Current Status of Patient Safety Regulations, Guidelines and Support Mechanisms in Korean Hospitals

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Purpose: This study was conducted to investigate patient safety regulations and guidelines in order to understand their current status, and to examine support measures to improve patient safety in Korean hospitals. **Methods:** The participants were the safety officers from hospitals with 200 or more beds and 112 hospitals responded to the online survey. The questions covered patient safety regulations, the performance level of patient safety activities, patient safety incident reporting systems, the dedicated professional, training, support mechanisms, and expectations of reporting systems. **Results:** Among preventative measures, fall prevention and hand hygiene were reported to be most widely practiced (92% and 91%, respectively). Time-out for invasive procedures showed a relatively low practice rate at 70%. Among patient care activities, transfusion, surgery and sedation, medication, and infection management were performed by 84, 74, 93 and 93% of the hospitals, respectively. Patient safety activities included patient safety committee, patient safety cooperation between decision-making bodies, patient safety workshops, seminars, lectures, and training for employees. **Conclusion:** Patient safety regulations and guidelines have not yet been sufficiently prepared, and a public institution such as a certification authority is of crucial importance to enforce these guidelines.

Key Words: Diabetes, Self-management, Motivation, Intention, Self-efficacy

INTRODUCTION

One in 10 hospitalized patients experience an adverse event, according to worldwide patient safety survey. Because this is such a widespread phenomenon, patient safety has come to be regarded as a global challenge that threatens the health and well-being of citizens of every nation.[1-8] At the 55th World Health Assembly in 2002, the World Health Organization (WHO) adopted a resolution that urges states to pay closer attention to patient safety and improve the quality of existing patient safety measures.[9] Recently, the topic of patient safety has been actively discussed, not only among researchers of the clinical., educational., and research fields, but also among professionals in most areas of the medical field, including medical industries, medical informatics technology, and medical tourism. Safe drugs, medical devices, surgical methods, and hospitals secure competitiveness in the medical industry; striving for increased safety is a task of utmost importance.

However, in South Korea, this important issue has evaded the interest of not only ordinary citizens but also the federal government; indeed, even rudimentary studies have not been conducted with government backing.

In the absence of any comprehensive study, estimates place the number of casualties at 36,473 people per annum.[10-11] The medical industry in South Korea is in its infancy regarding patient safety awareness, and lacks necessary data as well as mid- to long-term plans to spread awareness. Current patient safety regulation places more emphasis on management of the severity of the incident, prevention of harm instead of post-incident penalties, encouragement of reporting, and finding lessons from failures[1-7]; however, these only deal with the consequences of medical accidents.

Advancement of patient safety measures is an urgent issue, as numerous reports have indicated. The incident reporting system cannot alone improve healthcare quality, even in major hospitals. Problems arise from limited knowledge and experience regarding patient safety measures and patient safety culture. Hospitals should be provided with standardized clinical practice guidelines, Patient Safety Indicators, and Patient Safety Solutions to improve the patient safety climate which is measurable and actionable.

Objectives

- To investigate the current patient safety regulations and guidelines in Korean hospitals in order to improve patient safety.
- To identify the support measures that are suitable for these hospitals.
- To understand the core elements of patient safety

and utilize it for a systematic approach towards improvement of patient safety.

METHODS

We created a questionnaire to investigate hospitals' current regulations, guidelines, and administrative procedures required for patient safety. In order to develop the questionnaire, a focus group interview was conducted with 10 patient safety specialists working in tertiary hospitals. We then used the results of this focus group interview, in combination with a literature review, and an assessment of the accreditation domains for healthcare, to develop the questionnaire for use in this study. Ten key patient safety domains, regulation/accreditation, patient safety awareness, and support activities for patient safety were selected for the questionnaire. To secure content validity, six patient safety specialists from the Korean Society of Patient Safety reviewed and revised the developed questionnaire.

The final questionnaire consisted of 105~159 questions in total., and the total number of questions varied and the overall sequence was adapted relative to the answers of previous questions, covering 6 categories: general information, presence and practice rate of patient safety regulations and guidelines, patient safety incident reporting system, staff education and training, activities for improvement in patient safety, and support system at the hospital level and the national level (Table 1).

