INNOVATIONS JOURNALS

Research Article

Rates and Factors Associated With Serious Outcomes of Patient Safety Incidents in Malaysia: An Observational Study

Khairulina Haireen Khalid,[1,2] Eiko Yamamoto,[1] Nobuyuki Hamajima,[1] Tetsuyoshi Kariya[1]

[1]Department of Healthcare Administration, Nagoya University Graduate School of Medicine, Nagoya, Japan
[2]Medical Development Division, Ministry of Health, Malaysia

Address correspondence to Khairulina Haireen Khalid (haireen83@yahoo.com).

Source of Support: None. Conflict of interest: None.

Received: Dec 23, 2021; Revision Received: Mar 30, 2022; Accepted: Apr 5, 2022

Khalid KH, Yamamoto E, Hamajima N, Kariya T. Rates and factors associated with serious outcomes of patient safety incidents in Malaysia: An observational study. *Glob J Qual Saf Healthc*. 2022; 5:31–38. DOI: 10.36401/JQSH-21-19.

ABSTRACT

Introduction: This study aimed to examine the reporting rate and the factors associated with serious outcomes of patient safety incidents at public hospitals in Malaysia. **Methods:** All patient safety incidents reported in the e-Incident-Reporting System from January to December 2019 were included in the study. A descriptive study was used to describe the characteristics of incidents, and logistic models were used to identify factors associated with low reporting rates and severe harm or death outcomes of incidents. **Results:** There were 9431 patient safety incidents reported in the system in 2019. The mean reporting rate was 2.1/1000 patient bed-days or 1.5% of hospital admissions. The major category of incidents was drug-related incidents (32.4%). No-harm incidents contributed to 56.1% of all the incidents, while 1.1% resulted in death. More hospitals in the eastern (odds ratio [OR], 12.1) and southern regions (OR, 6.1) had low reporting rates compared to the central region. Incidents with severe harm or death outcomes were associated with more males (OR, 1.4) than females and with the emergency department (OR, 10.6), internal medicine (OR, 5.7), obstetrics and gynecology (OR, 2.4), and surgical department (OR, 5.0) more than the pharmacy department. Compared to drug-related incidents, operation-related (OR, 3.0), procedure-related (OR, 3.5), and therapeutic-related (OR, 4.8) incidents had significantly more severe harm or death outcomes, and patient falls (OR, 0.4) had less severe harm or death outcomes. **Conclusion:** The mean reporting rate was 2.1/1000 patient bed-days or 1.5% of hospital admissions. More hospitals in the eastern and southern regions had low reporting rates. Certain categories of incidents had significantly more severe outcomes.

Keywords: incident reporting, patient safety

INTRODUCTION

In December 2017, a nurse was charged with reckless homicide when she accidentally injected vecuronium into her patient instead of midazolam and caused his death.[1] In India on February 10, 2019, Mitarani Jena was unable to walk as a consequence of medical error when her doctor amputated the wrong leg.[2] These two sad stories were only a few of the millions of medical errors that happened in our healthcare setting. According to the World Health Organization (WHO), approximately 1 in 10 patients is harmed while receiving hospital treatment in developed countries.[3] Patient harm is the 14th leading cause of death and disability in the world, with the same rate as tuberculosis and malaria.[3] This situation was supported by a scoping review of 25 studies in 27 countries with the same findings.[4] Moreover, 50–80% of these harms were preventable incidents that were clearly avoidable.[3,4] These preventable adverse events are part of patient safety incidents that WHO defines as "an event or circumstances that could have resulted or did result in unnecessary harm to a patient."[5]

To our knowledge, there is no published study about the rate of adverse events in Southeast Asia, including Malaysia.[6] Recent evidence suggests that nearly 134 million adverse events occur each year due to unsafe care in low- and middle-income countries, resulting in 2.6 million deaths annually.[7] Wilson et al[8] described the rate of adverse events in eight developing countries in

the east Mediterranean and Africa as 2.5–18.4% per country. However, Wilson et al[8] also mentioned that the rate was not accurate because many other types of harm were not covered in the study.

One of the core elements for improving patient safety and reducing patient harm is to institutionalize a patient safety culture. To start a patient safety culture, strong reporting behavior is necessary. Several studies and experts concluded that reporting incidents was a key factor in improving patient safety culture.[9–14] When reporting is seen as a learning tool, there will be lessons learned for every error that happens; contributing factors that lead to an error will be identified, and mitigation factors will be created to avoid similar mistakes.[15] This will ultimately create a robust healthcare system and a safer environment, which is the original aim of a reporting system.

In Malaysia, adverse events are monitored via several systems. For the governmental hospitals, all patient safety incidents, including near misses and hazards, are required to be reported via the Incident Reporting and Learning System. As for the private hospitals, they are required to report an adverse event to the director-general of Health Malaysia.[16] There has been no published study regarding the exact number of patient safety incidents in Malaysia's hospitals. However, based on the number of hospital admissions in 2016 and the number of adverse events reported in the Malaysian Patient Safety Goals Report 2018,[17] approximately 6% of hospital admissions resulted in patient harm.[18] This was, of course, the tip of the iceberg as there were only a few types of adverse events included in the report.

