J Korean Med Sci. 2026 Oct 12;41(39):e301
https://doi.org/10.3346/jkms.2026.41.e301
eISSN 1598-6357·pISSN 1011-8934

JKMS

Original Article

Medicine General & Health Policy

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Incidence and Characteristics of Adverse Events: The 2024 Patient Safety Incidents Inquiry in Korea

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OPEN ACCESS

Received: Jul 4, 2026
Accepted: Jul 6, 2026
Published online: Aug 6, 2026

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ABSTRACT

Background: In accordance with Article 7-2 of the Patient Safety Act, the Ministry of Health and Welfare conducts a Patient Safety Incident Inquiry every 5 years to support patient safety policy. This study aimed to describe the methodology and main findings of the 2024 Patient Safety Incident Inquiry.
Methods: Ten Accountable Care Hospitals (five tertiary and five general hospitals) participated. From each hospital, 500 patients discharged in 2021 were randomly selected. A standardized three-stage retrospective medical record review was conducted: first-stage screening by nurses or health information managers, second-stage review and reporting of suspected adverse events by physicians or nurses, and final adjudication by a central expert committee.
Results: Of 5,000 patients, 2,208 (44.2%) met one or more the screening criteria. Following adjudication in the third review stage, confirmed adverse events were identified in 565 patients (11.3%), resulting in 612 confirmed adverse events. The most common type was patient care-related events (37.3%), followed by medication-/fluid-/blood-related (36.1%) and surgery-/procedure-related (26.8%) events. Temporary harm requiring intervention accounted for 62.4% of adverse events, and 3.6% of patients died. Prolonged hospitalization was associated with 36.3% confirmed adverse events, and 28.3% were classified as preventable. Variation in the incidence of confirmed adverse events across institutions was observed.
Conclusion: Using a standardized three-stage medical record review, the 2024 Patient Safety Incident Inquiry provides updated descriptive baseline data on confirmed adverse events across tertiary and general hospitals in Korea. These findings may support institutional patient safety improvement efforts and inform national patient safety planning.

Keywords: Patient Safety; Adverse Event; Medical Record Review; Medical Errors

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Funding
This research was funded by the Korea Institute for Healthcare Accreditation (KOIHA) in 2024.

Disclosure
The authors have no potential conflicts of interest to disclose.

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Conceptualization: Choi EY, Ock M, Central Patient Safety Center of the Korea Institute for Healthcare Accreditation. Data curation: Cho DB. Formal analysis: Cho DB. Funding acquisition: Ock M. Investigation: Cho DB, Lee W, Jang SG, Pyo J, Choi EY, Ock M. Methodology: Cho DB, Lee W, Jang SG, Pyo J, Choi EY, Ock M. Project administration: Cho DB, Pyo J, Ock M. Supervision: Choi EY, Ock M, Central Patient Safety Center of the Korea Institute for Healthcare Accreditation. Visualization: Cho DB. Writing - original draft: Cho DB, Choi EY, Ock M. Writing - review & editing: Cho DB, Lee W, Jang SG, Pyo J, Choi EY, Ock M, Central Patient Safety Center of the Korea Institute for Healthcare Accreditation.

INTRODUCTION

Monitoring patient safety at the institutional and national levels is a fundamental requirement for improving healthcare quality.[1] Understanding the frequency and types of adverse events (AEs) and the effectiveness of AE management provides a foundation for systematic safety improvements. The patient safety framework explicitly recognizes "knowing about" as a distinct domain alongside "preventing" and "responding" to safety incidents.[1]

Multiple methods for measuring patient safety are available,[1] including administrative data analyses using diagnostic codes,[2] incident reporting systems tailored to different event types,[3] patient[4] and healthcare provider surveys,[5] and retrospective medical record reviews.[6] Given that each approach has unique advantages and limitations, methodology selection is dependent on specific objectives, available resources, and data sources.[1] Consequently, healthcare systems benefit from building experience through multiple measurement approaches.

