Development of questionnaire

The questionnaire was designed to collect information about numbers of incident reports filed by physicians and nurses, system-level activities for patient safety, and design of incident reporting method. Questionnaire content was developed on the basis of a review of past literature on patient safety [20-24] and clinical experience of a multi-disciplinary panel of healthcare professionals and patient safety experts. The questionnaire included factors addressed in previous studies, most of which examined staff perceptions of barriers to reporting incidents: a busy and fatigued workforce,[8,9,25-41] fear of reporting,[8,9,28-38,42] and lack of knowledge about reporting.[8,9,23,25-27,30-32,35-43]

Since each question in the questionnaire was designed to investigate the method of current incident reporting, and the system-level activity status of each hospital are stringently recorded, the reliability of the responses may be thought of as high. Also, the questionnaire was validated through interviews with several managers of patient safety and discussions with panels of experts. Because our validation process involved literature reviews and expert consensus, we believe that the survey questions have at least face validity and are reliable markers of patient safety systems.

Dependent variables: numbers of incident reports

We measured numbers of incidents by type of professionals (physicians and nurses) reporting incidents during the six months from April to September 2006. As the hospital accreditation authority in Japan has a voluntary incident reporting system utilising a three-level classification scheme based on severity of injury, most hospitals refer to any of the following criteria as an incident: 1) an event occurred, but was caught before reaching the patient; 2) an event occurred and reached the patient, but patient was unharmed; and 3) an event occurred and the patient was affected, but the treatment attributable to the event was minimal. Incidents that involve a degree of harm to patients which requires more than the minimal amount of treatment are categorised as *accident*, and therefore were not included in our definition of incidents.

Independent variables: predictors of numbers of incident reports

Hospital characteristics

We controlled for certain hospital characteristics that were suspected to be confounding factors in counting the number of incident reports submitted. These characteristics included ownership and the number of inpatient-days.

Additionally, the length of time that the incident reporting was in place at each hospital was included, due to the following hypothesis that the longer an incident

reporting system has been in place, the higher the chance that the individual staff members understand the importance and methods to report incidents. We utilised this factor as a binary variable: below and above the median of elapsed years from implementation.

Design of incident reporting method

To control some suggested barriers to reporting incidents, patient safety managers were asked to evaluate the following four qualitative measures of design of incident reporting method: 1) Whether the incidents were reported electronically or via paper; 2) Average length of time staff spent to fill out an incident report; 3) Whether a policy of non-punitive reporting was guaranteed by written documentation and/or orally; 4) Numbers of recommendations per bed that the hospital implemented to improve systems, processes, or products resulting from incidents reported between April and September 2006.

The first question refers to the potential barrier of a cumbersome method of reporting, which may negatively effect staff perception of reporting.[25-30] The emphasis on the barrier of perceived staff busyness and fatigue is inherent in the second question. If the potential reporter is too busy and too tired to report incidents, decreasing extra work involved in reporting is important.[8,9,30-41] We required respondents to answer which of the following lengths of time was closest to the average for reporting: ≤ 15 minutes, ≤ 30 minutes, ≤ 45 minutes, ≤ 60 minutes, or > 60 minutes. Responses then were collapsed into two categories: ≤ 30 minutes and > 30 minutes.

Confidentiality or immunity from punishment may be essential for potential reporters to overcome the barrier of fear.[8,9,28-38,42] Therefore, we gave two options for the third aspect of reporting design — a policy of non-punitive reporting assured by written documentation and/or oral description, or no policy. The fourth aspect —recommendations derived from reported incidents— was based on past findings that giving feedback on results of incident reporting is useful to enhance reporting.[25-33,41]

Amount of system-level activities for patient safety

Since lack of knowledge about the reporting method is one of the most important barriers to reporting incidents,[23,25-27,30-32,35-43] we evaluated the amount of staff education for physicians and nurses. Staff education encompasses many aspects of patient safety and is not limited to incident reporting. Additionally, we assessed activities to advance the "plan-do-check-act" cycle and, thereby, to improve patient safety systems, including assignment of safety managers, conferences, and ward

rounds. The person-time spent on these practices was calculated for a specified six-month window (**Table 1**). To calculate the person-time for each patient safety activity, we surveyed number of staff, amount of time required per activity session, and frequency of activity sessions conducted between April and September 2006. Then we converted the time spent by personnel on patient safety programmes into 2007 US dollars, using the employee's hourly wage [44-46] and the Purchasing Power Parities.[47] Finally, by use of the number of beds and the distribution of amount of each system-level activities among respondent hospitals, we collapsed the cost per 100 beds into two categories: over and under the median.

