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Adverse Events Toolkit: Medical Record Review Methodology

Ann Maxwell
Deputy Inspector General
for Evaluation and Inspections

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TABLE OF CONTENTS

INTRODUCTION

This toolkit provides information about how we conducted medical record reviews to identify patient harm and our decision criteria for adverse events, which may be useful to health care providers and researchers dedicated to patient safety. The toolkit describes the methods used in a recent report, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018*, OEI-06-18-00400, and builds upon a broader series of reports about adverse events in hospitals and other health care settings. Of the 18 reports currently in this series, 7 studies used nurses and physicians to review medical records to identify adverse events (each focused on a different health care setting).

Companion Resource

For clinical guidance used during OIG's medical record reviews, see our companion resource: *Adverse Events Toolkit: Clinical Guidance for Identifying Harm*.

The goal of our medical record reviews was to establish a national, point-in-time rate of patient harm. The methodology builds upon the Global Trigger Tool (GTT) methodology developed by the Institute for Healthcare Improvement (IHI), which we adapted and used for screening and flagging medical records for possible patient harm.

During the course of our reviews, we recorded internal decisions, researched clinical literature and guidelines, interviewed experts in various fields, and conducted routine calls to gain consensus among reviewers on decisions regarding what constitutes harm and how to categorize harm events. A companion resource, *Adverse Events Toolkit: Clinical Guidance for Identifying Harm*, describes the clinical decision rules we developed for 29 conditions as well as suggestions for how to identify and document evidence of patient harm.

Standards

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

PROCESS FOR IDENTIFYING PATIENT HARM EVENTS

Patient harm events are commonplace in inpatient care settings, affecting approximately one in four hospital patients and similar numbers of patients in post-acute care settings, such as nursing homes. However, harm is not always acknowledged as such by providers and clinical staff, often because it is so routine. We believe it is important to identify all causes of harm—known risks, failure to provide care, and substandard care, as well as errors and other causes of harm. Tracking all causes of harm allows for better comparisons across time and provides a fuller picture of the patient experience. The challenge associated with tracking all causes of harm is systematically identifying events in an efficient way.

We conducted retrospective reviews of medical records to identify harm events using a two-stage process. Sample sizes ranged between 300 and 800, depending on the setting. The stages are (1) a manual screening process using a Global Trigger Tool (GTT) first devised by the Institute for Healthcare Improvement (IHI) and (2) a comprehensive physician review. Combined, this process was effective at identifying patient harm events.[1, 2]

Stage 1 – Screening: In the first stage of review, screeners (typically nurses experienced in GTT reviews) systematically reviewed records using a modified version of IHI's GTT methodology. The screeners searched the record for "triggers," which are clinical clues that may indicate that harm occurred. (In some cases, the trigger is itself the harm, such as a pressure injury.) When a trigger was identified, the screeners investigated further and recorded their results.

Screeners also did a targeted review to investigate diagnoses listed in claims data that were *not* present on admission to assess whether the diagnoses were potentially related to a harm event. Medical conditions that develop during a stay are sometimes the result of harm events.

Suggested order of review

When using a GTT methodology, reviewing medical record components in the order listed below may shorten the timeframe needed to conduct reviews.

1) Diagnosis and procedure codes
2) Discharge summary
3) History and physical
4) Medication administration record
5) Laboratory results and radiology reports
6) Prescriber orders
7) Operative record
8) Daily progress notes
9) Skin/wound assessment
10) Other pertinent records (e.g., contiguous emergency department records)

Medical records flagged by the screeners as having potential harm events were referred to the second stage of review. Detailed information about the triggers we used is included in the companion document: *Adverse Events Toolkit: Clinical Guidance for Identifying Harm*, and a comparison of our methodology to the original IHI-developed methodology is described in Appendix A.

In addition to the manual screening process, we automatically referred to the second stage of review the medical records for any patients who were readmitted within 30 days of the stay, as these

readmissions may have indicated that the patient was harmed during the original admission. Screeners also had the discretion to refer medical records in which they did not identify potential harm but found the case to be complex or to involve circumstances often associated with harm.

Stage 2 – Physician review: In the second stage, we used an interdisciplinary panel of physicians to conduct a comprehensive review of the records referred by the screeners. A physician reviewer independently reviewed each patient's medical records to confirm (or refute) harm events identified in the first stage of review and to identify any additional harm events. They assessed whether events were preventable and classified the events according to severity, the harm event type, and other characteristics. We routinely held calls, during which the physician reviewers discussed complex cases and questionable events to promote consensus around harm determinations. We included a wide range of specialties (e.g., infectious disease, cardiology, surgery, neurology, physiatry, orthopedics, critical care, and hospital medicine) on the physician panel to promote discussion, and this provided opportunities for reviewers to consult other members for nuanced or complex cases. See "Quality Assurance" section on page 16 for more information. For each referred record, the physician reviewer made the final determination of patient harm.

