# Adverse Events Among Medicare Hospitalizations in 2021–2023





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## I. Summary

An "adverse event" (AE) is defined as harm to a patient as a result of medical care or occurring within a health care setting, including the failure to provide needed care. The occurrence of an AE indicates that care resulted in an undesirable clinical outcome—not caused by underlying disease—that could include a prolonged patient stay, patient harm, additional intervention, or even death. Thus, understanding the frequency of AEs among hospitalized patients is a prerequisite to improving the quality and safety of care patients receive in the hospital.

In collaboration with the Centers for Medicare & Medicaid Services (CMS), the Agency for Healthcare Research and Quality (AHRQ) presents an overview of the Quality and Safety Review System (QSRS), a new data collection and analysis system designed to identify the occurrence of specified AEs to better understand patient safety in the hospital setting. We also contrast the QSRS with the previous data collection and analysis system called the Medicare Patient Safety Monitoring System (MPSMS). Using the QSRS, more than 22,000 inpatient hospitalization records for Medicare beneficiaries were systematically abstracted each year beginning in 2021, capturing information on more than 40 types of AEs in approximately 1,100 non-Federal, acute care hospitals in the United States.

This report reflects the evolution of combined efforts of AHRQ and CMS since 2001 to monitor inpatient hospital AEs through retrospective chart review. For the analyses in this report, the QSRS was used to conduct the underlying chart abstractions to determine whether specific AEs occurred in the inpatient hospital setting. Analyzing data from the QSRS, this report presents weighted national estimates of AEs experienced by Medicare patients hospitalized from 2021–2023. From 2021 to 2023, the weighted percentage of Medicare patients experiencing at least one AE per hospital stay decreased from 7.1 percent to 5.2 percent, and the weighted rate of AEs per 1,000 discharges decreased from 83.1 to 59.4. For all 3 years, medication events, pressure injuries/ulcers, and hospital-acquired infections (HAIs) accounted for approximately 80 percent of AEs among hospitalized Medicare patients. The weighted rate of Medication AEs (23.9 to 16.7) and HAIs (18.4 to 11.5) per 1,000 at-risk hospitalizations notably decreased from 2021 to 2023.

This report provides insight on the frequency and type of AEs experienced by Medicare beneficiaries in U.S. hospitals. Further data collection and research is needed to comprehensively understand the extent to which AEs are experienced by all patients, regardless of age or insurance provider, in all settings of care. AHRQ provides the public with a number of <u>resources to aid hospitals</u> and <u>other settings of care</u> in improving patient safety and reducing the occurrence of AEs.

# II. Background

#### A. Adverse Events in Hospitals and the Medicare Patient Safety Monitoring System

In 2000, the Institute of Medicine (now the National Academy of Medicine) published the landmark report *To Err Is Human*, estimating that between 2.9 and 3.7 percent of hospital patients experienced an AE and that AEs caused up to 98,000 deaths in hospitals each year. In response to this challenge, in 2001, the MPSMS was created under the auspices of the U.S. Department of Health and Human Services' Patient Safety Task Force to identify rates of select AEs within the Medicare population. Initially led by CMS in coordination with AHRQ, the

<sup>&</sup>lt;sup>i</sup> Institute of Medicine (US) Committee on Quality of Health Care in America, Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human: Building a Safer Health System*. Washington (DC): National Academies Press (US); 2000.

Centers for Disease Control and Prevention, the Food and Drug Administration, and the Department of Veterans Affairs, the MPSMS was designed to monitor and track in-hospital AEs through retrospective chart review of randomly selected charts. The MPSMS established a baseline for assessing the impact of national patient safety initiatives, employing explicit review criteria and a focus on patient harm rather than provider or system error. In 2009, primary coordination for the MPSMS was transferred from CMS to AHRQ.

For almost 20 years, MPSMS was used to collect data to determine national rates for specific adverse events. MPSMS data were used to produce the AHRQ National Scorecard on Hospital-Acquired Conditions. Using MPSMS data, AHRQ determined that national efforts to reduce hospital-acquired conditions, such as adverse drug events and injuries from falls, helped prevent 20,700 deaths and saved \$7.7 billion between 2014 and 2017. In addition, MPSMS data from 2010 to 2019 showed decreases from 31 percent to 39 percent in the number of in-hospital AEs for patients undergoing major surgery and those with a principal diagnosis of acute myocardial infarction, congestive heart failure, or pneumonia. MPSMS data were last collected for calendar year 2019. In 2020, the MPSMS reached the end of its service life and was replaced by the QSRS.

#### **B. QSRS**

The QSRS was developed as a web-based system by AHRQ in coordination with CMS to be the successor system to MPSMS and with a goal to eventually be made available for other users, such as hospitals interested in using the QSRS to estimate local AE rates<sup>vii</sup>. Like MPSMS, the QSRS relies on data populated by trained medical records personnel at CMS' Clinical Data Abstraction Centers (CDAC) through review of the medical records of hospitalized patients. Algorithms are coded into QSRS that use abstractors' responses to identify whether an AE occurred during a particular hospital stay and to capture information about events that are identified. The questions are intended to be objective and do not typically require the abstractor to make clinical decisions or judgments. The QSRS Abstractor's Guide provides guidance such as likely data sources (e.g., progress notes, radiology reports) in the patient's record to address each QSRS question along with instructions for the abstractor (including answer options). Additionally, skip logic within the algorithms enable abstractors to move through records, responding only to questions pertinent to specific AEs.

The main improvement in the QSRS is its modules, which focus on specific AE categories (e.g., falls, pressure injuries) and are built on standardized definitions and algorithms consistent with the <u>AHRQ Common Formats</u> <u>for Surveillance</u>. Using standardized specifications and algorithms ensures that AEs are reliably identified across all hospitals and facilitates capture of more than the 21 specific AEs examined by the MPSMS.

ii Hunt DR, Verzier N, Abend SL, Lyder C, Jaser LJ, Safer N, Davern P. Fundamentals of Medicare Patient Safety Surveillance: Intent, Relevance, and Transparency. In: Henriksen K, Battles JB, Marks ES, Lewin DI, editors. Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology). Rockville, MD: Agency for Healthcare Research and Quality (US); 2005 Feb. PMID: 21249817.

For a full list of hospital-acquired conditions (HACs) tracked by MPSMS, see:

https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/pfp/hacreport-2019.pdf.

<sup>&</sup>lt;sup>iv</sup> Previous reports and related information are available at <a href="https://www.ahrq.gov/hai/pfp/index.html">https://www.ahrq.gov/hai/pfp/index.html</a>.

<sup>&</sup>lt;sup>v</sup> Declines in Hospital-Acquired Conditions. Content last reviewed July 2020. Agency for Healthcare Research and Quality, Rockville, MD. <a href="https://www.ahrq.gov/data/infographics/hac-rates">https://www.ahrq.gov/data/infographics/hac-rates</a> 2019.html.

vi Eldridge N, Wang Y, Metersky M, et al. Trends in adverse event rates in hospitalized patients, 2010–2019. JAMA. 2022;328(2):173–183. doi:10.1001/jama.2022.9600.

vii Feasibility of the Partial Automation of Data Abstraction for the Quality and Safety Review System," AHRQ Publication No. 18-0034-EF. 2018. Available at: <a href="https://www.ahrq.gov/sites/default/files/wysiwyg/patient-safety/quality-measures/qsrs-final-report-feasibility-508.pdf">https://www.ahrq.gov/sites/default/files/wysiwyg/patient-safety/quality-measures/qsrs-final-report-feasibility-508.pdf</a>.

The QSRS captures 80 outcomes grouped into 41 AE types that are organized into 11 modules (topic areas). It also is used to track information about approximately 14 other "occurrences to be monitored," which includes AE measures in development or other information of interest that does not reflect an AE (e.g., indicators of possible AEs). Major additions when compared to the MPSMS include additional adverse drug events (such as opioid AEs), surgical site infections and numerous other types of surgical adverse events, and obstetric and neonatal adverse events. The event descriptions used by the QSRS are based on expert panel review, public comment, and for healthcare-associated infections, the CDC National Healthcare Safety Network definitions. Appendix A includes tables that list, by module, all the outcomes and AEs (Table A1) as well as occurrences to be monitored (Table A2) that the QSRS captures.