Although no single method can provide a complete picture of patient safety, medical record review is widely regarded as the gold standard for AE detection because it offers unparalleled depth in identifying diverse AEs while capturing a detailed clinical context.[7,8] Nevertheless, a medical record review requires greater resources and time than alternative methods[7] and is constrained by the challenge related to achieving adequate inter-reviewer reliability.[9] Despite these limitations, structured medical record review with trained reviewers has demonstrated acceptable reliability and has been widely used in national patient safety monitoring efforts worldwide.[7,8,10-12]

In Korea, an inquiry using medical record review methodology was first conducted in 2019 to assess AEs at the national level. Although this inquiry was conducted under the framework of the Patient Safety Act and referred to as the Patient Safety Incident Inquiry (PSII), the methodology focused on identifying AEs rather than the broader category of patient safety incidents. An AE refers to injury caused by medical management rather than the underlying condition,[13] whereas patient safety incidents include events or circumstances associated with unnecessary harm.[14] The 2019 inquiry, conducted across 15 regional public hospitals, reported that AEs occurred in 9.9% of hospitalized patients.

The 2019 PSII was limited to regional public hospitals, which constrained its ability to fully reflect patient safety conditions and incident characteristics in hospitals with different sizes and levels of clinical complexity, such as general and tertiary hospitals. To address these limitations, the 2024 PSII maintained the medical record review methodology and inquiry framework established in the 2019 inquiry while expanding the scope of participating hospitals to include institutions with more diverse characteristics. Specifically, this study was conducted in ten hospitals, comprising five tertiary hospitals and five general hospitals. This study aimed to describe the methodology and main findings of the 2024 PSII, characterize AEs across a broader range of hospital types, and provide empirical evidence for national-level discussions on patient safety policy.

METHODS

Study design

This retrospective cross-sectional study involved a review of medical records.

https://doi.org/10.3346/jkms.2026.41.e301

Setting

This study targeted general and tertiary hospitals designated as "Accountable Care Hospitals" by the Ministry of Health and Welfare.[15] Accountable Care Hospitals are regional hub institutions responsible for mandatory infection control and for implementing patient safety initiatives. Of the 16 hospitals that applied, ten institutions (five tertiary and five general hospitals) were selected based on their geographical distribution.

Study sample

From each participating institution, 500 patients who were discharged on randomly selected dates in 2021 were selected using a random number table. If fewer than 500 patients were discharged on the selected dates, additional dates were randomly selected until the cumulative number of discharged patients reached 500.

The patient selection criteria were as follows: 1) complete medical records, 2) hospital stay of at least 24 hours, and 3) age ≥ 19 years. Patients initially admitted to the traditional Korean medicine, dental, psychiatric, and rehabilitation departments were excluded. The scope of the review encompassed all medical records from 1 year before to 1 year after the index admission.

Reviewers and training

Each institution independently assigned first- and second-stage reviewers. The first-stage review was conducted by either two nurses or one nurse and one health information manager, whereas the second-stage review was conducted by either two physicians or one physician and one nurse. In total, 40 reviewers participated in the inquiry, including 18 nurses and two health information managers as the first-stage reviewers and 16 physicians and four nurses as the second-stage reviewers.

All reviewers met predefined qualification requirements prior to participation. Nurses and health information managers who participated as first-stage reviewers had at least three years of clinical experience following licensure. Physicians and nurses who participated as second-stage reviewers had at least ten years of clinical experience following licensure.

All reviewers underwent standardized training prior to participation. The training program consisted of online theoretical education and in-person practical sessions. Theoretical education was delivered through pre-recorded online lecture videos that reviewers could access independently. Subsequently, between July and August 2024, three-hour in-person practical training sessions were conducted at each institution. These sessions included instructions on inquiry system utilization and hands-on review exercises using two actual medical records.

Additionally, when approximately 10% of the first-stage reviews (50 patients) were completed at each institution, an interim assessment was conducted to verify the screening criteria assessment status and identify potential inconsistencies between reviewers. Throughout the inquiry period, real-time feedback was provided through the inquiry system to support consistent interpretation and application of the review criteria across institutions.

