# Users' Guide and Glossary

## AHRQ Common Formats for Event Reporting – Nursing Home Version 1.0

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# 1. Overview

The Agency for Healthcare Research and Quality (AHRQ) coordinates the development of Common Formats for patient/resident 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/resident 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/resident 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 will then 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/resident safety event reporting. The AHRQ Common Formats delineate definitions and data elements that allow healthcare providers to collect and submit standardized information regarding patient/resident safety concerns. The use of the AHRQ Common Formats is voluntary.

AHRQ coordinated the development of Common Formats for Event Reporting – Nursing Home; this Users' Guide is applicable to the AHRQ Common Formats for Event Reporting associated with the nursing home setting – Version 1.0. The AHRQ Common Formats are updated periodically to incorporate new content and technical specifications as they are developed. Any subsequent version is given a new release number.

## 1.1 Definition and Scope

### *1.1.1 Definition*

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

- Descriptions of patient/resident 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 reporting patient/resident safety concerns occurring in the nursing home setting.

*Quality and Safety.* At this time, the AHRQ Common Formats for Event Reporting – Nursing Home

are limited to issues of patient/resident safety – preventing harm to patients/residents from the delivery of healthcare services. These Common Formats apply to all three types of patient/resident safety concerns: incidents and near misses (collectively referred to as patient/resident safety events) and unsafe conditions.

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

The AHRQ Common Formats for Event Reporting – Nursing Home 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/resident safety reporting resulting in variability in the rate and inconsistency of reporting. Moreover, denominators are usually not defined or subject to data collection. As the focus on patient/resident 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/resident 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 the 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 healthcare quality.

*Improvement Cycle.* The AHRQ Common Formats for Event Reporting – Nursing Home currently address the initial phase of the improvement cycle – reporting.

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

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

*Structured* data permit organization of patient/resident 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 healthcare system. Structured data encompass important descriptors, known risk factors, and the use of established risk reduction methods to permit efficient analysis of patient/resident 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/resident safety concerns at the provider and/or PSO levels to reduce future risk.

**Note: The AHRQ Common Formats for Event Reporting – Nursing Home 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/resident safety data regardless of the type of reporting system.**

## 1.2 Development of Common Formats

The process AHRQ uses to develop the 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 the Common Formats is outside the scope of the regulations implementing the Patient Safety Act, AHRQ nevertheless seeks public comment on its overall approach during the rulemaking process.

AHRQ began the development of the Common Formats in 2005 by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provided an evidence base to inform the construction of the 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 Patient Safety Work Group (PSWG) to develop the Common Formats. Included in the PSWG are patient safety and clinical subject matter experts from the major health agencies within HHS – the CDC, the Centers 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, AHRQ solicits comments and advice from the public to guide the refinement of the Common Formats via the PSO Privacy Protection Center (PSOPPC). The PSOPPC convenes an expert panel to review the comments received from the public and to provide feedback to AHRQ. AHRQ, in conjunction with the PSWG, refines the Common Formats based upon the expert panel's feedback.

When appropriate, AHRQ may implement minor updates to existing 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/resident safety concerns.

### *1.2.1 AHRQ Common Formats for Event Reporting – Nursing Home*

AHRQ initiated and coordinated the development of Common Formats for the nursing home setting. The following versions of the Common Formats for Event Reporting – Nursing Home have been released:

- Version 0.1 Beta – February 2011
- Version 1.0 – September 2019

AHRQ will lead the continual upgrading/maintenance of the Common Formats for Event Reporting – Nursing Home, with input from the PSWG, and the public (via the PSOPPC), to assure these Common Formats remain consistent with definitions used by relevant reporting systems and/or government agencies.

## 2. Use of AHRQ Common Formats for Event Reporting – Nursing Home

The AHRQ Common Formats for Event Reporting – Nursing Home 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/resident 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, but almost certainly with significant loss of accuracy).

