Network of Patient Safety Databases Chartbook, 2020

Agency for Healthcare Research and Quality

NETWORK OF PATIENT SAFETY DATABASES CHARTBOOK, 2020

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857
https://www.ahrq.gov/

AHRQ Publication No. 20-0048
August 2020
https://www.ahrq.gov/npsd/data/chartbook/index.html

ACKNOWLEDGMENTS

The Network of Patient Safety Databases Chartbook, 2020 and accompanying online dashboards are the product of voluntary participation in the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Organization (PSO) program by providers and PSOs nationwide. Many individual providers, hospital facilities, and PSOs collaborated to collect and submit the data used in this report. Without the efforts of these dedicated individuals and organizations, the AHRQ and Network of Patient Safety Databases (NPSD) team would not have been able to produce this report.

Specifically, we thank:

Authors: ActioNet, Inc. (ActioNet) and Health Services Advisory Group, Inc. (HSAG).

Primary AHRQ Staff: Jeff Brady, Tahleah Chappel, Paula DiStabile, Erin Grace, Hamid Jalal, Tselote Tilahun, and Andrea Timashenka.

Data Support Contractors: ActioNet and HSAG.

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 submitted voluntarily by a portion of Agency for Healthcare Research and Quality (AHRQ)-listed Patient Safety Organizations (PSOs).
- As only data submitted in the Common Formats for Event Reporting-Hospitals (CFER-H) are included in the NPSD dashboards, the dashboards are characterized as reflecting data from the hospital setting. While it is believed that the CFER-H are primarily used as intended to capture patient safety events in hospital settings, providers may have used the CFER-H to report data from other settings.

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 Patient Safety and Quality Improvement Act of 2005 (PSQIA), 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 and submit 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. Because the NPSD contains a large volume of standardized, non-identifiable patient safety data from multiple sources across the country, it is a unique and valuable resource for research and learning about how to improve patient safety and prevent patient harm. 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.

This Network of Patient Safety Databases Chartbook, 2020 (NPSD Chartbook), and accompanying online Dashboards, represent a comprehensive look at patient safety data submitted to the PSOPPC through December 31, 2019.

Data and Analysis Available at the NPSD

Submission of patient safety event data by providers 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.

The NPSD Chartbook and Dashboards comprise three sections covering 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, 2019 was 270,098 for CFER-H V1.1 and 1,488,137 for CFER-H V1.2 for a combined total of 1,758,235 reports.

Generic Patient Safety Concerns

The Generic section pertains to all patient safety concerns – incidents, near misses, and unsafe conditions – and includes basic information about all types of events. Examples of generic information include type of event, location, contributing factors, and level of harm. This section displays the distributions of the types of events and unsafe conditions reported by the AHRQ-listed PSOs.

Event-specific Reports

The Common Formats include event-specific modules pertaining to nine patient safety event types that represent the majority of reported preventable injuries that happen in hospitals. 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 module. An example of additional detail from the Fall module would be the type of injury sustained in a fall.

The Event-specific section of the NPSD Chartbook displays more detailed information for the four types of safety events reported by PSOs: Blood or Blood Products, Device or Medical/Surgical Supply, Fall, and Medication or Other Substance. These four event-specific sections were initially developed for inclusion in the NPSD Chartbook 2019 because they were the most frequently reported events by PSOs, and there were insufficient data submitted to the PSOPPC to include results from the remaining five event-specific modules: Healthcare-Associated Infection, Perinatal, Pressure Ulcer, Surgery or Anesthesia, and Venous Thromboembolism. The NPSD Chartbook 2020 represents an update to the existing data displays. The intention is for future NPSD Chartbooks to expand upon these results as data become available and are analyzed for inclusion in the national learning system.

There were insufficient data submitted to the PSOPPC to include results from the remaining five event-specific modules: Healthcare-Associated Infection, Perinatal, Pressure Ulcer, Surgery or Anesthesia, and Venous Thromboembolism.

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 refer to the concepts reported in the CFER-H and captured through individual questions asked of reporters for each patient safety concern (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, the Data Element "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, four are explored in more detail in event type-specific sections: *Blood or Blood Product*, *Device or Medical/Surgical Supply*, *Fall*, and *Medication or Other Substance*. There are no detailed sections for the *Perinatal*, *Pressure Ulcer*, or *Surgery or Anesthesia* **EVENT TYPES** 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 (12,623) of CFER-H V1.2 *Healthcare-Associated Infection* reports submitted through December 31, 2019, and the high quality of the 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 (232) 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 and four types of safety events (i.e., *Blood or Blood Products*, *Device or Medical/Surgical Supply*, *Fall*, and *Medication or Other Substance*) were submitted in CFER-H V1.2. Data submitted in CFER-H V1.1 is omitted from the analysis for these figures.

DATA SUBMISSION SUMMARY

The Data Submission Summary section illustrates the adoption and use of the CFER-H V1.1 and CFER-H V1.2 for reporting patient safety concerns, 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 not enough reports have been submitted using this format to meet the requirements for the non-identification of the data.

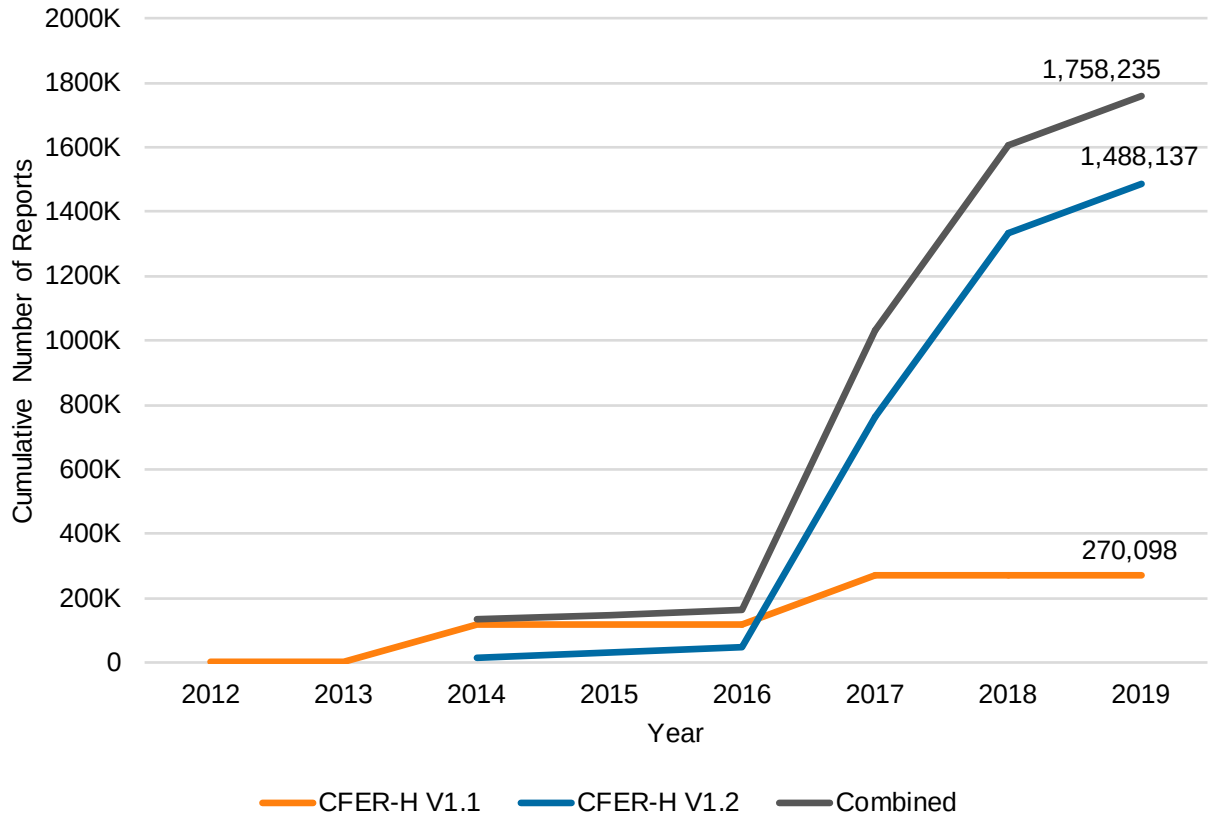
Cumulative Number of Reports Submitted by Common Formats Version by Year

This figure displays a running total of all reports submitted to the PSOPPC by calendar year (CY) from July 26, 2012 through December 31, 2019 in CFER-H V1.1 and CFER-H V1.2.

The total number of reports submitted was 270,098 for CFER-H V1.1 and 1,488,137 for CFER-H V1.2 for a combined total of 1,758,235 reports.

Important information is provided in the Technical Notes below.

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 was submitted to the PSOPPC. An examination of the lag time between report dates and submission dates indicated that submission dates ranged between July 26, 2012 and December 29, 2019, and the median number of days between **initial report date** and submission to the PSOPPC was 578 (1.6 years), with an interquartile range (25^{th}-75^{th} percentiles) from 249 days (0.7 years) to 1,159 days (3.2 years). The full range of differences between **initial report date** and submission date was 0 days to 3,474 days (9.5 years). Importantly, the initial 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 one of the specified modules of the CFER-H: the Generic Patient Safety Concern module; *Blood or Blood Product*; *Device or Medical/Surgical Supply*; *Fall*; and *Medication or Other Substance* patient safety event-specific modules. The excluded reports contained

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 considered outside the scope of CFER-H. Thus, these were excluded from report counts in the Generic Patient Safety Concern module and in the *Medication or Other Substance* module. It should also be noted that reports involving an *Adverse reaction in patient to the administered substance without any apparent incorrect action* have no further information associated with them. 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 located in Appendix A.

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 data systems that do not include the same data elements and 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.

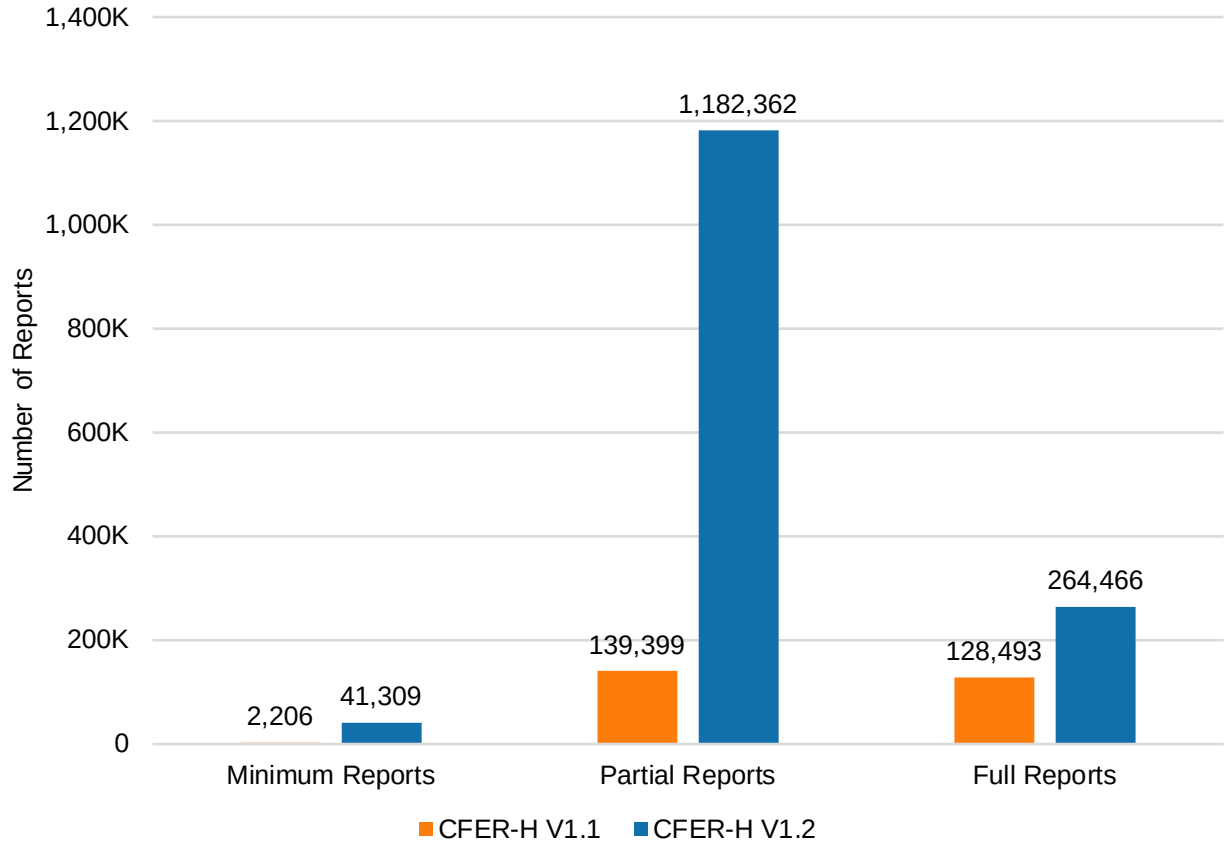
This figure displays the number of reports by completeness of fields (minimum, partial, or full) as submitted for CFER-H V1.1 and CFER-H V1.2.

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 / 270,098) for V1.1 compared to 17.8% for V1.2 (264,466 / 1,488,137). The vast majority of reports submitted in CFER-H V1.2 were partial reports (1,182,362 / 1,488,137; 79.5%), or only met the minimum Validation Data Set requirement for reports to be accepted by the PSOPPC import process (41,309 / 1,488,137; 2.8%).

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 informational 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.

Completeness of Reports Submitted by Common Formats Version



Note: The CFER-H V1.1 and V1.2 data presented indicate the number of reports submitted, stratified by CFER-H version. The total number of reports submitted via CFER-H V1.1 was 270,098; for CFER-H V1.2 the total was 1,488,137. The combined total number of reports was 1,758,235.

Technical Notes

- Data represent all reports received between July 26, 2012 and December 31, 2019. **INITIAL REPORT DATES** for the data range from August 1, 2007 through December 12, 2019. 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. An examination of the lag time between reporting and submission indicated the median number of days between **initial report date** and submission to the PSOPPC was 578 (1.6 years), with an interquartile range (25^{th}-75^{th} percentiles) from 249 days (0.7 years) to 1,159 days (3.2 years). The full range of differences between **initial report date** and submission date was 0 days to 3,474 days (9.5 years). Importantly, the initial submissions from many PSOs contained historical data, resulting in the appearance of a longer lag time between **initial report date** and submission date.

- 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 GENDER** and/or **NEONATE GENDER**, 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, 2019, data had not yet been included in this analysis for CFER-H V2.0a since not enough reports had been submitted in this format to meet the requirements for the non-identification of data.

- Some reports that were counted in the Data Submission Summary module were not counted in one of the specified modules of the CFER-H: the Generic Patient Safety Concern module: *Blood or Blood Product*; *Device or Medical/Surgical Supply, Including Health Information Technology* (*Device or Medical/Surgical Supply*); *Fall*; and *Medication or Other Substance* patient safety event-specific modules. The excluded reports contained 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 considered outside the scope of CFER-H. Thus, these were excluded from report counts in the Generic Patient Safety Concern module and in the *Medication or Other Substance* module. It should also be noted that reports involving an *Adverse reaction in patient to the administered substance without any apparent incorrect action* have no further information associated with them. 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 located in Appendix A.

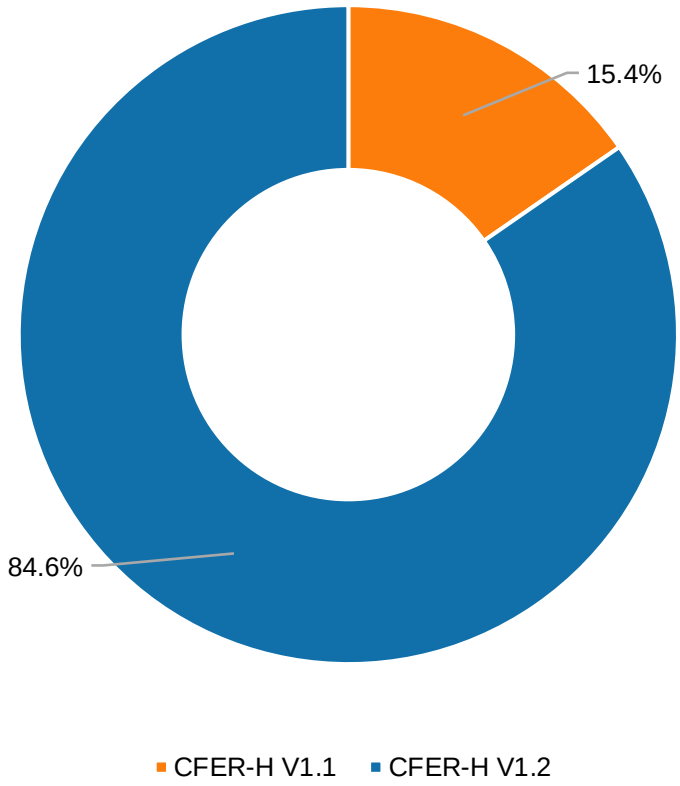
Percentage of Total Reports by Common Formats Version

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 270,098 for CFER-H V1.1 and 1,488,137 for CFER-H V1.2 for a combined total number of 1,758,235 reports. The majority of reports 1,488,137 / 1,758,235; 84.6%) were submitted using CFER-H V1.2. Far fewer (270,098 / 1,758,235; 15.4%) 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.

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, 2019. **INITIAL REPORT DATES** for the data range from August 1, 2007 through December 12, 2019. 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. An examination of the lag time between reporting and submission indicated the median number of days between **initial report date** and submission to the PSOPPC was 578 (1.6 years), with an interquartile range (25^{th}-75^{th} percentiles) from 249 days (0.7 years) to 1,159 days (3.2 years). The full range of differences between **initial report date** and submission date was 0 days to 3,474 days (9.5 years). Importantly, the initial 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 were not counted in one of the specified modules of the CFER-H: the Generic Patient Safety Concern module: *Blood or Blood Product*; *Device or Medical/Surgical Supply, Including Health Information Technology* (*Device or Medical/Surgical Supply*); *Fall*; and *Medication or Other Substance* patient safety event-specific modules. The excluded reports contained 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 considered outside the scope of CFER-H. Thus, these were excluded from report counts in the Generic Patient Safety Concern module and in the *Medication or Other Substance* module. It should also be noted that reports involving an *Adverse reaction in patient to the administered substance without any apparent incorrect action* have no further information associated with them. 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 located in Appendix A.

Percentage of Total Reports by Report Type

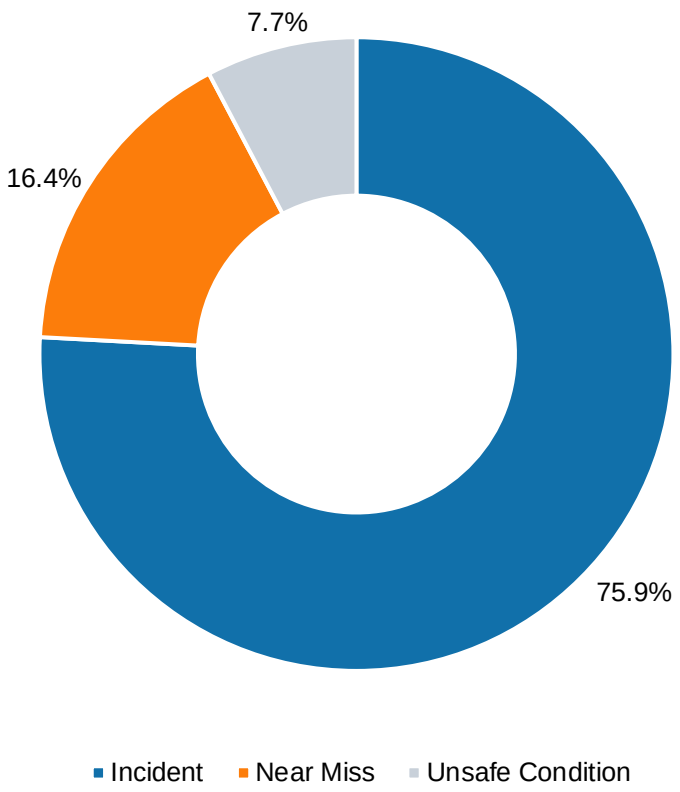
The data presented in this figure show the number of reports for each **REPORT TYPE** submitted as a percentage of all reports using CFER-H V1.1 and CFER-H V1.2.

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 (1,333,703 / 1,758,235; 75.9%) of the reports submitted involved *Incidents*, 16.4% (289,077 / 1,758,235) were *Near misses*, and 7.7% (135,455 / 1,758,235) 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.

Percentage of Total Reports by Report Type



Note: The total number of reports submitted via CFER-H V1.1 was 270,098; for CFER-H V1.2 the total was 1,488,137. The combined total number of reports was 1,758,235. Percentages may not sum to 100% due to rounding.

Technical Notes

- Data represent all reports received between July 26, 2012 and December 31, 2019. **INITIAL REPORT DATES** for the data range from August 1, 2007 through December 12, 2019. 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. An examination of the lag time between reporting and submission indicated the median number of days between **initial report date** and submission to the PSOPPC was 578 (1.6 years), with an interquartile range (25^{th}-75^{th} percentiles) from 249 days (0.7 years) to 1,159 days (3.2 years). The full range of differences between **initial report date** and submission date was 0 days to 3,474 days (9.5 years). Importantly, the initial submissions from many PSOs contained historical data, resulting in the appearance of a longer lag time between **initial report date** and submission date.

- In CFER-H V1.1 and V1.2, the **REPORT TYPE** is found in the Healthcare Event Reporting Form (HERF) Data Element (DE) 3, in response to the question: "What is being reported?"

- Some reports that were counted in the Data Submission Summary module were not counted in one of the specified modules of the CFER-H: the Generic Patient Safety Concern module:

Blood or Blood Product; *Device or Medical/Surgical Supply, Including Health Information Technology* (*Device or Medical/Surgical Supply*); *Fall*; and *Medication or Other Substance* patient safety event-specific modules. The excluded reports contained 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 administered substance without any apparent incorrect action* are considered outside the scope of CFER-H. Thus, these were excluded from report counts in the Generic Patient Safety Concern module and in the *Medication or Other Substance* module. It should also be noted that reports involving an *Adverse reaction in patient to the administered substance without any apparent incorrect action* have no further information associated with them. 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 located in Appendix A.

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 smaller proportion of *Other* in CFER-H V1.2 compared to CFER-H V1.1 (736,781 / 1,489,857; 49.5% versus 153,170 / 272,915; 56.1%); and (b) a larger proportion of *Medication or Other Substance* in CFER-H V1.2 compared to CFER-H V1.1 (334,613 / 1,489,857; 22.5% versus 39,219 / 272,915; 14.4%).

Of the nine **EVENT TYPES** shown in this figure, which was derived from the Generic module, four 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*; and *Medication or Other Substance*.