Inter-reviewer reliability of the PSII methodology has been examined in previous national inquiries, including the 2019 PSII[16] and a subsequent methodological evaluation in 2023.[17]

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Three-stage review process

A medical record review was conducted in three stages using the methodology established for the 2019 PSII.[6] This methodology was developed by integrating internationally established retrospective medical record review approaches with Korean methodological studies that designed and validated AE review forms and reviewer procedures.[18-23] The overall workflow of the three-stage medical record review process is illustrated in **Fig. 1**.

In the first stage, two reviewers from each institution independently reviewed the medical records of 500 randomly selected patients, focusing on screening criteria. The screening criteria included 41 items across seven categories: general, incidents, medication/fluids/blood transfusion, test results, surgery-related, obstetric and neonatal, and others. During this stage, information on reviewers (review time, etc.), patient information (sex, admission department, etc.), patient safety incident reporting status, screening criteria, and medical record quality assessment results was obtained.

In the second stage, two reviewers independently examined the medical records of patients with one or more positive screening criteria identified in stage 1 to identify suspected AEs. When a suspected AE was identified, a detailed report was prepared for that event. This report included a narrative description of the event, the type of event, the location of occurrence, the severity of patient harm, whether the event resulted in a prolonged hospital stay, assessments of causality and preventability, and an evaluation of medical record quality. Reviewer information, including review time, was also collected.

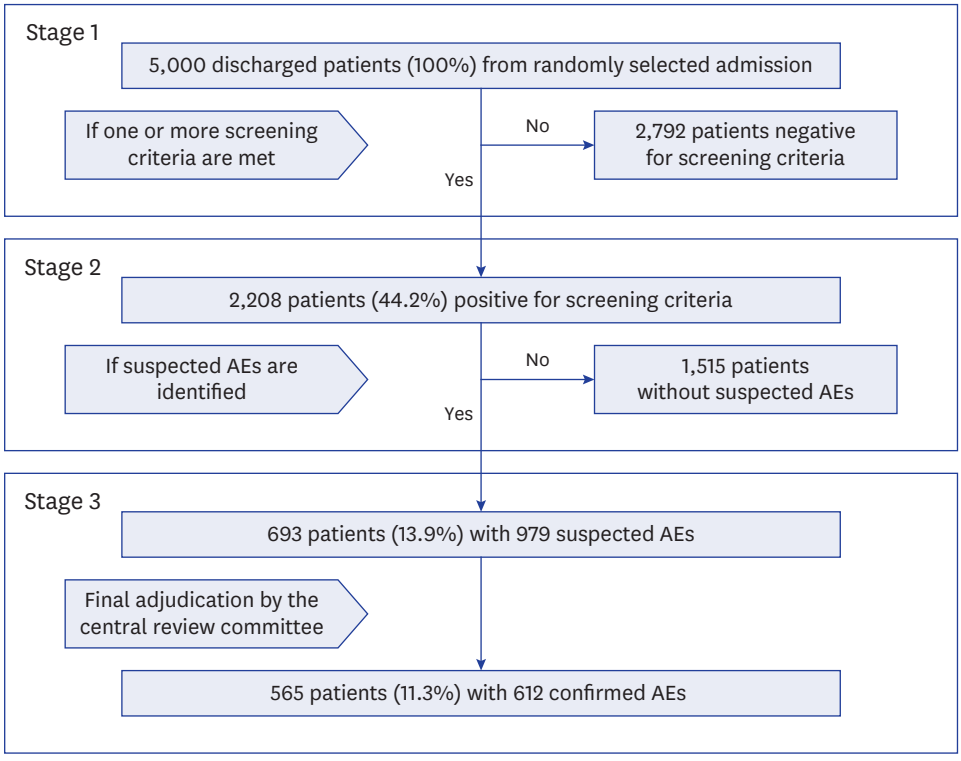


Fig. 1. Flowchart of the three-stage medical record review process.
AE = adverse event.

https://doi.org/10.3346/jkms.2026.41.e301

In the third stage, a central review committee comprising seven members, including experienced PSII reviewers, patient safety experts, and research team members, comprehensively reviewed the detailed suspected AE reports identified in stage 2. Based on a review of the causality and preventability assessments and the application of predefined cut-off criteria, the committee adjudicated each event and finalized the determination of confirmed AEs.

