Network of Patient Safety Databases Chartbook, 2023





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NETWORK OF PATIENT SAFETY DATABASES CHARTBOOK, 2023

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DATA LIMITATIONS:

- The Network of Patient Safety Databases (NPSD) does not contain a representative sample of patient safety concerns and cannot be used to calculate the actual incidence or prevalence of patient safety events. The reporting of patient safety concerns to the NPSD is voluntary as is the reporting to PSOs by providers.
- The NPSD is a summary of the elements in Hospital Common Formats Event Reports for specific types of patient safety concerns, that have been voluntarily submitted by Agency for Healthcare Research and Quality (AHRQ)-listed Patient Safety Organizations (PSOs).
- Descriptive analyses of patient safety concerns in the NPSD highlight potential issues worthy of attention and provide a snapshot of safety issues, but on their own cannot be used to establish causal relationships.
- While it is believed that the CFER-H are primarily used as intended to capture patient safety events in hospital settings, providers may also have used the CFER-H to report data from other settings. As only data submitted in the Common Formats for Event Reporting-Hospitals (CFER-H) are included in the NPSD dashboards and chartbooks, they are characterized as reflecting data from the hospital setting even though they may originate from other settings.

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INTRODUCTION TO THE NPSD

The Network of Patient Safety Databases (NPSD) provides an interactive, evidence-based management resource for healthcare providers, Patient Safety Organizations (PSOs), and others. The U.S. Department of Health & Human Services was authorized to create the NPSD by the <u>Patient Safety and Quality Improvement Act of 2005 (PSQIA)</u>, and it is implemented by the Agency for Healthcare Research and Quality (AHRQ), the lead federal agency for patient safety. The goal of the legislation is to create a national learning system that promotes using non-identifiable data about patient safety concerns to prevent patient harm and improve patient safety. Because the NPSD contains a large volume of standardized, non-identifiable patient safety data from across the country, it serves as a unique and valuable resource for research and learning.

AHRQ developed the Common Formats, a standardized reporting format using common language and definitions, to collect information about patient safety events and concerns from across the nation. PSOs collect voluntary reports from healthcare providers using Common Formats and submit this data to the PSO Privacy Protection Center (PSOPPC). The PSOPPC ensures the Common Formats data are non-identifiable before transmittal to the NPSD for aggregation and analysis. This data can then be used to identify trends and patterns in patient safety concerns, and to provide insight in how to mitigate patient safety risks and reduce harm across healthcare settings nationally. Each provider and PSO that participates by contributing data advances knowledge about patient safety.

Data was first submitted to the NPSD beginning on July 26, 2012. This Network of Patient Safety Databases Chartbook, 2023 (NPSD Chartbook) and accompanying online Dashboards focuses on patient safety data submitted to the PSOPPC in Common Formats for Event Reporting – Hospitals version 1.2 from June 26, 2014 through December 31, 2022.

Data and Analysis Available at the NPSD

Submission of patient safety event data by providers to PSOs and PSOs to the NPSD is completely voluntary. The NPSD data are not statistically comparable to clinical quality measures. For example, the data from clinical quality measures reported by agencies such as the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC), which may focus on all eligible members of a population, can establish denominators and calculate rates of occurrence. Voluntary patient safety reporting systems are, however, marked by variability in the rate and consistency of reporting, and denominators are typically unavailable. Hence, the event report data submitted to the NPSD cannot be used to calculate the actual incidence or prevalence of patient safety events. Also, while descriptive analyses of patient safety concerns in the NPSD highlight potential issues worthy of attention and provide a snapshot of safety issues, they cannot be used to establish causal relationships.

The NPSD Chartbooks and Dashboards comprise three different types of NPSD analyses:

Data Submission Summary

The Data Submission section provides a high-level overview of the frequency of patient safety concerns reported by AHRQ-listed PSOs. Examples include number of reports submitted by calendar year (CY), by version, and by completeness (of Common Formats elements). It also illustrates the adoption, implementation, and spread of the Common Formats over time. The total number of reports submitted between July 26, 2012 and

December 31, 2022 was 269,916 for CFER-H V1.1 and 2,347,775 for CFER-H V1.2 for a combined total of 2,617,691 reports.

Generic Patient Safety Concerns

The Generic Patient Safety Concerns analyses pertain to all patient safety concerns – incidents, near misses, and unsafe conditions – and includes basic information about all types of events. In the Common Formats for Event Reporting – Hospital Version 1.2 (CFER-H V1.2), the Healthcare Event Reporting Form (HERF), Patient Information Form (PIF), and Summary of Initial Report (SIR) Form are collectively referred to as the Generic Patient Safety Concerns module. Examples of generic information include type of event, location, contributing factors, and level of harm. These analyses display the distributions of the types of events and unsafe conditions reported by the AHRQ-listed PSOs from June 26, 2014 through December 31, 2022.

Event-Specific Modules

CFER-H V1.2 includes event-specific modules pertaining to nine patient safety event types. Event-specific modules capture information that goes beyond generic data and is related to relevant patient outcomes or processes of care in hospitals. Event-specific modules are employed in addition to, not in place of, the Generic Patient Safety Concerns module. An example of additional detail from the Fall module would be the type of injury sustained in a fall.

Event-specific modules are available for these nine types of safety events reported by PSOs: Blood or Blood Products, Device or Medical/Surgical Supply, Healthcare-Associated Infection, Fall, Medication or Other Substance, Perinatal, Pressure Ulcers, Surgery or Anesthesia, and Venous Thromboembolism. These event-specific analyses were developed because they were the most frequently reported events by PSOs, the data elements presented included at least 30 responses for reliable reporting, and data elements did not require extensive data suppression to meet non-identification requirements.

Six types of safety events (i.e., *Blood or Blood Products, Falls, Device or Medical/Surgical Supply, Medication or Other Substance, Perinatal,* and *Pressure Ulcers*) have been studied in greater depth via NPSD Dashboards and Chartbooks as they have the highest level of reporting. Specifically, the data submitted by the PSOs for these six types of patient safety events were the most complete with respect to reporting and provided the greatest amount of clinically relevant information. The data for the three remaining event types in CFER-H V1.2 (*Healthcare-Associated Infection, Surgery or Anesthesia, and Venous Thromboembolism*) had larger amounts of missing data, making the results more difficult to interpret clinically. As such, there are no standalone analyses for these event types.

Updates to Event-Specific Modules and Chartbooks

Beginning with the 2022 NPSD Chartbook and Dashboards, updated analyses have been developed for the existing data displays. The intention is for future NPSD Chartbooks to expand upon these results as more data become available and can be analyzed for inclusion in the national learning system. As displays are modernized and expanded upon, more

analyses and content will be generated. To enhance the user experience and streamline content, event-specific modules will no longer be combined in the same Chartbook as Generic Patient Safety Concerns and the Data Submission Summary. Instead, event-specific Chartbooks will be published as an accompaniment to their corresponding dashboard as new analyses and data displays are developed and published.

Carrying the 2022 NPSD Chartbook and Dashboards work forward, this Chartbook focuses on Generic Patient Safety Concerns, which introduces an examination of trends over time and new data: near miss prevention actions, contributing factors to events, and location of events to provide readers an enhanced analysis of the circumstances surrounding patient safety events. Additionally, analyses incorporate patient demographics (where available) to highlight potential disparities in patient safety outcomes.

NPSD Chartbook Text Formatting

The text of the NPSD Chartbook has been formatted to assist readers in recognizing when the discussion relates to a Common Formats Event Type, Data Element, and Answer Value. Event Types represent the distinct modules of the CFER-H (e.g., *Blood or Blood Product, Device or Medical/Surgical Supply, Fall, Healthcare-Associated Infection, Medication or Other Substance, Perinatal, Pressure Ulcer, Surgery or Anesthesia,* and *Venous Thromboembolism*). Data Elements (abbreviated DE) refer to the concepts reported in the CFER-H and captured through individual questions asked of event reporters for each patient safety concern reported (e.g., "What is being reported?" *Incident, Near miss,* or *Unsafe condition*). Answer Values represent the unique response options for each Data Element. Following the previous example, DE3: "What is being reported?" has three Answer Values: *Incident, Near miss,* and *Unsafe condition*.