Statistical analysis

We excluded hospitals lacking either data regarding incident reports, reporting design, or institutional characteristics. In the remaining hospitals, the top 1% of hospitals in terms of numbers of incident reports was further excluded from analysis, as we found that these hospitals showed inordinately high incident report numbers and would therefore act as outliers which substantially affect the estimates of regression analysis. As numbers of incident reports conform to a Poisson distribution, Poisson regression with over-dispersion was used to perform multivariable analysis. Standard errors were made heteroskedastically consistent via the Huber-White covariance matrix. STATA 9.2 was used for all analyses.

RESULTS

A total of 418 hospitals participated in the study (response rate, 40.2%). Hospitals that did not meet inclusion criteria were dropped from the statistical analysis, resulting in a final sample of 232 hospitals. No significant relationships were noted between response rates and hospital demographic information, including geographic location (χ^2 test, $p = 0.24$) and bed size (χ^2 test, $p = 0.94$).

The mean (standard error) of incident reports per 10,000 inpatient-days by physicians and nurses was 2.62 (0.18) and 91.3 (4.42), respectively. **Table 2** compares reporting design of incidents. Although 63.8% of hospitals surveyed required an average of ≤ 30 minutes to report incidents, approximately 80 hospitals (36.2%) took an average of > 30 minutes to fill out a report. Significantly more hospitals utilised paper-based reporting than online reporting (65.5% vs. 34.5%; $p < 0.001$).

The median (inter-quartile range) dollars spent on system-level activities per 100 beds during a 6-month period for assigning patient safety managers, conferences, ward rounds by peers, education for physicians, and education for nurses was $9,410

($5,729-$13,575), $1,326 ($873-$1,899), $204 ($79-$482), $992 ($50-$3,440), and $488 ($63-$1,128), respectively (**Table 3**).

Results of regression analyses presented in **Table 4** demonstrate that incident reports filed by physicians could be increased by online reporting (26%, $p < 0.05$) and shorter time required to file a report (27%, $p < 0.05$). Moreover, hospitals that implemented more education for physicians significantly increased reporting by 53% ($p < 0.001$). In hospitals with dedicated full-time staff for the purpose of patient safety, the number of incident reports by physicians significantly increased by 35% ($p < 0.05$). However, immunity policy and rate of recommendations derived from reported incidents did not significantly influence the number of physician-generated incident reports.

However, results of predictor factors in numbers of nurse-reported incidents, compared to physician-reported incidents, showed different relationships. Nurse-reported incidents were encouraged only by decreased time for reporting (22% increase, $p < 0.05$). Education for nurses was not a significant factor in reporting.

There was no significant relationship between the elapsed years of incident reporting system and number of incidents reported by physicians and nurses.

DISCUSSION

To our knowledge, this is the first empirical study that explores determinants associated with incident reporting and identifies the impact of system-level activities on numbers of incident reports which could increase capacity of organisational learning. Our results provide new evidence supporting most of the previous studies that examined staff perceptions regarding incident reporting.

Our rationale for the present study was an extension of other works hypothesising that system-level activities enable reporting of incidents by establishing a solid safety culture among employees. In the first outcome studies in patient safety, researchers focused on factors that contribute to improvement of safety culture. Ginsburg *et al* and Thomas *et al* found that an improved safety culture was associated with implementation of staff education and executive ward rounds, respectively.[21,22] Next, Naveh *et al* empirically demonstrated that enhanced safety culture was associated with increased reporting of incidents.[48] Later, a randomized controlled study by Figueiras *et al* showed that physician-generated reporting of adverse drug reactions was increased by implementing staff education.[23] Recent studies revealed that implementation of a multifaceted intervention package comprising staff education and changes in reporting designs could improve incident reporting.[25,26,30] Because

previous studies did not assess the effectiveness of each patient safety programme on incident reporting, we investigated these issues in the current study.

In contrast to the physician-generated reports, there was no significant association between education for nurses and the number of nurse-initiated reports. A possible reason for this difference is a decreased marginal effect of education for nurses. Considering that the average number of nurse-generated reports was more than 30 times higher than that of physicians and that educational time for nurses was more than 7 times greater than that for physicians, nurses' knowledge about incident reporting appears to be sufficient. According to past studies,[31,36,37,41] staff perspectives regarding reporting show that lack of knowledge was not a major deterrent for reporting by nurses, though it may be a major barrier to reporting by physicians. In addition, other studies demonstrated that implementing physician education resulted in significant improvement in reporting by physicians.[23,38] Therefore, our results were partially consistent with previous qualitative findings. Further, we shed light on the impact of assignment of safety manager on the number of incident reports filed by physicians for the first time. Though our survey focused on system-level activities for patient safety that were conducted organisationally, other daily detailed activities not specifically included in the survey were instead covered under the duties of full-time dedicated staff. For example, each dedicated staff member performs the activities involved in analysing reported incidents and giving feedback on results of incident reporting, and promotes awareness of patient safety throughout hospital via such routine activities. These activities might affect physicians' attitude to incident reporting.