Since the introduction of the incident-reporting system to facilitate reporting of these incidents in the governmental hospitals, there has been no published study to determine the reporting rate and its characteristics. This study analyzed the characteristics of patient safety incidents in the Ministry of Health, Malaysia (MoH) hospitals in 2019, concentrating on the reporting rate and the factors associated with severe harm and death outcomes. The information obtained from this study will be beneficial to our understanding of the severity of the problem and provide useful information to the policymakers for patient safety improvement.

METHODS

Ethical Considerations

No informed consent was taken because this was a retrospective study. It was conducted in compliance with ethical principles outlined in the Declaration of Helsinki and Malaysian Good Clinical Practice Guideline. This study was registered, and ethical approval was obtained from the Medical Research and Ethics Committee, National Institutes of Health, MoH, on Oct 26, 2020 (NMRR-20-2142-55452).

Data Sources

This study involved a descriptive analysis of the incident-reporting data from public hospitals, i.e., MoH hospitals and institutions. When patient safety incidents occurred in the hospitals, the reports were submitted through a web-based system called e-Incident Reporting (e-IR). The data for incidents that were reported to the e-IR from January 1, 2019, to December 31, 2019 were included in the study.

Characteristics of Patient Safety Incidents

A descriptive study was used to describe the characteristics of the incidents in the data set. The following variables were described: type of incident, sex, age, time (day or night), month of incident, type of hospital, region, department involved in the incident, type of staff (designation of the reporter) who reported the incident, category of incident, and patient outcome following the incident.

Reporting Rates of Incidents

Three types of means were calculated to compare the reporting behavior of each type of hospital and region. The first was the total number of incidents reported per hospital (number of incidents reported). The second was the number of incidents reported per 1000 patient bed-days (reporting rate). The third was the mean number of incidents reported per hospital admission. The denominator (the total number of patient bed-days and the number of hospital admissions for each hospital) was derived from the Health Information Centre, MoH.

Low Reporting Rates of Hospitals

To determine the factors associated with hospitals with a low reporting rate, all reported hospitals were divided into two groups. The median of the reporting rate was used as a cutoff point to divide hospitals with high reporting rates and hospitals with low reporting rates.

Factors Associated with Severe Harm or Death Outcomes

To examine the factors associated with more severe outcomes, the actual incidents were divided into two groups based on the severity of the patient outcome. No-harm, mild, and moderate outcomes were combined into one group, and severe harm and death outcomes were combined into another group. The following were excluded from the analysis: (1) all near-miss incidents; (2) incidents with an expected outcome (suicide); (3) incidents with an inapplicable outcome, i.e., forensic-related incidents and unexpected death (the incident in which the death of a patient is sudden and cannot be explained or occurs under suspicious circumstances and must be reported to the police); and (4) incidents with an unsure outcome.

Statistical Analysis

The data were downloaded into Microsoft Excel (Microsoft Corp., Redmond, WA, USA), manually cleaned, and analyzed using Microsoft Excel and SPSS Statistics ver. 27.0 (IBM SPSS Inc., New York, NY, USA). During manual cleaning, any duplicate reporting was removed. Kruskal-Wallis tests were used to examine the mean differences of reporting rates between the hospital variables, and χ^2 tests were used to examine the variables between the two groups of reporting rates and incident outcomes. Logistic regression analysis was performed to obtain the OR and 95% CI. A *p*-value less than 0.05 was considered a significant difference.

RESULTS

Characteristics of the Reported Incidents

In 2019, a total of 9431 incidents were reported in e-IR from 140 MoH hospitals and institutes (Table 1). Out of the 9431 incidents, 73.0% (n = 6888) were actual incidents, and the others (27%, n = 2543) were near misses. In terms of sex, 49.8% (n = 4699) of the incidents were female and 48.2% (n = 4549) were male. There were 183 incidents (1.9%) that involved more than one patient, such as an obstetric-related event (procedure-related incident) involving mother and baby and occurrence of fire (environmental-related incident).

The mean patient age was 42.1 (range, 0–97) years. However, most patients were in the age group of 61years old and above (26.8%, n = 2530) (Table 1). In this age group, most incidents were related to patient falls (45.3%, n = 1146) and drug-related incidents (30.9%, n = 783). The second highest age group was 21–40 years old, which comprised 26.5% (n = 2496) of the incidents. In this age group, obstetric-related incidents (23.3%, n = 583) and drug-related incidents (20.9%, n = 521) were the top two categories of incidents reported. Incidents in the age group 41–60 years accounted for 22.5% of all incidents and mostly consisted of patient falls (34.5%, n = 732) and drug-related incidents (33.9%, n = 719). Neonates and infants under 2 years of age accounted for 9.5% (n = 892) of all incidents. Most of them suffered drug-related incidents (35.0%, n = 312) and complications during delivery (procedure-related incidents), with 125 incidents (14.0%). For the pediatric and teenage age group 2–20 years old, they totaled 9.2% (n = 865) of the incidents. Almost half of the incidents in this age group were due to drug-related incidents (40.7%, n = 352), and patient falls were the second highest with 21.8% (n = 189).

