OPEN

The Korea National Patient Safety Incidents Inquiry Survey: Characteristics of Adverse Events Identified Through Medical Records Review in Regional Public Hospitals

Min Ji Kim, BS,* Hee Jung Seo, RN, MPH,* Hong Mo Koo, MD,* Minsu Ock, MD, PhD,†‡ Jee-In Hwang, RN, PhD,§ and Sang-Il Lee, MD, PhD‡

Objectives: In 2019, the Korean National Patient Safety Incidents Inquiry was conducted in the Republic of Korea to identify the national-level incidence of adverse events. This study determined the incidence and detailed the characteristics of adverse events at 15 regional public hospitals in the Republic of Korea.

Methods: Medical records data of 500 randomly selected patients (discharged in 2016) were extracted from each of the 15 studied hospitals and reviewed in 3 stages. First, for each hospital, 2 nurses independently reviewed the medical records, using 41 screening criteria. Second, 2 physicians independently reviewed the records of those patients with at least 1 screening criterion from the first stage for adverse events occurrence and their characteristics. Third, a 9-member committee conducted a final review and compiled the final adverse event report.

Results: Among 7500 patients, 4159 (55.5%) had at least 1 screening criterion; 745 (9.9%) experienced 901 adverse events (incidence, 12.0%). By type of institution, adverse event incidence varied widely from 1.2% to 45.6%. In 1032 adverse events, the majority (33.5%) were "patient care–related." By severity, the majority (638; 70.8%) were temporary, requiring intervention, whereas 38 (4.2%) resulted in death. The preventability score was high for "patient care–related" and "diagnosis-related" adverse events, with "diagnosis-related" (30.8%) and "surgery/procedural-related" (30.1%) types extended by at least 21 days.

Conclusions: A review of medical records aids in identifying adverse events in medical institutions with varying characteristics, thus helping prioritize interventions to reduce their incidence.

Key Words: medical record review, adverse event, medical error, Republic of Korea

(J Patient Saf 2022;18: 382-388)

There is a crucial need to enhance patient safety; therefore, an understanding of the current status of patient safety is essential.¹ Although various methods have been suggested to identify

this current status, the use of medical records review has consistently been the most frequently used method.² Although identifying adverse events costs more and takes more time,³ it has been shown to increase the reliability of medical records reviewers; hence, it is important.⁴ Thus, medical records review has become the worldwide criterion standard for comprehensively assessing patient safety using adverse events as the index.^{2,5}

Since it was first used in the United States,^{6,7} medical records review has been used worldwide for the identification of adverse events, including in Australia and Canada.^{8–15} In the Republic of Korea (hereinafter Korea), a large-scale, national-level medical records review to obtain an estimate of adverse events has not yet been performed. However, pilot studies have been conducted to develop a case report form for identifying adverse events¹⁶ and to report the incidence of adverse events from 1 or 2 medical institutions.^{17,18} Most recently, a retrospective review of medical records was conducted to identify adverse events at 6 medical institubefore a large-scale medical records review.¹⁹

According to the Patient Safety Act implemented in 2016, comprehensive plans for patient safety must be formulated every 5 years in Korea, along with the Korean National Patient Safety Incidents Inquiry (KNPSII) survey.²⁰ Specifically, the KNPSII survey is aimed at examining the characteristics of accidents, including the type, location of occurrence, degree of harm, and preventability score of patient safety incidents. Accordingly, in 2019, the KNPSII survey was conducted to determine the national-level incidence rate, focusing on organizations dedicated to patient safety within the Korea Institute for Healthcare Accreditation.

This study focused on the results of the KNPSII survey in Korea using retrospective medical records review methodology to identify adverse events. Although the results of medical records reviews are continuously published,^{2,5} the detailed characteristics of the identified adverse events and the variations among institutions have been relatively overlooked. This study aimed to determine the variations in the incidence of adverse events among 15 regional public hospitals in Korea, and the detailed characteristics of the adverse events were identified.

METHODS

Study Design

This survey was conducted in accordance with the Comprehensive Plans for Patient Safety, formulated every 5 years, in accordance with the Patient Safety Act. Furthermore, review by institutional review boards was exempted, based on Article 2, Paragraph 2, Subparagraph 1 of the Enforcement Rule of the Bioethics and Safety Act.

