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Factors associated with system-level activities for patient safety and infection control

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Abstract

Objective: We examined the relationship between hospital structural characteristics and system-level activities for patient safety and infection control, for use in designing an incentive structure to promote patient safety.
Methods: This study utilized a questionnaire to collect institutional data about hospital infrastructure and volume of patient safety activities from all 1039 teaching hospitals in Japan. The patient safety activities were focused on meetings and conferences, internal audits, staff education and training, incident reporting and infection surveillance. Generalized linear modeling was used.
Results: Of the 1039 hospitals surveyed, 418 (40.2%) hospitals participated. The amount of activities significantly increased by over 30% in hospitals with dedicated patient safety and infection control full-time staff ($P < 0.001$ and $P < 0.01$, respectively). High profit margins also predicted the increase of patient safety programs ($P < 0.01$). Perceived lack of administrative leadership was associated with reduced volume of activities ($P < 0.05$), and the economic burden of safety programs was found to be disproportionately large for small hospitals ($P < 0.05$).
Conclusions: Hospitals with increased resources had greater spread of patient safety and infection control activities. To promote patient safety programs in hospitals, it is imperative that policy makers require the assignment of dedicated full-time staff to patient safety. Economic support for hospitals will also be required to assure that safety programs are sustainable.

Keywords: Safety management; Infection control; Health resources; Health policy

1. Introduction

In 1999, the Institute of Medicine (IOM) released a pivotal report on safety in the health care system [1]. This report, which identified systemic gaps in patient safety systems, led to widespread development of new safety practices [2]. Despite the implementation of these safety practices, including those required by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), have the number of potential adverse events really decreased? While to the best of our knowledge, there has been no study that investigates the change of adverse events (which may be impossible due to the difficulties in

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identification of adverse events), some studies that focused on other indicators such as morbidity, failure to rescue and hospital-acquired infection have been reported. However, even these studies provide little evidence to suggest that the healthcare system is safer today than it was in 1999 [3–6]. Small improvements in healthcare safety have not yet been reflected in national statistics [7], suggesting that further work is needed to protect patients from adverse events [8,9]. Considering that public regard for patient safety issues have risen since 1999 in Japan and other countries including the United States (US) [1,10] and the state of implementation of patient safety systems in Japan is similar to that of the US [11], the phenomena in the US seem to be similar to the state of patient safety in Japan.

The movement toward improved patient safety continues to face significant barriers, including a lack of incentives for hospitals to develop safety programs [10,12]. First reason of a lack of incentive is the problem of the financial costs and benefits. Implementing hospital-wide safety practices requires considerable financial investment [10,11]. Although these costs may be theoretically offset by savings associated with improved care and fewer adverse events [13,14], in practice these savings are rarely apparent to hospital administrators [4]. Few measurement tools have been developed to accurately gauge the impact of safety programs [7,15], limiting the ability of hospitals to definitely link safety practices with improved patient care. Second barrier is concerned with public perception. A lack of data on hospital safety frequently limits the number of choices patients have in selecting a hospital, such that hospitals without safety programs are not necessarily penalized by reduced patient volume. The high cost and limited hospital benefit of patient safety programs makes the decision to implement rigorous safety practices extremely difficult.

In light of these barriers, financial incentives for quality care have been considered as an approach to encouraging hospitals to adopt patient safety practices [7]. When considering incentive programs, policy makers must understand the factors that influence the spread of system-level activities to improve patient safety. One such factor may indeed be financial considerations, and it is possible that the issue of patient safety might be a low priority for those who manage hospital finance [7,12,16]. A second factor that may play a role in the increase of patient safety measures is the presence of dedicated full-time staff for patient safety and infection control. It is clear that the presence of dedicated full-time infection control nurse have had success in implementing systematic infection control programs [17], which in turn have led to reduced rates of nosocomial infections [18,19]. While it remains difficult to evaluate the impact of patient safety programs on outcomes such as decreased adverse events because of lack of evaluation tools and difficulty in measuring rare outcomes over short time periods for small samples of patients with progressive diseases [15], the utility of employing this type of dedicated staffing as a mechanism to expand patient safety practices can be assessed. The Institute of Healthcare Improvement breakthrough collaboratives, for example, examined the presence or absence of implemented prevention programs in hospitals as a measure of outcome [20]. Finally, hospital size and infrastructure may influence the amount of safety programs. Because the financial investments involved in patient safety systems are development and maintenance costs, rather than the costs of safety practices for each individual inpatient, the economic burden associated with patient safety might be disproportionately large for small hospitals. In fact, there is evidence to suggest that there are economies of scale in the cost of patient safety and infection control programs [10].