More incidents occurred during the day (67.2%, n = 6338) compared to the night (32.8%, n = 3093) (Table 1). In terms of the month the incident occurred, there was not much difference among the quarters. The highest number of incidents was reported to occur from January to March (28.5%, n = 2684), and the least reported was from October to December (22.7%, n = 2141). State hospitals had the highest number of incidents (37.5%, n

Table 1. Characteristics of incidents reported in the e-IR system in 2019 in Malaysia (N = 9431)

Parameter	*n*	%
Type of incident		
Actual[a]	6888	73.0
Near-miss[b]	2543	27.0
Sex of patient		
Female	4699	49.8
Male	4549	48.2
Other[c]	183	1.9
Age of patient, years		
0–1	892	9.5
2–20	865	9.2
21–40	2496	26.5
41–60	2121	22.5
61+	2530	26.8
Other[c]	527	5.6
Time of incident		
Day[d]	6338	67.2
Night[e]	3093	32.8
Month of incident		
January–March	2684	28.5
April–June	2392	25.4
July–September	2212	23.5
October-December	2141	22.7
Other[c]	2	0.0
Type of hospital		
District hospital	1264	13.4
Major specialist hospital	3152	33.4
Minor specialist hospital	638	6.8
Institute	844	8.9
State hospital	3533	37.5
Region		
Peninsular Malaysia		
Central	3130	33.2
Eastern	732	7.8
Northern	2353	24.9
Southern	1332	14.1
Eastern Malaysia	1884	20.0
Department		
Pharmacy	621	6.6
Accident and emergency	461	4.9
Anesthesiology	186	2.0
Obstetrics and gynecology	1598	16.9
Internal medicine	2665	28.3
Pediatrics	1017	10.8
Psychiatry	591	6.3
Surgical	1493	15.8
Other[f]	799	8.5
Designation of reporter		
Doctor	3564	37.8
Nurse	4830	51.2
Other[g]	1037	11.0

[a]An incident that reached the patient.
[b]An incident that had been prevented before reaching the patient.
[c]Multiple patients involved in incident(s) with incomplete information.
[d]From 8:00 AM until 7:59 PM.
[e]From 8.00 PM until 7.59 AM.
[f]Other departments such as laboratory, dietetics, radiology, rehabilitation, and palliative care.
[g]Other professionals such as quality officers, medical assistants, and pharmacists.
e-IR: e-Incident Reporting.

Table 2. Category of incidents by patient outcome ($N = 9398$)[a]

	No Harm[b] ($n = 5270$)		Mild[c] ($n = 2370$)		Moderate[d] ($n = 793$)		Severe[e] ($n = 240$)		Death[f] ($n = 100$)		Unsure[g] ($n = 625$)		Total ($N = 9398$)	
Category	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**
Drug-related	2482	81.5	236	7.8	128	4.2	34	1.1	6	0.2	159	5.2	3045	32.4
Patient falls	1285	47.6	1167	43.2	141	5.2	43	1.6	13	0.5	52	1.9	2701	28.7
Procedure-related	356	22.5	546	34.5	345	21.8	90	5.7	46	2.9	201	12.7	1584	16.9
Therapeutic-related	597	67.7	93	10.5	55	6.2	36	4.1	27	3.1	74	8.4	882	9.4
Operation-related	193	41.0	120	25.5	74	15.7	23	4.9	4	0.8	57	12.1	471	5.0
Diagnostic-related	194	66.7	36	12.4	17	5.8	7	2.4	3	1.0	34	11.7	291	3.1
Environment-related	86	34.5	119	47.8	13	5.2	3	1.2	0	0.0	28	11.2	249	2.6
Self-harm	14	23.0	28	45.9	11	18.0	3	4.9	1	1.6	4	6.6	61	0.6
Other	63	55.3	25	21.9	9	7.9	1	0.9	0	0.0	16	14.0	114	1.2

[a]Includes all incidents except those with expected death outcome (suicide [$n = 10$]) and inapplicable outcome (forensic-related incidents [$n = 6$]) and unexpected death [$n = 17$]).
[b]The patient's outcome was asymptomatic or no symptoms were detected, necessitating no treatment.
[c]The patient's outcome was symptomatic, symptoms were mild, loss of function or harm was minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review, or minor treatment) was required or increased length of stay (up to 72 hours).
[d]The patient's outcome was symptomatic, requiring intervention (e.g., additional operative procedures, additional therapeutic treatment), and/or an increased length of stay (more than 72 hours to 7 days).
[e]The outcome was symptomatic, requiring life-saving intervention or major surgical or medical intervention, increased length of stay (more than 7 days), shortening life expectancy, or causing major permanent or long-term harm or loss of function.
[f]On the balance of probabilities, death was caused or brought forward in the short term by the incident.
[g]The definite outcome has yet to be determined or cannot be certain during the time of reporting.