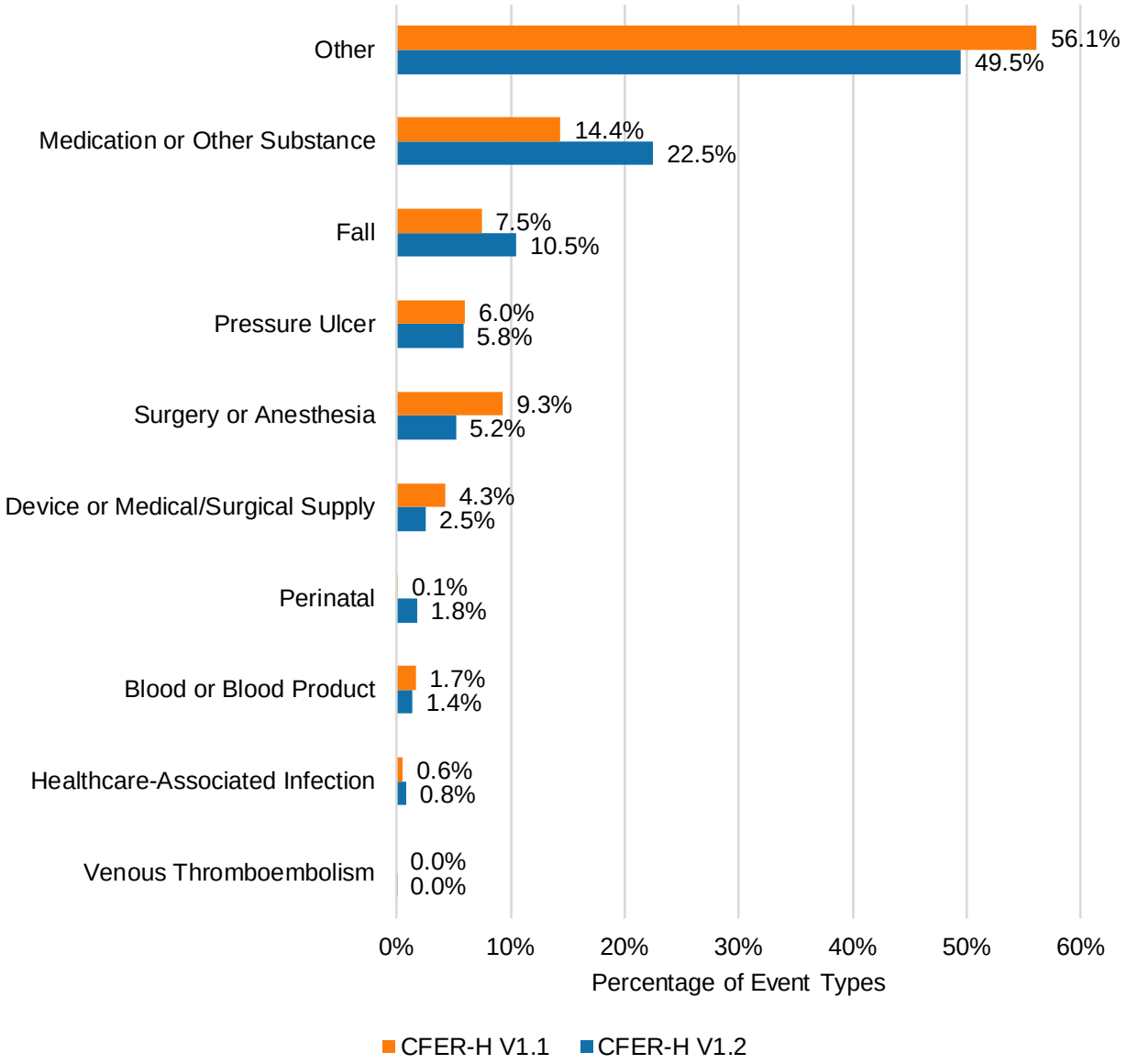
There are no detailed, event-specific figures for *Healthcare-Associated Infection, Perinatal, Pressure Ulcer, Surgery or Anesthesia,* or *Venous Thromboembolism* modules. Many AHRQ-listed PSOs were only able to capture a portion of all possible data elements, and their choice of how many, and which, elements to report varies by PSO and by provider. For these five modules, too few of the submitted reports were sufficiently complete to support detailed patient safety event-specific analyses. Three of these modules, *Perinatal, Pressure Ulcer,* and *Surgery or Anesthesia,* contained enough information to be included in the Generic Patient Safety Concern module. Data received for the *Healthcare-Associated Infection* and *Venous Thromboembolism* modules were not sufficient to support inclusion in the Generic Patient Safety Concern 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 (12,623) of CFER-H V1.2 *Healthcare-Associated Infection* reports submitted through December 31, 2019, 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 (232) 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.

Percentage of Event Type by Common Formats Version



Note: The data presented indicate the events submitted via CFER-H V1.1 and CFER-H V1.2 within each event type as a percentage of all events associated with that Common Formats version.

Percentages sum to 100% within each CFER-H version, but the sum of percentages may not total 100% due to rounding. 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.

Technical Notes

- Data represent all reports received between July 26, 2012 and December 31, 2019. **INITIAL REPORT DATES** for the data range from August 1, 2007 through December 12, 2019. 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. An examination of the lag time between reporting and submission indicated the median number of days between **initial report date** and submission to the PSOPPC was 578 (1.6 years), with an interquartile range (25^{th}-75^{th} percentiles) from 249 days (0.7 years) to 1,159 days (3.2 years). The full range of differences between **initial report date** and submission date was 0 days to 3,474 days (9.5 years). Importantly, the initial submissions from many PSOs contained historical data, resulting in the appearance of a longer lag time between **initial report date** and submission date.

- The total number of reports submitted in CFER-H V1.1 and CFER-H V1.2 was 1,758,235, representing 1,762,772 separate **EVENT TYPES**. A total of 272,915 **EVENT TYPES** were identified in CFER-H V1.1; a total of 1,489,857 were identified in CFER-H V1.2.

- 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?"

- 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. 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 Concern module, or those related to specific **EVENT TYPES**.

- Some reports that are counted in the Data Submission Summary module were not counted in one of the specified modules of the CFER-H: the Generic Patient Safety Concern module: *Blood or Blood Product*; *Device or Medical/Surgical Supply, Including Health Information Technology* (*Device or Medical/Surgical Supply*); *Fall*; and *Medication or Other Substance* patient safety event-specific modules. Criteria for exclusion may be found in the CFER-H Event Descriptions. The excluded reports contained 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 administered substance without any apparent incorrect action* are considered outside the scope of CFER-H. Thus, these were excluded from report counts in the Generic Patient Safety Concern module and in the *Medication or Other Substance* module. It should also be noted that reports involving an *Adverse reaction in patient to the administered substance without any apparent incorrect action* have no further information associated with them. 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 located in Appendix A.

GENERIC PATIENT SAFETY CONCERN

The Generic Patient Safety Concern section provides a high-level overview of the numbers and categories of patient safety events reported in CFER-H V1.2. The distributions of the types of events and unsafe conditions reported by PSOs, and descriptive statistics about the extent of residual harm experienced by patients who have been impacted by safety incidents are provided. These issues are studied in greater depth for four types of safety events (i.e., *Blood or Blood Products*, *Falls*, *Device or Medical/Surgical Supply*, and *Medication or Other Substance*) that have been the subject of the highest level of reporting. Specifically, the data submitted by the PSOs for these four 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 remaining event types in CFER-H V1.2 (*Healthcare-Associated Infection*, *Perinatal*, *Pressure Ulcer*, *Surgery or Anesthesia*, *and Venous Thromboembolism*) had larger amounts of missing data, making the results more difficult to interpret clinically. Residual harm is captured by AHRQ's Harm Scale and is 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 is noteworthy that the definitions associated with each response category include subjective assessments by reporters that may introduce some variability in the way specific events are reported.

The data presented in this section have initial report dates from December 31, 2009 through December 12, 2019. These reports include a total of 1,456,736 events, of which 1,119,335 represent incidents where a safety concern reached a patient. Additionally, the data presented do not include reports that met the exclusion criteria for each of the event-specific modules in the CFER-H V1.2. A complete list of exclusion criteria for CFER-H V1.2 may be found in Appendix A.

Percentage of Patient Safety Concerns (Event Types)

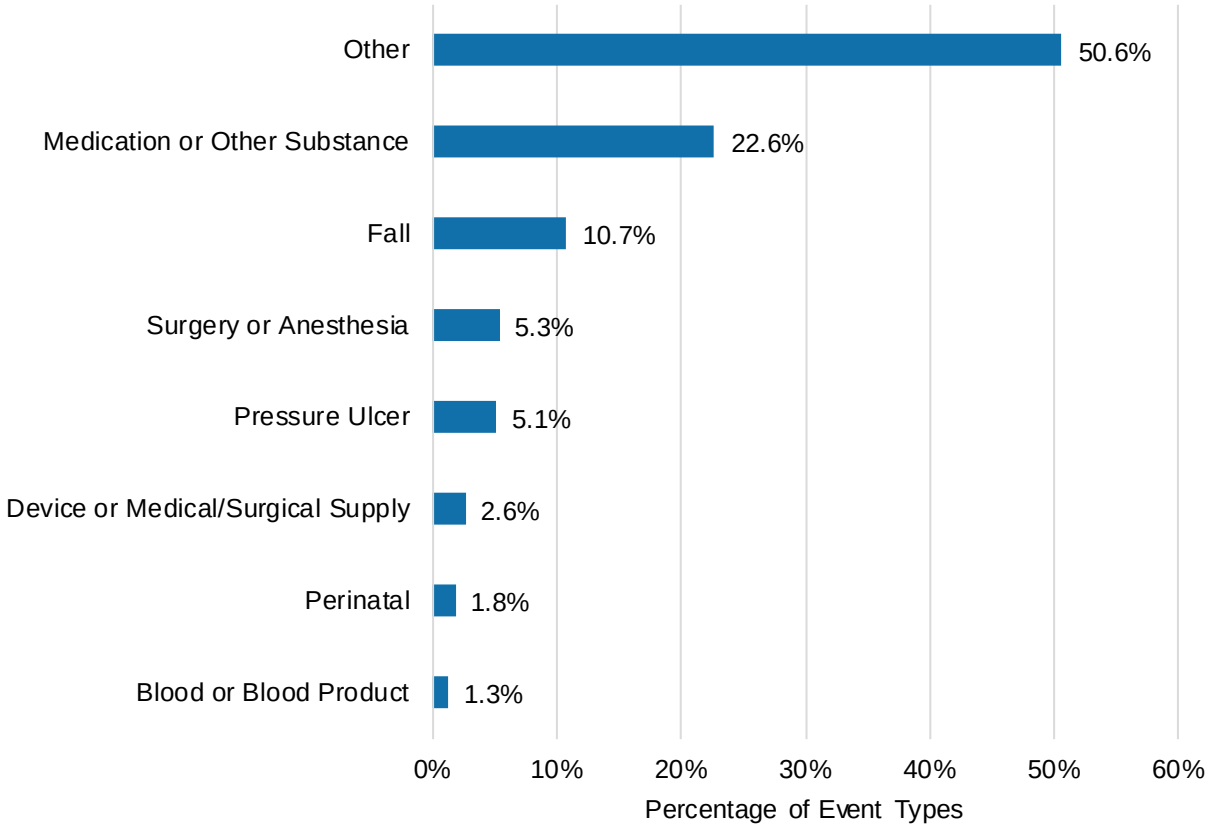
This figure displays each type of patient safety concern (**CATEGORY ASSOCIATED WITH EVENT OR UNSAFE CONDITION [EVENT TYPE]**) as a percentage of all **EVENT TYPES** identified in reports received by the PSOPPC in CFER-H V1.2, excluding the *Healthcare-Associated Infection* and *Venous Thromboembolism* **EVENT TYPES**. The totals differ from those presented in the Data Submission Summary module because some reports submitted in CFER-H V1.2 were outside the specific scope of the Common Formats and were excluded, and because AHRQ chose not to include *Healthcare-Associated Infection* and *Venous Thromboembolism* **EVENT TYPES** in this analysis for reasons discussed in the NPSD Chartbook Text Formatting and Percentage of Event Type by Common Formats Version sections.

The most frequently reported **EVENT TYPES** were *Other* at 50.6% (736,705 / 1,456,736), *Medication or Other Substance* at 22.6% (329,830 / 1,456,736) and *Fall* at 10.7% (155,696 / 1,456,736).

The large percentage of *Other* events reported to the PSOPPC 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 and 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 and instead were mapped into *Other*.

Important information is provided in the Technical Notes below.

Percentage of Patient Safety Concerns (Event Types)



Note: Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. The total number of **EVENT TYPES** is less than the total shown in the Data Submission Summary figures after application of exclusions and suppression of the *Healthcare-Associated Infection* and *Venous Thromboembolism* **EVENT TYPES** (please see the second Technical Note below for details). Reports could be associated with more than one **EVENT TYPE**. Percentages sum to 100% within each row, but the sum of percentages may not total 100% due to rounding.

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?"

- Some reports submitted via CFER-H V1.2 that were counted in the Data Submission Summary module were not counted in the Generic Patient Safety Concern module. Criteria for exclusion may be found in the CFER-H Event Descriptions. The excluded reports contained 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 Concern module. It should also be noted that reports involving an *Adverse reaction in patient to the administered substance without any apparent incorrect action* have no further

information associated with them. For this reason, frequencies and percentages displayed in the Data Submission Summary module differ from those shown in Generic Patient Safety Concern module. Criteria for exclusion may be found in the CFER-H Event Descriptions. A complete list of exclusion criteria for CFER-H V1.2 is located in Appendix A.

Report Type by Event Type

This figure examines the percentage of each **CATEGORY ASSOCIATED WITH EVENT OR UNSAFE CONDITION (EVENT TYPE)** that were *Incidents*, *Near misses*, or *Unsafe conditions*. *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 NPSD Chartbook Text Formatting and Percentage of Event Type by Common Formats Version sections.

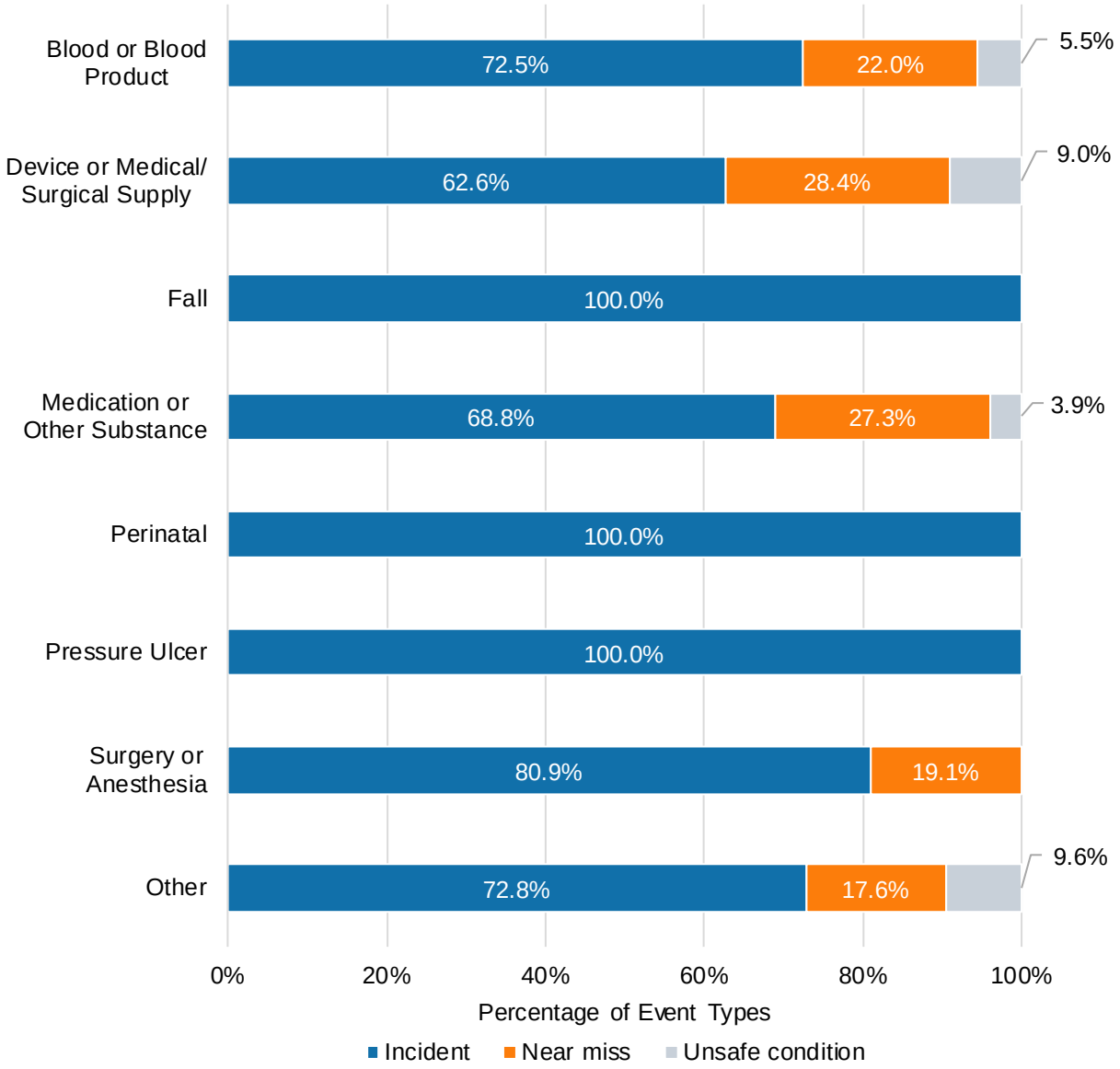
Incidents were the majority of each of the **EVENT TYPES**, with the largest proportion reported for *Surgery or Anesthesia* (62,761 / 77,611; 80.9%), followed by *Other* (536,215 / 736,705; 72.8%) *Blood or Blood Product* (13,322 / 18,379; 72.5%), *Medication or Other Substance* (227,000 / 329,830; 68.8%) and the lowest proportion in *Device or Medical/Surgical Supply* (23,684 / 37,858; 62.6%).

Five **EVENT TYPES** can be reported as *Incidents* or *Near misses*. For these **EVENT TYPES** *Near misses* were reported less frequently than *Incidents*, representing less than half of *Device or Medical/Surgical Supply* events (10,757 / 37,858; 28.4%), followed by *Medication or Other Substance* (89,984 / 329,830; 27.3%), *Blood or Blood Product* (4,043 / 18,379; 22.0%), *Surgery or Anesthesia* (14,850 / 77,611; 19.1%), and *Other* (130,012 / 736,705; 17.6%).

Four **EVENT TYPES** can be reported as *Incidents*, *Near misses*, or *Unsafe conditions*. For these event types, *Unsafe conditions* were always the smallest type of report within each **EVENT TYPE**. The largest proportion of *Unsafe conditions* was reported for *Other* (70,478 / 736,705; 9.6%), *Device or Medical/Surgical Supply* (3,417 / 37,858; 9.0%), and *Blood or Blood Product* (1,014 / 18,379; 5.5%), followed by *Medication or Other Substance* (12,846 / 329,830; 3.9%).

Important information is provided in the Technical Notes below.

Report Type by Event Type



Note: The CFER-H V1.2 data presented indicate the types of reports within each category of **EVENT TYPE** as a percentage of all events in that category, excluding *Healthcare-Associated Infection* and *Venous Thromboembolism*.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. The total number of **EVENT TYPES** is less than the total shown in the Data Submission Summary module after application of exclusions and suppression of the *Healthcare-Associated Infection* and *Venous Thromboembolism* **EVENT TYPES** (please see the second Technical Note below for details). Reports could be associated with more than one **EVENT TYPE**. Percentages sum to 100% within each row, but the sum of percentages may not total 100% due to rounding.

Report Type by Event Type (Data Table)

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

Event Type	Total	Incident		Near Miss		Unsafe Condition	
		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Blood or Blood Product	18,379	13,322	72.5%	4,043	22.0%	1,014	5.5%
Device or Medical/ Surgical Supply	37,858	23,684	62.6%	10,757	28.4%	3,417	9.0%
Fall	155,696	155,696	100.0%	NA	NA	NA	NA
Medication or Other Substance	329,830	227,000	68.8%	89,984	27.3%	12,846	3.9%
Perinatal	25,976	25,976	100.0%	NA	NA	NA	NA
Pressure Ulcer	74,681	74,681	100.0%	NA	NA	NA	NA
Surgery or Anesthesia	77,611	62,761	80.9%	14,850	19.1%	NA	NA
Other	736,705	536,215	72.8%	130,012	17.6%	70,478	9.6%

Note: NA indicates that there were no reports for that category of 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?" The **REPORT TYPE** is found in the HERF DE3 in response to the question: "What is being reported?"

- Some reports submitted via CHER-H V1.2 that were counted in the Data Submission Summary module were not counted in the Generic Patient Safety Concern module. The excluded reports contained 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 considered outside the scope of CFER-H. Thus, these were excluded from report counts in the Generic Patient Safety Concern module and in the *Medication or Other Substance* module. It should also be noted that reports involving an *Adverse reaction in patient to the administered substance without any apparent incorrect action* have no further information associated with them. For this reason, frequencies and percentages displayed in the Data Submission Summary module differ from those shown in the Generic Patient Safety Concern module. Criteria for exclusion may be found in the CFER-H Event Descriptions. A complete list of exclusion criteria for CFER-H V1.2 is located in Appendix A.

Extent of Harm

CFER-H V1.2 captures data regarding harm arising from or associated with plans or actions taken during the provision of healthcare rather than an underlying disease or injury. This figure displays *Incident* events associated with residual harm to patients. 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 NPSD Chartbook Text Formatting and Percentage of Event Type by Common Formats Version sections.

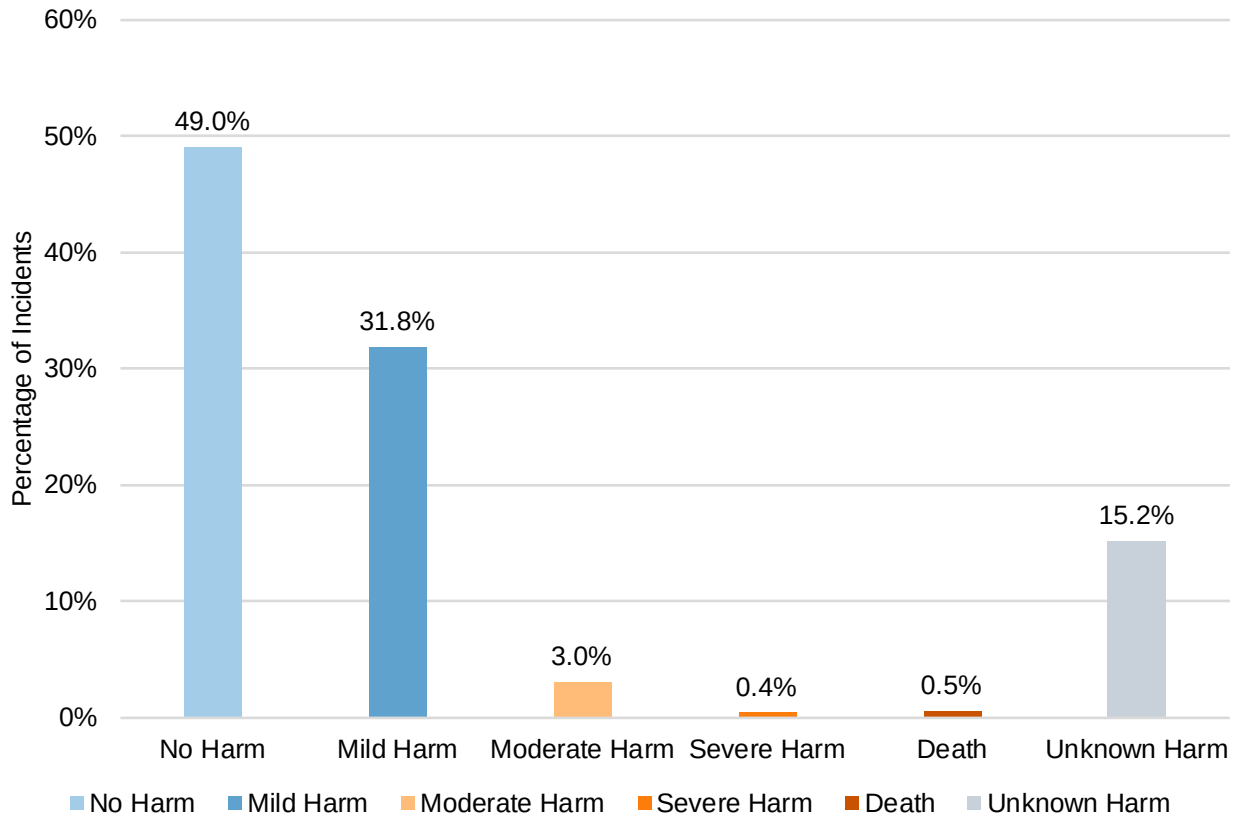
CFER-H V1.2 captures an assessment of the extent of harm to the patient after discovery of the incident and after any attempts to minimize adverse consequences, called residual harm in these figures. The AHRQ Harm Scale captures these data and provides the following possible responses: *No harm*, *Unknown harm*, *Mild harm*, *Moderate harm*, *Severe harm*, or *Death*. While *Unknown harm* is displayed in this figure, it is not described further.

Across all *Incident* events included in this analysis where **EXTENT OF HARM** was reported, *No harm* and *Mild harm* were reported most frequently. Combined, they comprised 80.9% (869,741 / 1,075,547) of *Incidents* with **EXTENT OF HARM** reported (percentage differs from the sum of percentages in the figure below due to rounding).

Among *Incidents* where the **EXTENT OF HARM** was reported, the most commonly reported category of **EXTENT OF HARM** was *No harm* for the majority of **CATEGORIES ASSOCIATED WITH EVENT OR UNSAFE CONDITION** (**EVENT TYPES**). Across two **EVENT TYPES**, however, *Mild harm* was more commonly reported: a total of 70.1% (52,097 / 74,270) of *Pressure Ulcers Incidents* were categorized as *Mild harm*, and a total of 52.6% (13,304 / 25,305) of *Perinatal Incidents* were categorized as *Mild harm*.

Important information is provided in the Technical Notes below.

Extent of Harm



Note: The CFER-H V1.2 data presented indicate *Incident* events in each harm category as a percentage of all *Incident* events, excluding *Healthcare-Associated Infection* and *Venous Thromboembolism Incidents*, with data on **EXTENT OF HARM**.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages sum to 100% within rows, but the sum of percentages may not total 100% due to rounding.

Technical Notes

- In CFER-H V1.2, the **EXTENT OF HARM** is found in the PIF 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)?" **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?"

