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. 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. A well-implemented reporting system to overcome barriers will accelerate the reporting attitude of healthcare providers. 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. 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. At present, many institutions have a large number of annual patient safety reports.

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. 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. 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).

**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. 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.

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. 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 electronical reporting system. Reports registered in the electronical 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.
In Table 1, the annual data of the hospital staff show the number of reports by profession from the first half of 2004 to the second half of 2011. The table includes data for nurses, physicians, pharmacists, laboratory technicians, radiologic technologists, clinical engineers, rehabilitation therapists, and office workers. The total number of staff and half of the staff's data are also provided. The table notes that the numbers of staff were described every 6 months.

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

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. The greatest barrier to reporting was fear of blame and adverse consequences from the report. 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, had been increasing. Although patient safety reports are additional and time-consuming work, an increased number of reports was observed in our institution. 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. 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. 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. The subjects would be...
Table 1

|               | 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 |
|---------------|-------------------|--------------------|-------------------|--------------------|-------------------|--------------------|-------------------|--------------------|-------------------|--------------------|-------------------|--------------------|--------------------|-------------------|--------------------|-------------------|--------------------|
|               | 1117              | 1164               | 1124              | 1066               | 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               | 117               | 116               | 113               | 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               | 196                | 191               | 194               | 184               | 195                | 200               | 212               | 208               | 208                | 206               | 216               | 222               | 242               | 245               |
|               | 299               | 316                | 342               | 355                | 347               | 376                | 371               | 351                | 338               | 335               | 335               | 331                | 345               | 349               | 341               | 362               | 351               |
|               | 2463              | 2571               | 2352              | 2699               | 2648              | 2822               | 2732              | 2820              | 2777              | 2877              | 2838              | 2923              | 2912              | 3113              | 3085              | 3231              | 3261              |

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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              | 2233              | 2227              | 2103              | 2170              | 2253              | 2354              | 2302              |
| Severity    |                  |                   |                   |                   |                   |                   |                   |                   |                   |                   |                   |                   |                   |                   |                   |                   |
| 0           | 110              | 147               | 143               | 142               | 109               | 113               | 135               | 223               | 249               | 275               | 283               | 241               | 230               | 297               | 326               | 386               |
| 1           | 409              | 601               | 577               | 472               | 413               | 515               | 520               | 720               | 1133              | 1287              | 1295              | 1260              | 1310              | 1322              | 1371              | 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                | 55                | 55                | 69                | 68                | 67                |
| 4           | 1                | 3                 | 2                 | 5                 | 3                 | 0                 | 5                 | 3                 | 2                 | 4                 | 2                 | 2                 | 2                 | 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                | 66                | 51                |

Type

|                | 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 |
|----------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Medication     | 170               | 254               | 245               | 213               | 258               | 281               | 302               | 354               | 542               | 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               | 138               | 185               | 141               | 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.\textsuperscript{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.\textsuperscript{5,11} A previous in-depth analysis pointed out that the patient safety reports contained insufficient or wrong information at a certain frequency.\textsuperscript{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             | 96,322|
| 345              | 446               | 513              | 558              | 1389             | 1410             | 1760             | 1980             | 2043             | 1664             | 1760             | 2770             | 2760             | 2867             | 3583             | 3248             | 32,525|
| 1153             | 1254              | 1468             | 1648             | 1394             | 1426             | 1688             | 1632             | 1707             | 2229             | 2153             | 2819             | 2540             | 2270             | 2460             | 36,368|
| 137              | 118               | 151              | 159              | 151              | 172              | 191              | 162              | 140              | 208              | 269              | 257              | 255              | 233              | 288              | 362              | 5495|
| 213              | 193               | 211              | 238              | 199              | 225              | 310              | 344              | 436              | 455              | 464              | 478              | 500              | 436              | 552              | 576              | 9421|
| 72               | 78                | 80               | 60               | 39               | 45               | 42               | 69               | 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              | 436              | 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|
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 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).
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.

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).
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.

Funding
No funding was obtained for this study.