= 3533) among all types of hospitals. The second highest was from major specialist hospitals with 33.4% (n = 3152). Minor specialist hospitals reported the least (6.8%, n = 638). Most incidents were reported from hospitals in the central region (33.2%, n = 3130), followed by the northern region (24.9%, n = 2353), and the least from the eastern region (7.8%, $n = 732$). In terms of the department involved, internal medicine had the highest number of reported incidents (28.3%, n = 2665), followed by the obstetrics and gynecology department (16.9%, n = 1598), surgical department (15.8%, $n = 1493$), and pediatrics department (10.8%, n = 1017). Most incidents were reported by nurses (51.2%) than by any other professions. Doctors reported 37.8% of the incidents (n = 3564). The rest were reported by other healthcare professionals such as pharmacist, medical assistant, laboratory technologist, physiotherapist, and quality manager (11.0%, $n = 1037$).

Categories of Incidents and Patient Outcomes

The most reported incidents were drug related (32.4%, $n = 3045$) (Table 2). The second most commonly reported incidents were patient falls (28.7%, n = 2701). Other reported incidents were as follows: procedure-related (16.9%, n = 1584), therapeutic-related (9.4%, n = 882), operation-related (5.0%, n = 471), diagnosis-related (3.1%, $n = 291$), environmental-related (2.6%, $n = 249$), self-harm (0.6%, n = 61), suicide (0.1%, n = 10), unexpected death (0.2%, n = 17), forensic-related (0.1%, $n = 6$), and others (1.2%, $n = 114$).

For patient outcomes following the incidents, half resulted in no harm (56.1%, n = 5270) (Table 2). Mild outcome was seen in 25.2% of the incidents ($n = 2,370$) and moderate outcome in 8.4% of the incidents (n = 793). Severe outcome was reported in 2.6% of the incidents ($n = 240$). Conversely, 1.1% or 100 incidents resulted in patient death following the incidents. Among those who had severe harm or death outcomes, most were the result of procedure-related incidents ($n = 136$) and therapeutic-related incidents ($n = 63$).

Number of Incidents Reported per Hospital

Among the types of hospitals, state hospitals had the highest number of incidents reported (mean 252.4, range, 89–719), and district hospitals had the lowest number of incidents reported (mean 17.7, range, 1–265) (Table 3). As for the region, the highest mean number of incidents was from the central region, with 126.2 (range, 1–719), and the lowest mean was from the eastern region, with a mean of 28.1 (range, 1–150) (Table 3).

Reporting Rate (per 1000 Patient Bed-Days)

The total number of patient bed-days in 2019 was 11,020,077. The reporting rate was not normally distributed between the hospitals, with the mean reporting rate of 2.1 incidents reported for every 1000 patient bed-days. The median was 0.7. The reporting rate distribution among the hospitals is illustrated in Figure 1.

There were significant differences in reporting rates between the regions and types of hospital (Table 3). For the types of hospital, institutes had the highest mean with a reporting rate of 10.3 (range, 0.0–80.1), and state hospitals reported the least, with only 0.8 (range, 0.3–2.2). The highest mean reporting rate between regions was from eastern Peninsular Malaysia (mean 4.2, range, 0.0–80.1), and the lowest was from Eastern Malaysia (mean 0.6, range, 0.1–4.1).

Table 3. Number of incidents and reporting rate according to types of hospital and regions

	No. of Hospitals (*n*)	Incidents Reported per Hospital, mean (range)	Reporting Rate per 1000 Patient Bed-Days, mean (range)
Types of hospital*			
District hospital	70	17.7 (1–265)	1.2 (0.1–11.2)
Major specialist hospital	27	116.2 (25–286)	0.9 (0.3–2.5)
Minor specialist hospital	20	33.6 (4–106)	3.8 (0.1–58.0)
Institute	9	94.2 (1–347)	10.3 (0.0–80.1)
State hospital	14	252.4 (89–719)	0.8 (0.3–2.2)
Region*			
Peninsular Malaysia			
Central	32	126.2 (1–719)	1.4 (0.1–3.8)
Eastern	26	28.1 (1–150)	0.6 (0.1–4.1)
Northern	21	68.8 (2–347)	0.7 (0.1–3.6)
Southern	15	88.9 (5–265)	1.3 (0.2–11.2)
Eastern Malaysia	46	41.0 (1–277)	4.2 (0.0–80.1)

*$p < 0.05$ (Kruskal-Wallis test) for mean reporting rate per 1000 patient bed-days.