The AHRQ Common Formats for Event Reporting – Nursing Home contain the data elements that AHRQ believes are most important for a complete patient/resident safety concern report. **Some of these elements comprise information that is identifiable to the patient/resident, reporter, provider, and facility. Such identifying information transmitted to a PSO as patient/resident 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 – Nursing Home 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 – Nursing Home Event Description

The AHRQ Common Formats for Event Reporting – Nursing Home Event Descriptions outline the subject matter of interest about each patient/resident safety concern and the resultant information to be collected. (The Event Descriptions are available at the PSOPPC website 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 will maintain 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 – Nursing Home in modules for conceptual clarity, ease of use, and consistent maintenance. In Version 1.0 of the AHRQ Common Formats for Event Reporting – Nursing Home, there are two types of Common Formats modules: Generic and Event-specific. The Generic module contains data elements that apply to all patient/resident 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/resident, near misses, and unsafe conditions. The Event-specific module pertains to specific types of patient/resident safety events (e.g., Fall or Pressure Injury). The Event-specific modules provide for the collection of information, in relevant detail, about specific patient/resident safety concerns occurring in a nursing home.

### *2.1.2 An Event-Centered System*

The AHRQ Common Formats for Event Reporting – Nursing Home 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/residents. 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 Datasets*

AHRQ designated all data elements pertaining to the AHRQ Common Formats for Event Reporting – Nursing Home as Core data elements. Core data elements are required for event reporting at the local level, by providers, to PSOs and the PSOPPC for national aggregation and analysis.

### *2.1.4 Generic Module*

The Generic module 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/resident (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/residents are involved in an event, a separate event report is to be completed for each patient/resident. 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/resident harm that results from patient/resident safety incidents of any and all types. It is to be applied *after* attempt(s) are made to improve a patient's/resident'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/residents as well as by an individual patient/resident.

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/resident would have sustained if there were no intervention by the healthcare team.
- Using the severity of the subsequent intervention (rescue) in the assessment of degree of patient/resident harm.

The first method involves subjective speculation about how events would have unfolded if no attempts were made to rescue the patient/resident (i.e., the patient/resident 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/resident (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/resident 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/resident 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/resident. 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/resident safety concerns in the nursing home. These modules are intended to supplement the information collected by the Generic module. The Event-specific modules allow for the report of risk factors, contributing factors, and other information that is 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. AHRQ created the following Event-specific modules for Version 1.0 of the Common Formats for Event Reporting – Nursing Home:

- Device or Medical/Surgical Supply, including Health Information Technology (HIT)
- Fall
- Medication or Other Substance
- Pressure Injury

The AHRQ Common Formats for Event Reporting – Nursing Home also capture concerns that occur less frequently and are not addressed by an Event-specific module. Specific details about these concerns can be captured in the narrative sections of the Generic module. AHRQ may develop additional Event-specific modules in the future.

### *2.1.7 Using the AHRQ Common Formats for Event Reporting – Nursing Home*

The AHRQ Common Formats for Event Reporting – Nursing Home 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/resident 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 information, please refer to the Implementation Guide.

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

- The Event Descriptions provide direction regarding what type or category of patient/resident safety event “should be” reported using these Common Formats.
- Technical specifications accompanying the AHRQ Common Formats for Event Reporting – Nursing Home indicate which items require the reporter to “check one” or “check all that apply”.
- AHRQ Common Formats-compliant software should follow the logic outlined in the technical specifications to report a patient/resident safety concern.
- The AHRQ Common Formats for Event Reporting – Nursing Home include an “Other: Please Specify” option to capture items not included in the developed documentation.
- If reporting events/unsafe conditions requires the use of more than one event-specific module (listed in section 2.1.6), the above guidance should be followed for each module.
- The AHRQ Common Formats for Event Reporting – Nursing Home focus on capturing, aggregating, and reporting data pertaining to patient/resident 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 AHRQ Common Formats for Event Reporting – Nursing Home.

## 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 – Nursing Home 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 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/Resident 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.
- **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/Resident Safety Report. The various paths of the data elements identify the valid data elements to be included within an AHRQ Common Formats Patient/Resident Safety Report.
- **Common Formats CDA XML File Samples** – The Common Formats CDA XML File Samples provide sample patient/resident 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.

## 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 – Nursing Home 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 nursing home version 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/resident safety reporting systems and the AHRQ Common Formats for Event Reporting.