A 3-stage retrospective medical records review was conducted at 15 regional public hospitals, based on previously established methodology,^{16,19,21-24} to identify the size and type of adverse events occurring at medical institutions. This study collected information

From the *Korea Institute for Healthcare Accreditation, Seoul; †Department of Preventive Medicine, Ulsan University Hospital, University of Ulsan College of Medicine, Ulsan; ‡Department of Preventive Medicine, University of Ulsan College of Medicine; and §Department of Nursing Management, College of Nursing Science, Kyung Hee University, Seoul, Republic of Korea.

Correspondence: Minsu Ock, MD, PhD, Ulsan University Hospital, University of Ulsan College of Medicine, 877 Bangeojinsunhwando-ro, Dong-gu,

Ulsan 44033, Republic of Korea (e-mail: ohohoms@naver.com).

Min Ji Kim: https://orcid.org/0000-0002-5780-2341.

Hee Jung Seo: https://orcid.org/0000-0001-8512-8051. Hong Mo Koo: https://orcid.org/0000-0002-0774-3240.

Minsu Ock: https://orcid.org/0000-0001-9949-9224.

Jee-In Hwang: https://orcid.org/0000-0003-2284-5795.

Sang-Il Lee: https://orcid.org/0000-0002-1068-7542.

This research was funded by the Ministry of Health & Welfare, Republic of Korea. Copyright © 2021 The Author(s). Published by Wolters Kluwer Health, Inc. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

related to adverse events using a previously developed case report form²¹ to implement the Web-based KNPSII system.

Measures

Depending on the item on the case report form, reviewer information (time of review, etc), patient information (sex, duration of hospitalization, department, hospitalization route, etc), occurrence of screening criteria, and the results of the medical records quality assessment were collected in the first stage of the review. At the second stage, reviewer information (time of review, etc), the occurrence of an adverse events, detailed adverse event report (type, degree, causality, and preventability of the adverse event), and the results of the medical records quality assessment were collected.

Causality was the index for assessing whether the underlying disease of the patient or the medical care received contributed more to the occurrence of adverse events. Causality was evaluated on a 6-point scale as follows: 1 (no evidence of causality), 2 (slight evidence of causality), 3 (evidence of causality with less than 50% certainty), 4 (evidence of causality with a certainty of 50% or more), 5 (strong evidence of causality), and 6 (definite evidence of causality). In addition, preventability (an index for assessing whether the adverse event could be prevented based on the currently available medical evidence) was also assessed on a 6-point scale as follows: 1 (no evidence for preventability), 2 (slight evidence of preventability), 3 (evidence of preventability with less than 50% certainty), 4 (evidence of preventability with certainty of 50% or more), 5 (strong evidence of preventability), and 6 (definite evidence of preventability). The cutoff criterion for both causality and preventability was 4 points. This is the point at which an adverse event was considered to have either high causality or was preventable.

The type of adverse events was classified into 6 categories, including diagnosis-related, drugs/fluids/blood-related, patient care–related, surgery/procedural-related, infection-related, and other events. The severity was classified into the following 5 levels based on the error classification system used by the National Coordinating Council for Medication Error Reporting and Prevention^{16,19}: level 1, "events with temporary harm requiring intervention or treatment"; level 2, "events requiring long-term hospitalization treatment"; level 3, "events with permanent harm"; level 4, "events requiring intervention to sustain life"; and level 5, "events contributing to or causing death."

Medical Institutions and Patients

Of 33 regional public hospitals in Korea, 15 at the general hospital level with \geq 200 beds were selected as participating medical institutions, considering regional distribution. This increased the representativeness of participating medical institutions to approximately 50%. At each institution, the medical records data of 500 randomly selected patients, who were discharged in 2016, were extracted and reviewed in 3 stages.

Specifically, the data of patients included in the survey were extracted from the data of those who were discharged (or died) on randomly extracted dates (index admission) between January 1, 2016, and December 31, 2016, using a random number table. If the cumulative number of discharged patients was <500, patients discharged were randomly extracted on a subsequent extraction date until the sample reached 500. This process of date selection was repeated until up to 500 patients were selected for each institution. For duplicate patients in the final selection, hospitalization for the initial discharge date was included and subsequent hospitalizations were excluded from the review.