Number of Incidents Reported per Hospital Admission

Total number of admissions in 2019 was 2,717,838. The mean number of incidents reported per hospital admission was 1.5%.

Comparison Between Hospitals with High and with Low Reporting Rates

Logistic regression analysis on low reporting rates showed that there were significant differences among the regions (Table 4). More hospitals in the eastern region (OR, 12.1; 95% CI, 3.3–44.5) and the southern region (OR, 6.1; 95% CI, 1.5–23.7) had low reporting rates compared with the central region.

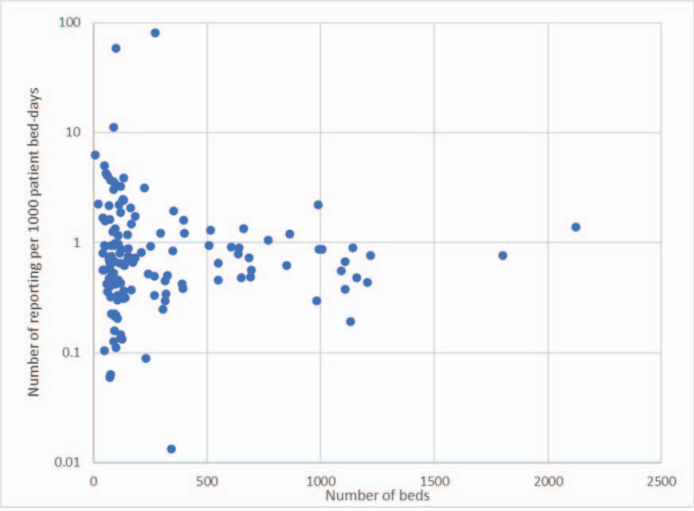

Figure 1. Distribution of the reporting rate per 1000 patient bed-days.

Table 4. Odds ratio (OR) and 95% CI of low reporting rate according to regions

	Hospitals with High Reporting Rate[a] (*N* = 70)		Hospitals with Low Reporting Rate[b] (*N* = 70)		
Region	*n*	%	*n*	%	OR (95% CI)
Peninsular Malaysia					
Central	22	68.8	10	31.2	1 (Reference)
Eastern	4	15.3	22	84.6	12.1 (3.3–44.5)*
Northern	6	28.6	15	71.4	5.5 (1.6–18.4)
Southern	4	26.7	11	73.3	6.1 (1.5–23.7)*
Eastern Malaysia	34	73.9	12	26.1	0.8 (0.2–1.8)

[a]Hospitals with an incidence rate ≥ 0.7 per 1000 patient bed-days.
[b]Hospitals with an incidence rate < 0.7 per 1000 patient bed-days.
*$p < 0.05$ (logistic regression).

Factors Associated with Severe Harm or Death Outcomes

No significant differences between the two groups of patient outcomes in terms of time of the incident, designation of the reporter, or the month of the incident as shown by χ^2 tests. Multivariate logistic regression analysis on severe harm or death outcomes was performed using variables that showed significant differences in χ^2 tests, i.e., sex, age category, the department where the incident happened, and the category of incident (Table 5). Incidents with severe harm or death outcomes were associated with males (OR, 1.4; 95% CI, 1.1–1.8) more than females. Compared to the pharmacy department, the emergency department (OR, 10.6; 95% CI, 2.4–46.1), internal medicine department (OR, 5.7; 95% CI, 1.4–24.1), obstetrics and gynecology department (OR, 2.4; 95% CI, 0.6–10.6), and surgical department (OR, 5.0; 95% CI, 1.2–21.5) were associated with more severe harm or death outcomes. Operation-related (OR, 3.0; 95% CI, 1.8–5.2), procedure-related (OR, 3.5; 95% CI, 2.4–5.3), and therapeutic-related incidents (OR, 4.8; 95% CI, 3.1–7.5) had significantly more severe harm or death outcomes, and patient falls (OR, 0.4; 95% CI, 0.3–0.6) had significantly less severe harm or death outcomes compared with drug-related incidents.

DISCUSSION

To the best of our knowledge, this is the first study to explore the characteristics of patient safety incidents in Malaysia's public hospitals. In this study, the majority of the reported incidents were actual incidents. This finding was supported by other studies that had a similar finding.[19,20] It was no surprise, for it was well known that healthcare workers tend to report more serious and higher-impact cases.[21] Because a near-miss incident does not result in harm to the patient, it is often underreported.

