Abstract

Prioritization of medical device safety issues in hospitals

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▢ Introduction

Ⅰ. Study rationale and purpose

Accidents involving medical devices are relatively rare in healthcare, as compared with other adverse events such as drug safety and falls. However, it is estimated that over a million cases of medical device accidents occur annually in the US. Further, according to the Medical Device Safety Monitoring Center of the Food and Drug Administration in Korea, the number of accidents involving medical devices is on the rise.

It is difficult to identify and classify the issues and challenges related to medical devices because a wide range of technologies are associated with medical devices, and because, typically, a medical device is operated, maintained, and used by different persons. This provides sufficient support for the need to concentrate efforts on improving safety management in this area. In other words, more attention should be invested on patient safety associated with medical devices, as well as on the potential harm that medical technology poses. Additionally, more robust safety measures, including benchmarking of the pharmaceutical safety information monitoring system, need to be implemented. Therefore, it is critical to identify the safety issues related to medical devices, to accordingly plan improvement measures.

Despite the importance of managing safety issues, clear identification of the issues related to medical devices is difficult. Indeed, collecting expert opinions on the matter offers a good starting point. In fact, safety issues vary because the range of devices includes something as small as a needle, as well as enormous examination equipment. Therefore, it is important to establish rational safety standards with the help of experts who handle such devices on a daily basis.

Ⅱ. Study methods

○ Identifying major safety issues associated with medical devices

A structured literature review was conducted on the common safety issues, with a focus on the devices and related issues. Further, medical device safety issues managed by major patient safety organizations in other countries were identified. Subsequently, the safety issues confirmed through the literature review and other data were classified into types.

○ Classification of medical devices based on safety accidents in Korea

Taking into account the similarities and comparability of medical devices, opinions of the experts at the medical device safety information center were collected and synthesized multiple times, in order to tease out the classification criteria.

○ Prioritization based on the Delphi survey and Analytical Hierarchy Process (AHP)

For prioritization of medical devices with safety issues, the Delphi survey method was applied. Further, the numerical value pertaining to the importance of each relevant factor was established through the AHP. These values were used to conduct pairwise comparisons of the devices, and then a priority list was created.

Thus, 11 field experts, including the chief evaluator of the medical device safety monitoring center, took part in the Delphi survey. Additionally, the AHP was performed by 11 experts from the medical device safety monitoring center and 12 medical examination management experts, by taking into account the characteristics of the medical devices and patient safety. The 12 medical examination management experts included managers of the medical examination room patient safety teams in the general hospitals located in the Seoul metropolitan area.

▢ Study results

Ⅰ. Literature review and classification of medical devices

○ Safety issues identified in the literature review

The key question selected for the systematic literature review was “What

is the major agenda pertaining to medical device safety in hospitals?" Safety issues included medical errors on patients and near misses. Upon eliminating duplicates, 34 pieces of literature were selected for the review. Most pieces were investigative studies, and American studies accounted for half of the selected studies. Majority of the studies involved medical records or patient safety databases.

Additionally, reports pertaining to the medical device safety issues selected and managed by the patient safety agencies in other countries were reviewed. In the case of the ECRI, safety issues such as alarm hazard, infusion pump error, information system error, and retained tools and materials were classified based on the location of the incidents. In the miscellaneous criteria, contaminated equipment and tools, pediatric safety incidents, device malfunction, information system error, treatment material and testing problems, injuries, and other general medical device problems were suggested. Moreover, because medical devices are found in multiple locations, safety issues were classified by specific locations as well. The final criteria for the classification of medical device safety issues were selected based on the above review and expert consultations, which were as follows:

Table S-1. Key agenda pertaining to medical device safety issues

N	Major safety incidents	Incident report type	Relevant studies	No. of studies
1	Injuries related to invasive device or materials	• Injuries: Sharp instrument,Needle stick Injury • Blood or body fluid exposure by sharp instrument of operation room(suture needle, blade, Bovieetc)	Myers (2008), Moreno (2006), Lamontagne (2007), Mehta (2005), Black (2013), Gillen (2003), Clark (2012)	7
2	Malfunction of devices/instruments	• Type of adverse event - malfunction of broken (needles, endoscopic equipment, Probesetc) - device errors, defects	Yasuharu (2012), Courdier (2009), Dahrab (2011), Wubben (2010)	4
3	Infusion pump errors	• Infusion rate error, connection omission, leakage etc	Beydon (2010), Zhu (2014), Samaranayake (2012), Cousins (2013)	4

N	Major safety incidents	Incident report type	Relevant studies	No. of studies
4	Pediatric adverse events	• Gastrointestinal tube, catheter infection, complication • Medical line torsion	Wang (2010), Larsen (2007), Goodin (2012)	3
5	False alarm of monitoring devices	• Ventilator alarm(mechanical error) • Unnecessary alarm during care(cough, breathing, post suction etc) • Fatigue alarm does not reauire medical staff	Gorges (2009), Gross (2011)	2
6	Inappropriate layout of devices and facilities	• Design of working environment (non-standardization) • Inconvenient structure for using medical equipment	Gurses (2012), Palmer (2013)	2
7	HIT related errors	• Software error(radiology, diagnostic test analysis, other device related software) • Hardware: Barcode system failure, Scanner error	Simone (2013), Kopel (2008)	2
8	Retained instruments/materials	• Surgery materials(sponges, pads, guidewires drains)	Chen (2011)	1
9	Medical devices related infections	• Intensive care unit ventilator related infection • Central venous line related blood infection • urological catheter related infection	Rosenthal (2006)	1

○ Classification criteria for medical device prioritization

In terms of medical devices, expert opinions were surveyed and organized around the FDA's detailed medical device classification criteria as well as manufacturers' product names because the experts' evaluation experience tended to be based on them. Thus, 52 medical devices were classified into 9 categories. The results are shown below.

