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Complete List of Authors:	Choi, Eun Young ; Ulsan University, Department of Preventive Medicine; Chung-Ang University, Department of Nursing Pyo, Jeehee; Ulsan University, Department of Preventive Medicine Lee, Won; Yonsei University, Graduate School of Public Health Jang, Seung Gyeong ; National Evidence Based Collaborating Agency Part, Young-Kwon ; Ulsan University Hospital, Prevention and Care Center Minsu, Ock; University of Ulsan College of Medicine, Lee, Sang-il; University of Ulsan,
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Nurses' experiences of patient safety incidents in Korea: a cross-sectional study

Title page

1. Author and Co-author's name

Eun Young Choi, Jeehee Pyo, Won Lee, Seung Gyeong Jang, Young-Kwon Park, Minsu Ock, Sang-Il Lee

2. The name, postal address, e-mail, telephone, and fax numbers of the corresponding author

1) Won Lee, RN, PhD

#410 Administration B/D Yonsei University Health System, 50-1, Yonsei-ro, Seodaemun-gu, Seoul 03722, Republic of Korea

Email: oness38@hanmail.net

82-2-2228-2531, 82-2-313-3292

2) Minsu Ock, MD, PhD

877 Bangeojinsunhwando-ro, Dong-gu, Ulsan 44033, Republic of Korea

Email: ohohoms@naver.com

82-52-250-8793/82-52-250-7289

3. The full names, institutions, city, and country of all co-authors

Eun Young Choi[1,2], Jeehee Pyo[1], Won Lee[3†], Seung Gyeong Jang[4], Young-Kwon Park[5], Minsu Ock[1,5,6†], Sang-Il Lee[6]

[1]Department of Preventive Medicine, Ulsan University Hospital, University of Ulsan College of Medicine, Ulsan, Republic of Korea

[2]Department of Nursing, Graduate School of Chung-Ang University.

[3]Graduate School of Public Health, Yonsei University, Seoul, Republic of Korea

[4]National Evidence-based Healthcare Collaboration Agency, Seoul, Republic of Korea

[5]Prevention and Care Center, Ulsan University Hospital, Ulsan, Republic of Korea

[6]Department of Preventive Medicine, University of Ulsan College of Medicine, Seoul, Republic of Korea

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Abstract

Objectives: The aim of this study was to investigate the scope and severity of the second victim problem among a group of nurses by examining the experiences and effects of patient safety incidents (PSIs) on them through a questionnaire.

Participants/setting: 492 nurses working in large South Korean medical institutions.

Design: Anonymous online self-report questionnaires were administered to nurses in order to examine the experiences and effects of PSIs. Scales measuring post-traumatic stress disorder (PTSD) and post-traumatic embitterment disorder (PTED) were used in the questionnaire for a more quantitative examination of the effects of PSIs. A chi-squared test was administered to find any difference in responses on difficulties due to PSIs between direct and indirect experience of PSIs. Furthermore, linear regression analysis was conducted to investigate the factors related to scores on the PTSD and PTED scales.

Results: A statistically significant difference was observed for participants who reported having experienced sleeping disorders, with those with direct experience showing 42.4% sleeping disorders and indirect experience at 21.0%. Also, there was a statistically significant difference between the 34.3% with direct experience and the 22.1% with indirect experience regarding having considered duty or job changes (resignation). Regression analysis showed total PTSD scores for indirect experience at 11.97 points (95% confidence interval: -17.31–-6.63), lower than direct experience. Moreover, those who thought medical error was not involved in PSI had a total PTED score 4.39 points (95% confidence interval: -7.23~-1.55) lower than those who thought it was involved.

Conclusions: A considerable number of nurses experienced psychological difficulties due to

PSIs at levels that could interfere with their work. The effect of PSIs on nurses with direct experience of PSIs was greater compared to those with indirect experience. There need to be psychological support programs for nurses to alleviate the negative effects of PSIs.

Strengths and limitations of this study

- This study examined the experiences and effects of patient safety incidents (PSIs) on nurses working in large South Korean medical institutions through a questionnaire.
- We determined the Korean nurses' PSI experiences and impacts in various aspect, including post-traumatic stress disorder (PTSD) and post-traumatic embitterment disorder (PTED) scales.
- In this study, participants were asked about their most memorable PSI. Future research should identify and analyze in detail the number and range of PSIs experienced by nurses.

INTRODUCTION

Medical personnel who experience emotional pain due to unanticipated adverse events, medical errors, and patient-related injuries are referred to as "second victims".[1] These second victims experience psychological pain, fear, decreased confidence, guilt, rage, exhaustion, and despair after patient safety incidents (PSIs),[2,3] and such symptoms are interpreted as indicators of post-traumatic stress disorder.[4] If the experiences of second victims aren't adequately treated, it can increase the likelihood of other errors due to fatigue, depression, and/or reduced sympathy.[5,6] It also leads to job changes and absences, negatively affecting the medical institution,[7] and efforts and approach to support second victims are required.

Since the term "second victim" appeared in 2000,[8] numerous studies have been conducted especially in the United States to investigate the second victim phenomenon and methods to support second victims. Discussions have continued in order to understand the prevalence and symptoms of second victims as well as to plan coping strategies and support programs.[2,3,9] Moreover, institutions such as the Institute for Healthcare Improvement and The Joint Commission have developed that provide guidelines to support second victims,[10,11] and individual medical institutions have also implemented support programs for second victims.[1,12] Such activities are gradually spreading throughout the United States and some countries in Europe.[6,12–14]

In South Korea, the *Patient Safety Act* was enacted in 2016 to establish the national Patient Safety Reporting & Learning System, building a foundation to systematically manage patient safety problems at the national level.[15] However, the focus remains on cause analysis and error prevention in PSIs, with relatively limited perception and research on counselling and supporting second victims.[16,17] A recent study by Lee et al.[15] showed that second victims

who experience PSIs in South Korea undergo various emotional reactions such as confusion, guilt, and depression, while also experiencing behavioral changes such as insomnia, avoidance, and considering job change, similar to findings in another previous study.[3] A study by Kim et al.[18] also showed that the effects of PSIs as perceived by Korean nurses were similar to those observed in a study in the United States.[7] This implies that the second victim phenomenon manifests similarly regardless of culture. Therefore, considering a study that has shown that all medical personnel are potential PSI or error victims and that almost half of medical personnel have had the experience of second victimization at least once in their clinical career,[19] the second victim phenomenon cannot be overlooked further, in South Korea as well.

A large number of patients are assigned to each South Korean nurse, and nurses have to provide various nursing services, such as the administration of medication and aid, within a set time. This environment occasionally affects nurses in a negative manner, which leads to exhaustion, disappointment, and despair at being unable to provide adequate treatment to patients.[20] This is also known to be the greatest factor leading nurses to consider changing jobs.[21] In this context, further difficulties will be added if a second victim problem occurs to the nurse. Thus, it is necessary to understand the pain nurses experience as second victims and to find ways of providing them with emotional support.

To this end, this study determined the Korean nurses' PSI experiences and impacts in various aspect, including post-traumatic stress disorder (PTSD) and post-traumatic embitterment disorder (PTED) scales.

METHODS

Within the overall project of examining the PSI experiences of the general public, physicians, and nurses, this study focused on the results of anonymous self-report online questionnaires administered to nurses. This study was approved by the Institutional Review Board of the University of Ulsan Hospital (IRB Number: 2018-07-003).

Questionnaire Development and Content

The questionnaire was developed and composed to enable comparison with the PSI experiences of the general public.[22] Questionnaire items were developed by referencing literature on the types and characteristics of PSIs[23–25] and previous studies on second victims.[3,26] The draft questionnaire was developed based on repeated discussions held among the entire research team (including 2 physicians and 3 nurses who have abundant research experience on patient safety). The questionnaire items and expressions were then refined based on the opinions of a nursing professor, the president of the Korean Intern Resident Association, and the CEO of a patient safety NGO.

The final questionnaire items can be classified as follows: 1) PSI characteristics; 2) the effects of PSI; 3) experience of disclosure of PSI; and 4) socio-demographic items. This study focused on the 1) PSI characteristics and 2) the effects of PSI. In further detail, 1) covered type of PSI experience (direct or indirect), elapsed time since the most memorable PSI, type of the most memorable PSI (diagnosis-related, patient care-related, etc.), level of harm caused by the most memorable PSI, and opinion on medical error in the most memorable PSI. In 2), the effects of PSI and the difficulties caused by the most memorable PSI were examined in categories of “sleep disorder;” “eating disorder;” “nausea, dyspnea, cold sweats, or stiffness in similar situations;” “vigilance in similar situations,” and “consideration of duty or job changes.” Additionally, the PTSD and PTED scales were used

for a more quantitative examination of the effects of PSIs. For 4), the participants' sex, age, and elapsed time since license acquisition were collected. The full questionnaire can be found in the supplementary information.

PTSD and PTED Scales

PTSD[27] and PTED[28] scales used in previous studies were adopted. The PTSD scale, designed to measure the past and present effects of trauma, is composed of 30 items. Responses for the PTSD scale were defined as follows: 1 point for "Strongly Disagree," 2 points for "Disagree," 3 points for "Slightly Disagree," 4 points for "Slightly Agree," 5 points for "Agree," and 6 points for "Strongly Agree." The PTED scale, on exceptionally negative incidents in life, is composed of 19 items, used after modifying them to check the effects of the participants' most memorable PSI. Responses on the PTED scale were defined as follows: 1 point for "Strongly Disagree," 2 points for "Disagree," 3 points for "Slightly Disagree," 4 points for "Agree," and 5 points for "Strongly Agree."

Participants and Questionnaire Administration

Participants were nurses who had experienced patient safety incidents and provide direct care in hospitals. The sample size of this study was determined in consideration of the study budget and the sample size of similar preceding studies.[22–25]

Online self-assessment questionnaires were administered over approximately 2 months, from April 2019 to May 2019. Since nurses may be unfamiliar with terminology related to patient safety, definitions of such terms, including *patient safety*, *medical error*, *adverse event*, and *patient safety incident*, were provided prior to the survey.[23,29,30] The survey was promoted via online blog posts and word-of-mouth among colleagues, and participants were gathered through snowball sampling. Participants were blocked from responding to the questionnaire more than once from the same IP address, to prevent possible

repeated participation in the survey.

