

Change in the Number of Patient Safety Reports Through a 16-Year Patient Safety Initiative: A Retrospective Study Focusing on the Incident Severity and Type in a Japanese Hospital

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Purpose: To describe the long-term quantitative change in the number of submissions of patient safety reports after the introduction of a patient safety reporting system, focusing on incident severity and type.

Patients and Methods: This study was performed at a tertiary care hospital in Japan. Patient safety reports from 2006 to 2020 were retrospectively reviewed. Incident severity was classified from level 0 (near miss) to level 5 (fatality). The incident types included those related to medication, patient care, drains and catheters, procedures and interventions, examinations, medical devices, and blood transfusions. The study period was divided into 1. 2004–2007; 2. 2008–2014; and 3. 2015–2020 based on the implementation of hospital patient safety strategies. The number of reports per hospital worker was compared among the study periods and the incident levels and types.

Results: We analyzed 96,332 reports extracted from the patient safety reporting system of the hospital. The total number of reports per hospital worker has increased over time. The numbers of levels 0 and 1 incidents increased throughout the study period. In addition, levels 3a and 3b incidents increased between periods 2 and 3. All incident types, except for procedure and intervention-related incidents, increased between periods 1 and 2 and between periods 1 and 3. The number of procedure and intervention-related incidents increased between periods 2 and 3, although it did not between periods 1 and 2.

Conclusion: We found increases in the number of patient safety reports according to the incident severity and type. This suggests two contextual changes occurring during the cultural maturity process, which reflected the development of organizational patient safety culture in our institution. The first was the establishment of a reporting attitude in the institution. The second was to overcome barriers to patient safety.

Keywords: patient safety report, reporting system, safety culture, incident report, incident type, incident severity

Introduction

Healthcare systems are currently developing new medicines, techniques, technologies, and processes. The development of the healthcare system has brought about the complexity of achieving high-quality care. Unfortunately, patient safety is threatened by preventable errors owing to the complexity of the development of the healthcare system.^{1,2} Patient safety is a serious public health concern worldwide.

Measurement, evaluation, and identification of the change in patient safety are important to improve and enhance patient safety, but they remain a challenge.³ Conceptually, the attitudes and behaviors of healthcare providers are a direct determinant of patient safety.⁴ Although there are many initiatives to encourage the staff to care for patients safely, patient safety reporting systems are thought to be a key to the realization of patient safety.⁵ The first step for patient

safety in a healthcare institution is to implement a reporting system appropriately because the patient safety reports submitted by the frontline staff reflect the attitudes of the healthcare providers.⁵ Patient safety reporting system requires various factors, such as the leadership of top management, adequate policy for patient safety, and participation of frontline staff. Many barriers hinder the development of a safety culture and patient safety.⁶ A well-implemented reporting system to overcome barriers will accelerate the reporting attitude of healthcare providers.⁷ Healthcare institutions are required to implement reporting systems with structured strategies, including environmental management for hospital workers to report, clear report management rules, analysis of incidents, and adequate feedback.⁵ The number of reports in patient safety reporting systems is considered an appropriate measurement of patient safety in the healthcare institution because an increased number of reports from the frontline staff implies a better implementation of patient safety.⁸ At present, many institutions have a large number of annual patient safety reports.^{5,9,10}

To our knowledge, few studies have investigated changes in patient safety reports, focusing on the contents such as incident severities and types, after a patient safety reporting system was introduced and developed. It is not well known when and what incident levels and types of patient safety reports increase as a medical institution has introduced a patient safety reporting system. To clarify this question, we investigated the trajectory of contextual changes in patient safety reports in a large-scale hospital in Japan over 16 years from the time of the introduction of a patient safety reporting system.

Materials and Methods

Study Setting

This study retrospectively used data collected from a tertiary academic hospital in Japan with more than 1400 beds. This hospital provides acute care and specialized stroke, neurology, coronary, and trauma units. The safety management system was developed in the hospital as follows. Each staff member reports the incident in which they were involved through a voluntary reporting system. The safety department collects and manages the reports on the incidents. Each department has a safety manager. The implementation process and strategies of the patient safety reporting system in this hospital have already been reported elsewhere in more detail.⁹ The safety department carries out multifaceted strategies for the reporting system, as follows: a blame-free policy was declared for frontline staff in the management of the incident reports; patient safety education was provided to all staff annually; positive feedback was returned by the safety department to the frontline staff; monthly in-hospital newspapers were published by the safety department to encourage reporting; an electronical reporting system was developed and timely revisions were performed for easy reporting. The reporting system in this institution had several features of an electronical system to enhance reporting.^{9,11} With the electronical reporting system, the hospital staff could easily and fully report the patient information and incident details, such as the date and time, location, type, and severity of the incidents, and the reporter's profession, which were defined by the safety department as mandatory information in the electronical reporting system. The reporting system is similar to the conceptual framework for the International Classification for Patient Safety (ICPS).⁵