The implication derived from past findings is that larger hospitals with sufficient financial resources and the ability to assign dedicated full-time staff to patient safety would have more extensive practices for patient safety and infection control. To date, however, few studies have evaluated the impact of these factors (e.g. financial condition, staffing resources and hospital infrastructure) on the amount of investments for patient safety and infection control programs. Expecting hospitals to unilaterally shoulder the burdens of maintaining patient safety systems is unrealistic due to a lack of incentives for hospitals to do so, which ultimately reduces the patient's right to safer health care. Therefore, policy makers are required to develop safer healthcare delivery systems; wherever patients visit, they will receive safe medical care because all hospitals will have effective patient safety programs. The purpose of the present study was therefore to identify which hospital characteristics are positively correlated with the spread of patient safety activities including infection control, for use in designing an incentive structure to promote patient safety and infection control for the purpose of decision making to allocate additional resources for patient safety.

2. Methods

2.1. Data and sampling

Between December 2006 and May 2007, we conducted a national questionnaire survey. We sent questionnaire surveys to the patient safety managers and the infection control practitioners of all 1039 teaching hospitals in Japan. Throughout the questionnaires, we requested that information about activity status of patient safety and infection control be provided by the patient safety managers and the infection control practitioners, respectively. To ensure participant anonymity, we also requested respondents to use the enclosed pre-addressed envelops. The questionnaires were re-sent two times to all hospitals. Teaching hospitals in Japan features a mix of private health care providers and public financing structures and therefore our survey included university, national, municipal, public and corporate models of ownership. This study was approved by the Institutional Review Board at the Graduate School of Medicine, Kyoto University.

2.2. Questionnaire

The questionnaire was designed to collect information about hospital financing and infrastructure, as well as the amount of activity (in person-time values) focused on patient safety and infection control. Development of our survey instrument followed generally accepted procedures, including a literature review [13], conduct of a preliminary study [10,11] and panel discussions.

To review past findings from previous studies that demonstrated the effectiveness and/or significance of patient safety and infection control programs, we searched Science Citation Index (ISI®) and Social Sciences Citation Index (ISI®) to find literature that cited the 32 articles reviewed by the Agency for Healthcare Research and Quality (AHRQ) [21]. We also collected activity items through a web-based interface, and public relations magazines of patient safety practices and hospital infection control.

The panel discussion consisted of seven members that included physicians, pharmacists and researchers. Some of the members were also representatives from professional associations in Japan. These participants identified a comprehensive list of hospital-centered patient safety activities based on their clinical experiences (as expert opinions), with particular focus on those aspects of patient safety which are emphasized in Japanese health policy [22]. As public regard for patient safety issues have risen since 1999 in Japan and other countries including the US [1,10] and the state of implementation of patient safety systems in Japan is similar to that of the US [11], there seem to be little discrepancy regarding policy discussion between Japan and other countries including the US.

The questionnaire was validated through interviews with several managers of patient safety and hospital infection control, and through expert panel discussions. Because our validation process involved literature reviews, past cost estimates and expert consensus, we believe that our questions have at least face validity and are reliable patient safety system markers.

The following open-ended survey questions were designed to calculate person-time for each patient safety activity:

- Number of staff (sorted by profession).
- Amount of time required per activity session.
- Frequency of activity sessions conducted between April and September 2006.

2.3. Dependent variables: the amount of system-level activities for patient safety and infection control

The system-level person-time spent on each patient safety or infection control practice, including meetings and conferences, internal audits, staff education and training, incident reporting and infection surveillance was calculated for a specified 6-month window (Table 1). Individual person-time values were adjusted to reflect the value of a unit of person-time (i.e. opportunity cost) by profession, according to the estimated hourly wage of each professional category [23–25]. Adjustment factors were based on the reference value

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

Activity domain	Brief description	Activity component	Question item for each component
Meetings and conferences	Convening of decision-making board meeting, regular meetings of practitioners or other conferences conducted for patient safety	[PS & IC] Supreme decision-making board committee [PS & IC] Regular meeting in safety division	No. of staff Amount of time per activity Frequency of activities
Internal audit	Internal assessment of patient safety and infection control environments	[PS & IC] Regular assessment of ward environment conducted by division [PS] Additional internal audit conducted by a separate division	No. of staff Amount of time per activity Frequency of activities Contents of audit
Staff education and training	Education and training conducted in hospitals to prevent and control adverse events and hospital infections	[PS & IC] Educational activities to promote patient safety or infection control	No. of staff by type of profession Amount of time per activity Frequency of activities Contents of education
Incident reporting	The activities involved in reporting incidents by staff	[PS] Filling out incident reports	No. of reports by type of profession Amount of time required to fill out one report
Infection surveillance	Medical chart review and analysis of microbiology data to prevent and control nosocomial infections	[IC] Target surveillance	No. of staff by type of profession Amount of person-time required Target of surveillance