In addition to a lack of knowledge as discussed above, our result that busyness and fatigue are barriers of incident reporting was consistent with past literature that examined the reasons of underreporting of incidents.[31-41] By decreasing the time to fill out incident reports, the number of incidents by physicians and nurses could be significantly increased by 27% and 22%, respectively. Meanwhile, the influence of reporting method (online vs. paper-based) was different depending on type of professions and this was again in concordance with previous findings. For example, the finding that physician-generated online reports significantly increased by 26% ($p < 0.05$) is in accordance with previous studies that examined numbers of incidents reported via online systems.[28,29] Regarding reporting by nurses, in contrast, our results are also similar to past studies.[29,30] Perceptions of usefulness versus the cumbersome nature of online reporting might depend on accessibility and a user-friendly interface. Since reducing the time required to fill out a report would obviously make reporting less burdensome, this reporting design could generate more reports by physicians and nurses.

Although fear of reporting has been previously found to be another barrier,[31-38,42] our studies did not observe this result. Willingness to report incidents could depend on the legislative system, such as presence of laws protecting patient safety whistle-blowers from retaliation. Japanese healthcare providers are susceptible to criminal prosecution for professional negligence.[49] Therefore, the impact of an immunity policy in hospitals might decrease the barrier of fear in reporting incidents.

Past studies that evaluated staff perception suggested that giving feedback to staff was useful to enhance reporting.[27,31-33] A possible reason why our study did not confirm a significant relationship between these factors is that since our study was an observational study and therefore unable to standardise the definition of recommendation derived from reported incidents, there would be discrepancy of content of feedback among participant hospitals. Further study is needed to examine the true impact of feedback on incident reporting.

Previous studies have paid little attention to the impact of elapsed years since implementation of a reporting system, whereas it is likely that the longer an incident reporting system has been in existence in a particular hospital might correlate with a better maturation of the reporting system, and therefore present an increased number of incidents. Though our model was unable to demonstrate this relationship, this result should be viewed with caution. Because the variable in our model used the elapsed years of the *first* adoption of incident reporting system, it did not reflect that of the *current* reporting system.

Our study has several limitations. Firstly, questions on the amount of system-level activities were answered by patient safety managers. Therefore, even if activities to improve patient safety systems were conducted within other departments, all activities implemented in a hospital might not be reflected in our survey, and thus might diminish the measurable effect of the activities. Secondly, many hospitals did not respond to our questionnaire, thus raising the existence of selection bias. Those that participated in our survey may systematically establish patient safety systems as compared to hospitals that did not respond our questionnaire, because it is likely that hospitals that recorded daily activity status may tackle the issue of patient safety in an organised way. Therefore, our results might reflect the status of teaching hospitals with relatively high motivation to enhance patient safety. Lastly, our findings could be favourable within a stage in which the incident reporting system has not been fully matured. When the understanding of the incident reporting system increases among professions, and each staff member will report all incidences that he or she encounter, the next stage will be that the number of *true* incidents will gradually diminish. Though the influence of secular trends on our results is unclear, our findings may offer an

effective way to attain such a desirable subsequent stage.

In conclusion, our results demonstrate empirically that the number of incident reports reflect the degree of staff education and have implications for initiatives to design better reporting methods. Further research is needed to develop successful educational content and to modify incident reporting formats. A challenge is to balance competing goals of ease of the reporting process and the need for more detailed information enabling prevention of recurrence of similar incidents.

ACKNOWLEDGMENTS

The authors thank all the hospitals that participated in this research. The work described in this article was funded in part by the Health Sciences Research Grants for the Research on Policy Planning and Evaluation from the Ministry of Health, Labor and Welfare of Japan and the Grant-in-aid for Scientific Research A from the Ministry of Education, Culture, Sports, Science and Technology of Japan.

Competing interests

None declared.

Funding

The work described in this article was funded in part by the Health Sciences Research Grants for the Research on Policy Planning and Evaluation from the Ministry of Health, Labor and Welfare of Japan and the Grant-in-aid for Scientific Research A from the Ministry of Education, Culture, Sports, Science and Technology of Japan.

