Users' Guide and Glossary

AHRQ Common Formats for Event Reporting – Hospital Version 2.0a

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1. Overview

The Agency for Healthcare Research and Quality (AHRQ) coordinates the development of Common Formats for patient safety event reporting and analysis. This activity is authorized by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule). A major goal of the legislation is to allow aggregation of data to identify and address underlying causal factors affecting patient care, quality and safety. This legislation also called for the establishment of Patient Safety Organizations (PSOs) and a Network of Patient Safety Databases (NPSD) to aggregate data and to analyze non-identifiable patient safety concerns. To render data non-identifiable for the NPSD, AHRQ contracts for a PSO Privacy Protection Center (PSOPPC) to receive information from PSOs and others and to provide technical assistance for data submission and utilization of the AHRQ Common Formats. When new releases of the AHRQ Common Formats are published, the PSOPPC Import Processor will accept data formatted only in the two most recent versions for each setting of care. Older versions of the AHRQ Common Formats then will be sunset. For more information on the Patient Safety Act and the Patient Safety Rule, please see AHRQ's PSO website: https://www.pso.ahrq.gov.

In order to facilitate standardized data collection and aggregation, AHRQ coordinates the development of Common Formats for patient safety event reporting. The AHRQ Common Formats delineate definitions, data elements, and reporting formats that allow healthcare providers to collect and submit standardized information regarding patient safety concerns. The use of the AHRQ Common Formats is voluntary.

In collaboration with the Federal interagency Patient Safety Work Group (PSWG), the National Quality Forum (NQF) and the public, AHRQ has developed Common Formats for Event Reporting – Hospital; this Users' Guide is applicable to the two most recent versions of the AHRQ Common Formats for Event Reporting associated with the hospital setting. The AHRQ Common Formats are updated periodically to incorporate new content and technical specifications as they are developed. Each subsequent version is given a new release number. The two most recent versions of the AHRQ Common Formats for Event Reporting – Hospital are:

- Version 1.2
- Version 2.0a

For more detail on the content changes implemented in the most recent version of the AHRQ Common Formats for Event Reporting – Hospital, please review the Data Element Conversion Mapping and Technical Release Notes documents.

1.1 Definition and Scope

1.1.1 Definition

The term "AHRQ Common Formats for Event Reporting – Hospital" is employed in this Users' Guide to describe the technical requirements pertaining to the collection and reporting of patient safety data, including all supporting material:

- Descriptions of patient safety concerns (i.e., events and unsafe conditions) to be reported (Event Descriptions)
- Technical specifications for software developers
- A metadata registry with data element attributes (Data Dictionary)

- A Users' Guide (this document)

1.1.2 Scope

Setting of care. AHRQ has released Common Formats for use in the hospital setting.

Quality and Safety. At this time, the AHRQ Common Formats for Event Reporting – Hospital are limited to issues of patient safety – preventing harm to patients from the delivery of health care services. These Common Formats apply to all three types of patient safety concerns: incidents and near misses (collectively referred to as patient safety events) and unsafe conditions.

- Incidents – patient safety events that reached the patient, whether or not the patient was harmed
- Near misses (or close calls) – patient safety events that did not reach the patient
- Unsafe conditions – any circumstance that increases the probability of a patient safety event

The AHRQ Common Formats for Event Reporting – Hospital share some attributes with quality measures. These Common Formats define events precisely thus comprising numerators of conventional measures. There are, however, substantial limitations to voluntary, spontaneous patient safety reporting resulting in rates variability and inconsistency of reporting. As the focus on patient safety increases and electronic health records (EHRs) become more widespread and clinically standardized, the opportunity to convert these Common Formats to complete measures will be enhanced.

The Patient Safety Act required the U.S. Department of Health and Human Services (HHS) to create and maintain the NPSD as a resource for PSOs, providers, and qualified researchers. The NPSD receives non-identifiable patient safety data from PSOs, providers, and other entities that voluntarily submit using common definitions and reporting formats. The PSOPPC ensures that only non-identifiable information is available at the NPSD, as is required by Patient Safety Act and Rule. The NPSD facilitates the aggregation and analysis of national trends and patterns in an effort to help reduce adverse events and improve health care quality.

Improvement Cycle. The AHRQ Common Formats for Event Reporting – Hospital currently address the initial phase of the improvement cycle - reporting. AHRQ intends these Common Formats to eventually support all phases of the improvement cycle.