PS, patient safety; IC, infection control.

of an average salary at a healthcare institution, and were distributed as follows: physicians, 2.24; pharmacists, 0.96; nurses, 0.87; other medical staff, 0.86; other non-medical staff, 0.76. Therefore, the dependent variables in this study were person-time of average healthcare staff in Japanese hospitals. In addition, the total amount of person-time values were adjusted to 100-beds because of differences in number of beds between hospitals.

2.4. Independent variables: predictors of activity volume

2.4.1. Hospital infrastructure

We controlled for certain characteristics of hospital infrastructure that were suspected to be confounding factors (e.g. location and hospital infrastructure) in calculating person-time values for specific patient safety and infection control activities. These characteristics included ownership structure, location, hospital size, profit ratio, nurse-to-patient ratio (the number of nurses per shift divided by the number of patients present during that shift) and designated hospitals for infection control.

Though rural areas faced a lack of medical resources for many years in Japan and policy makers have attempted to tackle the issue of maldistribution [26], there remains to be a geographical inequity between districts regarding the number and quality of hospitals and physicians [27]. Therefore, it is no wonder that areas with fewer medical resources are disadvantage with respect to the implementation of patient safety activities.

The profit ratio of each hospital, defined as the ratio of revenue to expenses, was estimated for the first 6 months of 2006. Because the calculated data points followed a normal distribution, we used profit ratio as a continuous variable.

In Japan, there are four types of categories for medical care systems according to the type of infectious disease as follows: (1) "Specified Infectious Disease Designated Hospitals", designated by the Minister of Health, Labor and Welfare to treat patients with category 1 infectious disease (Ebola virus, hemorrhagic fever, Crimean-Congo hemorrhagic fever, smallpox, South American hemorrhagic fever, plague, Marburg disease and Lassa fever), category 2 infectious disease (poliomyelitis, tuberculosis, diphtheria and severe acute respiratory syndrome) and other unknown emerging infectious diseases; (2) "Category 1 Infectious Disease Designated Hospital" designated by prefectural governors to treat the patients with category 1 infectious disease; (3) "Category 2 Infectious Disease Designated Hospital" designated by prefectural governors to treat the patients with category 2 infectious disease; (4) non-designated hospitals to treat patients with other infectious diseases. Any level of designations requires that hospitals must be able to isolate a patient and provide for negative pressure rooms ventilated with high-efficiency particulate air (HEPA) filters. Therefore, public administrations supported these designated hospitals to maintain functions for infection control. We categorized hospitals as either designated hospitals or non-designated since "Specified Infectious Disease Designated Hospital" and "Category 1 Infectious Disease Designated Hospital" was limited to only 29 hospitals throughout Japan.

2.4.2. Structure of staffing resources dedicated to patient safety and infection control

To assess the structure of staffing resources dedicated to patient safety and infection control, patient safety managers and infection control practitioners were also asked to evaluate three qualitative measures of hospital staffing structure (role of patient safety and infection control divisions, empowerment of patient safety and infection control divisions, leadership of administration around patient safety and infection control, respectively) and one quantitative measure (number of dedicated full-time staff).

The patient safety managers and the infection control practitioners of respondents were asked to rate the role of patient safety within the division, empowerment of the division and leadership of the administration by use of a 5-point Likert scale. Responses were then collapsed into two categories: agree (strongly agree, slightly agree) and not-agree (neutral, slightly disagree and strongly disagree). Reported numbers of dedicated full-time staff assigned to patient safety and infection control in each division were classified into three categories: none, one and two or more.

2.5. Statistical analysis

Hospitals were excluded from analysis if: (1) more than 50% of questions regarding dependent variables went unanswered, (2) dependent variable values were found to be outliers or (3) values for either independent variable were missing.

To determine the independent variable most predictive of person-time spent on patient safety activities, we used generalized linear modeling (GLM) with a log-link function. The log-link function represents the log-rate of the dependent variable. Because person-time values were zero-inflated and non-negative, person-time was modeled with a gamma distribution. Standard errors were made heteroskedastically consistent via the Huber–White covariance matrix, which was applied for all estimates. Stata 9.2 was used for all analyses. All reported P-values were two-tailed, and P-values <0.05 were considered significant.