Analysis

First, the socio-demographic factors and experienced PSI characteristics were examined through a frequency analysis. A chi-squared test was conducted to determine whether there was a difference in responses on difficulties due to PSIs by direct versus indirect experiences. To analyze the results of the PTSD and PTED scales, total scores derived by aggregating the item responses for each scale were used for analysis. A linear regression analysis was conducted to examine the factors related to the PTSD and PTED scores, which were used as dependent variables. Socio-demographic factors (sex, age, and career stage), type of PSI experience (direct and indirect), level of harm, elapsed time since PSI, and opinion on medical error were included as independent variables. Participants who had experienced PSIs both directly and indirectly were classified under direct experience.

Microsoft Excel 2007 was used to organize data, and all data analysis was conducted with Stata/SE13.1 (StataCorp, Texas, TX). Results were deemed statistically significant at a p-value under 0.05.

Patient and Public Involvement

No patient involved.

RESULTS

Socio-demographic Characteristics

A total of 492 nurses responded to the survey (Table 1). The absolute majority of the participants were female (470, 95.5%). The largest number of participants were in their 30s (244, 49.6%) in terms of age, with the greatest number having acquired their license between 10 and 20 years previously (183, 37.2%), followed by 5 to under 10 years (173, 35.2%) and under 5 years (112, 22.7%).

Characteristics of PSI Experiences

A total of 492 nurses provided responses regarding the characteristics of their PSI experiences. 297 nurses (60.4%) responded that they had directly experienced PSIs, while 195 (39.6%) had indirectly experienced them, through seeing or hearing of a coworker's incident. The largest number of memorable PSIs had occurred within 1 to under 5 years (205, 41.7%). For types of memorable PSIs (multiple responses possible), most were related to transfusion or IV injections (334, 67.9%), followed by PSIs related to patient care (269, 54.7%), and PSIs related to surgical procedure or treatment (104, 21.1%). Most PSIs were unharmful, according to 219 responses (44.5%), while incidents that resulted in permanent disability and in death were 23 (4.7%) and 41 (8.3%) respectively. A total of 297 participants (60.4%) believed that there had been medical error involved in the PSI, while 119 (24.2%) and 76 (15.4%) believed that medical error was not present and was uncertain respectively (Table 2).

Difficulties Following Direct and Indirect Experience of PSIs

Examining difficulties due to PSIs based on experience type, a statistically significant difference was observed, as 42.4% of those with direct experience but only 21.0% with indirect experience responded that they had experienced sleeping disorder due to the PSI.

33.3% of nurses with direct experience and 18.5% with indirect experience claimed to have experienced eating disorders. Statistically significant differences were also observed in experience of symptoms of nausea, dyspnea, cold sweats, or body tension when exposed to a similar situation, affecting 31.3% with direct experience and 21.5% with indirect experience. The difference between the 34.3% with direct experience who had considered changing duties or job (resignation) compared to the 21.1% with indirect experience who had was also found to be statistically significant (Table 3).

PTSD- and PTED-Related Factors

Linear regression results to find factors related to total PTSD and PTED scores of survey participants can be found in Table 4. PTSD scores were around 12.98 points (95% confidence interval: -25.68–-0.29) lower for females compared to males, and 11.73 points (95% confidence interval: 3.50–19.97) higher for nurses in their 30s and 13.60 points (95% confidence interval: 1.58–25.63) higher for those in their 40s or older compared to nurses in their 20s. Furthermore, total PTSD score was 11.97 points (-17.31–-6.63) lower for indirect experience compared to direct experience, and tended to decrease with increased elapsed time since the PSI. Finally, total PTSD score was 10.20 points (95% confidence interval: -16.52–-3.88) lower for nurses who did not believe that there had been a medical error compared to those who did.

PTED showed similar trends to PTSD: scores were around 6.51 points (95% confidence interval: -12.21–-0.81) lower for females than males, increased with age, and decreased with time elapsed since PSI. Additionally, PTED scores were 4.39 points (95% confidence interval: -7.23–-1.55) lower for those who did not think that there had been a medical error compared to those who did.

DISCUSSION

In this study, a questionnaire was administered to nurses who had experienced PSIs to investigate the impacts of PSIs, the difference in difficulties resulting from PSIs between direct and indirect experience, and factors related to post-PSI experience of PTSD and PTED. The characteristics of and difficulties resulting from PSIs experienced by 492 nurses were explored and the effects of incidents examined from various perspectives using the scores and factors affecting PTSD and PTED. While there have been previous studies in South Korea that examined the experiences of medical personnel who experienced error,[17] the coping process of medical personnel after experiencing PSIs,[26] and nurses' 2- and 3-dimensional experiences of PSIs,[18] almost no studies have been conducted on the topic of this study, that is, measuring factors relating to post-trauma and the difference between direct and indirect experience on the effects of PSI from various angles. A notably significant aspect of this study is that it verifies the need for support for nurses who experience PSIs and establishes base data and factors that can be considered when developing and implementing such support programs.

In this study, the most memorable type of PSI according to nurses was PSI related to transfusion or IV injection (67.9%), followed by PSI related to patient care, such as the occurrence of falls and pressure ulcers. According to the Korea Patient Safety Reporting & Learning System (KOPS), falling followed by medication error was reported to be the most frequent PSI by type, and in medication error reports, nurses appeared the most frequently under related personnel.[31] Despite the need to focus while administering medication given its potentially dangerous nature, interruption and disturbances during its measurement and administration are common due to inhibitors such as receiving telephone calls, patient and guardian reception, and communication with other health and medical personnel.[20] Previous

research reports that the risk of medication error increases due to such disturbances,[32] and that such medication error negatively affect nurses personally and professionally.[4,33] There is a necessity to reduce the negative effects of such PSIs by recognizing the common PSI experiences of nurses, analyzing their causes, and re-educating nurses based on the results.[33]

In all, 60.4% of the nurses who participated in this study had experienced PSIs. They can be seen to have frequent exposure to PSIs, as they are generally the medical professionals who work most closely with patients.[34] Harrison et al.[35] also found that nurses report more negative emotions after medical error, and this result was attributed to the nursing culture and the fact that nurses are in direct contact with the patients. In this regard, difficulties due to direct and indirect PSI experiences were examined separately in this study, and statistically significant differences between those with direct and indirect experience were seen for sleep disorder, eating disorder, symptoms such as nausea and dyspnea when exposed to a similar situation, and consideration of job or duty changes. There was a difference between direct and indirect experience on PTSD and PTED scale scores as well, with the PTSD scores for those with indirect experience being statistically significantly 11.97 points lower than for those with direct experience. As such, it was found that nurses who directly experience PSIs are affected to a greater degree in terms of psychological and physical symptoms as well as consideration of job changes. This is similar to the findings of Van Gerven et al.[36] in which medical personnel who had experienced a PSI in the past 6 months showed higher problematic medication use, burnout risk, and intention to change jobs compared to those who had not. In another study, physicians who had experienced an adverse event or a near miss were reported to have lower confidence, sleep disorder, and tension regarding the occurrence of PSIs.[37] Sleep disorder and symptoms of nausea, dyspnea, and body tension in particular directly influence patient safety, as they may cause additional PSIs.[38] Therefore,

psychological and administrative support must be provided to nurses exposed to PSIs, to minimize the negative effects on the psychological state of nurses and, by extension, on patient safety; in particular, nurses who directly experienced the incident should be prioritized for support and aid.

PTSD and PTED scores tended to significantly decrease as more time passed after a PSI. However, existing studies indicate that second victims actively try to overcome trauma after its occurrence and that such efforts may heal the wound but leave a scar.[2,26] In a study by Vanhaecht et al.[39] symptoms such as hypervigilance, flashbacks, shame, and doubts about one's knowledge and skill continued for over 6 months in some cases. Such results can be interpreted to mean that while post-incident trauma and frustration fade with time, they are not completely resolved, and that the type of difficulties varies across the stages. Thus, temporal factors such as whether it is immediately after the incident, medium-term, or long-term must be considered in developing second victim support programs,[26] and second victims must be managed so that such aid is seamlessly provided.

Existing research shows increased emotional difficulty when there is a possibility of medical malpractice,[40] which was also seen in this study, as PTSD and PTED scores were found to be higher when there was belief that medical error was present. On this note, a qualitative study on second victims expressed the need for institution-level support relating to medical malpractice and administrative processes that could result from PSIs.[26] Scott et al.[1] also proposed that long-term support and risk management directions should also be provided during legal proceedings stemming from PSIs if necessary. Medical malpractice cases are on the rise in South Korea, and nurses face increased risk of being involved in medical malpractice as their scope of work has expanded with the revisions to the *Medical Service Act*. As such, administrative and legal support, in addition to psychological support, should be

provided if necessary.

The limitations of this study are as follows. First, as this was a cross-sectional study on the PSI experiences and difficulties of the participants, it is limited in its ability to assess change over time. According to existing research on the coping process of second victims, their experiences of PSIs and their impacts must be studied longitudinally as they undergo change over time.[2,26] Second, as participants were asked about their most memorable PSI, the possibility of recall bias regarding the characteristics and difficulties of their PSI experiences in their responses should be kept in mind when interpreting the data. In addition, follow-up studies should identify and analyze in detail the number and range of PSIs experienced by nurses.

Despite the above limitations, a major source of significance of this study is that it analyzed the impacts of PSI experiences of nurses and the factors related to subsequent trauma from various angles. It showed that nurses who experienced PSIs face difficulties such as sleep disorder, eating disorder, and nausea and dyspnea in similar situations, an impact that was more prominent in nurses who directly experienced PSIs. Furthermore, the examination of PTSD- and PTED-related factors for PSIs revealed their differential relation to direct and indirect experiences, elapsed time, and presence of medical error. Second victim support programs that can provide realistic help to nurses who have experienced PSIs must be developed, reflecting the results of this study. Moreover, to fully support second victims there need to be efforts to create a broader patient safety culture, with the active participation of the government and medical institutions.