Classification and assessment of AEs

The classification and assessment of AEs, including event type, harm severity, causality, and preventability, followed the criteria applied in the 2019 PSII.[6]

The AE types were classified into six categories: diagnosis-related, medication-/fluid-/blood-related, patient care-related, surgery-/procedure-related, infection-related, and others. Multiple classifications were allowed for a single event.

Harm severity was categorized into five levels: level 1, temporary harm; level 2, prolonged hospital stay; level 3, permanent harm; level 4, sustained life; and level 5, death.

Causality was assessed to evaluate the extent to which medical care contributed to occurrence of AEs, while preventability was assessed to determine whether AEs could have been prevented based on current medical evidence. Causality and preventability were each evaluated using a six-point scale, with scores of 4 or higher indicating a likelihood of 50% or greater. For final adjudication, events with causality scores of 4 or higher were classified as confirmed AEs, and events with preventability scores of 4 or higher were classified as preventable AEs.

Data collection and analysis

Data were collected from July to November 2024 using a web-based inquiry system developed specifically for PSII. The data were organized using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) and descriptive statistical analyses were performed.

Ethics statement

The investigation was conducted in accordance with Article 7-2 of the Patient Safety Act.[24] The study protocol was reviewed by the Institutional Review Board of Ulsan University Hospital and was determined to be exempt from review (IRB No. UUH 2026-06-025). The exemption was granted pursuant to Article 13, Paragraph 1, Subparagraph 3 of the Enforcement Rule of the Bioethics and Safety Act.[25] The requirement for informed consent was waived.

RESULTS

Review process flow and AE detection

The results of the stepwise review process are shown in **Fig. 1**. During the first stage, independent reviews of the medical records from 5,000 discharged patients (500 from each institution) identified 2,208 patients (44.2%) who met one or more screening criteria. In the second stage, suspected AEs were identified in 693 patients (13.9%), in whom a total of 979 suspected AEs, indicating that some patients experienced more than one suspected AE. Following final adjudication in the third stage, confirmed AEs were identified in 565 patients (11.3%), with a total of 612 confirmed AEs.

https://doi.org/10.3346/jkms.2026.41.e301

Overall characteristics of confirmed AEs

The overall characteristics of the 612 confirmed AEs are summarized in **Table 1**. In terms of harm severity, 62.4% of AEs were associated with temporary harm, 33.3% led to prolonged hospitalization, and 3.6% resulted in death. Regarding causality, 29.9% of AEs showed strong evidence of causality, and 9.2% showed certain evidence of causality. In addition, 28.3% of AEs were classified as preventable, with a preventability score indicating a likelihood of 50% or greater. Prolonged hospitalization was associated with 36.3% (n = 222) of confirmed AEs. Among these events, the most common duration of prolonged hospital stay was 5 days or less (36.5%).

Among the 612 confirmed AEs, a total of 744 AE type assignments were identified, indicating that some events were classified into multiple categories. Patient care–related events were the most common (37.3%), followed by medication-/fluid-/blood-related events (36.1%), surgery-/procedure-related events (26.8%), infection-related events (16.3%), and diagnosis-related events (4.9%).

Institutional distribution of screening results and confirmed AEs

The screening results and confirmed AE rates across the medical institutions are shown in **Table 2**. The proportion of patients who met one or more screening criteria ranged from 20.4% to 64.2% across the institutions, with an overall average of 44.2%. The proportion of

Table 1. Overall characteristics of confirmed AEs (N = 612)