#### C. Differences in Data Between MPSMS and QSRS

While both systems have similar purposes, AE rates produced from MPSMS data and QSRS data are not directly comparable, as shown in Table 1. The MPSMS included 21 types of AEs, and the QSRS currently includes 41. The QSRS also expanded on some existing MPSMS events and updated some of the MPSMS measures based on newer evidence. Unlike the MPSMS, the QSRS also has the capacity to add, remove, or revise measures.

In 2009, CMS expanded from a Medicare-only to an all-payer sample. This all-payer sample was used through 2019. From 2010 to 2014, the sample of records for the MPSMS came exclusively from four patient groups: those with a principal diagnosis of acute myocardial infarction, congestive heart failure, pneumonia, or a major surgical procedure. Beginning in 2014, the new methodology added a fifth group of patient charts for most other conditions treated in acute care hospitals. VIIII

In contrast to the MPSMS, the QSRS does not divide patients into groups based on principal diagnosis. In addition, beginning in 2020, which coincides with the introduction of the QSRS, CMS changed its sampling methodology; the sample of patients transitioned back to a Medicare-only sample.

3

viii Wang Y, Eldridge N, Metersky ML, et al. National trends in patient safety for four common conditions, 2005–2011. N Engl J Med. 2014;370(4):341-351. doi:10.1056/NEJMsa1300991.

Table 1. Adverse Events Data by Collection System to Date

	MPSMS	QSRS, 2020–2024
Dates of data abstraction	2002–2007, 2009–2019*	September 2020 through 2024
	* No data were abstracted in 2008	* Due to the COVID-19 pandemic, CMS
		suspended inpatient data collection
		from January to August 2020
Setting of care	Acute care hospitals participating in	Acute care hospitals participating in
	IPPS	IPPS
Sampling design	From 2009–2019, multistage random	Stratified, two-stage cluster sample of
	sample of records for patients,	records of Medicare patients in selected
	regardless of payer, in selected	hospitals
	hospitals	
Number of hospitals	2002–2007: over 4,000	~1,100 per year
	2009–2014: 400–800	
	2015–2018: 300–400	
	2019: ~100	
Patient sample	From 2009–2019, all patients 18+	Patients 18+ years old with Medicare
	years old, regardless of insurance	Part A coverage (through traditional or
	2040 2044 1 1 1 1 1 1 1 1	Medicare Advantage)
	2010–2014: data abstracted for	
	patients discharged from hospital	
	with a principal diagnosis of AMI, HF,	
	pneumonia, or a major surgical procedure	
	procedure	
	2014–2019: Added "all other	
	conditions"	
Total number of medical	Varies: 10,199–36,788	Varies: 22,000–26,000 from 2021–2023
records per year	Valles: 10)133 30), 00	Turies: 22,000 20,000 Hom 2021 2020
AEs monitored	21 AEs in the following categories:	41 AEs in the following categories:
	- General	- Birth events (maternal and neonatal)
	- Hospital-Acquired Infections	- Blood or Blood Product
	- Postprocedural AEs	- Falls
	- Adverse Drug Events	- Hospital-Acquired Infections
		- Medication
		- Pressure Injury/Ulcer
		- Surgery or Anesthesia
		- Venous Thromboembolism
		- Other
Adverse events	Static set of AEs	Dynamic. AEs can be added, removed,
		or revised.

Abbreviations: AHRQ, Agency for Healthcare Research and Quality; AEs, adverse events; AMI, acute myocardial infarction; CHF, congestive heart failure; CMS, Centers for Medicare & Medicaid Services; IPPS, Inpatient Prospective Payment System; MPSMS, Medicare Patient Safety Monitoring System; QSRS, Quality Safety and Review System.

#### III. Methods

#### A. Sampling Frame

The 2021–2023 QSRS national sample represents Medicare beneficiaries (both Medicare Advantage and Fee-for-Service) ages 18 and older with hospital stays less than 120 days and who were discharged from acute care hospitals between January 1, 2021, to December 31, 2023. Records included any discharge status, including death.

Participating hospitals are stratified into five cohorts: (1) Medicare Rural Acute Care Hospitals ("RURAL") participating in the Inpatient Prospective Payment System (IPPS); (2) Medicare Targeted Urban Acute Care Hospitals ("TARGETED URBAN") participating in IPPS and also eligible for Hospital Quality Improvement Contractor (HQIC) services; (3) Critical Access Hospitals (CRITICAL ACCESS); (4) Indian Health Service (IHS) hospitals; and (5) Medicare Other Acute Care Hospitals ("OTHER") participating in IPPS. By definition, Department of Defense and Department of Veterans Affairs hospitals are excluded. The first four hospital cohorts are types of hospitals that CMS targets as part of the Quality Improvement Organizations Program, which aims to improve the effectiveness, efficiency, cost-effectiveness, and quality of services delivered to Medicare beneficiaries<sup>IX</sup>. More specifically, through September 2024, the program supported small, rural and critical access hospitals and facilities that care for vulnerable and underserved patients through contractors who focus on patient safety, among other initiatives. Medicare Other Acute Care Hospitals consist of all other acute care hospitals and are included to generate national estimates that are representative of acute care hospitals nationally.

Each hospital cohort is defined as follows:

- Rural Acute Care Hospitals are located outside of a Metropolitan Statistical Area, as defined by the federal Office of Management and Budget. These hospitals do not include rural census tracts within metropolitan counties. xi
- <u>Targeted Urban Acute Care Hospitals</u> are hospitals targeted in urban areas that represented a significant share of their healthcare market. These hospitals also had identified areas of improvement over time. They were targeted by the CMS HQIC program<sup>xii</sup>, consistent with the program's priorities for quality and safety.
- <u>Critical Access Hospitals</u> are rural hospitals designated by CMS as a separate provider type with their own Medicare Conditions of Participation as well as a separate payment method.<sup>xiii</sup>

<sup>ix</sup> U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Report to Congress: Fiscal Year 2023, The Administration, Cost, and Impact of the Quality Improvement Organization Program for Medicare Beneficiaries," 2024. Available at: <a href="https://www.cms.gov/files/document/report-congress-fiscal-year-2023-administration-cost-and-impact-quality-improvement-organization.pdf">https://www.cms.gov/files/document/report-congress-fiscal-year-2023-administration-cost-and-impact-quality-improvement-organization.pdf</a>.

<sup>\*</sup> Centers for Medicare & Medicaid Services, "Quality Improvement Organizations: Who We Help–Hospitals." [Online]. Available: https://dev-new-aws-os.pantheonsite.io/hospitals.

xi Centers for Medicare & Medicaid Services, "Publication #100-07 State Operations Manual." [Online]. Available: https://www.cms.gov/files/document/r210soma.pdf.

xii Centers for Medicare & Medicare Services, "Hospital Quality Improvement Contractors (HQICs): Your Quality Improvement Leaders for Acute Care." [Online]. Available: <a href="https://qualityimprovementcollaborative.org/docs/cms">https://qualityimprovementcollaborative.org/docs/cms</a> hqic fact sheet.pdf.
xiii Centers for Medicare & Medicaid Services, "Critical Access Hospitals." [Online]. Available: https://www.cms.gov/medicare/health-safety-standards/certification-compliance/critical-access-hospitals.

- <u>Medicare Other Acute Care Hospitals</u> consist of all other acute care hospitals that accept Medicare.
- Twenty-two acute care hospitals receiving services through the <u>Indian Health Service</u> (IHS).xiv

The estimates for this report are based on annual samples of medical records from four of the five hospital cohorts noted above: RURAL, TARGETED URBAN, CRITICAL ACCESS, and OTHER. While records from IHS hospitals were abstracted using the QSRS, information from these hospitals was excluded from this report due to differences in sampling strategies and the low number of hospitals in the IHS cohort.\*\*

For the hospital cohorts included in this report, CMS implemented a stratified, two-stage cluster sampling design. First, hospitals were stratified by cohort, and hospitals were selected using probability proportional to size (PPS) sampling within each cohort. Second, within each selected hospital, patient medical records were selected using simple random sampling. Total sample size per hospital was set at 40 per year (i.e., 10 per quarter) to minimize hospital burden, given that collection is not voluntary. Total sample sizes were determined by CMS' available budget each year.