Most incidents, although "actual," did not result in significant harm to patients. This finding was comparable with other studies in other countries.[20,22–26] Only a small fraction of the incidents led to severe harm or

Table 5. Odds ratio (OR) and 95% CI of incident with severe harm or death outcome ($N = 6230$)[a]

	No Harm, Mild, or Moderate		Severe Harm or Death		
Variable	***n***	**%**	***n***	**%**	**Adjusted OR (95% CI)**
Sex					
Female	2960	95.0	157	5.0	1 (Reference)
Male	2839	94.1	177	5.9	1.4 (1.1–1.8)*
Age, years					
0–1	611	93.3	44	6.7	1 (Reference)
2–20	524	96.7	18	3.3	0.5 (0.3–1.0)
21–40	1611	94.5	94	5.5	0.9 (0.5–1.5)
41–60	1318	94.1	83	5.9	1.0 (0.6–1.8)
61–	1709	94.9	92	5.1	1.0 (0.5–1.7)
Department					
Pharmacy	197	99.0	2	1.0	1 (Reference)
Emergency	200	85.1	35	14.9	10.6 (2.4–46.1)*
Anesthesiology	109	93.2	8	6.8	2.6 (0.5–12.9)
Internal medicine	1842	94.3	112	5.7	5.7 (1.4–24.1)*
Obstetric and gynecology	1137	94.6	65	5.4	2.4 (0.6–10.6)*
Orthopedic	316	96.9	10	3.1	2.0 (0.4–9.6)
Pediatric	691	94.8	38	5.2	3.4 (0.8–15.7)
Psychiatry	336	98.0	7	2.0	2.0 (0.4–10.8)
Surgical	599	93.0	45	7.0	5.0 (1.2–21.5)*
Other	463	96.3	18	3.7	2.8 (0.6–12.7)
Category of incident					
Drug-related	1043	96.3	40	3.7	1 (Reference)
Diagnosis-related	151	93.8	10	6.2	1.3 (0.6–2.8)
Environmental-related	176	98.3	3	1.7	0.4 (0.1–1.6)
Operation-related	299	91.7	27	8.3	3.0 (1.8–5.2)*
Patient falls	2584	97.9	56	2.1	0.4 (0.3–0.6)*
Procedure-related	1218	90.0	136	10.0	3.5 (2.4 –5.3)*
Self-harm	53	93.0	4	7.0	2.6 (0.8–8.4)
Theraputic-related	286	81.9	63	18.1	4.8 (3.1–7.5)*
Other	80	98.8	1	1.2	0.4 (0.0–2.6)

[a]Includes all actual incidents except those with expected death outcome (suicide, $n = 10$), inapplicable outcome (forensic-related incidents [$n = 6$] and unexpected death [$n = 17$]), and unsure outcome ($n = 625$).
*$p < 0.05$ (logistic regression).

death outcomes, although the percentage of death in other studies was somewhat lower at 0.1–0.4%.[20,26] This discrepancy could be due to the variety of incidents reported and the different levels of development in the study countries. All comparative studies were from developed countries. Similar studies were not found in Southeast Asia or other developing countries.

In this study, the reporting rate was 2.1 per 1000 patient bed-days or 1.5% of hospital admissions. Other studies using the incident-reporting system found a homogeneous reporting rate, ranging from 0.39 to 3.4 per 1000 patient bed-days.[19,27] However, studies using medical record reviews had a higher rate of adverse events (3.7–12.0%).[22,23,25,28,29] Many studies suggested that the incident-reporting system might detect only a small fraction of adverse events.[30–33] According to Bates et al,[34] medical record review by a physician is the gold standard for detecting adverse events because it is a highly sensitive and reliable method. However, it was time-consuming and costly because this method required human intervention to detect adverse events. Using an incident-reporting system was an easy way to regularly and routinely detect adverse events. It was faster, user friendly, less costly, and instantaneously.

There were significant differences in the reported incidents between the regions. The central region had the highest number of reported incidents compared to the other regions. The central region consists of Selangor, Kuala Lumpur (capital city of Malaysia), Putrajaya (federal administrative city of Malaysia), Negeri Sembilan, and the lower part of Perak. It was suggested that higher reporting would reflect higher awareness of patient safety.[35,36] The central region was an urban region and had many large hospitals. It was more developed compared to the other regions. Because of the location advantages, hospitals in this region had easier access and direct supervision from the MoH's office in Putrajaya. Therefore, it was assumed that this region had higher awareness of patient safety. In contrast, there was a significant reduction in the number of reports in the eastern region. More hospitals in the eastern region also had low reporting rates compared to the central region. The eastern region consisted of Pahang, Terengganu, and Kelantan. Among the regions in Peninsular Malaysia, this region is less developed and has a smaller population, hence could be considered to be a rural area. Moreover, this difference in reporting

could also be influenced by the attitude of local people who were not yet ready for openness and transparency.