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Table 1. Socio-demographic Information

		Frequency	%
Sex	Male	22	4.5
	Female	470	95.5
Age group	20s	195	39.6
	30s	244	49.6
	40s	40	8.1
	50 and older	13	2.7
Career after license acquisition	Under 5 years	112	22.7
	5 to under 10 years	173	35.2
	10 to under 20 years	183	37.2
	20 years or longer	24	4.9
Total		492	100.0

Table 2. Characteristics of PSIs Experienced by Research Participants

	Item	Frequency	%
PSI experience	Direct experience	115	23.4
	Indirect experience via seeing or hearing an incident experienced by a coworker at the same medical institution	195	39.6
	Both direct and indirect experiences	182	37.0
Elapsed time since PSI	Under 1 month	35	7.1
	1 to under 6 months	68	13.8
	6 months to under 1 year	65	13.2
	1 to under 5 years	205	41.7
	5 years or longer	119	24.2
Types of memorable PSIs (multiple responses)	PSIs related to diagnosis (misdiagnosis, delayed diagnosis, etc.)	63	12.8
	PSIs related to transfusion or IV injection (drug and transfusion complications, etc.)	334	67.9
	PSIs related to patient care (occurrence of falls, pressure ulcers, suicides, etc.)	269	54.7
	PSIs related to surgical procedure or treatment (post-endoscopy enterobrosia, etc.)	104	21.1
	PSIs related to infections (surgical site infections, catheter-associated urinary tract infection, etc.)	87	17.7
	Other PSIs	26	5.3
PSI level of harm	No harm	219	44.5
	Under 1 month required for harm recovery	138	28.0
	1 to under 6 months required for harm recovery	50	10.2
	6 months or longer required for harm recovery	21	4.3
	Resulted in permanent disability	23	4.7
	Death	41	8.3
Medical-error-relatedness of PSIs	Yes	297	60.4
	No	119	24.2
	I do not know	76	15.4
Total		492	100.0

Table 3. Difficulties Following Direct and Indirect Experience of PSIs

	Direct	Indirect	P-value
Experienced sleep disorders	42.4%	21.0%	<0.001
Experienced eating disorders	33.3%	18.5%	<0.001
Experienced symptoms of nausea, dyspnea, cold sweats, or body tension when exposed to a similar situation	31.3%	21.5%	0.017
Hypervigilance toward a similar situation	40.4%	34.9%	0.217
Considered changing duties or job (resignation)	34.3%	22.1%	0.003

Table 4. Regression Analysis of Factors Related to PTSD and PTED Instrument Scores

	PTSD			PTED		
	Coefficient	95% confidence interval		Coefficient	95% confidence interval	
		Lower	Upper		Lower	Upper
Gender						
Male	Ref			Ref		
Female	-12.98	-25.68	-0.29	-6.51	-12.21	-0.81
Age group						
20s	Ref			Ref		
30s	11.73	3.50	19.97	5.83	2.13	9.52
≥40s	13.60	1.58	25.63	9.70	4.30	15.10
Career						
<5	Ref			Ref		
5-10	5.18	-2.69	13.05	2.16	-1.37	5.70
≥10	-4.64	-15.15	5.87	-3.08	-7.80	1.64
Level of harm						
Under 1 month	Ref			Ref		
1 month or longer	5.18	-2.38	12.74	4.77	1.38	8.17
Permanent disability or death	-3.64	-11.50	4.23	-0.97	-4.50	2.56
Experience of PSIs						
Direct experience	Ref			Ref		
Indirect experience	-11.97	-17.31	-6.63	-1.48	-3.88	0.92
Elapsed time since PSIs						
Under 6 months	Ref			Ref		
6 months to under 5 years	-7.64	-14.42	-0.86	-5.12	-8.17	-2.08
5 years or longer	-11.02	-19.60	-2.44	-6.64	-10.49	-2.79
Medical-error-relatedness of PSIs						
Yes	Ref			Ref		
No	-10.20	-16.52	-3.88	-4.39	-7.23	-1.55
I do not know	-4.70	-12.08	2.68	-3.81	-7.12	-0.49

Survey on the Patient Safety Incident Experience

Department of Preventive Medicine, Ulsan University Hospital

Dear participants,

In this survey, we are attempting to understand the magnitude and impact of trauma injuries in Korea. The results of this survey will be used as a practical resource for the future development of a patient safety incident trauma recovery support program. Securing your personal information will be our utmost priority. The results of this study will be used only for academic purposes, and your personal information will be anonymized to prevent verification even for academic usage. The survey will take about 15 minutes, and you will receive two complimentary coffee coupons if you leave your cell phone number when you complete the survey.
Thank you for taking the time to cooperate and help our research.

September 2018

1. Characteristics of Patient Safety Incident

<Term Verification>

• Patient safety
- World Health Organization: "The prevention of errors and adverse effects to patients associated with health care."
• Error
- Failure to complete the intended action as planned(error in execution) or failure to construct a plan to achieve goals(error in planning)
• Adverse event
- American International Organization of Migration: "Damage resulted by an act of medical practice rather than by the underlying disease of the patient."
• Patient safety incident - Incidents of adverse event and medical error
• Medical accident
- Physical incidents during the entire process of medical practices, such as patient diagnosis, examination, and treatment, at a medical institution regardless of a doctor's error.

1. Have you ever experienced a **patient safety incident (PSI)**?

① I have a direct experience of a PSI. ☛ **Go to item 3**

② I have an indirect experience of a PSI, such as witnessing or hearing a PSI of a colleague in the same medical institution. ☛ **Go to item 3**

③ I have both direct and indirect experiences of PSIs. ☛ **Go to item 3**

④ I have never experienced a PSI. ☛ **End of the survey**

2. **How long is the elapsed time** since your experience of **the most memorable patient safety incident**?

① Less than a month

② More than a month to less than six months

③ More than six months to less than a year

④ More than one year to less than five years

⑤ More than five years

3. Please select **all types** of **patient safety incidents (PSI),** which were **the most memorable** to you. (Select all that apply).

① Diagnosis-related PSI (e.g., diagnosis error, delayed diagnosis, etc.)

② Medication, fluid administration and transfusion-related PSI (e.g., side effects of medication and transfusion, etc.)

③ Patinet care-related PSI (e.g., fall, pressure ulcer, suicide, etc.)

④ Surgery or procedure-related PSI (e.g., enterobrosia from an endoscope, etc.)

⑤ Infection-related PSI (e.g., surgical site infection, catheterization-related urinary tract infection, etc.)

⑥ Other PSI (Please describe:)

4. **How much harm** did **the most memorable patient safety incident** of your cause?

* **"Harm recovery"** means discharge or termination of treatment.

① No harm

② It took less than a month to recover from the harm

③ It took more than a month to less than six months to recover from the harm

④ It took more than six months to recover from the harm

⑤ It left permanent disability

⑥ Death

5. Do you think your most memorable **patient safety incident** has **a medical error**?

① There was a medical error

② There was not a medical error

③ I do not know

6. Have you experienced the following **difficulties** from your **most memorable patient safety incident** (PSI)?:

Difficulties from PSI	Yes	No
6-1. Experienced s**leep disorder** (insomnia, Insomnia, excessive sleep, nightmares, etc.)	①	②
6-2. Experienced **eating disorder** (anorexia, overeating)	①	②
6-3. Experienced symptoms such as **dizziness, dyspnea, cold sweating, or stiffness** at the time of the exposure of a similar incident	①	②
6-4. **Became excessively vigilant** at the time of the exposure of a similar incident (avoidance, asking colleagues to complete the task, etc.)	①	②
6-5. Considered **change of profession** or **job (resignation)**	①	②

7. Have you encountered any of the following **countermeasures** for your most memorable **patient safety incident**?

Disclosure of PSI	Yes	No
7-1. A medical professional **honestly disclosed the incident** to patients before the request of **patients and their caregivers**	①	②
7-2. A medical professional **shared empathy and regret** the incident before the request of patients and their caregivers	①	②
7-3. A medical professional promised an inquiry before the request of patients	①	②
7-4. A medical professional **delivered the fact** that there was no medical error from a completed inquiry to **patients and their caregivers**	①	②
7-5. A medical professional **delivered a sincere apology to patients and their caregivers** as a medical error was confirmed through an inquiry	①	②
7-6. **Offered adequate compensation** for the harm of patients	①	②
7-7. A medical professional made a **promise of preventing similar recurring incidents** to patients and their caregivers	①	②

2. Impacts of Patient Safety Incident – 1

Item	Strongly disagree	Disagree	Slightly disagree	Slightly agree	Agree	Strongly agree
11. At the time of the incident, it had an extreme impact on me.	①	②	③	④	⑤	⑥
12. After the incident, I had difficulty carrying out my daily life in the following days.	①	②	③	④	⑤	⑥
13. After the incident, I was suffered from nightmares.	①	②	③	④	⑤	⑥
14. After the incident, I was distressed by the painful memories of the incident.	①	②	③	④	⑤	⑥
15. After the incident, I felt as if I were re-living the incident.	①	②	③	④	⑤	⑥
16. After the incident, it was very painful every time I saw places, things, or people reminding me of the incident.	①	②	③	④	⑤	⑥
17. After the incident, it was very painful to see anything symbolizing or similar to the incident.	①	②	③	④	⑤	⑥
18. After the incident, I was withdrawn from others for a long time.	①	②	③	④	⑤	⑥
19. After the incident, I was very much afraid of experiencing a similar incident.	①	②	③	④	⑤	⑥
20. After the incident, I spent much time distracted and confused.	①	②	③	④	⑤	⑥
21. After the incident, I felt intense negative emotions.	①	②	③	④	⑤	⑥
22. After the incident, I did not feel positive emotions, such as joy, for a long time.	①	②	③	④	⑤	⑥
23. After the incident, I felt isolated from others.	①	②	③	④	⑤	⑥

24. After the incident, I felt as if my future life was shortened.	①	②	③	④	⑤	⑥
25. After the incident, I felt that I could not manage to live a healthy life.	①	②	③	④	⑤	⑥
26. I still live with the impacts of the incidents.	①	②	③	④	⑤	⑥
27. When the memory of the event occurs to me, I have a hard time taking care of my daily tasks.	①	②	③	④	⑤	⑥
28. Although a long time has passed, I sometimes still suffer from nightmares.	①	②	③	④	⑤	⑥
29. Although a long time has passed, I am often still distressed by the painful memories of the incident.	①	②	③	④	⑤	⑥
30. Although a long time has passed, I sometimes still feel as if I were reliving the same incident.	①	②	③	④	⑤	⑥
31. It is still very painful every time I see places, things, or people reminding me of the incident.	①	②	③	④	⑤	⑥
32. It is still very painful to see anything symbolizing or similar to the incident.	①	②	③	④	⑤	⑥
33. I am still withdrawn from people.	①	②	③	④	⑤	⑥
34. I am still very much afraid of experiencing a similar incident.	①	②	③	④	⑤	⑥
35. I still spend much time distracted and confused.	①	②	③	④	⑤	⑥
36. I sometimes still feel intense negative feelings since the incident.	①	②	③	④	⑤	⑥
37. I still feel less of positive emotions, such as joy, since the incident.	①	②	③	④	⑤	⑥
38. I sometimes still feel isolated from others.	①	②	③	④	⑤	⑥