The patients included in the review were those who had complete records (discharge summary and all records with completed coding) for at least 24-hour duration of hospitalization and were at least 19 years of age. Patients initially admitted to the Department of Traditional Korean Medicine, Dental Care, Psychiatry, or Rehabilitation Care were excluded from the review.

Medical Records Review

The medical records were reviewed in 3 stages. In stage 1, 2 nurses independently reviewed the medical records of the 500 discharged patients per institution, using 41 screening criteria: 8 criteria in "general (admission, discharge, and transfer)," 9 criteria in "events", 5 criteria in "drug, fluid, blood", 6 criteria in "test result", 8 criteria in "related surgery", 3 criteria in "obstetrics and neonates," and 2 criteria in "others."^{4,21} The scope of the medical records review entailed 1 year before and after the discharge date of the index admission. For example, if September 1, 2016, was selected as the discharge date, the scope of the review was from September 1, 2015, to September 1, 2017. Stage 1 review was conducted from August 19 to November 12, 2019.

In the second stage of the review, 2 physicians independently reviewed the medical records of discharged patients with at least 1 screening criterion from the stage 1 review to determine the occurrence of adverse events and their characteristics. In this process, the progress and outcomes of the review for the institutions were monitored to conduct an interim meeting for experts and staff. The goal was to discuss the review results with the stages 1 and 2 reviewers to reduce the differences in opinion among reviewers. Stage 2 review was conducted from August 23 to December 9, 2019.

Stage 3 review was conducted by a review committee consisting of 9 members. To minimize the variations among reviewers, the committee included those who had experience in a related previous study or had sufficient experience in the field of patient safety, along with those who conducted the survey. By compiling the completed adverse event reports, the decision criteria for the number of cases, severity, causality, and preventability were established by the stage 3 review committee. Based on the criteria established, some of the results were adjusted to group the review results according to each institution, and the final decision on adverse events was made by aggregating opinions at the institutional level.

Training of Reviewers

To facilitate the review of medical records, 2 nurses and 2 physicians, designated as the first and second reviewers, respectively, were recruited from within each institution. In one institution where reviewer recruitment was difficult, one of the second reviewers was recruited from an external institution with the assistance of an academic society.

Two instructors, with extensive experience in medical records review through prior research, conducted group or on-site training for the first and second reviewers on the theory and practice of medical records review and how to use the system. The training was performed for approximately 3 hours at each institution. Specifically, discussions were held on the definition of terms related to patient safety, including the introduction of the methodology for identifying adverse events through medical records, the severity of adverse events identified in previous studies, causality, and preventability during the training. In addition, a medical records review was conducted using 2 actual medical records, based on the survey system. Instructions were provided on how to use the bulletin board in the inquiry system as a response to queries that arise during medical records review.

Statistical Analysis

Review results were summarized using Microsoft Excel 2013, and a technical analysis was conducted using IBM SPSS Statistics



FIGURE 1. Flowchart of the medical records review process.

for Windows, version 20.0 (IBM Corp, Armonk, New York). Using descriptive statistics, the differences in the results by institution, as well as the results of the medical records review of all medical institutions, were examined. Because a single patient could experience 2 or more adverse events, the incidence of adverse events was analyzed for each patient, and the characteristics of each adverse event were analyzed by event. In addition, the incidence and type of adverse events were analyzed by institution, whereas the severity, causality, and preventability were analyzed according to the type of adverse event.

RESULTS

For all 7500 patients (500 per institution), 2 nurses per institution conducted an independent first review, and at least 1 screening criterion was identified in 4159 (55.5%) hospitalized patients. Among these, 2 physicians conducted an independent secondary review and found 777 (10.4% of 7500) patients with detailed adverse event reports. In case of discrepancy between the 2 second reviewers in the decision of an adverse event, the final decision was made through an interim meeting by the institutions, with the third review committee. Finally, after the review at the third stage, adverse events were reported for 745 patients (9.9% of 7500; Fig. 1).

After the first review, the percentages of patients with screening criteria selected for the second review varied widely among institutions from 29.6% to 84.0% (Table 1). In addition, the incidence of adverse events by institutions was examined among 901 (12.0%) incidents of adverse events; these also varied widely from 1.2% to 45.6%.