Regarding the reporting rate, the highest rate was from east Malaysia, followed by the central region. This means that there were more incidents reported per patient bed-day in east Malaysia than in the other regions. East Malaysia was also regarded as rural and underdeveloped when compared to Peninsular Malaysia. However, should we assume that the patient safety culture in this region was also as good as postulated in the central region? Perhaps it was more than that. Based on the observation of detailed reported data between the regions, certain categories of incidents were reported at higher-than-average rates in east Malaysia. The incidence rates of diagnosis-related incidents (e.g., missed diagnosis, laboratory-related incident) and therapeutic-related incidents (e.g., clinical management error, transfusion error, and dislodgement of catheter or tube) in east Malaysia were 1.5 to 2 times higher than in the central region. This suggests that the number of incidents in this region could be much higher and warrants further evaluation. One of the contributing factors was probably lack of transportation and accessibility difficulties that interfered with better diagnostic ability, technology, treatment, and specialist consultation in this region.[37]

Some categories of incidents were associated with more severe outcomes. In the results of this study, operation-related, procedure-related, and therapeutic-related incidents had a higher risk of developing severe harm or death outcomes compared with drug-related incidents. However, certain incidents were reported more frequently than others, such as drug-related incidents and patient falls. Although these incidents rarely resulted in a more serious outcome, they were more likely to be reported by the healthcare workers. Milch et al[20] and Nakajima et al[38] reported the same findings in their studies. It has been suggested that these incidents were more likely to be reported because healthcare workers were more familiar with them compared with other incidents.[39] As a well-known adage says, "your eyes cannot see what your brain does not know." Therefore, it is important for healthcare workers to know and identify an incident so that they are able recognize and report it.

There were some limitations in this study. First, the data obtained for this study referred only to the incidents that occurred in Malaysia's public hospitals. These data may not represent the whole country because private hospitals account for 30% of the total health services in Malaysia.[18] Second, there was a great possibility of underreporting as we relied on healthcare workers to report all incidents. This was reflected in the inconsistency in the number of reports across states as certain states had lower reporting rates compared to other states. Third, there could be information bias as the information collected for this study was based on healthcare workers' reports to the best of their knowledge. Further study using medical record review is needed to better estimate the rate of patient safety incidents in Malaysia. There is also a need to explore other factors that influence each category of incident, especially incidents that have a higher risk of developing more severe outcomes, so that specific preventive measures can be implemented. Other factors contributing to the low or high reporting rates in the eastern and east Malaysia regions also need to be identified.

CONCLUSION

In summary, the mean reporting rate of patient safety incidents in Malaysia was 2.1 per 1000 patient bed-days or 1.5% of hospital admissions, and the reporting rate differed among the five regions. Although the results were similar to other studies, we believe that the reporting rate was too low. There are still many other incidents that were underreported. Thus, this area is important for policymakers to explore in order to determine the exact causes of reporting differences and to address them so that reporting can be improved. Most incidents can be prevented if we know the root cause of the problem. As we have shown in our results, certain departments and categories of incidents were found to have significantly more severe outcomes (operation-related, procedure-related, and therapeutic-related incidents). Therefore, further studies are needed to explore the exact factors influencing the occurrence of individual incidents, particularly those with more severe outcomes, so that the risk of future incidents can be mitigated.

Acknowledgments

We thank the director-general of Health Malaysia for his permission to publish this study. We also give special thanks to Patient Safety Unit, Medical Care Quality Section, Ministry of Health Malaysia and Health Information Centre, Ministry of Health Malaysia for their contributions to this study.

References

1. Ross MS. 6 Medication Error Stories That Made Headlines. Cureatr. March 1, 2019. Accessed December 5, 2020. blog.cureatr.com/6-medication-error-stories-that-made-headlines
2. Adnal M. Doctors operate on wrong leg of patient, now she can barely walk. www.oneindia.com. February 10, 2019. Accessed December 5, 2020. www.oneindia.com/india/doctors-operate-on-wrong-leg-of-patient-now-she-can-barely-walk-2849631.html
3. World Health Organization. 10 facts on patient safety. 2019. Accessed October 10, 2020. www.who.int/news-room/photo-story/photo-story-detail/10-facts-on-patient-safety
4. Schwendimann R, Blatter C, Dhaini S et al. The occurrence, types, consequences and preventability of in-hospital adverse events - a scoping review. *BMC Health Serv Res*. 2018;18:1–13.
5. World Health Organization. The conceptual framework for the international classification for patient safety. Jan 15, 2009. Accessed Oct 10, 2020. www.who.int/publications/i/item/WHO-IER-PSP-2010.2
6. Harrison R, Cohen AWS, Walton M. Patient safety and quality of care in developing countries in Southeast Asia: a systematic literature review. *Int J Qual Health Care*. 2015;27:240–254.