Types of Data. The AHRQ Common Formats for Event Reporting – Hospital include data elements that are:

- Structured, (with a standardized range of content) or
- Narrative (free text)

Structured data permit organization of patient safety incidents, near misses, and unsafe conditions for event type/category analysis, as well as for pattern analysis and trending at all levels of the health care system. Structured data encompass important descriptors, known risk factors, and the use of established risk reduction methods to permit efficient analysis of patient safety concerns. Structured data can be aggregated within and across provider organizations, as well as nationally. When aggregated nationally at the NPSD, such data are non-identifiable, in accordance with the Patient Safety Act and Rule.

Although *Narrative* information cannot be aggregated, it provides the richness of detail about an individual event or unsafe condition necessary for understanding patient safety concerns at the provider and/or PSO levels to reduce future risk.

Note: The AHRQ Common Formats for Event Reporting – Hospital are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research-related reporting system, or other reporting/ recording system. They are designed to facilitate the collection, aggregation, and use of patient safety data regardless of the type of reporting system.

1.2 Development

The process to develop the AHRQ Common Formats: 1) is evidence-based; 2) harmonizes across governmental health agencies; 3) incorporates feedback from the private sector, including professional associations/organizations, those who use the formats, and the public; and 4) permits timely updating of these clinically-sensitive formats. AHRQ releases updates of the Common Formats periodically. Updates are announced in the Federal Register and issued by AHRQ as guidance. While the development and release of these Common Formats is outside the scope of the regulations implementing the Patient Safety Act, AHRQ nevertheless sought public comment on its overall approach during the rulemaking process. There were a significant number of highly supportive comments about the process; there were no negative comments.

In anticipation of the need for Common Formats, AHRQ began their development in 2005 by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory, numbering 70 systems, provided an evidence base to inform the construction of these Common Formats. The inventory contained many systems from the private sector, including prominent academic settings, hospital systems, and international reporting systems (e.g., the National Reporting and Learning System [NRLS] from the United Kingdom, the Japan Council for Quality Health Care [JCQHC] from Japan, and the Australian Incident Monitoring System [AIMS] from the Commonwealth of Australia). In addition, virtually all major Federal (U.S.) governmental systems are included, such as those from the Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD), the Food and Drug Administration (FDA), and the Department of Veterans Affairs (VA).

AHRQ convenes an interagency PSWG to develop draft Common Formats. Included in the PSWG are patient safety and clinical subject matter experts from the major health agencies within HHS – the CDC, the Center for Medicare & Medicaid Services (CMS), the FDA, the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), the National Institutes of Health (NIH), the National Library of Medicine (NLM), the Office of the National Coordinator for Health Information Technology (ONC), the Office of Public Health and Science (OPHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA) – as well as the DoD and the VA.

To allow for greater participation by the private sector in the development of the Common Formats for Event Reporting – Hospital, AHRQ engaged the NQF, a non-profit organization focused on health care quality, to solicit comments and advice from the public to guide the refinement of these Common Formats. The NQF convened an expert panel to review the received comments and to provide feedback to AHRQ. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, revised and refined these Common Formats.

When appropriate, AHRQ may implement minor updates to existing versions of the Common Formats to further clarify or bolster the information specified for reporting. These updates are published, by AHRQ, as part of a Technical Release for a given version and setting of the Common Formats. The Technical Release process offers AHRQ the flexibility to make improvements that help maintain the

conceptual clarity of the Common Formats, allowing for more consistent reporting of patient safety concerns.

Using this development process, AHRQ released several versions of the Common Formats for Event Reporting – Hospital:

- Version 0.1 Beta – August 2008
- Version 1.0 – September 2009
- Version 1.1 – March 2010
  - Device or Medical/Surgical Supply, including Health Information Technology (HIT) Beta – October 2010
  - Venous Thromboembolism Beta – November 2011
- Version 1.2 – April 2012
- Version 2.0 – May 2017
  - Version 2.0a – Technical Release update to Version 2.0 – June 2018

AHRQ, the PSWG, and the public (via the PSOPPC will continue to act as the foci for original development and continual upgrading/maintenance and will assure consistency of definitions/formats with those of relevant government agencies.