Each of these types of information contained in the CFER-H is formatted differently in the text to clarify the context of the information for readers. The following formatting is used throughout the remainder of this document:

- Event Types: All key words have first-letter capitalization, and are italicized (e.g., *Blood or Blood Product*)
- Data Elements: All letters are capitalized, and bold-faced (e.g., CATEGORY ASSOCIATED WITH EVENT OR UNSAFE CONDITION)
- Answer Values: First letter of the first word is capitalized, and all letters are italicized (e.g., *Unsafe condition* or *Moderate harm*)

Of the nine **EVENT-SPECIFIC CATEGORIES** (**EVENT TYPES**) collected for CFER-H, six are explored in more detail in event type-specific analyses in the NPSD: *Blood or Blood Product*, *Device or Medical/Surgical Supply, Fall, Medication or Other Substance, Perinatal,* and *Pressure Ulcer*. There are no detailed sections for the *Surgery or Anesthesia* **EVENT TYPE** because too few of the submitted reports were sufficiently complete for meaningful analysis. No structured data were collected for *Other* reports, precluding detailed analysis. Subsequent to the development of the CFER-H, reporting *Healthcare-Associated Infection* through the CDC NHSN has been mandated in many states and by CMS. Given the small number (16,726) of CFER-H V1.2 *Healthcare-Associated Infection* through December 31, 2022 and the high quality of data

collected through NHSN, AHRQ has elected not to report any CFER-H *Healthcare-Associated Infection* data beyond the number of reports submitted. Finally, while there is a recognized need to collect data on *Venous Thromboembolism Incidents*, the small number (236) of CFER-H V1.2 *Venous Thromboembolism* reports received was deemed insufficient for any analysis and, as with *Healthcare-Associated Infection*, AHRQ has chosen to report only the number of reports submitted.

The data in the NPSD Chartbook for the Generic Patient Safety Concerns module and six types of safety events (i.e., *Blood or Blood Products, Device or Medical/Surgical Supply, Fall, Medication or Other Substance, Perinatal,* and *Pressure Ulcer*) were submitted in CFER-H V1.2. Data submitted in CFER-H V1.1 (269,916 records) are omitted from the analysis for these figures as CFER-H V1.1 was retired on July 7, 2017.

GENERIC PATIENT SAFETY CONCERNS

This Chartbook provides a cross-sectional analysis overview of Generic Patient Safety Concerns reported in CFER-H V1.2. The analyses in this Chartbook comprises data submitted in CFER-H V1.2 only. Data submitted in CFER-H V1.1 are not analyzed. The reasons for omitting CFER-H V1.1 data from the analyses include: 1) it is not possible to sum results across different versions because of material changes in clinical content between the two versions; 2) V1.1 data were not suitable for standalone reports because: a) the quality of V1.1 data was not comparable to that of V1.2, and b) the volume of V1.1 reports was substantially less than the volume of V1.2 reports, resulting in many fewer reportable categories of V1.1 data. Also, CFER-H V1.1 was retired on July 7, 2017. Data submitted in CFER-H V2.0 are also not included in these analyses because: 1) it is not possible to sum results across different versions because of material changes in clinical content between the two version in the volume of V1.2 reports, resulting in many fewer reportable categories of V1.1 data. Also, CFER-H V1.1 was retired on July 7, 2017. Data submitted in CFER-H V2.0 are also not included in these analyses because: 1) it is not possible to sum results across different versions because of material changes in clinical content between the two versions; and 2) reports that have been submitted using this format do not yet meet the requirements for aggregate reporting of non-identifiable data.

The distributions of the types of events and unsafe conditions, along with circumstances surrounding patient safety events reported by PSOs, and descriptive statistics about the extent of residual harm experienced by patients who have been impacted by safety incidents are provided. Residual harm is captured by AHRQ's Harm Scale and is defined as harm to the patient after discovery of the incident and any attempts to minimize adverse consequences. While the AHRQ Harm Scale provides a basis for comparing harm across the different event types in CFER-H, it should be noted that the definitions associated with each response category include subjective assessments by event reporters that may introduce some variability in the way specific events are reported.

The data presented have initial report dates from April 24, 2008 through December 24, 2022. These reports include a total of 2,262,668 events, of which 1,661,223 represent incidents where a safety concern reached a patient. These data do not include reports that met the event-specific exclusion criteria in the CFER-H V1.2 (e.g., any report of a fall that is not an incident is considered invalid and excluded). A complete list of exclusion criteria for CFER-H V1.2 may be found in Appendix A.

Note that totals in this section differ from those presented in the Data Submission Summary (see: Appendix B) because some reports submitted in CFER-H V1.2 were outside the specific scope of the Common Formats. These excluded reports contain information that is not within the intended scope of CFER-H. For example, Medication or Other Substance events that were reported as Adverse reaction in patient to the administered substance without any apparent incorrect action are outside the scope of CFER-H. Thus, these were excluded from report counts in the Generic Patient Safety Concerns module. Additionally, *Healthcare-Associated Infection* and *Venous Thromboembolism* **EVENT TYPES** were excluded from this analysis for reasons discussed in the sections labeled "NPSD Chartbook Text Formatting" and "Percentage of Event Type by Common Formats Version" (see Appendix B).

Total Patient Safety Concerns by Report Year

This figure displays the total number of patient safety concerns reported in CFER-H V1.2 within the NPSD, excluding the *Healthcare-Associated Infection* and *Venous Thromboembolism* **EVENT TYPES**, by report year.

Until 2017, the number of patient safety concerns reported in CFER-H V1.2 increased steadily. With the release of CFER-H V2.0 on August 3, 2018, there has been a decrease in reports submitted in CFER-H V1.2 as more reports have been submitted in CFER-H V2.0. It should be noted that as CFER-H V1.2 was released on April 3, 2012, initial submissions from many PSOs contain historical patient safety concerns. Also, there is considerable lag between an initial report of a patient safety concern and submission. The median time between initial report date and date of report submission is 1.6 years.

Important information is provided in the Technical Notes below.





Technical Notes

- The year displayed corresponds to the year of the **INITIAL REPORT DATE** (DE30).
- Due to very small counts and risk of disclosure, reports prior to 2010 are presented with counts for 2010.

Percentage of Patient Safety Concerns (Event Types) by Year

This figure displays each type of patient safety concern (CATEGORY ASSOCIATED WITH EVENT OR UNSAFE CONDITION [EVENT TYPE]) as a percentage of all EVENT TYPES identified in reports received in CFER-H V1.2 within the NPSD, excluding the *Healthcare-Associated Infection* and *Venous Thromboembolism* EVENT TYPES, by year.

Over the last ten years (2013-2022), the most frequently reported **EVENT TYPES** were:

- *Other*, ranging from 43.0% (48,808 / 103,392) to 59.4% (76,227 / 128,371);
- Medication or Other Substance, ranging from 17.2 % (63,566 / 370,203) to 26.9% (27,843 / 103,392);
- *Fall*, ranging from 10.0% (10,384 / 103,392) to 17.8% (34,214 / 294,646).

The large percentage of *Other* events reported may reflect issues encountered when mapping data from primary event-reporting systems into the CFER-H, specific concerns not captured by any of the event-specific modules, or concerns that can be considered administrative matters and should not have been reported using the CFER-H. In some cases, events that could have been captured in a CFER-H event-specific module (e.g., *Medication and Other Substance, Fall*, etc.) lacked compatible data fields within the primary event-reporting system and instead were mapped into *Other*.

Important information is provided in the Technical Notes below.



Figure 2: Percentage of Patient Safety Concerns (Event Types) by Year

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Technical Notes

- In CFER-H V1.2, the EVENT TYPE is found in the HERF DE21 in response to the question: "Which of the following categories are associated with the event or unsafe condition?" The year displayed corresponds to the year of the INITIAL REPORT DATE (DE30).
- Due to very small counts and risk of disclosure, reports prior to 2010 are presented with counts for 2010. Percentages sum to 100% within columns, but the sum of percentages may not total 100% due to rounding.

Report Types by Year

This figure examines the percentage of **REPORT TYPES**, that is, *Incidents, Near misses*, or *Unsafe conditions* by year. *Incidents* can be reported for any **EVENT TYPE**, but *Incident* is the only **REPORT TYPE** possible for *Fall, Healthcare-Associated Infection, Perinatal, Pressure Ulcer*, and *Venous Thromboembolism*; for these **EVENT TYPES**, 100% of **REPORT TYPES** are *Incidents*. Note, however, that AHRQ has chosen not to include *Healthcare-Associated Infection* and *Venous Thromboembolism* **EVENT TYPES** in this figure for reasons discussed in the sections labeled "NPSD Chartbook Text Formatting" and "Percentage of Event Type by Common Formats Version."

Within the last ten years (2013-2022), *Incidents* were the majority of each of the **REPORT TYPES**, ranging from 64.3% (82,536 / 128,371) to 78.8% (260,378 / 330,256) of report types. The percentage of reported *Near misses* decreased steadily from 26.1% (27,011 / 103,392) in 2013 to 9.9% (2,212 / 22,320) in 2022 while the percentage of reported *Unsafe conditions* increased from 6.0% (6,207 / 103,392) in 2013 to 24.0% in 2020, then levelled off to 16.5% in 2021 (7,010 / 42,401) and 14.3% in 2022 (3,194 / 22,320).