Questions regarding regulations and guidelines were

Table 1. Questionnaire Items and Description

Categories	Items	Description
General information	4~5	Items assess hospital size, accreditation, and presence of division/staff dedicated for quality improvement and patient safety.
Presence and practice rate of patient safety regulations (guidelines)	22~75	Further sub-categorized into patient safety activities, clinical activities, operation & sedation management, drug management, and infection management, to investigate the presence, practice rate, and source of interference to patient safety regulations. With sub-questions, the number of items can vary from a minimum of 22 to a maximum of 71.
Patient safety incident reporting system	37	Detailed information about the operation and culture of the patient safety reporting system, confidentiality, independence, responsibility, and root cause analysis. Patient safety incident was categorized by severity
Health information technology, staff education and training for patient safety, and activities to improve patient safety	7	Usage of health information technology, training or educational programs related to patient safety issues and multiple-choice questions regarding currently implemented activities aimed at improving patient safety
Support from hospitals for quality improvement in patient safety	35	Items were separated by internal and external source support, and asked about hospital patient safety culture and the need for improvement of patient safety. We asked for opinions regarding national level institutions and the incident reporting system.

given options of "yes," "no," or "other", whereas those regarding current state, such as practice rate, used a 5-point Likert scale where 1="Strongly disagree", 2="Disagree", 3="Neutral", 4="Agree", 5="Srongly agree". Questions regarding necessities were formatted similarly 1="Definitely unnecessary", 2="Unnecessary", 3="Neutral", 4="Necessary", 5="Definitely necessary".

Staff participants were dedicated to Quality Improvement (QI) and Patient Safety (PS), and were responsible for patient safety at over 310 hospitals nationwide with over 200 beds. Staff participants were informed of their confidentiality and voluntary participation, and the purpose and methods of this study were explained to them. Personnel who were interested in this survey were provided with a link for the online survey via email. The purpose, confidentiality, and researcher contact information, and other information related to this study were offered to participants before they began the online survey. The online survey was conducted through the professional online research institute. The study was conducted between November 22, 2011 and December 7, 2011, and a total of 112 hospitals participated in the survey voluntarily.

RESULTS

1. General Characteristics

Hospital capacities in terms of hospital beds were as follows: 47.4% had "500~999" beds, 37.5% had "300~499," and 7.1% had "more than 1000." The largest group in the distribution of staff number (38.4%) reported having at least 1,000 employees. 44.6% had received accreditation from the Korea Institute for Healthcare Accreditation; 77.7% reported having staff dedicated to"QI and PS," while 51.7% reported having 2 to 5 staff members.

2. Presence and Performance Rates of Patient Safety Regulations

A total of five hospitals performed in accordance with patient safety-related regulations or guidelines; the degree of status and measured results are shown in Table 2. The five areas comprising this component of the questionnaire were patient safety activities, clinical activities, operation and sedation management, drug management, and infection management.

For patient safety activities, 92% and 91.1% of the responding hospitals had regulations for fall prevention and hand hygiene, respectively, which were the highest

within this category, whereas only 69.6% of the hospitals had a regulation concerning time-out before invasive procedures. The level of performance was 4.0 out of 5 for fall prevention regulation, and 3.9 out of 5 for invasive procedure time-out regulation.

Regarding clinical activities, 83.9% had a transfusion management regulation and showed a mean performance level of 4.4 for blood storage, return, and inventory management and disposal. In the operation and sedation management category, 74.1% had peri-operational management and had a performance level of 4.4. In the drug management category, 92.9% had a safe-storage regulation, with a performance level of 4.0. In the infection management category, 92.9% had washing, disinfecting, sterilizing equipment and laundry regulations, which was the highest in this category; furthermore, infection management in the artificial kidney room had a performance level of 4.3, which was the highest in this category.

3. Patient Safety Reporting System

The results for this portion of the questionnaire are shown in Tables 3 and 4. Ninety-six percent of hospitals had a reporting system for patient safety, and 23.2% operated the system in select departments. Reporting for sentinel and adverse events were described as voluntary or mandatory (51.8% and 49.1%, respectively), whereas for near-miss events, voluntary reporting was 66%. Regarding the methods of reporting sentinel and adverse events, written reports were used most often (at 56.3% and 51.8%, respectively), whereas for near-miss events, electronic filing was used most, at 39.3%. The participating hospitals practiced different reporting systems, depending on the types of patient safety incidents. Incidents of higher severity resulted in better-executed incident reports, with scores of 3.9 for sentinel events and adverse events and 3.1 for near-miss events. Reported patient safety incidents regularly reached the administration (score of 4.2), and reporting of patient safety incidents were encouraged (4.1). When a patient safety incident occurred, more attention was focused on how and why it happened (4.1), rather than whose responsibility the incident was (3.0). Regarding the enforcement of the anonymity of the reporter, involved employee, and patient in the incident report, it appeared to be more difficult to guarantee anonymity for more severe incidents. Similarly, anonymity of the reporting person could not be as readily enforced for incidents of increased severity. Similar rates of incident investigation

