect any information for these harm events. We conducted Chi-square tests for independence to identify statistically significant differences in rates of harm events captured by hospital and harm event characteristics. (See Appendix A for point estimates, the associated 95-percent confidence intervals, and statistical test results.)

Interviews. We interviewed officials from several HHS agencies. We asked CMS officials from the Center for Clinical Standards and Quality about Medicare requirements to track patient harm events and challenges associated with ensuring hospital compliance with those requirements. We also asked about expectations for hospitals' responses to the harm events they identify, including external reporting. We asked officials from AHRQ's Center for Quality Improvement and Patient Safety about the role of PSOs, the agency's harm event disclosure guidance, and officials' perspectives on hospitals' harm event policies. We compared the survey responses to the information provided by CMS and AHRQ to assess any differences in expectations and perceptions about harm events.

APPENDICES

Appendix A: Estimates, Confidence Intervals, and Key Statistics

We obtained our sample of harm events from the data in our national incidence report *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400). In that study, we sampled 770 Medicare patients discharged from short-term acute-care hospitals in October 2018. These patients experienced 299 harm events during their stays across 179 hospitals. The estimates included in this report are based on a sample of 164 Medicare patients who experienced 266 harm events during their hospital stays. In our sample, 159 hospitals responded to questions about policies and practices. Below, we present the corresponding 95-percent confidence intervals.

Exhibit A-1: Event-level estimates and confidence intervals by hospital capture status of harm events (*n*=266)

Estimate Description	Number of Events in Sample	Estimated Percentage of Events	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Events by hospital capture status				
Events *not* captured by at least one hospital incident reporting or surveillance system (i.e., missed)	130	48.9%	42.9%	54.9%
Events captured by at least one hospital incident reporting or surveillance system	94	35.3%	29.8%	41.3%
Event capture information unknown	42	15.8%	11.9%	20.7%

Source: OIG analysis of survey data, 2024. These data include 266 harm events experienced by 164 hospitalized Medicare patients in October 2018.

Exhibit A-2: Event-level estimates and confidence intervals for harm events not captured (i.e., missed) (*n*=130)

Estimate Description	Number of Events in Sample	Estimated Percentage of Events	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Reasons the hospital did not capture the event*				
Event was not considered to be harm	60	46.2%	37.7%	54.8%
It was difficult to distinguish from an underlying disease	26	20.0%	14.0%	27.8%
Not the standard practice to capture this kind of event	21	16.2%	10.7%	23.6%
Event should have been captured by their systems	11	8.5%**	4.7%	14.7%
Symptoms developed after the patient was discharged	5	3.8%	1.6%	9.0%

Estimate Description	Number of Events in Sample	Estimated Percentage of Events	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Event not captured due to other reasons not listed	24	18.5%**	12.7%	26.1%
Unable to determine/no response†	18	13.8%	8.9%	21.0%
Events not captured by severity of harm				
Events not captured that were adverse events	50	38.5%	30.5%	47.1%
Events not captured that were temporary harm events	80	61.5%	52.9%	69.5%

Source: OIG analysis of survey data, 2024. These data include 130 harm events experienced by 86 hospitalized Medicare patients in October 2018.

* The percentages do not add up to 100 percent because hospitals could provide more than one reason for not capturing harm events.

** Number was rounded to the tenth percentage point. The corresponding number in the report was rounded to the nearest whole number.

† The category "Unable to determine/no response" reflects events for which hospitals did not have access to necessary documentation or believed their response was protected by the Patient Safety Act. It does not indicate a missing value.