The sampling frame includes all discharges by Medicare beneficiaries 18 years and older from acute care hospitals (excluding children's hospitals, cancer hospitals, inpatient psychiatric facilities, and long-term care facilities). The data are derived from the National Claims History Part A inpatient claims database. The hospital selection process begins with the exclusion of ineligible hospitals. Only acute care hospitals are included; other facilities such as children's hospitals, cancer hospitals, inpatient psychiatric facilities, and long-term care facilities are all excluded. Among acute care hospitals, excluded hospitals include those that closed, were selected for the Inpatient Quality Reporting Program, located in an area experiencing a natural disaster (known as a Federal Emergency Management Agency [FEMA] waiver), or those not designated in the IPPS.

The number of operating acute care hospitals at the time of sampling varied each year: 4,542 in 2021; 4,535 in 2022; and 4,334 in 2023. Of these, the number of hospitals excluded from the sampling frame due to participation in the Hospital Inpatient Quality Reporting program was 197 in 2021, 372 in 2022, and 190 in 2023. In 2021, 722 hospitals were selected for record abstraction. Of these, 113 were granted a FEMA waiver and did not provide hospital records for 1 or 2 months during the waiver period. Similarly, 138 of 1,125 hospitals sampled in 2022 did not submit records due to FEMA waivers. Sampled hospitals that closed or received a FEMA waiver were replaced with additional hospitals sampled from within the same cohort.

Table 2 shows a total of 22,678 records from 2021; 26,291 records from 2022; and 26,681 records from 2023 that were obtained and abstracted. The overall number of abstracted records increased each year from 2021 to 2023.

xiv Indian Health Service, "Indian Health Service: A Quick Look." [Online]. Available: https://www.ihs.gov/sites/newsroom/themes/responsive2017/display\_objects/documents/factsheets/QuickLook.pdf.

<sup>&</sup>lt;sup>xv</sup> For Indian Health Service Hospitals, a simple random sample of 100 Medicare beneficiary discharges each month is selected. In months where fewer than 100 Medicare beneficiaries receive acute inpatient care in an IHS hospital, all discharges were selected.

Table 2. Unweighted Number and Percentage of Sampled Records in QSRS, by Hospital Cohorts, for CY 2021, 2022, and 2023

	CY 2	2021	CY 2	2022	CY 2	2023
Hospital Cohort	Number of Records	Percentage of Records in Sample	Number of Records	Percentage of Records in Sample	Number of Records	Percentage of Records in Sample
RURAL	4,997	22.0%	5,246	20.0%	5,397	20.2%
TARGETED URBAN	4,922	21.7%	7,331	27.9%	7,411	27.8%
CRITICAL ACCESS	4,470	19.7%	5,287	20.1%	5,089	19.1%
OTHER	8,289	36.6%	8,427	32.1%	8,784	32.9%
Total	22,678		26,291		26,681	

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System (QSRS), 2021 to 2023. Abbreviations: CY, Calendar Year; QSRS, Quality and Safety Review System.

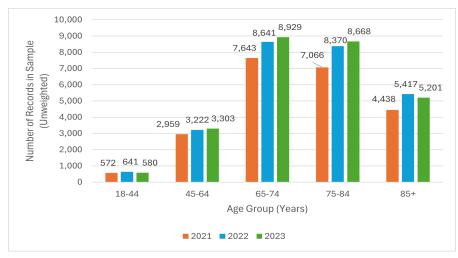
Additional information about the sample is available in "QSRS 2020–2024 Sampling Design and Weighting Methodology."xvi

#### **B.** Sample Characteristics

References below to the "QSRS sample" refer to the sample of 22,678 records of Medicare patients hospitalized in 2021, the sample of 26,291 records of Medicare patients hospitalized in 2022, and the sample of 26,681 records of Medicare patients hospitalized in 2023 in the following four hospital cohorts: RURAL, TARGETED URBAN, CRITICAL ACCESS, and OTHER.

Consistent with the distribution of age among Medicare beneficiaries, only about 15 percent of the QSRS sample of records were for Medicare patients between 18 and 64 years old (N=3,531 out of 22,678 records or 15.6% in 2021, N=3,863 out of 26,291 records or 14.7% in 2022, and N=3,883 out of 26,681 records or 14.6% in 2023).

Figure 1. Unweighted Sample Records Among Medicare Beneficiaries in QSRS by Patient Age, CY 2021 to 2023



Source: Agency for Healthcare Research and Quality, Quality and Safety Review System (QSRS), 2021 to 2023. Abbreviations: CY, Calendar Year; QSRS, Quality and Safety Review System.

xvi QSRS 2020–2024 Sampling Design and Weighting Methodology. AHRQ Publication No. 25-0072.

These patients likely reflect dually eligible beneficiaries, defined as:

...people enrolled in both Medicare and Medicaid who are eligible by virtue of their age or disability and low incomes. This is a diverse population that includes people with multiple chronic conditions, physical disabilities, mental illness, and cognitive impairments such as dementia and developmental disabilities. It also includes individuals who are relatively healthy. xvii

The remaining approximately 85 percent of the Medicare patients in the QSRS sample are 65 years old or over. Table 3 compares the demographic distribution of the 2021 QSRS sample of inpatient hospital records with the overall 2021 Medicare population.

With respect to patient sex in the QSRS sample, there are more records from female patients than male patients, similar to the overall Medicare enrollee population.

Table 3. Unweighted QSRS Sample Demographics Compared to Overall Medicare Population, 2021

Patient Demographic	Percentage of CY 2021 QSRS Sample (N=22,678)	Percentage of CY 2021 Medicare Population (N=63,555,949)
Age (years)		
18–64	15.6%	12.6%
65 and older	84.4%	87.4%
Sex		
Female	54.3%	54.4%
Male	45.7%	45.6%
Race/Ethnicity		
Non-Hispanic White	77.5%	72.8%
Black (or African American)	11.6%	10.5%
Hispanic	6.4%	9.7%
Asian/Pacific Islander	1.7%	3.7%
American Indian/Alaska Native	1.2%	0.4%
Other	0.6%	0.9%
Unknown	1.1%	2.0%

Source: Age and Sex data QSRS sample, Agency for Healthcare Research and Quality, Quality and Safety Review System, 2021; Race/Ethnicity data for QSRS sample, CMS Center for Clinical Standards and Quality; all patient demographic data for CY 2021 Medicare population, CMS, https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/cms- program-statistics-medicare-total-enrollment.

Abbreviations: CY, Calendar Year; QSRS, Quality and Safety Review System.

xvii Medicaid and CHIP Payment and Access Commission, "Dually Eligible Beneficiaries." [Online]. Available: <a href="https://www.macpac.gov/topic/dually-eligible-beneficiaries/">https://www.macpac.gov/topic/dually-eligible-beneficiaries/</a>.

Tables 4 and 5 provide information on length of stay and patients who died during their hospitalization. Of note, the death-during-stay information is derived from the discharge status for the records in the sample. This information is not connected to whether the patient was determined to have an AE during their hospitalization.

Table 4. Unweighted Length of Stay in the Sample of Records for Hospitalized Medicare Beneficiaries in the QSRS CY 2021 to 2023

Calendar Year	Mean Length of Stay (Days)	Standard Deviation	Median Length of Stay (Days)	25 <sup>th</sup> Percentile, 75 <sup>th</sup> Percentile
2021	5.4	5.5	4.0	2.0, 6.0
2022	5.5	5.8	4.0	2.0, 6.0
2023	5.3	6.0	4.0	2.0, 6.0

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2021 to 2023.

Abbreviations: CY, Calendar Year; QSRS, Quality and Safety Review System.

Table 5. Unweighted In-Hospital Deaths in the Sample of Records for Hospitalized Medicare Beneficiaries in the QSRS CY 2021 to 2023

Calendar Year	Number of In- Hospital Deaths (unweighted)	Number of Records (unweighted)	Percentage of In- Hospital Deaths	95% CI
2021	992	22,678	4.4%	4.1-4.6
2022	1,066	26,291	4.1%	3.8–4.3
2023	923	26,681	3.5%	3.2-3.7

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2021 to 2023. Abbreviations: CI, Confidence Interval; CY, Calendar Year; QSRS, Quality and Safety Review System.