Table 2. Presence of Regulations and Performance Levels   (*N*=112)

Regulations		n (%)	Level of performance (5 point scale)	
Patient safety activities	Verbal prescription	86 (76.8)		3.4
	Time-out for invasive procedure	78 (69.6)		3.9
	Fall prevention	103 (92.0)		4.0
	Hand hygiene	102 (91.1)		3.4
Clinical activities	Prevention and management of decubitus ulcer	93 (83.0)	Prevention and management of decubitus ulcer	4.0
			Regular evaluation of the management	4.0
	timely treatment of serious emergency patients	76 (67.9)		3.9
	Cardio-pulmonary resuscitation (CPR)	93 (83.0)	Performing CPR	3.9
			Evaluating and improving CPR practice	3.7
	Transfusion management	94 (83.9)	Safe transfusion	4.3
			Blood storage, return, inventory management and disposal	4.4
	Cancer chemotherapy	69 (61.6)	Preparing drugs safely	4.2
			Administering drugs safely	4.2
			Monitoring side-effects	4.1
Operation and sedation management	Peri-operational management of patient safety	83 (74.1)		4.4
	Sedation treatment	72 (64.3)		3.5
Medication management	Safe storage of drug	104 (92.9)		4.0
	Safe, clean preparation and dispensation of drugs	96 (85.7)		3.9
	Safe drug administration	102 (91.1)		4.0
	Drug side-effect monitoring	87 (77.7)		3.7
Infection management	Efficient infection management	100 (89.3)		4.0
	Infection management of operation rooms	90 (80.4)		4.2
	Infection management of intensive care unit	90 (80.4)		4.2
	Infection management of endoscopy room	91 (81.3)		4.2
	Infection management of artificial kidney room	83 (74.1)		4.3
	Washing, disinfecting, sterilizing equipment & laundry	104 (92.9)		4.1
	Protection of patients and staff	97 (86.6)		4.1

Table 3. Patient Safety Reporting System by Incident Type   (*N*=112)

Items			n (%)
Presence of patient safety reporting system		Institution-wide	82 (73.2)
		In select departments	26 (23.2)
		No	4 (3.6)
Type of patient safety incident reporting system (multiple choice allowed)	Sentinel events	Voluntary	17 (15.2)
		Mandatory	36 (32.1)
		Voluntary + Mandatory	58 (51.8)
		None	3 (2.7)
		Others	1 (0.9)
		Paper report	63 (56.3)
		Verbal report	51 (45.5)
		Electronic report	38 (33.9)
		Others	2 (1.8)
	Adverse events	Voluntary	23 (20.5)
		Mandatory	30 (26.8)
		Voluntary + Mandatory	55 (49.1)
		None	5 (4.5)
		Others	1 (0.9)
		Paper report	58 (51.8)
		Verbal report	41 (36.6)
		Electronic report	39 (34.8)
		Others	2 (1.8)
	Near miss events	Voluntary	74 (66.1)
		Mandatory	6 (5.4)
		Voluntary + Mandatory	27 (24.1)
		None	6 (5.4)
		Others	0 (0.0)
		Paper report	40 (35.7)
		Verbal report	33 (29.5)
		Electronic report	44 (39.3)
		Others	1 (0.9)

were carried out among different incident severity levels. Resolutions in accordance with incident investigation were carried out at a higher rate for incidents of higher severity, where sentinel events scored 3.7 and near-miss events scored 3.4 (Table 4).

4. Patient Safety Staffing and Training

Of the hospitals in this study, 37.5% provided a patient-safety-related training/education program for the staff once a year, whereas 25% did it once every 6 months. 86.6% of institutions had their personnel trained externally.

5. Patient Safety Improvement Activities

When asked multiple-choice questions regarding currently implemented activities aimed at improvement of patient safety, 62.5% of hospitals responded to having either interdepartmental cooperation operations, such as a patient safety committee, or holding patient safety workshops, seminars, or lectures for all employees. 52.5 % produced promotional material and events for patients and their guardians. The diverse effort was evident- 50.9% answered positively to holding patient safety awareness days/weekly events or contests for promotional slogans or posters. The preferred incentive for patient safety improvement was monetary, at 26.8% (Table 5).