Materials

An electronical patient safety reporting system has been implemented since 2004 in our hospital. We extracted data from a reporting system registered between April 2004 and March 2020. Information regarding the reporters or staff involved in the incident was kept confidential. This reporting system facilitates voluntary reporting. Reports could be submitted by all professionals, including physicians, nurses, pharmacists, laboratory technicians, radiologic technologists, clinical engineers, rehabilitation therapists, office workers, and others. The reports were delivered to the safety managers of each department and the safety management department. The safety department reviewed all reports, interviewed the stakeholders, and revised the submitted data, including severity or type of incident, if necessary. An incident might have been duplicated by two or more hospital workers of different professions. Our hospital allows and encourages this since it suggests that our hospital staff assertively submits patient safety reports when they are involved in an incident and that several points of view by different professions are necessary to clarify why the incident occurs. The number of reports per hospital worker was considered an indicator of safety culture in this study.

Definitions of Severity and Type of Incident

The severity of each incident was submitted by a reporter and determined by the safety management department in our hospital based on the Japanese National University Council for Clinical Quality Management, ranging from 0 to 5.¹² Level 0 was defined as a near miss, level 1 was an incident of no harm for which some treatment was necessary, level 2 was a minor and temporal effect that required close observation, level 3a was a minor and temporally adverse incident that required minor intervention, level 3b was an adverse incident that required major intervention, level 4 required intensive care or caused a permanent disorder, and level 5 was defined as patient death. The types of each incident were classified by a reporter and verified into seven categories based on the Japan Council for Quality Health Care: medication, patient care, drain and catheter, procedure and intervention, examination, medical device, and blood transfusion.¹³

Data Analysis

We described the number of patient safety reports according to the severity and type of incidents and the fiscal year in which the incidents occurred. The numbers were calculated every six months; the first half was from April to October, and the latter was from November to March according to the Japanese fiscal year, which starts in April and ends in March. The entire study period was divided into three groups based on an increase in the number of reports. This resulted from our hospital's intense implementation strategies as we already reported.⁹ The first, second, and third periods were defined as from 2004 to 2007, from 2008 to 2015, and from 2016 to 2019, respectively. The Kruskal–Wallis test was used to compare the number of patient safety reports among the three periods based on the severity and type of incidents. Multiple comparisons were performed using Dunn–Bonferroni post-hoc correction when the results of the Kruskal–Wallis test were statistically significant. Statistical analyses were performed using SPSS version 25 (IBM, Armonk, NY). Statistical significance was set at $P < 0.05$.

Results

A total of 110,058 reports were collected from April 2004 to March 2020 from the electronic reporting system. Reports registered in the electronic reporting system as draft or pre-revision reports were excluded, and 96,332 reports were analyzed in this study. The total number of institutional staff members is presented in Table 1, and the number of reports by profession is presented in Table 2. The number of reports per hospital worker was significantly different among the three periods (Figure 1).

The number of patient safety reports, according to the severity of the incident, is presented in Table 3. Level 1 was the most frequently reported level, followed by levels 0, 3a, and 2. The number of reports per hospital worker differed among the three periods for levels 0, 1, 2, 3a, and 3b. No significant differences were observed in levels 4 and 5 reports. The number of levels 0 and 1 reports per hospital worker was different between periods 1 and 2, between periods 2 and 3, and between periods 1 and 3 (Figure 2). A significant difference in level 2 reports was observed only between periods 1 and 3. A significant increase in levels 3a and 3b reports was observed between periods 1 and 3, and between periods 2 and 3.

The number of patient safety reports by incident type is presented in Table 3. Medication-related incidents were most frequently reported, followed by patient care-related, drain and catheters-related, and procedure and intervention-related incidents. The number of reports per hospital worker differed among the three periods for all incident types. The number of medication-, patient care-, drain and catheter-, and medical device-related reports per hospital worker differed between periods 1 and 2, between periods 2 and 3, and between periods 1 and 3 (Figure 3). A significant difference was observed in procedure and intervention-related incidents between periods 1 and 3 and between periods 2 and 3. A significant increase in examination- and blood transfusion-related incidents was observed between periods 1 and 2, and between periods 1 and 3.