# C. Estimating the Occurrence of Adverse Events in Medicare Hospital Stays

Sampled hospitalization records were abstracted by the CDAC using the QSRS tool. Based on these abstractions, the QSRS algorithms determine whether any of the specified adverse events occurred during that particular hospital stay. Patients may experience multiple AEs during their hospital stay; however, QSRS AE counts only reflect the count of AE types that occur during a stay and may not capture all the AEs that a patient experiences. This is because abstractors are instructed to only report the highest severity AE within a given AE type. In other words, the QSRS may show that several different AEs occurred during a single hospital stay (e.g., a fall and hospital-acquired pneumonia). However, the QSRS would not show two or more of the same AE for the same patient during a single hospitalization (e.g., two or more falls).

Exports of QSRS data for 2021 through 2023 were prepared and provided to a data analytics team, who provided a quality check of QSRS data and calculated the weighted AE estimates according to the methods described below.

This report highlights two weighted composite estimates of AEs overall. The first is the percentage of Medicare hospital stays with at least one AE identified by the QSRS (i.e., any of the AEs collected in QSRS). This percentage is calculated by taking the number of hospital stays with at least one AE, dividing it by the total number of hospital stays, and multiplying that by 100. The second is the total number of AEs per 1,000 discharges. This rate is calculated by taking the total number of identified AEs, dividing by the total number of discharges, and multiplying this number by 1,000.

In some cases, more than one AE type was identified during a single hospital stay for a patient. Table 6 provides more information on the number of AEs per stay based on combined unweighted data across all four hospital cohorts. The percentage was calculated by dividing the number of hospital stays where the AEs were identified by the total number of hospital stays (22,678 in 2021; 26,291 in 2022; and 26,681 in 2023).

Table 6. Unweighted Number and Percent of Hospital Stays with an AE Among the Sample of Records in the QSRS, CY 2021 to 2023

	CY 20	)21	CY 20	022	CY 2	2023
Number of Adverse Events (AEs)	Number of Hospital Stays With an AE (unweighted)	Percentage of All Hospital Stays (unweighted)	Number of Hospital Stays With an AE (unweighted)	Percentage of All Hospital Stays (unweighted)	Number of Hospital Stays With an AE (unweighted)	Percent of All Hospital Stays (unweighted)
Stays with one or more AE type	1,444	6.4%	1,511	5.7%	1,242	4.7%
Stays with 1 AE type	1,250	5.5%	1,314	5.0%	1,114	4.2%
Stays with 2 AE types	167	0.7%	161	0.6%	107	0.4%
Stays with 3 or more AE types	27	0.1%	36	0.1%	21	0.1%

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2021 to 2023. Abbreviations: AE, Adverse event; CY, Calendar Year; QSRS, Quality and Safety Review System.

Further analyses of categories of and individual AEs are included to provide insight into events that drive the overall weighted composite rates. Table A1 in Appendix 1 outlines all the AEs identified with their corresponding module in the QSRS. The Common Formats for Surveillance – Hospitals includes further information on how each event is defined. It should be noted that the sample did not include any neonatal or pediatric patients, so while the QSRS can capture neonatal birth events and pediatric seizures, these AEs are not included in this report. In addition, while the hospital stays captured in 2021 through 2023 did include maternal birth events, the total population at risk included fewer than 100 patients and less than 12 events were identified. These events did not meet reliability standards for publication.

Table 7 provides the distribution of AE categories (QSRS topic-area modules) for 2021, 2022, and 2023. The percentages shown are based on combined unweighted data across all four hospital cohorts. Medication events, pressure injuries/ulcers, and hospital-acquired infections accounted for approximately 80 percent of all AEs observed across all 3 years (79.5% in 2021, 81.0% in 2022, and 82.3% in 2023).

Table 7. Unweighted Number and Percentage of AEs Observed in the Sample Discharge Records in QSRS by Category, CY 2021 to 2023

	CY	2021	CY 2	2022	CY 2	CY 2023		
Category	AEs Observed	Percentage of AEs Observed (unweighted)	Number of AEs Observed (unweighted)	Percentage of AEs Observed (unweighted)	Number of AEs Observed (unweighted)	Percentage of AEs Observed (unweighted)		
Blood or Blood Product	37	2.2%	15	0.9%	17	1.2%		
Fall	124	7.4%	132	7.5%	100	7.2%		
Hospital-Acquired Infections (HAIs)	319	19.0%	319	18.2%	260	18.6%		
Medication	511	30.5%	543	31.0%	413	29.5%		
Pressure Injury/Ulcer	502	30.0%	558	31.8%	478	34.2%		
Surgery or Anesthesia	79	4.7%	77	4.4%	54	3.9%		
Venous Thromboembolism	65	3.9%	69	3.9%	41	2.9%		
Other AEs	39	2.3%	39	2.2%	35	2.5%		
All AEs	1,676		1,752		1,398			

Note: Sum of AEs shown exceeds total number of hospitalizations as multiple AEs may occur during a hospital stay. Birth–Maternal module not included as it did not meet standards for publication.

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2021 to 2023.

Abbreviations: AE, Adverse event; CY, Calendar Year; QSRS, Quality and Safety Review System.

#### D. Weighting Methodology

CMS' current sampling plan for the hospital cohorts does not reflect the true percentage of these hospital cohorts in the United States. For the reported AE estimates to be more nationally representative of hospitalized Medicare patients, a weighting strategy was developed to account for the over- or underrepresentation of the hospital types included in the sample to ensure that estimates are not affected by variation across years in:

- 1. The percentage of patients in the samples of records representing each of the hospital cohorts
- 2. The monthly and total number of discharges for each hospital
- The number of hospitals sampled due to natural disasters or other emergency waivers or changes in CMS priorities and/or budgetary considerations

The weights applied to the estimates in this report account for the above issues and consider the exact probability of a given hospital and the associated number of records selected and available for a given month. In addition, the weights account for nonresponse bias and differences between the final sample distribution and the target population distribution. Monthly weighted rates are combined to provide an annual weighted rate. SAS® code was created to deploy the weighting methodology. Additional information about the weighting methodology is available in "QSRS 2020–2024 Sampling Design and Weighting Methodology."xviii

xviii QSRS 2020–2024 Sampling Design and Weighting Methodology. AHRQ Publication No. 25-0072.

#### E. Reporting of Rates and Statistical Testing for Comparisons

The relative standard error (RSE)—the standard error of a weighted rate divided by the estimate itself—was used to determine the reliability of AE rates. AE rates with an RSE less than 0.30 (30%) and based upon at least 12 patient records and a population at risk of at least 100 were considered reliable for publishing. Differences in estimates were considered statistically significant where confidence intervals did not overlap.

## IV. Findings

#### A. 2021 Findings From the QSRS

Overall, after accounting for weighting of the hospital cohorts, analyses showed that in 7.1 percent of the sampled records from Medicare patients in 2021, at least one AE occurred during the stay (Table 8). Among the four cohorts, the CRITICAL ACCESS cohort had the lowest occurrence of AEs (3.4%). The weighted number of AEs per 1,000 discharges followed the same pattern, which resulted in a weighted rate of 83.1 AEs per 1,000 discharges.

Table 8. Weighted Estimates of Hospitalizations With AEs Among Medicare Patients in QSRS, CY 2021

			Medicare Patients With at Least One AE  During Hospitalization				AEs Per 1,000 Discharges for Medicare Patients			
Cohorts	Weighted Number of Hospitalizations	Weighted Number of Hospitalizations With at Least One AE	Rate (%)	95% CI	RSE (%)	Weighted Number AEs	Rate per 1,000 Discharges	95% CI	RSE (%)	
RURAL	810,179	51,066	6.3	5.6-7.0	5.7	57,795	71.3	63.0-79.7	6.0	
TARGETED URBAN	1,248,604	108,638	8.7	7.4–10.0	7.7	133,029	106.5	87.4–125.7	9.0	
CRITICAL ACCESS	226,345	7,583	3.4	2.7–4.0	10.0	8,377	37.0	29.6–44.4	10.2	
OTHER	6,846,276	480,519	7.0	6.4-7.6	4.5	559,784	81.8	74.1–89.5	4.8	
Total	9,131,405	647,806	7.1	6.6–7.6	3.6	758,984	83.1	76.7–89.5	3.9	

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2021.