6. Differences in Patient Safety Improvement Activities among Hospitals of Different Capacities

With the number of hospital beds at 500 as a reference point, there were statistically significant differences in nine categories (e.g., patient safety incident reporting system, formation of interdisciplinary team, in-service education and staff training, and patient safety day/ week events). This indicates that larger hospitals perform more activities. However there were no statistical differences in terms of the production of promotional

Table 4. Status of Patient Safety Incident Reporting (*N*=112)

Items	Scale (5 point scale)	
Patient safety incident reports are carried out correctly in accordance with the procedures.	Sentinel events Adverse events Near-miss events	3.9 3.9 3.1
Reported patient safety incidents are shared frequently with the management staff.		4.2
Reported patient safety incidents are shared with personal information removed.		3.5
Reporting of patient safety incidents is encouraged.		4.1
Approval of superior is required for reporting patient safety incident.		2.6
When a patient safety incident occurs, more attention is focused on whose responsibility it was.		3.0
When a patient safety incident occurs, more attention is focused on how and why it happened.		4.1
Patients' involvement in clinical decision-making was encouraged and the importance of the patients' involvement was acknowledged.		3.3
Implemented a supporting plan for encouraging patients' involvement in clinical processes.		3.1
When a patient safety incident is reported, the reporting person is kept anonymous.	Sentinel events Adverse events Near-Miss events	2.3 2.4 3.0
When a patient safety incident is reported, the involved medical personnel are kept anonymous.	Sentinel events Adverse events Near-Miss events	2.3 2.4 2.9
When patient safety incident is reported, the involved patient (s) is (are) kept anonymous.	Sentinel events Adverse events Near-Miss events	2.0 2.1 2.5
Those who report patient safety incidents do not face negative consequences from the management or administration.	Sentinel events Adverse events Near-Miss events	3.7 3.8 4.1
Improvement recommendations for patient safety incidents involve focusing on system, process, and procedures.		3.8
Improvement recommendations for patient safety incidents involve focusing on individuals' education and training.		3.4
Practical solutions are recommended by the department responsible for processing patient safety incident reports.		3.4
Evaluation for the effectiveness of improvement activities is done after the reporting and improvement activities.		3.3
Within a specified period, patient safety incidents are analyzed and investigated.	Sentinel events Adverse events Near-Miss events	3.6 3.6 3.4
In accordance with the root cause analysis results, appropriate actions are taken.	Sentinel events Adverse events Near-Miss events	3.7 3.6 3.4
In accordance with the root cause analysis results, failure mode and effects analyses are performed.		2.6
In accordance with the failure mode and effects analyses results, improvement activities are performed.		2.6

material or rounds by hospital executives (Table 5).

7. Support for Patient Safety Improvement by the Medical Institution

Questions were asked to determine the relative importance of the formation of patient safety culture for patient safety improvement, categorized by context (in-hospital and out-of-hospital). All subcategories of the in-hospital context scored higher than 4.4. Among these, the necessity of establishing a patient safety culture scored highest, at 4.6. The necessity of patient safety education targeted toward executives and heads of departments showed a demand for changes in leadership. Further, responses to"the necessity of enough staffing for the patient safety department"scored high at 4.6, for smooth and active execution of patient safety activities. In the areas outside hospitals, with overall distribution between 4.2 and 4.5 points, "national level patient safety education protocols and guidelines" scored the highest at 4.5, followed by "government policies and protection of patient safety activities," "technical support for patient safety improvement," "patient safety curriculum development for colleges of medicine and nursing and allied health professionals," all with scores of 4.4. Interestingly, the reporting system of the national scale

received the lowest score, at 3.1 points.

8. Expectation of Patient Safety Agencies at the Governmental Level

In terms of the hospitals' expectations from government agencies, 92% expressed desire for proposed patient safety-related protocols and guidelines, as well as educational programs relevant to patient safety. Furthermore, 69.6% wished for training and education of patient safety specialists, 68.8% for an education program targeted at executive-level personnel, and 65.2% for an advisory consulting service for the hospital, which indicates expectation of variable roles and responsibilities toward the National Patient Safety Agency.

Contrarily, patient safety research and patient safety incident analysis were rated at only 46.4%, and timely analysis of patient safety incidents at 40.2%, which were lower than the other roles.