Discussion

This study demonstrates the development process of patient safety with contextual changes in reported incidents based on real-world experience. This change in the reporting context was observed in both the severity and type of incidents. This change reflected organizational patient safety and suggested the development of a safety culture at our institution.

Table 1 Annual Data of the Hospital Staff

	First Half of 2004	Second Half of 2004	First Half of 2005	Second Half of 2005	First Half of 2006	Second Half of 2006	First Half of 2007	Second Half of 2007	First Half of 2008	Second Half of 2008	First Half of 2009	Second Half of 2009	First Half of 2010	Second Half of 2010	First Half of 2011
Nurse	869	859	904	885	882	871	972	963	1083	1067	1157	1103	1155	1117	1181
Physician	349	393	417	412	434	430	470	467	507	495	530	531	545	536	527
Pharmacist	43	43	42	45	64	56	59	57	66	66	68	66	68	64	72
Laboratory technician	88	89	89	88	104	102	101	100	108	105	111	111	110	106	108
Radiologic technologist	56	57	56	56	64	63	66	66	67	69	75	74	75	74	80
Clinical engineer	30	29	29	28	26	26	24	25	26	26	25	25	27	31	30
Rehabilitation therapist	32	38	33	36	38	38	39	38	45	44	49	49	53	53	54
Office worker	173	174	190	180	207	196	208	202	218	212	228	221	224	220	226
Others	178	171	180	169	159	159	171	173	180	170	180	297	303	317	303
Total number of staff	1818	1853	1940	1899	1978	1941	2110	2091	2300	2254	2423	2477	2560	2518	2581

Note: The numbers of staff were described every 6 months.

Table 2 Annual Data of the Reports by Profession

	Total Number of Reports	First Half of 2004	Second Half of 2004	First Half of 2005	Second Half of 2005	First Half of 2006	Second Half of 2006	First Half of 2007	Second Half of 2007	First Half of 2008	Second Half of 2008	First Half of 2009	Second Half of 2009	First Half of 2010	Second Half of 2010
Nurse	54,379	498	769	795	658	623	742	771	1030	1558	1651	1643	1526	1617	1654
Physician	7352	69	109	102	102	109	160	149	130	207	219	216	217	183	187
Pharmacist	19,076	16	38	28	51	63	71	63	70	47	56	58	52	63	80
Laboratory technician	4569	56	103	77	80	26	50	22	171	123	138	144	132	148	161
Radiologic technologist	3604	31	13	27	40	15	21	46	58	68	78	69	89	100	109
Clinical engineer	3351	0	0	0	0	0	0	0	0	1	1	0	2	0	1
Rehabilitation therapist	1192	2	8	8	8	11	11	18	13	20	25	30	32	29	38
Office worker	444	9	14	48	12	5	3	3	2	21	39	35	32	6	4
Others	2365	15	30	22	18	11	26	7	19	20	31	32	21	24	19

Note: The numbers of reports were described every 6 months.

The first stage in cultural change was observed between periods 1 and 2. In terms of severity, levels 0 and 1 incidents, which meant near misses and incidents with no harm, increased significantly and remarkably in the early phase. No-harm incidents tend to be reported more than adverse incidents.¹⁴ The greatest barrier to reporting was fear of blame and adverse consequences from the report.⁶ Reporters would have felt no fear of blame or little sense of guilt for levels 0 and 1 incidents because of the lack of patient harm. In contrast, levels 3a and 3b reports or higher, which affected a patient's clinical course, did not increase during the early phase. At the same time, the number of all types of reports, except for incidents related to procedures and interventions, has been increasing. Although patient safety reports are additional and time-consuming work, an increased number of reports was observed in our institution.⁶ The reports increasing in the early phase could reflect the appropriate implementation of a patient safety reporting system and the establishment of a reporting culture.^{7,15} In summary, the first change in safety culture was the establishment of a reporting attitude of the patient events and the development of transparency in the institution.