Abbreviations: AE, Adverse event; CY, Calendar Year; CI, Confidence Interval; QSRS, Quality and Safety Review System; RSE, Relative Standard Error.

#### B. 2022 Findings From the QSRS

Overall, after accounting for weighting of the hospital cohorts, analyses showed that in 6.2 percent of the sampled records from Medicare patients in the 2022 QSRS sample, at least one AE occurred during the stay (Table 9). Among the four cohorts, the CRITICAL ACCESS cohort had the lowest occurrence of AEs (3.2%). The number of AEs per 1,000 discharges followed the same pattern, which resulted in a weighted rate of 70.8 AEs per 1,000 discharges.

Table 9. Weighted Estimates of Hospitalizations With AEs Among Medicare Patients in QSRS, CY 2022

			Medicare Patients With at Least One AE  During Hospitalization				1,000 Dischar	ges for Medicar	e Patients
Cohorts	Weighted Number of Hospitalizations	Weighted Number of Hospitalizations With at Least One AE	Rate (%)	95% CI	RSE (%)	Weighted Number AEs	Rate per 1,000 Discharges	95% CI	RSE (%)
RURAL	827,469	44,198	5.3	4.7-5.9	5.7	50,913	61.5	54.1-69.0	6.3
TARGETED URBAN	933,254	67,755	7.3	6.6–7.9	4.3	81,753	87.6	79.3–95.9	4.8
CRITICAL ACCESS	220,282	6,957	3.2	2.7–3.6	7.9	7,632	34.6	29.0–40.3	8.4
OTHER	7,483,335	467,669	6.2	5.7-6.8	4.4	529,768	70.8	64.4-77.2	4.6
Total	9,464,341	586,580	6.2	5.8–6.6	3.5	670,065	70.8	65.6–76.0	3.7

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2022.

Abbreviations: AE, Adverse event; CY, Calendar Year; CI, Confidence Interval; QSRS, Quality and Safety Review System; RSE, Relative Standard Error.

# C. 2023 Findings From the QSRS

Overall, after accounting for weighting of the hospital cohorts, analyses showed that in 5.2 percent of the sampled records from Medicare patients in the 2023 QSRS sample, at least one AE occurred during the stay (Table 10). Among the four cohorts, the CRITICAL ACCESS cohort had the lowest occurrence of AEs (2.3%). The number of AEs per 1,000 discharges followed the same pattern, which resulted in a weighted rate of 59.4 AEs per 1,000 discharges.

Table 10. Weighted Estimates of Hospitalizations With Adverse Events Among Medicare Patients in QSRS, CY 2023

			Medicare Patients With at Least One AE  During Hospitalization				AEs Per 1,000 Discharges for Medicare Patients			
Cohorts	Weighted Number of Hospitalizations	Weighted Number of Hospitalizations With at Least One AE	Number of Hospitalizations With at Least Rate (%) 95% CI RSE			Weighted Number AEs	Rate per 1,000 Discharges	95% CI	RSE (%)	
RURAL	815,569	35,561	4.4	3.8-4.9	6.5	38,402	47.1	40.9–53.3	6.7	
TARGETED URBAN	983,442	56,407	5.7	5.2-6.3	4.9	64,599	65.7	58.9–72.5	5.3	
CRITICAL ACCESS	202,847	4,614	2.3	1.7-2.8	12.1	4,839	23.9	18.2–29.5	12.0	
OTHER	7,891,723	420,605	5.3	4.8-5.8	4.7	479,876	60.8	54.9–66.7	5.0	
Total	9,893,581	517,187	5.2	4.8–5.6	3.9	587,716	59.4	54.6–64.2	4.1	

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2023.

Abbreviations: AE, Adverse event; CY, Calendar Year; CI, Confidence Interval; QSRS, Quality and Safety Review System; RSE, Relative Standard Error.

#### **D.** Comparisons

Table 11 shows that the composite AE rates have significantly declined from 2021–2023, both in terms of patients experiencing at least one AE and the AEs per 1,000 discharges.

Table 11. Comparison of CY 2021 – 2023 Overall Weighted Composite AE Rates

		Medicare Patients W During Hosp		AEs Per 1,000 Discharges			
	Weighted Number of Hospitalizations	Weighted Number of Hospitalizations With at Least One AE	Rate (%)	95% CI	Weighted Number AEs	N per 1,000 discharges	95% CI
CY 2021	9,131,405	647,806	7.1	6.6–7.6	758,984	83.1	76.7– 89.5
CY 2022	9,464,341	586,580	6.2	5.8–6.6	670,065	70.8	65.6– 76.0
CY 2023	9,893,581	517,187	5.2	4.8-5.6	587,716	59.4	54.6– 64.2

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2021–2023.

Abbreviations: AE, Adverse event; CY, Calendar Year; CI, Confidence Interval.

Figure 2 displays, by category (QSRS topic-area module), for 2021 through 2023, the weighted AEs per 1,000 stays where the patient was at risk for the AE. For each category, the weighted number of AEs was divided by the total number of hospital stays where the patient was at risk for the AEs in that category. For example, while all patients are considered at risk for experiencing a fall during their hospitalization, only those patients who undergo certain procedures are considered at risk for a surgery or anesthesia event. The data shown are based on combined weighted data across all four hospital cohorts. In all categories, the number of AEs per 1,000 discharges was lower in 2023 compared with 2021. Further information is available in Table A3.

<sup>-</sup>

xix Section 2.1 of the "Event Description Overview and Application Guide: AHRQ Common Formats for Surveillance – Hospital Version 1.0R" provides more information on the populations at risk (denominators) for the AE calculations. Available at: <a href="https://www.psoppc.org/psoppc">https://www.psoppc.org/psoppc</a> web/DLMS/downloadDocument?groupId=2493&pageName=surveillance%20common%20formats.

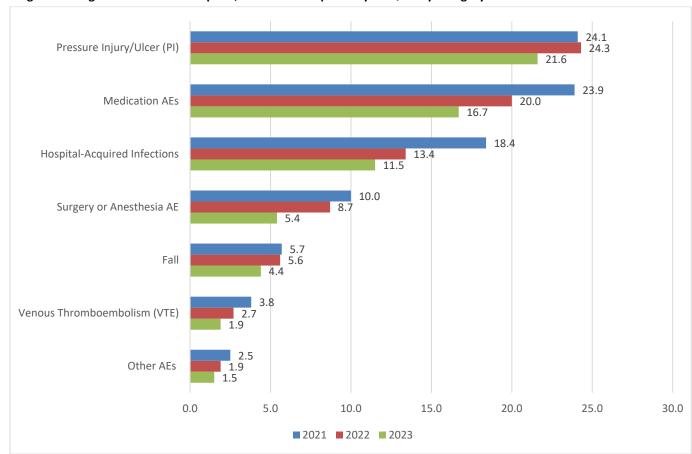


Figure 2. Weighted Number of AEs per 1,000 At-Risk Hospital Stays in QSRS by Category in CY 2021–2023

Note: Birth–Maternal and Blood or Blood Product modules excluded due to RSE above the 30 percent threshold for statistical reliability. Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2021–2023.

Abbreviations: AE, Adverse event; CY, Calendar Year; QSRS, Quality and Safety Review System.

#### V. Discussion

#### A. AEs Among Medicare Patients, 2021 to 2023

Encouragingly, the above findings suggest that both the percentage of Medicare patients experiencing an AE during a hospital stay and the number of AEs per 1,000 discharges for 2022 and 2023 are lower than in the prior year. Of significance, the weighted rate of Medication AEs (23.9 to 16.7) and HAIs (18.4 to 11.5) per 1,000 at-risk hospitalizations notably decreased from 2021 to 2023 (Table A3).