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Table 1. Contents of system-level activities for patient safety

Activity domain	Activity component
Assignment of safety managers	Assignment of dedicated full-time and part-time staff to patient safety division.
Conferences	Supreme decision-making board/committee.
	Regular meetings in patient safety division.
Ward rounds by peers	Regular assessment of ward environment conducted by patient safety division.
	Additional internal audit conducted by a separate department, such as nursing.
Staff education	Physicians' participation in educational seminars to promote patient safety.
	Nurses' participation in educational seminars to promote patient safety.

Table 2. Design of incident reporting method in eligible hospitals (n = 232)

Reporting design	No. of hospitals (%)*	No. of hospitals (%)†
Time involved in documenting an incident		
≤ 5 minutes	6 (2.6%)	
≤ 15 minutes	69 (29.7%)	148 (63.8%)
≤ 30 minutes	73 (31.5%)	
≤ 45 minutes	41 (17.7%)	
≤ 60 minutes	13 (5.6%)	84 (36.2%)
> 60 minutes	30 (12.9%)	
Reporting media & format of report		
Online based: Only structured questions	1 (0.4%)	
Online based: Open-ended & structured questions	76 (32.8%)	80 (34.5%)
Online based: Only open-ended questions	3 (1.3%)	
Paper based: Only structured questions	8 (3.5%)	
Paper based: Open-ended & structured questions	129 (55.6%)	152 (65.5%)
Paper based: Only open-ended questions	15 (6.5%)	
Immunity policy		
Both documentation & oral explanation	167 (72.0%)	218 (94.0%)
Only oral explanation	51 (22.0%)	
No policy	14 (6.0%)	14 (6.0%)
Rate of recommendations derived from the incidents		
≤ 1st quartile (0.90 cases per 100 beds)	59 (25.4%)	119 (51.3%)
≤ 2nd quartile (2.00 cases per 100 beds)	60 (25.9%)	
≤ 3rd quartile (3.61 cases per 100 beds)	55 (23.7%)	113 (48.7%)
> 3rd quartile (3.61 cases per 100 beds)	58 (25.0%)	

* Crude data on responses in accordance with the questionnaire.

† Converted data for use in multi-variable regression.

Table 3. Status of system-level activities for patient safety (n = 232)

Activity component	Activity status Median (IQR)	Cost*, US$† Median (IQR)
Assignment of safety managers to patient safety division		$9,410 ($5,729-$13,575)
Assignment of full-time staff		
Physician [No. staff per 100 beds]	0.0 (0.0-0.0)	
Nurse [No. staff per 100 beds]	0.2 (0.1-0.3)	
Allied staff [No. staff per 100 beds]	0.0 (0.0-0.2)	
Assignment of part-time staff		
Physician [Person-hours per week per 100 beds]	0.3 (0.0-0.7)	
Nurse [Person-hours per week per 100 beds]	0.0 (0.0-1.5)	
Allied staff [Person-hours per week per 100 beds]	0.2 (0.0-1.5)	
Conferences		$1,326 ($873-$1,899)
Supreme decision-making board/committee		
No. staff [per session per 100 beds]	2.6 (1.9-3.8)	
Time required [minutes per session]	60 (60-75)	
Frequency [during a 6-month period]	6.0 (6.0-6.0)	
Regular meeting in safety division		
No. staff [per session per 100 beds]	4.1 (2.6-6.3)	
Time required [minutes per session]	60 (60-80)	
Frequency [during a 6-month period]	6.0 (5.0-6.0)	
Ward rounds		$204 ($79-$482)
By patient safety division		
No. staff [per session per 100 beds]	0.6 (0.1-1.1)	
Time required [minutes per session]	60 (13-90)	
Frequency [during a 6-month period]	3.0 (1.0-6.0)	
By other department		
No. staff [per session per 100 beds]	0.6 (0.0-1.6)	
Time required [minutes per session]	30 (0-60)	
Frequency [during a 6-month period]	1.0 (0.0-4.8)	
Educational seminars		
Physicians' participation [person-hours during a 6-month period]	12.1 (5.6-25.7)	$992 ($50-$3,440)
Nurses' participation [person-hours during a 6-month period]	93.3 (51.4-171.0)	$488 ($63-$1,128)

IQR, inter-quartile range

*Cost per 100 beds during a 6-month period in a hospital.