The second stage of cultural change in this study was observed between periods 2 and 3. In the late phase of the study, a significant increase in the reports of intervention-related incidents and adverse incidents, such as levels 3a and 3b, was observed. Invasive procedures pose a significant risk for the patient, and intervention-related incidents occur at a certain frequency.¹⁴ However, in reporting an adverse incident, healthcare workers usually felt a great barrier with fear of adverse consequences due to reporting, such as a sense of guilt, punishment, and litigation.⁶ The subjects would be

Second Half of 2011	First Half of 2012	Second Half of 2012	First Half of 2013	Second Half of 2013	First Half of 2014	Second Half of 2014	First Half of 2015	Second Half of 2015	First Half of 2016	Second Half of 2016	First Half of 2017	Second Half of 2017	First Half of 2018	Second Half of 2018	First Half of 2019	Second Half of 2019
1117	1164	1124	1206	1174	1265	1210	1276	1242	1291	1270	1304	1285	1362	1363	1495	1459
530	533	529	551	552	576	565	590	576	584	581	597	596	647	638	658	636
69	82	80	82	79	83	80	85	89	95	96	106	106	113	106	124	127
103	108	105	108	109	116	113	107	108	115	111	120	118	125	121	134	133
78	85	87	93	89	96	94	96	96	101	100	104	101	105	103	113	112
27	31	32	31	32	36	36	35	30	34	34	37	37	41	39	42	41
47	62	59	75	75	80	79	85	85	107	103	116	120	155	152	161	157
193	190	194	198	191	194	184	195	200	212	208	208	206	216	222	242	245
299	316	342	355	347	376	371	351	351	338	335	331	343	349	341	362	351
2463	2571	2552	2699	2648	2822	2732	2820	2777	2877	2838	2923	2912	3113	3085	3331	3261

First Half of 2011	Second Half of 2011	First Half of 2012	Second Half of 2012	First Half of 2013	Second Half of 2013	First Half of 2014	Second Half of 2014	First Half of 2015	Second Half of 2015	First Half of 2016	Second Half of 2016	First Half of 2017	Second Half of 2017	First Half of 2018	Second Half of 2018	First Half of 2019	Second Half of 2019
1703	1613	1349	1537	1741	1744	1891	1603	1718	1809	2355	2674	3065	2993	3010	2481	2775	2783
248	230	220	210	225	220	245	237	239	254	265	304	372	355	408	345	432	384
72	96	84	82	77	130	941	902	1125	1361	989	497	250	1149	2288	2415	3101	2761
150	160	144	119	149	149	114	194	306	299	314	245	243	158	111	146	90	47
127	135	122	166	207	198	175	158	115	101	113	117	126	157	152	167	231	273
0	0	10	6	20	34	38	164	196	197	191	276	289	245	506	430	452	292
25	32	22	16	30	24	19	20	39	37	87	43	47	87	91	78	134	108
1	6	6	13	11	1	3	1	4	4	12	14	26	39	19	22	17	12
28	30	9	14	29	38	54	14	38	35	79	53	615	760	63	66	67	78

worried about the prosecution, retribution, or betrayal of the intervention operator potentially resulting from the patient safety reporting. Healthcare providers are afraid of being punished by coworkers for their reporting. Self-reporting by physicians was also challenging because they often felt fear of blame and were worried about inappropriate management of the report.^{6,16} Therefore, increasing numbers of patient safety reports on adverse incidents and intervention-related reports indicate that frontline staff prioritize patient safety over individual or organizational barriers. The secondary change in safety culture was overcoming these multiple barriers to patient safety and priority change in healthcare providers. Severe-harm incidents rated at levels 4 and 5 did not increase during the study period. The reason for this is the rarity of such highly severe incidents. A similar low incidence rate of severe-harm events was reported in another institution.¹⁰ The results suggest that the development of a safety culture could not be evaluated only based on the number of severe-harm incident reports.

The change in the patient safety report, which reflects the attitude of frontline staff, is considered to suggest the development of safety culture.⁸ Several stepwise models were developed to explain the safety maturation.^{17–19} Our findings of both the increasing number of reports per hospital worker and the contextual change of reports suggest that our institution experienced a two-step contextual change, which could be explained by the maturing process of the safety culture. In the primary step of safety culture, the institution ignores the safety issues, but reacts to them when a patient safety incident occurs in the second step. Between periods 1 and 2 at our institution, incidents of low-level severity (ie,