Pressure injury/ulcers, medication events, and hospital-acquired infections (HAIs) accounted for the majority of AEs in the QSRS sample. In particular, medication-related AEs accounted for approximately a third of AEs observed, which is consistent with research indicating that these events are among the largest contributors to hospital-related complications and most frequent hospital AEs<sup>xx</sup>. Similarly, the proportion of HAIs observed (approximately 18–19%) in 2021, 2022, and 2023 is consistent with the Office of Inspector General's (OIG) report on AEs among Medicare patients during October 2018<sup>xxi</sup>. The proportion of pressure injuries/ulcers observed in 2021 (30.0%), 2022 (31.8%), and 2023 (34.2%) were both considerably higher than the prevalence of pressure injuries observed in the OIG report, but the OIG report only considered severe pressure injuries (Stage 3, Stage 4, and unstageable) and used data from an unweighted sample from October 2018.

The CRITICAL ACCESS cohort had the lowest occurrence of AEs in each of the 3 years. This may in part relate to the transfer of certain patients from CRITICAL ACCESS hospitals to other facilities for highly specialized care (e.g., patients requiring an intensive care unit). Patients requiring a higher level of care may be at an increased risk of experiencing an adverse event. If such patients experienced an adverse event after transfer, it would not be attributed to the CRITICAL ACCESS hospital.

#### **B.** Limitations

These findings may not be representative of, and should not be extrapolated to, the entire population of patients hospitalized in the United States in 2021, 2022, or 2023. Per the sampling methodology for the inpatient hospitalization records as defined by CMS, records were drawn from a hospital encounter database for only Medicare beneficiaries. By definition, only Medicare beneficiaries with Part A coverage are included in this database, which includes about 99 percent of all Medicare beneficiaries. The occurrence of the AEs specified in the QSRS may be different among patients with other insurance types. The sample is also not necessarily geographically representative as hospital location within the United States is not a sampling criterion.

xx Office of Disease Prevention and Health Promotion, "National Action Plan for Adverse Drug Event Prevention," United States Department of Health and Human Services, Washington, DC, 2014. Available at: https://odphp.health.gov/sites/default/files/2019-09/ADE-Action-Plan-508c.pdf.

xxi Office of Inspector General, "Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018," U.S. Department of Health and Human Services, Washington, DC, 2022. Available at: <a href="https://oig.hhs.gov/reports/all/2022/adverse-events-in-hospitals-a-quarter-of-medicare-patients-experienced-harm-in-october-2018/">https://oig.hhs.gov/reports/all/2022/adverse-events-in-hospitals-a-quarter-of-medicare-patients-experienced-harm-in-october-2018/</a>.

In addition, no records were obtained from patients under 18, who may experience AEs differently than the adult Medicare population. While demographic information about the patient population is presented above, the findings in this report have not been adjusted to reflect patient characteristics or other potential confounding variables.

While the QSRS was designed to capture the vast majority of AEs occurring during inpatient hospitalizations, these findings should not be interpreted as reflecting all possible AEs that may have occurred during the reviewed hospital stays. The QSRS primarily is used to identify the specific events listed in Appendix 1.

Additional possible AEs may not be accounted for in the QSRS, such as those that are not compatible with the abstraction method used in the QSRS and those that would not be discernible from review of the inpatient hospitalization record (e.g., those that manifest after the patient is discharged from the hospital).

# Appendix A. AEs Collected in the QSRS, 2021 to 2023

Table A1 further describes the information within QSRS and how it is organized. Similar AEs are grouped together by topic area (module). Many AEs reflect a single outcome (e.g., hospital-acquired pneumonia) whereas other AEs combine several outcomes into one AE type. The AE column in the table shows where multiple outcomes have been combined into one AE. Where the AE column is blank, the outcome and the AE are the same.

Table A1. QSRS Adverse Events by Module

1. Birth–Maternal R		Outcome
		Antibiotic administration more than 24 hours
N	Maternal AE including all 8	following term vaginal birth
0	outcomes	Eclampsia
		Fetal death after admission: related to labor and
		delivery and not expected
		Hemorrhage requiring transfusion
		Infection not present on admission (Chorioamnionitis
		or Endometritis)
		Injury to other body part or organ during labor or birth
		Maternal death
		Third- or fourth-degree perineal laceration
2. Birth–Neonatal* R	Reflected as one Birth-	Abduction of neonate
l N	Neonatal AE including all	Anoxic or hypoxic-ischemic encephalopathy
1	10 outcomes	Five-minute Apgar < 7 when birthweight > 2,500 grams
		Injury to brachial plexus, including Erb's or Klumpke's
		paralysis
		Infection
		Massive aspiration syndrome or meconium aspiration
		syndrome
		Neonate death: related to labor and delivery and not
		expected
		Seizures
		Severe hyperbilirubinemia
		Subdural or cerebral hemorrhage
3. Blood or Blood R	Reflected as one Blood or	Administration of incompatible ABO type
Product B	Blood Product AE including	Transfusion reaction coded
a	all 3 outcomes	Transfusion reaction notated
4. Fall		Assisted Fall
		Unassisted Fall
5. Hospital-Acquired		Catheter-associated urinary tract infection (CAUTI)
Infections (HAI)		Central line-associated bloodstream infection (CLABSI)
, ,		, ,
		Clostridioides difficile infection (CDI)
		Coronavirus (COVID-19)
		Pneumonia
		Surgical site infection (SSI) following operating room
		Procedures
		Urinary tract infection (UTI); not catheter-associated

Module	Adverse Event (AE)	Outcome
6. Medication		Anticoagulant event—Intravenous unfractionated
		heparin event
		Anticoagulant event—Warfarin event
		Anticoagulant event—Low molecular weight heparin, thrombin inhibitor, or factor Xa inhibitor
		AE associated with hypoglycemic agent
		AE within 24 hours following opioid administration
		Anaphylaxis
		Potential overdose
7. Pressure Injury/Ulcer (PI)		Advancing PI or secondary comorbidity in PI present on admission
		New PI
8. Surgery or Anesthesia	Reflected as one AE	Air or other gas embolus
	including all 22 outcomes	Burn or electric shock
		Cardiac or circulatory event during or within 48 hours of OR procedure or administration of anesthesia
		Central nervous system event (e.g., CVA, seizures, coma)
		Death during or shortly after anesthesia in ASA Class 1 patient
		Dehiscence, flap or wound failure or disruption, or graft failure
		Dental injury
		High spinal requiring intubation and/or assisted ventilation
		Incorrect OR procedure
		Injury to peripheral or cranial nerve or spinal cord; Malignant hyperthermia
		Ocular injury
		Peri-operative injury
		Post-dural puncture headache
		Respiratory failure indicated by unplanned respiratory support within 24 hours of OR procedure or administration of anesthesia
		Retained object(s)
		Unintended awareness (during general anesthesia)
		Unintended blockage, obstruction, or ligation
		Unintended iatrogenic pneumothorax
		Unintended laceration or puncture
		Unplanned conversion to general anesthesia
		Unplanned removal of normal organ
		Unplanned return to operating room
9. Venous Thromboembolism (VTE)		Deep-vein thrombosis (DVT) without pulmonary embolism (PE)
THIOTHDOETHDOHSHI (VIE)		PE without DVT
		Both DVT and PE developed during stay

Module	Adverse Event (AE)	Outcome
10. Other		AE attributed to failure to communicate laboratory,
		pathology, imaging, and physiologic test results
		AE due to the receipt of wrong, contaminated, or no
		anesthesia gas
		AE involving invasive, non-OR procedure – Incorrect
		non-OR procedure
		AE involving invasive, non-OR procedure – Laceration
		or unintended puncture
		AE involving invasive, non-OR procedure – Unintended
		iatrogenic pneumothorax
		AE related to a radiologic or imaging study, including
		radiation overdose, imaging procedure on wrong
		person or wrong body region, event related to
		introduction of inappropriate metallic object in MRI
		room, and other
		Intravascular air embolism during stay
		Irretrievable loss of irreplaceable biologic specimen
		Mechanical AE associated with central venous
		Catheter
		Non-OR related burn and electric shock events
		Patient attempted suicide
		Patient elopement
		Patient harmed from accident associated with bedrails
		(other than fall)
		Patient harmed from use of physical restraint (other
		than bedrails)
		Pediatric seizure*
		Unintended arterial puncture

Note: \*Not included in this report given sample limitations.