- Some reports submitted via CFER-H V1.2 that were counted in the Data Submission Summary module were not counted in the Generic Patient Safety Concern module. The excluded reports contained 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 considered outside the scope of CFER-H. Thus, these were excluded from report counts in the Generic Patient Safety Concern module. It should also be noted that reports involving an *Adverse reaction in patient to the administered substance without any apparent incorrect*

action have no further information associated with them. For this reason, frequencies and percentages displayed in the Data Submission Summary module differ from those shown in Generic Patient Safety Concern module. Criteria for exclusion may be found in the CFER-H Event Descriptions. A complete list of exclusion criteria for CFER-H V1.2 is located in Appendix A.

Extent of Harm by Event Type

This figure displays **EXTENT OF HARM** experienced by patients affected by *Incidents* within each of the **CATEGORIES ASSOCIATED WITH EVENT OR UNSAFE CONDITION (EVENT TYPES)** defined for CFER-H V1.2. 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 NPSD Chartbook Text Formatting and Percentage of Event Type by Common Formats Version sections.

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 in these figures. The AHRQ Harm Scale captures these data and provides the following possible responses: *No harm*, *Unknown harm*, *Mild harm*, *Moderate harm*, *Severe harm*, or *Death*. While *Unknown harm* is displayed in this figure, it is not described further.

Across all **EVENT TYPES** included in this analysis, some level of harm (i.e., *Mild harm*, *Moderate harm*, *Severe harm*, or *Death*) was reported in 42.2% (385,327 / 912,555) of *Incident* events where the **EXTENT OF HARM** was known.

Where the **EXTENT OF HARM** was known (i.e., excluding *Incidents* with *Unknown harm*), the **EVENT TYPES** for which the largest proportion of *Incidents* involved some level of harm were *Pressure Ulcer* (54,523 / 73,155; 74.5%) and *Perinatal* (14,601 / 25,253; 57.8%).

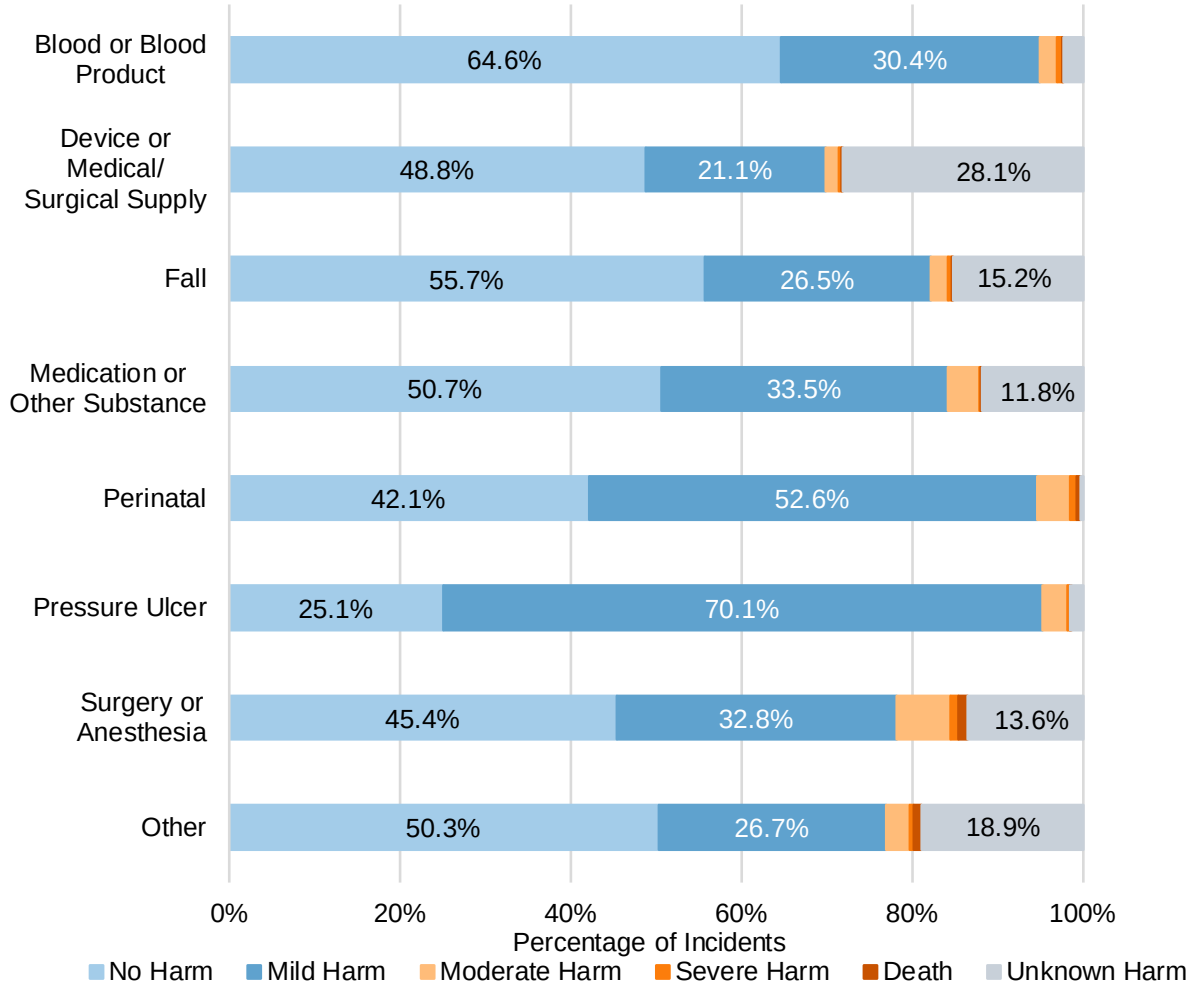
The **EVENT TYPES** with the smallest proportion of harm reported among *Incidents* where the **EXTENT OF HARM** was known were *Blood or Blood Product* (4,352 / 12,837; 33.9%), *Fall* (42,319 / 123,603; 34.2%), and *Device or Medical/Surgical Supply* (5,385 / 16,775; 32.1%).

The **EVENT TYPES** with the largest proportion of patient deaths reported among *Incidents* where the **EXTENT OF HARM** was known were *Surgery or Anesthesia* (615 / 53,671; 1.1%) and *Other* (4,368 / 429,996; 1.0%). For no other **EVENT TYPE** did the proportion of deaths exceed 0.5%.

No harm was reported for more than one-quarter (18,632 / 73,155; 25.5%) of *Pressure Ulcer Incidents* where the **EXTENT OF HARM** was known. This was unexpected, as pressure ulcers, like HAIs and venous thromboembolism (VTE), 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*.

Important information is provided in the Technical Notes below.

Extent of Harm by Event Type



Note: Segments with less than 10% of the total responses are not labeled, but all percentages are provided in the Data Table below.

Extent of Harm by Event Type (Data Table)

Event Type	No Harm	Mild Harm	Moderate Harm	Severe Harm	Death	Unknown Harm
Blood or Blood Product	64.6%	30.4%	1.9%	0.6%	0.3%	2.2%
Device or Medical/Surgical Supply	48.8%	21.1%	1.6%	0.2%	0.2%	28.1%
Fall	55.7%	26.5%	2.0%	0.4%	0.1%	15.2%
Medication or Other Substance	50.7%	33.5%	3.6%	0.2%	0.1%	11.8%
Perinatal	42.1%	52.6%	3.8%	0.8%	0.5%	0.2%
Pressure Ulcer	25.1%	70.1%	3.0%	0.3%	0.0%	1.5%
Surgery or Anesthesia	45.4%	32.8%	6.3%	1.0%	1.0%	13.6%
Other	50.3%	26.7%	2.8%	0.4%	0.8%	18.9%

Note: The CFER-H V1.2 data presented indicate the **EXTENT OF HARM** experienced by patients within each **EVENT TYPE** as a percentage of all *Incidents* associated with that **EVENT TYPE**, excluding *Healthcare-Associated Infection* and *Venous Thromboembolism*.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages sum to 100% within rows, but the sum of percentages may not total 100% due to rounding.

Technical Notes

- In CFER-H V1.2, the **EXTENT OF HARM** in the Patient Information Form (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)?" **EVENT TYPE** in the HERF is DE21 in response to the question: "Which of the following categories are associated with the event or unsafe condition?"

- Some reports that were counted in the Data Submission Summary module were not counted in the Generic Patient Safety Concern module. The excluded reports contained 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 considered outside the scope of CFER-H. Thus, these were excluded from report counts in the Generic Patient Safety Concern module. It should also be noted that reports involving an *Adverse reaction in patient to the administered substance without any apparent incorrect action* have no further information associated with them. For this reason, frequencies and percentages displayed in the Data Submission Summary module differ from those shown in the Generic Patient Safety Concern module. Criteria for exclusion may be found in the CFER-H Event Descriptions. A complete list of exclusion criteria for CFER-H V1.2 is located in Appendix A.

Event Type by Extent of Harm

This figure illustrates the extent to which incidents associated with each **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) contributed to various levels of harm. Note, however, that AHRQ has chosen not to include *Healthcare-Associated Infection* and *Venous Thromboembolism* **EVENT TYPES** in this for reasons discussed in the NPSD Chartbook Text Formatting and Percentage of Event Type by Common Formats Version sections.

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 in these figures. The AHRQ Harm Scale captures these data and provides the following possible responses: *No harm*, *Unknown harm*, or, if harm is known to have occurred, it is described as *Mild harm*, *Moderate harm*, *Severe harm*, or *Death*.

Other **EVENT TYPE** *Incidents* contributed the highest proportion within each level of harm, ranging from a low in *Mild harm* of 41.4% (141,887 / 342,513), to a high in *Death* of 78.8% (4,368 / 5,541).

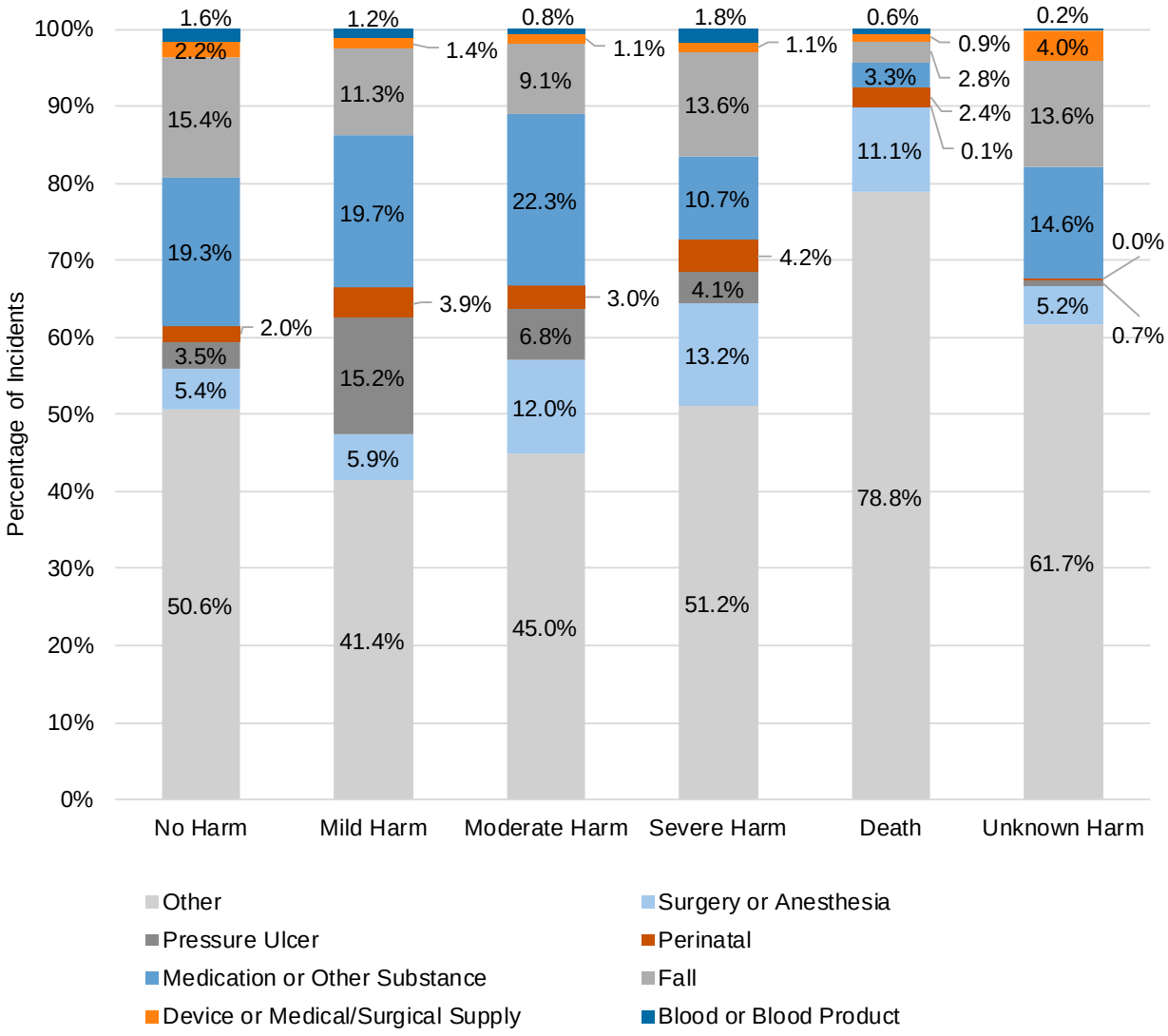
Among *Incidents* associated with *Death*, the most commonly reported specific **EVENT TYPES** (that is, excluding *Other*) were *Surgery or Anesthesia* (615 / 5,541; 11.1%) and *Medication or Other Substance* (183 / 5,541; 3.3%).

Among *Incidents* with *Severe harm*, the most commonly reported specific **EVENT TYPE** (excluding *Other*) was *Fall* (618 / 4,533; 13.6%), followed by *Surgery or Anesthesia* (598 / 4,533; 13.2%).

Among *Incidents* with *Mild harm* and *Moderate harm* levels, the specific **EVENT TYPES** (excluding *Other*) reported most often were *Medication or Other Substance* (74,704 / 375,253; 19.9%) and *Pressure Ulcer* (54,332 / 375,253; 14.5%).

Important information is provided in the Technical Notes below.

Event Type by Extent of Harm



Note: The CFER-H V1.2 data presented indicate *Incident* events in each **EVENT TYPE** (excluding *Healthcare-Associated Infection* and *Venous Thromboembolism*) as a percentage of *Incidents* in each **EXTENT OF HARM** category.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages sum to 100% within columns, but the sum of the percentages may not total 100% due

to rounding.

Technical Notes

- In CFER-H V1.2, the **EXTENT OF HARM** is found in the PIF 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)?" **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?"

- Some reports submitted via CFER-H V1.2 that were counted in the Data Submission Summary module may not be counted in the Generic Patient Safety Concern. The excluded reports contained 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 considered outside the scope of CFER-H. Thus, these were excluded from report counts in the Generic Patient Safety Concern module and in the *Medication or Other Substance* module. It should also be noted that reports involving an *Adverse reaction in patient to the administered substance without any apparent incorrect action* have no further information associated with them. For this reason, frequencies and percentages displayed in the Data Submission Summary module differ from those shown in the Generic Patient Safety Concern module. Criteria for exclusion may be found in the CFER-H Event Descriptions. A complete list of exclusion criteria for CFER-H V1.2 is located in Appendix A.

BLOOD OR BLOOD PRODUCT

The *Blood or Blood Product* module of CFER-H V1.2 collects reports of events and unsafe conditions involving the processing and/or administration of blood or blood products. The module collects data on the specific processes of care involved and does not require that a patient outcome be identified.

Even without specific event rates, data regarding the relative frequencies of types of products involved in reports, the processes of care where reported events are originating, and data regarding residual harm, will be informative for patient safety improvements.

The following figures present summary information from the *Blood or Blood Product* reports received by the PSOPPC that met inclusion and exclusion criteria. Therefore, percentages displayed in these figures are expected to differ from those presented in the Data Submission Summary module. Specific exclusions from *Blood or Blood Product* reports are:

- Blood and blood product collection and other processes prior to receipt of the product by the blood bank

- Incidents involving adverse reaction during or following administration without any apparent incorrect action

Extent of Harm

This figure displays the reports of residual harm to patients from *Blood or Blood Product Incidents*. Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences. The AHRQ Harm Scale provides the following possible responses:

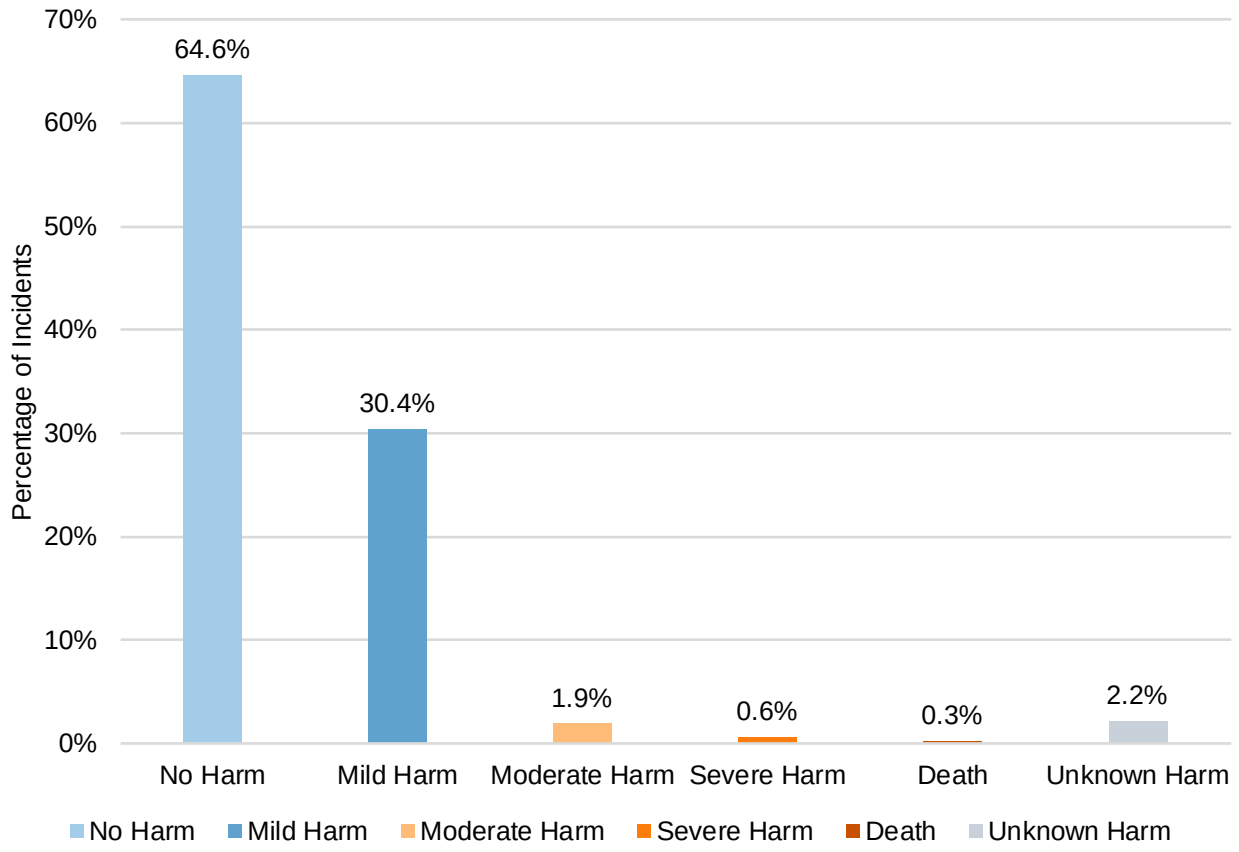
No harm, *Mild harm*, *Moderate harm*, *Severe harm*, *Death*, or *Unknown harm*. While *Unknown harm* is displayed in this figure, it is not described further.

Among *Blood or Blood Product Incidents* where the **EXTENT OF HARM** was known (i.e., excluding *Unknown harm*), the majority resulted in either *No harm* (8,485 / 12,837; 66.1%) or *Mild harm* (3,988 / 12,837; 30.1%).

Only 0.3% (34 / 12,837) of *Blood or Blood Product Incidents* where the **EXTENT OF HARM** was known resulted in *Death*, 0.6% (81 / 12,837) resulted in *Severe harm*, and 1.9% (249 / 12,837) resulted in *Moderate harm*.

Important information is provided in the Technical Notes below.

Extent of Harm



Note: The CFER-H V1.2 data presented indicate the number of *Blood or Blood Product Incident* reports resulting in various levels of harm reported as a percentage of all *Blood or Blood Product Incident* reports with information on harm.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding.

Technical Notes

- In CFER-H V1.2, **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 scope of reporting for the CFER-H V1.2 *Blood or Blood Product* **EVENT TYPE** excludes patient safety concerns arising prior to receipt of the blood or blood product by the blood bank. Also excluded from CFER-H V1.2 were incidents involving adverse reactions during or following administration without any apparent incorrect action.

Type of Blood Product

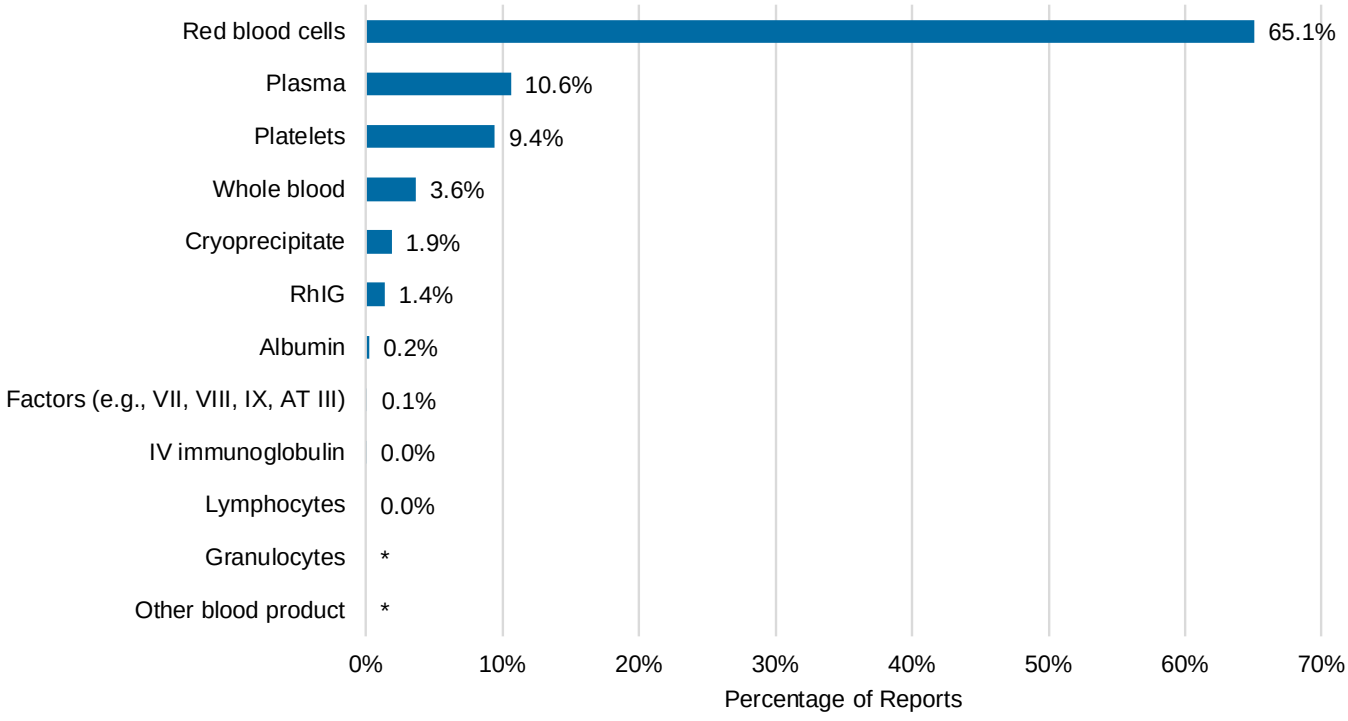
This figure presents the distribution of reports of *Blood or Blood Product* patient safety concerns (i.e., *Incidents*, *Near misses*, and *Unsafe conditions*) by **TYPE OF BLOOD PRODUCT** involved. CFER-H V1.2 data show the number of *Blood or Blood Product* reports involving different types of blood products as a percentage of all *Blood or Blood Product* reports with data for **TYPE OF BLOOD PRODUCT**. CFER-H V1.2 captures data for 12 types of blood products, including *Other* blood product.

The **TYPE OF BLOOD PRODUCT** most frequently involved was *Red blood cells* at 65.1% (3,356 / 5,156) followed by *Plasma* at 10.6% (548 / 5,156) and *Platelets* at 9.4% (486 / 5,156).

*Granulocytes** was among the least frequently reported Types of blood product, along with *Albumin* (12 / 5,156, 0.2%), *Factors (e.g., VII, VIII, IX, and AT III)* (5 / 5,156, 0.1%), and *IV immunoglobulin* (2 / 5,156, 0.0%). To date, there have been no *Blood or Blood Product* reports regarding *Lymphocytes*.

Important information is provided in the Technical Notes below.