DEFINITION OF PATIENT HARM

We define 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. Below, we further describe the criteria we used to identify patient harm and we explore additional boundaries pertaining to patient harm in subsequent sections. Patient harm refers collectively to adverse events and temporary harm events. An "adverse event" indicates that the harm prolonged the hospital stay; resulted in an elevation of care or transfer to another facility; caused permanent harm; required life-saving intervention; or contributed to death. A "temporary harm event" is an event that resulted in patient harm and required medical intervention but did not prolong the patient stay, cause permanent harm, or require life-sustaining intervention. (See the "Severity of Harm" section on page 7 for details about the distinction between adverse events and temporary harm events.)

Patient harm includes all causes of harm that occur as a result of medical care, or lack thereof, and that necessitate treatment or intervention. It includes both preventable and nonpreventable harm events. Nonpreventable harm can include expected side effects where harm was foreseeable but considered acceptable given alternatives or known complications of treatment that required intervention. Our definition of patient harm does not include near misses that had the potential to cause harm. For each harm event, we identify (1) a clinical cause (commission or omission) demonstrating that the event is not the result of underlying disease, (2) signs and symptoms of harm to the patient, and (3) a medical intervention to treat the harm. Other researchers and government agencies have tracked harm events by creating lists of specific harm events, see box below.

Differences in patient harm definitions, terms, and lists

Researchers and organizations use a variety of terms and lists to define patient harm, so it is important to articulate the specific definition used in each research effort. The literature on patient safety sometimes uses the term "adverse events" to indicate a specific list of harm events but OIG focuses on all causes of harm and does not limit to a specific list.

Some researchers use alternative terms such as never events, serious reportable events (SREs), sentinel events, hospital-acquired conditions (HACs), healthcare-associated infections (HAIs), and adverse drug events (ADEs) to focus on a specific subset of harms or that fit specific criteria. Below are some examples of terms currently used:

- The Centers for Medicare & Medicaid Services (CMS) uses a specific list of HACs, that includes HAIs, to meet statutory requirements for its payment programs and policies. See Deficit Reduction Act HAC list, the HAC Reduction Program list, and provider-preventable conditions list.
- The Joint Commission (TJC) focuses on sentinel events when instructing onsite surveyors to assess hospital compliance with accreditation standards. See Sentinel Event Policy for Hospitals.
- The Centers for Disease Control and Prevention (CDC) focuses on HAIs in its surveillance programs to track infections acquired in health care facilities and tracks ADEs as part of the Healthy People initiative. See Types of Healthcare-associated Infections and see National Electronic Injury Surveillance System.
- The Agency for Healthcare Research and Quality (AHRQ), with support from CMS and CDC, tracks 35 types of adverse events in the Quality Safety and Review System. See Quality Safety and Review System.
- The National Quality Forum (NQF) developed a list of serious reportable events (also known as never events) to facilitate uniform and comparable public reporting. See List of Serious Reportable Events.

Patient Harm Event Criteria

The sections below provide details regarding what we, in OIG, include and exclude as patient harm.

Exclude underlying disease. We excluded events that resulted from the natural progression of underlying disease. For example, symptomatic anemia would not be considered a harm event if it resulted from an underlying condition, such as bone marrow cancer. In contrast, we included disease exacerbations that resulted directly from hospital care or omissions of care during the hospital stay. For example, we would consider symptomatic anemia that is due to anticoagulants requiring a blood transfusion a harm event.

Include both commission and omission of care. We included harm events that resulted from acts of commission (i.e., events related to the active delivery of care) and omission of care (i.e., events related to the failure to provide necessary care). Omissions of care may represent errors or substandard care, such as failing to implement preventative measures. Some researchers exclude omission events because the linkage between the care and patient harm is more ambiguous.

Examples of commission events:

- administration of penicillin to a patient who had an allergic reaction
- administration of beta blocker to a patient that resulted in complete heart block

Examples of omission events:

- delayed recognition of Type 2 myocardial infarction leading to pulmonary edema
- failure to diagnose and treat a patient with serious hypertension (i.e., not providing antihypertension medication) resulting in a stroke

Exclude present on admission (POA). We excluded harm events caused by care provided in another setting prior to the hospital stay.[3] These are categorized as POA events. Some researchers include POA events in order to track harm across health care providers rather than limiting to a single hospital stay.

POA events are those that occurred:

- during a previous stay in that same facility,
- in another facility (e.g., a skilled nursing facility, a different hospital),
- in an ED observation or outpatient encounter from which the patient was discharged prior to the admission,[4]
- in an ambulance on the way to the hospital, or
- at the patient's home.

