

Executive Summary

□ Introduction

Since the US Institute of Medicine (IOM) published the report titled “To Err is Human: Building a Safer Health System” in 1999, there has been growing attention to patient safety globally. The report included the frequency of medical errors, classification type, and conceptualization; it also suggested development of a national-level reporting system for voluntary reporting by health and medical facilities and relevant professionals as one strategy to secure the health and medical system’s safety. After the report, the US established the Federal Drug Administration (FDA) medication error management system. The Department of Veterans Affairs and the National Aeronautics and Space Administration (NASA) worked together to develop a Patient Safety Reporting System (PSRS) based on the Aviation Safety Reporting System (ASRA); it is now the archetype for the current US patient safety information system.

Many other countries including the UK, Denmark, and Australia are making efforts to prevent and manage patient safety incidents by collecting and analyzing relevant data through various voluntary or compulsory systems. They established and operate patient safety systems with various training and research activities to encourage voluntary efforts. Korea enacted and proclaimed a patient safety act as of last January 28, with its main focus on the operation of a patient safety reporting training system. Such an infrastructure system to collect, analyze, and use relevant data can clearly identify information regarding patient safety incidents happening in Korean medical institutions and minimize further incidents by making improvements; its implementation can be the foundation to secure patient safety at the national level.

In addition, it is also important to enhance patient safety research in order to implement a system to collect and manage patient safety incident information, especially because Korea is in the beginning stages. According to the World Health Organization (WHO), the concept of patient safety is still unclear; research to collect related data is insufficient. In addition, improvements for patient safety require changes at every step of the health and medical system. Therefore, the WHO emphasizes strong national policies along with strategic execution plans.

Each country type has different research priorities to identify patient safety issues and take measures (WHO, 2009). Therefore, since Korea just enacted the patient safety act and is beginning its efforts at the national level, its priorities in identifying the issues and making improvements are different from other countries. When a patient safety related accident occurs, it is currently identified by only limited people within the medical institution; the information sharing is insufficient. Against this backdrop, it is not effective to decide to invest in identifying patient safety issues and making improvements based on the available Korean data or evidence. Instead, it is possible to gather experts' opinions and make decisions, although there are gaps in information and experience. This will enable efforts made with limited resources and insufficient information to be more efficient.

Because there is a growing necessity to establish a patient safety information system with the enactment of the patient safety act, this study finds implications for the establishment of the Korean system by reviewing examples of other countries with patient safety related information systems and sets priorities in related research especially to investigate patient safety issues. To this end, we researched and analyzed details of patient safety reporting systems of other countries and compared and verified their characteristics; we reviewed detailed measures to establish a Korean patient safety information system for reporting, analysis, and feedback of patient safety accidents.

Moreover, we conducted a Delphi survey on the priorities of patient safety research among Korean experts based on the priorities previously defined by the WHO. This set the research priorities and identified their characteristics as a basis for more systematic and effective execution of patient safety research in Korea.

Patient Safety Information System Operation by Country

I. Examples of Other Countries

Agency in Charge

The US operates patient safety organizations at the state level, centered on the Agency for Healthcare Research and Quality (AHRQ) under the Department of Health and Human Resources (HHS). In the meantime, Denmark, Australia, Norway, and the UK are operating relevant systems at the national level.

	US	UK	Australia	Denmark	Norway
Agency In Charge	<ul style="list-style-type: none"> Federal level: AHRQ, PSOs State level: Pennsylvania Patient Safety Authority etc. 	<ul style="list-style-type: none"> National level: Imperial College Healthcare National Health Services Trust 	<ul style="list-style-type: none"> National level: Australian Patient Safety Foundation (APSF) Local level: Victoria Department of Human Services Department of Health (South Australia) etc. 	<ul style="list-style-type: none"> National level: National Health Board/ National Agency for Patients' Rights & Complaints (NAPRC) 	<ul style="list-style-type: none"> National level: Norwegian Knowledge Centre for the Health Services (NOKC)

Reporting

In most countries, healthcare personnel in health institutions, patients and public can report patient safety incidents to the reporting and learning system. In Denmark and Norway, main reporters are healthcare personnel and risk managers in public hospitals.

	US	UK	Australia	Denmark	Norway
Reporting	<ul style="list-style-type: none"> Healthcare personnel Public Patient safety manager via PSO 	<ul style="list-style-type: none"> Healthcare personnel Patient/ public 	<ul style="list-style-type: none"> Healthcare personnel in public hospitals Patient/ public 	<ul style="list-style-type: none"> frontline staff in healthcare organizations risk manager in hospitals/region 	<ul style="list-style-type: none"> healthcare personnel in hospitals

Confidentiality

Most of countries deleted personally identifiable information to encourage reporting and keep confidentiality. Only UK provide patient safety incidents information with hospital and regional base.

	US	UK	Australia	Denmark	Norway
Confiden-tiality	<ul style="list-style-type: none"> Transmission to NPSD after deleting identifiable information of medical institutions or healthcare providers 	<ul style="list-style-type: none"> publicly open Patient Safety incidents statistics by hospital and region 	<ul style="list-style-type: none"> Reporting system that ensures anonymity through the network 	<ul style="list-style-type: none"> Reporting system that ensures anonymity from regional level 	<ul style="list-style-type: none"> Incident data input in the hospital information system automatically synchronized with the NOKC system

Reporting Contents

Most countries focus on incident description. In Denmark, root causes are analyzed first and the results are additionally reported. The UK requires reporting the information to the police and media as well as contact points.