Type of Blood Product



Note: *The frequency for this response category was suppressed to meet non-identification requirements.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding and suppression.

Technical Notes

- In CFER-H V1.2, **TYPE OF BLOOD PRODUCT** in the *Blood or Blood Product* module is DE114 in response to the question: "What type of blood product was involved in the event or unsafe condition?"
- The scope of reporting for the CFER-H V1.2 *Blood or Blood Product* **EVENT TYPE** excludes patient safety concerns arising prior to receipt of the blood or blood product by the blood bank. Also excluded from CFER-H V1.2 were incidents involving adverse reactions during or following administration without any apparent incorrect action.

Type of Blood Product by Extent of Harm

This figure compares the distribution of residual harm to the distribution of no residual harm for each **TYPE OF BLOOD PRODUCT** as reported in *Blood or Blood Product Incident* reports. Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences.

Red blood cells were involved in 70.4% (1,849 / 2,628) of all *Incidents* shown in this figure, which may reflect their high frequency of use. More harm was associated with *Incidents* involving *Red blood cells* than with any other **TYPE OF BLOOD PRODUCT**, accounting for 47.6% (n = 60) of all reported harm.[1]

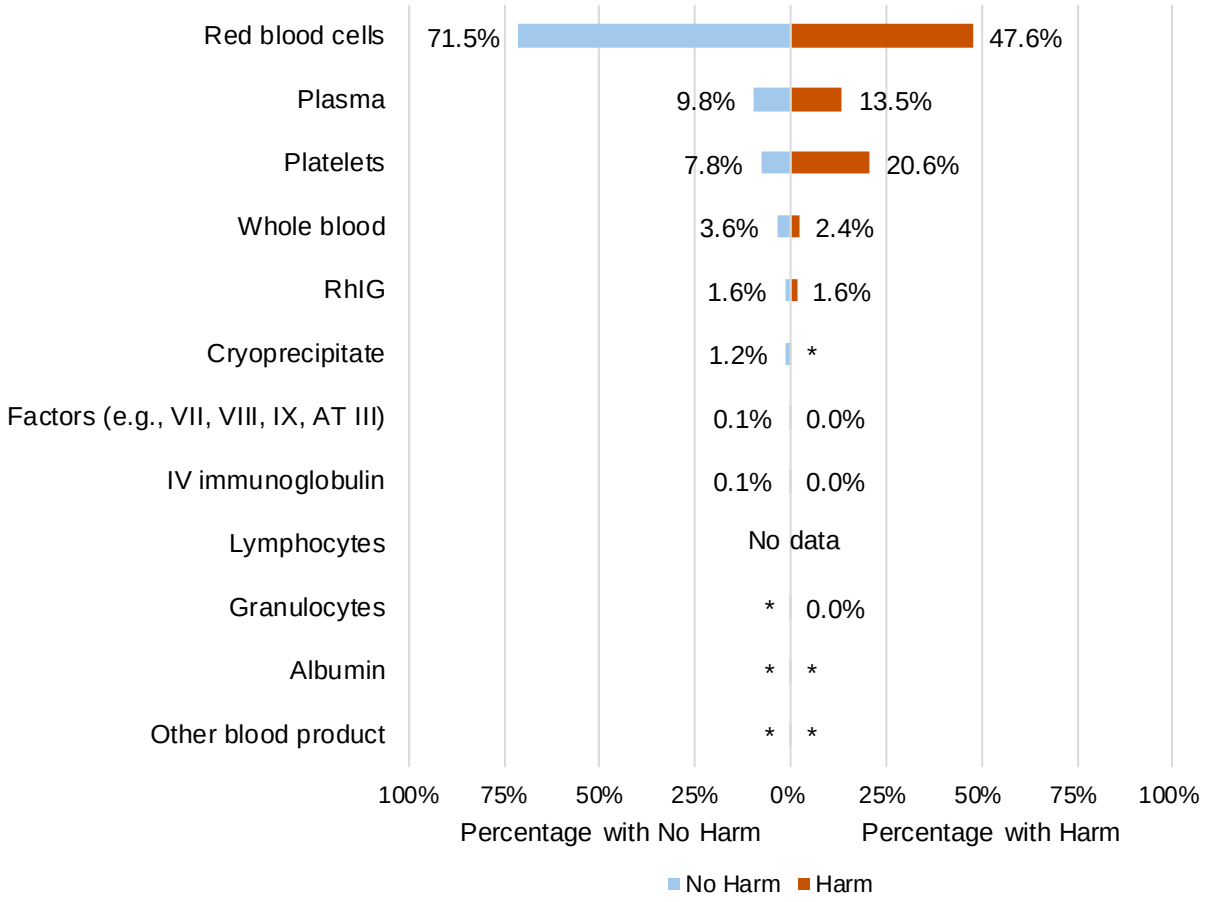
Despite having the largest number of *Incidents* resulting in harm that involved *Red blood cells*, the proportion of *Incidents* involving *Red blood cells* that resulted in residual harm was 3.2% (60 / 1,849). Among other **TYPES OF BLOOD PRODUCT** that were less frequently reported, the proportion with residual harm was often higher, including *Platelets* (26 / 220; 11.8%) and *Plasma* (17 / 261; 6.5%).

Please note: For this figure, all *Incident* reports with **EXTENT OF HARM** reported were classified as either No Harm, or Harm (i.e., *Mild harm*, *Moderate harm*, *Severe harm* or *Death*). Reports of *Unknown harm* were excluded from the analysis.

Important information is provided in the Technical Notes below.

[1] The presentation of percentages differs on this chart because the use of data suppression during the non-identification process prevents the NPSD from precisely identifying the denominator used to calculate the percentage. The NPSD therefore presents the percentage calculated by the PSOPPC during their analysis, and the sample size of reports that represent the percentage.

Type of Blood Product by Extent of Harm



Note: * The frequency for this response category was suppressed to meet non-identification requirements.

The CFER-H V1.2 data presented indicate the number of *Blood or Blood Product Incidents* that were reported for each **TYPE OF BLOOD PRODUCT** as a percentage of all reports with data for **TYPE OF BLOOD PRODUCT** and **EXTENT OF HARM**, stratified by whether the patient experienced a harm or not.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages sum to 100% within Harm and No Harm columns, but the sum of percentages shown may not total 100% due to rounding and suppression.

Technical Notes

- In CFER-H V1.2, **TYPE OF BLOOD PRODUCT** in the *Blood or Blood Product* module is DE114 in response to the question: "What type of blood product was involved in the event or unsafe condition?" **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 scope of reporting for the CFER-H V1.2 *Blood or Blood Products* **EVENT TYPE**

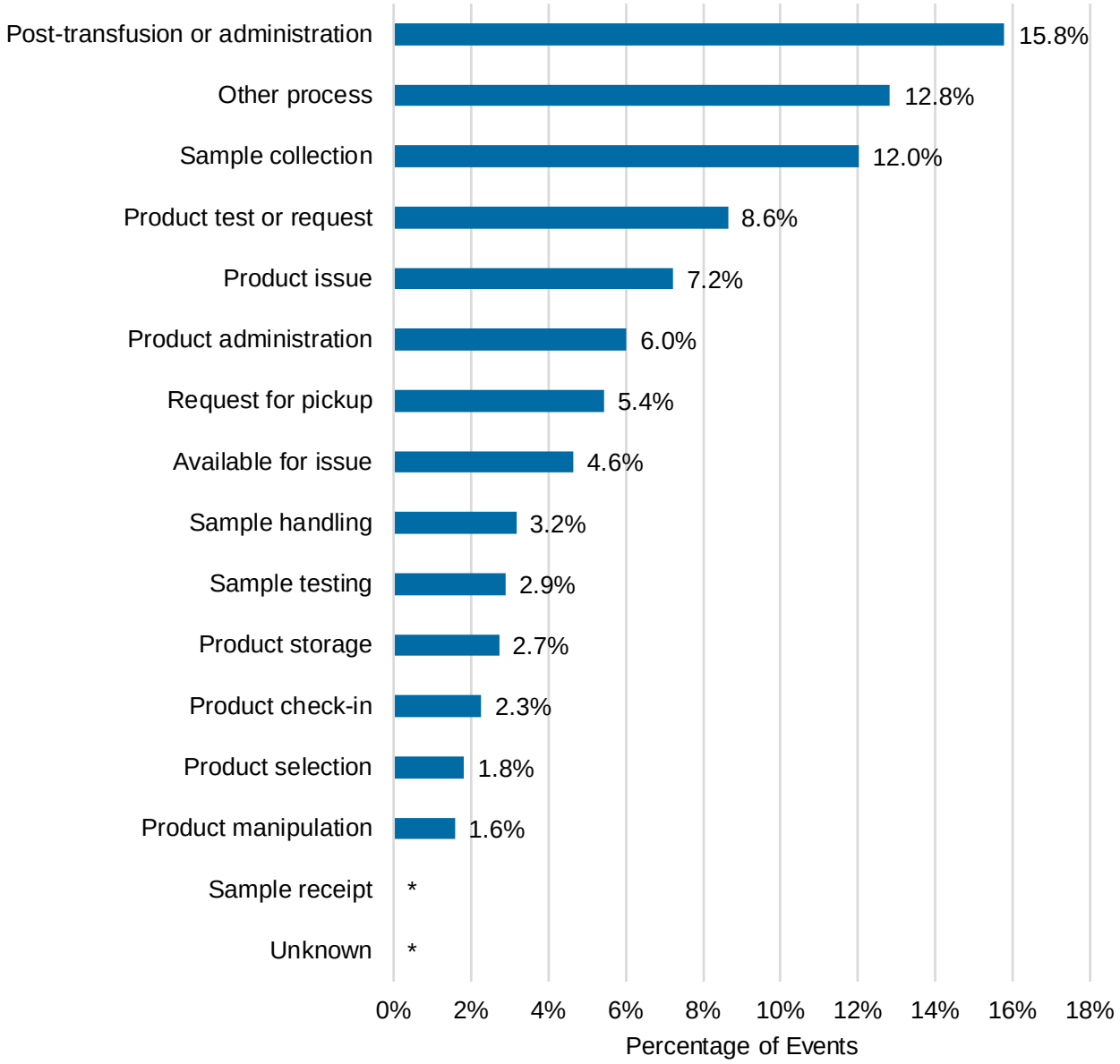
excludes patient safety concerns arising prior to receipt of the blood or blood product by the blood bank. Also excluded from CFER-H V1.2 were incidents involving adverse reactions during or following administration without any apparent incorrect action.

Stage of the Process When Blood or Blood Product Event Originated

This figure presents the distribution of reports of *Blood or Blood Product* patient safety events (i.e., *Incidents* or *Near misses*) for the stage of **PROCESS WHEN BLOOD OR BLOOD PRODUCT EVENT ORIGINATED**. CFER-H V1.2 captures data on 16 different stages of the process from collection to administration of blood or blood products in the hospital. These data are only captured for *Blood or Blood Product* events (i.e., *Incidents* or *Near misses*) involving an incorrect action. For these events, the stage in the process most frequently reported as the point of origination was *Post-transfusion or administration* (458 / 2,907; 15.8%), followed by *Other process* (373 / 2,907; 12.8%), and *Sample collection* (349 / 2,907; 12.0%). No other stage of the process was identified in more than 10.0% of *Blood or Blood Product* events.

Important information is provided in the Technical Notes below.

Stage of the Process When Blood or Blood Product Event Originated



Note: *The frequency for this response category was suppressed to meet non-identification requirements.

The CFER-H V1.2 data presented indicate the number of patient safety events associated with different stages of the **PROCESS WHEN BLOOD OR BLOOD PRODUCT EVENT ORIGINATED** as a percentage of all *Blood or Blood Product* events reported as involving an incorrect action and having data on the process.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding and suppression.

Technical Notes

- In CFER-H V1.2, **PROCESS WHEN BLOOD OR BLOOD PRODUCT EVENT ORIGINATED** in the *Blood or Blood Product* module is DE138 in response to the question: "During which stage did the event originate (regardless of the stage when it was discovered)?"

- The scope of reporting for the CFER-H V1.2 *Blood or Blood Products* **CATEGORY ASSOCIATED WITH EVENT OR UNSAFE CONDITION (EVENT TYPE)** excludes patient safety concerns arising prior to receipt of the blood or blood product by the blood bank. Also excluded from CFER-H V1.2 were incidents involving adverse reactions during or following administration without any apparent incorrect action.

Stage of the Process When Blood or Blood Product Event Originated by Extent of Harm

This figure compares the distribution of residual harm to the distribution of no residual harm for events that originated at various stages in the process of administering blood or blood products (**PROCESS WHEN BLOOD OR BLOOD PRODUCT EVENT ORIGINATED**), as reported in *Blood or Blood Product Incident* reports. Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences.

Nearly a quarter (382 / 1,553; 24.6%) of *Incidents* involving preparation or administration of *Blood or Blood Products* were reported to have occurred *Post-transfusion or administration*. However, the largest number of total harm events (n = 14; 28.0%) occurred during *Product test or request*, even though this stage of the **PROCESS WHEN BLOOD OR BLOOD PRODUCT EVENT ORIGINATED** accounted for only 7.7% (120 / 1,553) of *Incidents* shown on this figure. [2]

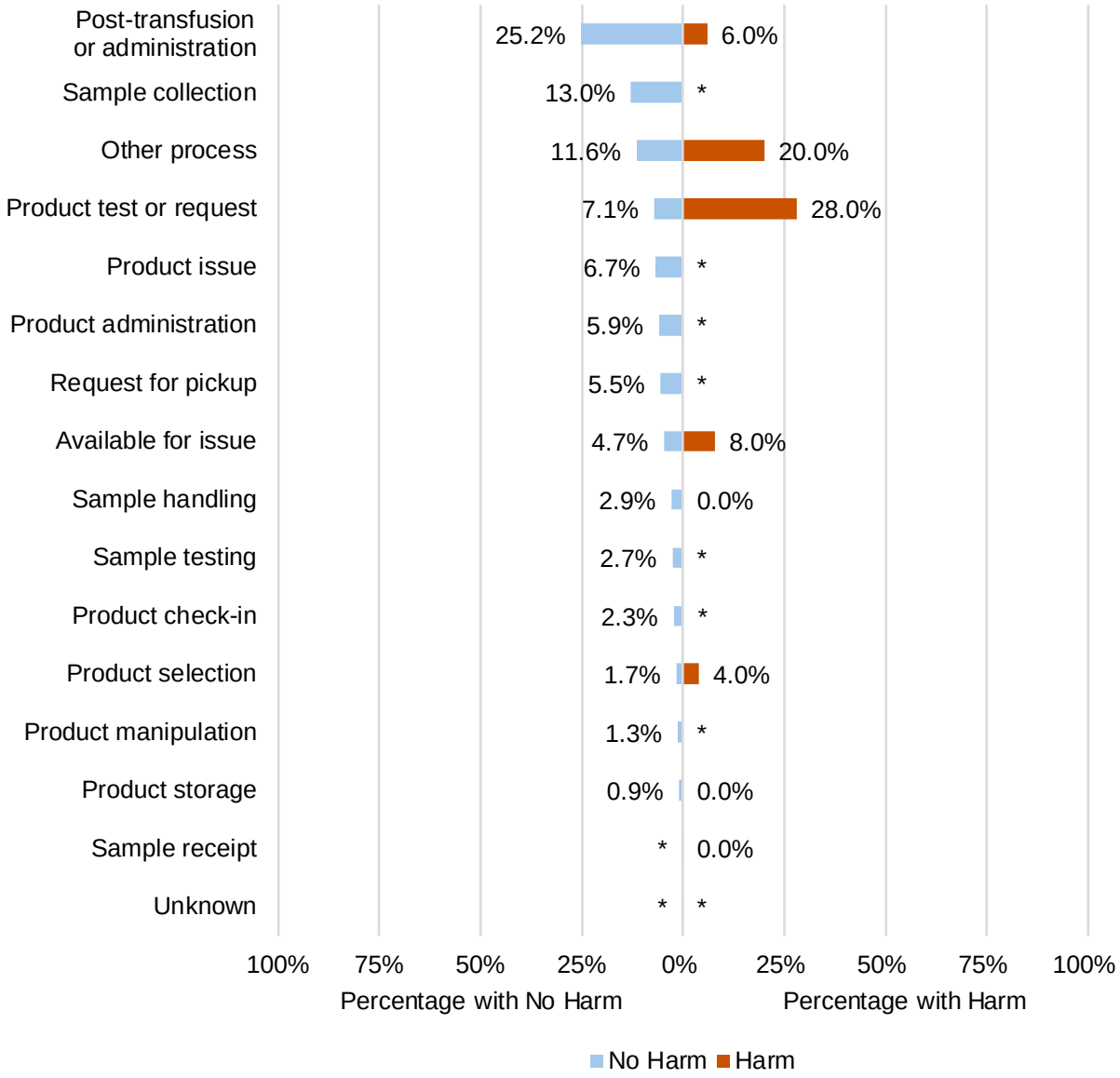
Other points in the process of preparing or administering *Blood or Blood Products* were associated with proportions of residual harm: *Product selection* (2 / 27; 7.4%); *Other process* (10 / 184; 5.4%); and *Available for issue* (4 / 75; 5.3%).

Please note: For this figure, all *Incident* reports with **EXTENT OF HARM** reported were classified as either No Harm, or Harm (i.e., *Mild harm*, *Moderate harm*, *Severe harm* or *Death*). Reports of *Unknown harm* were excluded from the analysis.

Important information is provided in the Technical Notes below.

[2] The presentation of percentages differs on this chart because the use of data suppression during the non-identification process prevents the NPSD from precisely identifying the denominator used to calculate the percentage. The NPSD therefore presents the percentage calculated by the PSOPPC during their analysis, and the sample size of reports that represent the percentage.

Stage of the Process When Blood or Blood Product Event Originated by Extent of Harm



Note: *The frequency for this response category was suppressed to meet non-identification requirements.

The CFER-H V1.2 data presented indicate the number of *Blood or Blood Product Incidents* originating during different stages of the process of care as a percentage of all *Blood or Blood Products Incident* reports involving an *Incorrect action* and having data on the stage of the **PROCESS WHEN BLOOD OR BLOOD PRODUCT EVENT ORIGINATED** and **EXTENT OF HARM**, stratified by whether the patient experienced harm or not.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. A total of 1,553 *Blood or Blood Product Incident* reports included data for the **PROCESS WHEN BLOOD OR BLOOD PRODUCT EVENT ORIGINATED** and **EXTENT OF HARM**. Percentages sum to 100% within Harm and No Harm columns, but the sum of percentages shown may not total 100% due to rounding and suppression.

Technical Notes

- In CFER-H V1.2, **PROCESS WHEN BLOOD OR BLOOD PRODUCT EVENT ORIGINATED** in the *Blood or Blood Product* module is DE138 in response to the question: "During which stage did the event originate (regardless of the stage when it was discovered)?" **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 scope of reporting for the CFER-H V1.2 *Blood or Blood Product* **EVENT TYPE** excludes patient safety concerns arising prior to receipt of the blood or blood product by the blood bank. Also excluded from CFER-H V1.2 were incidents involving adverse reactions during or following administration without any apparent incorrect action.

DEVICE OR MEDICAL/SURGICAL SUPPLY, INCLUDING HEALTH INFORMATION TECHNOLOGY (HIT)

The *Device or Medical/Surgical Supply, Including Health Information Technology* (*Device or Medical/Surgical Supply*) **EVENT TYPE** of CFER-H V1.2 collects reports of events and unsafe conditions involving a defect, failure, or incorrect use of a device, including devices using Health Information Technology (HIT).

The module collects data on whether the event or *Unsafe condition* involved an error in the device, use error, or a combination of the two. It does not require that a patient outcome be identified.

Even without specific event rates, data regarding the types of products involved in reports, the processes of care where reported events are originating, and data regarding residual harm, will be informative for patient safety improvements.

These figures present summary information from the *Device or Medical/Surgical Supply* reports received by the PSOPPC that met inclusion and exclusion criteria. Therefore, percentages displayed in these figures are expected to differ from those presented in the Data Submission Summary module. The exclusion criteria for *Device or Medical/Surgical Supply* reports are:

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

Extent of Harm

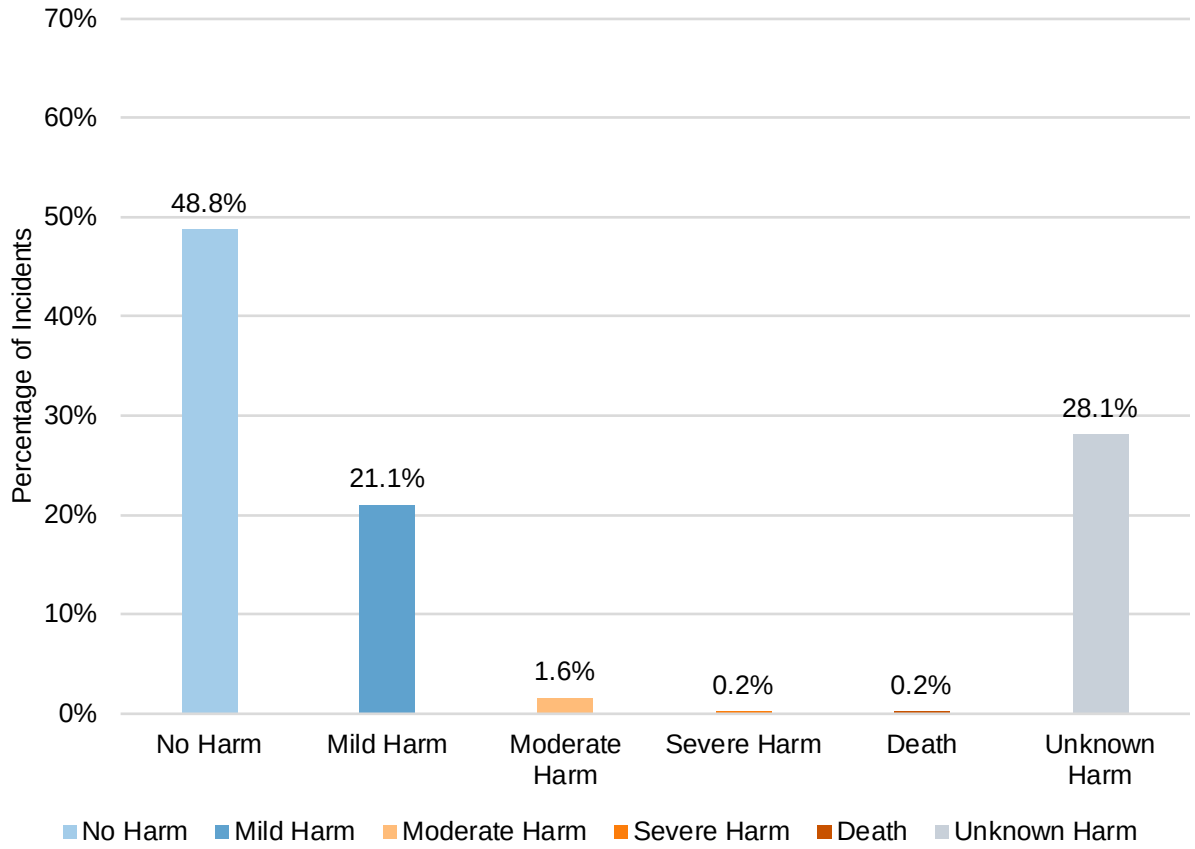
This figure displays the reports of residual harm to patients reported as *Device or Medical/Surgical Supply Incidents*. Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences. The AHRQ Harm Scale provides the following possible responses: *No harm*, *Mild harm*, *Moderate harm*, *Severe harm*, *Death*, or *Unknown harm*. While *Unknown harm* is displayed in this figure, it is not described further.

Among *Device or Medical/Surgical Supply Incidents* where the **EXTENT OF HARM** was known (i.e., excluding *Unknown harm*), the majority resulted in *No harm* (11,390 / 16,775; 67.9%) or *Mild harm* (4,913 / 16,775; 29.3%).

Death resulted in 0.3% (49 / 16,775) of *Device or Medical/Surgical Supply Incidents*; 0.3% (51 / 16,775) resulted in *Severe harm*, and 2.2% (372 / 16,775) resulted in *Moderate harm*.

Important information is provided in the Technical Notes below.

Extent of Harm



Note: The data presented indicate *Device or Medical/Surgical Supply Incident* reports in CFER-H V1.2 that resulted in various levels of harm as a percentage of all *Device or Medical/Surgical Supply Incidents* with data for **EXTENT OF HARM**.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding.

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 scope of reporting for the CFER-H V1.2 *Device or Medical/Surgical Supply* **CATEGORY ASSOCIATED WITH EVENT OR UNSAFE CONDITION** (**EVENT TYPE**) does not capture defects or events discovered prior to market approval or clinical deployment.