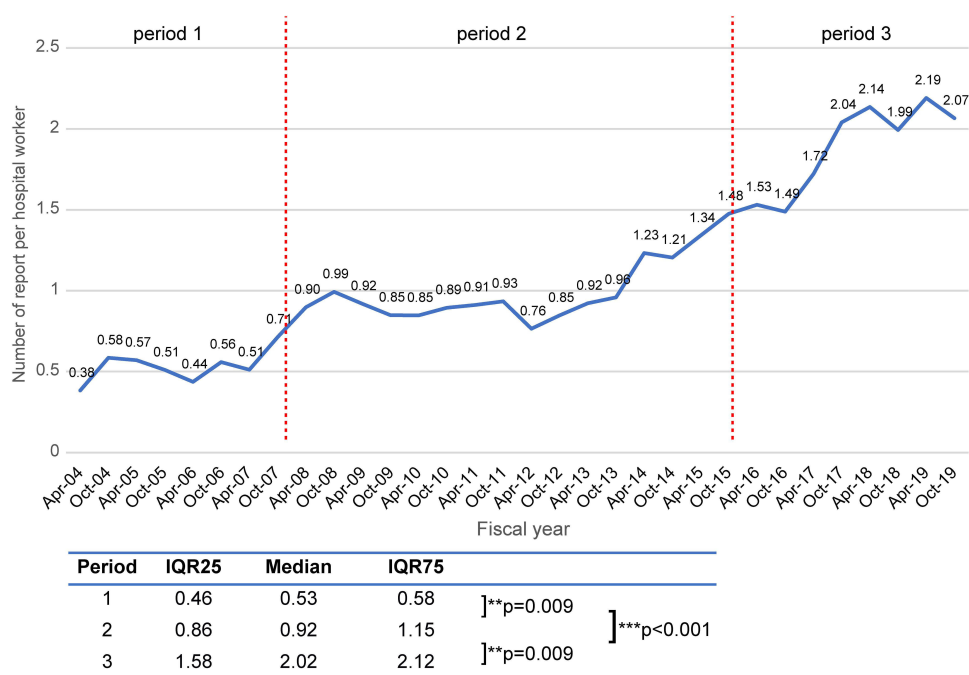


Figure 1 Total number of reports per hospital worker. The study was divided into three periods. A comparison of the report rate between the three periods was performed using Dunn's test with Bonferroni correction since the Kruskal–Wallis test was significant. (**p<0.01, ***p<0.001).

Table 3 Incident Severity and Type

Fiscal Year	First Half of 2004	Second Half of 2004	First Half of 2005	Second Half of 2005	First Half of 2006	Second Half of 2006	First Half of 2007	Second Half of 2007	First Half of 2008	Second Half of 2008	First Half of 2009	Second Half of 2009	First Half of 2010	Second Half of 2010	First Half of 2011	Second Half of 2011
Total	696	1084	1107	969	863	1084	1079	1493	2065	2238	2227	2103	2170	2253	2354	2302
Severity																
0	110	147	143	142	109	113	135	223	269	275	283	241	230	297	326	386
1	409	601	577	472	413	515	520	720	1133	1287	1295	1260	1310	1232	1271	1343
2	42	56	80	70	66	116	126	206	211	190	224	211	216	226	212	188
3a	57	129	146	168	149	176	192	207	289	305	279	242	278	354	392	242
3b	0	0	0	0	55	53	33	47	84	78	66	59	55	69	68	67
4	1	3	2	5	3	0	5	3	2	4	2	2	1	2	8	6
5	4	7	9	11	12	8	1	6	3	8	10	17	10	7	16	19
Unclassified	73	141	150	101	56	103	67	81	74	91	68	71	70	66	61	51
Type																
Medication	170	254	245	213	258	281	302	354	562	599	655	589	597	628	603	628
Patient care	219	289	315	287	232	285	268	361	488	484	498	416	480	459	462	489
Drain and catheter	97	174	158	162	138	166	166	229	277	326	371	355	330	355	363	353
Procedure and intervention	58	92	74	93	92	154	130	202	298	343	298	257	257	277	272	190
Examination	65	103	88	78	44	66	51	143	216	226	194	221	242	284	322	334
Medical device	14	21	24	15	12	13	17	51	49	53	36	43	62	49	62	54
Transfusion	8	4	10	13	5	7	13	10	17	22	14	27	26	21	23	10
Unclassified	65	147	193	108	82	112	132	143	158	185	161	195	176	180	247	244

Note: The numbers of reports were described every 6 months.

levels 0 and 1) were mainly registered in the reporting system. This corresponds to awareness of safety issues, suggesting that our institute might have moved from the primary step toward the second step. Between periods 2 and 3 in our institute, we observed an increase in the number of patient safety reports of moderate-level severity, that is, levels 3a and 3b, and of procedure and intervention-related incidents. In the latter steps of safety culture, the institution establishes a rule of safety, determines the importance of patient safety, and ranks safety as a high priority. Increasing reports of severe patient harm and intervention-related incidents suggest that our institution might have tackled the healthcare safety issues positively and moved toward the latter steps of safety culture. Although the current study results suggest the availability of a reporting system to evaluate cultural maturity, further investigation is warranted to verify the utility of patient safety reports for analysis of the safety culture.