Exhibit A-3: Event-level estimates and confidence intervals for captured harm events (*n*=94)

Estimate Description	Number of Events in Sample	Estimated Percentage of Events	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Incident reporting or other surveillance systems (i.e., method) that captured the event*				
Medical record review	51	54.3%	44.1%	64.1%
Real-time patient monitoring system	38	40.4%	31.0%	50.7%
Hospital incident or occurrence reporting systems	29	30.9%	22.3%	40.9%
Administrative/claims data	25	26.6%	18.6%	36.5%
Nursing or unit incident logs	21	22.3%	15.0%	31.9%
Infection tracking systems	21	22.3%	15.0%	31.9%
Pharmacy or medication error tracking systems	15	16.0%	9.8%	24.9%
Patient/family complaint tracking	14	14.9%	9.0%	23.7%
Telephone hotlines for reporting events	12	12.8%	7.4%	21.2%
Malpractice claims	8	8.5%	4.3%	16.2%
Other systems	12	12.8%	7.4%	21.2%
Relationship with a PSO at the time of the event				
Events associated with hospitals that were *not* in relationship with a PSO at time of event	48	51.1%	41.0%	61.1%
Events associated with hospitals that were in relationship with a PSO at time of event	46	48.9%	38.9%	59.0%

Source: OIG analysis of survey data, 2024. These data include 94 harm events experienced by 61 hospitalized Medicare patients in October 2018.

* The percentages of these systems do not add up to 100 percent because events could be captured through more than one method.

Exhibit A-4: Event-level estimates and confidence intervals for captured harm events disclosed to patients (*n*=94)

Estimate Description	Number of Events in Sample	Estimated Percentage of Events*	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Disclosure of the event to patient or patient's family				
Did not know whether or not events were disclosed to patient or patient's family	40	42.6%	32.9%	52.8%
Disclosed to patient or patient's family	34	36.2%	27.1%	46.4%
Not disclosed to patient or patient's family	20	21.3%	14.1%	30.8%

Source: OIG analysis of survey data, 2024. These data include 94 harm events experienced by 61 hospitalized Medicare patients in October 2018.

* The percentages of these events do not add up to 100 percent because of rounding.

Exhibit A-5: Chi-square test results for harm events by captured status and selected event types or hospital characteristics (excluding events within protected PSES systems)

Subgroup Description	Sample Size	Number of Events	Estimated Percentage of Events	95-Percent Confidence Interval		P-Value
				Lower Bound	Upper Bound	
Events captured by severity of harm						
Adverse events	84	34	40.5%*	30.5%	51.3%	0.7266
Temporary harm events	140	60	42.9%	34.9%	51.2%	
Events not captured related to surgeries or procedures						
Events related to surgeries or procedures	51	37	72.5%**	58.7%	83.1%	0.0168†
Events not related to surgeries or procedures	173	93	53.8%	46.3%	61.1%	
Events not captured by hospitals related to teaching status						
Events at teaching hospitals	165	103	62.4%	54.7%	69.5%	0.0260†
Events at non-teaching hospitals	59	27	45.8%**	33.5%	58.6%	

Source: OIG analysis of survey data, 2024. These data include 224 harm events experienced by 140 hospitalized Medicare patients in October 2018. We excluded 42 events for which we did not collect information because hospitals asserted that one or more hospital systems was protected.

Note: We conducted Chi-square tests for independence to identify statistically significant differences between captured harm events by event type or hospital characteristic.

* Number was rounded to the tenth percentage point. The corresponding number in the report was rounded to the nearest whole number.

** The 95-percent confidence intervals for these estimates slightly exceed 10-percent absolute precision.

† P-values are statistically significant at the 95-percent confidence level.

Appendix B: Agency Comments

Following this page are the official comments from AHRQ and CMS.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Date: June 11, 2025

To: Ann Maxwell
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General (OIG)

From: Mamatha S. Pancholi, MS MSP
Acting Director, Agency for Healthcare Research and Quality (AHRQ)

Subject: AHRQ Comments on OIG Draft Report, *Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer,* OEI-06-18-00401

Thank you for the opportunity to provide comment on this draft report and more broadly for OIG's continued efforts to promote safe care for hospitalized Medicare patients. It is encouraging that the report's findings suggest hospitals have made improvements in identifying patient safety events between 2012 and 2022, and AHRQ recognizes the efforts by hospitals to identify and learn from such events to mitigate future patient harm.