3. 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 final respective samples sizes of 252 (24.3%) and 215 (20.7%) for patient safety and infection control. No significant relationships were noted between response rates and hospital demographic information including geographic location ($P = 0.24$, χ^2-test) and bed size ($P = 0.94$, χ^2-test).

A median rather than a mean was taken for the analysis because the distribution of activities was skewed to low figures. The wage-adjusted median person-time per month devoted to patient safety (27.6 person-hours per 100-beds) was higher than that for infection control (19.3 person-hours per 100-beds). Person-time values for each independent variable are presented in Table 2.

Models were created to describe the relationship between the structural hospital characteristics captured by the independent variables, and the person-time values for both patient safety and infection control. No variables were found to be multi-collinear. Table 3 describes the predictive value of each independent variable on person-time values per 100-beds for patient safety and infection control.

The relationships between person-time values per 100-beds and the independent variables of hospital ownership and location were mixed. The university-associated ownership structure was positively correlated with person-time values in the patient safety model, but showed no association with person-time values in the infection control model. Conversely, location was a positive predictor of person-time val-

Table 2
Association of study variables with person-time values for patient safety and infection control

Predictor variables	Operational definition	Patient safety ($n = 252$)			Infection control ($n = 215$)		
		n	Person-time[a]	P-value[b]	n	Person-time[a]	P-value[b]
Hospital infrastructure							
Ownership structure	University Hospital	18	77.9	<0.001	15	34.2	0.191
	National Hospital	21	28.3		14	15.0	
	Municipal Hospital	54	22.9		46	19.2	
	Public Hospital	76	24.6		66	17.5	
	Corporate Hospital and other	83	33.3		74	20.0	
Location	Hokkaido	23	25.7	0.141	17	16.8	0.245
	Tohoku	27	22.8		22	15.4	
	Kanto-Shinetsu	67	31.6		58	22.1	
	Tokai-Hokuriku	40	30.1		35	22.6	
	Kinki	45	24.7		41	17.5	
	Chugoku	18	28.4		14	21.0	
	Shikoku	11	18.3		11	15.2	
	Kyusyu	21	31.3		17	15.0	
Hospital Size	Below 1st percentile; <315 beds	64	31.2	0.017	53	18.4	0.446
	Below 2nd percentile; 315–431 beds	62	28.3		49	18.8	
	Below 3rd percentile; 432–591 beds	71	23.7		65	17.5	
	Above 3rd percentile; ≥592 beds	55	29.2		48	23.4	
Designations for infection control	Any designations; specified/1st/2nd	–	–	–	65	19.7	0.873
	No designation	–	–		150	18.5	
Profit margin (%)	(Revenue/expenses) × 100	252	27.4	–	215	18.8	–
Nurse staffing	1RN per 7 patients	55	29.3	0.078	49	24.5	0.001
	1RN per 10 patients	184	26.8		156	17.9	
	1RN per 13 or 15 patients	13	22.8		10	13.6	
Structures of patient safety and infection control							
Dedicated staff	Two or more dedicated persons	58	31.8	0.006	13	34.2	<0.001
	One dedicated person	148	27.8		46	23.6	
	No dedicated person	46	24.5		156	17.4	
Clear division role	Agree; Likert scale from 1 to 2	238	27.6	0.071	191	19.4	0.128
	Not agree; Likert scale from 3 to 5	14	22.9		24	14.8	
Empowerment to division	Agree; Likert scale from 1 to 2	200	27.6	0.516	167	20.8	0.004
	Not agree; Likert scale from 3 to 5	52	26.0		48	15.0	
Administrative leadership	Agree; Likert scale from 1 to 2	226	27.5	0.228	177	20.8	0.003
	Not agree; Likert scale from 3 to 5	26	26.5		38	14.5	

RN: registered nurse.
[a] Median person-hours/(100-beds month).
[b] Kruskal–Wallis rank test.