Examples of POA events:

- a complication, such as an infection, from a procedure performed during a preceding hospitalization that was recognized upon admission and treated appropriately during the hospital stay
- a pressure injury that developed prior to admission and did not progress to a higher stage during the hospital stay

Include expected side effects. We included harm events resulting from expected side effects when they required intervention. This was true even when the provider explained the potential complication during informed consent. For example, we would consider vomiting and dehydration due to chemotherapy treatment a harm event if the patient required repeated use of antinausea medication that was more than expected or needed intravenous fluids.

Exclude solely abnormal laboratory test results. We did not typically consider abnormal laboratory test results without symptoms to be harm events even when providers intervened to correct the abnormal finding. For example, we would not consider a patient with no signs or symptoms of infection but who had an indwelling urinary catheter and a positive urine culture of 100,000 colony-forming units (CFUs) per milliliter to have experienced a harm event. If the same patient had accompanying signs and symptoms, such as pain or fever, we considered the bacteriuria a harm event.

Exclude pain. We excluded events composed solely of pain without evidence of harm. For example, we would not count routine post-surgical site pain as a harm event unless it was associated with a hospital-acquired infection or other surgical complication. In addition, we may consider significant pain that impacted patient care, such as the patient being unable to ambulate, part of a harm event if this was the result of a fall or other trauma.

SEVERITY OF HARM

We assigned each patient harm event a severity level based on a modified version of the National Coordinating Council for Medication Error Reporting and Prevention's (NCC MERP's) index for categorizing events. NCC MERP devised this index to categorize medication errors by the degree of harm and the resources expended to treat the patient.[5] The NCC MERP Index ranks errors from levels A to I on the index. Levels A through D constitute "near misses" in which the error did not result in patient harm but had the potential to cause harm. These errors typically consist of quality-of-care problems such as staff not following national clinical guidelines or best practices. Levels E through I progress from temporary harm (E-level harm) to harm that contributes to or results in death (I-level harm). These harm levels are not necessarily sequential, since an H-level harm could have a short-lasting effect if resolved quickly whereas F-level and G-level harms may result in longer-lasting effects.

Although the NCC MERP Index was initially developed to categorize the severity of medication errors, researchers, such as those at IHI, have modified the Index to measure and distinguish other types of patient harm events. Our physician reviewers assigned each harm event to a severity level between E and I. We also used the index to distinguish between temporary harm events and adverse events. See Exhibit 1 below for a description of each severity level.

Exhibit 1: 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 February 20, 2001.

In determining the level of harm, reviewers considered the impact to the patient and specific circumstances of the harm event. Below we provide more detail about each level of the index.

E-level. We categorized harm events that caused temporary harm and required an intervention, including the need for additional monitoring, as "E-level." Although adverse events are often more serious, temporary harm events can also be serious and lead to severe consequences if left untreated. For example, if treated promptly, clinically significant hypoglycemia (low blood glucose) is usually a temporary harm event, but it can become a life-threatening adverse event if left untreated. Other examples of temporary harm events could include a surgical bladder perforation with immediate

surgical repair, an asymptomatic procedural bleed corrected with blood transfusions, a skin rash caused by allergies, and a Stage 1 pressure injury.

F-level. We categorized harm events as "F-level" if they prolonged the hospital stay, required an elevation in level of care (e.g., patient moved to the intensive care unit (ICU)), required a transfer to another facility (for observation, emergency care, or inpatient admission), or required a subsequent admission. If the patient was transferred, we considered the reason for the transfer when determining the level of harm and only assessed harm events as "F-level" if the patient was transferred to receive a higher level of care for the event. Examples of F-level harm could include surgical site infections and injuries from falls which prolonged the patient stays.

We expanded the original NCC-MERP definition of an F-level event to include harm events that contributed to or resulted in an elevation in level of care, transfer to another facility, or subsequent admission. We expanded the definition to include these cases after identifying events in long-term care facilities that would be considered an F in an acute care setting but did not meet the F-level criteria due to a lengthy anticipated stay. Similar to other F-level events, these scenarios indicate the need for additional care and resources to treat the harm event.

G-level. We categorized harm events that contributed to or resulted in permanent patient harm as "G-level." This included either cognitive or physical impairment and often represents very significant implications for the patient. Examples of G-level harm could include complications (e.g., strokes) from major surgeries resulting in lifelong impaired coordination and mobility.

H-level. We categorized harm events that required an intervention to sustain the patient's life as "H-level." The intervention typically occurs within 1 hour of the act of commission or omission that led to the patient harm to save the patient's life. These events could include permanent harm and always required a life-saving intervention to prevent death. In distinguishing life-saving intervention (H-level) from permanent harm (G-level harm), reviewers considered which had the more profound impact on the patient. Examples of H-level harm could include respiratory failure due to excessive use of opioids and hypoglycemic coma due to insulin, which can be life-threatening if not corrected within the hour.