	US	UK	Australia	Denmark	Norway
Reporting Contents	<ul style="list-style-type: none"> · Classification of incident, background, pt information, reporting personnel information, reporting contents etc. 	<ul style="list-style-type: none"> · Incident time, location, incident type, investigation type, incident description, information for the police and media, contact points, Immediate measures taken to decrease risks, detailed information about reporting target organizations and personnel, personnel in charge, reporting personnel, their positions, reporting time 	<ul style="list-style-type: none"> · Incident location, date and time, involved people, incident details, etc. · Incident details based on clinical facts, etc. 	<ul style="list-style-type: none"> · Individual reporting on harmful incident details and results · reporting of incident results after root cause analysis of the incident classified by safety assessment code evaluation. 	<ul style="list-style-type: none"> · Incident location, date and time, involved people, incident details, relevant opinions, etc.

Patient Safety Research Priorities

I. Survey Methods

We benchmarked WHO studies on patient safety ranking process to decide patient safety research priorities in Korea. To this end, we translated WHO patient safety research subjects into Korean and applied the Delphi technique. The Delphi survey was conducted with 20 patient safety experts (10 quality improvement department heads, 10 patient safety researchers).

The survey was conducted two times and the importance of each subject was measured on a nine-point scale. The criteria were the same as the WHO's, including frequency of the safety issue; magnitude of harm and its population distribution; its effect on efficiency of health system; availability, feasibility, and sustainability of solutions; and urgency or political support to address the problem.

II. Survey Results

On the Delphi survey, experts responded that 'lack of communication and

coordination' is top priority, followed by 'poor patient safety culture and blame-oriented processes', 'inadequate safety indicators', 'health care-associated infections', and 'adverse events due to drugs and medication errors'. The research subjects with the lowest priority were 'counterfeit and substandard drugs'. The reliability values were 0.87 for the first survey and 0.94 for the second. These values indicated that participating experts reached an agreement.

Compared to WHO study results, the high ranked subjects are similar to the developed countries as was the low ranked ones. 'The lack of adequate reporting on patient safety', 'the effect of work pressure on patient safety', 'patient identification', 'inadequate staffing', 'falls', and 'wrong site surgery' showed higher ranking but 'patient role in shaping the research agenda' was a far lower ranking in Korea than other country groups.

The level of average score determining research priorities was higher than WHO results. This meant the importance of the necessity of such research was generally high in Korea. 'Lack of communication and coordination', 'lack of patient safety culture and blame oriented processes', and 'developing better safety indicators' are receiving the most attention from the medical industry consistent with the adoption of the patient safety act. The averages of those subjects were also much higher than other countries. In addition, infection and drug side effects, known as general patient safety incidents, showed high scores with a wide gap from other countries.

□ Conclusions and Proposal

There are many patient safety subjects require immediate research regarding the first Korean Patient Safety Law. They include establishment of the patient safety reporting and learning system, development of measures to facilitate patient safety incidents reporting, building up cooperative system among hospitals and agencies related to patient safety, and development of technology to prevent occurrence and recurrence of patient safety incident. The scope of patient safety research issues which we conducted priority setting with is much broader including organizational process, structure, and patient outcomes in order to identify patient safety problems and solutions inside and outside of healthcare institutions. Experts reached a consensus of ranking priority of patient safety research issues through the Delphi process as showed in table

below. However, further discussion of the study result is required to enhance the levels of experts' agreement and determine investment priorities from the list.

Table. Research Subjects with High Priority in Patient Safety Research

No.	Definition	Korea	
		Average	Median
1	Lack of communication and coordination (including coordination across organizations and discontinuity)	8.50	8.50
2	Lack of patient safety culture and blame oriented processes	7.70	8.00
3	Developing better safety indicators	7.35	7.00
4	Healthcare-associated infections	7.10	7.00
5	adverse drug events/drug errors	7.05	7.00
6	Latent organizational failures	7.05	7.00
7	Cost effectiveness of risk reducing strategies	7.00	7.00
8	Lack of adequate safety reporting (ie, incident reporting)	6.95	7.00
9	Effect of work pressure on patient safety	6.85	7.00
10	Extent and nature of the problem of patient safety	6.50	7.00
11	Health information technology/ information systems (including computerized physician order entry)	6.40	6.00
12	Adverse medical device events	6.35	6.00
13	Lack of adequate test follow-up	6.35	6.00
14	Inadequate competences, training, and skills	6.30	6.50
15	Surgical errors	6.20	6.00
16	Patient identification	6.20	6.00
17	Inadequate staffing	6.20	6.00
18	Misdiagnosis	6.15	6.50
19	Falls	6.10	6.00
20	Medication reconciliation (including the management of drugs brought by patients from outside)	6.10	6.00
21	Lack of recognition of adverse events	6.05	6.50
22	Lack of appropriate knowledge and transfer of knowledge	6.05	6.00
23	Devices that lack human factors consideration built into design and operation	6.00	6.00

Keywords: Patient Safety, Patient Safety Reporting and learning System, Priority, Patient Safety Research, Delphi