Abbreviations: ASA, American Society of Anesthesiologists; CVA, Cerebrovascular Accident; OR, Operating Room; QSRS, Quality and Safety Review System.

Table A2. Occurrences To Be Monitored in QSRS-Not Treated as AEs

Module	Occurrences To Be Monitored			
1. Birth–Maternal	Patients with other maternal outcome(s) during stay			
2. Birth–Neonatal	Other birth injury			
3. Blood or Blood Product	Treatment suggestive of transfusion reaction			
4. Device	Stay during which one or more occurrences associated with the use of a device Occurred			
5. Hospital-Acquired Infections (HAI)	Stay with other HAI			
6. Medication	Other medication event identified by abstractor			
7. Other	Other occurrences			
	Renal failure			
	Unplanned transfer			
	Ventilator support (non-OR)			
8. Surgery or Anesthesia	Other anesthesia events			
	Other complications manifested post-op			
	Other major complications associated with either surgery or anesthesia			
	Other unplanned returned to OR			

Note: Not every module has occurrences to be monitored; those modules without any have been omitted from Table A2. At this time, the Device module only includes occurrences to be monitored and does not appear in Table A1. Abbreviations: Operating Room; QSRS, Quality and Safety Review System.

# **Appendix B. Additional Data Analyses of QSRS AEs**

Table A3. Weighted Number of AEs per 1,000 At Risk Hospital Stays in QSRS by Category in CY 2021–2023

AE Module		2021			2022			2023	
	N per 1,000 At- Risk Hospital Stays	95% CI	RSE (%)	N per 1,000 At- Risk Hospital Stays	95% CI	RSE (%)	N per 1,000 At- Risk Hospital Stays	95% CI	RSE (%)
Blood or Blood Product	14.8	8.4– 21.1	22.0	*	*	*	*	*	*
Fall	5.7	4.4-7.1	12.3	5.6	4.2-6.9	12.2	4.4	3.3-5.6	13.0
Hospital-Acquired Infections	18.4	15.6– 21.2	7.6	13.4	11.3– 15.5	8.1	11.5	9.6– 13.4	8.4
Medication AEs	23.9	21.0– 26.9	6.2	20.0	17.6– 22.3	6.0	16.7	14.5– 18.8	6.6
Pressure Injury/Ulcer	24.1	21.2– 27.0	6.2	24.3	21.6– 27.1	5.8	21.6	18.9– 24.2	6.3
Surgery or Anesthesia AE	10.0	7.3– 12.8	13.9	8.7	6.1– 11.3	15.4	5.4	3.4–7.3	18.6
Venous Thromboembolism	3.8	2.6-5.0	16.2	2.7	1.8-3.6	17.4	1.9	1.1–2.7	20.6
Other AEs	2.5	1.5-3.4	19.0	1.9	1.1-2.7	21.9	1.5	0.8-2.2	22.5

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2021 to 2023.

Abbreviations: AE, Adverse event; CY, Calendar Year; CI, Confidence Interval; RSE, Relative Standard Error; QSRS, Quality and Safety Review System.

Note: Birth–Maternal module excluded and Blood or Blood Product module suppressed due to RSE above the 30 percent threshold for statistical reliability.

Table A4. Weighted Number of Individual AEs per 1,000 At Risk Hospital Stays in QSRS, CY 2021

AE	Weighted	Weighted	N per 1,000 At	95% CI	RSE (%)
	Number of AEs	Number of At-	Risk Hospital		
	(N)	Risk Stays	Stays		
Birth-Maternal	*	*	*	*	≥ 30
Blood or Blood Product	17,285	1,170,894	14.8	8.4-21.1	22.0
Fall	52,370	9,131,405	5.7	4.4-7.1	12.3
Hospital-Acquired Infections					
Catheter-associated urinary tract infection	*	*	*	*	≥ 30
Clostridioides difficile infection	24,003	8,248,777	2.9	1.9-3.9	18.1
Central line-associated					
bloodstream infection	17,918	1,124,692	15.9	9.5–22.4	20.6
Hospital-acquired COVID-19	*	*	*	*	≥ 30
Hospital-acquired pneumonia (HAP)	89,384	8,248,777	10.8	8.9–12.8	9.1
Surgical site infection	*	*	*	*	≥ 30
Urinary tract infections	*	*	*	*	≥ 30

AE	Weighted Number of AEs (N)	Weighted Number of At- Risk Stays	N per 1,000 At Risk Hospital Stays	95% CI	RSE (%)
Medication AEs	, ,	,			
Anticoagulant Events	54,208	4,919,429	11.0	8.4–13.6	12.1
Intravenous unfractionated	3 1,233	1,0 20,120			
heparin event	35,478	819,019	43.3	30.6-56.0	14.9
Warfarin event	*	*	*	*	≥ 30
Low molecular weight heparin, thrombin inhibitor, or factor Xa inhibitor	16,731	4,301,425	3.9	2.3–5.5	20.5
Hypoglycemic Events					
Opioid Events	148,673	3,094,356	48.0	41.3–54.8	7.1
•	13,635	5,150,070	2.6	1.5–3.8	22.9
Anaphylaxis	*	*	*	*	≥ 30
Potential Overdoses	*	*	*	*	≥ 30
Pressure Injury/Ulcer (PI)	220,099	9,131,405	24.1	21.2-27.0	6.2
New PI	176,843	9,131,405	19.4	16.8–21.9	6.8
Advancing PI or complication in PI present on admission	43,256	859,323	50.3	37.0–63.7	13.5
Surgery or Anesthesia AE	39,316	3,913,839	10.0	7.3–12.8	13.9
Venous Thromboembolism				2.6–5.0	
Deep vein thrombosis (DVT) without pulmonary embolism (PE)	33,273	8,694,893	3.8		16.2
PE without DVT	23,561	8,694,893 *	2.7	1.7–3.8	19.9
		т	*	т	≥ 30
Both DVT and PE developed during stay	*	*	*	*	≥ 30
Other AEs					
AE attributed to failure to communicate laboratory, pathology, imaging, and physiologic test results	0	9,131,405	0.0	N/A	N/A
AE due to the receipt of wrong, contaminated, or no anesthesia gas	0	9,131,405	0.0	N/A	N/A
AE related to a radiologic or imaging study	*	*	*	*	≥ 30
Incorrect non-OR procedure	0	9,131,405	0.0	N/A	N/A
Intravascular air embolism during stay	*	*	*	*	≥ 30
Irretrievable loss of irreplaceable biologic specimen	*	*	*	*	≥ 30
Laceration or unintended puncture	*	*	*	*	≥ 30
Mechanical AE associated with central venous catheter	*	*	*	*	≥ 30
Non-OR-related burn or electric shock events	*	*	*	*	≥ 30
Patient attempted suicide	*	*	*	*	≥ 30
Patient elopement	*	*	*	*	≥ 30

AE	Weighted Number of AEs (N)	Weighted Number of At- Risk Stays	N per 1,000 At Risk Hospital Stays	95% CI	RSE (%)
Patient harmed from accident associated with bedrails (other					
than fall)	*	*	*	*	≥ 30
Patient harmed from use of physical restraint (other than					
bedrails)	0	9,131,405	0.0	N/A	N/A
Unintended arterial puncture	10,034	1,151,272	8.7	3.7-13.7	29.2
Unintended iatrogenic pneumothorax	*	*	*	*	≥ 30

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2021.

Abbreviations: AE, Adverse event; CY, Calendar Year; CI, Confidence Interval; N/A, not applicable; QSRS, Quality and Safety Review System; RSE, Relative Standard Error.

Note: Data not reported where RSE  $\geq$  30%.