I-level. We categorized harm events that may have contributed to or resulted in a patient's death as "I-level." If a patient experienced multiple events that contributed to or resulted in their death during their hospital stay, only one event that most directly contributed to or resulted in their death could be categorized as I-level. Therefore, each patient could only have one I-level event. Other events may be cited at another level of severity. A patient with a terminal illness or receiving end-of-life care can also experience an I-level event that may likely not be preventable. In such cases, reviewers considered whether the patient's death was hastened as a result of the event.

PREVENTABILITY OF HARM

Measuring all causes of harm results in capturing both preventable and nonpreventable patient harm events. This comprehensive measurement of harm improves our ability to compare rates across time and across research. However, we believe it is important to allow providers, researchers, and policymakers to focus on preventable events, in which they have greater opportunity to reduce harm. Therefore, we determined the preventability of harm events. Preventability assessments, however, are inherently subjective and assessments can be affected by the quality of documentation and advances in medical practice. Physician reviewers assessed the preventability of each harm event individually and considered the clinical cause of the event, whether the event was anticipated, and other questions (see list below).

Measuring Preventability – Pros and Cons

Pros:

- Improves our understanding of harm events
- Assists with designing and prioritizing interventions to prevent the recurrence of preventable harm events
- Assists with designing policies to avert payment for preventable harm events

Cons:

- Changes in clinical guidance over time may affect how reviewers assess preventability
- Inherent subjectivity can make it difficult to achieve high inter-rater reliability in determinations of preventability
- Reviewers may be affected by hindsight bias in determining preventability
- Limited information in medical records may hinder preventability assessments

Questions To Consider When Determining Preventability

- Was an identifiable error or system failure documented in the medical record? If yes, the event can be considered preventable.
- Could the care provider have anticipated this event with the information available at the time? If no, the event is *likely not preventable*.
- Were appropriate precautions taken to prevent this event? If yes, the event is *likely not preventable*. If no, the event is *likely preventable*.
- Did the providers follow national clinical guidelines or best practices when providing care? If not, the event may be preventable.
- Was there an omission of care (e.g., delay in providing care)? If yes, this would be considered an error and would be preventable.
- Was the harm event the result of an expected side effect of medication that was more severe or prolonged than normal and required intervention? If yes, this could be considered *likely preventable* if preventative measures were considered the standard of care and providers did not take those measures.

We then assigned each harm event to one of five preventability determinations. We created a preventability scale to provide our physician reviewers with flexibility in calling an event *likely* to *clearly preventable* or *likely* to *clearly not preventable*. If physicians were unable to determine preventability,

they could label an event *unable to determine*. Physicians also explained their rationale for each preventability determination based on a list of contributing factors gleaned from prior research and experience in OIG studies of adverse events. See Appendix B for a list of contributing factors.

Assessing an event as clearly preventable or clearly not preventable required a greater degree of certainty on the part of the reviewer. Although we collapsed the designations of clearly and likely into the larger categories of preventable or not preventable for presentation in the report, the five-point scale enabled physicians to make more precise determinations, which was useful during quality assurance activities. Reviewers also selected from a pre-determined list of factors that could have contributed to harm events. For example, preventable events may be related to substandard treatment, medical error, or inadequate monitoring depending on the factors involved. Events that were 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 a particular type of harm event because of poor health. These factors are not necessarily exclusive of each other and we asked clinicians to use their clinical experience and judgment in selecting the factors that applied to each harm event. Clinicians based their decisions on the circumstances of the specific case and also considered accepted standards of care, guidance developed during the review process, and group discussion of the patients and events. Additionally, clinicians referenced condition-specific guidance developed by OIG, see the *Adverse Events Toolkit: Clinical Guidance for Identifying Harm*.

COMPLEX CASES

During our reviews, some patients had complex medical conditions or circumstances that made it difficult for our reviewers to determine whether a patient harm event occurred and how to assess its preventability. Below, we describe some of these circumstances and how we addressed them.

Cascade harm events. When a patient experienced an initial harm event that causes a series of related and dependent events, physician reviewers combined the events into a "cascade" and counted it as a single event. The purpose of combining the events was to avoid overcounting harm events. This was in contrast to cases where a patient experienced multiple, unrelated harm events during a hospital stay, which we counted as separate events (see "Examples of two independent harm events" below). To ensure accuracy and consistency, we instructed clinicians to clearly distinguish between each harm event that occurred in the cascade and to identify the initial event that cascaded to other harms.