AHRQ has also aligned the Common Formats for Event Reporting – Hospital, to the extent practicable, with World Health Organization (WHO) concepts, framework, and definitions contained in their draft International Classification for Patient Safety (ICPS). As of 2012, WHO was expanding their delineation of patient safety concerns via a Technical Advisory Group (TAG) on patient safety. This TAG is creating the International Classification of Diseases Eleventh Revision (ICD-11) coding to encompass patient safety concerns and is considering these Common Formats as an important input to their work.

AHRQ's Common Formats development process thus draws on information from systems in both the public and private sectors, public comments, Federal patient safety experts, and a private sector panel of experts convened by the PSOPPC.

2. Use of AHRQ Common Formats for Event Reporting – Hospital

The AHRQ Common Formats for Event Reporting – Hospital are designed to be used at the point of care, where events occur and where initial information should be collected as soon after an event as possible. Resultant data can be reviewed at healthcare provider organizations (e.g., headquarters of a multi-facility organization), at PSOs, and, after a non-identification process, by the NPSD. Data on patient safety published in AHRQ's annual National Healthcare Quality and Disparities Report (NHQDR), and/or released to the public by PSOs, flows from these Common Formats, although published in aggregate, non-identifiable form. These Common Formats define the information to be collected at the first instance, because information formulated differently, or with some elements missing, cannot later be converted reliably to AHRQ Common Format data (It is possible that formats developed and used by others can be mapped to these Common Formats, potentially with some loss of accuracy).

The Common Formats for Event Reporting – Hospital contain the data elements that AHRQ believes are most important for a complete patient safety concern report. **Some of these elements comprise information that is identifiable to the patient, reporter, provider, and facility. Such identifying information transmitted to a PSO as patient safety work product is confidential and prohibited from disclosure as delineated in the Patient Safety Act and Rule.**

The AHRQ Common Formats for Event Reporting – Hospital contain technical specifications that allow local implementation and electronic transfer to the PSOPPC and NPSD. Please see section A. Technical Specifications for more details on the components of the technical specifications.

2.1 AHRQ Common Formats for Event Reporting – Hospital Event Description

The AHRQ Common Formats for Event Reporting – Hospital Event Descriptions outline the subject matter of interest about each patient safety concern and the resultant information to be collected. (The two most recent versions of the Event Descriptions are available at https://www.psoppc.org/psoppc_web). Within a particular event/category type, information specified by the description will vary depending on the details of the event/category. These plain language descriptions convey the objectives of each of these Common Formats more easily than review of questions and 'skip logic' or, alternatively, review of all questions and algorithmic instructions embedded within a software program. For those charged with developing software programs, expanded technical specifications are also available at the PSOPPC website (https://www.psoppc.org/psoppc_web). AHRQ maintains metadata for these Common Formats at the United States Health Information Knowledgebase (USHIK) (https://ushik.ahrq.gov/mdr/portals), which is a health metadata registry funded and directed by AHRQ in partnership with CMS. The USHIK registry supports browsing, comparison, synchronization, and harmonization of AHRQ Common Formats data elements with standards development organizations, such as Health Level Seven International (HL7), and other healthcare organizations.

2.1.1 Modular Construction

AHRQ developed the Common Formats for Event Reporting – Hospital in modules for conceptual clarity, ease of use, and consistent maintenance. In Version 2.0a of the AHRQ Common Formats for Event Reporting – Hospital, there are only two types of Common Formats modules: Generic and Event-specific. The Generic module contains data elements that apply to all patient safety concerns. Structured questions in the Generic module allow for the capture of basic information along the spectrum of harm, including events resulting in harm, no-harm

events that reached the patient, near misses, and unsafe conditions. The Event-specific module pertains to specific types of patient safety events (e.g., Fall or Perinatal). The Event-specific modules provide for the collection of information, in relevant detail, about many specific patient safety concerns reported in a hospital.

2.1.2 An Event-Centered System

The AHRQ Common Formats for Event Reporting – Hospital are designed to capture information on single events (or unsafe conditions). In some circumstances, there may be related events separated by space and time. For example, medications may be switched for two different patients. In this case, each is considered a separate event, and each will require a Generic and Event-specific module to be completed. Specific information on events can also be captured via narrative text.