Important information is provided in the Technical Notes below.



Figure 3: Report Type by Year

Technical Notes

- In CFER-H V1.2, the **REPORT TYPE** is found in the HERF DE3 in response to the question: "What is being reported?" The year displayed corresponds to the year of the **INITIAL REPORT DATE** (DE30).
- Due to very small counts and risk of disclosure, reports prior to 2010 are presented with counts for 2010. Percentages sum to 100% within each year, but the sum of percentages may not total 100% due to rounding.

Report Types by Year and Event Type

These figures examine the percentage of each CATEGORY ASSOCIATED WITH EVENT OR UNSAFE CONDITION (EVENT TYPE) that were *Incidents*, *Near misses*, or *Unsafe conditions* by year. As Incident is the only **REPORT TYPE** possible for *Fall*, *Healthcare-Associated Infection*, *Perinatal*, *Pressure Ulcer*, and *Venous Thromboembolism*, these event types are excluded from this analysis.

Incidents were the majority of each of the **EVENT TYPES** across the last ten years, with the largest proportion reported for *Surgery or Anesthesia* (100,938 / 128,442; 78.6%), followed by *Blood or Blood Product* (16,714 / 26,129; 64.0%) and *Medication or Other Substance* (313,128 / 466,911; 67.1%). The lowest proportion of *Incidents* was reported for *Device or Medical/Surgical Supply* (38,810 / 65,699; 59.1%).

Four **EVENT TYPES** can be reported as *Incidents*, *Near misses*, or *Unsafe conditions*. For these event types, the largest proportion of *Unsafe conditions* was reported for *Device or Medical/Surgical Supply* (17.3%) across all years, followed by *Blood or Blood Product* (17.0%) and *Medication or Other Substance* (6.2%). The largest proportion of *Near misses* were reported for *Medication or Other Substance* events (26.8%), followed by *Device or Medical/Surgical Supply* (23.6%) and *Blood or Blood Product* (19.1%).

Surgery or Anesthesia event types can be reported as Incidents or Near misses. For these Surgery or Anesthesia events, Near misses were reported less frequently than Incidents across all years of data.

Important information is provided in the Technical Notes below.



Figure 4a: Report Type by Year – Blood or Blood Product Events

■ Incident ■ Near Miss ■ Unsafe Condition





■ Incident ■ Near Miss ■ Unsafe Condition



Figure 4c: Report Type by Year – Medication or Other Substance Events

■ Incident ■ Near Miss ■ Unsafe Condition



Figure 4d: Report Type by Year – Surgery or Anesthesia Events

Incident Near Miss

Technical Notes

- In CFER-H V1.2, the EVENT TYPE is found in the HERF DE21 in response to the question: "Which of the following categories are associated with the event or unsafe condition?" The REPORT TYPE is found in the HERF DE3 in response to the question: "What is being reported?" The year displayed corresponds to the year of the INITIAL REPORT DATE (DE30).
- The data presented above indicate the types of reports within each category of EVENT TYPE as a percentage of all events in that category where reports of *Incidents*, *Near misses*, or *Unsafe conditions* are permitted in CFER-H V1.2.
- Reports had INITIAL REPORT DATES from January 1, 2013 through December 24, 2022. The total number of EVENT TYPES is less than the total shown in the Data Submission Summary after application of exclusions and suppression of the *Healthcare-Associated Infection* and *Venous Thromboembolism* EVENT TYPES (please see Appendix B, section: Percentage of Event Type by Common Formats Version). Percentages sum to 100% within each row, but the sum of percentages may not total 100% due to rounding.

Location of Event or Unsafe Condition by Report Type

This figure examines the percentage of each LOCATION OF EVENT OR UNSAFE CONDITION by REPORT TYPE. Across all REPORT TYPES, *Inpatient care area* was the most frequently reported location (33.3%; 594,231 / 1,787,132) making up 34.7% (440,369 / 1,269,364) of Incidents, 31.1% (93,824 / 301,812) of *Near misses*, and 27.8% (60,038 / 215,956) of *Unsafe conditions*.

Outside of Inpatient care areas, incidents mostly occurred in Special care areas (13.1%; 166,412 / 1,269,364), Operating rooms or procedure areas (10.4%; 131,918 / 1,269,364), and Emergency departments (10.2%; 130,014 / 1,269,364). Near misses and Unsafe conditions were similarly distributed, however a larger share of Near misses occurred in Pharmacies (8.9%; 26,990 / 215,956), Laboratories (4.3%; 12,978 / 215,956), and Operating rooms or procedure areas (13.6%; 40,922 / 215,956) than for either Unsafe conditions or Incidents. Other (either outside of the facility or not otherwise specified) location was more frequent among Unsafe condition reports (27.1%; 58,606 / 215,956) than either Incidents (14.8%; 187,358 / 1,269,364) or Near misses (12.1%; 36,486 / 301,812).

Important information is provided in the Technical Notes below.



Figure 5: Location of Event or Unsafe Condition by Report Type

Technical Notes

- In CFER-H V1.2, the **REPORT TYPE** is found in the HERF DE3 in response to the question: "What is being reported?" LOCATION OF EVENT OR UNSAFE CONDITION is defined by DE78 in response to the question "Where did the event occur, or if an unsafe conditions, where does it exist?"
- *Other location* was defined by values for DE78 that included either "Other: please specify" (A66) or "Other area in this facility" (A273).
- Totals may be less than those shown in "Report Type by Event Type" section as this figure further excludes 475,536 reports where DE78 is missing. Percentages sum to 100% within each row, but the sum of percentages may not total 100% due to rounding.

Location of Event or Unsafe Condition by Event Type

This figure examines the percentage of each **LOCATION OF EVENT OR UNSAFE CONDITION** by **EVENT TYPE**. *Inpatient care area* was the most frequently reported location for more than half of all event types.

Inpatient care and Special care areas made up about half of locations where *Blood or Blood Product* events and unsafe conditions occurred, accounting for 32.3% (6,760 / 20,943) and 18.4% (3,860 / 20,943) of these events, respectively. *Operating rooms or procedure areas*, *Laboratories*, and *Emergency departments* were also cited locations, accounting for 12.6% (2,630 / 20,943), 8.9% (1,867 / 20,943), and 11.0% (2,295 / 20,943), respectively. Outside of *Perinatal* events, *Blood or Blood Product* events and unsafe conditions had the highest proportion of reports from *Labor and delivery* (2.7%; 572 / 20,943).

Operating rooms or procedure areas made almost a third of reported locations for *Device or medical/surgical supply, including HIT* (30.5%; 17,127 / 56,108) events and unsafe conditions. *Inpatient care* (18.4%; 10,315 / 56,108) *and Special care areas* (15.5%; 8,679 / 56,108) were also common locations for these events. *Other* locations made up 18.3% (10,245 / 56,108) of reported locations for *Device or medical/surgical supply, including HIT*.

Over one half of *Falls* occurred in *Inpatient care areas* (51.5%; 92,861 / 180,345). *Emergency departments* (6.9%; 12,523 / 180,345), *Special care areas* (6.6%; 11,955 / 180,345), and *Outpatient care areas* (6.4%; 11,592 / 180,345) were also a source of falls. *Other* was the second most common reported location for falls (23.6%; 42,514 / 180,345).

Almost 40% (39.3%; 130,606 / 332,652) of *Medication or other substance* events and unsafe conditions occurred in *Inpatient care areas*. Not surprisingly, *Medication or other substance* events and unsafe conditions had the highest proportion of reports from the *Pharmacy* (16.4%; 48,669 / 332,652) of all **EVENT TYPES**. *Medication or other substance* events and unsafe conditions also had the second highest proportion of reports from *Labor and delivery* (2.6%; 7,661 / 332,652) outside of *Perinatal* events.

About half (49.0%; 29,384 / 60,021) of *Pressure ulcers* were reported in *Inpatient care areas*. *Special care areas* (36.1%; 21,692 / 60,021) and *Operating rooms or procedure areas* (5.7%; 3,439

/ 60,021) were also a source of pressure ulcers.

Intuitively, the majority of *Surgery or anesthesia* (71.7%; 75,913 / 105,949) events were reported from *Operating rooms or procedure areas* and most *Perinatal* events were reported from *Labor and delivery* (88.4%; 15,911 / 19,009). *Inpatient care areas* also made up 6.8% (7,213/ 105,949) and 5.2% (990 / 19,009) of these events, respectively.

Important information is provided in the Technical Notes below.