***Table 1. Glossary of terms used in the AHRQ Common Formats for Event Reporting – Nursing Home***

| Word or Phrase | Definition |
|---|---|
| Accident | See: Patient/Resident safety incident. |
| Adverse Event | See: Harm incident. |
| Adverse Outcome | Undesired patient/resident outcome of healthcare; clinical complication of healthcare (which may or may not be a patient/resident 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/resident; 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/resident safety concern report. |
| Complete Patient/Resident Safety Concern Report | A complete initial report of a patient/resident 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/resident. 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/resident 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/resident 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/Resident 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/resident safety event, when 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/resident safety concern, the characteristics of a patient/resident involved in an incident and all data elements to assess and to encode the patient/resident safety concern. The completion of this module completes the basic 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 healthcare professional updates another on the status of one or more patient/resident 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/residents 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/residents 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/resident. |
| Harm to Health | Impairment of structure or function of the body and/or any deleterious effect arising therefrom. |

| Word or Phrase | Definition |
|---|---|
| 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 healthcare 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/) |
| 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 nursing home, 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/Resident safety incident. |
| Injury | See: Bodily injury & Psychological injury. |
| 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/Resident Incidents | An incident that involves two or more patients/residents (e.g., patient/resident given a medication intended for another - 2 patients/residents affected by the same incident); includes incidents involving a population of patients/residents (e.g., fire in a patient/resident section of a nursing home). |
| Near Miss | An event that did not reach a patient/resident. For example: discovery of a dispensing error by a nurse as part of the process of administering the medication to a patient/resident (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/resident but no discernible harm resulted. |
| Nursing Home | A facility with the staff and equipment to give skilled nursing care and, in most cases, skilled rehabilitative services and other health services. Nursing home care can include custodial care, such as help with bathing or dressing. |
| Patient/Resident Safety Concern | Any circumstance involving patient/resident safety; encompasses patient/resident safety event (both incident and near miss) and unsafe condition. |
| Patient/Resident Safety Event | Something that happens to or involves a patient/resident; encompasses patient/resident safety incident and near miss. |

| Word or Phrase | Definition |
|---|---|
| Patient/Resident Safety Incident** | A patient/resident safety event that reached a patient/resident and either resulted in no harm (no harm incident) or harm (harm incident). The concept “reached a patient/resident” encompasses any action by a healthcare practitioner or worker or healthcare circumstance that exposes a patient/resident to harm. For example: if a nurse gives a patient/resident an incorrect medication to take and the patient/resident 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/resident safety, to prevent a patient/resident safety event. |
| 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. |
| 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 healthcare organization who reports a patient/resident 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/resident safety incident that is intended to prevent, to minimize, or to reverse harm to the affected patient/resident. |
| 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/resident care impact (criticality).<br>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 healthcare) 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/resident 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. |

| Word or Phrase | Definition |
|---|---|
| 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/resident 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/resident safety concern was discovered. |
| Time of Occurrence of Event | Date/time when a patient/resident 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/resident's treatment plan; harm suffered as a result of an incident. |
| Unnecessary Harm | Healthcare-associated harm that was not expected to result from a patient's/resident's treatment plan; harm resulting from an incident. |
| Unplanned Intervention | An intervention that was not part of a patient's/resident's treatment plan prior to the event that necessitated the additional intervention. |
| Unsafe Condition | Any circumstance that increases the probability of a patient/resident 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/resident safety event. An unsafe condition does not involve an identifiable patient/resident. For example, an out-of-date medicine on a shelf represents an unsafe condition. It might be given to a patient/resident, but the identity of such patient/resident is unknown at the time of discovery. The attempt to administer the out-of-date medicine to a patient/resident would either represent a near miss (if not administered) or an incident (if administered). |

## C. Acronyms

***Table 2. Acronyms used in the Users' Guide for AHRQ Common Formats for Event Reporting – Nursing Home***

| Acronym | Expanded Phrase |
|---|---|
| AHRQ | Agency for Healthcare Research and Quality |
| AIMS | Australian Incident Monitoring System, Commonwealth of Australia |
| CDA XML | Clinical Document Architecture Extensible Markup Language |
| CDC | Centers for Disease Control and Prevention |
| CMS | Centers for Medicare & Medicaid Services |
| DoD | Department of Defense |
| EHR | Electronic Health Records |
| FDA | Food and Drug Administration |
| HHS | U.S. Department of Health and Human Services |
| HIT | Health Information Technology |
| HL7 | Health Level Seven |
| HRSA | Health Resources and Services Administration |
| ICPS | International Classification for Patient Safety, WHO |
| IHS | Indian Health Service |
| JCQHC | Japan Council for Quality Health Care |
| NHQDR | National Healthcare Quality and Disparities Report, AHRQ |
| 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 |
| USHIK | United States Health Information Knowledgebase |
| VA | Department of Veterans Affairs |
| WHO | World Health Organization |