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

References
1. Kohn L, Corrigan J, Donaldson M. To Err is Human: Building a Safer Health System. National Academies Press; 2000.
2. Sakai H. The research of nationwide incidence rate of medical error in Japan; 2006. Available from: https://www.mhlw.go.jp/stf/shingi/2r985200001f7zad-att/2r985200001iz7gi.pdf. Accessed June 22, 2022.
3. Rosen CB, Kelz RR. Processes to create a culture of surgical patient safety. Surg Clin North Am. 2021;101(1):29–36. doi:10.1016/j.suc.2020.09.008
4. Morello RT, Lowthian JA, Barker AL, McGinnes R, Dunt D, Brand C. Strategies for improving patient safety culture in hospitals: a systematic review. BMJ Qual Saf. 2013;22(1):11–18. doi:10.1136/bmjqs-2011-000582
5. World Health Organization. Patient safety incident reporting and learning systems: technical report and guidance. Available from: https://www.who.int/publications/i/item/9789240010338. Accessed January 27, 2021.
6. Archer S, Hall L, Soukup T, et al. Development of a theoretical framework of factors affecting patient safety incident reporting: a theoretical review of the literature. BMJ Open. 2017;7(12):e017155. doi:10.1136/bmjopen-2017-017155
7. Howell AM, Burns EM, Bouras G, Donaldson LJ, Athanasiou T, Darzi A. 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(12):e0144107. doi:10.1371/journal.pone.0144107
8. Hospital survey on patient safety culture, agency for healthcare research and quality. Available from: https://www.ahrq.gov/sops/surveys/hospital/index.html. Accessed May 18, 2022.
9. Koike D, Ito M, Horiguchi A, Yatsuya H, Ota A. Implementation research: a retrospective mixed-method analysis. BMC Health Serv Res. 2022;22(1):409. doi:10.1186/s12913-022-07822-9
10. Fukami T, Uemura M, Nagao Y. Significance of incident reports by medical doctors for organizational transparency and driving forces for patient safety. Patient Saf Surg. 2020;14(1):13. doi:10.1186/s13037-020-00240-y
11. Gong Y, Kang H, Wu X, Hua L. Enhancing patient safety event reporting. A systematic review of system design features. Appl Clin Inform. 2017;8(3):893–909. doi:10.4383/ACI-2016-02-R-0023
12. National University Hospital Council of Japan. Guidelines for the Public Announcement of Medical Accidents at National University Hospitals. rev. ed. Tokyo: National University Hospital Council of Japan; 2012. Available from: http://www.univ-hosp.net/guide_cat_04_15.pdf. Accessed January 27, 2021.
13. Japan council for quality health care. Project to collect medical near-miss/adverse event information. Available from: https://www.med-safc.jp/contents/english/index.html. Accessed April 22, 2022.
14. Eagle CJ, Davies JM, Reason J. Accident analysis of large-scale technological disasters applied to an anaesthetic complication. Can J Anaesth. 1992;39(2):118–122. doi:10.1007/BF0308640
15. Reason J. Managing the Risks of Organizational Accidents. 1st ed. UK: Ashgate; 1997.
16. Tevis SE, Schmocker RK, Wetterneck TB. Adverse event reporting: harnessing residents to improve patient safety. J Patient Saf. 2020;16(4):294–298. doi:10.1097/PTS.0000000000000333
17. Hudson P. Applying the lessons of high risk industries to health care. Qual Saf Health Care. 2003;12(Suppl1):i7–12. doi:10.1136/qhc.12.suppl1.17
18. dss+ Bradley Curve. DSS sustainable solutions Switzerland. Available from: https://www.consultdss.com/transform-culture/dss-bradley-curve/. Accessed September 14, 2022.
19. The impact of safety culture on contractor safety management, North highland company. Available from: https://www.northhighland.com/insights/white-papers/the-impact-of-safety-culture-on-contractor-safety-management. Accessed September 14, 2022.
20. Flott K, Nelson D, Moorcroft T, et al. Enhancing safety culture through improved incident reporting: a case study in translational research. Health Aff. 2018;37(11):1797–1804. doi:10.1377/hlaff.2018.0706
21. Gong Y. Data consistency in a voluntary medical incident reporting system. J Med Syst. 2011;35(4):609–615. doi:10.1007/s10916-009-9398-y