Figure 6a: Location of Event or Unsafe Condition – Blood or Blood Products



Figure 6b: Location of Event or Unsafe Condition – Device or medical/surgical supply, including HIT



- Operating room or procedure area
- Inpatient general care area (e.g., medical/ surgical unit)
- Other
- Special care area (e.g., ICU, CCU, NICU)
- Emergency department
- Outpatient care area
- Radiology/ imaging department, including onsite mobile units
- Labor and delivery
- Unknown
- Pharmacy
- Laboratory, including pathology department and blood bank
- Outside area (i.e., grounds of this facility)

Figure 6c: Location of Event – Falls



Unknown

Figure 6d: Location of Event or Unsafe Condition – Medications or Other Substances



Figure 6e: Location of Event or Unsafe Condition – Perinatal



- Labor and delivery
- Inpatient general care area (e.g., medical/ surgical unit)
- Other
- Operating room or procedure area
- Special care area (e.g., ICU, CCU, NICU)
- Emergency department
- Outpatient care area
- Laboratory, including pathology department and blood bank
- Radiology/ imaging department, including onsite mobile units
- Outside area (i.e., grounds of this facility)

Figure 6f: Location of Event – Pressure Ulcers



- Inpatient general care area (e.g., medical/ surgical unit)
- Special care area (e.g., ICU, CCU, NICU)
- Other
- Operating room or procedure area
- Emergency department
- Outpatient care area
- Radiology/ imaging department, including onsite mobile units
- Labor and delivery
- Laboratory, including pathology department and blood bank
- Outside area (i.e., grounds of this facility)

Figure 6g: Location of Event or Unsafe Condition – Surgery or Anesthesia



Technical Notes

- In CFER-H V1.2, the EVENT TYPE is found in the HERF DE21 in response to the question: "Which of the following categories are associated with the event or unsafe condition?" LOCATION OF EVENT OR UNSAFE CONDITION is defined by DE78 in response to the question "Where did the event occur, or if an unsafe conditions, where does it exist?"
- Reports where the location was indicated as *Outside area* (n=11,725) were excluded from this analysis. *Other location* was defined by values for DE78 that included either "Other: please specify" (A66) or "Other area in this facility" (A273).

Totals may be less than those shown in "Report Type by Event Type" section as this figure further excludes 475,536 reports where DE78 is missing. Percentages sum to 100% within each pie, but the sum of percentages may not total 100% due to rounding.

Contributing Factors by Report Type

This figure examines the percentage of **CONTRIBUTING FACTORS** by **REPORT TYPE**. Across all **REPORT TYPES**, *Other* factors were the most common (81.4%; 563,114 / 691,719). Excluding reports where *Other* factors contributed to the event or unsafe condition, *Human factors* were the most frequently reported contributing factor (35.3%; 45,365 / 128,605 reports) making up 34.2% (32,807 / 95,918) of Incidents, 38.8% (11,824 / 30,843) of *Near misses*, and 38.9% (734 / 1,844) of *Unsafe conditions*.

Communication was a contributing factor for over 1 in 5 *Incidents* and *Near misses*, accounting for 22.9% (21,967 / 95,918) and 23.8% (7,335 / 30,843) of *Incidents* and *Near misses*, respectively. *Multiple factors* contributed to nearly 1 in 4 *Unsafe conditions* and over a quarter of *Incidents*, accounting for 24.5% (452 / 1,844) and 27.4% (26,287 / 95,918) of *Unsafe conditions* and *Incidents*, respectively. *Staff qualifications* contributed to 10.1% (3,105 / 30,843) of *Near* misses and contributed to a smaller proportion of *Incidents* (7,616/ 95,918) and *Unsafe conditions* (101 / 1,844). *Supervision/support* contributed to only 0.4% of all events and unsafe conditions (472 / 128,605).

Important information is provided in the Technical Notes below.





Technical Notes

- In CFER-H V1.2, the **REPORT TYPE** is found in the HERF DE3 in response to the question: "What is being reported?" **CONTRIBUTING FACTOR(S) FOR EVENT** is defined by DE105 in response to the question "What factor(s) contributed to the event?"
- To avoid potential risk of disclosure due to small counts, possible responses for DE105 were recategorized into broader contributing factors. For instance, for reports where the contributing factors were *Data: Availability, Data: Accuracy*, or *Data: Legibility*, the contributing factor is presented as *Data* for analysis. For reports where more than one type of response was selected for DE78 (e.g., *Data* and *Communication*), the contributing factor is presented as *Multiple*.
- For ease of visualization, this figure excludes 563,114 reports where the contributing factor was "Other: please specify" (A66). Percentages sum to 100% within each row, but the sum of percentages may not total 100% due to rounding.
- Totals may be less than the those shown in "Report Type by Event Type" section as this figure only includes reports that indicated that contributing factors were known (had a response of *Yes* for DE102, "Are any contributing factors to the event known?") and there were valid, non-missing responses for DE105 (n= 691,719).

Contributing Factors by Event Type

This figure examines the percentage of **CONTRIBUTING FACTORS** by **EVENT TYPE**. Across all **EVENT TYPES**, *Other* factors were the most common (80.0%; 224,662/280,943). Excluding reports where *Other* factors contributed to the event or unsafe condition, *Human factors* were the most frequently reported contributing factor across most **EVENT TYPES**, particularly for *Falls* (45.9%; 5,233 / 11,399) and *Pressure Ulcers* (43.6%; 535 / 1,226).

Communication was the leading contributor for *Surgery or Anesthesia* events (42.0%; 2,125 / 5,063), followed by *Human factors* (22.0%; 1,115 / 5,063). *Multiple factors* accounted for a large proportion of contributors to events, ranging from 20.7% (1,049 / 5,063) of *Surgery or Anesthesia* events to 33.5% (110 / 328) of *Perinatal* events. *Staff qualifications* contributed to more than 1 in 10 *Pressure Ulcer* (13.8%; 169 / 1,226), *Device or Medical/Surgical Supply* (14.7%; 422 / 2,875), and *Blood or Blood Product* (14.4%; 191 / 1,326) events.

Environmental factors were minor contributors for events, except for *Falls* (11.2%; 1,274 / 11,399) and, to some extent, *Device or Medical/Surgical Supply* (4.6%; 133 / 2,875) events.

Important information is provided in the Technical Notes below.

Figure 8: Contributing Factors by Event Type



Technical Notes

- In CFER-H V1.2, the EVENT TYPE is found in the HERF DE21 in response to the question: "Which of the following categories are associated with the event or unsafe condition?" CONTRIBUTING FACTOR(S) FOR EVENT is defined by DE105 in response to the question "What factor(s) contributed to the event?"
- To avoid potential risk of disclosure due to small counts, possible responses for DE105 were recategorized into broader contributing factors. For instance, for reports where the contributing factors were *Data: Availability, Data: Accuracy*, or *Data: Legibility*, the contributing factor is presented as *Data* for analysis. For reports where more than one type of response was selected for DE78 (e.g., *Data* and *Communication*), the contributing factor is presented as *Multiple*.
- For ease of visualization, this figure excludes 224,662 reports where the contributing factor was "Other: please specify" (A66). Percentages sum to 100% within each row, but the sum of percentages may not total 100% due to rounding.
- Totals may be less than the those shown in "Report Type by Event Type" section as this figure only includes reports that indicated that contributing factors were known (had a response of *Yes* for DE102, "Are any contributing factors to the event known?") and there were valid, non-missing responses for DE105 (n= 280,943).

Near Miss Prevention Actions by Event Type

This figure examines the percentage of each NEAR MISS PREVENTION ACTION by EVENT TYPE. Blood or Blood Product, Device or Medical/Surgical Supply, Medication or Other Substance, and Surgery or Anesthesia events can be reported as Near misses. Across these four EVENT TYPES, 75.6% (28,646 / 37,891) of NEAR MISS PREVENTION ACTIONS were Unknown.

Excluding reports where the **NEAR MISS PREVENTION ACTION** was *Unknown*, a *Fail-safe designed into the process and/or a safeguard worked effectively* prevented 63.6% (5,884 / 9,245) of events from reaching the patient. *Fail-safe designed into the process and/or a safeguard worked effectively* prevented the majority of *Medication or Other Substance* events (67.5%; 4,525 / 6,701) from reaching patients and over half of *Surgery or Anesthesia* events (58.7%; 1,248 / 2,127).

Spontaneous action by a practitioner or staff member prevented about a quarter of events from reaching patients (25.9%; 2,396 / 9,245). Among Device or Medical/Surgical Supply, including HIT, Spontaneous action by a practitioner or staff member prevented 46.9% (143 / 305) of events from reaching the patient.