Of 1023 patients, the "patient care–related" type of adverse events accounted for the highest proportion, with 346 (33.5%) cases, followed by "drugs/fluids/blood-related" type with 268 (26.0%) cases, "surgery/procedural-related" type with 184 (17.8%) cases, and least in "diagnosis-related" (n = 72; 7.0%) type (Table 2). When examined according to institution, "drugs/fluids/blood-related" type adverse events were identified the most at 6 institutions, whereas "diagnosis-related" type had relatively high incidence at 2 institutions.

In surveying the severity of the adverse events, events with temporary harm that required intervention or treatment accounted for the highest proportion with 638 (70.8%) cases, whereas events causing death occurred in 38 (4.2%) cases (Table 3). The "drugs/fluids/blood-related," "patient care–related," and "surgery/procedural-related" types were events with temporary harm, and the highest percentages were 81.7%, 79.2%, and 56.5%, respectively. In contrast, "diagnosis-related" and "infection-related" types required long-term hospitalization treatment at 55.6% and 51.2%, respectively.

When the causality scores were analyzed according to the type of adverse events, the causality score was relatively high for the "surgery/procedural-related" type of adverse events, whereas "patient care-related" type showed the lowest score, based on the minimum and mean scores. In the case of preventability scores, they were relatively high for "patient care-related" types of adverse

Medical Institution	Percentage With Screening Criteria, n (%)	Percentage Determined as Adverse Event, n (%)	Confidence Interval
A	271 (54.2)	62 (12.4)	9.50-15.30
В	282 (56.4)	7 (1.4)	0.37-2.43
С	367 (73.4)	66 (13.2)	10.23-16.17
D	230 (46.0)	228 (45.6)	41.22-49.98
Е	157 (31.4)	6 (1.2)	0.24-2.16
F	343 (68.6)	67 (13.4)	10.40-16.40
G	232 (46.4)	82 (16.4)	13.14-19.66
Н	314 (62.8)	74 (14.8)	11.68-17.92
Ι	284 (56.8)	59 (11.8)	8.96-14.64
J	297 (59.4)	18 (3.6)	1.96-5.24
К	307 (61.4)	66 (13.2)	10.22-16.18
L	420 (84.0)	66 (13.2)	10.22-16.18
М	229 (45.8)	54 (10.8)	8.07-13.53
Ν	148 (29.6)	29 (5.8)	3.74-7.86
0	278 (55.6)	17 (3.4)	1.81-4.99
Total	4159 (55.5)	901 (12.0)	11.28–12.75

	Type of Adverse Event								
Medical Institution	Diagnosis- Related, n (%)	Drugs/Fluids/ Blood-Related, n (%)	Patient Care–Related, n (%)	Surgery or Procedure-Related, n (%)	Infection- Related, n (%)	Total, n (%)			
А	4 (6.3)	28 (43.8)	28 (43.8)	2 (3.1)	2 (3.1)	64 (100.0)			
В	0 (0.0)	3 (30.0)	1 (10.0)	2 (20.0)	4 (40.0)	10 (100.0)			
С	18 (21.4)	43 (51.2)	13 (15.5)	7 (8.3)	3 (3.6)	84 (100.0)			
D	5 (2.1)	52 (21.8)	132 (55.5)	10 (4.2)	39 (16.4)	238 (100.0)			
Е	0 (0.0)	0 (0.0)	5 (83.3)	1 (16.7)	0 (0.0)	6 (100.0)			
F	2 (2.9)	16 (23.2)	19 (27.5)	26 (37.7)	6 (8.7)	69 (100.0)			
G	16 (17.0)	30 (31.9)	16 (17.0)	25 (26.6)	7 (7.4)	94 (100.0)			
Н	4 (3.6)	11 (9.9)	48 (43.2)	28 (25.2)	20 (18.0)	111 (100.0)			
Ι	3 (4.5)	16 (24.2)	7 (10.6)	31 (47.0)	9 (13.6)	66 (100.0)			
J	0 (0.0)	3 (13.0)	4 (17.4)	8 (34.8)	8 (34.8)	23 (100.0)			
K	18 (22.0)	11 (13.4)	15 (18.3)	24 (29.3)	14 (17.1)	82 (100.0)			
L	0 (0.0)	7 (10.0)	37 (52.9)	0 (0.0)	26 (37.1)	70 (100.0)			
М	0 (0.0)	30 (49.2)	7 (11.5)	14 (23.0)	10 (16.4)	61 (100.0)			
Ν	0 (0.0)	11 (33.3)	10 (30.3)	4 (12.1)	8 (24.2)	33 (100.0)			
0	2 (9.5)	7 (33.3)	4 (19.0)	2 (9.5)	6 (28.6)	21 (100.0)			
Total	72 (7.0)	268 (26.0)	346 (33.5)	184 (17.8)	162 (15.7)	1032 (100.0)			