2.1.3 Core vs Supplemental Data Sets

In the AHRQ Common Formats for Event Reporting – Hospital Version 2.0a, Event Descriptions were divided into two categories of items: Core and Supplemental. Core data elements are required for event reporting at the local level, by providers, to PSOs and the PSOPPC for national aggregation and analysis. Supplemental data elements may be collected at the local level for additional analysis, and may be reported to PSOs, but will not be accepted by the PSOPPC for national aggregation and analysis.

2.1.4 Generic Module

The Generic module (or, formerly known as Healthcare Event Reporting Form [HERF], Patient Information Form [PIF], and Summary of Initial Report [SIR]) captures information on incidents, near misses, and unsafe conditions. This module is designed to be completed by the individual who witnessed, first discovered, or is most familiar with the details of the event or unsafe condition. Demographic information, additional information regarding the impact of the event on the patient (e.g., level of harm, unplanned interventions), and a brief summary of the event or unsafe condition are captured within the Generic module. Once this module is completed, the user is directed to complete an Event-specific module, if applicable. When multiple patients are involved in an event, a separate event report is to be completed for each patient. These reports can subsequently be linked at the local level.

2.1.5 AHRQ Harm Scale

The AHRQ harm scale is used to document the degree of patient harm that results from patient safety incidents of any and all types. It is to be applied *after* attempt(s) are made to improve a patient's condition following occurrence of an incident. The scale is intended to measure the harm that remains after both the incident and any subsequent "rescue" attempts are completed, or "net iatrogenic harm" (net harm caused by the delivery of care). The AHRQ harm scale thus permits the aggregation of harm over all types of incidents and serves as a measure of the level of harm experienced by a population of patients as well as by an individual patient.

The AHRQ harm scale explicitly avoids two methods that have been used in other harm assessment tools:

- Assessing the severity of harm that the patient would have sustained if there were no intervention by the health care team.

- Using the severity of the subsequent intervention (rescue) in the assessment of degree of patient harm.

The first method involves subjective speculation about how events would have unfolded if no attempts were made to rescue the patient (i.e., the patient would have died if…). The second method is circular and incorporates the competence of the response team in the rating of harm to the patient (e.g., an incident could receive a lower harm score than warranted if the team responding employed a less severe intervention than was indicated, even if the patient ended up with greater harm as a result. Another team, responding properly to the same incident and employing more drastic measures, would cause that patient to receive a higher harm score.).

The first method referred to above can be of some value in assessing the incident (potential severity of process errors), but a harm score derived using this method may bear little relationship to the final level of harm sustained by a patient. While employing both the AHRQ harm scale and an initial severity assessment, absent any intervention, might yield more information than using the AHRQ harm scale alone, it is felt to be operationally impractical, and possibly confusing, to expect busy practitioners to apply two separate harm scales.

2.1.6 Event-Specific Modules

Event-specific modules have been created for the most commonly-occurring types of patient safety concerns. These modules are intended to supplement the information collected by the Generic module. The Event-specific modules allow for the report of contributing factors and are unique to the event type. Additional structured information is collected about the concern itself, as well as information about the use or employment of measures designed to prevent the occurrence of the concern. (Specific details about concerns that occur less frequently and are not addressed by an Event-specific module can be captured in the narrative sections of the Generic module.) AHRQ may develop additional Event-specific modules in the future.

The table below depicts the evolution of Event-specific modules across versions of the AHRQ Common Formats for Event Reporting – Hospital.

Table 1. Event-specific modules across versions of the AHRQ Common Formats for Event Reporting – Hospital

AHRQ Common Formats for Event Reporting – Hospital Module Type	Hospital Version 1.1	Hospital Version 1.2	Hospital Version 2.0a
Anesthesia			X
Blood or Blood Product	X	X	X
Device or Medical/Surgical Supply	X		X
Device or Medical/Surgical Supply, including Health Information Technology related event		X	
Fall	X	X	X
Healthcare-associated Infection (HAI)	X	X	
Medication or Other Substance	X	X	X
Perinatal	X	X	X
Pressure Injury			X
Pressure Ulcer	X	X	
Surgery			X
Surgery or Anesthesia	X	X	

AHRQ Common Formats for Event Reporting – Hospital Module Type	Hospital Version 1.1	Hospital Version 1.2	Hospital Version 2.0a
Venous Thromboembolism		X	X

2.1.7 Using the AHRQ Common Formats for Event Reporting – Hospital

The AHRQ Common Formats for Event Reporting – Hospital comprises the Generic module and the Event-specific modules. Note that some Event-specific modules are not eligible for completion as a near miss or unsafe condition. For example: a patient fell to the ground while getting out of bed, sustaining an injury to the head. This incident would be first reported using the Generic module, and then the Event-specific module for Fall. However, the fall would not be reported as a near miss or unsafe condition on the Generic module even if the fall were assisted. The event information captured on the Generic module should be consistent with the information reported on the Event-specific module to ensure that summary statements are as complete as possible. For more version-specific information, please refer to the Implementation Guide for each version released.