In this study, the number of reports per hospital worker was used as an indicator of reporting culture. Some studies used the reports per 1000 bed days or per 100 admissions, adjusting for care volume.^{7,20} These indicators focused on hospital volume or patient number. Since our study focused on the staff's attitude and behavior of reporting, we chose the indicator of the number of reports per hospital worker. As a result, the indicator of reports per hospital worker was able to describe contextual changes in reporting behavior.

The quality of patient safety reports could be a concern in evaluating the patient safety reporting system. Not all healthcare institutions introduce appropriate systems for compliance with the ICPS.^{5,11} A previous in-depth analysis pointed out that the patient safety reports contained insufficient or wrong information at a certain frequency.²¹ However, the electronic reporting system used in this study is equipped with a framework that complies with the ICPS, and all reports were reviewed by the safety department. Through this process, the quality of reports was ensured in this study.

First Half of 2012	Second Half of 2012	First Half of 2013	Second Half of 2013	First Half of 2014	Second Half of 2014	First Half of 2015	Second Half of 2015	First Half of 2016	Second Half of 2016	First Half of 2017	Second Half of 2017	First Half of 2018	Second Half of 2018	First Half of 2019	Second Half of 2019	Total
1966	2163	2489	2538	3480	3293	3780	4097	4405	4223	5033	5943	6648	6150	7299	6738	96,332
345	446	513	558	1389	1410	1760	1980	2043	1664	1760	2770	2760	2867	3583	3248	32,525
1153	1254	1468	1461	1648	1394	1426	1488	1632	1707	2229	2153	2819	2360	2547	2270	43,368
137	118	151	159	151	172	191	162	140	208	269	257	255	233	288	362	5695
213	193	211	238	199	225	310	344	434	455	464	478	500	426	552	574	9421
72	78	80	60	39	45	42	68	92	123	215	172	224	189	215	196	2644
3	8	6	6	7	1	4	6	7	8	6	6	4	2	14	7	148
14	6	7	11	4	8	6	6	3	5	13	7	11	19	8	6	287
29	60	53	45	43	38	41	43	54	53	77	100	75	54	92	75	2256
534	574	655	736	1626	1409	1772	1947	1678	1239	1708	2679	3151	3081	3761	3492	36,980
390	442	519	545	549	516	503	601	694	732	784	701	797	756	788	831	16,180
362	386	420	398	400	407	407	437	453	516	526	472	578	532	644	605	11,563
154	178	194	200	215	243	174	209	264	301	537	718	613	442	494	434	8457
242	255	257	256	298	247	243	219	352	295	399	346	320	273	364	398	7441
77	90	122	125	120	296	450	434	421	520	521	428	629	599	546	371	6324
24	21	32	14	19	14	12	15	26	22	33	25	25	23	35	18	588
183	217	290	264	253	161	219	235	517	598	525	574	535	444	667	589	8799