Table 3
Predictors of patient safety and infection control activities

Variable	Increase (%) in person-hours/(100-beds month)			
	Patient safety (*n* = 252)		Infection control (*n* = 215)	
	Coefficient	95% CI	Coefficient	95% CI
Ownership				
University Hospital	75.0***	34.5–115.5	25.0	−25.3 to 75.3
National Hospital	−14.7	−43.1 to 13.6	−14.7	−54.8 to 25.4
Municipal Hospital	−26.5*	−48.4 to −4.7	9.3	−23.5 to 42.2
Public Hospital	−22.0*	−39.6 to −4.4	−13.9	−39.3 to 11.6
Corporate Hospital	Reference		Reference	
Location				
Hokkaido	Reference		Reference	
Tohoku	15.7	−15.1 to 46.5	24.2	−26.2 to 74.6
Kanto-Shinetsu	15.4	−8.6 to 39.4	36.8*	6.0–67.6
Tokai-Hokuriku	23.2	−4.6 to 51.0	52.9**	16.7–89.1
Kinki	1.0	−23.7 to 25.8	54.2**	15.8–92.5
Chugoku	16.2	−22.4 to 54.8	47.1*	5.8–88.4
Shikoku	−10.3	−48.5 to 27.9	99.8*	20.8–178.8
Kyusyu	23.4	−5.8 to 52.6	16.7	−25.4 to 58.7
Hospital size				
1st quartile (<315)	Reference		Reference	
2nd quartile (315–431 beds)	−21.2*	−37.9 to −4.6	−16.0	−46.9 to 14.9
3rd quartile (432–591 beds)	−41.5***	−59.8 to −23.3	−28.5*	−56.3 to −0.8
4th quartile (≥592 beds)	−37.9**	−62.3 to −13.5	−37.6*	−68.8 to −6.4
Designations for infection control				
No designation	NA		Reference	
Any designations	NA		14.4	−5.9 to 34.7
Finance				
Profit margin (%)	0.9**	0.4–1.5	0.7	−0.3 to 1.6
Nurse staffing				
1RN per 13 or 15 patients	Reference		Reference	
1RN per 10 patients	11.5	−14.2 to 37.1	50.3*	8.0–92.5
1RN per 7 patients	18.5	−7.4 to 44.5	91.8***	47.8–135.7
Dedicated staff for each activity				
No staff	Reference		Reference	
1 person	36.2***	18.0–54.3	34.0***	9.8–58.2
≥2 persons	50.0***	26.0–73.9	59.7***	19.4–100.1
Assessment of division or activity[a]				
Clear role of division	28.7	−1.8 to 59.1	−18.4	−50.4 to 13.6
Empowerment to division	3.5	−13.0 to 20.0	16.2	−12.4 to 44.9
Leadership from administrator	21.1*	0.6–41.6	32.5*	1.8–63.2

Note. The dependent variables were volume of patient safety activities and one of infection control activities, in person-hours/(100-beds month). CI, confidence interval; NA, not applicable; RN, registered nurse. *$P < 0.05$, **$P < 0.01$, ***$P < 0.001$.
[a] Reference for each variable is “not agree”.

ues in the infection control model, with no correlation identified in the patient safety model.

Smaller hospital size was significantly related to increased person-time values per 100-beds for both patient safety and infection control ($P < 0.05$), that is, smaller hospital tend to shoulder a higher burden compared to larger hospitals. Hospitals with lower profit margins had fewer patient safety person-time values than those more profitable ($P < 0.01$). There was no significant relationship between person-time values and the infrastructural variable of facility for infection control status.

In hospitals with dedicated full-time staffing for patient safety or infection control, person-time values per 100-beds for both patient safety and infection control significantly increased by over 30% ($P < 0.001$ and $P < 0.01$, respectively). Hospitals with higher nurse-to-patient ratios also had significantly higher person-time values for infection control ($P < 0.01$). Nurse-to-patient ratios were not significant in the patient safety model, though the point estimates tended toward increased person-time values.

Clear roles for the patient safety and infection control divisions answered by patient safety managers and infection control practitioners had no correlation to person-time values, and perceived empowerment of each division was similarly unrelated. Staff perception regarding hospital administration leadership in implementing patient safety and infection control activities, however, was significantly linked to increased person-time values ($P < 0.05$).

4. Discussion

This study is the first to link person-time dedicated to patient safety activities with characteristics of hospital infrastructure and organization. Our findings confirmed that hospitals with greater financial and organizational resources are more able to promote the amount of activities for patient safety and infection control. The use of detailed quantitative measurement (volume of activities for patient safety and infection control) rather than qualitative data (presence or absence of practices for patient safety and infection control) was a distinct strength of this study.