Important information is provided in the Technical Notes below.
Figure 9: Near Miss Prevention Actions by Event Type



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Technical Notes

- In CFER-H V1.2, the EVENT TYPE is found in the HERF DE21 in response to the question: "Which of the following categories are associated with the event or unsafe condition?" NEAR MISS PREVENTION ACTION is defined by DE93 in response to the question "What prevented the near miss (close call) from reaching the patient?" The REPORT TYPE is found in the HERF DE3 in response to the question: "What is being reported?"
- This figure only includes *Near miss* (indicated by values of A6 for DE3) reports. Percentages sum to 100% within each row, but the sum of percentages may not total 100% due to rounding.

Incident-Specific Analysis: Trends in Extent of Harm¹

CFER-H V1.2 captures an assessment of the extent of harm to the patient after discovery of the incident and after any attempts to minimize adverse consequences, called residual harm. The AHRQ Harm Scale captures these data and provides the following possible responses: *No harm, Mild harm, Moderate harm, Severe harm, Death*, or *Unknown harm*.

These figures display *Incident* events associated with residual harm to patients by year. However, due to small counts across the categories of *Moderate* to *Severe harm*, this figure displays *Incident* events where the **EXTENT OF HARM** is categorized as *No harm*, *Harm*, or *Unknown harm*.

Across all patients, years, and *Incident* events included in this analysis where information on **EXTENT OF HARM** was reported, *No harm* was reported most frequently (47.0%; 781,254 / 1,661,223). From 2010 to 2019, *Incidents* where *Harm* was reported decreased from 42.3% (14,043 / 33,197) to 14.4% (29,744 / 206,384). In 2020, *Incidents* where *Harm* was reported increased to 38.6% (31,894 / 82,526), but has decreased since. *Incidents* where the **EXTENT OF HARM** was reported as *Unknown* comprised 25.2% (418,016 / 1,661,223) of all events included in this analysis and has fluctuated across all years.

As *Incident* events in the NPSD are the only data that also include patient demographics, these figures further display **EXTENT OF HARM** by patient age and sex. Among patients *Under 18*, rates of *Harm* by year were consistently lower than their *Adult (aged 18-64)* and *Senior (aged 65 and older)* counterparts. Among *Senior (aged 65 and older)* patients, rates of *Harm* by year were consistently higher than their *Adult (aged 18-64)* and *Under 18* counterparts. Trends in the reported rates of *Harm* by year were similar across male and female patients (see: Appendix C).

Important information is provided in the Technical Notes below.

¹ Extent of harm and Patient information are only collected for incidents, which are defined by the **REPORT TYPE** or HERF DE3 in CFER-H V1.2, in response to the question: "What is being reported?"



Figure 10a: Extent of Harm by Year – All Patients









Figure 10d: Extent of Harm by Year – Senior Patients (Aged 65 and Older)



Technical Notes

- In CFER-H V1.2, the EXTENT OF HARM in the PIF is DE55 in response to the question: "After any intervention to reduce harm, what was the degree of residual harm to the patient from the incident (and subsequent intervention)?" The year displayed corresponds to the year of the INITIAL REPORT DATE (DE30).
- In CFER-H V1.2, PATIENT AGE is indicated by DE 45. While the AHRQ Age Scale provides the following possible responses: Neonate (0-28 days), Infant (>28 days >1 year), Child (1-12 years), Adolescent (13-17 years), Adult (18-64 years), Mature Adult (65-74 years), Older adult (75-84 years), and Aged adult (85+ years), the Neonate through Adolescent categories were condensed into a single Under 18 age group due to small cell counts and reduce risk of disclosure. To balance counts across groups, Mature Adults (65-74 through Aged adult (85+ years) were condensed into a single Senior (aged 65 and older) group for analysis. The age-specific figures above are based on reported data for 134,906 Under 18, 832,801 Adult, and 612,340 Senior patients, respectively. Age was unknown for 81,176 patients.
- The data presented above indicate *Incident* events in each harm category as a percentage of all *Incident* events with data on **EXTENT OF HARM**. Out of 1,661,223 reported *Incidents*, 4.5% (74,714) did not have any data on **EXTENT OF HARM** reported. The data above excludes these reports. Additionally, AHRQ has chosen not to include Healthcare-Associated Infection and Venous Thromboembolism **EVENT TYPES** in this figure for reasons discussed in the sections labeled "NPSD Chartbook Text Formatting" and "Percentage of Event Type by Common Formats Version" and as such, these events are not included in the data above.
- This figure includes reports of *No harm* for 19,664 patients in *Pressure Ulcer Incidents* (1.2% of all 1,661,223 *Incidents*), which reflects a misinterpretation of the CFER-H V1.2 question regarding the **EXTENT OF HARM**. *Pressure Ulcers* result in harm to the patient by their very nature. A report of *No harm* here suggests that the reporter perceived no residual harm because the patient recovered. However, the **EXTENT OF HARM** for these patients should never be reported as *No harm*; it should always be at least *Mild harm*.
- Due to very small counts and risk of disclosure, reports prior to 2010 are included in counts for 2010. Percentages sum to 100% within each year, but the sum of percentages may not total 100% due to rounding.

Incident-Specific Analysis: Extent of Harm by Event Type

This figure displays **EXTENT OF HARM** experienced by patients affected by year within each of the **CATEGORIES ASSOCIATED WITH EVENT OR UNSAFE CONDITION (EVENT TYPES)** defined for CFER-H V1.2. CFER-H V1.2 captures an assessment of the extent of harm to the patient after discovery of the incident and after any attempts to minimize adverse consequences, called residual harm. The AHRQ Harm Scale captures these data and provides the following possible responses: *No harm, Unknown harm, Mild harm, Moderate harm, Severe harm, Death*, or *Unknown harm*.

These figures display *Incident* events associated with residual harm to patients by year. Due to small counts across the categories of *Moderate* to *Severe harm*, this figure includes *Incident* events where the **EXTENT OF HARM** was reported as *No harm*, *Harm*, or *Unknown harm*.

Across all **EVENT TYPES** and patients included in this analysis, *Harm* was reported in 27.8% (461,953 / 1,661,223) of all *Incident* events.

The **EVENT TYPES** with the smallest proportion of *Harm* reported among *Incidents* were *Device* or *Medical/Surgical Supply* (16.0%; 6,218 / 38,810) and *Medication or Other Substance* (27.0%; 84,559 / 313,128). However, the proportion of *Unknown harm* for both events accounted for 35.8% (13,896 / 38,810) and 26.0% (81,476 / 313,128) of event reports, respectively. Balancing the proportion of events with *Unknown harm*, *Blood or Blood Product* (28.3%; 4,723 / 16,714) events had a relatively low proportion of events that resulted in *Harm*. Conversely, *Pressure Ulcers* had the highest proportion of events that resulted in *Harm* (71.3%; 58,091 / 81,427). Similarly, over half of *Perinatal* events resulted in *Harm* (52.5%; 15,919 / 30,346).

No harm was reported for nearly one-quarter (19,664 / 81,427; 24.1%) of *Pressure Ulcer Incidents* where the **EXTENT OF HARM** was known. This is unexpected, as pressure ulcers result in harm to the patient by their very nature. Reports of *No harm* for these incidents reflect a misinterpretation of the CFER-H V1.2 question regarding the **EXTENT OF HARM**: "After any intervention to reduce harm, what was the degree of residual harm to the patient from the incident (and subsequent intervention)?" A report of *No harm* for a pressure ulcer suggests that the reporter perceived no residual harm because the patient recovered. However, the **EXTENT OF HARM** for these incidents should never be reported as *No harm*; it should always be at least *Mild harm*.

Across **EVENT TYPES**, reported rates of *Harm* by year were similar across male and female patients (see: Appendix C). Overall, the proportion of *Harm* reported was highest among *Seniors* (*aged 65 and older*) at 31.8% (194827 / 612,340) and lowest among patients *Under* 18 at 23.7% (31,920 / 134,906). Among *Senior* (*aged 65 and older*) patients, rates of *Harm* by year were consistently higher than their *Adult* (*aged 18-64*) and *Under 18* counterparts for *Falls* (24.7%; 29,146 / 117,957), *Medication or Other Substance* (30.0%; 36,765 / 122,430), and *Surgery or Anesthesia Incidents* (34.3%; 12,492 / 36,407).

Within *Pressure ulcer Incidents*, the proportion of *Harm* was highest among patients *Under 18* at 84.9% (2,695 / 3,176) --- notably higher than 73.1% (22,066 / 30,199) and 69.8% (33,091 / 47,396) reported among *Adults (aged 18-64)* and *Seniors (aged 65 and older)*, respectively. Similarly, the proportion of *Harm* was highest among patients *Under 18* (32.7%; 404 / 1,237) for *Blood or Blood Product Incidents*.