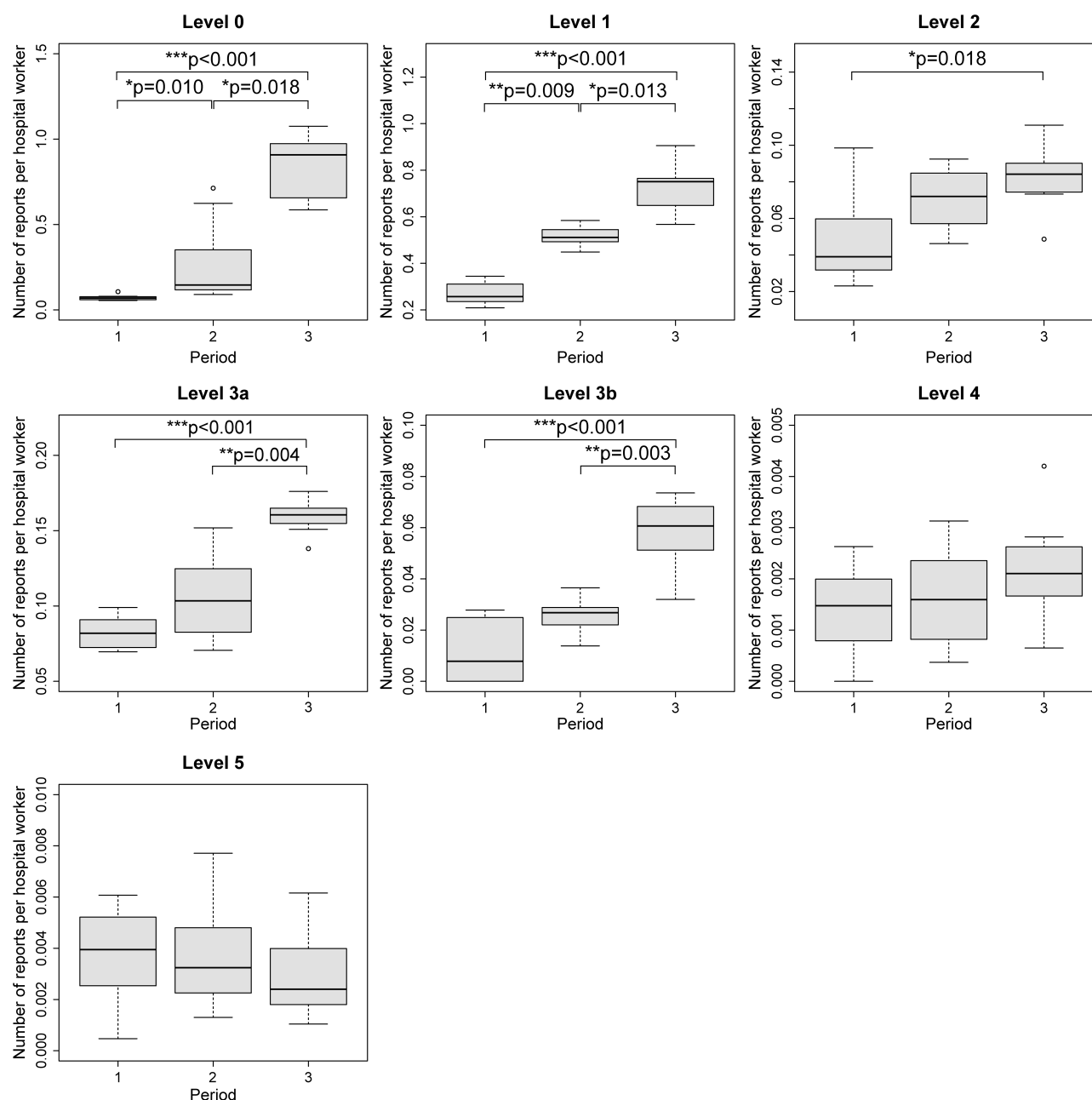


Figure 2 Change in the number of patient safety reports according to incident severity. A comparison of the report rate between the three periods was performed using Dunn's test with Bonferroni correction when the Kruskal–Wallis test was significant. ($*p < 0.05$, $**p < 0.01$, $***p < 0.001$).

Limitation

This study has some limitations, as this analysis was performed in a single institution. The generalizability of the development process of safety culture using a patient safety reporting system has not been well-established. Our institution must have had more room for an increase in the number of patient safety reports than other average hospitals in Japan since it is one of the largest tertiary hospitals in Japan and provides acute and tertiary care, which is associated with high safety risk. The order of cultural development also should be investigated in greater detail, especially using the incident severity and type. The present findings should be duplicated in other settings. A multicenter and international study could reveal the safety culture development process and the availability of the reporting data, although there is a difficulty due to data availability or compatibility of multiple institutional contexts.