The relationships of ownership structure, location and profit ratio to person-time values were inconsistent between the model of patient safety and that of infection control. In the patient safety model, university-associated ownership structures promoted volume of programs while the location of the hospital was unrelated. By contrast, location positively impacted increase of programs in the infection control model, while ownership structure had no association with person-time values. This tension may be closely related to recent developments in Japanese health policy. In an effort to systematically increase patient safety measures, the Japanese government issued a series of patient safety regulations to be implemented in all teaching hospitals [10]. By requiring these practices to be implemented throughout Japan, the impact of location on spread of patient safety programs was significantly diminished. Because the financial and human resources of a hospital vary significantly between ownership structures, however, university-associated hospitals were able to encourage amount of patient safety programs to a much greater degree than municipal hospitals that are often smaller and have less profit margins. No corresponding government intervention, however, took place for infection control by the year 2006. In Japan, geographic isolation tends to produce greater disparities in access to resources than does variations in hospital ownership structures. Therefore, policies requiring specific programs might impact the increase of patient safety programs to a certain level. This information regarding the relationship between policy and patient safety will be important in the further development of hospital regulations.

The positive impact of profit margins on the spread of patient safety programs has important policy implications. The finding that increased profit margins are predictive factors for person-time values in the patient safety model suggests that the issue of patient safety may be a low priority for hospital administrators. Previous research has found that leadership may be a critical influence in advancing patient safety [20,28,29]. Confirming the role of hospital administration in implementation of safety programs, perceived administrative leadership was also significantly related to the size of both patient safety and infection control practices ($P < 0.05$). However, when we changed the cut-point of the scales measuring the perceived leadership for patient safety and infection control to categorize the response of "neutral" as "agree" (the model shown in Table 3 used the cut-point to include the response of "neutral" into "not agree"), the results of the impact of perceived leadership on the amount of activity was only changed in the infection control model. There were no substantial changes in coefficient value and the significance of each predictor variable except for the administrative leadership variable in the infection control model. Therefore, when we consider the impact of administrative leadership on infection control activities, a cautious interpretation would be needed. In contrast to the profit margin findings for patient safety, there was no association between increased profit margins and spread of infection control practices. One explanation for these discrepancies between patient safety and infection control model may again be the lack of government regulatory control over infection control practices in Japan. Hospital administrators may be more likely to prioritize a program that is presented as a national requirement, as is the case for patient safety programs.

In accordance with our hypothesis (that financial status, staffing resources and hospital infrastructure would be potential predictors of spread of activities for patient safety and infection control), hospitals with sufficient staffing resources (the presence of dedicated full-time staff and nurse-to-patient ratios) were significantly linked to increased person-time values. Although few studies examined the mechanism of this effect, prior studies have reported increased nurse-to-patient ratio to be inversely associated with nosocomial infection rates [30–37]. By demonstrating the positive impact of nurse-to-patient ratios on spread of infection control activities, our findings lend support to these conclusions. Our results also showed increased spread of both patient safety and infection control activities with the presence of dedicated full-time staffing ($P < 0.001$ and $P < 0.01$, respectively), despite the political differences in regulatory control of the two systems. This result was consistent with findings previously reported in infection control [17–19], but to our knowledge is the first such finding in the field of patient safety. To promote the spread of hospital safety programs, therefore, it may be necessary to develop policies around dedicated full-time staffing, rather than more specific requirements that safety programs be implemented. The economic impact of such policies would include the costs associated with assigning dedicated staff to safety activities, as well as the costs of conducting increased numbers of hospital-wide patient safety and infection control activities. To avoid undue strain on staffing resources and the healthcare system, government financial support would be essential in offsetting these costs and promoting patient safety.

Ideally, all hospitals should be required to develop patient safety systems [1], regardless of hospital size. Because the financial investments involved in patient safety systems are development and maintenance costs, rather than the costs of safety practices for each individual inpatient, the economic burden associated with patient safety is disproportionately large for small hospitals. Our results match these theoretical expectations. As reported in our earlier study [10], these economies of scale play a significant role in the total cost of patient safety activities, a factor which should be weighed in considering incentive schemes for hospitals of varying sizes.