Institution
r

events as well as for the "diagnosis-related" types. The type of adverse events with the lowest preventability score was the "drugs/ fluids/blood-related" type (Table 4).

For all adverse events, the duration of hospitalization was extended in 463 (44.9%) cases. Of those, the duration of hospitalization was extended in 77.2% of "infection-related," followed by "diagnosisrelated" with 72.2% and "surgery/procedural-related" adverse events with 56.0%. For "drugs/fluids/blood-related" type, extension by less than 5 days accounted for the highest proportion (42.9%), and the same was true for "patient care-related" type (41.5%). For "diagnosis-related" type, extension by more than 21 days (30.8%) accounted for the highest proportion, and the same was true for "surgery/procedural-related" (30.1%) and "infection-related" (27.2%) types (Table 5).

DISCUSSION

This study presents institutional variations in the incidence of adverse events and their detailed characteristics using the results

TABLE 3. Degree of Harm According to Type of Adverse Events

of the KNPSII survey conducted in accordance with the Korean Patient Safety Act. The KNPSII survey was conducted in a 3-stage medical records review of 7500 discharged patients from 15 regional public hospitals. A total of 901 adverse events were identified for 745 patients (9.9%). The results of this study are of great significance, in that they are the first to comprehensively evaluate the status of patient safety at the national level in Korea.

One of the major characteristics of the methodology for surveying patient safety accidents is the use of a 3-stage medical records review. The reason for the use of these stages was to address the issue of variations among reviewers. In pilot studies conducted in Korea before the implementation of the KNPSII survey, variations were confirmed as an issue among reviewers. This was particularly important in the evaluation of causality and preventability scores in the second-stage review.^{4,19} This study attempted to reduce the variations among reviewers in the determination and assessment of adverse events through a 3-stage review conducted by a third 9-member expert review committee with experience in related prior research or activities in the field of patient safety.

	Degree of Harm						
Type of Adverse Event	Temporary Harm, n (%)	Prolonged Hospital Stay, n (%)	Permanent Harm, n (%)	Sustain Life, n (%)	Resulted in Death, n (%)	Total, n (%)	
Total adverse events*	638 (70.8)	217 (24.1)	2 (0.2)	6 (0.7)	38 (4.2)	901 (100.0)	
Diagnosis-related [†]	15 (20.8)	40 (55.6)	0 (0.0)	2 (2.8)	15 (20.8)	72 (100.0)	
Drugs/fluids/blood-related [†]	219 (81.7)	37 (13.8)	1 (0.4)	3 (1.1)	8 (3.0)	268 (100.0)	
patient care-related*	274 (79.2)	56 (16.2)	0 (0.0)	1 (0.3)	15 (4.3)	346 (100.0)	
Surgery or procedure-related [†]	104 (56.5)	68 (37.0)	1 (0.5)	1 (0.5)	10 (5.4)	184 (100.0)	
Infection-related [†]	60 (37.0)	83 (51.2)	1 (0.6)	1 (0.6)	17 (10.5)	162 (100.0)	
Others [†]	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Total [†]						1032 (100.0)	

*Single response.

[†]Duplicate responses.