Characteristics	Values
Severity of harm	
Temporary harm	382 (62.4)
Prolonged hospital stay	204 (33.3)
Permanent harm	0 (0.0)
Life-sustaining intervention	4 (0.7)
Resulted in death	22 (3.6)
Causality	
Evidence of causality, ≥ 50% certainty	373 (60.9)
Strong evidence of causality	183 (29.9)
Certain evidence of causality	56 (9.2)
Preventability	
No evidence of preventability	67 (10.9)
Slight evidence of preventability	225 (36.8)
Evidence of preventability, < 50% certainty	147 (24.0)
Evidence of preventability, ≥ 50% certainty	110 (18.0)
Strong evidence of preventability	48 (7.8)
Certain evidence of preventability	15 (2.5)
Length of prolonged hospital stay	
Not prolonged	390 (63.7)
≤ 5 days	81 (13.2)
6–10 days	67 (10.9)
11–15 days	34 (5.6)
16–20 days	18 (2.9)
≥ 21 days	22 (3.6)
AE types (multiple responses)[a]	
Diagnosis-related	30 (4.9)
Medication-/fluid-/blood-related	221 (36.1)
Patient care-related	228 (37.3)
Surgery-/procedure-related	164 (26.8)
Infection-related	100 (16.3)
Others	1 (0.2)

Values are presented as number (%).
AE = adverse event.
[a]AE types allowed multiple responses; percentages are based on the number of responses (n = 744).

https://doi.org/10.3346/jkms.2026.41.e301

Table 2. Screening results and confirmed AE rates across medical institutions (N = 5,000)

Medical institution	Hospital type	Patients meeting screening criteria	Patients with confirmed AEs	95% CI for confirmed AE rates
A	Tertiary	220 (44.0)	65 (13.0)	10.05–15.95
B	Tertiary	154 (30.8)	65 (13.0)	10.05–15.95
C	Tertiary	287 (57.4)	76 (15.2)	12.05–18.35
D	Tertiary	102 (20.4)	53 (10.6)	7.90–13.30
E	General	242 (48.4)	6 (1.2)	0.25–2.15
F	Tertiary	292 (58.4)	40 (8.0)	5.62–10.38
G	General	177 (35.4)	21 (4.2)	2.44–5.96
H	General	197 (39.4)	80 (16.0)	12.79–19.21
J	General	321 (64.2)	52 (10.4)	7.72–13.08
K	General	216 (43.2)	107 (21.4)	17.81–24.99
Total	-	2,208 (44.2)	565 (11.3)	10.42–12.18

Values are presented as number (%).
AE = adverse event, CI = confidence interval.

patients with confirmed AE also varied substantially across institutions, ranging from 1.2% to 21.4%. Overall, confirmed AEs were identified in 11.3% of patients, with a 95% confidence interval of 10.42% to 12.18%.

Severity of harm according to AE types

The severity of harm according to the AE type is shown in **Table 3**. Type-specific analysis revealed that patient care-related events had the highest proportion of temporary harm (71.5%, n = 163), followed by medication-/fluid-/blood-related events (68.3%, n = 151) and surgery-/procedure-related events (50.6%, n = 83). In contrast, infection-related events had prolonged hospital stays as the predominant category (65.0%, n = 65), exceeding temporary harm (21.0%, n = 21). Diagnosis-related events showed high rates of prolonged hospital stay (50.0%, n = 15) and death (13.3%, n = 4). Infection-related events exhibited the highest mortality rate (12.0%, n = 12).

Causality and preventability scores according to AE types

The causality and preventability scores according to the AE type are presented in **Table 4**. The overall mean causality and preventability scores were 4.48 ± 0.65 and 2.89 ± 1.22,

Table 3. Severity of harm according to AE types (N = 744)

AE types	Severity of harm					
	Temporary harm	Prolonged hospital stay	Permanent harm	Sustained life	Resulted in death	Total
Diagnosis-related	11 (36.7)	15 (50.0)	0 (0.0)	0 (0.0)	4 (13.3)	30 (100.0)
Medication-/fluid-/blood-related	151 (68.3)	64 (29.0)	0 (0.0)	2 (0.9)	4 (1.8)	221 (100.0)
Patient care-related	163 (71.5)	48 (21.1)	0 (0.0)	1 (0.4)	16 (7.0)	228 (100.0)
Surgery-/procedure-related	83 (50.6)	75 (45.7)	0 (0.0)	2 (1.2)	4 (2.4)	164 (100.0)
Infection-related	21 (21.0)	65 (65.0)	0 (0.0)	2 (2.0)	12 (12.0)	100 (100.0)
Others	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)
Total	430 (57.8)	267 (35.9)	0 (0.0)	7 (0.9)	40 (5.4)	744 (100.0)

Values are presented as number (%).
AE = adverse event.