General guidance for using the AHRQ Common Formats for Event Reporting – Hospital includes:

- If reporting events/unsafe conditions requires the use of one or more of the modules listed above, these Common Formats should be completed in the order outlined under *Using the AHRQ Common Formats for Event Reporting – Hospital*.
- The Event Descriptions provide direction regarding what type or category of patient safety event “should be” reported using these Common Formats.
- Technical specifications accompanying the AHRQ Common Formats for Event Reporting – Hospital indicate which items require the reporter to “check one,” or “check all that apply,” or “check first applicable.” “Check first applicable” indicates a priority based, time-based, or degree-of-harm-based option relevant to the question. This technique allows efficient collection, analysis, and reporting of data where multiple items on a list might apply in a given instance, but it is only necessary to know the most important category that applies.
- AHRQ Common Formats-compliant software should follow the logic outlined in the technical specifications to report a patient safety concern.
- The AHRQ Common Formats for Event Reporting – Hospital include an “Other: Please Specify” option to capture items not included in the developed documentation.
- The AHRQ Common Formats for Event Reporting – Hospital focus on capturing, aggregating, and reporting data pertaining to patient safety concerns, not the workflows that are necessarily an integral part of any reporting system. It is recognized that, for the most part, provider organizations have already established such workflows, including the handling of multiple initial reports of an event.

2.2 Technical Assistance

Event Descriptions, sample reports, and accompanying reference documentation are available for

download at the PSOPPC website (https://www.psoppc.org/psoppc_web) for the two most recent versions of the AHRQ Common Formats for Event Reporting – Hospital.

A. Technical Specifications

The technical specifications promote standardization by ensuring that data collected by providers, Patient Safety Organizations (PSOs), and other entities are clinically and electronically comparable. The specifications provide direction to software developers, so the AHRQ Common Formats for Event Reporting – Hospital can be implemented electronically, and direction to PSOs, so the data reported using these Common Formats can be submitted electronically to the PSO Privacy Protection Center (PSOPPC) for non-identification and transmission to the Network of Patient Safety Databases (NPSD).

The technical specifications consist of the following:

- **Data Element Conversion/Mapping Guide** – The Data Element Conversion/Mapping Guide provides information on mapping data elements across the hospital versions of the AHRQ Common Formats for Event Reporting, where applicable. This document also includes information on which data elements have been modified between released versions.
- **Data Dictionary** – The Data Dictionary defines the data elements and their attributes (data element name, data element ID, answer values, answer codes, Health Level Seven International [HL7] data type, guide for use, etc.).
- **Implementation Guide** – The Implementation Guide provides the Clinical Document Architecture Extensible Markup Language (CDA XML) file specifications to transmit AHRQ Common Formats Patient Safety Reports to the PSOPPC.
- **Resources Workbook** – The Resources Workbook provides information about the data elements and their associated answer values (where applicable) that will assist with the development of a CDA XML file. It also contains the validation rules that will be applied to the data elements and the associated answer values submitted to the PSOPPC and the CDC Location Codes that are acceptable for PSOPPC submissions.
- **Common Formats Flow Charts** – The Common Formats Flow Charts provide the data elements and associated answer values (where applicable) recommended to be captured based on the report type and event category associated with the AHRQ Common Formats Patient Safety Report. The various paths of the data elements identify the valid data elements to be included within a AHRQ Common Formats Patient Safety Report.
- **Common Formats CDA XML File Samples** – The Common Formats CDA XML File Samples provide sample patient safety concerns scenarios and the associated CDA XML file output. The sample CDA XML file contains all data elements necessary for a complete report and conforms to the AHRQ Common Formats Technical Specifications.
- **Report Specifications** – The Report Specifications provide the functional requirements for generating both aggregate as well as event-level reports. Included in this set of documents are report layouts as well as detailed mapping for each of the AHRQ Common Formats data elements collected. The aggregate report specifications encompass provider, PSO, and national-level reports.