Identifying and examining patient safety events is one important way to improve patient safety and healthcare quality. An effective approach for hospitals to identify, learn from, and mitigate harm from patient safety events is to cultivate a strong culture of safety. In hospitals with a strong safety culture, all staff recognize when patient safety events occur, report those, and seek to learn from such events. These hospitals strategically apply their resources to triage their review of safety events, to determine which may require review by individual experts to surface necessary corrective actions and which may require more comprehensive investigations such as root cause analyses. Detected failure points and improvements made following patient safety events can then be communicated back to staff. Collectively, these actions reinforce staff vigilance – especially to newly emerging hazards to patient safety. Thus, in these hospitals, the priority on improving patient safety exceeds compliance with requirements set by regulatory or payor organizations. AHRQ's surveys on patient safety culture offer a suite of tools for hospitals to assess their safety culture. OIG's recommendations for alignment around a more prioritized (and perhaps streamlined) set of safety events to report may help to reduce some of the burden hospitals experience in defining, reporting on, and ultimately learning from patient safety events to reduce their occurrence.

Only the first recommendation in the draft report is for AHRQ (in conjunction with CMS). AHRQ's specific response to this recommendation appears below. As noted in the draft report, in March 2025, HHS announced that AHRQ will merge with another office to create the HHS Office of Strategy. AHRQ will inform OIG if this restructuring impacts this response.

OIG Recommendation: Work with Federal partners and other organizations to align harm event definitions and create a taxonomy of patient harm to drive a more comprehensive capture rate of harm events

AHRQ Response: AHRQ concurs with this recommendation and will work with CMS as well as other private and public partners to align definitions of patient safety events and patient harm. AHRQ further agrees with the recommendation to build upon existing initiatives to further this work. Specifically, AHRQ and CMS are participating in the National Quality Forum's "Focus on HARM" initiative, a public-private partnership, which launched to update the Serious Reportable Events (SRE) list to reflect current healthcare delivery harm events and harmonize reporting of such events.[1] The National Quality Forum (NQF) cites a 2023 systematic review which "concluded that the lack of alignment on terminology and reporting structures for patient safety events impedes our ability to learn from these events and reduce their occurrence."[2] The key actions of this initiative include:

- Updating the SRE list
- Harmonizing various safety measurement taxonomies to eliminate redundancies and inconsistencies
- Establishing a consensus-based unified framework and taxonomy of healthcare harms and safety events, with specific data definitions and reporting standards
- For the NQF and The Joint Commission (TJC) to align the SRE list and Sentinel Event taxonomies to reduce measurement burden and increase measurement value
- Develop new implementation guidance to help different reporting systems—including the 25-plus states currently using the SRE list—better harmonize SRE definitions, report safety events more consistently, and reduce administrative burden.

At present, the NQF and TJC are seeking public comment on the SRE List through July 1, 2025.

AHRQ will continue to participate in this initiative. Upon its completion, AHRQ will review its patient safety classification systems and measures, namely, the Common Formats and Patient Safety Indications (PSIs), to determine whether updates are needed to align with the output of the "Focus on HARM" initiative. Additionally, AHRQ plans to continue an in-progress project to identify gaps and opportunities to update the PSIs. The project includes an independent review of published patient safety practices and preventable harm events for which standardized measures are lacking. The interim results from the independent review were published, and AHRQ has hosted a public listening session inviting public input on the results.[3] These results and this public input will be reviewed by experts representing health systems from across the country, states, and health plans. Additionally, federal partners from CMS and CDC will be included in the review process. Opportunities to contribute to and

[1] National Quality Forum. (2024, Apr 04). *NQF to Update and Harmonize Serious Adverse Event Reporting Criteria Essential to Protect Patients From Preventable Harm*. https://www.qualityforum.org/News_And_Resources/Press_Releases/2024/NQF_to_Update_and_Harmonize_Serious_Adverse_Event_Reporting_Criteria_Essential_to_Protect_Patients_From_Preventable_Harm.aspx

[2] Cara L Bowman, Ria De Gorter, Joanna Zaslow, Jacqueline H Fortier, Gary Garber - Identifying a list of healthcare 'never events' to effect system change: a systematic review and narrative synthesis: BMJ Open Quality 2023;12:e002264.