Table 4. Causality and preventability scores according to AE types (N = 744)

AE types	No.	Causality, mean ± SD	Preventability, mean ± SD
Diagnosis-related	30	4.50 ± 0.63	3.63 ± 1.38
Medication-/fluid-/blood-related	221	4.41 ± 0.64	2.53 ± 1.18
Patient care-related	228	4.41 ± 0.63	3.25 ± 1.28
Surgery-/procedure-related	164	4.69 ± 0.72	2.65 ± 1.04
Infection-related	100	4.42 ± 0.57	3.00 ± 1.07
Others[a]	1	-	-
Total	744	4.48 ± 0.65	2.89 ± 1.22

AE = adverse event, SD = standard deviation.
[a]Others are not reported because of the presence of a single case.

https://doi.org/10.3346/jkms.2026.41.e301

Table 5. Length of prolonged hospital stay according to AE types (N = 300)

AE types	Length of prolonged hospital stay (days)					
	≤ 5	6–10	11–15	16–20	≥ 21	Total
Diagnosis-related	5 (31.3)	6 (37.5)	1 (6.3)	2 (12.5)	2 (12.5)	16 (100.0)
Medication-/fluid-/blood-related	22 (31.9)	21 (30.4)	14 (20.3)	4 (5.8)	8 (11.6)	69 (100.0)
Patient care-related	15 (25.0)	19 (31.7)	12 (20.0)	4 (6.7)	10 (16.7)	60 (100.0)
Surgery-/procedure-related	34 (43.0)	20 (25.3)	12 (15.2)	5 (6.3)	8 (10.1)	79 (100.0)
Infection-related	19 (25.0)	26 (34.2)	12 (15.8)	8 (10.5)	11 (14.5)	76 (100.0)
Others	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	95 (31.7)	92 (30.7)	51 (17.0)	23 (7.7)	39 (13.0)	300 (100.0)

AE = adverse event.

respectively. Regarding causality scores, surgery-/procedure-related events had the highest score (4.69 ± 0.72), followed by diagnosis-related events (4.50 ± 0.63). Regarding preventability scores, diagnosis-related events scored highest at 3.63 ± 1.38, whereas medication-/fluid-/blood-related events showed the lowest preventability score at 2.53 ± 1.18.

Length of prolonged hospital stay according to AE types

The length of prolonged hospital stay according to AE type is shown in **Table 5**. Among the 744 AE type assignments, hospital stay was prolonged in 300 assignments (40.3%). Infection-related events had the highest extension rate (76.0%, 76/100), followed by diagnosis-related events (53.3%, 16/30), surgery-/procedure-related events (48.2%, 79/164), medication-/fluid-/blood-related events (31.2%, 69/221), and patient care-related events (26.3%, 60/228). Among cases with prolonged hospital stay, surgery-/procedure-related events more commonly resulted in shorter extensions (43.0% lasting for 5 days or less), whereas infection-related events showed more prolonged patterns (34.2% requiring 6–10 days and 14.5% extending 21 days or more).

DISCUSSION

The current study presented the methodology and key findings of the 2024 PSII. The inquiry used a standardized three-stage retrospective medical record review across 10 Accountable Care Hospitals (five tertiary and five general hospitals) nationwide. Whereas the 2019 inquiry was limited to regional public hospitals,[6] this study expanded the scope of participating institutions to include regional referral hospitals of more diverse types and sizes. As a result, this study provides descriptive baseline information on AEs within the expanded scope of participating hospitals. In addition, this study provides empirical baseline data to inform the direction of national-level quinquennial inquiries mandated under the Patient Safety Act, with implications for national-level patient safety planning.[24]