39. I sometimes still feel as if my future life is shortened.	①	②	③	④	⑤	⑥
40. I still feel that I cannot manage to live a healthy life.	①	②	③	④	⑤	⑥

3. Impacts of Patient Safety Incident – 2

Item	Not true at all	Hardly true	True	Very much true	Extremely true
41. During the last years, there was a severe and negative life incident that hurt my feelings and caused considerable embitterment.	①	②	③	④	⑤
42. During the last years, there was a severe and negative life incident that led to a noticeable and persistent negative change in my mental well-being.	①	②	③	④	⑤
43. During the last years, there was a severe and negative life incident that I see as very unjust and unfair.	①	②	③	④	⑤
44. During the last years, there was a severe and negative life incident of which I had repetitively thought over.	①	②	③	④	⑤
45. During the last years, there was a severe and negative life incident that causes that caused me to be extremely upset when I was reminded of it.	①	②	③	④	⑤
46. During the last years, there was a severe and negative life incident that triggered me to harbor thought of revenge.	①	②	③	④	⑤
47. During the last years, there was a severe and negative life incident for which I had blamed and was with myself.	①	②	③	④	⑤
48. During the last years, there was a severe and negative life incident that led to either strive my willingness or became lethargic.	①	②	③	④	⑤
49. During the last years, there was a severe and negative life incident that made me feel sullen and unhappy.	①	②	③	④	⑤
50. During the last years, there was a severe and negative life incident that impaired my overall physical well-bing.	①	②	③	④	⑤

51. During the last years, there was a severe and negative life incident that made me avoid certain places or people that reminded me of the people associated with the event.	①	②	③	④	⑤
52. During the last years, there was a severe and negative life incident that made me feel helpless and disempowered.	①	②	③	④	⑤
53. During the last years, there was a severe and negative life incident that triggered feelings of satisfaction when I thought that the responsible party having to experience a similar situation as mine.	①	②	③	④	⑤
54. During the last years, there was a severe and negative life incident that led to a considerable decrease in my physical strength and drive.	①	②	③	④	⑤
55. During the last years, there was a severe and negative life incident that made me easily irritated than before.	①	②	③	④	⑤
56. During the last years, there was a severe and negative life incident that forced me to distract myself with business in order to experience a normal mood.	①	②	③	④	⑤
57. During the last years, there was a severe and negative life incident that made me unable to pursue occupational activities or have an interaction with family as before.	①	②	③	④	⑤
58. During the last years, there was a severe and negative life incident that caused me to draw back from friends and social activities.	①	②	③	④	⑤
59. During the last years, there was a severe and negative life incident which frequently evoked painful memories.	①	②	③	④	⑤

4. Socio-demographic factor

DQ1. What is your sex?

① Male ② Female

DQ2. What is your age?

( ) years old

DQ3. How many years have you practiced medicine (On the basis of period after the license acquisition)?

( ) years

DQ4. If you write down your cell phone number, we will assume that you have agreed to provide personal information and will provide 2 complimentary coffee coupons for participating in the survey. If you do not agree, do not fill out this form.

( )

The survey is completed.

Thank you for taking the time to complete this survey.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Check (page number)
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	✓ **(3)**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	✓ **(3-4)**
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	✓ **(5-6)**
Objectives	3	State specific objectives, including any prespecified hypotheses	✓ **(6)**
Methods			
Study design	4	Present key elements of study design early in the paper	✓ **(7)**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	✓ **(7)**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	✓ **(8-9)**
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	✓ **(8)**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	✓ **(7-8)**
Bias	9	Describe any efforts to address potential sources of bias	✓ **(8)**
Study size	10	Explain how the study size was arrived at	✓ **(8)**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	✓ **(9)**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	✓ **(8-9)**
		(*b*) Describe any methods used to examine subgroups	

	and interactions
	(*c*) Explain how missing data were addressed
	(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
	(*e*) Describe any sensitivity analyses

Continued on next page

Results			**Check (page number)**
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	✓ **(10)**
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	✓ **(10)**
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	✓ **(10-11)**
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	✓ **(10-11)**
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	✓ **(11)**
Discussion			
Key results	18	Summarise key results with reference to study objectives	✓ **(12)**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	✓ **(15)**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	✓ **(13-14)**
Generalisability	21	Discuss the generalisability (external validity) of the study results	✓ **(15)**
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	✓ **(16)**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Nurses' experiences of patient safety incidents in Korea: a cross-sectional study

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Nurses' experiences of patient safety incidents in Korea: a cross-sectional study

Title page

1. Author and Co-author's name

Eun Young Choi, Jeehee Pyo, Won Lee, Seung Gyeong Jang, Young-Kwon Park, Minsu Ock, Sang-Il Lee

2. The name, postal address, e-mail, telephone, and fax numbers of the corresponding author

1) Won Lee, RN, PhD

84 Heukseok-ro, Dongjak-gu, Seoul 06974, Republic of Korea

Email: oness38@hanmail.net

82-2-820-5742, 82-2-820-5672

2) Minsu Ock, MD, PhD

877 Bangeojinsunhwando-ro, Dong-gu, Ulsan 44033, Republic of Korea

Email: ohohoms@naver.com

82-52-250-8793/82-52-250-7289

3. The full names, institutions, city, and country of all co-authors

Eun Young Choi[1,2], Jeehee Pyo[1], Won Lee[3†], Seung Gyeong Jang[4], Young-Kwon Park[5], Minsu Ock[1,5,6†], Sang-Il Lee[6]

[1]Department of Preventive Medicine, Ulsan University Hospital, University of Ulsan College of Medicine, Ulsan, Republic of Korea

[2]Department of Nursing, Graduate School of Chung-Ang University.

[3]Department of Nursing, Chung-Ang University, Seoul, Republic of Korea

[4]National Evidence-based Healthcare Collaboration Agency, Seoul, Republic of Korea

[5]Prevention and Care Center, Ulsan University Hospital, Ulsan, Republic of Korea

[6]Department of Preventive Medicine, University of Ulsan College of Medicine, Seoul, Republic of Korea

4. Keywords

Second victims, Health & safety, Human resource management, Quality in health care

5. Word count

3428 words

Nurses' experiences of patient safety incidents in Korea: a cross-sectional study

Abstract

Objectives: The aim of this study was to investigate the scope and severity of the second victim problem among nurses by examining the experiences and effects of patient safety incidents (PSIs) on them.

Participants/setting: 492 nurses who had experienced PSIs and provide direct care in South Korean medical institutions.

Design: A cross-sectional study with anonymous online self-report questionnaires was conducted to nurses in order to examine the experiences and effects of PSIs. Scales measuring post-traumatic stress disorder (PTSD) and post-traumatic embitterment disorder (PTED) were used for a more quantitative examination of the effects of PSIs. A chi-squared test was administered to find any difference in responses on difficulties due to PSIs between direct and indirect experience of PSIs. Furthermore, linear regression analysis was conducted to investigate the factors related to scores on the PTSD and PTED scales.

Results: A statistically significant difference was observed for participants who reported having experienced sleeping disorders, with those with direct experience showing 42.4% sleeping disorders and indirect experience at 21.0%. Also, there was a statistically significant difference between the 34.3% with direct experience and the 22.1% with indirect experience regarding having considered duty or job changes (resignation). Regression analysis showed total PTSD scores for indirect experience at 11.97 points (95% confidence interval: -17.31–-6.63), lower than direct experience. Moreover, those who thought medical error was not involved in PSI had a total PTED score 4.39 points (95% confidence interval: -7.23~-1.55) lower than those who thought it was involved.

Conclusions: A considerable number of nurses experienced psychological difficulties due to PSIs at levels that could interfere with their work. The effect of PSIs on nurses with direct experience of PSIs was greater compared to those with indirect experience. There need to be psychological support programs for nurses to alleviate the negative effects of PSIs.

Strengths and limitations of this study

- This study examined the experiences and effects of patient safety incidents (PSIs) on nurses who had experienced PSIs and provide direct care in South Korean medical institutions through a questionnaire.
- We determined the Korean nurses' PSI experiences and impacts in various aspect, including post-traumatic stress disorder (PTSD) and post-traumatic embitterment disorder (PTED) scales.
- An analysis was conducted to determine whether there was a difference in responses on difficulties due to PSIs by direct versus indirect experiences.
- We examined the factors related to the PTSD and PTED scores by a linear regression analysis.
- In this study, participants were asked about their most memorable PSI. Future research should identify and analyze in detail the number and range of PSIs experienced by nurses.

INTRODUCTION

Medical personnel who experience emotional pain due to unanticipated adverse events, medical errors, and patient-related injuries are referred to as "second victims".[1] These second victims experience psychological pain, fear, decreased confidence, guilt, rage, exhaustion, and despair after patient safety incidents (PSIs),[2,3] and such symptoms are interpreted as indicators of post-traumatic stress disorder.[4] If the experiences of second victims aren't adequately treated, it can increase the likelihood of other errors due to fatigue, depression, and/or reduced sympathy.[5,6] It also leads to job changes and absences, negatively affecting the medical institution,[7] and efforts and approach to support second victims are required.