[3] https://qualityindicators.ahrq.gov/announcements/2025/05

provide feedback on these activities will continue to be shared through the Patient Safety Organization (PSO) network supported by AHRQ.

We look forward to working with you on the proposed activities described above. Please feel free to contact Craig Umscheid, MD, MS, Director, Center for Quality Improvement and Patient Safety at AHRQ, with any questions.

Mamatha Pancholi

Mamatha S. Pancholi

DATE: June 13, 2025

TO: Ann Maxwell
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General

FROM: Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer, OEI-06-18-00401

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on this OIG draft report on hospitals' identification of patient harm events among sampled Medicare patients discharged in October 2018.

CMS is strengthening quality and patient safety efforts to improve health outcomes for all Americans through actions including rigorous hospital survey requirements, meaningful quality measure reporting and value-based purchasing requirements, and innovative quality improvement programs. Through these efforts, CMS is holding providers and health care systems accountable and advancing a proactive culture of safety. In addition, CMS actively collaborates with federal partners and other interested parties on quality and patient safety efforts. For example, CMS is an active partner in the National Action Alliance for Patient and Workforce Safety, a public-private collaboration to improve both patient and workforce safety. Each federal agency has a distinct role in the quality enterprise, and aligning across agencies amplifies impact by prioritizing and focusing on similar goals and objectives.

CMS sets high standards for patient safety and quality, generally known as the Medicare Conditions of Participation (CoPs), and surveys Medicare providers and suppliers against these standards. While the Quality Assessment & Performance Improvement (QAPI) CoP focuses on a hospital's internal ongoing and comprehensive program to reduce harm and promote patient safety through leadership oversight and staff engagement, there are many other hospital CoPs that have an impact on patient safety and quality as well. Surveyors assess compliance and cite noncompliance deficiencies to hold hospitals accountable for all requirements related to patient safety and quality. For hospitals to be compliant with the QAPI requirements, facilities are required, among other things, to track adverse patient events, systematically analyze their causes, implement preventive actions, and develop mechanisms that include feedback and learning throughout the hospital.

In 2023, CMS released updated guidance to surveyors for assessing hospital compliance with the QAPI CoP.[1] The guidance emphasizes the integral role hospital leadership plays in advancing a sustained program for improvement throughout the hospital. Additionally, CMS notes the importance of a well-designed and well-maintained QAPI program that fully engages in hospital-wide continuous assessment and improvement efforts. This guidance not only serves as an essential guide for surveyors assessing hospital compliance but also serves as a resource for hospitals as they seek to improve their QAPI programs.

In addition to hospital surveys, CMS collects quality data from hospitals with the goal of driving quality improvement through measurement, payment incentives, and transparency by publicly displaying data on the Care Compare website to empower consumers to make more informed decisions about their health care. Specifically, CMS administers quality reporting and value-based purchasing programs, as required by law, 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.

Among these programs, 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.[2] For example, there is a measure on the death rate among surgical inpatients with serious treatable complications. 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 measures are also publicly reported on the Care Compare website and contribute to Hospital Star Ratings.[3]

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.[4] The HACRP reduces hospital payments by one percent for those hospitals that fall in the bottom quartile based on their performance on HAC measures.[5]

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 2.0 initiative, CMS has ensured that patient safety is a prominent theme in the measure areas. CMS highlighted patient safety as a CMS quality measurement priority in the triennial 2021 National Impact Assessment of CMS Quality Measures Report,[6] in which CMS identified and analyzed