Examples of cascade events:

- After placement of a contaminated central venous catheter, a patient developed an infection that resulted in sepsis, shock, acute kidney injury, respiratory failure, and ultimately the patient's death. Our reviewers assigned this series of related events to the most serious applicable severity level—I-level harm (an event that contributed to or resulted in death). Each harm event shares an initial act of commission, which was the central line-associated bloodstream infection.
- A patient undergoing a transcatheter aortic valve replacement experienced prolonged hypotension during the procedure which led to pulseless electrical activity requiring cardiopulmonary resuscitation, vasopressor medication, a heart pump insertion, and fluid resuscitation. The hypotension contributed to permanent brain injury from a stroke. Our reviewers assigned this as a cascade event with a severity level of "G-level harm" (an event that contributed to permanent harm).

Examples of two independent harm events (i.e., not cascade events):

- A patient developed a catheter-associated urinary tract infection (CAUTI) and oversedation due to medication during the hospital stay. The harm events are not related.
- A patient developed a CAUTI and was treated with antibiotics and then developed a rash as a reaction to the antibiotics. The use of antibiotics leading to the rash was considered an independent harm event because it had a clinical cause that was separate and distinct from the CAUTI.

Latent harm events. We reviewed medical records for subsequent admissions within 30 days of the patient's discharge. This review allowed us to identify some adverse events that were not known at the time of discharge, such as the development of a deep surgical infection. In cases where harm from care in an initial stay became evident in a subsequent stay, we attributed the harm to the initial stay and not to the readmission.

Repeat similar events. When a patient experienced repeat similar events during a hospital stay, we generally counted each event separately. For example, if a patient fell twice during the hospital stay and was injured both times, we counted both falls as events.

Exceptions: The following are exceptions to separately counting multiple, similar events.

- We collapsed multiple hypoglycemic events within 24 hours into a single event because these repeated events are often related to a single cause (e.g., insulin or other diabetic agents) that can affect a patient for an extended time (e.g., 24 hours). We counted recurrences after 24 hours as separate events.

- We collapsed multiple pressure injuries into a single event when the pressure injury (1) was at the same anatomical site, including bilateral pressure injury of the same anatomical site (e.g., bilateral buttocks), and (2) occurred within 24 hours of the initial pressure injury. We counted pressure injuries at different anatomic sites as separate events. This is because they have different causes or means of prevention. For example, pressure injuries of the foot are often caused by not using a foam boot, whereas pressure injuries of the buttock are often caused by failure to turn the patient.

Drug abuse. Although we included any adverse drug event that occurs in a health care setting, our reviewers considered the patient's history of drug abuse or dependence when assessing whether an event was preventable. A harm event may not be preventable if a drug-dependent patient failed to disclose recent drug use prior to admission, posing increased risk for interaction effects or oversedation.

End of life and hospice. Acute care patients at the end of life may be converted to hospice during their stay. For these patients, we included certain harm events if the harm was not the intended result of palliative care. For example, our reviewers would consider central-line infections to be harm events for hospice patients. If patients were particularly susceptible to the harm, given their frailty status or other risk factors, reviewers designated the harm as *likely not preventable*. In contrast, a fall from bed with a resultant fracture or other injury would be considered preventable harm if staff did not take the appropriate preventative measures. Oversedation due to medication was *not* considered a harm event if the intention was to improve comfort and care for these patients.

In some cases, providers had to weigh the potential impact of appropriate intervention with known side effects or physical toll on an already fragile patient. For example, providers may decide to avoid routine turning to lessen a hospice patient's pain. In such situations, reviewers may determine that a related pressure injury is a nonpreventable harm event. In addition, our physician reviewers considered documented patient or family wishes to determine if end-of-life events were preventable.

MEDICAL RECORD REVIEW PROTOCOL

In this section, we provide a simplified and condensed version of OIG's physician protocol for collecting information about adverse events from the medical record. Our reviewers captured data elements listed below for each harm event identified during their medical record reviews and entered their responses into an electronic instrument.

Core Data Elements

1. **Harm:** Did you find patient harm?

   ○ Yes

   ○ No

2. **Harm Event Date:** On what date did the harm event begin? _____

3. **Description of Event:** Briefly describe the harm event in one-two sentences; include the cause of the event.

4. **Clinical Cause:** Identify the commission or omission that precipitated this harm event.

5. **Background:** Provide background information about the patient's condition, including medical history, comorbidities, history of present illness, and reason for hospitalization.

6. **Evidence:** Describe the evidence in the medical record that supports your findings, including signs and symptoms, exam results, laboratory results, imaging results, and other clinical findings.

7. **Intervention:** Describe the medical intervention administered to treat the event.

Severity and Preventability Data Elements

8. **Severity Level:** Which severity level best describes this harm event?

- ○ E – Temporary harm, intervention required and/or performed
- ○ F – Prolonged inpatient stay, elevation in level of care, or transfer to another facility
- ○ G – Permanent patient harm
- ○ H – Life-sustaining intervention required
- ○ I – Contributed to death

9. **Preventability Rating:** Provide your clinical assessment regarding whether this event was preventable and select the factors that contributed to the harm event.