This study had several limitations. Firstly, our study sample was limited to teaching hospitals, which tend to have greater financial and human resources than non-teaching hospitals. The study results may therefore not be generalizable to non-teaching hospitals, which are often smaller and have fewer resources. Secondly, all responses were self-reported, and may thereby be subject to reporting bias. Because responders were aware that survey responses would be anonymous, however, we believe that survey results were a reasonable reflection of actual patient safety and infection control activities. In fact, although 34.7% of hospitals voluntarily identified themselves, no difference in person-time values were noted between these hospitals and those who chose to remain anonymous. Thirdly, the survey possibly underestimates the total investment for patient safety. Since we evaluated the activities of maintaining patient safety systems based on hospital-level activities, investments made at the patient—(e.g. bed side nursing time and informed consent), unit—(e.g. nurse manager investigates errors) and department—(e.g. department measures or safety) levels were not included. However, as stated by the Institute of Medicine [1], since the most important strategy for improving patient safety is to develop systems that will reduce the probability of error and improve the probability of safety, targeting hospital-level efforts would seem to be adequate focus for this study.

Additional research into establishing patient safety outcome measures will be a critical step in the development of a valid, accountable system of financial incentives for patient safety. This study has important implications for the design of this incentive system, but evidence is needed to demonstrate that the health care system will be safer following implementation of patient safety practices. Future studies should also focus on the cost-effectiveness of risk-reducing strategies.

5. Conclusion

Using quantitative data from teaching hospitals across Japan, we identified predictive factors for increase of patient safety and infection control programs. To promote patient safety programs in hospitals, it is imperative that policy makers require the assignment of staff dedicated to patient safety. We also found that an important barrier to promoting the amount of patient safety practices was lack of administrative leadership. Future research will be needed to determine outcome measurements for patient safety programs. Reliable and validated outcome measurements will allow hospitals to demonstrate accountability, a critical step in the development of government incentive programs around patient safety and infection control.

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References

[1] Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. Washington, DC: National Academy Press; 2000.

[2] Longo DR, Hewett JE, Ge B, Schubert S. The long road to patient safety: a status report on patient safety systems. Journal of the American Medical Association 2005;294:2858–65.

[3] Rosen AK, Zhao SB, Rivard P, Loveland S, Montez-Rath ME, Elixhauser A, et al. Tracking rates of patient safety indicators over time: lessons from the veterans administration. Medical Care 2006;44:850–61.

[4] Brennan TA, Gawande A, Thomas E, Studdert D. Accidental deaths, saved lives, and improved quality. New England Journal of Medicine 2005;353:1405–9.

[5] National Healthcare Quality Report. Rockville, MD: Agency for Healthcare Research and Quality and US Department of Heath and Human Services; December 2004. AHRQ Publication No. 05-0013.

[6] Kaiser Family Foundation. Agency for Healthcare Research and Quality, Harvard School of Public Health. National survey on consumers' experiences with patient safety and quality information. Menlo Park, CA: Kaiser Family Foundation; 2004.

[7] Leape LL, Berwick DM. Five years after to err is human: What have we learned? Journal of the American Medical Association 2005;293:2384–90.

[8] Wachter RM. The end of the beginning: patient safety five years after 'to err is human'. Health Affairs 2005;24:W9–20.

[9] Altman DE, Clancy C, Blendon RJ. Improving patient safety: five years after the IOM report. New England Journal of Medicine 2004;351:2041–3.

[10] Fukuda H, Imanaka Y, Hayashida K. Cost of hospital-wide activities to improve patient safety and infection control: a multi-centre study in Japan. Health Policy, in press.

[11] Fukuda H, Imanaka Y, Hirose M, Hayashida K. Economic evaluations of maintaining patient safety systems in teaching hospitals. Health Policy, in press.

[12] Wachter RM, Shojania KG. Internal bleeding: the truth behind America's terrifying epidemic of medical mistakes. New York: Rugged Land; 2005.

[13] Fukuda H, Imanaka Y. Assessment of transparency of cost estimates in economic evaluations of patient safety programs. Journal of Evaluation in Clinical Practice, in press.

[14] Field TS, Gilman BH, Subramanian S, Fuller JC, Bates DW, Gurwitz JH. The costs associated with adverse drug events among older adults in the ambulatory setting. Medical Care 2005;43:1171–6.

[15] Pronovost PJ, Miller MR, Wachter RM. Tracking progress in patient safety—an elusive target. Journal of the American Medical Association 2006;296:696–9.

[16] Galvin RS, Delbanco S, Milstein A, Belden G. Has the leapfrog group had an impact on the health care market? Health Affairs 2005;24:228–33.

[17] Brusaferro S, Quattrin R, Barbone F, D'Alessandro D, Finzi GF. Factors influencing hospital infection control policies in Italian hospitals. Journal of Hospital Infection 2003;53: 268–73.

[18] Haley RW, Culver DH, White JW, Morgan WM, Emori TG, Munn VP, et al. The efficacy of infection surveillance and control programs in preventing nosocomial infections in US hospitals. American Journal of Epidemiology 1985;121:182–205.