Since the term "second victim" appeared in 2000,[8] numerous studies have been conducted especially in the United States to investigate the second victim phenomenon and methods to support second victims. Discussions have continued in order to understand the prevalence and symptoms of second victims as well as to plan coping strategies and support programs.[2,3,9] Moreover, institutions such as the Institute for Healthcare Improvement and The Joint Commission have developed that provide guidelines to support second victims,[10,11] and individual medical institutions have also implemented support programs for second victims.[1,12] Such activities are gradually spreading throughout the United States and some countries in Europe.[6,12–14]

In South Korea, the *Patient Safety Act* was enacted in 2016 to establish the national Patient Safety Reporting & Learning System, building a foundation to systematically manage patient safety problems at the national level.[15] However, the focus remains on cause analysis and error prevention in PSIs, with relatively limited perception and research on counselling and supporting second victims.[16,17] A recent study by Lee et al.[15] showed that second victims

who experience PSIs in South Korea undergo various emotional reactions such as confusion, guilt, and depression, while also experiencing behavioral changes such as insomnia, avoidance, and considering job change, similar to findings in another previous study.[3] A study by Kim et al.[18] also showed that the effects of PSIs as perceived by Korean nurses were similar to those observed in a study in the United States.[7] This implies that the second victim phenomenon manifests similarly regardless of culture. Therefore, considering a study that has shown that all medical personnel are potential PSI or error victims and that almost half of medical personnel have had the experience of second victimization at least once in their clinical career,[19] the second victim phenomenon cannot be overlooked further, in South Korea as well.

A large number of patients are assigned to each South Korean nurse, and nurses have to provide various nursing services, such as the administration of medication and aid, within a set time. This environment occasionally affects nurses in a negative manner, which leads to exhaustion, disappointment, and despair at being unable to provide adequate treatment to patients.[20] This is also known to be the greatest factor leading nurses to consider changing jobs.[21] In this context, further difficulties will be added if a second victim problem occurs to the nurse. Thus, it is necessary to understand the pain nurses experience as second victims and to find ways of providing them with emotional support.

To this end, this study determined the Korean nurses' PSI experiences and impacts in various aspect, including post-traumatic stress disorder (PTSD) and post-traumatic embitterment disorder (PTED) scales.

METHODS

This was a cross-sectional study within the overall project of examining the PSI experiences of the general public, physicians, and nurses, and this study focused on the results of anonymous self-report online questionnaires administered to nurses. This study was approved by the Institutional Review Board of the University of Ulsan Hospital (IRB Number: 2018-07-003). All participants were notified of the purpose and process of this study and only those who agreed to participate conducted this survey. Each participant received a 4,500 won (about 3.7 US dollars) coffee coupon.

Questionnaire Development and Content

The questionnaire was developed and composed to enable comparison with the PSI experiences of the general public.[22] Questionnaire items were developed by referencing literature on the types and characteristics of PSIs[23–25] and previous studies on second victims.[3,26] The draft questionnaire was developed based on repeated discussions held among the entire research team (including 2 physicians and 3 nurses who have abundant research experience on patient safety). The questionnaire items and expressions were then refined based on the opinions of a nursing professor, the president of the Korean Intern Resident Association, and the CEO of a patient safety NGO. Furthermore, we conducted cognitive debriefing with 3 nurses to determine if there were any difficult or confusing parts in the survey questions or phrases.

The final questionnaire items can be classified as follows: 1) PSI characteristics; 2) the effects of PSI; 3) experience of disclosure of PSI; and 4) socio-demographic items. This study focused on the 1) PSI characteristics and 2) the effects of PSI. In further detail, 1) PSI characteristics included • covered type of PSI experience (direct or indirect), • elapsed time

since the most memorable PSI, • type of the most memorable PSI (diagnosis-related, patient care-related, etc.), • level of harm caused by the most memorable PSI, and • opinion on medical error relatedness of the most memorable PSI. In 2) the effects of PSI, • the effects of PSI and • the difficulties caused by the most memorable PSI were examined in categories of "sleep disorder;" "eating disorder;" "nausea, dyspnea, cold sweats, or stiffness in similar situations;" "vigilance in similar situations," and "consideration of duty or job changes." Additionally, the PTSD and PTED scales were used for a more quantitative examination of the effects of PSIs. For 4) socio-demographic items, the participants' sex, age, and elapsed time since license acquisition were collected. The full questionnaire can be found in the supplementary information.

PTSD and PTED Scales

PTSD[27] and PTED[28] scales used in previous studies were adopted. The PTSD scale, designed to measure the past and present effects of trauma, is composed of 30 items. Responses for the PTSD scale were defined as follows: 1 point for "Strongly Disagree," 2 points for "Disagree," 3 points for "Slightly Disagree," 4 points for "Slightly Agree," 5 points for "Agree," and 6 points for "Strongly Agree." The PTED scale, on exceptionally negative incidents in life, is composed of 19 items, used after modifying them to check the effects of the participants' most memorable PSI. Responses on the PTED scale were defined as follows: 1 point for "Strongly Disagree," 2 points for "Disagree," 3 points for "Slightly Disagree," 4 points for "Agree," and 5 points for "Strongly Agree."

Participants and Questionnaire Administration

Participants were nurses who had experienced patient safety incidents and provide direct care

in hospitals. The sample size of this study was determined in consideration of the study budget and the sample size of similar preceding studies.[22–25] Because this study focused on the analysis of current status rather than hypothesis testing, we did not set up parameters to determine sample size, such as effect size, alpha error, beta error, etc. Furthermore, the sampling error was not available because the non-probability sampling method was used, but it was intended to overcome the representativeness problem by recruiting as many participants as possible.

Online self-assessment questionnaires were administered over approximately 2 months, from April 2019 to May 2019. Since nurses may be unfamiliar with terminology related to patient safety, definitions of such terms, including *patient safety*, *medical error*, *adverse event*, and *patient safety incident*, were provided prior to the survey.[23,29,30] The survey was promoted via online blog posts and word-of-mouth among colleagues, and participants were gathered through snowball sampling. Participants were blocked from responding to the questionnaire more than once from the same IP address, to prevent possible repeated participation in the survey.

Analysis

First, the socio-demographic factors and experienced PSI characteristics were examined through a frequency analysis. A chi-squared test was conducted to determine whether there was a difference in responses on difficulties due to PSIs by direct versus indirect experiences. To analyze the results of the PTSD and PTED scales, total scores derived by aggregating the item responses for each scale were used for analysis. The range of total scores of the PTSD and PTED was from 30 to 180 and from 19 to 95, respectively. A linear regression analysis was conducted to examine the factors related to the PTSD and PTED scores, which were used as dependent variables. Socio-demographic factors (sex, age, and career stage), type of PSI

experience (direct and indirect), level of harm, elapsed time since PSI, and opinion on medical error relatedness of the PSI (Yes, No, I do not know) were included as independent variables. Participants who had experienced PSIs both directly and indirectly were classified under direct experience.

Microsoft Excel 2007 was used to organize data, and all data analysis was conducted with Stata/SE13.1 (StataCorp, Texas, TX). Results were deemed statistically significant at a p-value under 0.05.

Patient and Public Involvement

Patients or the public were not involved in the study design.

RESULTS

Socio-demographic Characteristics

A total of 492 nurses responded to the survey (Table 1). The absolute majority of the participants were female (470, 95.5%). The largest number of participants were in their 30s (244, 49.6%) in terms of age, with the greatest number having acquired their license between 10 and 20 years previously (183, 37.2%), followed by 5 to under 10 years (173, 35.2%) and under 5 years (112, 22.7%).

Characteristics of PSI Experiences

A total of 492 nurses provided responses regarding the characteristics of their PSI experiences. 297 nurses (60.4%) responded that they had directly experienced PSIs, while 195 (39.6%) had indirectly experienced them, through seeing or hearing of a coworker's incident. The largest number of memorable PSIs had occurred within 1 to under 5 years (205, 41.7%). For types of memorable PSIs (multiple responses possible), most were related to transfusion or IV injections (334, 67.9%), followed by PSIs related to patient care (269, 54.7%), and PSIs related to surgical procedure or treatment (104, 21.1%). Most PSIs were unharmful, according to 219 responses (44.5%), while incidents that resulted in permanent disability and in death were 23 (4.7%) and 41 (8.3%) respectively. A total of 297 participants (60.4%) believed that there had been medical error involved in the PSI, while 119 (24.2%) and 76 (15.4%) believed that medical error was not present and was uncertain respectively (Table 2).

Difficulties Following Direct and Indirect Experience of PSIs

Examining difficulties due to PSIs based on experience type, a statistically significant difference was observed, as 42.4% of those with direct experience but only 21.0% with indirect experience responded that they had experienced sleeping disorder due to the PSI.

33.3% of nurses with direct experience and 18.5% with indirect experience claimed to have experienced eating disorders. Statistically significant differences were also observed in experience of symptoms of nausea, dyspnea, cold sweats, or body tension when exposed to a similar situation, affecting 31.3% with direct experience and 21.5% with indirect experience. The difference between the 34.3% with direct experience who had considered changing duties or job (resignation) compared to the 21.1% with indirect experience who had was also found to be statistically significant (Table 3).

PTSD- and PTED-Related Factors

Linear regression results to find factors related to total PTSD and PTED scores of survey participants can be found in Table 4. PTSD scores were around 12.98 points (95% confidence interval: -25.68–-0.29) lower for females compared to males, and 11.73 points (95% confidence interval: 3.50–19.97) higher for nurses in their 30s and 13.60 points (95% confidence interval: 1.58–25.63) higher for those in their 40s or older compared to nurses in their 20s. Furthermore, total PTSD score was 11.97 points (-17.31–-6.63) lower for indirect experience compared to direct experience, and tended to decrease with increased elapsed time since the PSI. Finally, total PTSD score was 10.20 points (95% confidence interval: -16.52–-3.88) lower for nurses who did not believe that there had been a medical error compared to those who did.

PTED showed similar trends to PTSD: scores were around 6.51 points (95% confidence interval: -12.21–-0.81) lower for females than males, increased with age, and decreased with time elapsed since PSI. Additionally, PTED scores were 4.39 points (95% confidence interval: -7.23–-1.55) lower for those who did not think that there had been a medical error compared to those who did.

DISCUSSION

In this study, a questionnaire was administered to nurses who had experienced PSIs to investigate the impacts of PSIs, the difference in difficulties resulting from PSIs between direct and indirect experience, and factors related to post-PSI experience of PTSD and PTED. The characteristics of and difficulties resulting from PSIs experienced by 492 nurses were explored and the effects of incidents examined from various perspectives using the scores and factors affecting PTSD and PTED. While there have been previous studies in South Korea that examined the experiences of medical personnel who experienced error,[17] the coping process of medical personnel after experiencing PSIs,[26] and nurses' 2- and 3-dimensional experiences of PSIs,[18] almost no studies have been conducted on the topic of this study, that is, measuring factors relating to post-trauma and the difference between direct and indirect experience on the effects of PSI from various angles. A notably significant aspect of this study is that it verifies the need for support for nurses who experience PSIs and establishes base data and factors that can be considered when developing and implementing such support programs.