†2007 US$ (JPN¥ = US$0.85)

Table 4. Results of Poisson regression for predictors of the number of incident reports in a hospital (n = 232)

Variable	Physician-generated reports		Nurse-generated reports	
	IRR (95% CI)	*p* value	IRR (95% CI)	*p* value
Hospital size				
No. of inpatient-days per 10,000	1.11 (1.08, 1.14)	< 0.001	1.10 (1.07, 1.13)	< 0.001
Ownership				
University hospital	1.93 (1.47, 2.55)	< 0.001	1.00 (0.76, 1.30)	0.972
National hospital	1.20 (0.87, 1.66)	0.268	1.31 (1.03, 1.67)	0.028
Municipal hospital	0.78 (0.58, 1.05)	0.103	1.04 (0.84, 1.29)	0.713
Public hospital	0.92 (0.70, 1.19)	0.509	1.02 (0.84, 1.24)	0.817
Healthcare corporation and others	1.00 (1.00, 1.00)		1.00 (1.00, 1.00)	
Elapsed years of incident reporting system				
-6 years (≤ Median)	1.00 (1.00, 1.00)		1.00 (1.00, 1.00)	
+7 years (> Median)	1.19 (0.97, 1.47)	0.100	1.11 (0.95, 1.30)	0.177
Design of incident reporting method				
Reporting media				
Paper-based reporting	1.00 (1.00, 1.00)		1.00 (1.00, 1.00)	
Online reporting	1.26 (1.05, 1.52)	0.012	0.95 (0.82, 1.11)	0.516
Time involved with filing a report				
> 30 minutes	1.00 (1.00, 1.00)		1.00 (1.00, 1.00)	
≤ 30 minutes	1.27 (1.05, 1.53)	0.014	1.22 (1.05, 1.42)	0.011
Immunity policy in hospital				
No policy	1.00 (1.00, 1.00)		1.00 (1.00, 1.00)	
Non-punitive policy	1.35 (0.88, 2.06)	0.172	0.99 (0.72, 1.35)	0.938
Rate of recommendations to staff				
Low (≤ Median)	1.00 (1.00, 1.00)		1.00 (1.00, 1.00)	
High (> Median)	1.01 (0.82, 1.24)	0.939	1.01 (0.86, 1.19)	0.872
System-level activities for patient safety				
Assignment of safety managers				
Low (≤ Median)	1.00 (1.00, 1.00)		1.00 (1.00, 1.00)	
High (> Median)	1.35 (1.10, 1.66)	0.004	1.04 (0.89, 1.21)	0.650
Conferences				
Low (≤ Median)	1.00 (1.00, 1.00)		1.00 (1.00, 1.00)	
High (> Median)	1.09 (0.89, 1.33)	0.414	1.02 (0.87, 1.20)	0.821
Ward rounds by peers				
Low (≤ Median)	1.00 (1.00, 1.00)		1.00 (1.00, 1.00)	
High (> Median)	1.04 (0.87, 1.25)	0.661	1.02 (0.89, 1.18)	0.748
Physicians' attendance at educational seminars				
Low (≤ Median)	1.00 (1.00, 1.00)		–	
High (> Median)	1.53 (1.24, 1.89)	< 0.001	–	
Nurses' attendance at educational seminars				
Low (≤ Median)	–		1.00 (1.00, 1.00)	
High (> Median)	–		1.08 (0.93, 1.25)	0.334

IRR, incidence-rate ratio; CI, confidence interval.

Available online at www.sciencedirect.com
ScienceDirect
Health Policy 87 (2008) 100–111
HEALTH POLICY
www.elsevier.com/locate/healthpol

Cost of hospital-wide activities to improve patient safety and infection control: A multi-centre study in Japan

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Abstract

Objective: The aim of this study was to assess the financial costs to hospitals for the implementation of hospital-wide patient safety and infection control programs.
Methods: We conducted questionnaire surveys and structured interviews in seven acute-care teaching hospitals with an established reputation for their efforts towards improving patient safety. We defined the scope of patient safety activities by use of an incremental activity measure between 1999 and 2004. Hospital-wide incremental manpower, material, and financial resources to implement patient safety programs were measured.
Results: The total incremental activities were 19,414–78,540 person-hours per year. The estimated incremental costs of activities for patient safety and infection control were calculated as US$ 1.100–2.335 million per year, equivalent to the employment of 17–40 full-time healthcare staff. The ratio of estimated costs to total medical revenue ranged from 0.55% to 2.57%. Smaller hospitals tend to shoulder a higher burden compared to larger hospitals.
Conclusions: Our study provides a framework for measuring hospital-wide activities for patient safety. Study findings suggest that the total amount of resources is so great that cost-effective and evidence-based health policy is needed to assure the sustainability of hospital safety programs.