- ○ Clearly preventable
- ○ Likely preventable
- ○ Clearly not preventable
- ○ Likely not preventable
- ○ Unable to determine

10. **Contributing Factors:** Select the factors that contributed to the event. (See Appendix B for Contributing Factors used in OIG reports.)

11. **Preventability Rationale:** In your own words, describe the reason for the preventability rating and rationale(s) selected.

Harm Event Category and Type Data Elements

12. **Clinical Category:** Which clinical category is most related to this harm event?

- ○ Medication
- ○ Patient Care
- ○ Procedure/Surgery
- ○ Infection

13. **Harm Event Type:** Which event type best describes this harm event? (See the *Adverse Events Toolkit: Clinical Guidance for Identifying Harm* for examples of common harm events we identified in our reviews.)

14. **NQF/HAC Event:** Was the event on the CMS HAC and/or NHQ lists? (This inquiry was composed of a series of skip pattern questions to facilitate navigation and overlap of these lists. See CMS's HACRP and DRA-HAC lists, and the NQF SRE list for more information.)

Quality Assurance-related Data Elements

15. **Cascade:** Is this harm a cascade event?

    ○ Yes

    ○ No

16. **Group Discussion Call:** Would you like to discuss this admission during a consensus call? (See Group discussions for more information about these calls.)

    ○ Yes

    ○ No

17. **Present on Admission:** Was the harm event present on admission?

    ○ Yes

    ○ No

18. **Portion of Stay:** During which portion of the stay did the harm event begin?

    ○ During the inpatient hospitalization

    ○ In a contiguous emergency room visit

    ○ In a contiguous outpatient department visit

    ○ In a contiguous observation stay

    ○ Other (describe)

    ○ Unable to determine (describe)

19. **Triggers:** Which triggers were most helpful in identifying this potential harm event? (See the *Adverse Events Toolkit: Clinical Guidance for Identifying Harm* for the list of triggers used.)

20. **Record Quality:** Did the quality of the medical record documentation negatively affect your ability to review this admission?

    ○ Yes

    ○ No

21. **Anything Else:** Is there anything else about this admission that you would like to convey, such as care problems that did not lead to harm?

    ○ Yes

    ○ No

QUALITY ASSURANCE

In this section, we provide suggestions for ensuring the quality and integrity of medical record reviews to identify harm events. Quality assurance reviews ensure accuracy and consistency by helping promote standardization across reviews and by minimizing false-positive (as well as false-negative) results. Below is a description of the quality assurance practices used in our reviews.

Pre-review trainings. Prior to beginning medical record reviews, we conducted training sessions for all OIG reviewers to ensure that they understood our screening method, definition of harm, data collection instrument, and study protocols and practices found in this toolkit. Each reviewer performed pre-test reviews and received feedback on the results of those reviews. These training sessions and pre-test reviews helped improve reviewer accuracy and consistency.

Insufficient records. We also assessed each record for completeness prior to beginning the reviews. If critical components of a record were missing, we considered excluding the record from the reviews. In cases where the records appeared to be complete, but some portion of documentation was insufficient to determine the circumstances surrounding an event, we instructed our reviewers to rely on their clinical judgment. Our reviewers based their harm event and preventability determinations on clear and logical conclusions supported by existing documentation. In some cases, it was clear that a patient harm event occurred, but it was not clear why it occurred. In such cases, our reviewers chose to identify preventability as "unable to determine."

Documentation of events. During the process of the reviews, we instructed our reviewers to capture sufficient details from the medical records to support their findings. Without sufficient details, reviewers may need to re-review the medical record to answer questions that might arise during group discussions and quality assurance reviews, which can be time-consuming and costly. We provide documentation recommendations for individual conditions in the *Adverse Events Toolkit: Clinical Guidance for Identifying Harm*.

Group discussions. Throughout the duration of the study, we facilitated regular conference calls to promote consistency across reviewers and to reach a final consensus determination about harm events. During these calls, reviewers discussed categories of events as follows:

- Complex or unusual,
- Difficult to assess,
- Involving clinical matters outside their area of expertise,
- Possible implications for other events,
- Contributed to or resulted in death,
- Cascade event, and/or
- Unable to determine preventability.

We documented the discussions and conclusions made during these calls and compared these notes to the determinations to further promote consistency.

Once physician reviewers completed initial reviews and discussions for all cases, we compared groupings of cases for each type of event to identify outliers in severity levels and preventability

determinations. The physician reviewers discussed case-specific differences in the cases to ensure consistency across reviewers.