7. National Academies of Sciences, Engineering, and Medicine. *Crossing the Global Quality Chasm: Improving Healthcare Worldwide*. The National Academies Press; 2018.
8. Wilson RM, Michel P, Olsen S, et al. Patient safety in developing countries: retrospective estimation of scale and nature of harm to patients in hospital. *BMJ*. 2012;344:e832.
9. Vincent C. Incident reporting and patient safety. *Br Med J*. 2007;334:51.
10. Leappe LL. Reporting of adverse events. *N Engl J Med*. 2002;347:1633–1638.
11. Donaldson L. An organisation with a memory. *Clin Med (Lond)*. 2002;2:452–457.
12. Wang X, Liu K, You LM, et al. The relationship between patient safety culture and adverse events: a questionnaire survey. *Int J Nurs Stud*. 2014;51:1114–1122.
13. Deufel CL, McLemore LB, de los Santos LEF, et al. Patient safety is improved with an incident learning system—clinical evidence in brachytherapy. *Radiother Oncol*. 2017;125:94–100
14. Nygren M, Roback K, Öhrn A, et al. Factors influencing patient safety in Sweden: perceptions of patient safety officers in the county councils. *BMC Health Serv Res*. 2013;13.
15. Flemons WW, McRae G. Reporting, learning and the culture of safety. *Healthc Q*. 2012;15:12–17.
16. Laws of Malaysia. Private Healthcare Facilities and Services Act 1998. Government of Malaysia; 1998. medicalprac.moh.gov.my/v2/uploads/ACT%20586%20PHFS%201998(English).pdf
17. Ministry of Health, Malaysia. Malaysian patient safety goals annual report 2018. Ministry of Health Malaysia; 2018. doc-14-bk-docs.googleusercontent.com/docs/securesc/rj7rsgps71q3hs8a1aij1sdm1f8djaed/1l070fak8fcl4b928q6t2ptbm03th5mu/1607182275000/10098171202159136293/09412615002285840480/1aqc-wPEbe1Y_GBMGDWYfS3AkvW9OsVSo?authuser=0
18. Ministry of Health, Malaysia. Health Facts 2017. Ministry of Health, Malaysia; 2017. www.moh.gov.my/moh/resources/Penerbitan/Penerbitan%20Utama/HEALTH%20FACTS/HEALTH%20FACTS%202017.pdf
19. Ramírez E, Martín A, Villán Y, et al. Effectiveness and limitations of an incident-reporting system analyzed by local clinical safety leaders in a tertiary hospital: prospective evaluation through real-time observations of patient safety incidents. *Medicine*. 2018;97.
20. Milch CE, Salem DN, Pauker SG, et al. Voluntary electronic reporting of medical errors and adverse events: an analysis of 92,547 reports from 26 acute care hospitals. *J Gen Intern Med*. 2006;21:165–170.
21. Mayo AM, Duncan D. Nurse perceptions of medication errors: what we need to know for patient safety. *J Nurs Care Qual*. 2004;19:209–217.
22. 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.
23. 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.
24. Correa CS, Bagatini A, Prates CG, et al. Patient safety in endoscopy unit: an observational retrospective analysis of reported incidents. *Braz J Anesthesiol*. 2021;71:137–141.
25. 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.
26. Howell AM, Burns EM, Bouras G, et al. Can patient safety incident reports be used to compare hospital safety? Results from a quantitative analysis of the English National Reporting and Learning System data. *PLoS One*. 2015;10:1–15.
27. Danielis M, Bellomo F, Farneti F, et al. Critical incidents rates and types in Italian intensive care units: a five-year analysis. *Intensive Crit Care Nurs*. 2021;62:102950.
28. Panagioti M, Khan K, Keers RN, et al. Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis. *BMJ*. 2019;366:l4185.
29. 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.
30. Sari ABA, Sheldon TA, Cracknell A, et al. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *Br Med J*. 2007;334:79–81.
31. Olsen S, Neale G, Schwab K, et al. Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place. *Qual Saf Health Care*. 2007;16:40–44.
32. Toyabe S. Characteristics of inpatient falls not reported in an incident reporting system. *Glob J Health Sci*. 2015;8:17–25.
33. Rutberg H, Borgstedt Risberg M, Sjödahl R, et al. Characterisations of adverse events detected in a university hospital: a 4-year study using the Global Trigger Tool method. *BMJ Open*. 2014;4:e004879.
34. Bates DW, Evans RS, Murff H, et al. Detecting adverse events using information technology. *J Am Med Inform Assoc*. 2003;10:115–128.
35. Hutchinson A, Young TA, Cooper KL, et al. Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from the national reporting and learning system. *Qual Saf Health Care*. 2009;18:5–10.
36. Kumbi M, Hussen A, Lette A, et al. Patient safety culture and associated factors among health care providers in Bale Zone hospitals, southeast Ethiopia: an institutional based cross-sectional study. *Drug Healthc Patient Saf*. 2020;12:1–14.
37. Zarida H, Mohamad Salleh AA, Milton LSW, et al. Ministry of Education, Malaysia and Ministry of Health. [Malaysia's Policy implementation: effectiveness of implementation on the demand and production of medical doctors in Malaysia.] [in Malay]. 2014. DOI: 10.13140/RG.2.1.3932.0163
38. Nakajima K, Kurata Y, Takeda H. A web-based incident reporting system and multidisciplinary collaborative projects for patient safety in a Japanese hospital. *Qual Saf Health Care*. 2005;14:123–129.
39. Kreckler S, Catchpole K, Mcculloch P, et al. Factors influencing incident reporting in surgical care. *Qual Saf Health Care*. 2009;18:116–120.