[1] CMS, Center for Clinical Standards and Quality, Quality, Safety & Oversight Group, Revision to State Operations Manual (SOM), Hospital Appendix A - Interpretive Guidelines for 42 CFR 482.21, Quality Assessment & Performance Improvement (QAPI) Program, QSO-23-09-Hospital. March 9, 2023. Accessed at https://www.cms.gov/files/document/qso-23-09-hospital.pdf
[2] Section 1886(b)(3)(B)(viii) of the Act
[3] CMS, *Hospital Compare Overall Ratings Data Collection Periods*, April 2021, https://qualitynet.cms.gov/inpatient/public-reporting/overall-ratings/data-collection
[4] Section 1886(o)(7)(C)(v) of the Act
[5] Section 1886(p)(1) of the Act
[6] 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.

patient safety measure performance trends. In addition, in August 2024, CMS finalized a new patient safety structural measure to drive action and improvement in safety.

Finally, through the Quality Improvement Organization (QIO) program, CMS is supporting direct technical assistance to improve patient safety in hospitals that includes sharing best practices, fostering leadership and governance that prioritize safety, and promoting data-driven decision making. The QIO Program is one of the largest federal programs focused on improving the quality of services for Medicare beneficiaries. Safety has remained a core aim of the QIO Program in its 13th Scope of Work (SoW), which began May 28, 2025, with a specific focus on infection prevention and control, adverse drug events, and safety events. The QIO Program will continue to emphasize implementation of evidence-based interventions and measure improved outcomes.

Safety events are rarely the result of individual error, but rather reflect system level flaws, and CMS continues to support efforts to enable a holistic safety culture to improve the quality of our health care system and protect patients from medical errors. CMS remains committed to the goal of protecting the health and safety of all Americans receiving care in hospitals and partnering with others in these efforts. CMS looks forward to continued focus on this goal from federal partners, health professionals, hospitals, and the OIG.

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

OIG Recommendation

Work with Federal partners and other organizations to align harm event definitions and create a taxonomy of patient harm to drive a more comprehensive capture rate of harm events.

CMS Response

CMS concurs with this recommendation. CMS actively collaborates with federal partners and other interested parties on quality efforts. Each federal agency has a distinct role in the quality enterprise, and aligning across agencies amplifies impact by prioritizing and focusing on similar goals and objectives. For example, CMS is an active partner in the National Action Alliance for Patient and Workforce Safety, a public-private collaboration to improve both patient and workforce safety. Through this partnership, CMS supported the Agency for Healthcare Research and Quality (AHRQ) in the launch of the National Healthcare Safety Dashboard[7] in December 2024. The dashboard aggregates hospital safety data from several measurement sources, creating one comprehensive resource of patient safety. CMS will continue to participate in the National Action Alliance for Patient and Workforce Safety and work with federal partners and other organizations in aligning harm event definitions and creating a taxonomy of patient harm.

OIG Recommendation

Ensure that surveyors prioritize the Medicare QAPI requirement to hold hospitals accountable for patient harm.

[7] Agency for Healthcare Research and Quality. National Action Alliance for Patient and Workforce Safety. Accessed at https://datatools.ahrq.gov/action-alliance

CMS Response

As OIG notes, its findings predate efforts CMS has taken to provide guidance to surveyors when assessing hospital compliance with the QAPI CoP. OIG's findings stem from patient harm events among Medicare patients discharged from hospitals in October 2018. Since this time, in an effort to clarify the requirements to develop and maintain a comprehensive QAPI program to enable the hospitals to deliver safe, quality care to its patients, CMS released comprehensive guidance in 2023 that not only serves as an essential guide for surveyors assessing hospital compliance but also serves as a resource for hospitals as they seek to improve their QAPI programs. In FY 2025, QAPI CoP deficiencies were the third most frequently cited of the 24 CoPs for Medicare-certified hospitals. These data show that surveyors are now thoroughly assessing hospitals' QAPI programs and citing them for deficiencies where applicable. Moreover, surveyors prioritize their survey activities based on the risk of harm to patients in the facility, and there are many CoPs that affect the health and safety of patients. This means surveyors may find patient harm that does not necessarily serve as evidence of a QAPI deficiency.