Type of Device

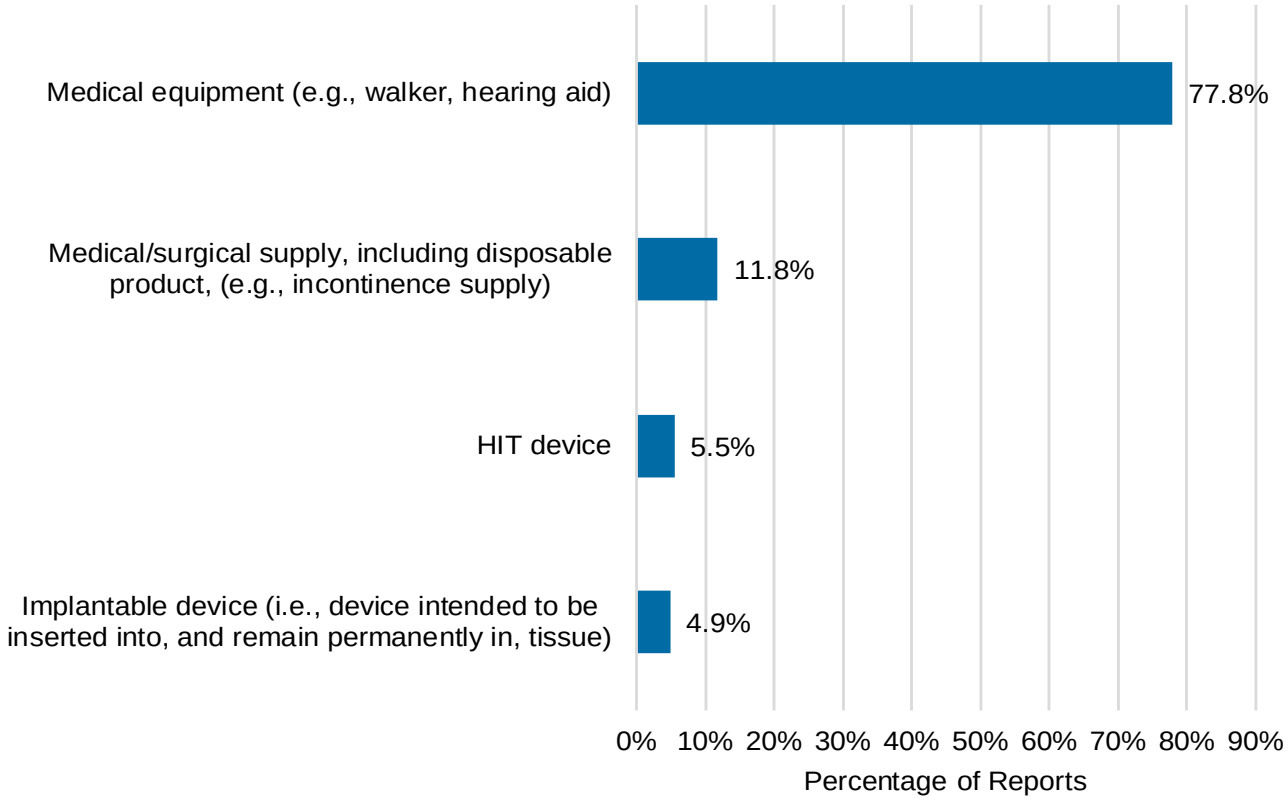
This figure presents the distribution of reports of *Device or Medical/Surgical Supply* patient safety concerns (i.e., *Incidents, Near misses,* and *Unsafe conditions*) by **TYPE OF DEVICE** involved. CFER-H V1.2 data show the number of *Device or Medical/Surgical Supply* reports involving different **TYPES OF DEVICES** as a percentage of all *Device or Medical/Surgical Supply* reports. CFER-H V1.2 captures data for four **TYPES OF DEVICES**.

Medical equipment (e.g., walker, hearing aid) (13,691 / 17,597; 77.8%) was reported to be involved in an event or *Unsafe condition* more than three times as often as the other three types of devices combined. *Medical/surgical supply, including disposable product, (e.g., incontinence supply)* was involved in 11.8% (2,070 / 17,597) of *Incidents, Near misses,* or *Unsafe conditions,* and *HIT devices* were involved in 5.5% (976 / 17,597).

Implantable device (i.e., device intended to be inserted into, and remain permanently in, tissue) was the least frequently reported **TYPE OF DEVICE**, accounting for 4.9% (860 / 17,597) of all *Device or Medical/Surgical Supply* reports.

Important information is provided in the Technical Notes below.

Type of Device



Note: Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding.

Technical Notes

- In CFER-H V1.2, the **TYPE OF DEVICE** in the *Device or Medical/Surgical Supply* module is Data Element (DE) 141 in response to the question: "What type of device was involved in the event or unsafe condition?"

- The scope of reporting for the CFER-H V1.2 *Device or Medical/Surgical Supply* **CATEGORY ASSOCIATED WITH EVENT OR UNSAFE CONDITION** (**EVENT TYPE**) does not capture defects or events discovered prior to market approval or clinical deployment.

Type of Device by Extent of Harm

This figure compares the distribution of residual harm to the distribution of no residual harm by **TYPE OF DEVICE** as reported in *Device or Medical/Surgical Supply Incident* reports. Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences.

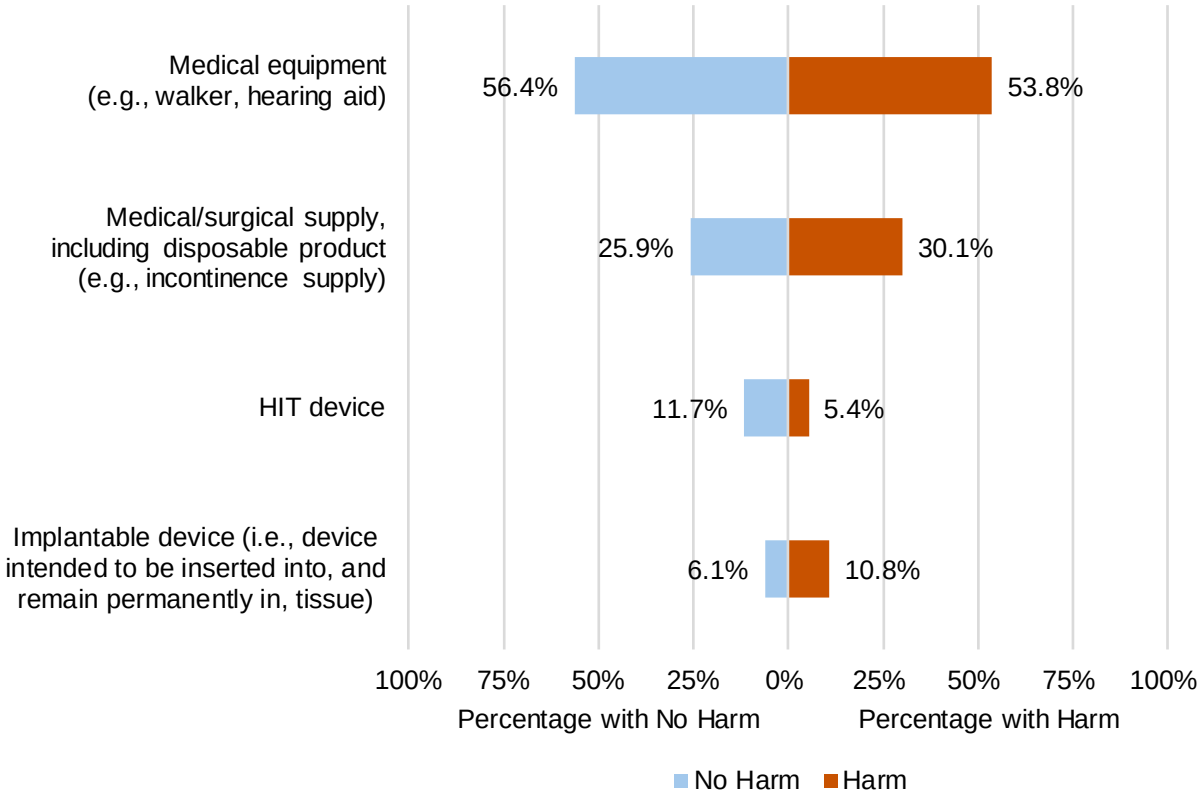
Medical equipment (e.g., walker, hearing aid) accounted for more than half (1,922 / 3,434; 56.0%) of all *Incidents* shown in this figure. This broad category of devices also accounted for more than half (279 / 519; 53.8%) of all residual harm shown in this figure. In contrast, the **TYPE OF DEVICE** least frequently involved in *Device or Medical/Surgical Supply Incidents* was *Implantable device (i.e., device intended to be inserted into, and remain permanently in, tissue)* (233 / 3,434; 6.8%), and the **TYPE OF DEVICE** accounting for the smallest number of harm events was *HIT Device* (28 / 519; 5.4%).

Across all **TYPES OF DEVICE**, the proportion of *Incidents* that resulted in patient residual harm was 15.1% (519 / 3,434). Among *Incidents* involving *Implantable devices (i.e., device intended to be inserted into, and remain permanently in, tissue)*, 24.0% (56 /233) were associated with residual harm, which was the highest proportion among all **TYPES OF DEVICE**. The lowest proportion of residual harm was associated with *HIT devices* (28 / 368; 7.6%).

Please note: For this figure, all *Incident* reports with **EXTENT OF HARM** reported were classified as either No Harm, or Harm (i.e., *Mild harm*, *Moderate harm*, *Severe harm* or *Death*). Reports of *Unknown harm* were excluded from the analysis.

Important information is provided in the Technical Notes below.

Type of Device by Extent of Harm



Note: The CFER-H V1.2 data presented indicate patient safety *Incident* reports that were reported for each **TYPE OF DEVICE** as a percentage of all *Incident* reports with information on **TYPE OF DEVICE** and **EXTENT OF HARM**, stratified by whether the patient experienced harm or not.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages sum to 100% within Harm and No Harm columns, but the sum of percentages shown may not total 100% due to rounding.

Technical Notes

- In CFER-H V1.2, the **TYPE OF DEVICE** in the *Device or Medical/Surgical Supply* module is Data Element (DE) 141 in response to the question: "What type of device was involved in the event or unsafe condition?" The **EXTENT OF HARM** in the PIF 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 scope of reporting for the CFER-H V1.2 *Device or Medical/Surgical Supply* **CATEGORY ASSOCIATED WITH EVENT OR UNSAFE CONDITION** (**EVENT TYPE**) does not capture defects or events discovered prior to market approval or clinical deployment.

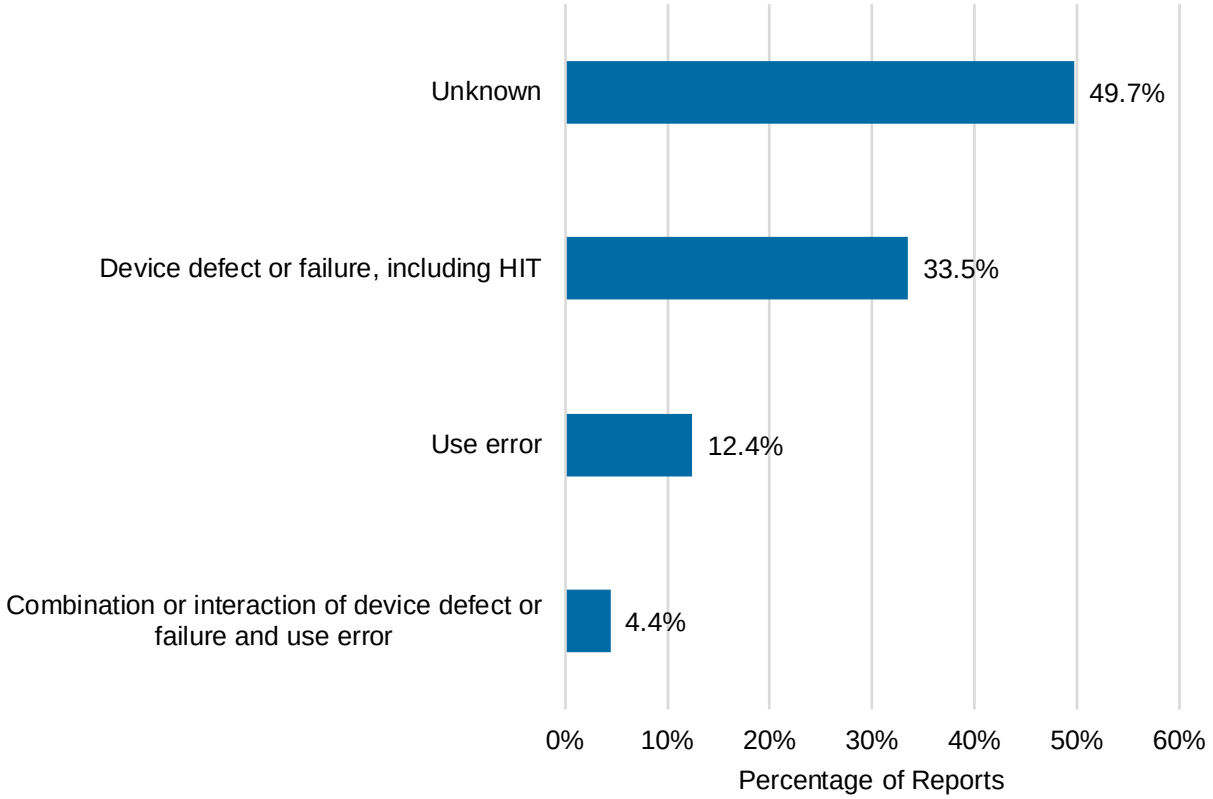
Device Event Description

This figure presents the distribution of reports of *Device or Medical/Surgical Supply* patient safety concerns (i.e., *Incidents*, *Near misses*, and *Unsafe conditions*) by **DEVICE EVENT DESCRIPTION**. The figure shows each category of **DEVICE EVENT DESCRIPTION** as a percentage of all *Device or Medical/Surgical Supply* reports.

Most frequently reported was *Unknown* at 49.7% (7,192 / 14,476), followed by *Device defect or failure, including HIT* at 33.5% (4,846 / 14,476). *Use error* was reported in 12.4% of *Device or Medical/Surgical Supply* reports (1,798 / 14,476); however, *Combination or interaction of device defect or failure and use error* was reported in 4.4% (640 / 14,476) of cases.

Important information is provided in the Technical Notes below.

Device Event Description



Note: Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding.

Technical Notes

- In CFER-H V1.2, the **DEVICE EVENT DESCRIPTION** in the *Device or Medical/Surgical Supply* module is DE56 in response to the question: "Which of the following best describes the event or unsafe condition?"
- The scope of reporting for the CFER-H V1.2 *Device or Medical/Surgical Supply* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION (EVENT**

TYPE) does not capture defects or events discovered prior to market approval or clinical deployment.

Device Event Description by Extent of Harm

This figure compares the distribution of residual harm to the distribution of no residual harm by **DEVICE EVENT DESCRIPTION** as reported in *Device or Medical/Surgical Supply Incident* reports. Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences.

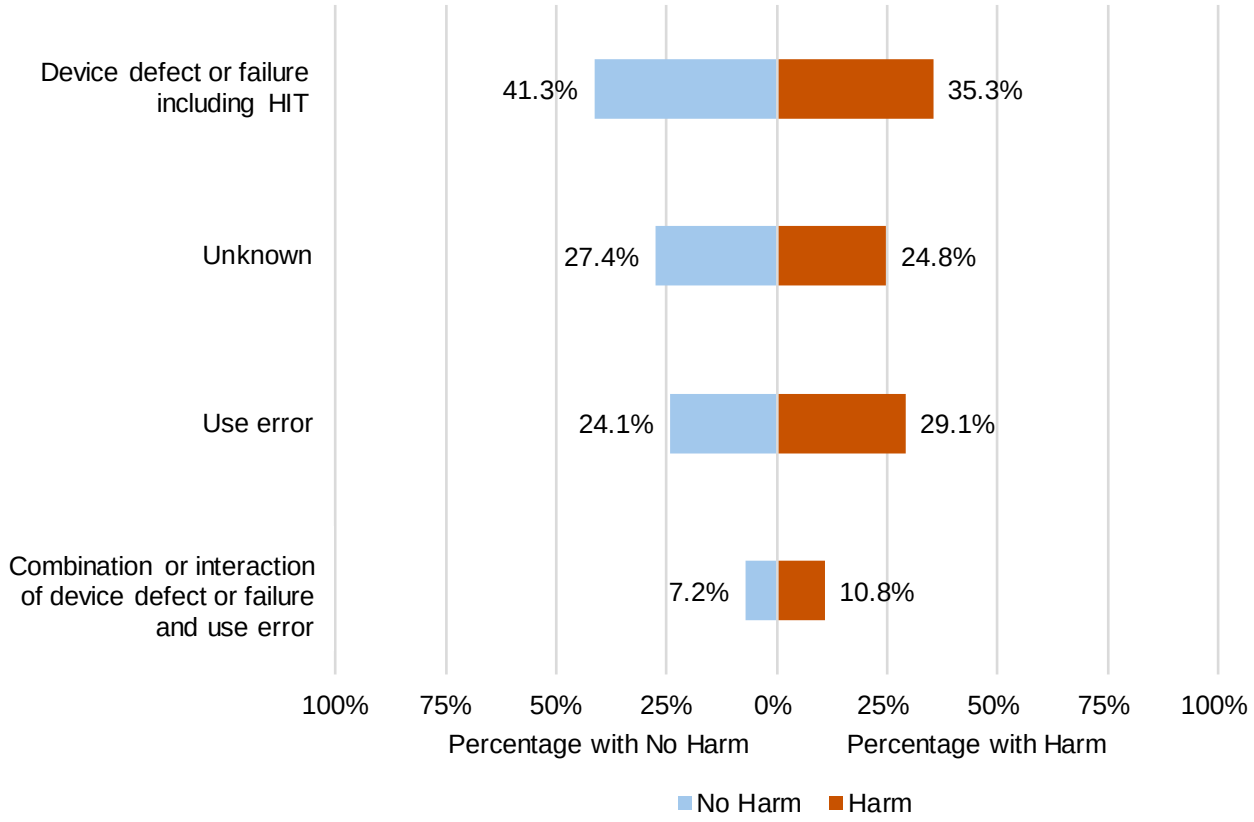
Device defect or failure, including HIT was the most frequently reported category of **DEVICE EVENT DESCRIPTION**, accounting for 40.3% (986 / 2,447) of all *Incidents* shown in this figure. *Device defect or failure, including HIT* also accounted for 35.3% (147 / 416) of residual harm across all categories of **DEVICE EVENT DESCRIPTION**.

Across all *Incidents* where **DEVICE EVENT DESCRIPTION** was reported, 17.0% (416 / 2,447) of reports were associated with residual patient harm. The category of **DEVICE EVENT DESCRIPTION** with the largest proportion of residual patient harm was *Combination or interaction of device defect or failure and use error* at 23.6% (45 / 191). The category with the smallest proportion of residual patient harm was *Device defect or failure, including HIT* at 14.9% (147 / 986).

Please note: For this figure, all *Incident* reports with **EXTENT OF HARM** reported are classified as either No Harm, or Harm (i.e., *Mild harm*, *Moderate harm*, *Severe harm* or *Death*). Reports of *Unknown harm* were excluded from the analysis.

Important information is provided in the Technical Notes below.

Device Event Description by Extent of Harm



Note: The CFER-H V1.2 data presented indicate the number of patient safety *Incidents* that were reported for each type of **DEVICE EVENT DESCRIPTION** as a percentage of all *Device or Medical/Surgical Supply Incidents* with data on **DEVICE EVENT DESCRIPTION** and **EXTENT OF HARM**, stratified by whether the patient experienced a harm or not.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages sum to 100% within Harm and No Harm columns, but the sum of percentages shown may not total 100% due to rounding.

Technical Notes

- In CFER-H V1.2, **DEVICE EVENT DESCRIPTION** in the *Device or Medical/Surgical Supply* module is DE156 in response to the question: "Which of the following best describes the event or unsafe condition?" **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 scope of reporting for the CFER-H V1.2 *Device or Medical/Surgical Supply* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) does not capture defects or events discovered prior to market approval or clinical deployment.

HIT Device Related to Event or Unsafe Condition

This figure presents the distribution of **HIT DEVICE RELATED TO EVENT OR UNSAFE CONDITION** (**HIT-RELATED DEVICE**) among *Device or Medical/Surgical Supply* patient safety concerns (i.e., *Incidents*, *Near misses*, and *Unsafe conditions*) that were identified as involving a HIT-related device. CFER-H V1.2 captures data for seven types of **HIT-RELATED DEVICES**.

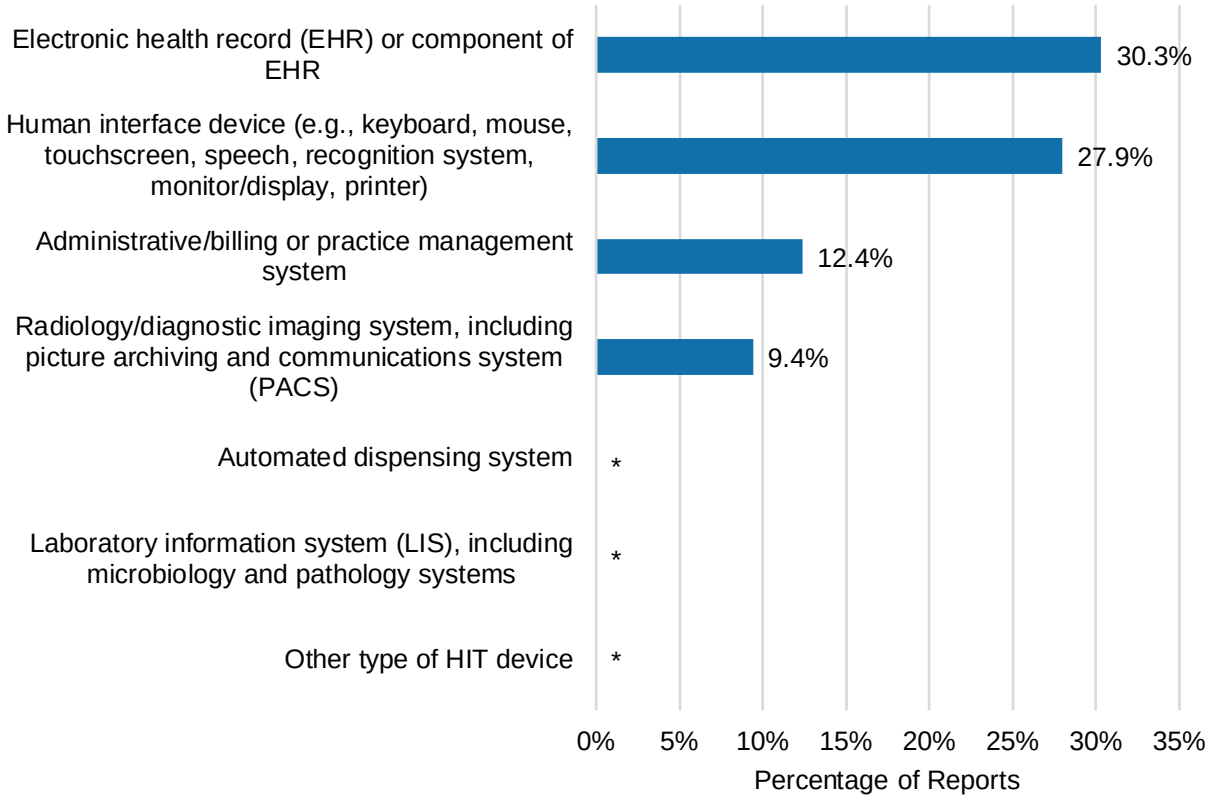
The types of HIT devices most often reported were *Electronic health record (EHR) or component of EHR* (103 / 340; 30.3%) and *Human interface device (e.g., keyboard, mouse, touchscreen, speech recognition system, monitor/display, printer)* (95 / 340; 27.9%).

*Laboratory information systems (LIS), including microbiology and pathology systems** were the least frequently cited.

Please note: The data presented in this figure represents a relatively small portion (340 reports) of the entire data set. The addition of even small numbers of reports could produce substantial changes in the percentages presented here.

Important information is provided in the Technical Notes below.

HIT Device Related to Event or Unsafe Condition



Note: *The frequency for this response category was suppressed to meet non-identification requirements.

The CFER-H V1.2 data presented indicate the number of *Device or Medical/Surgical Supply*

reports that involved different types of HIT devices as a percentage of all reports with information on type of **HIT-RELATED DEVICE**.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding and suppression.

Technical Notes

- In CFER-H V1.2, the **HIT-RELATED DEVICE** in the *Device or Medical/Surgical Supply* module is DE534 in response to the question: "Which of the following best characterizes the type of HIT device related to the event or unsafe condition?"
- The scope of reporting for the CFER-H V1.2 *Device or Medical/Surgical Supply* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) does not capture defects or events discovered prior to market approval or clinical deployment.

HIT Device Related to Event or Unsafe Condition by Extent of Harm

This figure compares the distribution of residual harm to the distribution of no residual harm by type of **HIT-RELATED DEVICE** as reported in *Device or Medical/Surgical Supply Incident* reports. Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences.