[19] Vandenberghe A, Laterre PF, Goenen M, Reynaert M, Wittebole X, Simon A, et al. Surveillance of hospital-acquired infections in an intensive care department: the benefit of the full-time presence of an infection control nurse. Journal of Hospital Infection 2002;52:56–9.

[20] Leape LL, Kabcenell AI, Gandhi TK, Carver P, Nolan TW, Berwick DM. Reducing adverse drug events: lessons from a breakthrough series collaborative. The Joint Commission Journal on Quality Improvement 2000;26:321–31.

[21] Shojania KG, Duncan BW, McDonald BW, Wachter RM, editors. Making health care safer: a critical analysis of patient safety practices. Evidence Report/Technology Assessment no. 43. Rockville, MD: Agency for Healthcare Research and Quality; 2001. AHRQ publication 01-E058. Available at: http://www.ahrq.gov/clinic/ptsafety/pdf/ptsafety.pdf [accessed April 17, 2008].

[22] Ministry of Health, Labour and Welfare. Kongo no iryo anzen taisaku ni tsuite; 2005 [in Japanese]. http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/3/kongo/02.html [accessed April 17, 2008].

[23] Ministry of Health, Labour and Welfare. Iryo Keizai Zittai Chousa Houkoku; 2005 [in Japanese]. http://www.mhlw.go.jp/shingi/2006/06/s0621-6.html [accessed April 17, 2008].

[24] Ministry of Health, Labour and Welfare. Basic Survey of Wage Structure; 2005 [in Japanese]. http://wwwdbtk.mhlw.go.jp/toukei/kouhyo/data-rou4/data17/30501.xls [accessed April 17, 2008].

[25] Ministry of Internal Affairs and Communication. Annual Report on the Labour Force Survey; 2005 [in Japanese]. http://www.stat.go.jp/data/roudou/2005n/ft/zuhyou/201420.xls [accessed April 17, 2008].

[26] Kobayashi Y, Takaki H. Geographic distribution of physicians in Japan. Lancet 1992;340:1391–3.

[27] Hirose M, Imanaka Y, Ishizaki T, Evans E. How can we improve the quality of health care in Japan? Learning from JCQHC hospital accreditation. Health Policy 2003;66: 29–49.

[28] Ginsburg L, Norton PG, Casebeer A, Lewis S. An educational intervention to enhance nurse leaders' perceptions of patient safety culture. Health Services Research 2005;40: 997–1020.

[29] Pronovost PJ, Weast B, Holzmueller CG, Rosenstein BJ, Kidwell RP, Haller KB, et al. Evaluation of the culture of safety: survey of clinicians and managers in an academic medical center. Quality & Safety in Health Care 2003;12:405–10.

[30] Stone PW, Mooney-Kane C, Larson EL, Horan T, Glance LG, Zwanziger J, et al. Nurse working conditions and patient safety outcomes. Medical Care 2007;45:571–8.

[31] Needleman J, Buerhaus P, Mattke S, Stewart M, Zelevinsky K. Nurse-staffing levels and the quality of care in hospitals. New England Journal of Medicine 2002;346:1715–22.

[32] Amaravadi RK, Dimick JB, Pronovost PJ, Lipsett PA. ICU nurse-to-patient ratio is associated with complications and resource use after esophagectomy. Intensive Care Medicine 2000;26:1857–62.

[33] Kovner C, Gergen PJ. Nurse staffing levels and adverse events following surgery in US hospitals. Image-The Journal of Nursing Scholarship 1998;30:315–21.

[34] Arnow PM, Allyn PA, Nichols EM, Hill DL, Pezzlo M, Bartlett RH. Control of methicillin-resistant *Staphylococcus aureus* in a burn unit: role of nurse staffing. Journal of Trauma-Injury Infection and Critical Care 1982;22:954–9.

[35] Haley RW, Bregman DA. The role of understaffing and overcrowding in recurrent outbreaks of staphylococcal infection in a neonatal special-care unit. Journal of Infectious Diseases 1982;145:875–85.

[36] Vicca AF. Nursing staff workload as a determinant of methicillin-resistant *Staphylococcus aureus* spread in an adult intensive therapy unit. Journal of Hospital Infection 1999;43:109–13.

[37] Fridkin SK, Pear SM, Williamson TH, Galgiani JN, Jarvis WR. The role of understaffing in central venous catheter-associated bloodstream infections. Infection Control and Hospital Epidemiology 1996;17:150–8.