Table S-2. Final medical device classification criteria

Type	No	Device name	Type	No.	Device name
Respiratory and circulatory devices (5)	1	Ventilator	treatment device (7)	27	Radiation treatment device
	2	Defibrilator		28	Ultrasonic treatment device
	3	Tourniquet or compression		29	Laser treatment
	4	cardiopulmonary bypass		30	Extracorporeal lithotripsy system
	5	Hemodialysis devices machine		31	Electronic stimulator
Monitoring devices (6)	6	Cardio-respiratory monitoring system		32	Light treatment device
	7	Respiratory monitoring system	Infusion devices (5)	33	Infusion pump
	8	Electroencephalography machine		34	Contrast medium injector system
	9	Musculoskeletal monitoring system		35	Blood transfusion set
	10	Tocomonitor		36	Intravascular administration set
	11	Other patient monitoring devices		37	Needles

Type	No	Device name	Type	No.	Device name
Surgical instruments (6)	12	Surgical ligator and suture instrument	Medical tubes and catheters (5)	38	Respiratory tube catheter
	13	Endoscopic surgical instruments		39	suction tube catheter
	14	Robotic surgery system		40	urological catheter
	15	Anesthesia instrument		41	Vascular catheter
	16	Electro surgery and high frequency machine		42	Gastrointestinal tube catheter
	17	Laser	Facilities and system devices (4)	43	Medical gas system
Imaging diagnosis machine (8)	18	X-ray system		44	Sterilizer and irrigation unit
	19	CT		45	Hospital information system
	20	Endoscopic imaging device		46	Power supply system
	21	Mammographic x-ray system	Transplant devices (6)	47	Venous and non-venous stent
	22	MRI		48	Pacemaker
	23	PET		49	Artificial joint
	24	Angiography device		50	Neurostimulation devices (DBS, SCS)
	25	Dental X-ray system		51	Breast implants
treatment device	26	Thermal treatment device		52	Fillers

Ⅱ. Prioritization via the Delphi survey and AHP

○ Factors related to the evaluation of medical device safety issues according to the Delphi survey

The results of the initial Delphi survey conducted with the medical device experts indicated that frequency topped the chart, followed by severity, prevention possibility, ripple effects, popularity, recognition, and chance of recurrence, respectively. The second and third surveys used 7 criteria and a 5-point scale to measure the importance of these factors. Based on the results, the severity, frequency, ripple effect, prevention possibility, and chance of recurrence were selected as the five criteria.

○ AHP results

The AHP was conducted to establish the following: weighted values of the five criteria for medical device safety issue prioritization, weighted values of the nine types of medical devices, final order of priority by medical devices and evaluation criteria, and medical device safety issues according to the literature review. The results were as follows:

① Weighted values by evaluation criteria for the prioritization

The table below displays the weighted values of the five criteria for medical device safety issue prioritization. Severity was found to be the most significant factor, where the weighted value for the severity of proper medical examination was particularly high.

TableS-3. Weighted values of the prioritization criteria

Standard	Severity	Frequency	Ripple effect	Chance of recurrence	Prevention possibility
Weighted value 1	0.389	0.233	0.140	0.136	0.103
Weighted value 2	0.518	0.124	0.164	0.096	0.098

② Weighted values by medical device types

The significance of the nine types of medical devices was as follows. The weighted values of respiratory and circulatory devices were the highest. In both groups, the weighted value for medical tubes was the lowest.

Table S-4. Weighted values by medical device types

Standard	Respiratory/ circulatory	Monitoring device	Surgical instrument	Imaging diagnosis machine	treatment device	Injection device	Medical tube	Facility/system device	Transplant device
Weighted value 1	0.194	0.106	0.163	0.078	0.091	0.093	0.052	0.059	0.164
Weighted value 2	0.227	0.104	0.197	0.095	0.065	0.069	0.059	0.067	0.116

③ Order of priority by medical devices

The table below displays the order of priority of the 52 medical devices with safety issues. Note that ventilators showed the highest priority, followed by anesthesia instruments, and the cardiopulmonary bypass, defibrillator, and Hemodialysis devices.