			Causality		Preventability			
Type of Adverse Event	n	Maximum (SD)	Minimum (SD)	Average (SD)	Maximum (SD)	Minimum (SD)	Average (SD)	
Diagnosis-related	72	4.22 ± 0.56	4.21 ± 0.56	4.22 ± 0.56	3.35 ± 1.12	3.03 ± 1.19	3.19 ± 1.09	
Drugs/fluids/blood-related	268	4.34 ± 0.57	4.22 ± 0.46	4.28 ± 0.48	2.63 ± 1.16	2.20 ± 1.01	2.41 ± 0.99	
patient care-related	346	4.24 ± 0.51	4.12 ± 0.45	4.18 ± 0.43	3.64 ± 0.90	3.16 ± 1.10	3.40 ± 0.89	
Surgery or procedure-related	184	4.36 ± 0.63	4.25 ± 0.57	4.30 ± 0.56	2.83 ± 1.00	2.50 ± 0.88	2.67 ± 0.86	
Infection-related	162	4.30 ± 0.54	4.17 ± 0.45	4.23 ± 0.46	3.10 ± 1.08	2.67 ± 1.10	2.88 ± 0.99	
Total	1032	4.30 ± 0.56	4.18 ± 0.49	4.24 ± 0.49	3.13 ± 1.11	2.71 ± 1.12	2.92 ± 1.02	

TABLE 4.	Causality	and	Preventability	According to	Type	e of Adverse Events

The incidence rate of adverse events identified in this study was 9.9%, which is similar to the 9.2% reported in a systematic review article.5 However, there was a significant difference in the incidence of adverse events by institution, with a minimum of 1.2% and a maximum of 45.6%. These differences could be attributed to the differences in the functional aspects of the medical institutions included in the study. Although all institutions participating in this study were regional public hospitals, there was a difference in the extent of their role as general hospitals in the region. This could be inferred based on the types of adverse events identified. For example, there were medical institutions that mostly reported surgery/procedural-related adverse events (such as institutions I and F) and those that did not (institutions L and E). It would be difficult to identify adverse events related to surgeries or procedures if the given medical institutions do not perform such types of surgeries or procedures. In addition, attempts were made to address the issue of variations in determining adverse events using the 3-stage medical records review. However, that variations could still exist among reviewers may explain the variations in the incidence of adverse events among institutions.

The strength of this study is that it identified the characteristics of the identified adverse events in detail. Focusing only on the incidence of adverse events may distract from the need to lower the incidence, which can be achieved by introducing interventions. Interventions can only be prioritized when the type and severity of adverse events, as well as the incidence, are determined. This study identified 5 types of adverse events including patient care–related adverse events including falls and decubitus ulcers in 346 cases (33.5%) followed by drugs/fluids/blood-related type. However, these types of adverse events are mostly of temporary harm. Events that extended the duration of hospitalization or involved significant harm were diagnosis-related, infectionrelated, or surgery/procedural-related. Therefore, it would be necessary to determine the priorities for introducing interventions

TABLE C. Dealers and the criteric factors Dealer of Assessmin as to T

to lower the incidence of adverse events by considering their frequency and severity concurrently.

In particular, the least frequently identified type of adverse events was diagnosis-related type (72 cases; 7.0%) and highest for death (15 cases; 20.8%), with a relatively high preventability score compared with the overall mean score. In Korea, an intervention strategy has been developed with a focus on the adverse events most frequently reported in the Korea Patient Safety Reporting & Learning System, which include falls or medication error events.25 However, considering the severity of diagnosis-related adverse events identified in this study, it seems critical to develop an interest in and develop preventive measures to address this.²⁶ It is necessary to develop measures to complement the identification of adverse events that were not recorded through patient or medical staff reports.^{27–29} This could be achieved by ensuring the preparation of medical records on delays or errors in diagnosis to increase the likelihood of identifying diagnosisrelated events.

It would be meaningful to calculate the economic burden caused by adverse events, based on the data on extended hospitalization period, and as confirmed by the results of this study. Calculating the cost of adverse events at the public health level, including direct and indirect costs, is expected to raise awareness of patient safety. However, it seems that there are few studies measuring the economic burden caused by adverse events. Furthermore, the methodology does not seem to be clearly established.² The economic cost of adverse events can be calculated by multiplying the length of hospitalization data by the average cost per day of hospitalization. However, to increase the validity of the estimation, it is necessary to calculate the average cost per hospitalization more accurately by calculating the medical cost for each patient when performing a medical records review.