Systematic logic checks. During the reviews, we conducted systematic logic checks of each reviewer's findings by reading through case summaries to identify inconsistencies and through data analysis of key variables. These checks involved identification of missing values, aberrancies, and logical inconsistencies. They were employed for all records in our sample. After conducting the systematic logic checks, we followed up with individual reviewers and reassessed information in the records as needed. The following were important checks during our review:

- The harm date recorded by the reviewer was not before admission or after discharge,
- Infections were not counted as harm if diagnosed before the third calendar day after admission (with exceptions for *Clostridioides difficile* and infections attributable to devices),
- The description of the harm or evidence recorded by the reviewer was consistent with the harm event type's criteria (see the *Adverse Events Toolkit: Clinical Guidance for Identifying Harm*),
- Evidence recorded by the reviewer supported the harm event's severity level,
- The rationale provided by the physician in the second stage of review explained the reason for not confirming a potential harm event identified in the first stage of review,
- Preventability determinations were supported by narrative explanations and similar cases were assessed consistently across reviewers unless case-specific differences were noted, and
- Cascade events only included a series of logically connected harm events and did not include unrelated harm events.

Quality assurance re-reviews. We also conducted quality assurance re-reviews, in which a second reviewer reviewed the medical record and compared their responses to those of the initial reviewer. We conducted these re-reviews to ensure the accuracy of reviewers' findings and their adherence to the guidelines in this toolkit. We conducted two main types of quality assurance re-reviews listed below.

- In the first stage, we re-reviewed all records that were not forwarded to the second stage of review to identify any potential harm events missed by screeners using the GTT method. This review allowed us to identify false negative results.
- In the second stage, we re-reviewed a small sample of records that were forwarded to the second stage of review to validate the physician review results. These records were selected after the initial physician review but were cases that were not included in group discussions. These re-reviews supplemented the quality assurance efforts of the group discussions and systematic logic checks.

We selected the medical records for re-review based on potential areas of concern (e.g., complicated cases not included in group discussions) and to ensure representation from all reviewers.

APPENDICES

Appendix A: IHI Methodology for Identifying Harm

For our medical record screening process, we adopted and modified the Institute for Healthcare Improvement's (IHI's) Global Trigger Tool (GTT) process. Understanding the modifications and reasons for them may be helpful to hospitals and researchers as they develop and/or refine their own medical record review procedures. Toolkit users may want to consult additional resources for adapting the GTT for their facilities.[6]

IHI developed the IHI GTT as a tool for hospitals to assess patient safety by providing on-going, statistically valid monitoring of patient harm, including trends of events over time. The methodology relies on a retrospective medical record review to identify "triggers" that then prompt reviewers to search for adverse events.[7, 8] This method was designed to be used primarily by acute care hospitals while conserving limited resources. To increase efficiency of reviews, IHI recommends using two independent medical record reviewers (e.g., nurses) who are limited to 20-minute reviews of the records. The reviewer determines if harm was present and its severity. Then, a physician, who is not tasked with conducting reviews, authenticates the results from the primary reviewers and arbitrates any differences of opinion. IHI also recommended criteria regarding which events to include or not include in results. More information about IHI's GTT method can be found at IHI's website.

In contrast, our primary objective was to provide statistically valid point-in-time estimates of patient harm across the Nation for use in policy decisions and planning. We conducted two stages of review. Nurses screened the records for triggers in the first stage, and physicians conducted a full medical record review in the second stage. We allowed longer timeframes for reviews to reduce the likelihood of false negative results (i.e., missing events in the record). We gave physicians a more significant responsibility for identifying events and encouraged discussion across reviewers to improve the accuracy of our decisions, particularly with respect to complex cases. This also allowed us to gather rich clinical information about each harm event with nuanced detail about the event and its circumstances, such as the patient's condition prior to and following the event. A hospital with the goal of monitoring basic trends over time may not require the same level of rigor in its estimates of harm.

In addition to these differences in the review process, we captured and classified harm events differently. We expanded our definition of harm to include events that were a result of omission of care (e.g., delayed care) because we believe these events can be correctly identified during our in-depth review process and are of interest to clinicians and policymakers. On the other hand, we did not include present on admission (POA) events because we attributed the patient harm events to the hospital or other health care setting that provided the care and did not want to include events that occurred in the extended community. We were also interested in distinguishing events by preventability because we believe that this information can help policymakers and clinicians identify where to focus resources. IHI's alternative approach is designed to identify a broad range of common harm events in a way that can be replicated over time. Standards of care and expectations about preventability can evolve over time and affect results. See Exhibit A-1 for a summary of key differences between the OIG and IHI methods.