9. Promotion of a Patient Safety Incident Reporting System on the National Level

Regarding the requirement for a successfully operating national reporting system, "no parties should be adversely affected as a result of reporting" scored the high-

Table 5. Differences in Improvement Activities between Hospitals of Varying Scales (*N*=112)

Patient safety activities	No. of beds ≥500 (n=61) n (%)	No. of beds <500 (n=51) n (%)	Total n (%)	*p*
Establishment of computerized patient safety incident reporting system	47 (77.0)	10 (19.6)	57 (50.9)	<.001
Formation of interdisciplinary teams such as a patient safety committee and patient safety decision-making body	46 (75.4)	24 (47.1)	70 (62.5)	.002
Staff training such as patient safety workshops, seminars, and lectures.	44 (72.1)	26 (51.0)	70 (62.5)	.021
Improvement of EMR* such as electronic warning messages	39 (63.9)	11 (21.6)	50 (44.6)	<.001
Production of promotional material and events for employees	37 (60.7)	16 (31.4)	53 (47.3)	.002
Patient safety day or week events, patient safety competitions	37 (60.7)	20 (39.2)	57 (50.9)	.024
Contests and awards for promotional material such as slogans and posters	36 (59.0)	21 (41.2)	57 (50.9)	.060
In-service education and staff training for patient safety leadership	36 (59.0)	18 (35.3)	54 (48.2)	.012
Production of promotional material and events for patients and guardians	35 (57.4)	24 (47.1)	59 (52.7)	.276
Regular surveys for patient safety culture among the employees	31 (50.8)	10 (19.6)	41 (36.6)	.001
Onsite visits/rounds by hospital executives, or patient safety representatives	25 (41.0)	20 (39.2)	45 (40.2)	.849
Incentives for patient safety incident reporting	24 (39.3)	6 (11.8)	30 (26.8)	.001
Others	4 (6.6)	1 (2.0)	5 (4.5)	.241

EMR=electronic medical records.

est at 4.7, followed by "anonymity of the patient and the reporting person must be guaranteed" and "the goal must be improvement of the system, process, or service, rather than personal gains," each of which scored 4.6.

DISCUSSION

This study is among the first investigations of the state of patient safety in South Korea. Despite the efforts put forth by many hospitals nationwide, the culture of patient safety improvement has not yet gained a strong foothold. Examining the 10 key areas of patient safety, the absence of a reporting system and systematic study is evident.[12,13] Although different institutions have attempted different methods, there are no established standards by which the effectiveness of patient safety can be evaluated. Without such standards, the pursuit of patient safety cannot gain momentum, and it is difficult to implement necessary policies. Many developed countries, such as the United States, and other developing countries have analyzed and reported the state of their country's patient safety.[14] According to these reports, it is clear that promotional activities for patient safety improvement are being implemented by many governmental and non-governmental organizations. Objective study and reporting provide the driving force behind the movement for patient safety improvement and formation of relevant organizations as well as government policies, all of which South Korea currently lacks. The desire to promote patient safety awareness alone cannot be productive, if not paired with an appropriate evaluation method. Thus, it is crucial to promote investigation of patient safety incidents with diversified methods, and determination of patient safety status through reviewing medical records must be enforced. By doing so, a tangible reference point may be established, upon which timely improvement can be judged as well as compared with that of other countries. To this end, cooperative participation of all hospitals, as well as a trusting working relationship among agencies such as the Korean Hospital Association and Korea Institute for Healthcare is necessary. This will make it possible to study and analyze not only the present findings, but also previous findings and findings in 5 or 10 years' time. It would also be possible to investigate any medical institution's sentinel events and near-miss events, as well as different types of failures. Such investigations and research will inevitably contribute to the improvement of patient safety. Additionally, a systematic approach will be necessary, such as the 7-step strategy implemented by the National

Patient Safety Agency (NPSA) in the United Kingdom.[15]

CONCLUSIONS

In this study, a majority of the participating hospitals share their vision and expectations of patient safety, despite having adopted different patient safety cultures and reporting systems. This may be attributed to the rapid maturation of a patient safety culture in South Korea within a relatively short time, dating back to the early 2000s. One of the main reasons for this maturation is the increased demand of quality health care, stemming from standardized evaluation of hospitals leading to measurable advancement, which has social, cultural, and economical relevance. Currently, research findings are being published in South Korea through master's and doctoral theses from medical and nursing schools, as well as through various academic programs at the Korean Society of Quality Assurance in Health Care and the Korean Quality Improvement Nurse Society. As this study was conducted at the national scale, our findings can easily be used as preliminary data in future policy development of patient safety.

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