Figure 11b: Extent of Harm by Event Type – Patients Under 18



Figure 11c: Extent of Harm by Event Type – Adult Patients (Aged 18-64)



Figure 11d: Extent of Harm by Event Type – Senior Patients (Aged 65 and Older)

Important information is provided in the Technical Notes below.

Technical Notes

- In CFER-H V1.2, the EXTENT OF HARM in the PIF is DE55 in response to the question: "After any intervention to reduce harm, what was the degree of residual harm to the patient from the incident (and subsequent intervention)?" The year displayed corresponds to the year of the INITIAL REPORT DATE (DE30).
- In CFER-H V1.2, PATIENT AGE is indicated by DE 45. While the AHRQ Age Scale provides the following possible responses: Neonate (0-28 days), Infant (>28 days >1 year), Child (1-12 years), Adolescent (13-17 years), Adult (18-64 years), Mature Adult (65-74 years), Older adult (75-84 years), and Aged adult (85+ years), the Neonate through Adolescent categories were condensed into a single Under 18 age group due to small cell counts and reduce risk of disclosure. To balance counts across groups, Mature Adults (65-74 through Aged adult (85+ years)) were condensed into a single Senior (aged 65 and older) group for analysis. The age-specific figures above are based on reported data for 134,906 Under 18, 832,801 Adult, and 612,340 Senior patients, respectively. Age was unknown for 81,176 patients.
- The data presented above indicate *Incident* events in each harm category as a percentage of all *Incident* events with data on **EXTENT OF HARM**. Out of 1,661,223 reported *Incidents*, 4.5% (74,714) did not have any data on **EXTENT OF HARM** reported. The data above excludes these reports. Additionally, AHRQ has chosen not to include Healthcare-Associated Infection and Venous Thromboembolism **EVENT TYPES** in this figure for reasons discussed in the sections labeled "NPSD Chartbook Text Formatting" and "Percentage of Event Type by Common Formats Version" and as such, these events are not included in the data above.
- Reports had INITIAL REPORT DATES from April 24, 2008 through December 24, 2022. Percentages sum to 100% within columns, but the sum of percentages may not total 100% due to rounding.

APPENDIX A: COMMON FORMATS FOR EVENT REPORTING – HOSPITAL V1.2 EXCLUSION CRITERIA AND COUNTS OF INCLUDED DATA

The Common Formats for Event Reporting – Hospital was designed to exclude reports of patient safety events and unsafe conditions where the nature of the patient safety concern could not be attributed to the hospital, did not appear to involve incorrect actions, or were otherwise not part of the focus of the event-specific module. The exclusion criteria are documented in the CFER-H V1.2 Technical Specifications – Event Descriptions and Aggregate Report Specifications. For each section of the NPSD Chartbook, reports meeting the listed criteria are excluded from analysis:

Data Submissions

No exclusions apply.

Generic Patient Safety Concerns

All exclusions listed below apply.

Blood and Blood Product

- Blood and blood product collection and other processes prior to receipt of the product by the blood bank
- Incident involving adverse reaction during or following administration without any apparent incorrect action

Device or Medical/Surgical Supply, including Health Information Technology (HIT)

• Defects or events discovered prior to market approval or clinical deployment

Fall

- A fall resulting from a purposeful action or violent blow (e.g., a patient pushes another patient)
- Near fall loss of balance that does not result in a fall

Medication or Other Substance

- Adverse drug reaction with no apparent incorrect action
- Patient food (not suspected in drug-food interactions)
- Radiopharmaceuticals
- Appropriateness of therapeutic choice or decision making, (e.g., physician decision to prescribe medication despite known drug-drug interaction)
- Drug-drug, drug-food, or adverse drug reaction as a result of a prescription and/or administration of a drug and/or food prior to admission

Perinatal

• Adverse events not associated with the birthing process (nor with an intrauterine procedure)

Pressure Ulcer

- A pressure ulcer that, on admission, was at stage/category III or stage/category IV or was unstageable
- A lesion that, on admission, was a suspected Deep Tissue Injury
- A pressure ulcer at stage/category I or stage/category II
- A pressure ulcer whose most advanced stage is unknown
- A mucosal ulcer without skin or tissue involvement
- An arterial or venous ulcer

• A diabetic foot ulcer

Surgery/Anesthesia

- American Society of Anesthesiologists (ASA) Class 6 Brain-dead patient whose organs are being removed for donor purposes
- Handling of an organ after procurement

Other

No exclusions apply.

Data Included for 2023 Analyses by Event Type and Report Type

Throughout the NPSD Dashboard, the eligible population of reports for a number of sections can be derived from the frequency of reports provided in the table below.

Event Type	Total	Incident		Near Miss		Unsafe Condition	
		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Blood or Blood Product	26,129	16,714	64.0%	4,981	19.1%	4,443	17.0%
Device or Medical/ Surgical Supply	65,699	38,810	59.1%	15,509	23.6%	11,380	17.3%
Fall	243,449	243,449	100.0%	NA	NA	NA	NA
Medication or Other Substance	466,911	313,128	67.1%	124,967	26.8%	28,816	6.2%
Perinatal	30,346	30,346	100.0%	NA	NA	NA	NA
Pressure Ulcer	81,427	81,427	100.0%	NA	NA	NA	NA
Surgery or Anesthesia	128,442	100,938	78.6%	27,504	21.4%	NA	NA
Other	1,217,623	834,339	68.5%	176,608	14.5%	206,676	17.0%
Multiple	2,642	2,072	78.4%	257	9.7%	313	11.8%

Note: NA indicates that there were no reports for that category of EVENT TYPE.

APPENDIX B: DATA SUBMISSION SUMMARY

The Data Submission Summary illustrates the adoption and use of the CFER-H V1.1 and CFER-H V1.2 for reporting patient safety concerns and examining the frequency and types of reports submitted to the PSOPPC. Individual figures provide the distributions of the types of events and unsafe conditions reported by the AHRQ-listed PSOs in these two versions, as well as descriptive statistics about the number of reports submitted for each patient safety category or event type.

CFER-H V1.1 was released on March 31, 2010 and retired on July 7, 2017. CFER-H V1.2 was released on April 3, 2012 and remains in use. CFER-H V2.0a was released on August 3, 2018, but no data have been included using this version of the specifications since reports that have been submitted using this format do not yet meet the requirements for aggregate reporting of non-identifiable data.

Cumulative Number of Reports Submitted by Common Formats Version by Year

This figure displays a running total of all reports submitted to the PSOPPC by calendar year (CY) from July 26, 2012 through December 31, 2022 in CFER-H V1.1 and CFER-H V1.2. The total number of reports submitted between July 26, 2012 and December 31, 2022 was 269,916 for CFER-H V1.1 and 2,347,775 for CFER-H V1.2 for a combined total of 2,617,691 reports.

Important information is provided in the Technical Notes below.



Figure 12: Cumulative Number of Reports Submitted by Common Formats Version by Year

Note: The data presented indicate a running total of the number of reports submitted to the PSOPPC via CFER-H V1.1 and CFER-H V1.2. Counts shown in the figure are cumulative, therefore it is not appropriate to sum the counts shown across years.

Technical Notes

- The year displayed indicates the calendar year (CY) a report was submitted by a PSO to the PSOPPC. Note that this is neither the date the patient safety concern occurred nor the date the concern was reported by the health care provider or facility. While not reported here, the INITIAL REPORT DATE is the CFER-H data element representing the date the report was initially entered into the system at the provider facility and is often different from the date the report dates and submission dates indicated that submission dates ranged between July 26, 2012 and December 24, 2022, and the median number of days between initial report date and submission to the PSOPPC was 584 (1.6 years), with an interquartile range (25th-75th percentiles) from 318 days (0.9 years) to 1,057 days (2.9 years). The full range of differences between initial report date and submissions from many PSOs contained historical data, resulting in the appearance of a longer lag time between initial report date and submission date.
- Some reports that were counted in the Data Submission Summary module may not be counted in other analyses of the CFER-H data. The excluded reports contain information that is not within the intended scope of CFER-H. For this reason, frequencies and percentages displayed in the Data Submission Summary module differ from those shown in other modules. Criteria for exclusion may be found in the CFER-H Event Descriptions. A complete list of exclusion criteria for CFER-H V1.2 is in Appendix D.

Completeness of Reports Submitted by Common Formats Version

Although the CFER-H were developed to collect a large number of detailed data elements related to patient safety concerns, many PSOs were only able to capture a portion of all possible data elements. There are numerous reasons for this partial reporting, such as the providers' use of risk management and/or incident reporting data systems that do not include the same data elements as CFER-H, as well as the expense required to convert existing data to meet CFER-H specifications. The difference between partial reporting and full reporting was revealed when the data were submitted to the PSOPPC.