Table S-5. Priority by medical devices

Priority			
1	Ventilator	27	Respiratory tube catheter
2	Anesthesia device	28	Breast implant
3	Cardiopulmonary bypass	29	Laser treatment
4	Defibrilator	30	CT
5	Hemodialysis devices	31	Tocomonitor Tocomonitor
6	Pacemaker	32	Extracorporeal lithotripsy syste
7	Robotic surgery system	33	Filler
8	Cardiovascular monitoring system	34	Intravascular administration set
9	Respiratory monitoring system	35	PET
10	Venous and non-venous stentf	36	MRI
11	Endoscopic surgery machine	37	Sterilizer and irrigation unit
12	Surgical ligator and suture instrument	38	Needles
13	Electrosurgery/high frequency	39	Hospital information system
14	Neurostimulation devices (DBS, SCS)	40	X-ray system
15	Tourniquet and compression	41	Stimulator
16	Medical gas system	42	Musculoskeletal monitoring system
17	Infusion pump	43	Endoscopic imaging system
18	Laser(surgery)	44	Ultrasonic treatment device
19	Radiation	45	Suction tube catheter
20	Artificial joint	46	Other patient monitoring system
21	Power supply system	47	Thermal treatment device
22	Blood transfusion set	48	Mammographic x-ray system
23	Angiography machine	49	Urological catheter
24	Vascular catheter	50	Gastrointestinal tube catheter
25	Contrast medium injector system	51	Light therapy device
26	Brain-nervous monitoring system	52	Dental X-ray system

The order of priority pertaining to medical device types showed that the respirator, among the respiratory and circulatory devices; cardiac machines, among the monitoring systems; and an esthesia instruments,

among the surgical instruments, had the highest priority. Among the imaging diagnosis machines, the angiography machine, among treatment devices; the radiation, among injection devices; the Infusion pump, among the medical tubes and catheters; and the vascular catheters had the highest priority. In terms of facility and systems, the medical gas systems, and pacemakers, among transplant devices, had the highest priority.

Table S-6. Priority by medical device types

Category	Priority	Device	Category	Priority	Device
Respiratory and circulatory	1	Respirator	treatment device	2	Laser treatment
	2	Cardiopulmonary bypass		3	Extracorporeal lithotripsy system
	3	Defibrilator		4	Stimulator
	4	Hemodialysis devices		5	Ultrasonic treatment device
	5	Tourniquet or compression		6	Thermotreatment device
Monitoring devices	1	Cardiovasculor monitoring system		7	Light treatment device
	2	Respiratory monitor	Injection devices	1	Infusion pump
	3	Brain-nervous monitoring system		2	Blood transfusion set
	4	Tocomonitor		3	Contrast medium injector system
	5	Musculoskeletal monitoring system		4	Intravascular administration set
	6	Other patient monitoring systems		5	Needles
Surgical devices	1	Anesthesia equipment	Medical tubes and catheters	1	Vascular catheter
	2	Robotic surgery machine		2	Respiratory tube catheter
	3	Endoscopic surgical instrument		3	Suction tube catheter
	4	Surgical ligator and suture instruments		4	Urinary tube catheter
	5	Electro and high frequency machine		5	Gastrointestinal tube catheter
	6	Laser	Facility and system devices	1	Medical gas supply system
Imaging diagnosis	1	Angiography machine		2	Power supply system
	2	CT		3	Sterilizer and irrigation unit

devices	3	PET			
	4	MRI		4	Hospital information system
	5	X-ray system	Transplant devices	1	Pacemaker
	6	Endoscopic imaging system		2	Venous and non-venous stent
	7	Mammographic x-ray system		3	Neurostimulator
	8	Dental X-ray system		4	Artificial joint
treatment device	1	Radiation treatment device		5	Breast implant
				6	Filler

④ The order of priority by medical device safety issues

The order of priority based on the literature review and review of the medical device safety issues in other countries is as follows. "invasive use of medical device," had the highest priority, followed by pediatric safety incidents, defective surgical instruments/device malfunction, contaminated respiratory tubes, infusion pump malfunction, monitoring devices alarm errors, software and system errors, retained surgical tools and materials, and inappropriate lay out of equipment and facility, respectively.

Table S-7. SLR priority

Priority	
1	Injuries related to invasive device or materials
2	Pediatric adverse events
3	Malfunction of devices/instruments
4	Medical devices related infections
5	Infusion pump errors
6	False alarm of monitoring devices
7	HIT related errors
8	Retained instruments/materials
9	Inappropriate layout of devices and facilities

▢ Discussion and conclusion

The current study categorized and prioritized medical devices by the safety issue types. Priority criteria obtained via a Delphi survey reflected the characteristics of the safety issues through the weighted values of severity, frequency, ripple effects, prevention possibility, and chance of recurrence. The weighted value of severity was relatively high, which is thought to have influenced the order of priority. Further, in general, the opinions of the medical device safety information monitoring experts and quality healthcare and patient safety experts were similar. However, regarding some items, there were discrepancies. Further, in some aspects, the order of priority in the current study was different from that observed in foreign studies. However, this is thought to be due to the focus on quality improvement activity, in addition to severity, when it comes to the respirator, which had the highest priority. The discrepancies in expert opinions, and in the findings of the current study and foreign studies, stem from the differences in healthcare systems, education, and experience. Future studies need to examine these factors closely.

Keywords: Medical device safety issues, Priority-setting, Analytical Hierarchy Process, Delphi