The most frequently reported category of **HIT-RELATED DEVICE** *Incidents* shown in this figure involved *Electronic health record (EHR) or component of EHR*, accounting for more than one-third (n = 55; 34.2%) of No harm reports. [3]

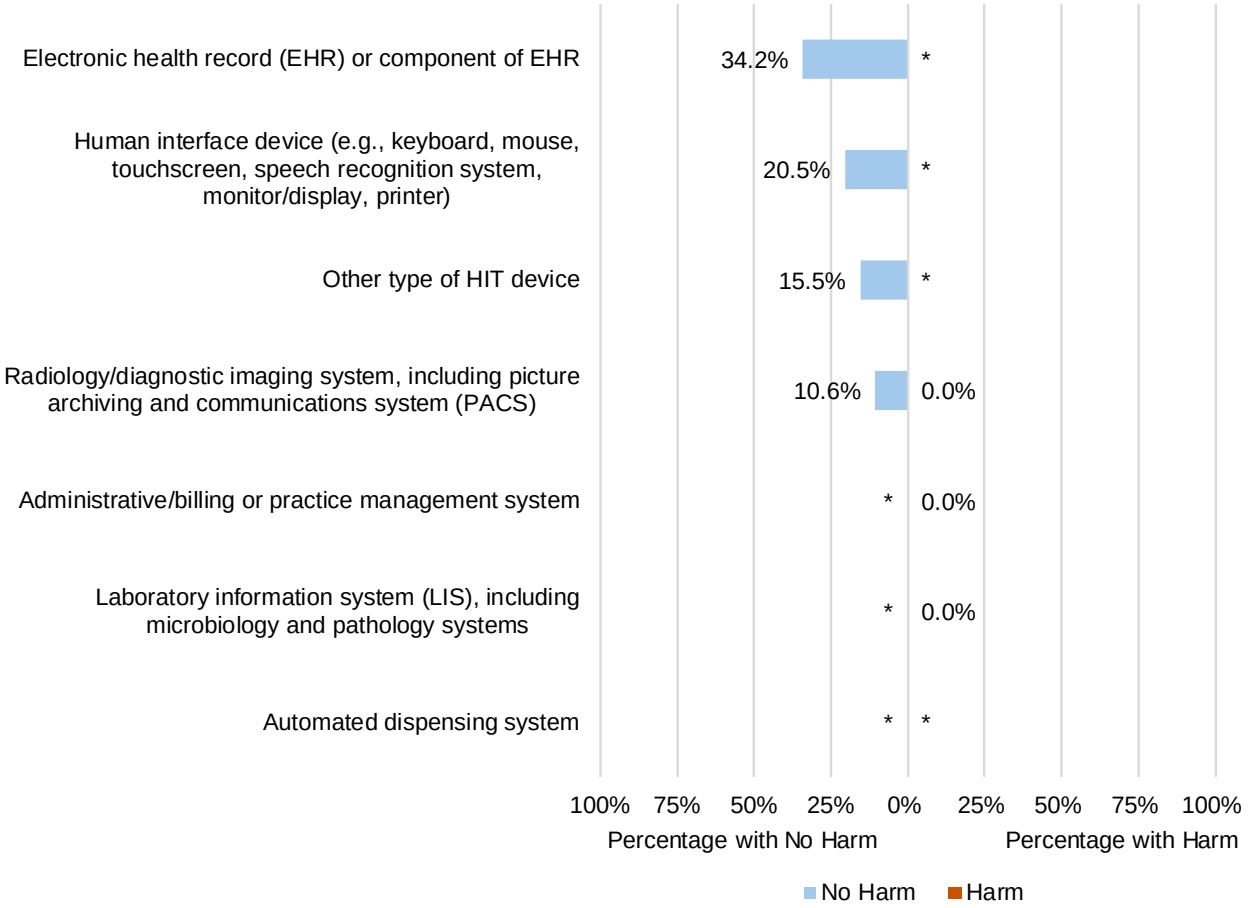
HIT-RELATED DEVICE *Incidents* involving four types of HIT devices were associated with harm: *Electronic health record (EHR) or component of EHR*, Human interface device (e.g., keyboard, mouse, touchscreen, speech recognition system, monitor/display, printer)*, Automated dispensing system**, and *Other type of HIT device**.

Please note: The data presented in this figure represents a relatively small portion (177 reports) of the entire data set. The addition of even small numbers of reports could produce substantial changes in the percentages presented here. No inferences should be drawn from this small number of reports. For this figure, all *Incident* reports with **EXTENT OF HARM** reported were classified as either No Harm, or Harm (i.e., *Mild harm*, *Moderate harm*, *Severe harm* or *Death*). Reports of *Unknown harm* were excluded from the analysis.

Important information is provided in the Technical Notes below.

[3] The presentation of percentages differs on this chart because the use of data suppression during the non-identification process prevents the NPSD from precisely identifying the denominator used to calculate the percentage. The NPSD therefore presents the percentage calculated by the PSOPPC during their analysis, and the sample size of reports that represent the percentage.

HIT Device Related to Event or Unsafe Condition by Extent of Harm



Note: *The frequency for this response category was suppressed to meet non-identification requirements.

The CFER-H V1.2 data presented indicate patient safety *Incidents* that were reported for each type of HIT device as a percentage of *Incidents* with **TYPE OF DEVICE** identified as *HIT device* and with information on type of **HIT-RELATED DEVICE**, and **EXTENT OF HARM** stratified by whether the patient experienced a harm or not.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages sum to 100% within Harm and No Harm columns, but the sum of percentages shown may not total 100% due to rounding and suppression.

Technical Notes

- In CFER-H V1.2, the **HIT-RELATED DEVICE** in the *Device or Medical/Surgical Supply* module is in DE534 in response to the question: "Which of the following best characterizes the type of HIT device related to the event or unsafe condition?" 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 scope of reporting for the CFER-H V1.2 Device or *Medical/Surgical Supply* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) does not capture defects or events discovered prior to market approval or clinical deployment.

FALL

The *Fall* event type in CFER-H V1.2 collects reports of *Incidents* involving a fall. Falls are divided between those known to have been *Assisted* and those which are considered *Unassisted*, which includes all falls that were *Unassisted* or for which the presence of assistance was *Unknown*. The *Fall* **EVENT TYPE** collects data regarding the location of the fall, as well as the specific patient outcome of a fall and does not require that a process failure be identified.[4]

Even without specific event rates, data regarding whether and how harm or injury varies with assistance or by the location of a fall, will be informative for patient safety improvements.

Two types of information about the patient's outcome are presented; the AHRQ Harm Scale captured residual harm, and a separate question unique to the *Fall* **EVENT TYPE** collected data on the specific type of physical injury sustained in the fall. Note that these two data elements for reporting harm or injury should be considered independently due to variability in the way that data submitters may have interpreted the residual harm question in CFER-H V1.2. The extent of overlap between the extent of residual harm and the severity of injury from a fall is unknown.

These figures present summary information from the *Fall* reports received by the PSOPPC that met inclusion and exclusion criteria. Therefore, percentages displayed in these figures are expected to differ from those presented in the Data Submission Summary module. The exclusion criteria for *Fall* reports are:

- 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

Extent of Harm

This figure displays reports of *Falls* resulting in residual harm to patients. Residual harm is the extent of harm to the patient after discovery of the incident and after any attempts to minimize adverse consequences. The AHRQ Harm Scale provides the following possible responses: *No harm*, *Mild harm*, *Moderate harm*, *Severe harm*, *Death*, or *Unknown harm*. This figure includes *Incidents* where the **EXTENT OF HARM** was reported. While *Unknown harm* is displayed in this figure, it is not described further.

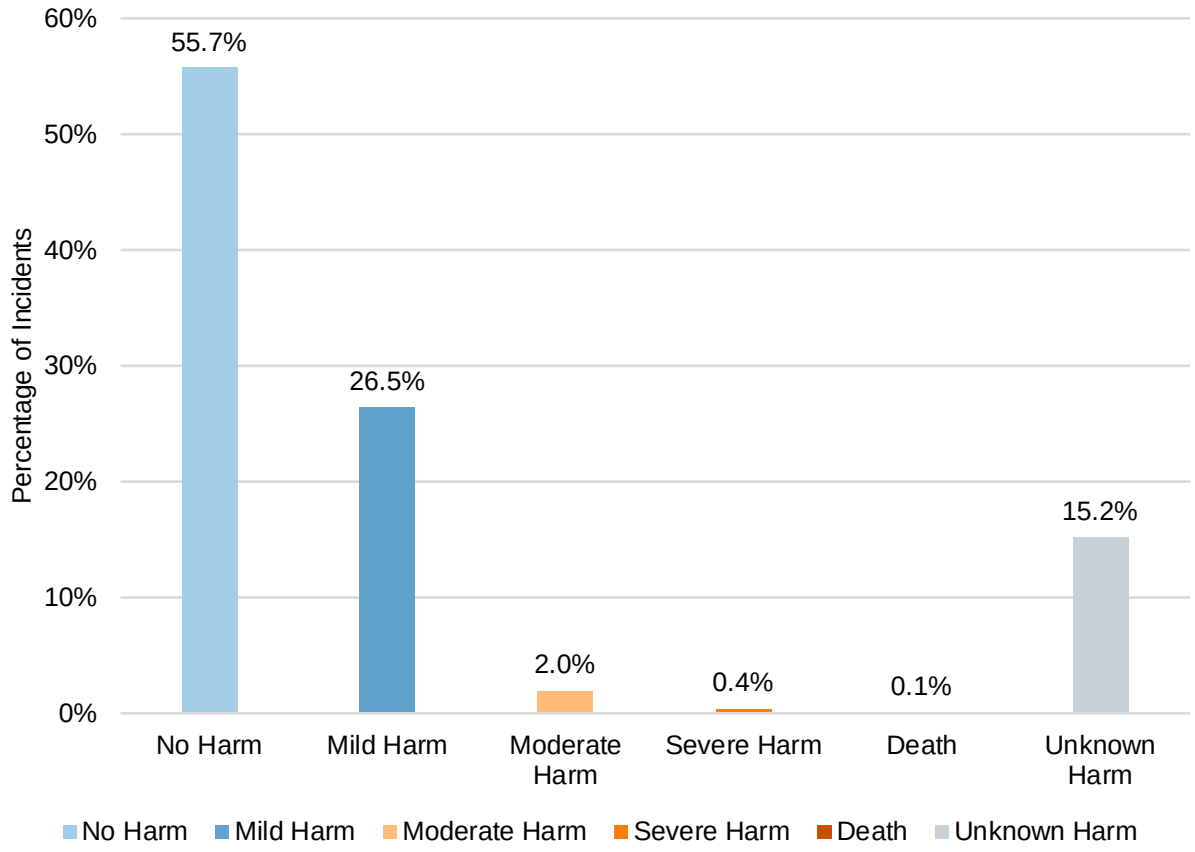
Among *Fall Incidents* where the **EXTENT OF HARM** was known (i.e., excluding *Unknown harm*) and after all attempts to mitigate harm, the majority of *Fall Incidents* resulted in either *No harm* at 65.8% (81,284 / 123,603) or *Mild harm* at 31.2% (38,580 / 123,603).

[4] Although the module was designed to capture information about patient activity prior to the fall, the use of risk assessments and of various fall prevention protocols, the data were insufficient to be included in this report.

A total of 0.1% (157 / 123,603) of reported *Fall Incidents* where the **EXTENT OF HARM** was known resulted in *Death*; 0.5% (618 / 123,603), resulted in *Severe harm*; and 2.4% (2,964 / 123,603) resulted in *Moderate harm*.

Important information is provided in the Technical Notes below.

Extent of Harm



Note: The CFER-H V1.2 data presented indicate *Fall Incidents* resulting in various levels of harm as a percentage of all *Fall Incidents* with data for **EXTENT OF HARM**.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding.

Technical Notes

- In CFER-H V1.2, **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 scope of reporting for the CFER-H V1.2 *Fall* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) excludes a fall resulting from a purposeful action or violent blow (e.g., a patient pushes another patient) or a near fall (i.e., loss of balance that does not result in a fall).

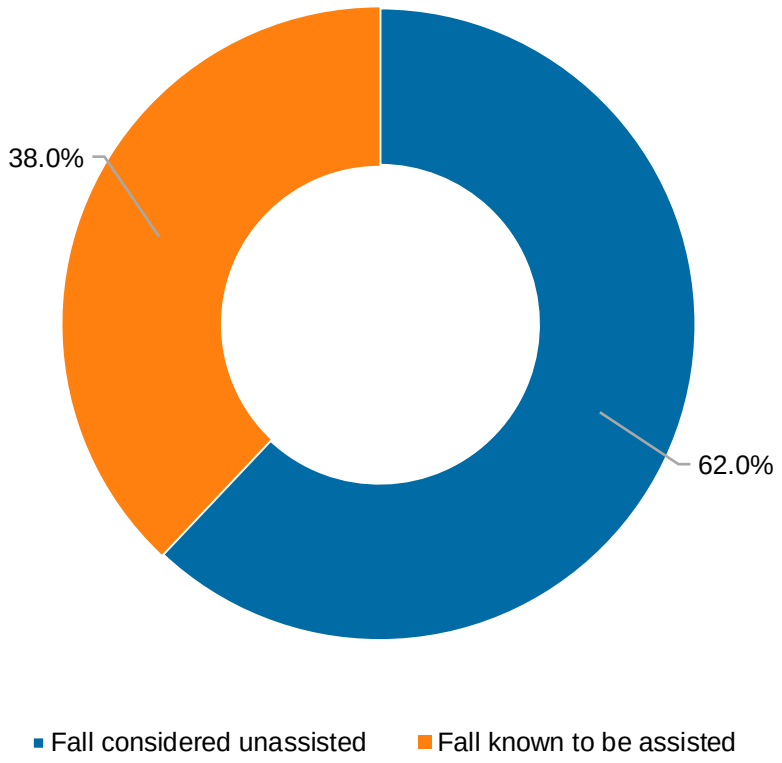
Fall Assistance

This figure presents the distribution of fall assistance for patients experiencing an **UNASSISTED OR ASSISTED FALL**. Falls were divided into two groups: *Falls* known to have been *Assisted*, and *Falls* considered *Unassisted*, which includes both *Falls* known to be *Unassisted* and *Falls* where it is *Unknown* whether assistance was provided or not.

The frequency of *Falls* considered *Unassisted* (31,297 / 50,450; 62.0%) was higher than that of *Falls* known to be *Assisted* (19,153 / 50,450; 38.0%).

Important information is provided in the Technical Notes below.

Fall Assistance



Note: The CFER-H V1.2 data presented indicate *Fall Incidents* for which the patient was assisted to the ground by another individual, or not, as a percentage of all *Fall Incidents* with data for **UNASSISTED OR ASSISTED FALL**.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding.

Technical Notes

- In CFER-H V1.2, **UNASSISTED OR ASSISTED FALL** in the *Fall* module is captured in DE192 in response to the question: "Was the fall unassisted or assisted?"

- The scope of reporting for the CFER-H V1.2 *Fall* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) excludes a fall resulting from a purposeful action or violent blow (e.g., a patient pushes another patient) or a near fall (i.e., loss of balance that does not result in a fall).

Fall Assistance by Extent of Harm

This figure compares the distribution of residual harm to the distribution of no residual harm by whether *Fall Incidents* involve **UNASSISTED OR ASSISTED FALLS**. Falls were divided into two groups: *Falls* known to have been *Assisted*, and *Falls* considered *Unassisted*, which includes both *Falls* known to be *Unassisted* and *Falls* where it is *Unknown* whether assistance was provided or not. Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences.

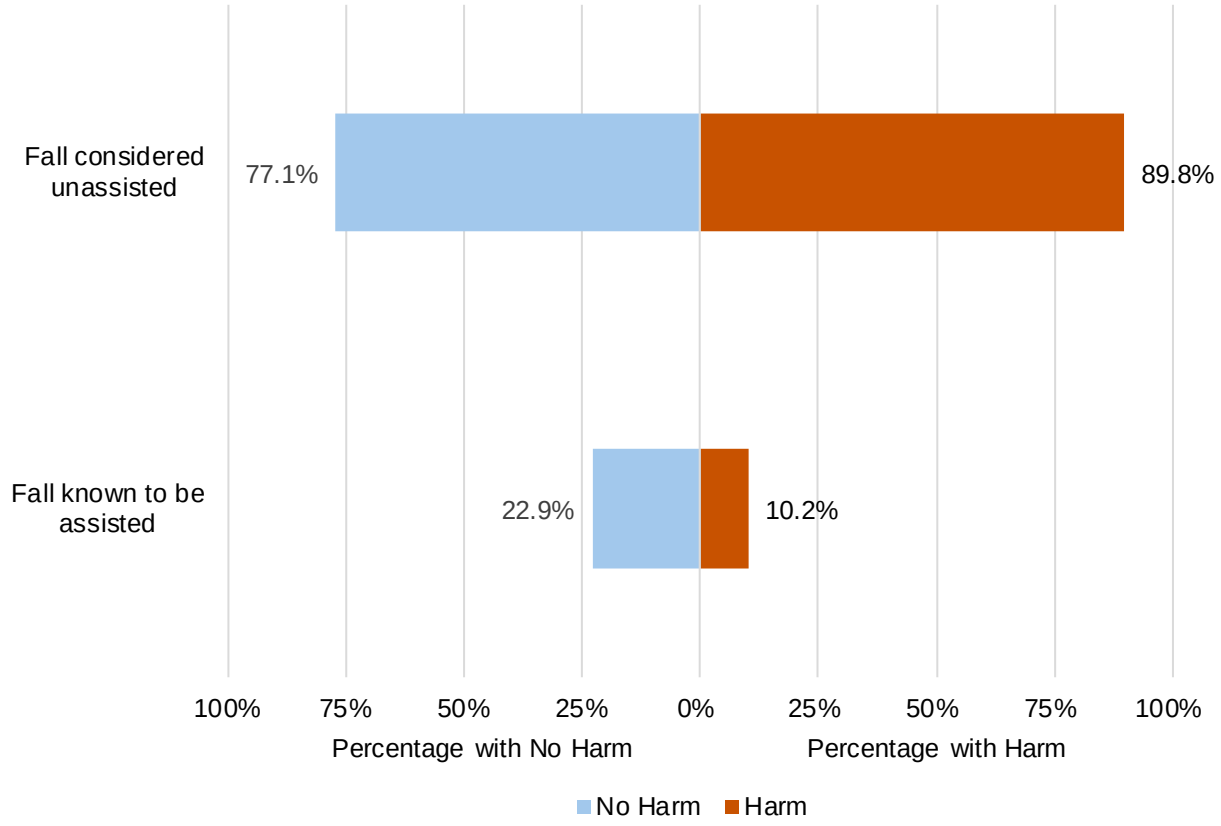
Falls considered *Unassisted* accounted for 80.7% (22,124 / 27,414) of *Fall Incidents* shown on this dashboard, as well as 89.8% (6,993 / 7,787) of all *Fall Incidents* with residual harm reported.

Falls resulted in residual patient harm 28.4% (7,787 / 27,414) of the time. However, when a fall was considered *Unassisted*, residual harm was associated with 31.6% (6,993 / 22,124) of reports. This was more than twice the proportion of harm reported among falls known to be *Assisted* (794 / 5,290; 15.0%).

Please note: For this figure, all *Incident* reports with **EXTENT OF HARM** reported were classified as either No harm, or Harm (i.e., *Mild harm*, *Moderate harm*, *Severe harm* or *Death*). Reports of *Unknown harm* were excluded from the analysis.

Important information is provided in the Technical Notes below.

Fall Assistance by Extent of Harm



Note: The CFER-H V1.2 data presented indicate patient safety *Incidents* where falls were *Assisted* or *Unassisted* as a percentage of all *Fall Incidents* with **UNASSISTED OR ASSISTED FALL** and **EXTENT OF HARM** reported, stratified by whether the patient experienced a harm or not.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages sum to 100% within Harm and No Harm columns, but the sum of percentages shown in the figure may not total 100% due to rounding.

Technical Notes

- In CFER-H V1.2, **UNASSISTED OR ASSISTED FALL** in the *Fall* module is DE192 in response to the question: "Was the fall unassisted or assisted?" **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 scope of reporting for the CFER-H V1.2 *Fall* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) excludes a fall resulting from a purposeful action or violent blow (e.g., a patient pushes another patient) or a near fall (i.e., loss of balance that does not result in a fall).

Type of Injury Experienced by Patient with Fall Resulting in Injury

This figure presents data unique to the *Fall* module, which captures the specific type of physical injury sustained in the fall as **TYPE OF INJURY AS RESULT OF FALL**. Note that this data element is independent of the data captured as **EXTENT OF HARM** based on the AHRQ Harm Scale and its assessment of residual harm. These two data elements for reporting harm or injury should be considered independently due to potential variability in the way that data submitters interpret "residual harm." Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences.

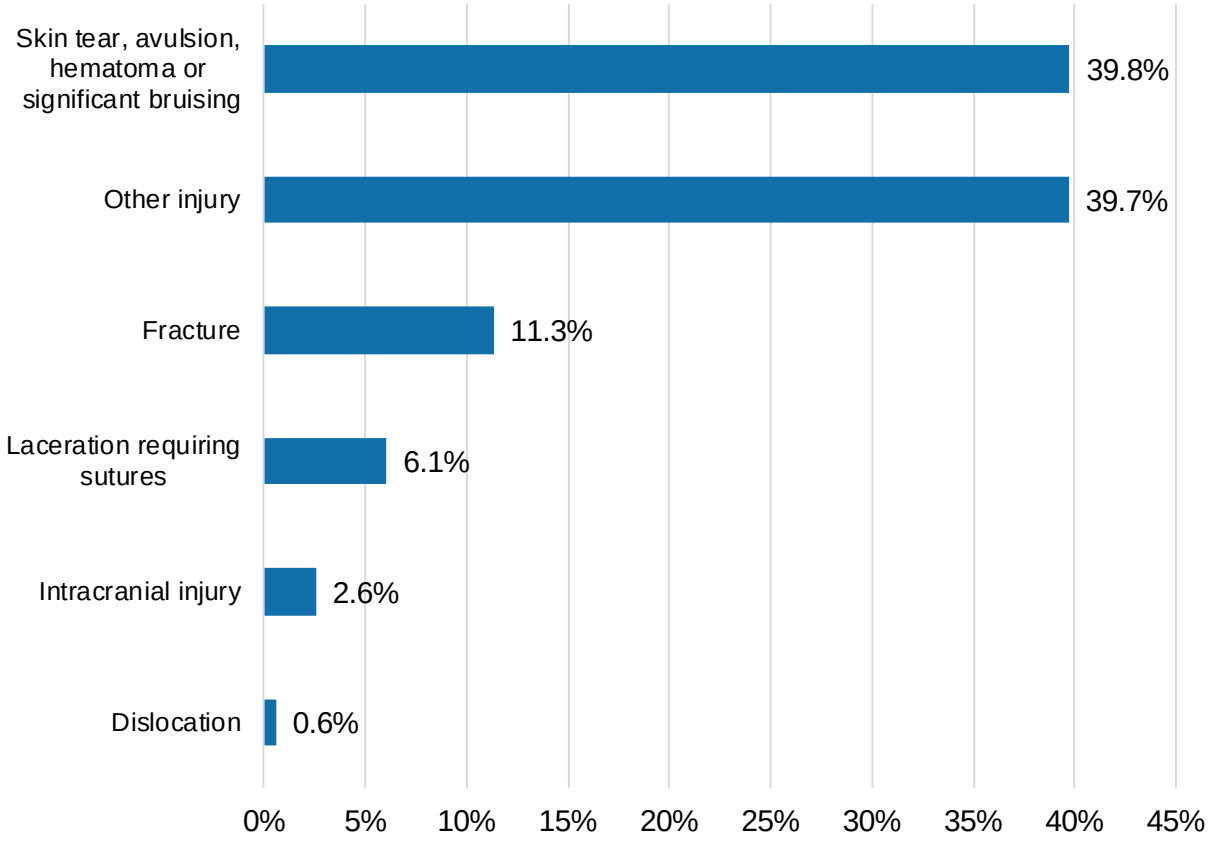
Skin tear, avulsion, hematoma or significant bruising were the types of injury most frequently identified in *Fall* reports where the fall resulted in injury and the report included information on **TYPE OF INJURY AS RESULT OF FALL** at 39.8% (3,272 / 8,229).

The second most frequent type of injury reported was O*ther injury*, representing 39.7% (3,268 / 8,229) of all *Fall Incidents*. Within the accompanying text field describing the *Other injury*, further review of these reports indicated that they represent minor injuries such as soreness, bumps, and minor abrasions.

The least common type of injury in *Fall Incidents* was *Dislocation* at 0.6% (48 / 8,229).

Important information is provided in the Technical Notes below.