In this study, the most memorable type of PSI according to nurses was PSI related to transfusion or IV injection (67.9%), followed by PSI related to patient care, such as the occurrence of falls and pressure ulcers. According to the Korea Patient Safety Reporting & Learning System (KOPS), falling followed by medication error was reported to be the most frequent PSI by type, and in medication error reports, nurses appeared the most frequently under related personnel.[31] Despite the need to focus while administering medication given its potentially dangerous nature, interruption and disturbances during its measurement and administration are common due to inhibitors such as receiving telephone calls, patient and guardian reception, and communication with other health and medical personnel.[20] Previous

research reports that the risk of medication error increases due to such disturbances,[32] and that such medication error negatively affect nurses personally and professionally.[4,33] There is a necessity to reduce the negative effects of such PSIs by recognizing the common PSI experiences of nurses, analyzing their causes, and re-educating nurses based on the results.[33]

In all, 60.4% of the nurses who participated in this study had experienced PSIs. They can be seen to have frequent exposure to PSIs, as they are generally the medical professionals who work most closely with patients.[34] Harrison et al.[35] also found that nurses report more negative emotions after medical error, and this result was attributed to the nursing culture and the fact that nurses are in direct contact with the patients. In this regard, difficulties due to direct and indirect PSI experiences were examined separately in this study, and statistically significant differences between those with direct and indirect experience were seen for sleep disorder, eating disorder, symptoms such as nausea and dyspnea when exposed to a similar situation, and consideration of job or duty changes. There was a difference between direct and indirect experience on PTSD and PTED scale scores as well, with the PTSD scores for those with indirect experience being statistically significantly 11.97 points lower than for those with direct experience. As such, it was found that nurses who directly experience PSIs are affected to a greater degree in terms of psychological and physical symptoms as well as consideration of job changes. This is similar to the findings of Van Gerven et al.[36] in which medical personnel who had experienced a PSI in the past 6 months showed higher problematic medication use, burnout risk, and intention to change jobs compared to those who had not. In another study, physicians who had experienced an adverse event or a near miss were reported to have lower confidence, sleep disorder, and tension regarding the occurrence of PSIs.[37] Sleep disorder and symptoms of nausea, dyspnea, and body tension in particular directly influence patient safety, as they may cause additional PSIs.[38] Therefore,

psychological and administrative support must be provided to nurses exposed to PSIs, to minimize the negative effects on the psychological state of nurses and, by extension, on patient safety; in particular, nurses who directly experienced the incident should be prioritized for support and aid.

PTSD and PTED scores tended to significantly decrease as more time passed after a PSI. However, existing studies indicate that second victims actively try to overcome trauma after its occurrence and that such efforts may heal the wound but leave a scar.[2,26] In a study by Vanhaecht et al.[39] symptoms such as hypervigilance, flashbacks, shame, and doubts about one's knowledge and skill continued for over 6 months in some cases. Such results can be interpreted to mean that while post-incident trauma and frustration fade with time, they are not completely resolved, and that the type of difficulties varies across the stages. Thus, temporal factors such as whether it is immediately after the incident, medium-term, or long-term must be considered in developing second victim support programs,[26] and second victims must be managed so that such aid is seamlessly provided.

Existing research shows increased emotional difficulty when there is a possibility of medical malpractice,[40] which was also seen in this study, as PTSD and PTED scores were found to be higher when there was belief that medical error was present. On this note, a qualitative study on second victims expressed the need for institution-level support relating to medical malpractice and administrative processes that could result from PSIs.[26] Scott et al.[1] also proposed that long-term support and risk management directions should also be provided during legal proceedings stemming from PSIs if necessary. Medical malpractice cases are on the rise in South Korea, and nurses face increased risk of being involved in medical malpractice as their scope of work has expanded with the revisions to the *Medical Service Act*. As such, administrative and legal support, in addition to psychological support, should be

provided if necessary.

The limitations of this study are as follows. First, this was a cross-sectional study on the PSI experiences and difficulties of the participants and we promoted participants through online blog posts and snowball sampling. Therefore, it is limited in its ability to assess change over time and many of the study participants were women and younger participants. According to existing research on the coping process of second victims, their experiences of PSIs and their impacts must be studied longitudinally as they undergo change over time,[2,26] and further research that designed as to compensate for limitation such as self-selection is needed. Second, in this study, we did not identify the participants' work setting. According to Lewis et al, characteristics of the work unit such as the overall environment of the nursing unit, nurse manager, and so on were important to nurses' experiences of PSIs,[41] further research that includes the characteristics of the nursing unit is needed. Third, as participants were asked about their most memorable PSI, the possibility of recall bias regarding the characteristics and difficulties of their PSI experiences in their responses should be kept in mind when interpreting the data. In addition, follow-up studies should identify and analyze in detail the number and range of PSIs experienced by nurses. Fourth, the response rate of was not obtained due to the methodological limitations of anonymous self-report online survey. Accordingly, information on the characteristics of those who refused to participate in the survey was not collected to ensure the anonymity of the participants. This limitation may restrict the representativeness of this study, but this study sought to overcome this problem by taking as many nurses as possible into the survey.

Despite the above limitations, a major source of significance of this study is that it analyzed the impacts of PSI experiences of nurses and the factors related to subsequent trauma from various angles. It showed that nurses who experienced PSIs face difficulties

such as sleep disorder, eating disorder, and nausea and dyspnea in similar situations, an impact that was more prominent in nurses who directly experienced PSIs. Furthermore, the examination of PTSD- and PTED-related factors for PSIs revealed their differential relation to direct and indirect experiences, elapsed time, and presence of medical error. Second victim support programs that can provide realistic help to nurses who have experienced PSIs must be developed, reflecting the results of this study. Moreover, to fully support second victims there need to be efforts to create a broader patient safety culture, with the active participation of the government and medical institutions.

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Table 1. Socio-demographic Information

		Frequency	%
Sex	Male	22	4.5
	Female	470	95.5
Age group	20s	195	39.6
	30s	244	49.6
	40s	40	8.1
	50 and older	13	2.7
Career after license acquisition	Under 5 years	112	22.7
	5 to under 10 years	173	35.2
	10 to under 20 years	183	37.2
	20 years or longer	24	4.9
Total		492	100.0

Table 2. Characteristics of PSIs Experienced by Research Participants

	Item	Frequency	%
PSI experience	Direct experience	115	23.4
	Indirect experience via seeing or hearing an incident experienced by a coworker at the same medical institution	195	39.6
	Both direct and indirect experiences	182	37.0
Elapsed time since PSI	Under 1 month	35	7.1
	1 to under 6 months	68	13.8
	6 months to under 1 year	65	13.2
	1 to under 5 years	205	41.7
	5 years or longer	119	24.2
Types of memorable PSIs (multiple responses)	PSIs related to diagnosis (misdiagnosis, delayed diagnosis, etc.)	63	12.8
	PSIs related to transfusion or IV injection (drug and transfusion complications, etc.)	334	67.9
	PSIs related to patient care (occurrence of falls, pressure ulcers, suicides, etc.)	269	54.7
	PSIs related to surgical procedure or treatment (post-endoscopy enterobrosia, etc.)	104	21.1
	PSIs related to infections (surgical site infections, catheter-associated urinary tract infection, etc.)	87	17.7
	Other PSIs	26	5.3
PSI level of harm	No harm	219	44.5
	Under 1 month required for harm recovery	138	28.0
	1 to under 6 months required for harm recovery	50	10.2
	6 months or longer required for harm recovery	21	4.3
	Resulted in permanent disability	23	4.7
	Death	41	8.3
Medical-error-relatedness of PSIs	Yes	297	60.4
	No	119	24.2
	I do not know	76	15.4
Total		492	100.0

Table 3. Difficulties Following Direct and Indirect Experience of PSIs

	Direct (N=297)		Indirect (N=195)		P-value	95% confidence interval for difference	
	n	%	n	%		Lower	Upper
Experienced sleep disorders	126	42.4%	41	21.0%	<0.001	13.4%	29.4%
Experienced eating disorders	99	33.3%	36	18.5%	<0.001	7.2%	22.5%
Experienced symptoms of nausea, dyspnea, cold sweats, or body tension when exposed to a similar situation	93	31.3%	42	21.5%	0.017	2.0%	17.6%
Hypervigilance toward a similar situation	120	40.4%	68	34.9%	0.217	-3.2%	14.2%
Considered changing duties or job (resignation)	102	34.3%	43	22.1%	0.003	4.4%	20.2%

Table 4. Regression Analysis of Factors Related to PTSD and PTED Instrument Scores

	PTSD			PTED		
	Coefficient	95% confidence interval		Coefficient	95% confidence interval	
		Lower	Upper		Lower	Upper
Gender						
Male	Ref			Ref		
Female	-12.98	-25.68	-0.29	-6.51	-12.21	-0.81
Age group						
20s	Ref			Ref		
30s	11.73	3.50	19.97	5.83	2.13	9.52
≥40s	13.60	1.58	25.63	9.70	4.30	15.10
Career						
<5	Ref			Ref		
5-10	5.18	-2.69	13.05	2.16	-1.37	5.70
≥10	-4.64	-15.15	5.87	-3.08	-7.80	1.64
Level of harm						
Under 1 month	Ref			Ref		
1 month or longer	5.18	-2.38	12.74	4.77	1.38	8.17
Permanent disability or death	-3.64	-11.50	4.23	-0.97	-4.50	2.56
Experience of PSIs						
Direct experience	Ref			Ref		
Indirect experience	-11.97	-17.31	-6.63	-1.48	-3.88	0.92
Elapsed time since PSIs						
Under 6 months	Ref			Ref		
6 months to under 5 years	-7.64	-14.42	-0.86	-5.12	-8.17	-2.08
5 years or longer	-11.02	-19.60	-2.44	-6.64	-10.49	-2.79
Medical-error-relatedness of PSIs						
Yes	Ref			Ref		
No	-10.20	-16.52	-3.88	-4.39	-7.23	-1.55
I do not know	-4.70	-12.08	2.68	-3.81	-7.12	-0.49

Survey on the Patient Safety Incident Experience

Department of Preventive Medicine, Ulsan University Hospital

Dear participants,

In this survey, we are attempting to understand the magnitude and impact of trauma injuries in Korea. The results of this survey will be used as a practical resource for the future development of a patient safety incident trauma recovery support program. Securing your personal information will be our utmost priority. The results of this study will be used only for academic purposes, and your personal information will be anonymized to prevent verification even for academic usage. The survey will take about 15 minutes, and you will receive two complimentary coffee coupons if you leave your cell phone number when you complete the survey.
Thank you for taking the time to cooperate and help our research.