This figure displays the number of reports by completeness of fields (minimum, partial, or full) stratified by CFER-H version (CFER-H V1.1 and CFER-H V1.2). The total number of reports submitted via CFER-H V1.1 was 269,916; for CFER-H V1.2 the total was 2,347,775. The combined total number of reports was 2,617,691.

The percentage of reports that met the standard for full reporting in CFER-H V1.1 was higher than CFER-H V1.2: 47.6% (128,493 / 269,916) for V1.1 compared to 29.4% for V1.2 (690,543/2,347,775). The vast majority of reports submitted in CFER-H V1.2 were partial reports (1,604,595/2,347,775; 68.4%), or only met the minimum Validation Data Set requirement for reports to be accepted by the PSOPPC import process (52,637 / 2,347,775; 2.2%).

Although a larger percentage of reports were considered full among CFER-H V1.1 submissions

when compared to CFER-H V1.2, most of the difference was not more detailed data, but the result of selecting *Other* as the **CATEGORY ASSOCIATED WITH EVENT OR UNSAFE CONDITION** (**EVENT TYPE**). When a patient safety concern is reported as an *Other* **EVENT TYPE**, only a limited number of generic data elements are collected, in contrast to each specific **EVENT TYPE** for which detailed event-specific data elements are collected. This means that *Other* **EVENT TYPE** records are more likely to be classified as full than records from the remaining **EVENT TYPES**. Additionally, a smaller number of PSOs reported a larger proportion of full *Other* records in V1.1 than occurred in V1.2, causing the portion of full records for *Other* events to decline in V1.2. The frequent selection of *Other* appeared to be predominantly the result of mapping data from various systems into CFER-H data elements.

Important information is provided in the Technical Notes below.



Figure 13: Completeness of Reports Submitted by Common Formats Version

Technical Notes

Data represent all reports received between July 26, 2012 and December 31, 2022. INITIAL REPORT DATES for the data range from August 1, 2007 through December 24, 2022. The INITIAL REPORT DATE is when the report was entered into a data system at the provider facility and is often different from the date the report is submitted to the PSOPPC.

- Data completeness is electronically assessed sequentially as follows: (a) Does the report meet the Validation Data Set requirements contained in the Implementation Guide in the CFER-H Technical Specifications? The Validation Data Set requires that each report contain identifying numbers for the PSO (PSO OID), provider (PROVIDER ID), and event (EVENT ID); and the REPORT TYPE, category of event (EVENT TYPE), and INITIAL REPORT DATE. In addition, *Incident* reports must provide PATIENT SEX and/or NEONATE SEX, and PATIENT DATE OF BIRTH and/or PATIENT AGE and NEONATE DATE OF BIRTH. Reports lacking any of these data elements are rejected during the PSOPPC import process and do not become part of the NPSD data set. Those that pass are considered minimum reports in the context of this figure. (b) Next, the data element responses are evaluated to determine if they follow the logic of the Flow Charts in the CFER-H Technical Specifications. A report is defined as either full or partial as follows: (i) full all data elements are answered according to the Flow Charts; or (ii) partial contains more than the Validation Data Set but does not provide all data elements according to the Flow Charts.
- Based on information from some PSOs about the methodology needed to map data to comply with the Flow Charts, as well as other challenges to receiving meaningful data sets at the PSOPPC, the AHRQ PSO program revised the CFER-H specifications and implemented Core Data Sets with CFER-H V2.0a. AHRQ consulted with the Federal Interagency Patient Safety Work Group, the Common Formats Expert Panel of the National Quality Forum (NQF), and sought comment from the public to develop this new version. The goal of reducing the number of questions for each module was to facilitate more complete submission of key data elements. As of December 31, 2022, data had not yet been included in this analysis for CFER-H V2.0a since reports that have been submitted using this format do not yet meet the requirements for aggregate reporting of non-identifiable data.
- Some reports that were counted in the Data Submission Summary module may not be counted in other analyses of the CFER-H data. The excluded reports contain information that is not within the intended scope of CFER-H. For this reason, frequencies and percentages displayed in the Data Submission Summary module differ from those shown in other modules. Criteria for exclusion may be found in the CFER-H Event Descriptions. A complete list of exclusion criteria for CFER-H V1.2 is in Appendix D.

Percentage of Total Reports by Common Formats Version

This figure shows the percentage of reports submitted using CFER-H V1.1 and CFER-H V1.2 as a percentage of all reports submitted. The total number of reports received by the PSOPPC was 269,916 for CFER-H V1.1 and 2,347,775 for CFER-H V1.2 for a combined total number of 2,617,691 reports. The majority of reports 2,347,775 / 2,617,691 ; 89.7%) were submitted using CFER-H V1.2. Far fewer (269,916 / 2,617,691 ; 10.3%) were submitted using the earlier version, CFER-H V1.1, which was retired in 2017. This pattern is consistent with the observations noted in the trend analysis in 2017 and 2018 (see figure: Cumulative Number of Reports Submitted by Common Formats Version by Year in the Data Submission Summary module, showing the movement of the field toward the adoption of the Common Formats over the first decade of the program, as the AHRQ PSO Program and PSOPPC offered technical assistance to PSOs to encourage and facilitate submission of data to the PSOPPC).

Important information is provided in the Technical Notes below.



Figure 14: Percentage of Total Reports by Common Formats Version

Note: Percentages may not sum to 100% due to rounding.

Technical Notes

Data represent all reports received between July 26, 2012 and December 31, 2022. INITIAL REPORT DATES for the data range from August 1, 2007 through December 24, 2022. The INITIAL REPORT DATE is when the report was entered into a data system at the provider facility and is often different from the date the report is submitted to the PSOPPC. Some reports that were counted in the Data Submission Summary module may not be counted in other analyses of the CFER-H data. The excluded reports contain information that is not within the intended scope of CFER-H. For this reason, frequencies and percentages displayed in the Data Submission Summary module differ from those shown in other modules. Criteria for exclusion may be found in the CFER-H Event Descriptions. A complete list of exclusion criteria for CFER-H V1.2 is in Appendix D.

Percentage of Total Reports by Report Type

The data presented in this figure show the number of reports for each **REPORT TYPE** submitted as a percentage of all reports using CFER-H V1.1 and CFER-H V1.2.

The CFER-H capture patient safety concerns in three REPORT TYPES: Incidents, Near misses

and *Unsafe conditions*. An *Incident* is a patient safety event that reached the patient, whether or not the patient was harmed. A *Near miss* (often called a close call) is a patient safety event that transpired but did not reach the patient. An *Unsafe condition* is any circumstance that increases the probability that a patient safety event may occur.

Approximately three-quarters (1,876,996/2,617,691; 73.4%) of the reports submitted involved *Incidents*, 15.1% (387,532/2,617,691) were *Near misses*, and 11.5% (293,598/2,617,691) were *Unsafe conditions*. Both near misses and unsafe conditions may occur more commonly in practice than incidents. Recognition and understanding of near misses and unsafe conditions can provide valuable learning opportunities about how to prevent patient harm.

Important information is provided in the Technical Notes below.



Figure 15: Percentage of Total Reports by Report Type

Note: The total number of reports submitted via CFER-H V1.1 was 269,916; for CFER-H V1.2 the total was 2,347,775. The combined total number of reports was 2,617,691. Percentages may not sum to 100% due to rounding.

Technical Notes

Data represent all reports received between July 26, 2012 and December 31, 2022. INITIAL REPORT DATES for the data range from August 1, 2007 through December 24, 2022. The INITIAL REPORT DATE is when the report was entered into a data system at the provider facility and is often different from the date the report is submitted to the PSOPPC.

- In CFER-H V1.1 and V1.2, the **REPORT TYPE** is found in the HERF DE3, in response to the question: "What is being reported?"
- Some reports that were counted in the Data Submission Summary module may not be counted in other analyses of the CFER-H data. The excluded reports contain information that is not within the intended scope of CFER-H. For this reason, frequencies and percentages displayed in the Data Submission Summary module differ from those shown in other modules. Criteria for exclusion may be found in the CFER-H Event Descriptions. A complete list of exclusion criteria for CFER-H V1.2 is in Appendix D.

Percentage of Event Type by Common Formats Version

The data presented in this figure show the percentages of different **EVENT TYPES**. In addition to a **REPORT TYPE**, each patient safety concern is categorized by one or more **EVENT TYPES** describing the nature of the patient safety concern. CFER-H V1.2 recognizes nine specific **EVENT TYPES** and allows reporting of *Other* as well, although there is no module for *Other*.

Because each report could be related to more than one **EVENT TYPE**, a count by **EVENT TYPES** results in a larger sum than a count by **REPORT TYPE**.