In this study, the confirmed AEs were identified in 11.3% of discharged patients, and approximately 28.3% of confirmed AEs were deemed to be preventable. These estimates fall within the range reported in previous studies using medical record review methods, where AE rates ranged from 2.9% to 21.9% and preventability rates ranged from 7.0% to 94.4%.[26-28] However, substantial variability related to study design, reviewer composition and experience, and institutional characteristics limits direct comparisons across studies.[8,22,29] In addition, the study period coincided with the COVID-19 pandemic, which may have influenced AE patterns.[30]

The distribution of AE types and harm severity was broadly consistent with previous studies.[26] Patient care-related, medication-/fluid-/blood-related, and surgery-/procedure-

https://doi.org/10.3346/jkms.2026.41.e301

related events accounted for the majority of AEs, with most AEs resulting in temporary harm. A small proportion of AEs (3.6%) were associated with patient death. Although less frequent, diagnosis- and infection-related events were more often associated with prolonged hospitalization and mortality, warranting particular attention.

AE rates varied substantially across institutions, potentially reflecting differences in inquiry experience, reviewer expertise, and communication structures.[11,12,28] Only two institutions had prior inquiry experience, which may have contributed to inter-institutional heterogeneity. Previous studies have reported that structured communication and supervision within reviewer teams can facilitate review reliability[10]; however, in this study, reviewers were assigned at the institutional level, limiting opportunities for cross-institutional calibration and shared oversight. Although practical training based on actual cases and interim assessments were implemented to support consistency during the first-stage reviews, inter-institutional variation persisted. These findings suggest the need for methodological refinement in future national inquiries, including the establishment of centralized and standardized oversight mechanisms that systematically train and utilize reviewers to enhance inter-institutional standardization.

Another distinctive feature of this study was the expansion of the reviewer profession. While the 2019 inquiry used two nurses for first-stage reviews and two physicians for second-stage reviews,[6] this inquiry utilized nurses or health information managers for first-stage reviews and physicians or nurses for second-stage reviews. Although the impact of expanding reviewer professions was not empirically examined, previous studies suggest that reliability may be maintained when experienced reviewers consistently participate.[31] Future inquiries may therefore consider broader reviewer participation while ensuring continuity of experienced reviewers.

Regarding practical applications, the results of this PSII may be used at both institutional and national levels. At the institutional level, they provide a basis for comprehensively assessing the patient safety status and setting priorities for improvement. At the national level, they may inform evaluations of existing methods for monitoring patient safety. For example, a reanalysis of the 2019 inquiry revealed the low validity of patient safety incident codes and present-on-admission codes in Korea.[32] The current results may help inform assessments of patient safety incident coding and in-hospital reporting systems. Furthermore, as the 2019 results were previously used to estimate the burden of disease attributable to patient safety incidents,[33] the 2024 findings may enable analyses of burden trends over time, thereby underscoring the need for heightened societal attention and policy efforts to improve patient safety.

This study had some limitations. First, although the inquiry included both tertiary and general hospitals, the findings may not fully represent patient safety status across all healthcare settings; therefore, caution is warranted when generalizing the results beyond acute care hospitals. Second, suspected AEs were not assessed among the patients who screened negative in the first-stage review, and some events may have been missed, although two independent reviewers were used. Third, inter-reviewer reliability was not formally assessed, as this inquiry was designed as a national descriptive investigation rather than a methodological validation study. Finally, this study did not analyze patient-level or hospital-level factors associated with AE occurrence, as the inquiry was designed to provide national-level descriptive estimates rather than to identify determinants of AEs.

https://doi.org/10.3346/jkms.2026.41.e301

In conclusion, the 2024 PSII applied a standardized three-stage medical record review methodology across 10 medical institutions, including tertiary and general hospitals, and provides updated descriptive baseline data on AE rates, types, severity, and preventability in Korea. When interpreted alongside accumulated PSII data over time, the findings of the present study may contribute to a more systematic understanding of AE occurrence and support evidence-based prioritization of patient safety improvement efforts at both institutional and national levels.

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