Type of Injury Experienced by Patient with Fall Resulting in Injury



Note: The CFER-H V1.2 data presented indicate the number of *Fall Incidents* for each category of

TYPE OF INJURY AS RESULT OF FALL as a percentage of all *Fall Incidents* with data on whether the fall resulted in injury and the type of the injury.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding.

Technical Notes

- In CFER-H V1.2, **INJURY AS RESULT OF FALL** is captured in the *Fall* module, DE201 in response to the question: "Did the patient sustain a physical injury as a result of the fall?" **TYPE OF INJURY AS A RESULT OF FALL** is captured in the *Fall* module, DE204 in response to the question "What type of injury was sustained?"
- The scope of reporting for the CFER-H V1.2 *Fall* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) excludes a fall resulting from a purposeful action or violent blow (e.g., a patient pushes another patient) or a near fall (i.e., loss of balance that does not result in a fall).

Location of Fall

This figure presents data on the locations of *Fall Incidents* captured in CFER-H V1.2. Location data are captured for all patient safety concerns (*Incidents*, *Near misses*, and *Unsafe conditions*). CFER-H V1.2 captures information on where patient safety concerns occur in thirteen **LOCATION (AREA OF OCCURRENCE) OF EVENT OR UNSAFE CONDITION** (**LOCATION**) categories including *Other* and *Unknown*. This figure presents data on the **LOCATION** of *Fall Incidents* captured in CFER-H V1.2.

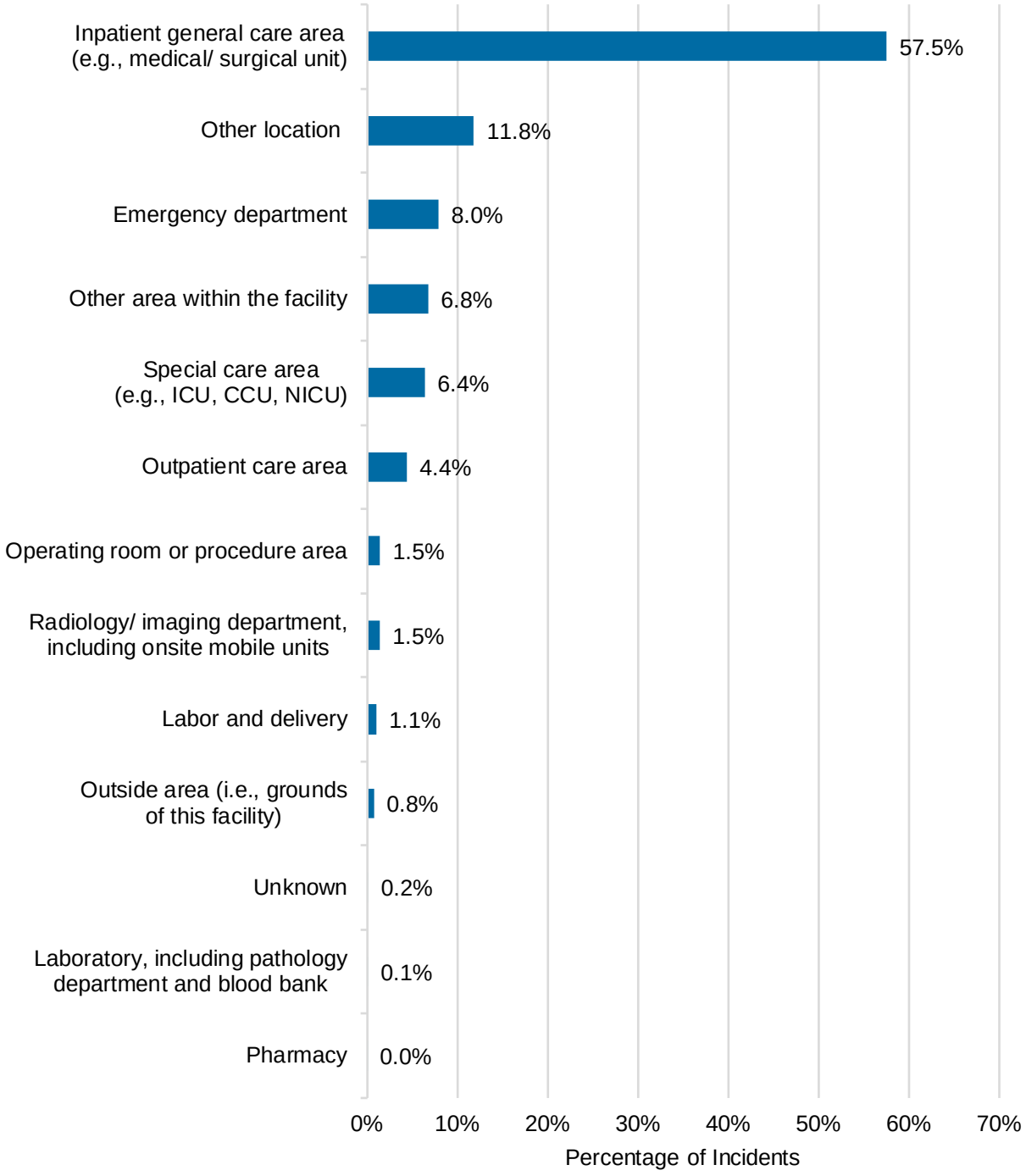
Inpatient general care areas (e.g., medical/surgical unit) was the most frequently reported **LOCATION** for falls, identified in 57.5% (65,124 / 113,268) of *Fall* reports.

Numerous falls (13,384 /113,268; 11.8%) were reported to have occurred in *Other location*. Because there are two narrower "other" responses available – *Other area within the facility* and *Outside area (i.e., grounds of this facility)* – the relatively high number of *Other location* events may reflect difficulties encountered by PSOs and/or providers when converting reports initially captured by incident reporting systems not based on CFER-H V1.2.

The location in the facility with the fewest reported *Fall Incidents* was *Pharmacy* with 0.0% (28 / 113,268) of *Fall Incidents*.

Important information is provided in the Technical Notes below.

Location of Fall



Note: The CFER-H V1.2 data presented indicate *Fall Incidents* occurring in different locations of the hospital facility as a percentage of all *Fall Incidents* with **LOCATION** information. *Operating room* or *procedure area* includes for example, cardiac catheter labs, other endoscopy areas, and PACU (post-anesthesia care unit) or recovery areas.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding.

Technical Notes

- In CFER-H V1.2, **LOCATION** is captured in the Summary of Initial Report form DE 78 in response to the question: "Where did the event occur, or, if an unsafe condition, where does it exist?"

- The scope of reporting for the CFER-H V1.2 *Fall* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) excludes a fall resulting from a purposeful action or violent blow (e.g., a patient pushes another patient) or a near fall (i.e., loss of balance that does not result in a fall).

MEDICATION OR OTHER SUBSTANCE

The *Medication or Other Substance* module in CFER-H V1.2 collects reports of events and *Unsafe conditions* involving medications or other substances, including biological products, nutritional products, and medical gasses. The **EVENT TYPE** collects data on the specific processes of care involved and does not require that a patient outcome be identified.

Even without specific event rates, data regarding the types of activities that give rise to *Medication or Other Substance* reports, the stage of the process where reported events are originating, and the residual harm, will be informative for patient safety improvements.

These figures present summary information from the *Medication or Other Substance* reports received by the PSOPPC that met inclusion and exclusion criteria. Therefore, percentages displayed in these figures are expected to differ from those presented in the Data Submission Summary module. The exclusion criteria for *Medication or Other Substance* reports are:

- 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 the result of a prescription and/or administration of a drug and/or food prior to admission

Extent of Harm

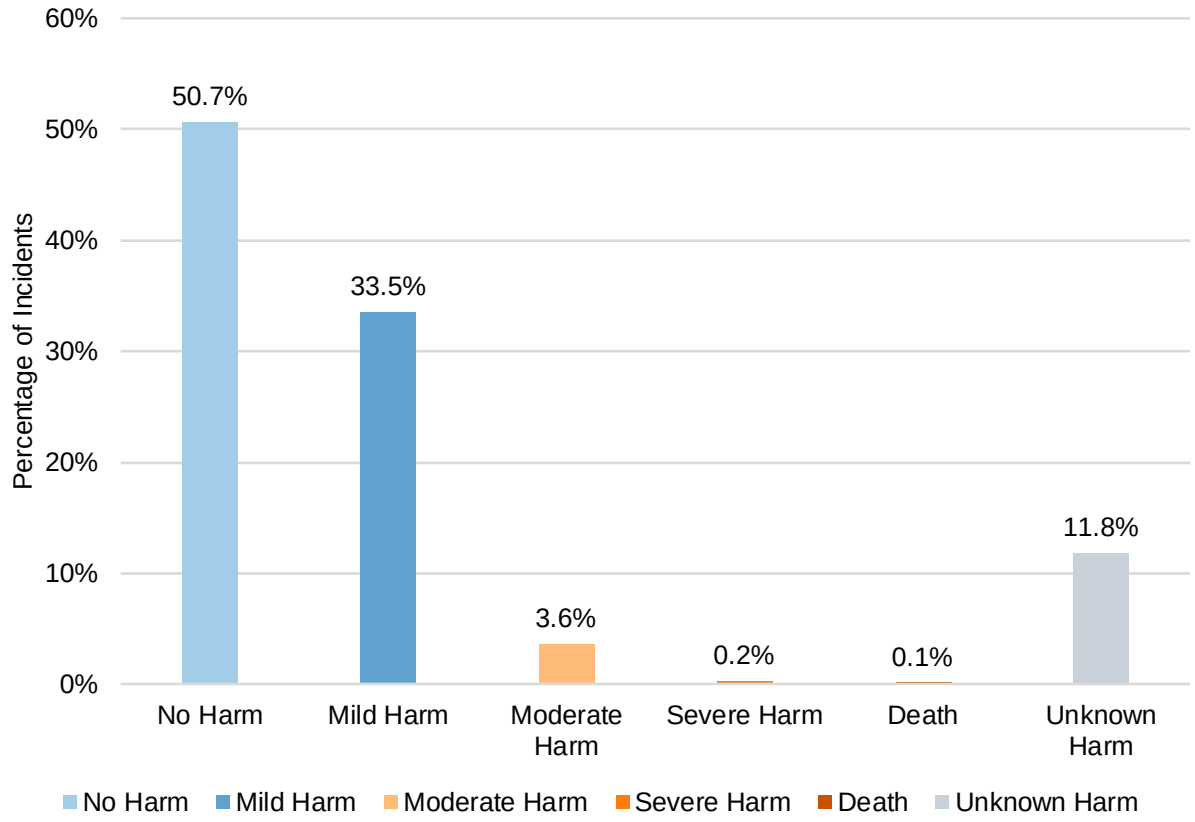
This figure displays the reports of residual harm to patients from *Medication or Other Substance Incidents*. Residual harm is the extent of harm to the patient after discovery of the incident and after any attempts to minimize adverse consequences. The AHRQ Harm Scale provides the following possible responses: *No harm*, *Mild harm*, *Moderate harm*, *Severe harm*, *Death*, or *Unknown harm*. This figure includes *Incidents* where the **EXTENT OF HARM** was reported. While *Unknown harm* is displayed in this figure, it is not described further.

Among *Medication or Other Substance Incidents* where the **EXTENT OF HARM** was known (i.e., excluding *Unknown harm*), the majority resulted in either *No harm* (101,892 / 177,265; 57.5%) or *Mild harm* (67,407 / 177,265; 38.0%).

Among the remaining *Medication or Other Substance Incidents* where **EXTENT OF HARM** was known, 0.1% (183 / 177,265) resulted in *Death*; 0.3% (486 / 177,265) resulted in *Severe harm*; and 4.1% (7,297 / 177,265) resulted in *Moderate harm*.

Important information is provided in the Technical Notes below.

Extent of Harm



Note: The CFER-H V1.2 data presented indicate patient safety *Incidents* resulting in various levels of harm as a percentage of all *Medication or Other Substance Incidents* with information on harm.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding.

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 scope of reporting for the CFER-H V1.2 *Medication or Other Substance* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) excluded the following: adverse drug events with no apparent incorrect action; patient food (not suspected in drug-food interactions); radiopharmaceuticals; 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.

Incorrect Actions

This figure presents the distribution of reports of *Medication or Other Substance* patient safety events (i.e., *Incidents* and *Near misses)* that involved an incorrect action, by the type of **INCORRECT ACTION INVOLVING A SUBSTANCE** (**INCORRECT ACTION**). CFER-H V1.2 captures data on 15 different types of **INCORRECT ACTIONS** that may occur in the hospital, including *Other*.

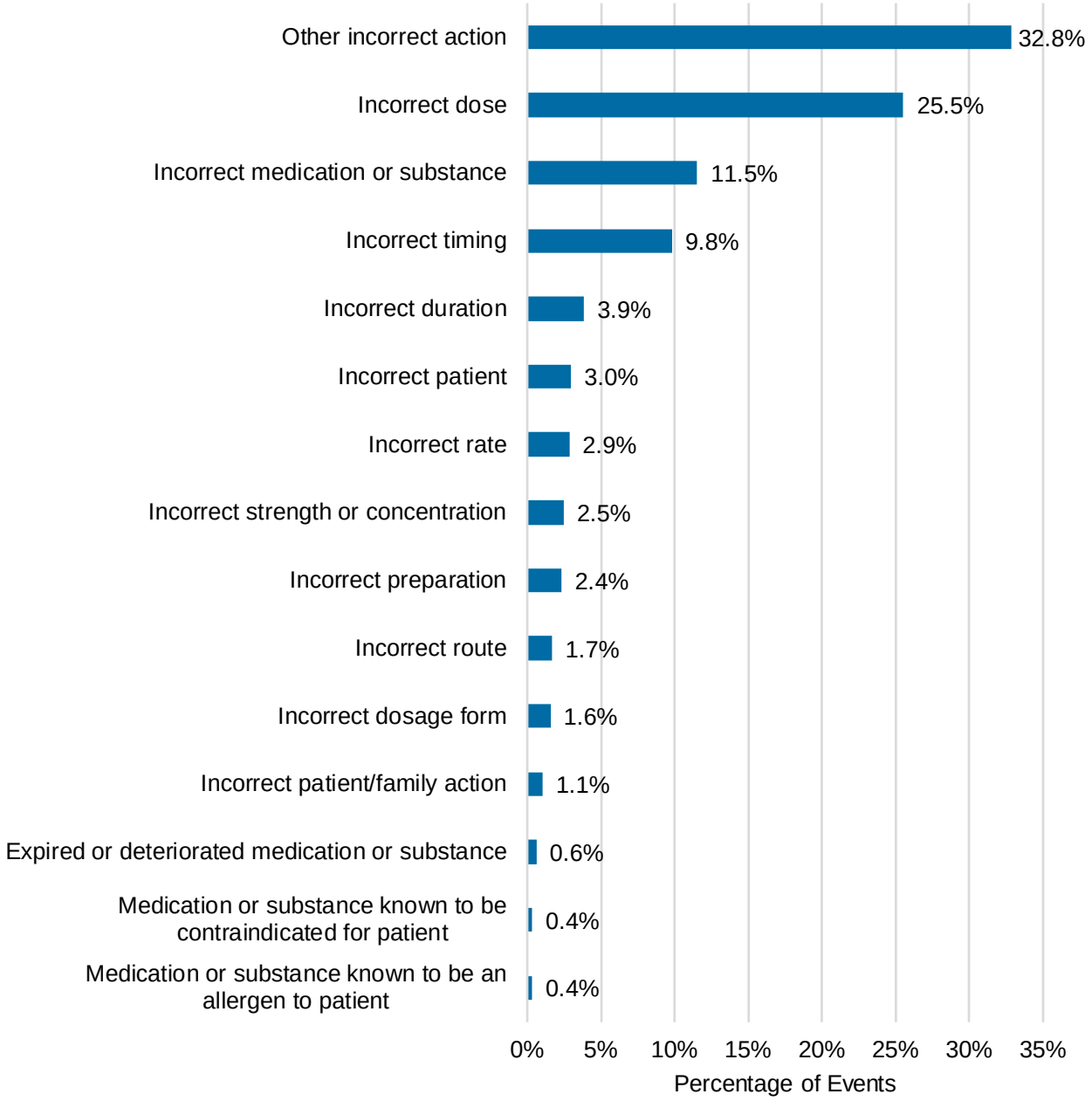
The most frequently reported type of **INCORRECT ACTION** was *Other incorrect action*, comprising 32.8% (15,655 / 47,672) of the **INCORRECT ACTIONS** reported. A review of free text descriptions of *Other incorrect action* found that approximately one-quarter of the 15,655 *Other incorrect action*s could have been reported in a different substantive response category such as *Incorrect dose*. Apparent misclassification of incorrect actions into the *Other* category could be the result of issues introduced when data are mapped using the CFER-H from a different reporting format.

The second most frequent type of **INCORRECT ACTION** was *Incorrect dose* (12,168 / 47,672; 25.5%), followed by *Incorrect medication or substance* (5,497 / 47,672; 11.5%).

One of the least frequent incorrect action reported was *Expired or deteriorated medication or substance* (308 / 47,672; 0.6%), followed by *Medication or substance known to be an allergen to patient* and *Medication or substance known to be contraindicated for patient* which were each identified in 0.4% of **INCORRECT ACTIONS** (169 / 47,672 and 172 / 47,672, respectively).

Important information is provided in the Technical Notes below.

Incorrect Actions



Note: The CFER-H V1.2 data presented indicate patient safety events that were reported in each category of **INCORRECT ACTION** as a percentage of all *Medication or Other Substance* events.

Incorrect timing is an **INCORRECT ACTION** that involves medications or other substances being administered too early or too late. *Incorrect rate* is an **INCORRECT ACTION** that involves medications or other substances being administered too quickly or too slowly.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. The data for one PSO were suppressed in this figure (see the second Technical Note below for details). Percentages may not sum to 100% due to rounding.

Technical Notes

- In CFER-H V1.2, **INCORRECT ACTION** in the *Medication or Other Substance* module is DE291 in response to the question: "What was the incorrect action?" **DESCRIPTION OF SUBSTANCE EVENT** in the *Medication or Other Substance* module is DE288 in response to the question: "Which of the following best characterizes the event?"

- The eligible sample excluded reports from one PSO because of a data quality issue related to the **INCORRECT ACTION** data element. A mapping error caused other types of **INCORRECT ACTION** to be reported as *Incorrect patient/family action*.

- A *Medication or Other Substance Incident* report can be associated with more than one **INCORRECT ACTION**. A total of 45,400 reports, including 1,777 associated with two or more types of **INCORRECT ACTION**, accounted for the 47,672 types of **INCORRECT ACTIONS** shown in this figure.

- The scope of reporting for the CFER-H V1.2 *Medication or Other Substance* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION (EVENT TYPE)** excluded the following: adverse drug events with no apparent incorrect action; patient food (not suspected in drug-food interactions); radiopharmaceuticals; 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.

Incorrect Action by Extent of Harm

This figure compares the distribution of residual harm to the distribution of no residual harm associated with different incorrect actions that may occur during the administration of medications or other substances in the hospital setting, as reported in *Medication or Other Substance Incident* reports. Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences.

Incorrect Dose was associated with more *Incidents* than any other **INCORRECT ACTION** (4,050 / 14,947; 27.1%). Additionally, more reports of residual harm were associated with *Incorrect dose* than with any other type of **INCORRECT ACTION**, representing nearly one-third (497 / 1,559; 31.9%) of all residual harm shown in this figure. *Incidents* involving an *Incorrect medication or substance* accounted for more than ten percent of the residual harm (161 / 1,559; 10.3%) reported in this figure. *Incidents* where a medication or other substance was administered to an *Incorrect patient* and residual harm was observed were less common, at 2.2% (35 / 1,559) of *Incidents* with an **INCORRECT ACTION**. *Medication or substance known to be an allergen to patient* and *Incidents* involving *Medication or substance known to be contraindicated for patient* were also very infrequently reported, representing only 0.8% (116 / 14,947) and 0.7% (102 / 14,947) of all **INCORRECT ACTIONS** reported. Administration of an *Expired or deteriorated medication or substance* was the least frequently reported type of **INCORRECT ACTION**, comprising 0.3% (39 / 14,947) of all **INCORRECT ACTIONS** with or without harm reported.

Across all types of **INCORRECT ACTION** reported in this figure, the proportion of *Incidents* that resulted in residual harm was 10.4% (1,559 / 14,947). Examining only reports associated with an *Incorrect dose*, the proportion with residual harm was 12.3% (497 / 4,050). The proportion of *Incidents* involving an *Incorrect medication or substance* that were associated with residual harm was 7.3% (161 / 2,219), and where a medication or other substance was administered to an

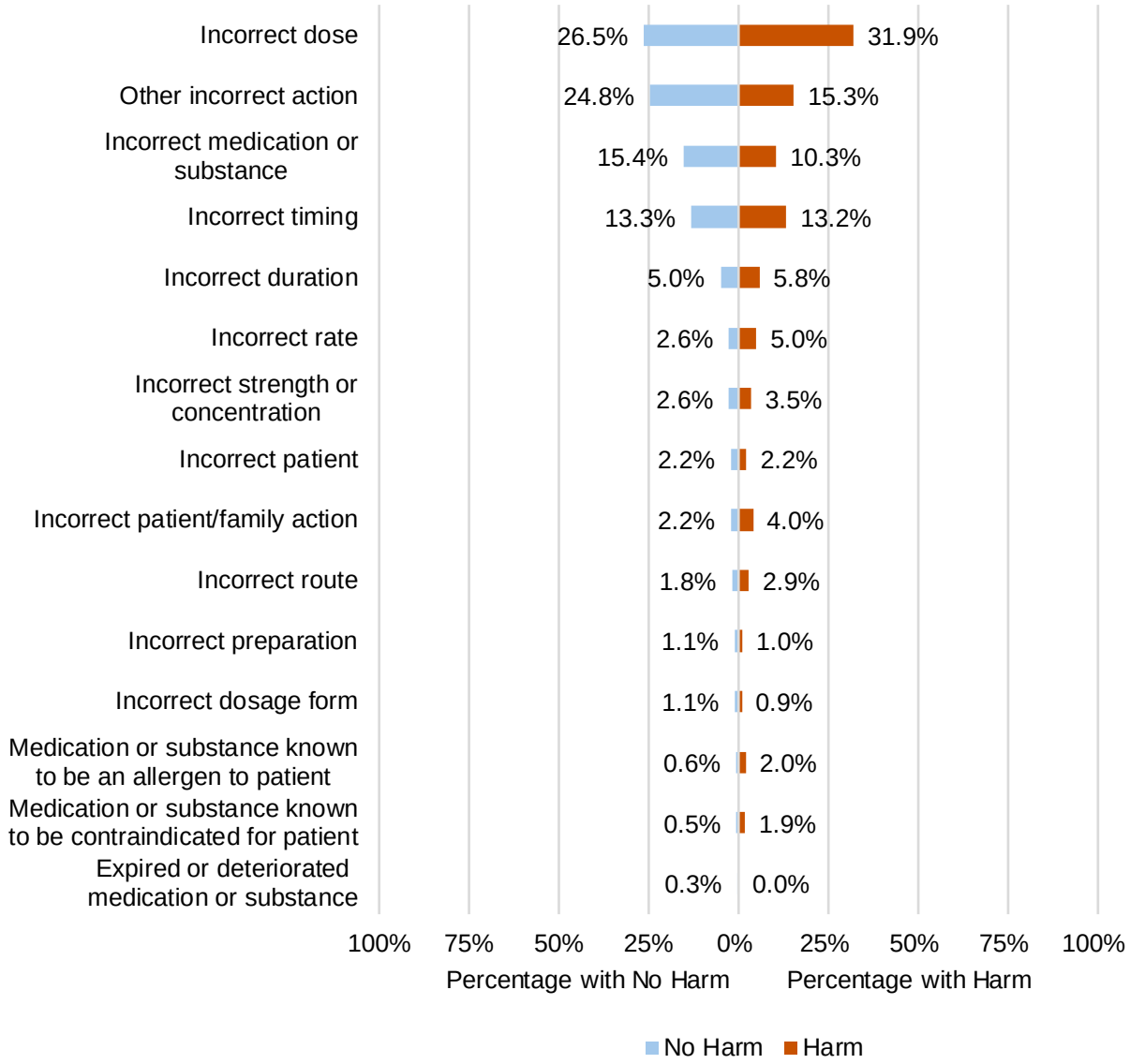
Incorrect patient, the proportion of *Incidents* with residual harm was also 10.8% (35 / 324). The percentage of *Other incorrect action* reports associated with residual harm was relatively low at 6.7% (238 / 3,555).

The proportion of *Incidents* with some residual harm reported varied considerably across types of **INCORRECT ACTION**. Administration of an *Expired or deteriorated medication or substance* was the only **INCORRECT ACTION** associated with no reports of residual harm (0 / 39; 0%).*Medication or substance that was contraindicated for patient* and *Medication or substance known to be an allergen to patient* were both associated with high proportions of residual harm: 28.4% (29 / 102) and 26.7% (31 / 116), respectively.