The *Other* **EVENT TYPE** was included in the Common Formats to be used only for events that could not be classified as one of the nine categories of **EVENT TYPE**. The fact that *Other* was so widely used, noted in more than half of the reports submitted in CFER-H V1.2, is believed to be largely an artifact of the mapping strategies of the providers as they moved toward integrating Common Formats reporting with their pre-existing data systems.

The profiles of CFER-H V1.1 and CFER-H V1.2 data submissions by **EVENT TYPE** were broadly similar. Among the more evident differences were: (a) a larger proportion of *Medication or Other Substance* in CFER-H V1.2 compared to CFER-H V1.1 (479,035 / 2,347,775; 20.4% versus 38,695 / 269,916; 14.3%); and (b) a smaller proportion of *Surgery or Anesthesia* in CFER-H V1.2 compared to CFER-H V1.1 (129,956/ 2,347,775; 5.5% versus 25,008 / 269,916; 9.3%);

Of the **EVENT TYPES** shown in this figure, which was derived from the Generic Patient Safety Concerns module, six are explored in more detail in event-specific modules: *Blood or Blood Product*; *Device or Medical/Surgical Supply, Including Health Information Technology (Device or Medical/Surgical Supply)*; *Fall*; *Medication or Other Substance; Perinatal*; and *Pressure Ulcer*.

There are no detailed, event-specific figures for *Healthcare-Associated Infection, Surgery or Anesthesia*, or *Venous Thromboembolism* modules. Many AHRQ-listed PSOs were only able to capture a portion of all possible data elements, and their choice of how many, and which, elements to report varies by PSO and by provider. For these three modules, too few of the submitted reports were sufficiently complete to support detailed patient safety event-specific analyses. One of these modules, *Surgery or Anesthesia*, contained enough information to be included in the Generic Patient Safety Concerns module. Data received for the *Healthcare-Associated Infection* and *Venous Thromboembolism* modules were not sufficient to support inclusion in the Generic Patient Safety Concerns module.

AHRQ is aware that healthcare-associated infection (HAI) reporting using the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) is required by the Centers for Medicare and Medicaid Services (CMS) and many individual states. Also, PSOs have indicated that almost all providers are using NHSN for reporting and tracking HAIs. The low numbers of HAI reports received reflects the fact that reporting of HAIs through the Common Formats would be redundant at this time.

Given the small number (16,726) of CFER-H V1.2 *Healthcare-Associated Infection* reports submitted through December 31, 2022, AHRQ has elected not to report any *Healthcare-Associated Infection* data beyond the quantity of reports submitted at this time. Finally, while there is a recognized need to collect data on *Venous Thromboembolism Incidents*, the small number (236) of CFER-H V1.2 *Venous Thromboembolism* reports received was deemed insufficient for any analysis and, as with *Healthcare-Associated Infection*, AHRQ has chosen to report only the quantity of reports submitted at this time.

Important information is provided in the Technical Notes below.



Figure 16: Percentage of Event Type by Common Formats Version

Technical Notes

- The total number of reports submitted via CFER-H V1.1 was 269,916; for CFER-H V1.2 the total was 2,347,775. The combined total number of reports was 2,617,691. Percentages sum to 100% within each CFER-H version, but the sum of percentages may not total 100% due to rounding.
- In CFER-H V1.1 and V1.2, the EVENT TYPE is found in the HERF DE21 in response to the question: "Which of the following categories are associated with the event or unsafe condition?" N/A indicates that data for this EVENT TYPE were not collected in CFER-H V1.1. Events related to Health Information Technology (HIT) were added to the *Device or Medical/Surgical Supply* EVENT TYPE in CFER-H V1.2. The *Venous Thromboembolism* EVENT TYPE was added in CFER-H V1.2.
- Data represent all reports received between July 26, 2012 and December 31, 2022. INITIAL REPORT DATES for the data range from August 1, 2007 through December 24, 2022. The INITIAL REPORT DATE is when the report was entered into a data system at the provider facility and is often different from the date the report is submitted to the PSOPPC.
- More than one EVENT TYPE may have been submitted in a single report because one person experienced multiple patient safety concerns, or because one patient safety concern involved multiple aspects. These are indicated by the *Multiple* EVENT TYPE. For example, the incorrect programming of an infusion pump may also have involved an incorrect medication, so that responses to both the *Device or Medical/Surgical Supply* and *Medication or Other Substance* EVENT TYPES were appropriate.
- This Data Submission Summary figure presents summary information on all EVENT TYPES identified in all reports received by the PSOPPC. Therefore, percentages displayed in this figure differ from those reported in the other Data Submission Summary figures, as well as from the other figures related to the Generic Patient Safety Concerns module, or those related to specific EVENT TYPES.
- Some reports that were counted in the Data Submission Summary module may not be counted in other analyses of the CFER-H data. The excluded reports contain information that is not within the intended scope of CFER-H. For this reason, frequencies and percentages displayed in the Data Submission Summary module differ from those shown in other modules. Criteria for exclusion may be found in the CFER-H Event Descriptions. A complete list of exclusion criteria for CFER-H V1.2 is in Appendix D.

Total Number of PSOs Represented in the NPSD by Report Year

This figure displays the total number of PSOs represented in patient safety concerns in CFER-H V1.2 within the NPSD, excluding the *Healthcare-Associated Infection* and *Venous Thromboembolism* **EVENT TYPES**, by report year.

The number of PSOs represented in CFER-H V1.2 increased steadily until 2015. As noted in the section above, initial submissions from many PSOs contain historical patient safety concerns (CFER-H V1.2 was released on April 3, 2012).

Important information is provided in the Technical Notes below.



Figure 17: Total Number of PSOs Represented in the NPSD by Report Year

- The year displayed corresponds to the year of the **INITIAL REPORT DATE** (DE30).
- Due to very small counts and risk of disclosure, reports prior to 2010 are presented with counts for 2010.

APPENDIX C: SUPPLEMENTAL FIGURES Extent of Harm by Year and Patient Sex



Figure 18a: Extent of Harm by Year – Males



Figure 18b: Extent of Harm by Year – Females

Technical Notes

- In CFER-H V1.2, the EXTENT OF HARM in the PIF is DE55 in response to the question: "After any intervention to reduce harm, what was the degree of residual harm to the patient from the incident (and subsequent intervention)?" The year displayed corresponds to the year of the INITIAL REPORT DATE (DE30). PATIENT SEX is indicated by DE42. The figures above are based on reported data for 728,881 *Male* and 786,018 *Female* patients, respectively. Sex was not specified for 146,324 patients.
- The data presented above indicate *Incident* events in each harm category as a percentage of all *Incident* events with data on **EXTENT OF HARM**. Note, however, that AHRQ has chosen not to include Healthcare-Associated Infection and Venous Thromboembolism **EVENT TYPES** in this figure for reasons discussed in the sections labeled "NPSD Chartbook Text Formatting" and "Percentage of Event Type by Common Formats Version."
- This figure includes reports of *No harm* for a number of patients in *Pressure Ulcer Incidents*, which reflects a misinterpretation of the CFER-H V1.2 question regarding the **EXTENT OF HARM**. *Pressure Ulcers* result in harm to the patient by their very nature. A report of *No harm* here suggests that the reporter perceived no residual harm because the patient recovered. However, the **EXTENT OF HARM** for these patients should never bereported as *No harm*; it should always be at least *Mild harm*.
- Due to very small counts and risk of disclosure, reports prior to 2010 are included in counts for 2010. Percentages sum to 100% within each year, but the sum of percentages may not total 100% due to rounding.

Extent of Harm by Event Type and Patient Sex

Figure 19a: Extent of Harm by Event – Males



Event Type



Figure 19b: Extent of Harm by Event – Females

- In CFER-H V1.2, the EXTENT OF HARM in the PIF is DE55 in response to the question: "After any intervention to reduce harm, what was the degree of residual harm to the patient from the incident (and subsequent intervention)?" The year displayed corresponds to the year of the INITIAL REPORT DATE (DE30). PATIENT SEX is indicated by DE42. The figures above are based on reported data for 728,881 *Male* and 786,018 *Female* patients, respectively. Sex was not specified for 146,324 patients.
- The data presented above indicate *Incident* events in each harm category as a percentage of all *Incident* events with data on **EXTENT OF HARM**. Note, however, that AHRQ has chosen not to include Healthcare-Associated Infection and Venous Thromboembolism EVENT TYPES in this figure for reasons discussed in the sections labeled "NPSD Chartbook Text Formatting" and "Percentage of Event Type by Common Formats Version."
- Percentages sum to 100% within columns, but the sum of percentages may not total 100% due to rounding.