The KNPSII will be conducted every 5 years in Korea in accordance with the Patient Safety Act, and similar surveys are periodically

	Prolonged Period, n (%)							
Type of Adverse Event	<5 d	6–10 d	11–15 d	16–20 d	>21 d			
Diagnosis-related	10 (19.2)	14 (26.9)	6 (11.5)	6 (11.5)	16 (30.8)	52 (100.0)		
Drugs/fluids/blood-related	33 (42.9)	27 (35.1)	5 (6.5)	7 (9.1)	5 (6.5)	77 (100.0)		
patient care-related	44 (41.5)	25 (23.6)	12 (11.3)	5 (4.7)	20 (18.9)	106 (100.0)		
Surgery/procedural-related	21 (20.4)	20 (19.4)	19 (18.4)	12 (11.7)	31 (30.1)	103 (100.0)		
Infection-related	27 (21.6)	32 (25.6)	16 (12.8)	16 (12.8)	34 (27.2)	125 (100.0)		
Total	134 (29.2)	118 (25.5)	58 (12.5)	46 (9.9)	106 (22.9)	463 (100.0)		

*Only analysis of matched results between reviewers.

conducted at the national level in other countries as well¹³⁻¹⁵; thus, it seems necessary to consider the role of medical records review for the identification of adverse events in a comprehensive review of the current status of patient safety. Although medical records review for the identification of adverse events is commonly regarded as the criterion standard for assessing patient safety,^{2,5} it is difficult to conduct it annually because of time and cost issues. Considering the characteristics of a large-scale medical records review that cannot be conducted on an annual basis, it is necessary to prepare a supplementary measure that can identify the incidence of adverse events for the years during which medical records review was not conducted. One possible measure is to examine the International Classification of Diseases, Ninth Revision codes corresponding to patient safety incidents in the administrative data.^{30,31} When using administrative data in the identification of adverse events, the validity of the codes is important; it seems to be an appropriate measure to evaluate the accuracy of the codes during the medical records review.

The limitation of this study is that medical institutions with a wider range of characteristics could not be included in the study. Although the number of medical institutions participating in this study was higher than that of other studies conducted in Korea, there is a limitation in that all medical institutions were regional public hospitals. A repeat study conducted at a larger medical institution, such as a university hospital, is required. Another limitation is that the incidence of adverse events for patients who were not screened in the first review was not verified. Although an independent review was conducted in the first review by 2 reviewers, the possibility that patients with adverse events were missed during the screening process cannot be ruled out. This limitation may lead to an underestimation of the incidence of adverse events in this study.

CONCLUSIONS

This study comprehensively presented the current status of adverse events for patients in hospitals in Korea using the results of the KNPSII survey, conducted for the first time based on the Korean Patient Safety Act. The issue of variations among institutions in the incidence of adverse events suggests that medical records review should be performed for medical institutions with a variety of characteristics in the future. In addition, the detailed characteristics of the identified adverse events could assist in determining the priority of intervention for reducing adverse events. The supplementary use of administrative data for the continuous calculation of adverse event incidence and costs should be addressed in future studies.

REFERENCES

- The research cycle: measuring harm. [World Health Organization Web site]. Available at: http://www.who.int/patientsafety/research/strengthening_ capacity/measuring_harm/en/. Accessed December 27, 2020.
- Klein DO, Rennenberg RJMW, Koopmans RP, et al. A systematic review of methods for medical record analysis to detect adverse events in hospitalized patients [published online march 11, 2020]. *J Patient Saf.* doi:10.1097/PTS. 000000000000670.
- Ock M, Kim HJ, Jeon B, et al. Identifying adverse events using International Classification of Diseases, Tenth Revision Y codes in Korea: a cross-sectional study. J Prev Med Public Health. 2018;51:15–22.
- Ock M, Lee SI, Jo MW, et al. Assessing reliability of medical record reviews for the detection of hospital adverse events. *J Prev Med Public Health*. 2015;48:239–248.
- de Vries EN, Ramrattan MA, Smorenburg SM, et al. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care*. 2008;17:216–223.

- Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med. 1991;324:370–376.
- Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med.* 1991;324:377–384.
- Wilson RM, Runciman WB, Gibberd RW, et al. The quality in Australian health care study. *Med J Aust.* 1995;163:458–471.
- Baker GR, Norton PG, Flintoft V, et al. The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada. *CMAJ*. 2004;170:1678–1686.
- Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ*. 2001;322:517–519.
- Letaief M, El Mhamdi S, El-Asady R, et al. Adverse events in a Tunisian hospital: results of a retrospective cohort study. *Int J Qual Health Care*. 2010;22:380–385.
- Sousa P, Uva AS, Serranheira F, et al. Patient and hospital characteristics that influence incidence of adverse events in acute public hospitals in Portugal: a retrospective cohort study. *Int J Qual Health Care*. 2018;30: 132–137.
- Rafter N, Hickey A, Conroy RM, et al. The Irish National Adverse Events Study (INAES): the frequency and nature of adverse events in Irish hospitals—a retrospective record review study. *BMJ Qual Saf.* 2017;26: 111–119.
- Smits M, Langelaan M, de Groot J, et al. Examining causes and prevention strategies of adverse events in deceased hospital patients: a retrospective patient record review study in the Netherlands. *J Patient Saf.* 2021;17: 282–289.
- Nilsson L, Borgstedt-Risberg M, Soop M, et al. Incidence of adverse events in Sweden during 2013–2016: a cohort study describing the implementation of a national trigger tool. *BMJ Open.* 2018;8:e020833.
- Ock M, Lee SI, Kim Y, et al. Development of case review form for detecting adverse events. *Qual Improv Health Care*. 2015;21:66–76.
- Hwang JI, Chin HJ, Chang YS. Characteristics associated with the occurrence of adverse events: a retrospective medical record review using the global trigger tool in a fully digitalized tertiary teaching hospital in Korea. J Eval Clin Pract. 2014;20:27–35.
- Hwang JI, Kim J, Park JW. Adverse events in Korean traditional medicine hospitals: a retrospective medical record review. *J Patient Saf.* 2018;14: 157–163.
- Kim S, Shin HG, Jo AEJ, et al. Variation between hospitals and reviewers in detection of adverse events identified through medical record review in Korea. *Int J Qual Health Care.* 2020;32:495–501.
- Korea Law Translation Center. Patient Safety Act. Available at: https://elaw. klri.re.kr/kor_service/lawView.do?hseq=34939&lang=ENG. Accessed December 27, 2020.
- 21. Korea Institute for Healthcare Accreditation. Development of Korean Patient Safety Incident Information Collection Model and Study on Demand Analysis of Medical Safety R&D Service Report. Seoul, South Korea: Korea Health Industry Development Institute; 2019.
- Zegers M, de Bruijne MC, Wagner C, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Qual Saf Health Care*. 2009;18:297–302.
- Baines RJ, Langelaan M, de Bruijne MC, et al. Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. *BMJ Qual Saf.* 2013;22:290–298.
- Baines R, Langelaan M, de Bruijne MC, et al. How effective are patient safety initiatives? A retrospective patient record review study of changes to patient safety over time. *BMJ Qual Saf.* 2015;24:561–571.
- Korea patient safety reporting & learning system. Available at: https:// statistics.kops.or.kr/biWorks/dashBoardMain.do?roleId=ROLE_ HEALTHCARE&status=O. Accessed December 27, 2020.

- National Academies of Sciences, Engineering, and Medicine. *Improving Diagnosis in Health Care*. Washington, DC: The National Academies Press; 2015.
- Ock M, Jo MW, Choi EY, et al. Patient safety incidents reported by the general public in Korea: a cross-sectional study. *J Patient Saf*. 2020;16: e90–e96.
- Pyo J, Choi EY, Lee W, et al. Physicians' difficulties due to patient safety incidents in Korea: a cross-sectional study. J Korean Med Sci. 2020;35:e118.
- Choi EY, Pyo J, Lee W, et al. Nurses' experiences of patient safety incidents in Korea: a cross-sectional study. *BMJ Open.* 2020;10:e037741.
- McIsaac DI, Hamilton GM, Abdulla K, et al. Validation of new ICD-10–based patient safety indicators for identification of in-hospital complications in surgical patients: a study of diagnostic accuracy. *BMJ Qual Saf.* 2020;29:209–216.
- Southern DA, Burnand B, Droesler SE, et al. Deriving ICD-10 codes for patient safety indicators for large-scale surveillance using administrative hospital data. *Med Care*. 2017;55:252–260.