Please note: For this figure, all *Incident* reports with **EXTENT OF HARM** reported were classified as either No harm, or Harm (i.e., *Mild harm, Moderate harm, Severe harm* or *Death*). Reports of *Unknown harm* were excluded from the analysis.

Important information is provided in the Technical Notes below.

Incorrect Action by Extent of Harm



Note: The CFER-H V1.2 data presented indicate patient safety incidents that were reported in each category of **INCORRECT ACTION** as a percentage of all *Medication or Other Substance Incidents* where **INCORRECT ACTION** and **EXTENT OF HARM** were reported, stratified by whether the patient experienced a harm or not.

Incorrect timing is an **INCORRECT ACTION** that involves medications or other substances being administered *too early* or *too late*. *Incorrect rate* is an **INCORRECT ACTION** that involves medications or other substances being administered *too quickly* or *too slowly*.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. The data for one PSO were suppressed in this figure see the second Technical Note below for details). A total of 13,282 *Medication or Other Substance Incident* reports with an *Incorrect action* included information on **INCORRECT ACTION** and **EXTENT OF HARM**. Percentages sum to 100% within Harm and No Harm columns, but the sum of percentages shown may not total 100% due to rounding.

Technical Notes

- In CFER-H V1.2, **INCORRECT ACTION** in the *Medication or Other Substance* module is DE291 in response to the question: "What was the incorrect action?" and **DESCRIPTION OF SUBSTANCE EVENT** in the *Medication or Other Substance* module is DE288 in response to the question: "Which of the following best characterizes the event?" **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 eligible sample excluded reports from one PSO because of a data quality issue related to the **INCORRECT ACTION** data element. A mapping error caused other types of **INCORRECT ACTION** to be reported as *Incorrect patient/family action*.

- A *Medication or Other Substance Incident* report can be associated with more than one **INCORRECT ACTION**. A total of 13,282 reports, including 1,316 that were associated with two or more types of **INCORRECT ACTION**, accounted for the 14,947 **INCORRECT ACTION** types shown in this figure.

- The scope of reporting for the CFER-H V1.2 *Medication or Other Substance* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) excluded the following: adverse drug events with no apparent incorrect action; patient food (not suspected in drug-food interactions); radiopharmaceuticals; 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.

Description of Incorrect Dose

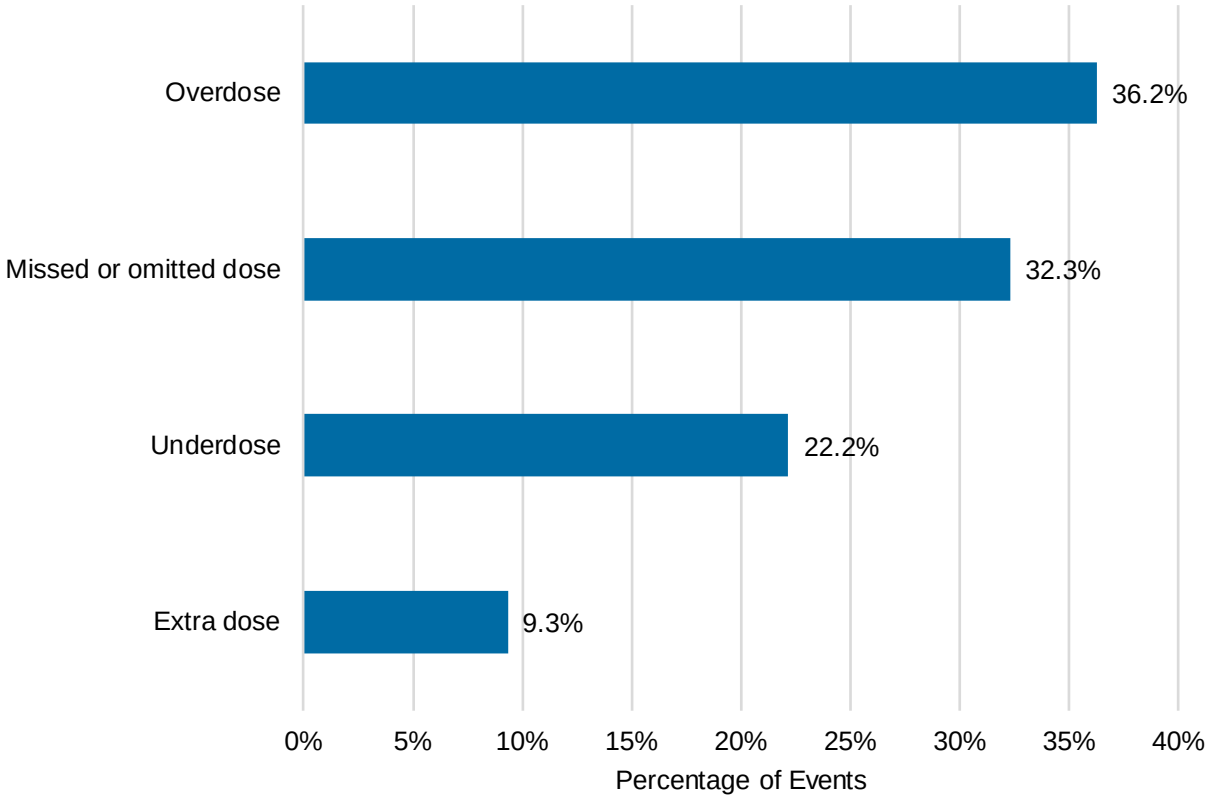
This figure presents the distribution of **DESCRIPTION OF INCORRECT DOSE** among *Medication or Other Substance* events that involved an **INCORRECT ACTION** where the incorrect action was an *Incorrect dose.* CFER-H V1.2 captures data on five different **DESCRIPTIONS OF INCORRECT DOSE** that may occur in the hospital, including *Unknown**.

Overdose were the most frequent **DESCRIPTION OF INCORRECT DOSE** reported in *Medication or Other Substance* events (4,894 / 13,505; 36.2%).

Missed or omitted doses and *Underdose* accounted for 32.3% (4,360 / 13,505) and 22.2% (2,992 / 13,505) respectively.

Important information is provided in the Technical Notes below.

Description of Incorrect Dose



Note: In this figure, the *Unknown* category was removed from the total sample reported in the text to meet non-identification requirements.

The CFER-H V1.2 data presented indicate patient safety events associated with different types of incorrect doses presented as a percentage of all *Medication or Other Substance* events where an *Incorrect dose* was identified as the **INCORRECT ACTION** and information was provided on the **DESCRIPTION OF INCORRECT DOSE**.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding and suppression.

Technical Notes

- In CFER-H V1.2, **DESCRIPTION OF INCORRECT DOSE** in the *Medication or Other Substance* module is DE294 in response to the question: "Which best describes the incorrect dose(s)?" and **INCORRECT ACTION** in the *Medication or Other Substance* module is DE291 in response to the question: "What was the incorrect action?" and **DESCRIPTION OF SUBSTANCE EVENT** in the *Medication or Other Substance* module is DE288 in response to the question: "Which of the following best characterizes the event?"
- The scope of reporting for the CFER-H V1.2 *Medication or Other Substance* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) excluded the following: adverse drug events with no apparent incorrect action; patient food (not suspected in drug-food interactions); radiopharmaceuticals; 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.

Description of Incorrect Dose by Extent of Harm

This figure compares the distribution of residual harm to the distribution of no residual harm associated with different **DESCRIPTIONS OF INCORRECT DOSE** that may occur during the administration of medications or other substances in the hospital setting, as reported in *Medication or Other Substance Incident* reports. Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences.

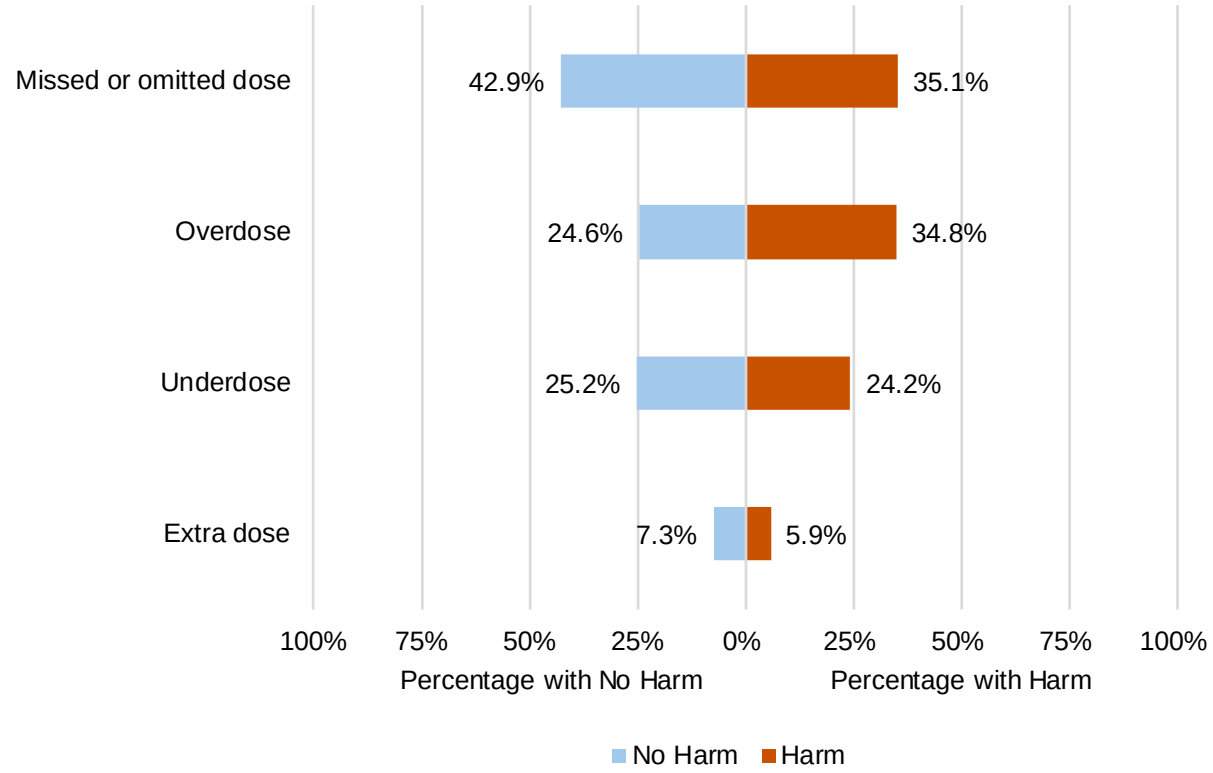
Missed or omitted dose was the category of **DESCRIPTION OF INCORRECT DOSE** most frequently involved in *Incidents* shown in this figure (2,398 / 5,706; 42.0%), and was also the category associated with the largest number of harm events, comprising more than one-third of the overall total (216 / 615; 35.1%).

Across all categories of **DESCRIPTION OF INCORRECT DOSE**, the proportion of *Incidents* associated with residual harm was 10.8% (615 / 5,706). The highest proportion of residual harm was 14.6% (214 / 1,467) for *Overdose*. The proportion of *Incidents* with residual harm was 10.4% (149 /1,432) where the **DESCRIPTION OF INCORRECT DOSE** was *Underdose*, and 9.0% (216 / 2,398) for *Missed or omitted dose.*

Please note: For this figure, all *Incident* reports with **EXTENT OF HARM** reported were classified as either No Harm, or Harm (i.e., *Mild harm*, *Moderate harm*, *Severe harm* or *Death*). Reports of *Unknown harm* were excluded from the analysis.

Important information is provided in the Technical Notes below.

Description of Incorrect Dose by Extent of Harm



Note: In this figure, the *Unknown* category was removed from the total sample reported in the text to meet non-identification requirements.

The CFER-H V1.2 data presented indicate patient safety events associated with different **DESCRIPTIONS OF INCORRECT DOSE** presented as a percentage of all *Medication or Other Substance* events where *Incorrect dose* was identified as the **INCORRECT ACTION** and information was provided on the **DESCRIPTION OF INCORRECT DOSE** and **EXTENT OF HARM**, stratified by whether the patient experienced a harm or not.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages sum to 100% within Harm and No Harm columns, but the sum of percentages shown may not total 100% due to rounding and suppression.

Technical Notes

- In CFER-H V1.2, **DESCRIPTION OF INCORRECT DOSE** in the *Medication or Other Substance* module is in DE294 in response to the question: "Which best describes the incorrect dose(s)?" and **INCORRECT ACTION** in the *Medication or Other Substance* module is Data Element DE291 in response to the question: "What was the incorrect action?" **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 scope of reporting for the CFER-H V1.2 *Medication or Other Substance* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) excluded

the following: patient food (not suspected in drug-food interactions); radiopharmaceuticals; 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.

Stage Event Originated

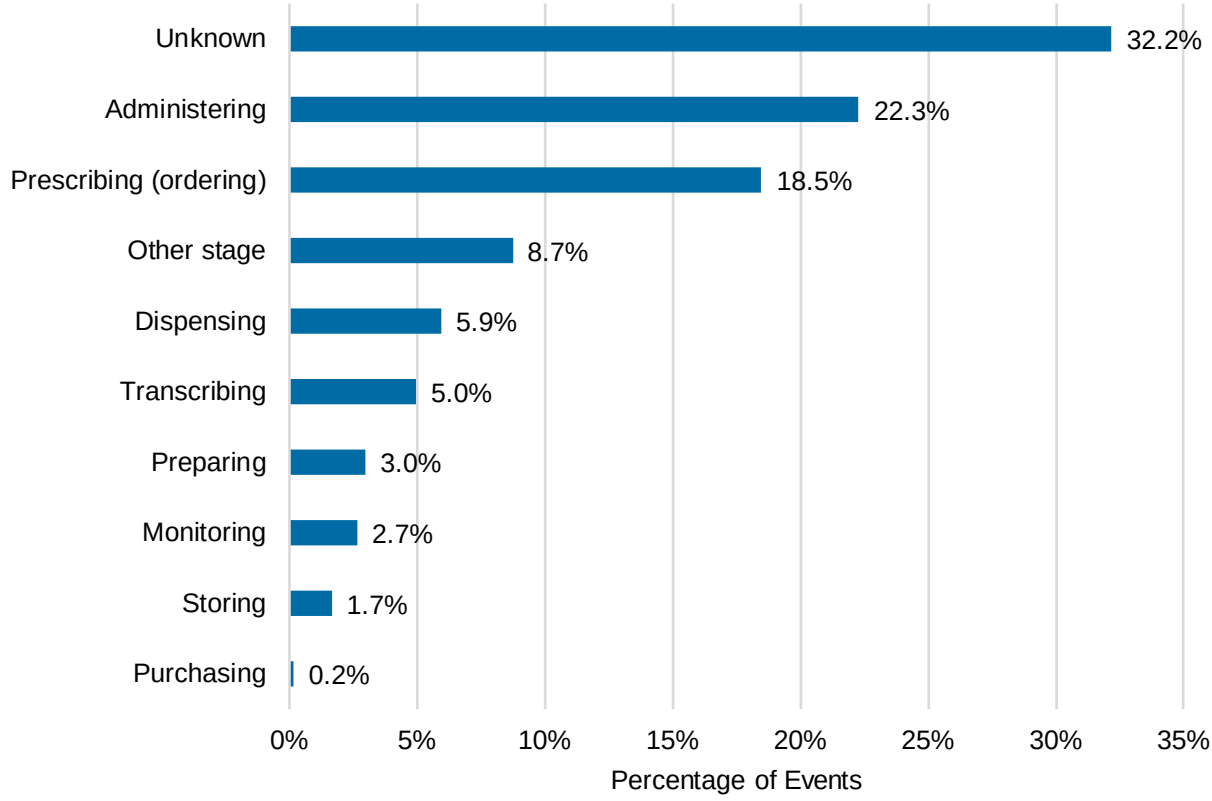
This figure presents the distribution of reports of *Medication and Other Substance* patient safety events (i.e., *Incidents* and *Near misses*) that involved an incorrect action by the **STAGE EVENT ORIGINATED**. CFER-H V1.2 captures data on 10 different stages of the medication use process where the event originated, including *Other stage* and *Unknown* as shown in this figure. These data are only captured for *Medication or Other Substance* events involving an *Incorrect action*.

The stage of the medication use process most frequently identified as the origination of medication events was in *Unknown* (22,196 / 69,032; 32.2%), *Administering* stage (15,376 / 69,032; 22.3%), and followed by *Prescribing (ordering)* at 18.5% (12,744 / 69,032).

The stage of the medication process least frequently identified as the origination of medication events was *Purchasing* at 0.2% (122 / 69,032).

Important information is provided in the Technical Notes below.

Stage Event Originiated



Note: The CFER-H V1.2 data presented indicate patient safety events associated with different **STAGES EVENT ORIGINATED** as a percentage of medication events where an *Incorrect action* was.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages may not sum to 100% due to rounding.

Technical Notes

- In CFER-H V1.2, **STAGE EVENT ORIGINATED** in the *Medication or Other Substance* module is DE315 in response to the question: "At what stage in the process did the event originate, regardless of the stage at which it was discovered?" and **DESCRIPTION OF SUBSTANCE EVENT** in the *Medication or Other Substance* module is DE288 in response to the question: "Which of the following best characterizes the event?"

- The scope of reporting for the CFER-H V1.2 *Medication or Other Substance* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) excluded the following: adverse drug events with no apparent incorrect action; patient food (not suspected in drug-food interactions); radiopharmaceuticals; 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.

Stage Event Originated by Extent of Harm

This figure compares the distribution of residual harm to the distribution of no residual harm associated with events that originated at various stages in the medication use process (**STAGE EVENT ORIGINATED**), as reported in *Medication or Other Substance Incident* reports. Residual harm is harm to the patient after the discovery of the incident and any attempts to minimize adverse consequences.

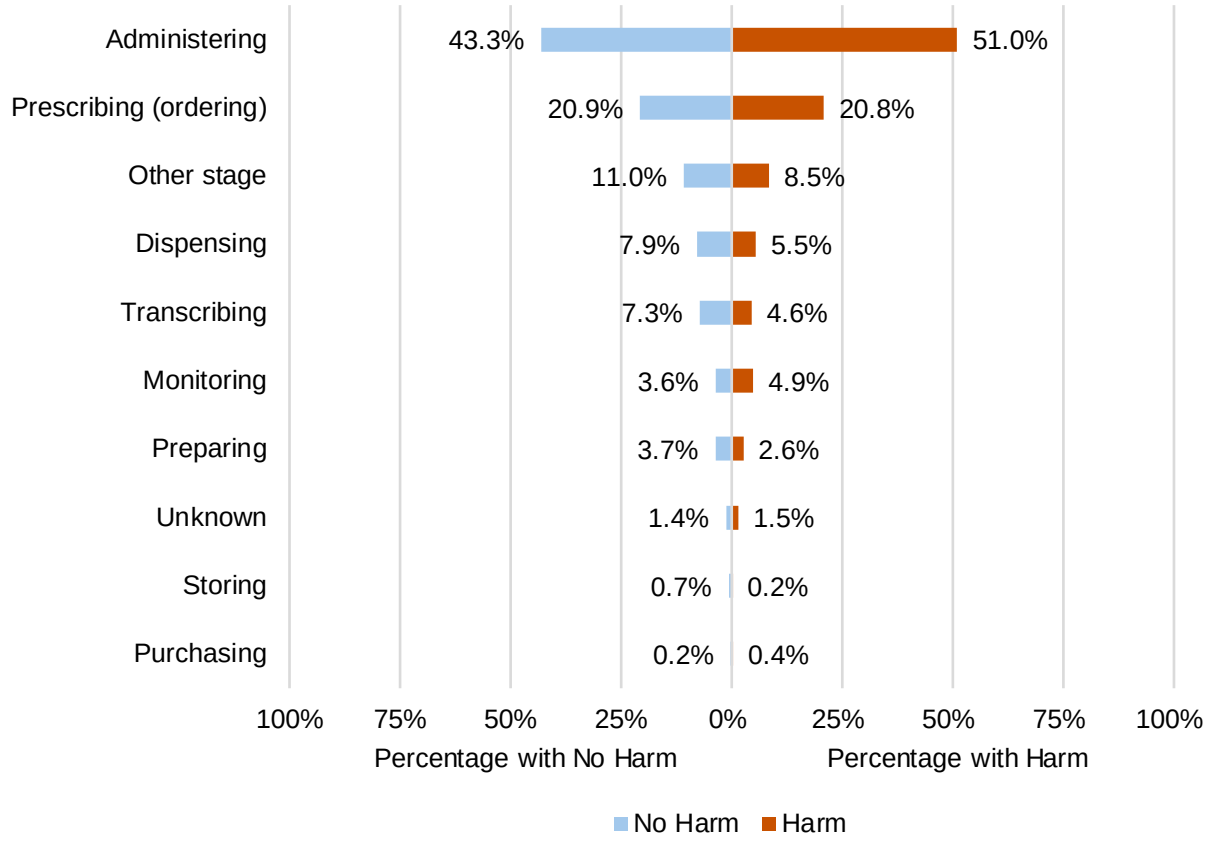
Administering medication or other substances was the **STAGE EVENT ORIGINATED** associated with the greatest number of *Incidents* shown in this figure (10,513 / 23,943; 43.9%) and over half (983 / 1,928; 51.0%) of all *Incidents* with residual harm.

Across **STAGES EVENT ORIGINATED**, the proportion where residual harm resulted from an *Incident* was 8.1% (1,928 / 23,943). The proportion of *Incidents* with residual harm was highest among *Incidents* originating with *Purchasing*, 13.7% (7 / 51), and lowest among *Incidents* originating with *Storing*, 2.5% (4 / 161). Among *Incidents* associated with *Administering*, the proportion of reports with residual harm was 9.4% (983 / 10,513).

Please note: For this figure, all *Incident* reports with **EXTENT OF HARM** reported were classified as either No Harm, or Harm (i.e., *Mild harm*, *Moderate harm*, *Severe harm* or *Death*). Reports of *Unknown harm* were excluded from the analysis.

Important information is provided in the Technical Notes below.

Stage Event Originiated by Extent of Harm



Note: The CFER-H V1.2 data presented indicate patient safety events associated with different stages of the process where the event originated as a percentage of events where the **DESCRIPTION OF SUBSTANCE EVENT** was *Incorrect action* and information on **STAGE EVENT ORIGINATED** and **EXTENT OF HARM** were provided, stratified by whether the patient experienced harm.

Reports had **INITIAL REPORT DATES** from December 31, 2009 through December 12, 2019. Percentages sum to 100% within Harm and No Harm columns, but the sum of percentages shown may not total 100% due to rounding.

Technical Notes

- In CFER-H V1.2, **STAGE EVENT ORIGINATED** in the *Medication or Other Substance* module is DE315 in response to the question: "At what stage in the process did the event originate, regardless of the stage at which it was discovered?" and **DESCRIPTION OF SUBSTANCE EVENT** in the *Medication or Other Substance* module is DE288 in response to the question: "Which of the following best characterizes the event?" **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 scope of reporting for the CFER-H V1.2 *Medication or Other Substance* **CATEGORY ASSOCIATED WITH EVENT OF UNSAFE CONDITION** (**EVENT TYPE**) excluded

the following: adverse drug events with no apparent incorrect action; patient food (not suspected in drug-food interactions); radiopharmaceuticals; 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.

Appendix A: Common formats for Event Reporting – Hospital V1.2 Exclusion Criteria

The Common Formats for Event Reporting – Hospital were 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
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

Healthcare-associated Infection (HAI)
Infection that was determined to be present or incubating on admission (except SSI in patient operated on at this facility in the past 30 days or, if an implant, in the past year)

- Community acquired infection that was determined to be present or incubating on admission with no treatment at any facility
- Presumed HAI (other than SSI) that developed following a discharge from this facility
- Presumed HAI (other than SSI) that developed following treatment at an outpatient site, operated by this facility
- Presumed HAI that developed following treatment at another inpatient or outpatient facility

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

Venous Thromboembolism (VTE)
Asymptomatic VTE (i.e., DVT and/or PE identified on screening exam or incidentally)

VTE occurring in a patient receiving palliative or comfort care

Thrombosis involving another venous system such as intracranial veins or sinuses, or splanchnic, portal or renal veins

VTE that develops within 48 hours of admission, except if the patient had been discharged from the reporting facility within the prior 30 days

VTE in a patient admitted to hospital with a diagnosis of, or suspected diagnosis of, acute DVT or PE, except if discharged from the reporting facility within 30 days of being readmitted to that same facility

VTE in a patient with prior or chronic VTE who has leg swelling and no documentation of acute changes on ultrasound report

VTE diagnosed more than 30 days after hospital discharge

VTE diagnosed based on any one, or any combination of, (1) clinical criteria, (2) D-dimer test results, or (3) imaging test results that are “inconclusive” or are of “low probability”

Superficial vein thrombosis and/or phlebitis that does not extend into a deep vein

Non-thrombotic emboli (e.g., air, fat, amniotic fluid, or foreign body or material)

Other
No exclusions apply.

Publication No. 20-0048
August 2020
www.ahrq.gov