- **Data Collection Order** – The Data Collection Order document suggests the order in which AHRQ Common Formats for Event Reporting – Hospital data should be collected when the event involves two or more event-specific categories. The guidelines take into account the relationships of data elements between event-specific categories. They are designed to be used in conjunction with the Flow Charts, which detail the order in which AHRQ Common Formats questions and answers should be asked of users where the event involves an Event-specific category (applicable to AHRQ Common Formats for Event Reporting – Hospital Versions 1.1 and 1.2 only).

B. Glossary

Terms were selected for inclusion in the glossary only if they were central to the purposes of the AHRQ Common Formats for Event Reporting – Hospital or their implementation. AHRQ excluded terms defined in the Statute and Regulations as well as terms that may be found in a common English language or medical dictionary.

Terms included in the glossary have been defined to meet the purposes of, and to be consistent with, the conceptual model used to develop the hospital versions of the AHRQ Common Formats for Event Reporting.[1] Definitions of terms were developed after considering definitions of the exact term or conceptually similar terms used in other patient safety reporting systems and the AHRQ Common Formats for Event Reporting.

Table 2. Glossary of terms used in the AHRQ Common Formats for Event Reporting – Hospital

Word or Phrase	Definition
Accident	See: Patient safety incident.
Adverse Event	See: Harm incident.
Adverse Outcome	Undesired patient outcome of healthcare; clinical complication of healthcare (which may or may not be a patient safety incident).
Adverse Reaction	Unexpected adverse outcome resulting from a justified action where the correct process was followed for the context in which the event occurred.
Bodily Injury	Physical harm or damage to a person's body.
Chain of Events	A series of events in which one event leads to another with the possibility that the final event reaches the patient; collectively, an event episode.
Circumstance	Condition surrounding and affecting a person, process, etc.; as related to healthcare, the context within which processes are performed to deliver healthcare services, including culture of safety, management structure and incentives, staffing levels, qualification and training of staff, acquisition and maintenance of devices, condition of care environment, etc.
Close Call	See: Near miss.
Complete Event Report	See: Complete patient safety concern report.
Complete Patient Safety Concern Report	A complete initial report of a patient safety concern, including, as applicable, data elements comprising the following AHRQ Common Format modules: Generic module and, when applicable, one or more Event specific module.
Complication	See: Adverse outcome.
Contributing Factor	A circumstance determined retrospectively to have increased the likelihood of the event and that is generally external to the patient. Contributing Factors frequently relate to the physical environment or to the care delivery system.
Degree of Harm	The severity and duration of harm, and any treatment implications, that result from an incident.
Detection	Identification of a patient safety concern; a broader concept than discovery as it also encompasses identification by automated and other systems.

[1] Asterisks (**) indicate terms and definitions that are similar to the World Health Organization International Classification for Patient Safety (WHO ICPS) preferred terms.

Word or Phrase	Definition
Device	See: Medical device.
Discovery	Identification of a patient safety concern during the course of performing duties in a healthcare facility; a narrower concept than detection.
Duration of Harm	The period over which disease, disability, disfigurement, dysfunction, etc. may be evident; often denoted as none, transient, temporary (short-term), or permanent (life-long).
Error**	Failure to carry out a planned action as intended or application of an incorrect plan.
Event	See: Patient safety event.
Event Episode	Single event or chain of events from point of origin of a process failure or error within a healthcare organization to its termination in a near miss or incident.
Event Reporter	See: Reporter.
Event Specific Common Format	A supplemental module collecting select data elements relevant to a specific type of patient safety event if applicable.
Facility	See: Healthcare facility.
Fail-safe	Process designed to prevent the failure of a healthcare process or error made in the delivery of a healthcare service from propagating; usually an integral element of that process; may be a secondary system designed to ensure the continued function or operation of a primary system.
Generic Common Format	The AHRQ Common Formats module comprising data elements designed to capture the essence of a patient safety concern, the characteristics of a patient involved in an incident and all data elements to assess and to encode the patient safety concern. The completion of this module completes the report of an unsafe condition, near miss, or incident. It may, or may not, be accompanied by one or more event-specific modules.
Handover/Handoff	The process when one health care professional updates another on the status of one or more patients for the purpose of taking over their care. Typical examples involve a physician who has been on call overnight telling an incoming physician about patients she has admitted so he can continue with their ongoing management, know what immediate issues to watch out for, and so on. Nurses similarly conduct a handover at the end of their shift, updating their colleagues about the status of the patients under their care and tasks that need to be performed. When the outgoing nurses return for their next duty period, they will in turn receive new updates during the change of shift handover. In addition, it is often used to refer to the information transfer that occurs from one clinical setting to another (e.g., from hospital to nursing home).
Harm	Physical or psychological injury (including increased anxiety), inconvenience (such as prolonged treatment), monetary loss, and/or social impact, etc. suffered by a person.
Harm Incident	An incident that resulted in harm to a patient.
Harm to Health	Impairment of structure or function of the body and/or any deleterious effect arising therefrom.
Health Information Technology (HIT)	The application of information processing involving both computer hardware and software that deals with the storage, retrieval, sharing, and use of health care information, data, and knowledge for communication and decision making. (Brailer, D., & Thompson, T. (2004). Health IT strategic framework. Washington, DC: Department of Health and Human Services.) (https://www.healthit.gov/)