Table A5. Weighted Number of Individual AEs per 1,000 At Risk Hospital Stays in QSRS, CY 2022

AE	Weighted Number of AEs (N)	Weighted Number of At- Risk Stays	N per 1,000 At- Risk Hospital Stays	95% CI	RSE (%)
Birth–Maternal	0	5,290	0.0	N/A	N/A
Blood or Blood Product	*	*	*	*	≥ 30
Fall	52,608	9,464,341	5.6	4.2-6.9	12.2
Hospital-Acquired Infections					
Catheter-associated urinary tract infection	*	*	*	*	≥ 30
Clostridioides difficile infection	19,441	8,517,084	2.3	1.4-3.1	18.6
Central line-associated bloodstream infection	16,948	933,179	18.2	10.7–25.6	21.0
Hospital-acquired COVID-19	*	*	*	*	≥ 30
Hospital-acquired Pneumonia (HAP)	56,862	8,517,084	6.7	5.2-8.2	11.4
Surgical site infection	*	*	*	*	≥ 30
Urinary tract infection	11,356	8,517,084	1.3	0.7-2.0	26.0
Medication AEs					
Anticoagulant Events	36,720	5,011,345	7.3	5.4-9.3	13.6
Intravenous unfractionated heparin event	21,679	811,731	26.7	17.3–36.1	18.0
Warfarin event	*	*	*	*	≥ 30
Low molecular weight heparin, thrombin inhibitor, or factor Xa					
inhibitor	12,957	4,439,377	2.9	1.7-4.2	22.2
Hypoglycemic Events	137,463	3,145,634	43.7	37.7–49.7	7.0
Opioid Events	14,587	5,234,014	2.8	1.6-4.0	22.3
Anaphylaxis	*	*	*	*	≥ 30
Potential Overdoses	0	9,464,341	0.0	N/A	N/A

AE	Weighted Number of AEs (N)	Weighted Number of At- Risk Stays	N per 1,000 At- Risk Hospital Stays	95% CI	RSE (%)
Pressure Injury/Ulcer (PI)	230,076	9,464,341	24.3	21.6–27.1	5.8
New PI	182,729	9,464,341	19.3	16.8–21.8	6.7
Advancing PI or complication	202). 20	37.6.75.2	23.0	20.0 22.0	0.7
in PI present on admission	47,347	761,699	62.2	47.3-77.0	12.2
Surgery or Anesthesia AE	34,666	3,984,816	8.7	6.1–11.3	15.4
Venous Thromboembolism	24,659	9,135,152	2.7	1.8-3.6	17.4
Deep vein thrombosis (DVT)					
without pulmonary					
embolism (PE)	15,254	9,135,152	1.7	1.0-2.3	20.7
PE without DVT	*	*	*	*	≥ 30
Both DVT and PE developed					
during stay	*	*	*	*	≥ 30
Other AEs					
AE attributed to failure to communicate laboratory,					
pathology, imaging, and physiologic test results	*	*	*	*	≥ 30
AE due to the receipt of					2 30
wrong, contaminated, or no					
anesthesia gas	*	*	*	*	≥ 30
AE related to a radiologic or					
imaging study	0	9,464,341	0.0	N/A	N/A
Incorrect non-OR procedure	*	*	*	*	≥ 30
Intravascular air embolism					
during stay	*	*	*	*	≥ 30
Irretrievable loss of					
irreplaceable biologic					
specimen	0	9,464,341	0.0	N/A	N/A
Laceration or unintended		_		_	
puncture	*	*	*	*	≥ 30
Mechanical AE associated	*	*	*	*	> 20
with central venous catheter  Non-OR-related burn or		*		*	≥ 30
electric shock events	0	9,464,341	0.0	N/A	N/A
Patient attempted suicide	0				N/A
Patient elopement	*	9,464,341	0.0	N/A *	
	<u> </u>	*		*	≥ 30
Patient harmed from accident associated with					
bedrails (other than fall)	*	*	*	*	≥ 30
Patient harmed from use of					
physical restraint (other than					
bedrails)	*	*	*	*	≥ 30
Unintended arterial puncture	*	*	*	*	≥ 30
Unintended iatrogenic					
pneumothorax	*	*	*	*	≥ 30

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2022.

Abbreviations: AE, Adverse event; CY, Calendar Year; CI, Confidence Interval; QSRS, Quality and Safety Review System; RSE, Relative Standard Error.

Note: Data not reported where RSE  $\geq$  30%.

Table A6. Weighted Number of Individual AEs per 1,000 At-Risk Hospital Stays in QSRS, CY 2023

AE	Weighted Number of AEs (N)	Weighted Number of At- Risk Stays	N per 1,000 At- Risk Hospital Stays	95% CI	RSE (%)
Birth-Maternal	*	*	*	*	≥ 30
Blood or Blood Product	*	*	*	*	≥ 30
Fall	43,946	9,893,581	4.4	3.3 – 5.6	13.0
Hospital-Acquired Infections					
Catheter-associated urinary					
tract infection	*	*	*	*	≥ 30
Clostridioides difficile					
infection	10,175	8,848,485	1.1	0.6 – 1.7	24.4
Central line-associated					
bloodstream infection	*	*	*	*	≥ 30
Hospital-acquired COVID-19	*	*	*	*	≥ 30
Hospital-acquired pneumonia					
(HAP)	71,279	8,848,485	8.1	6.4 – 9.7	10.3
Surgical site infection	*	*	*	*	≥ 30
Urinary tract infection	7,981	8,848,485	0.9	0.4 - 1.4	28.6
Medication AEs					
Anticoagulant Events	20,194	5,269,466	3.8	2.3 – 5.3	19.8
Intravenous unfractionated	,	, ,			
heparin event	12,165	838,277	14.5	7.0 – 22.0	26.3
Warfarin event	*	*	*	*	≥ 30
Low molecular weight heparin, thrombin inhibitor, or factor Xa inhibitor	*	*	*	*	≥ 30
Hypoglycemic Events	130,834	3,187,563	41.0	35.1 – 47.0	7.4
Opioid Events	12,471	5,471,055	2.3	1.3 – 3.3	23.0
Anaphylaxis	*	*	*	*	≥30
Potential Overdoses	0	9,893,581	0.0	N/A	N/A
Pressure Injury/Ulcer (PI)	213,460	9,893,581	21.6	18.9 – 24.2	6.3
New PI	183,382	9,893,581	18.5	16.1 – 21.0	6.8
Advancing PI or complication		2,222,222			
in PI present on admission	30,079	869,672	34.6	24.4 – 44.7	15.0
Surgery or Anesthesia AE	23,262	4,339,565	5.4	3.4 – 7.3	18.6
Venous Thromboembolism	18,219	9,579,302	1.9	1.1 – 2.7	20.6
Deep vein thrombosis (DVT) without pulmonary embolism		2,0.0,002		2.2 2.7	
(PE)	12,556	9,579,302	1.3	0.7 – 1.9	24.2
PE without DVT	*	*	*	*	≥ 30
Both DVT and PE developed during stay	*	*	*	*	≥ 30

AE	Weighted Number of AEs (N)	Weighted Number of At- Risk Stays	N per 1,000 At- Risk Hospital Stays	95% CI	RSE (%)
Other AEs					
AE attributed to failure to					
communicate laboratory,					
pathology, imaging, and					
physiologic test results	0	9,893,581	0.0	N/A	N/A
AE due to the receipt of					
wrong, contaminated, or no					
anesthesia gas	0	9,893,581	0.0	N/A	N/A
AE related to a radiologic or					
imaging study	*	*	*	*	≥ 30
Incorrect non-OR procedure	0	9,893,581	0.0	N/A	N/A
Intravascular air embolism					
during stay	*	*	*	*	≥ 30
Irretrievable loss of					
irreplaceable biologic					
specimen	0	9,893,581	0.0	N/A	N/A
Laceration or unintended					
puncture	*	*	*	*	≥ 30
Mechanical AE associated					
with central venous catheter	*	*	*	*	≥ 30
Non-OR-related burn or					
electric shock events	0	9,893,581	0.0	N/A	N/A
Patient attempted suicide	*	*	*	*	≥ 30
Patient elopement	*	*	*	*	≥ 30
Patient harmed from					
accident associated with					
bedrails (other than fall)	*	*	*	*	≥ 30
Patient harmed from use of					
physical restraint (other than					
bedrails)	*	*	*	*	≥ 30
Unintended arterial puncture	*	*	*	*	≥ 30
Unintended iatrogenic					
pneumothorax	*	*	*	*	≥ 30

Source: Agency for Healthcare Research and Quality, Quality and Safety Review System, 2023.

Abbreviations: AE, Adverse event; CY, Calendar Year; CI, Confidence Interval; QSRS, Quality and Safety Review System; RSE, Relative Standard Error.

Note: Data not reported where RSE  $\geq$  30%.