Exhibit A-1: Key Differences between the OIG and IHI Methods in Identifying Harm

Component	OIG Method	IHI Method
ELEMENTS OF REVIEW		
Primary Objective	OIG's primary objective is to provide statistically valid estimates of patient harm for use in policy decisions and planning.	IHI's primary objective for the GTT is to provide a tool for hospitals to assess patient safety and provide on-going monitoring of all patient harms through tracking and trending over time.
Number of Reviewers per Patient Record	One screener (typically a nurse) and 1 physician reviewer if the record is referred by the screener	Two reviewers (typically a nurse, pharmacist, or respiratory therapist) and 1 physician who authenticates the results from the 2 reviewers and arbitrates differences in findings of harm
Process for Arbitrating Complex Cases	Consensus by a panel of physician reviewers from multiple specialties, (typically 5-7 members)	One physician who serves as a tiebreaker if reviewers disagree
Time Limit for Medical Record Review per Patient Record	No (typically, 30 to 45 minutes)	Yes (20 minutes)
HARM EVENT CRITERIA		
Include POA Events	No	Yes
Include Commission Events	Yes	Yes
Include Omission Events	Yes	No
Include Events That Are Not Preventable	Yes	Yes
Include Events Related to Underlying Disease	No	No
HARM CLASSIFICATION		
Use a Modified NCC MERP Index for Severity Level	Yes*	Yes
Distinguish Between Adverse Events and Temporary Harm Events	Yes	No
Distinguish by Harm Event Preventability	Yes	No

Source: OIG comparison of OIG-modified GTT with IHI GTT method at Griffin, F.A., and Resar, R.K., *IHI Global Trigger Tool for Measuring Adverse Events* (Second Edition), Institute for Healthcare Improvement Innovation Series, 2009.
*OIG expanded severity level F on the NCC MERP index to include harm that contributed to or resulted in an elevation in level of care, transfer to another facility, or subsequent admission.

Appendix B: Contributing Factors for Preventability

Preventable Factors That Contributed to the Event

Inadequate admission assessment	Equipment failure or other system breakdown
Inadequate care plan	Poor communication between caregivers
Inadequate monitoring	Possible abuse, neglect, or other trauma associated with care
Substandard or inadequate preventative care	Lack of access to physician/specialist
Substandard treatment or therapeutic care	Event that rarely happens when proper precautions and procedures are followed
Necessary treatment not provided	Other, describe
Error related to medical judgment, skill, or patient management	

Nonpreventable Factors That Contributed to the Event

Event occurred even though providers followed proper preparation and procedures	Patient was highly susceptible to this type of event due to health status
Provider could not have anticipated this event with the information available at the time	Harm was foreseeable but was considered acceptable given alternatives
Patient's diagnosis was unusual or complex, making care difficult	Other, describe
Patient's treatment was unusual or complex, making care difficult	

Rationales for Unable to Determine

Poor and/or absent documentation	Patient's health status was particularly complex or unusual, making determination difficult
Care was particularly complex or unusual, making determination difficult	Other, describe

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Contact

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

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REFERENCES

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

[2] OIG, *Adverse Events in Hospitals: Methods for Identifying Events*, OEI-06-08-00221, March 2010.

[3] In some cases, patients had multiple admissions in OIG's sample period. If an event was attributable to care provided during a sample admission, we included it in our harm rate, regardless of whether it was a POA event for a subsequent admission.

[4] Exception: We included harm events that occurred in the emergency department (ED), observation unit, or other outpatient department contiguous to the inpatient admission as long as the patient was directly admitted to the hospital. For example, we would include a patient who experienced a harm event during outpatient surgery and was then directly admitted to the hospital as an inpatient. We also counted harm events that occurred during a prior hospital stay if it was within our study period but that resulted in a readmission 30 days after discharge.

[5] NCC MERP, Index for Categorizing Medication Errors, 2001. Accessed at http://www.nccmerp.org/sites/default/files/indexColor2001-06-12.pdf on April 27, 2021.

[6] For more information on the development of the triggers and their applications to different health care settings, Classen, et al., "Development and Evaluation of the Institute for Healthcare Improvement Global Trigger Tool," *Journal of Patient Safety*, Volume 4, Issue 3, September 2008. Accessed at https://journals.lww.com/journalpatientsafety/Abstract/2008/09000/Development_and_Evaluation_of_the_Institute_for.6.aspx on May 25, 2023. Also see Hibbert, et al., "The application of the Global Trigger Tool: a systematic review," *International Journal for Quality in Health Care*, Volume 28, Issue 6, December 2016. Accessed at https://doi.org/10.1093/intqhc/mzw115 on May 25, 2023.

[7] Griffin F.A., and Resar R.K., *IHI Global Trigger Tool for Measuring Adverse Events* (Second Edition), Institute for Healthcare Improvement Innovation Series, 2009. Accessed at https://www.ihi.org/resources/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx on May 25, 2023.

[8] IHI's first GTT was aimed at detecting adverse medication events. IHI's GTT methods have since expanded to a wider range of triggers for different types of adverse events and across different health care settings.