Keywords: Costs and cost analysis; Safety management; Infection control; Health resources

1. Introduction

Adverse events including hospital-acquired infections enact heavy disease tolls on patients and place large financial burdens on healthcare institutions. According to the Institute of Medicine [1], preventable adverse events in the United States (US) cause 44,000–98,000 deaths annually and represent a cost of US$ 17–29 billion. In the United Kingdom (UK), between 0.3 and 1.4 million patients in the National Health Service hospital sectors are affected by adverse events each year, resulting in £2 billion in inpatient costs. The costs attributable to hospital-acquired infections were estimated at nearly £1 billion a year, which

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doi:10.1016/j.healthpol.2008.02.006

was regarded as preventable in about 15% of cases [2].

Over the past 10 years, the Japanese government has taken measures against adverse events in healthcare institutions. The first measures were conducted in 1996 for the prevention and control of hospital-acquired infection [3]. These measures included new medical regulations requiring hospitals to implement several infection control policies, including establishing infection control committees, reporting comprehensive infection data, and developing hand hygiene activities. By implementing these programs, hospitals received additional payments of US$ 0.43 (JPN¥ 50) per patient-day as an incentive. Later, in 2000, following growing concerns for patient safety, the reimbursement system was changed to a punitive approach whereby hospitals failing to implement these programs were charged a decreased hospital reimbursement US$ 0.43 (JPN¥ 50) per patient-day [4].

After a devastating medical error at a university hospital in 1999, concerns over patient safety in Japan further increased. The government responded by issuing a new series of patient safety regulations for healthcare institutions. These measures were enacted in 2000, requiring all university hospitals and two large medical centres to (1) establish institutional guidelines for patient safety, (2) develop reporting systems of adverse events, (3) organize patient safety committees, and (4) provide continuous staff education and training about patient safety [5]. In 2002 these measures were extended to all hospitals in Japan [6]. Additionally, the government took a punitive approach in providing a decreased hospital reimbursement of US$ 0.85 (JPN¥ 100) per patient-day for those hospitals that did not implement these programs [7].

In 2006, regulations for infection control and for patient safety did not reflect national fee schedules. Instead, as long as hospitals employed full-time staff who had professional training for patient safety, hospitals could receive additional payment of about US$ 4.26 (JPN¥ 500) per patient [8]. In contrast, in the US, the Centres for Medicare and Medicaid Services will stop reimbursing hospitals for clearly preventable adverse events from 2008 [9].

Contrary to the policies encouraging hospitals to implement these programs for patient safety, there are few financial incentives in Japan's payment system to invest in such programs. Under the existing fee-for-service reimbursement system or new per-diem payment system, even the costs incurred by treatment of complications resulting in additional length of stay are compensated by the payment systems. In such systems, there is a conflict of interest between society and hospitals; decreases in healthcare resources benefit society and patients, but increases in resources are financially beneficial for hospitals. Moreover, increasing pressure to contain the growth of healthcare expenditures has made safety program implementation extremely difficult, since there are limited resources, and the challenge of balancing the hospital budget is great. If studies demonstrate that safety programs can improve patient outcomes, the information could be used to support the financial worth of patient safety activities. However, patient safety is difficult to measure and there is a limited number of validated measures to use [10–12]. Therefore, the formulation or use of such outcomes remains highly unlikely.

Despite these formidable barriers, the healthcare system should be well poised to increase the pace of improving patient safety. The first step is to assess the costs of activities related to patient safety. Detailed cost information is valuable for the following reasons. First, cost information can help hospital administrators make decisions that contribute to the front-line practitioners who work to promote patient safety. Cost analysis is an essential tool for visualizing actual activity conditions in a quantitative context. Second, cost information can help in the budgeting of safety improvement activities [13]. The sustainability of hospital safety programs is a potential threat to the medical delivery system due to constrained finances and limited staff time to implement safety-related activities. A potential way to deal with this problem is clear budgeting, for which cost information is imperative. Finally, from a societal perspective, cost information can provide a guide for how to supply health services at a patient safety level that the community agrees to. The main driving force for patient safety regulations has been an increased demand from the community. Although the community has good reasons to ensure their own safety in hospitals, the underlying and inevitable increase in associated costs has received little attention in the claim. However, in order for patient safety levels to increase, the community must also be prepared to bear an equitable share of these costs. Successive improvements in safety are generally associated with progressively higher costs

for each increment of improvements gained [14]. Without knowing the actual costs of safety programs, it can be impossible to decide what measure is feasible within a constrained financial environment. At present, however, past estimates of the costs associated with programs for patient safety have had serious limitations; they have either mainly focused only on single programs for infection control such as education [15] and surveillance [16], or targeted material interventions [17]. Therefore there is scant data regarding the resources necessary to implement hospital-wide activities involving patient safety and infection control. To address this lack of data, this study aimed to perform a multi-centre cost analysis to assess the amount of financial resources that Japanese hospitals invest for patient safety activities. The main outcome measures were the volume and the monetary value of activities for patient safety and hospital infection control.