Several CoP requirements are intentionally broad to allow hospitals flexibility to meet the specific needs of their facility and patient population; they also require hospitals to focus on high-risk, high-volume, or problem-prone areas. CMS guidance directs surveyors to ask the governing body to demonstrate the focus of their QAPI program. The surveyors review a hospital's QAPI program activities during a survey and they must rely on the hospital's identified priorities to determine compliance with the CoPs. This means that patient safety events a hospital chooses to focus on can look different for each facility. For instance, one hospital might prioritize reducing surgical site infections, while another might concentrate on fall prevention. CMS will continue to assess whether further actions are needed to hold hospitals accountable for patient harm.

OIG Recommendation

Instruct Quality Improvement Organizations to use information about harm events to assist hospitals in identifying weaknesses in their incident reporting or other surveillance systems.

CMS Response

CMS concurs with this recommendation. Through the Quality Improvement Organization (QIO) program, CMS is supporting direct technical assistance to improve patient safety in hospitals that includes sharing best practices, fostering leadership and governance that prioritize safety, and promoting data-driven decision making. Safety has remained a core aim of the QIO Program in its 13th Scope of Work (SoW), with a specific focus on infection prevention and control, adverse drug events, and safety events. CMS also directs the QIOs to assess whether hospitals appropriately investigated and escalated patient harm events. CMS will further promote this work by requiring QIOs to address executive level governance of hospitals' quality and safety programs, including capture and monitoring of patient harm events, and providing assistance in addressing process weaknesses.

ENDNOTES

[1] OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries* (OEI-06-09-00090), Nov. 15, 2010.

[2] OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400), May 5, 2022.

[3] The Joint Commission (TJC) has a list of hospitals that are committed to quality and zero harm. See TJC, *Committed to Quality*. Accessed on Sept. 20, 2024.

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

[5] Social Security Act (SSA) §§ 1864, 1865, 1886(o), 1886(p), and 1862(g).

[6] CMS, *Quality Improvement Organizations*. Accessed on Jan. 17, 2025.

[7] Prior OIG work found that over half of hospitals worked with QIOs on quality improvement projects and that hospitals reported QIOs as beneficial to improving care. See OIG, *Quality Improvement Organizations Provide Support to More Than Half of Hospitals but Overlap With Other Quality Improvement Programs* (OEI-01-12-00650), Jan. 22, 2015.

[8] The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorized the establishment of PSOs for voluntary reporting and analysis of patient safety events. Pub. L. No. 109-41 (July 29, 2005), codified at 42 U.S.C. §§ 299b-21 to -26.

[9] The Secretary of HHS delegated to the HHS Office for Civil Rights the authority to enforce the privilege and confidentiality protections of the Patient Safety Act, and to AHRQ all other authorities under the Patient Safety Act. 71 Fed. Reg. 28701 (May 17, 2006). Note that as of March 2025, the Office for Civil Rights reports to the new HHS Assistant Secretary for Enforcement.

[10] AHRQ, *Patient Safety Organization (PSO) Program*. Accessed on June 6, 2024.

[11] Pursuant to the Patient Safety Act and implementing regulations, certain privilege and confidentiality protections attach to information that satisfies the definition of "patient safety work product." 42 U.S.C. § 299b–22; 42 CFR §§ 3.204-3.212. Information reported by health care providers to PSOs must satisfy the statutory definition.

[12] As of January 2025, AHRQ tracked 43 types of patient harm events and its most recent report from the Quality and Safety Review System focused on 41 types of events. See AHRQ, *Quality and Safety Review System (QSRS)*. Accessed on July 29, 2024.

[13] AHRQ, *About Common Formats*. Accessed on Feb. 18, 2025.

[14] HHS, *HHS Announces Transformation to Make America Healthy Again*, Mar. 27, 2025. Accessed on Apr. 14, 2025.

[15] 42 CFR § 482.21.

[16] SSA §§ 1861(e), 1864, and 1865.

[17] CMS, *State Operations Manual, Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals*, Rev. 220, Apr. 2024.