September 2018

1. Characteristics of Patient Safety Incident

<Term Verification>

• Patient safety
- World Health Organization: "The prevention of errors and adverse effects to patients associated with health care."
• Error
- Failure to complete the intended action as planned(error in execution) or failure to construct a plan to achieve goals(error in planning)
• Adverse event
- American International Organization of Migration: "Damage resulted by an act of medical practice rather than by the underlying disease of the patient."
• Patient safety incident - Incidents of adverse event and medical error
• Medical accident
- Physical incidents during the entire process of medical practices, such as patient diagnosis, examination, and treatment, at a medical institution regardless of a doctor's error.

1. Have you ever experienced a **patient safety incident (PSI)**?

① I have a direct experience of a PSI. ☞ **Go to item 3**

② I have an indirect experience of a PSI, such as witnessing or hearing a PSI of a colleague in the same medical institution. ☞ **Go to item 3**

③ I have both direct and indirect experiences of PSIs. ☞ **Go to item 3**

④ I have never experienced a PSI. ☞ **End of the survey**

2. **How long is the elapsed time** since your experience of **the most memorable patient safety incident**?

① Less than a month

② More than a month to less than six months

③ More than six months to less than a year

④ More than one year to less than five years

⑤ More than five years

3. Please select **all types** of **patient safety incidents (PSI),** which were **the most memorable** to you. (Select all that apply).

① Diagnosis-related PSI (e.g., diagnosis error, delayed diagnosis, etc.)

② Medication, fluid administration and transfusion-related PSI (e.g., side effects of medication and transfusion, etc.)

③ Patinet care-related PSI (e.g., fall, pressure ulcer, suicide, etc.)

④ Surgery or procedure-related PSI (e.g., enterobrosia from an endoscope, etc.)

⑤ Infection-related PSI (e.g., surgical site infection, catheterization-related urinary tract infection, etc.)

⑥ Other PSI (Please describe:)

4. **How much harm** did **the most memorable patient safety incident** of your cause?

* **"Harm recovery"** means discharge or termination of treatment.

① No harm

② It took less than a month to recover from the harm

③ It took more than a month to less than six months to recover from the harm

④ It took more than six months to recover from the harm

⑤ It left permanent disability

⑥ Death

5. Do you think your most memorable **patient safety incident** has **a medical error**?

① There was a medical error

② There was not a medical error

③ I do not know

6. Have you experienced the following **difficulties** from your **most memorable patient safety incident** (PSI)?:

Difficulties from PSI	Yes	No
6-1. Experienced s**leep disorder** (insomnia, Insomnia, excessive sleep, nightmares, etc.)	①	②
6-2. Experienced **eating disorder** (anorexia, overeating)	①	②
6-3. Experienced symptoms such as **dizziness, dyspnea, cold sweating, or stiffness** at the time of the exposure of a similar incident	①	②
6-4. **Became excessively vigilant** at the time of the exposure of a similar incident (avoidance, asking colleagues to complete the task, etc.)	①	②
6-5. Considered **change of profession** or **job (resignation)**	①	②

7. Have you encountered any of the following **countermeasures** for your most memorable **patient safety incident**?

Disclosure of PSI	Yes	No
7-1. A medical professional **honestly disclosed the incident** to patients before the request of **patients and their caregivers**	①	②
7-2. A medical professional **shared empathy and regret** the incident before the request of patients and their caregivers	①	②
7-3. A medical professional promised an inquiry before the request of patients	①	②
7-4. A medical professional **delivered the fact** that there was no medical error from a completed inquiry to **patients and their caregivers**	①	②
7-5. A medical professional **delivered a sincere apology to patients and their caregivers** as a medical error was confirmed through an inquiry	①	②
7-6. **Offered adequate compensation** for the harm of patients	①	②
7-7. A medical professional made a **promise of preventing similar recurring incidents** to patients and their caregivers	①	②

2. Impacts of Patient Safety Incident – 1

Item	Strongly disagree	Disagree	Slightly disagree	Slightly agree	Agree	Strongly agree
11. At the time of the incident, it had an extreme impact on me.	①	②	③	④	⑤	⑥
12. After the incident, I had difficulty carrying out my daily life in the following days.	①	②	③	④	⑤	⑥
13. After the incident, I was suffered from nightmares.	①	②	③	④	⑤	⑥
14. After the incident, I was distressed by the painful memories of the incident.	①	②	③	④	⑤	⑥
15. After the incident, I felt as if I were re-living the incident.	①	②	③	④	⑤	⑥
16. After the incident, it was very painful every time I saw places, things, or people reminding me of the incident.	①	②	③	④	⑤	⑥
17. After the incident, it was very painful to see anything symbolizing or similar to the incident.	①	②	③	④	⑤	⑥
18. After the incident, I was withdrawn from others for a long time.	①	②	③	④	⑤	⑥
19. After the incident, I was very much afraid of experiencing a similar incident.	①	②	③	④	⑤	⑥
20. After the incident, I spent much time distracted and confused.	①	②	③	④	⑤	⑥
21. After the incident, I felt intense negative emotions.	①	②	③	④	⑤	⑥
22. After the incident, I did not feel positive emotions, such as joy, for a long time.	①	②	③	④	⑤	⑥
23. After the incident, I felt isolated from others.	①	②	③	④	⑤	⑥

24. After the incident, I felt as if my future life was shortened.	①	②	③	④	⑤	⑥
25. After the incident, I felt that I could not manage to live a healthy life.	①	②	③	④	⑤	⑥
26. I still live with the impacts of the incidents.	①	②	③	④	⑤	⑥
27. When the memory of the event occurs to me, I have a hard time taking care of my daily tasks.	①	②	③	④	⑤	⑥
28. Although a long time has passed, I sometimes still suffer from nightmares.	①	②	③	④	⑤	⑥
29. Although a long time has passed, I am often still distressed by the painful memories of the incident.	①	②	③	④	⑤	⑥
30. Although a long time has passed, I sometimes still feel as if I were reliving the same incident.	①	②	③	④	⑤	⑥
31. It is still very painful every time I see places, things, or people reminding me of the incident.	①	②	③	④	⑤	⑥
32. It is still very painful to see anything symbolizing or similar to the incident.	①	②	③	④	⑤	⑥
33. I am still withdrawn from people.	①	②	③	④	⑤	⑥
34. I am still very much afraid of experiencing a similar incident.	①	②	③	④	⑤	⑥
35. I still spend much time distracted and confused.	①	②	③	④	⑤	⑥
36. I sometimes still feel intense negative feelings since the incident.	①	②	③	④	⑤	⑥
37. I still feel less of positive emotions, such as joy, since the incident.	①	②	③	④	⑤	⑥
38. I sometimes still feel isolated from others.	①	②	③	④	⑤	⑥

39. I sometimes still feel as if my future life is shortened.	①	②	③	④	⑤	⑥
40. I still feel that I cannot manage to live a healthy life.	①	②	③	④	⑤	⑥

3. Impacts of Patient Safety Incident – 2

Item	Not true at all	Hardly true	True	Very much true	Extremely true
41. During the last years, there was a severe and negative life incident that hurt my feelings and caused considerable embitterment.	①	②	③	④	⑤
42. During the last years, there was a severe and negative life incident that led to a noticeable and persistent negative change in my mental well-being.	①	②	③	④	⑤
43. During the last years, there was a severe and negative life incident that I see as very unjust and unfair.	①	②	③	④	⑤
44. During the last years, there was a severe and negative life incident of which I had repetitively thought over.	①	②	③	④	⑤
45. During the last years, there was a severe and negative life incident that causes that caused me to be extremely upset when I was reminded of it.	①	②	③	④	⑤
46. During the last years, there was a severe and negative life incident that triggered me to harbor thought of revenge.	①	②	③	④	⑤
47. During the last years, there was a severe and negative life incident for which I had blamed and was with myself.	①	②	③	④	⑤
48. During the last years, there was a severe and negative life incident that led to either strive my willingness or became lethargic.	①	②	③	④	⑤
49. During the last years, there was a severe and negative life incident that made me feel sullen and unhappy.	①	②	③	④	⑤
50. During the last years, there was a severe and negative life incident that impaired my overall physical well-bing.	①	②	③	④	⑤

51. During the last years, there was a severe and negative life incident that made me avoid certain places or people that reminded me of the people associated with the event.	①	②	③	④	⑤
52. During the last years, there was a severe and negative life incident that made me feel helpless and disempowered.	①	②	③	④	⑤
53. During the last years, there was a severe and negative life incident that triggered feelings of satisfaction when I thought that the responsible party having to experience a similar situation as mine.	①	②	③	④	⑤
54. During the last years, there was a severe and negative life incident that led to a considerable decrease in my physical strength and drive.	①	②	③	④	⑤
55. During the last years, there was a severe and negative life incident that made me easily irritated than before.	①	②	③	④	⑤
56. During the last years, there was a severe and negative life incident that forced me to distract myself with business in order to experience a normal mood.	①	②	③	④	⑤
57. During the last years, there was a severe and negative life incident that made me unable to pursue occupational activities or have an interaction with family as before.	①	②	③	④	⑤
58. During the last years, there was a severe and negative life incident that caused me to draw back from friends and social activities.	①	②	③	④	⑤
59. During the last years, there was a severe and negative life incident which frequently evoked painful memories.	①	②	③	④	⑤

4. Socio-demographic factor

DQ1. What is your sex?

① Male ② Female

DQ2. What is your age?

( ) years old

DQ3. How many years have you practiced medicine (On the basis of period after the license acquisition)?

( ) years

DQ4. If you write down your cell phone number, we will assume that you have agreed to provide personal information and will provide 2 complimentary coffee coupons for participating in the survey. If you do not agree, do not fill out this form.