2. Methods

2.1. Study setting

Seven acute-care teaching hospitals in Japan participated in this study. We recruited hospitals located across distinct geographic regions in Japan, under various kinds of ownership (public sector, healthcare corporations, and company). All were hospitals with an established reputation for their efforts to improve patient safety and infection control. In most cases, the individuals interviewed were department managers of patient safety and infection control. When necessary, we also interviewed the directors of nursing, pharmacy and administrative staff. We conducted questionnaire surveys and structured interviews between August 2005 and March 2006.

2.2. The concept of incremental activity

To measure activities and financial costs of patient safety, we focused on the scope of patient safety activities through the incremental activities concept. We assessed all the activities which were aimed at enhancing patient safety systems and were introduced between 1999 and 2004. Within this scope, we estimated the annual volume of activities conducted in 2004. It is typically difficult to distinguish the activities for patient safety and the activities for quality that healthcare inherently sustains. In this case, however, there was a dramatic rise in social concern and health policy, sparked by the media coverage of a wave of medical accidents in Japan since 1999. This time thus marked a major turning point that allowed us to better assess the incremental activities changes. Therefore, we retrospectively assessed the additional patient safety activities provided in hospitals in 2004 compared to typical activity levels in 1999 (the base case).

2.3. Development of scope of patient safety and questionnaire

The incremental concept was reified in the form of questionnaire. The draft of the questionnaire was developed through a review of the findings from previous studies that demonstrated the effectiveness and/or significance of patient safety programs [1,17–21], and from a review of the items of the Japan Council for Quality Health Care (JCQHC) [22] hospital accreditation standards. We also collected activity items through a web-based interface, and public relations magazines from a variety of hospitals. We modified questionnaires through interviews conducted with several managers of patient safety practices and hospital infection control, and through panel discussions with experts. The scope of the questionnaire included the following domains: staff assignment, meetings and conferences, materials and equipments, prevention of occupational infection, internal audit activities, internal education and training, external education and training, incident report system and its related activities, infection surveillance, standardized processes and their manuals, external audits, management of medical equipment, and management of medication (Table 1).

To assess the volume of activities annually, we surveyed the following four items: (1) type of activity component, (2) number of staff by type of profession, (3) volume of time required, and (4) frequency of activities conducted in 2004. For example, in the domain of meetings and conferences, we asked what type of conferences were conducted, which specialists the members belonged to, how many hours were allotted for the functioning of each committee (such as a supreme decision-making board committee or a regular meeting in patient safety division), and how many times the committee met in 2004. We surveyed the same

Table 1
Contents of the study questionnaire to measure activities for patient safety and infection control

Activity domain	Brief description	Example components[a]	Reference
Staff assignment	Deployment of safety managers or infection control practitioners who worked in division of patient safety or hospital infection.	Number of staff by type of profession, volume of activities in each division, floor space of each division, etc.	[18,21]
Meetings and conferences	Convening of decision-making board meetings, regular meetings of practitioners or other conferences conducted for patient safety.	Supreme decision-making board committee, regular meetings in safety division, medical accident investigation committee, etc.	[21]
Materials and equipments	Implementation of materials and equipment designed for patient safety.	Prevention of patient misidentification, falls, pressure ulcers, hospital infection and adverse drug events, etc.	[17,20]
Prevention of occupational infection	Immunization for the prevention of occupational infection.	Vaccination against influenza, tuberculin skin test, etc.	[19]
Internal audit	Walk rounds to audit the environment for patient safety by internal practitioners.	Walk rounds of ward environment, review for adherence to manual, clinical chart review, etc.	[17]
Internal education and training	Education and training conducted in hospitals to prevent and control adverse events and hospital infections.	Staff education prepared by safety division and nursing department, orientation for new members, etc.	[17,19–21]
External education and training	Participation in educations and trainings for patient safety held outside the hospitals.	Seminar conducted by government, professional organization, accreditation council, etc.	[21]
Incident report systems and related activity	The activities involved in reporting incidents, analyzing them, and considered measures for patient safety.	Submitting incident reports, review by manager, data entry, analysis by safety division, feedback, etc.	[1,17]
Infection surveillance	Reviews of medical charts and reports of microbiologic results and analysis of data to prevent and control hospital infection.	Review of medical charts and bacteriologic examination of MRSA, surgical site infection, ventilator-associated infection, catheter-associated infection, etc.	[18,21]
Development of standardized processes and manuals	The activities for the development of generalization for the process and measures to prevent and control of adverse events or hospital infection.	Institutional guidelines and handbook for safety procedures, informed consent, fall, antimicrobial drug use, needle stick, hand hygiene, etc.	[21]
External audit	An examination of the quality or management systems of hospital environment conducted by an outside party.	Japan Council for Quality Health Care, International Organization for Standardization, etc.	[17]
Management of medical equipment	Regular health device inspection and preventive maintenance by clinical engineering departments.	Monitor and repair of medical equipment by clinical engineering and outsourcing, etc.	[17]
Management of medication	Management of medication by medication teaching, maintaining medication histories, delivering drug information, and consulting of medication issues by pharmacists.	Medication history management, drug information service, dispensing instructions, etc.	[17,20]
Other activities	Other activities related to patient safety and infection control and not categorized as above activity.	Waste disposal, environmental cleaning, patient safety campaigns, public relations, etc.	[21]