[18] CMS formal comments to OIG. See OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400), May 5, 2022, p. 96.

[19] CMS, *Quality, Certification & Oversight Reports (QCOR), Hospital Citation Frequency Report for Conditions 2022-2023*. Accessed on July 11, 2024.

[20] CMS, *Revision to State Operations Manual (SOM), Hospital Appendix A - Interpretive Guidelines for 42 CFR 482.21, Quality Assessment & Performance Improvement (QAPI) Program*, QSO-23-09-Hospital, Mar. 9, 2023. Accessed on June 6, 2024.

[21] OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October* 2018 (OEI-06-18-00400), May 5, 2022.

[22] 89 Fed. Reg. 68986, 69455-69626 (Aug. 28, 2024).

[23] AHRQ announced the National Action Alliance for Patient and Workforce Safety in November 2022 and had a soft launch in March 2024. See AHRQ, *National Action Alliance for Patient and Workforce Safety*. Accessed on June 6, 2024.

[24] AHRQ, *Recommendations from the Subcommittee to Inform the National Action Alliance to Advance Patient and Workforce Safety*, Feb. 2024. Accessed on July 12, 2024.

[25] President's Council of Advisors on Science and Technology, *Report To The President: A Transformational Effort on Patient Safety*, Sept. 2023. Accessed on May 19, 2025.

[26] Ratwani, et al., "Patient Safety and Artificial Intelligence in Clinical Care," *JAMA Health Forum*, Feb. 2, 2024.

[27] OIG, *Adverse Events*. Accessed on Oct. 22, 2024.

[28] OIG, *Hospitals Reported Few Captured Patient Harm Events to CMS and States* (OEI-06-18-00402), July 23, 2025.

[29] OIG, *Patient Safety Organizations: Key Insights, Challenges, and Opportunities* (OEI-01-24-00150), expected to be released in fiscal year 2025.

[30] A listing of the identified harm events is publicly available in the aforementioned OIG report (OEI-06-18-00400).

[31] Note that this rate may vary given that some hospitals did not provide us information per their interpretation of the Patient Safety Act; see page 10.

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

[33] We were unable to conduct a comparison to the 2012 OIG report because some respondent hospitals did not provide certain information about harm events. These hospitals asserted that the systems used to capture these harm events (and thereby the information about the events) were protected under the Patient Safety Act.

[34] Harm event reporting policies at these hospitals may allow for voluntary reporting of additional types of events, but the staff chose not to voluntarily report the events.

[35] 42 CFR § 482.21.

[36] CMS, *Revision to State Operations Manual (SOM), Hospital Appendix A - Interpretive Guidelines for 42 CFR 482.21, Quality Assessment & Performance Improvement (QAPI) Program*, QSO-23-09-Hospital, Mar. 9, 2023. Accessed on June 6, 2024.

[37] The difference between the capture rates of harm events and severity levels was not statistically significant at the 95-percent confidence level (p=0.7266).

[38] See page 13 of OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400), May 5, 2022.

[39] This analysis is based on the subset of events for which we had information. It excludes events from hospitals that claimed Patient Safety Act protections to their systems.

[40] The difference between the capture rates of harm events and whether they were surgery/procedure-related was statistically significant at the 95-percent confidence level ($p<0.05$). In addition, the 95-percent confidence interval for the surgery/procedure-related harm event estimate slightly exceeds 10-percent absolute precision.

[41] Note that these numbers do not add up to 37 harm events and may overlap because hospitals could provide more than one reason for not capturing harm events in their incident reporting or other surveillance systems.

[42] The difference between the capture rates of harm events and hospital teaching status was statistically significant at the 95-percent confidence level ($p<0.05$). In addition, the 95-percent confidence interval for the non-teaching hospital estimate slightly exceeds 10-percent absolute precision.

[43] Kaiser Health News Editors, "Penalizing Hospitals for Being Unsafe: Why Adverse Events Are a Big Problem," *Kaiser Health News*, June 25, 2014. Accessed on Apr. 30, 2024.