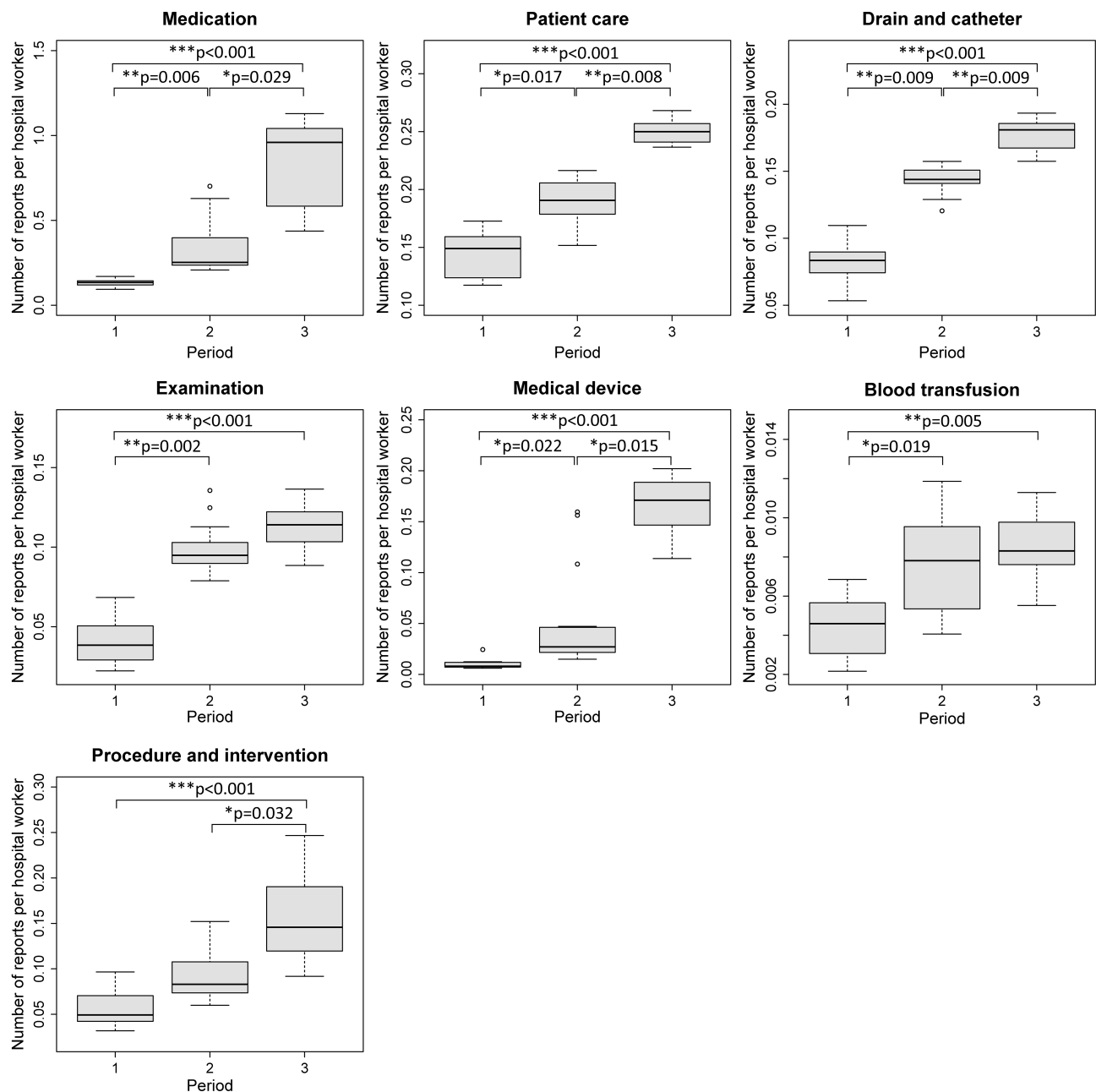


Figure 3 Change in the number of patient safety reports according to incident type. A comparison of the report rate between the three periods was performed using Dunn's test with Bonferroni correction when the Kruskal–Wallis test was significant. ($*p<0.05$, $**p<0.01$, $***p<0.001$).

Conclusion

This study demonstrates our experience with the trajectory of a reporting system for patient safety. The number of incidents of light severity increased in the early phase, while that of moderate severity and owing to procedure and intervention increased in the late phase. This implied two contextual changes during the cultural maturity process. The first was the preceding establishment of a reporting attitude, and the second succeeded in overcoming the barrier to patient safety. Cultural changes in healthcare institutions can be identified by analyzing contextual changes in the patient safety reporting system. Further studies are warranted to investigate the trajectory of safety culture in healthcare.

Data Sharing Statement

The datasets analyzed in the current study are available from the corresponding author upon reasonable request.

Ethics Approval and Informed Consent

This study was not applicable for ethical approval because patient data were not included in this study. The names of the reporters were anonymized in this study.

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Disclosure

The authors declare that they have no competing interests in this work.

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