[a] Within each activity component, we surveyed a number of staff by type of profession, volume of time required, and frequency of activities conducted in 2004. We also estimated the costs of material resources such as space, handouts and participation fees within each activity component, and materials or equipments designed for patient safety and infection control.

questions across all activity domains. We also elicited from interview respondents information regarding non-personnel expenses such as space, handouts and participation fees within each activity component, as well as materials or equipments designed for patient safety and infection control. Table 1 shows the possible activity components within each activity domain. Categories for type of profession included doctor, nurse, pharmacist, other medical staff, and administrative staff. Additionally, all staff were categorized by whether they had 10 years in practice or not.

2.4. Data

We first sent the questionnaire to each participant and, using the collected data from the questionnaire, we then conducted individual face-to-face interviews to examine costs incurred in 2004. In each hospital, we interviewed around 5–10 staff members who belonged to either patient safety division, infection control teams, nursing sections, pharmaceutical sections and administrative sections. HF participated in all interviews. Interviews were supplemented by e-mail, phone or additional interviews. To reduce institutional differences in definitions of activities, we also sent feedback of the whole lists of activity components collected through these interviews to participant hospitals. Components in the list that participants did not respond to were also included in the definition and added to estimates of activities volume. Such feedback was continued until discrepancy between the actual activities and reporting activities in each hospital was resolved. When there were intra-institutional discrepancies, all authors met to discuss and reach a consensus about activity inclusion. There were no instances of disagreement in which consensus could not be reached. This study was approved by the Institutional Review Board at the Graduate School of Medicine of Kyoto University.

2.5. Cost analysis

We converted the annual volume of activities into monetary values through the use of conversion rates of activity per hour to cost from national statistical data [23–26]. The annual volume within each activity component was calculated by multiplying the number of staff by the annual time spent by the frequency of activities within each component. The conversion rates by type of profession were computed by taking a weighted average of annual income divided by annual labor hours. The rates of activity per hour to cost (US$) by years in practice for under 10 years, for 10+ years and for not adjusted by years in practice were, respectively: doctors, 38.5, 51.5 and 49.1; nurses, 21.0, 30.4 and 26.3; pharmacists, 21.3, 31.1 and 28.7; other medical staff, 21.3, 30.6 and 28.5; administrative staff, 18.6, 29.4 and 26.8; and other staff, 19.5, 26.5 and 26.3. The estimates were converted to 2007 dollars using the Japanese consumer price index (adjusting to the 2007 Yen value) and the Purchasing Power Parities (JPN¥ 100 = US$ 0.85; April 2007) [27].

In addition to manpower resources, we estimated the costs of material resources such as spaces for conference or training, handouts, participation fees for training sessions, and materials or equipment designed for patient safety and infection control. The costs of spaces were calculated by adjusting the cost of a rental conference room in Tokyo by the value of land in each locality of the participant hospital. The costs for training, and materials or equipments were actual costs. All estimates were converted into the 2007 US dollar value. Throughout the study, the cost perspective was that of the hospital. All cost estimates are presented in values equivalent to the 2007 US dollar value.

Since the annual amount of resources consumed depended on the hospital size, we estimated incremental costs adjusted to 100 beds, incremental costs per bed, incremental costs per patient-day, and ratio to medical revenue. We also calculated the number of full-time healthcare staff that could be hired from the total costs by dividing total incremental costs by the average annual revenue of healthcare staff.

3. Results

Of eight hospitals referred, seven hospitals were included in this study. All sites were tertiary referral centres with bed numbers ranging from 300 to 1100 and more than 100,000 inpatient-days per year (Table 2).

3.1. Activity volume

The cumulative volumes for each activity component within each domain of hospital preventive