Word or Phrase	Definition
Healthcare-Associated Harm	Harm arising from or associated with plans or actions taken during the provision of healthcare rather than an underlying disease or injury.
Healthcare Facility	Physical structure, such as a hospital, in which healthcare services are performed.
Healthcare Location	Physical place within a healthcare facility; includes a location in which healthcare services are delivered (healthcare service delivery location), as well as such other areas as corridors, elevators, and those where supporting services are performed (e.g., laundry, meal preparation, and power generation).
Incident	See: Patient safety incident.
Injury	See: Bodily injury & Psychological injury.
Inpatient Facility	Healthcare facility with beds for patients to stay overnight.
Location	See: Healthcare location.
Medical Device	A medical device is any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes (includes both medical equipment (e.g., walker, hearing aid) and medical/surgical supply, including disposable product (e.g., incontinence supply)).
Medical Supply	See: Medical device.
Multiple Patient Incident	An incident that involves two or more patients (e.g., patient given a medication intended for another - 2 patients affected by the same incident); includes incidents involving a population of patients (e.g., fire in a patient section of a hospital).
Near Miss	An event that did not reach a patient. For example: discovery of a dispensing error by a nurse as part of the process of administering the medication to a patient (which if not discovered would have become an incident); discovery of a mislabeled specimen in a laboratory (which if not discovered might subsequently have resulted in an incident).
No-Harm Incident	An incident which reached a patient but no discernible harm resulted.
Patient Safety Concern	Any circumstance involving patient safety; encompasses patient safety event (both incident and near miss) and unsafe condition.
Patient Safety Event	Something that happens to or involves a patient; encompasses patient safety incident and near miss.
Patient Safety Incident**	A patient safety event that reached a patient and either resulted in no harm (no harm incident) or harm (harm incident). The concept “reached a patient” encompasses any action by a healthcare practitioner or worker or healthcare circumstance that exposes a patient to harm. For example: if a nurse gives a patient an incorrect medication to take and the patient recognizes it as such and refuses to take it, an incident has occurred.
Preventable	Accepted by the relevant community as avoidable in the particular set of circumstances.
Preventive Measure	Process designed, or course of action taken, to keep something possible or probable from happening or existing; as related to patient safety, to prevent a patient safety event.