[44] These protections are intended to encourage reporting of harm events and other safety incidents to PSOs without fear of liability. PSOs then analyze this information and offer feedback and advice to hospitals to reduce patient safety incidents. See 42 CFR § 3.20; 42 U.S.C. § 299b–22; and 42 CFR §§ 3.204-3.212.

[45] 42 U.S.C. § 299b-21(7)(B)(ii); 42 CFR § 3.20.

[46] We could not confirm PSO participation for one of these 28 hospitals.

[47] Note that we excluded captured harm events where hospitals did not disclose information due to their participation with a PSO. As a result, of the 94 captured harm events, we had information for only 48 harm events regarding whether an investigation was conducted by the hospital.

[48] In some cases, hospital staff reported that they did not have documentation to determine whether staff conducted an investigation of the harm event.

[49] CFR § 482.21(f).

[50] Hospital administrators at the remaining hospitals reported that all members of their Governing Board are notified within a month (56 hospitals) or the hospital administrators were unaware of when their Governing Boards are notified (23 hospitals).

[51] Methangkool, et al., "Best Practices for Addressing Adverse Event Analysis: A Scoping Review," *International Anesthesiology Clinics*, Mar. 1, 2024. Also see AHRQ, *Communication and Optimal Resolution (CANDOR)*. Accessed on Jan. 27, 2025.

[52] Some States and accreditation organizations may require disclosure of certain types of harm events or unanticipated outcomes from treatment. According to a 2019 review, 10 States mandate disclosure of unanticipated outcomes, which may include harm events, to patients or their authorized representatives. See AHRQ, *Disclosure of Errors*, Sept. 7, 2019. Accessed on Aug. 28, 2024. The Joint Commission requires accredited hospitals to disclose unanticipated outcomes to patients or their authorized representatives. See William M. Barron and Mark G. Kuczewski, "Unanticipated Harm to Patients: Deciding When to Disclose Outcomes," *Joint Commission Journal on Quality and Safety*, Oct. 2003.

[53] Patients have the right to be informed of their health status; involved in care planning and treatment; and able to request or refuse treatment; see 42 CFR § 482.13(b)(2).

Report Fraud, Waste, and Abuse

OIG Hotline Operations accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in HHS programs. Hotline tips are incredibly valuable, and we appreciate your efforts to help us stamp out fraud, waste, and abuse.

TIPS.HHS.GOV

Phone: 1-800-447-8477

TTY: 1-800-377-4950

Who Can Report?

Anyone who suspects fraud, waste, and abuse should report their concerns to the OIG Hotline. OIG addresses complaints about misconduct and mismanagement in HHS programs, fraudulent claims submitted to Federal health care programs such as Medicare, abuse or neglect in nursing homes, and many more. Learn more about complaints OIG investigates.

How Does It Help?

Every complaint helps OIG carry out its mission of overseeing HHS programs and protecting the individuals they serve. By reporting your concerns to the OIG Hotline, you help us safeguard taxpayer dollars and ensure the success of our oversight efforts.

Who Is Protected?

Anyone may request confidentiality. The Privacy Act, the Inspector General Act of 1978, and other applicable laws protect complainants. The Inspector General Act states that the Inspector General shall not disclose the identity of an HHS employee who reports an allegation or provides information without the employee's consent, unless the Inspector General determines that disclosure is unavoidable during the investigation. By law, Federal employees may not take or threaten to take a personnel action because of whistleblowing or the exercise of a lawful appeal, complaint, or grievance right. Non-HHS employees who report allegations may also specifically request confidentiality.

Stay In Touch

Follow HHS-OIG for up to date news and publications.

 OIGatHHS

 HHS Office of Inspector General

Subscribe To Our Newsletter

OIG.HHS.GOV

Contact Us

For specific contact information, please visit us online.

U.S. Department of Health and Human Services
Office of Inspector General
Public Affairs
330 Independence Ave., SW
Washington, DC 20201

Email: Public.Affairs@oig.hhs.gov