Word or Phrase	Definition
Prevention Action	A change implemented that should have been performed or in place prior to the event, to prevent or mitigate its occurrence. This includes the precise circumstances in which such actions should have been taken.
Principal Diagnosis	The condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital. (Uniform Hospital Discharge Data Set)
Principal Procedure	The procedure performed for definitive treatment rather than diagnostic or exploratory purposes, or which is necessary to take care of a complication. (Uniform Hospital Discharge Data Set)
Process of Care	The delineation of process error(s) that caused/are the defined event; these can include near misses.
Psychological Injury	Harm or damage to a person's psyche, psychological functioning, or mental well-being.
Reporter	Person in a health care organization who reports a patient safety concern; may (or may not) be the person who discovered the concern.
Rescue Action	Action taken or started within the first 24 hours after the discovery of a patient safety incident that is intended to prevent, to minimize, or to reverse harm to the affected patient.
Risk	The probability that an incident will occur.
Risk Assessment	1. An assessment that examines a process in detail, including sequencing of events; assesses actual and potential risk, failure, or points of vulnerability; and, through a logical process, prioritizes areas for improvement based on the actual or potential patient care impact (criticality). 2. The qualitative or quantitative estimation of the likelihood of (adverse) effects that may result from exposure to specified events or processes or from the absence of beneficial influences
Risk Factor	For the purposes of the AHRQ Common Formats, a risk factor is an inborn or inherited characteristic, personal behavior or life-style choice, or environmental exposure (including prior experience with health care) that is associated (or correlated) with a significantly increased probability of the occurrence of a specified event or condition of concern and/or increased magnitude of harm if the event occurs; such perceived risk may be based on scientific evidence or the opinion of qualified experts. A risk factor is discernible prior to the possible occurrence of the event of interest, although it may be overlooked or disregarded. A risk factor may be the target of preventive actions.
Safeguard	Aspect of a healthcare process that is designed to prevent harm from reaching a patient in the event of a failure or error (including the failure of a fail-safe).
Severity of Harm	The extent of harm at a point in time; often categorized as none, mild, moderate, severe, or death.
Side Effect	An effect (usually an adverse outcome) caused by something (such as a drug or procedure) that was not the intended or indicated effect. The occurrence of a known side effect, even if an adverse outcome, by itself, is not a patient safety incident. It should be considered a quality of care problem; if, for example, the prescribing physician failed to weigh properly the potential health benefits and risks of prescribing a medication with a potentially lethal, or otherwise adverse, side effect.
Surgical Supply	See: Medical device.
Time of Discovery	Date/time when a patient safety concern was discovered.

Word or Phrase	Definition
Time of Occurrence of Event	Date/time when a patient safety event occurred (point in time) or started (if it occurred over a period of time).
Unexpected Adverse Outcome	Adverse outcome that was not expected to be a result of the patient's treatment plan; harm suffered as a result of an incident.
Unintentionally Retained Item	Foreign object introduced into the body during a surgical operation or another invasive procedure, without removal prior to finishing the surgery or procedure. The surgeon or other practitioner did not intend to leave the object in the body.
Unnecessary Harm	Healthcare-associated harm that was not expected to result from a patient's treatment plan; harm resulting from an incident.
Unplanned Intervention	An intervention that was not part of a patient's treatment plan prior to the event that necessitated the additional intervention.
Unsafe Condition	Any circumstance that increases the probability of a patient safety event; includes a defective or deficient input to or environment of a care process that increases the risk of an unsafe act, care process failure or error, or patient safety event. An unsafe condition does not involve an identifiable patient. For example, an out-of-date medicine on a shelf represents an unsafe condition. It might be given to a patient, but the identity of such patient is unknown at the time of discovery. The attempt to administer the out-of-date medicine to a patient would either represent a near miss (if not administered) or an incident (if administered).

C. Acronyms

Table 3. Acronyms used in the Users' Guide for AHRQ Common Formats for Event Reporting – Hospital

Acronym	Expanded Phrase
AHRQ	Agency for Healthcare Research and Quality
AIMS	Australian Incident Monitoring System, Commonwealth of Australia
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
DoD	Department of Defense
FDA	Food and Drug Administration
HAI	Healthcare-associated Infection
HHS	U.S. Department of Health and Human Services
HL7	Health Level Seven
HRSA	Health Resources and Services Administration
ICPS	International Classification for Patient Safety, WHO
IHS	Indian Health Service
ISBT	International Society Blood Transfusion
NHQDR	National Healthcare Quality and Disparities Report, AHRQ
NHSN	National Healthcare Safety Network
NIH	National Institutes of Health
NLM	National Library of Medicine
NRLS	National Reporting and Learning System, United Kingdom
NPSD	Network of Patient Safety Databases
NQF	National Quality Forum
ONC	Office of the National Coordinator for Health Information Technology
OPHS	Office of Public Health and Science
PSWG	Patient Safety Work Group
PSO	Patient Safety Organization
PSOPPC	PSO Privacy Protection Center
SAMHSA	Substance Abuse and Mental Health Services Administration
SDO	Standards Development Organization(s)
SRE	Serious Reportable Event
USHIK	United States Health Information Knowledgebase
VA	Department of Veterans Affairs
WHO	World Health Organization