( )

The survey is completed.

Thank you for taking the time to complete this survey.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Check (page number)
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	✓ **(3)**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	✓ **(3-4)**
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	✓ **(5-6)**
Objectives	3	State specific objectives, including any prespecified hypotheses	✓ **(6)**
Methods			
Study design	4	Present key elements of study design early in the paper	✓ **(7)**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	✓ **(7)**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	✓ **(8-9)**
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	✓ **(8)**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	✓ **(7-8)**
Bias	9	Describe any efforts to address potential sources of bias	✓ **(8)**
Study size	10	Explain how the study size was arrived at	✓ **(8)**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	✓ **(9)**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	✓ **(8-9)**
		(*b*) Describe any methods used to examine subgroups	

	and interactions
	(*c*) Explain how missing data were addressed
	(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
	(*e*) Describe any sensitivity analyses

Continued on next page

Results			**Check (page number)**
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	✓ **(11)**
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	✓ **(11)**
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	✓ **(11-12)**
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	✓ **(11-12)**
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	✓ **(12)**
Discussion			
Key results	18	Summarise key results with reference to study objectives	✓ **(13)**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	✓ **(16)**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	✓ **(14-15)**
Generalisability	21	Discuss the generalisability (external validity) of the study results	✓ **(16)**
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	✓ **(18)**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Nurses' experiences of patient safety incidents in Korea: a cross-sectional study

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Nurses' experiences of patient safety incidents in Korea: a cross-sectional study

Title page

1. Author and Co-author's name

Eun Young Choi, Jeehee Pyo, Won Lee, Seung Gyeong Jang, Young-Kwon Park, Minsu Ock, Sang-Il Lee

2. The name, postal address, e-mail, telephone, and fax numbers of the corresponding author

1) Won Lee, RN, PhD

84 Heukseok-ro, Dongjak-gu, Seoul 06974, Republic of Korea

Email: oness38@hanmail.net

82-2-820-5742/82-2-820-5672

2) Minsu Ock, MD, PhD

877 Bangeojinsunhwando-ro, Dong-gu, Ulsan 44033, Republic of Korea

Email: ohohoms@naver.com

82-52-250-8793/82-52-250-7289

3. The full names, institutions, city, and country of all co-authors

Eun Young Choi[1,2], Jeehee Pyo[1,3], Won Lee[4†], Seung Gyeong Jang[5], Young-Kwon Park[6], Minsu Ock[1,6,7†], Sang-Il Lee[7]

[1]Department of Preventive Medicine, Ulsan University Hospital, University of Ulsan College of Medicine, Ulsan, Republic of Korea

[2]Department of Nursing, Graduate School of Chung-Ang University.

[3]Department of Preventive Medicine, Asan Medical Institute of Convergence Science and Technology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Republic of Korea

[4]Department of Nursing, Chung-Ang University, Seoul, Republic of Korea

[5]College of Nursing, The Catholic University of Korea, Seoul, Republic of Korea

[6]Prevention and Care Center, Ulsan University Hospital, Ulsan, Republic of Korea

[7]Department of Preventive Medicine, University of Ulsan College of Medicine, Seoul, Republic of Korea

4. Keywords

Second victims, Health & safety, Human resource management, Quality in health care

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3437 words

Nurses' experiences of patient safety incidents in Korea: a cross-sectional study

Abstract

Objectives: The aim of this study was to investigate the scope and severity of the second victim problem among nurses by examining the experiences and effects of patient safety incidents (PSIs) on them.

Participants/setting: 492 nurses who had experienced PSIs and provide direct care in South Korean medical institutions.

Design: A cross-sectional study with anonymous online self-report questionnaires was conducted to nurses in order to examine the experiences and effects of PSIs. Scales measuring post-traumatic stress disorder (PTSD) and post-traumatic embitterment disorder (PTED) were used for a more quantitative examination of the effects of PSIs. A chi-squared test was administered to find any difference in responses on difficulties due to PSIs between direct and indirect experience of PSIs. Furthermore, linear regression analysis was conducted to investigate the factors related to scores on the PTSD and PTED scales.

Results: A statistically significant difference was observed for participants who reported having experienced sleeping disorders, with those with direct experience showing 42.4% sleeping disorders and indirect experience at 21.0%. Also, there was a statistically significant difference between the 34.3% with direct experience and the 22.1% with indirect experience regarding having considered duty or job changes (resignation). Regression analysis showed total PTSD scores for indirect experience at 11.97 points (95% confidence interval: -17.31–-6.63), lower than direct experience. Moreover, those who thought medical error was not involved in PSI had a total PTED score 4.39 points (95% confidence interval: -7.23~-1.55) lower than those who thought it was involved.

Conclusions: A considerable number of nurses experienced psychological difficulties due to PSIs at levels that could interfere with their work. The effect of PSIs on nurses with direct experience of PSIs was greater compared to those with indirect experience. There need to be psychological support programs for nurses to alleviate the negative effects of PSIs.

Strengths and limitations of this study

- This study examined the experiences and effects of patient safety incidents (PSIs) on nurses who had experienced PSIs and provide direct care in South Korean medical institutions through a questionnaire.
- Nurses who experienced PSIs face difficulties such as sleep disorder, eating disorder, and nausea and dyspnea in similar situations, an impact that was more prominent in nurses who directly experienced PSIs.
- PTSD and PTED scores tended to significantly decrease as more time passed after a PSI.
- PTSD and PTED scores were found to be higher when there was belief that medical error was present.
- Further researches that designed as to compensate for limitation such as self-selection and representativeness, are needed.

INTRODUCTION

Medical personnel who experience emotional pain due to unanticipated adverse events, medical errors, and patient-related injuries are referred to as "second victims".[1] These second victims experience psychological pain, fear, decreased confidence, guilt, rage, exhaustion, and despair after patient safety incidents (PSIs),[2,3] and such symptoms are interpreted as indicators of post-traumatic stress disorder.[4] If the experiences of second victims aren't adequately treated, it can increase the likelihood of other errors due to fatigue, depression, and/or reduced sympathy.[5,6] It also leads to job changes and absences, negatively affecting the medical institution,[7] and efforts and approach to support second victims are required.

Since the term "second victim" appeared in 2000,[8] numerous studies have been conducted especially in the United States to investigate the second victim phenomenon and methods to support second victims. Discussions have continued in order to understand the prevalence and symptoms of second victims as well as to plan coping strategies and support programs.[2,3,9] Moreover, institutions such as the Institute for Healthcare Improvement and The Joint Commission have developed that provide guidelines to support second victims,[10,11] and individual medical institutions have also implemented support programs for second victims.[1,12] Such activities are gradually spreading throughout the United States and some countries in Europe.[6,12–14]

In South Korea, the *Patient Safety Act* was enacted in 2016 to establish the national Patient Safety Reporting & Learning System, building a foundation to systematically manage patient safety problems at the national level.[15] However, the focus remains on cause analysis and error prevention in PSIs, with relatively limited perception and research on counselling and supporting second victims.[16,17] A recent study by Lee et al.[15] showed that second victims

who experience PSIs in South Korea undergo various emotional reactions such as confusion, guilt, and depression, while also experiencing behavioral changes such as insomnia, avoidance, and considering job change, similar to findings in another previous study.[3] A study by Kim et al.[18] also showed that the effects of PSIs as perceived by Korean nurses were similar to those observed in a study in the United States.[7] This implies that the second victim phenomenon manifests similarly regardless of culture. Therefore, considering a study that has shown that all medical personnel are potential PSI or error victims and that almost half of medical personnel have had the experience of second victimization at least once in their clinical career,[19] the second victim phenomenon cannot be overlooked further, in South Korea as well.

A large number of patients are assigned to each South Korean nurse, and nurses have to provide various nursing services, such as the administration of medication and aid, within a set time. This environment occasionally affects nurses in a negative manner, which leads to exhaustion, disappointment, and despair at being unable to provide adequate treatment to patients.[20] This is also known to be the greatest factor leading nurses to consider changing jobs.[21] In this context, further difficulties will be added if a second victim problem occurs to the nurse. Thus, it is necessary to understand the pain nurses experience as second victims and to find ways of providing them with emotional support.

To this end, this study determined the Korean nurses' PSI experiences and impacts in various aspect, including post-traumatic stress disorder (PTSD) and post-traumatic embitterment disorder (PTED) scales.

METHODS

This was a cross-sectional study within the overall project of examining the PSI experiences of the general public, physicians, and nurses, and this study focused on the results of anonymous self-report online questionnaires administered to nurses. This study was approved by the Institutional Review Board of the University of Ulsan Hospital (IRB Number: 2018-07-003). All participants were notified of the purpose and process of this study and only those who agreed to participate conducted this survey. Each participant received a 4,500 won (about 3.7 US dollars) coffee coupon.

Questionnaire Development and Content

The questionnaire was developed and composed to enable comparison with the PSI experiences of the general public.[22] Questionnaire items were developed by referencing literature on the types and characteristics of PSIs[23–25] and previous studies on second victims.[3,26] The draft questionnaire was developed based on repeated discussions held among the entire research team (including 2 physicians and 3 nurses who have abundant research experience on patient safety). The questionnaire items and expressions were then refined based on the opinions of a nursing professor, the president of the Korean Intern Resident Association, and the CEO of a patient safety NGO. Furthermore, we conducted cognitive debriefing with 3 nurses to determine if there were any difficult or confusing parts in the survey questions or phrases.

The final questionnaire items can be classified as follows: 1) PSI characteristics; 2) the effects of PSI; 3) experience of disclosure of PSI; and 4) socio-demographic items. This study focused on the 1) PSI characteristics and 2) the effects of PSI. In further detail, 1) PSI characteristics included • covered type of PSI experience (direct or indirect), • elapsed time

since the most memorable PSI, • type of the most memorable PSI (diagnosis-related, patient care-related, etc.), • level of harm caused by the most memorable PSI, and • opinion on medical error relatedness of the most memorable PSI. In 2) the effects of PSI, • the effects of PSI and • the difficulties caused by the most memorable PSI were examined in categories of "sleep disorder;" "eating disorder;" "nausea, dyspnea, cold sweats, or stiffness in similar situations;" "vigilance in similar situations," and "consideration of duty or job changes." Additionally, the PTSD and PTED scales were used for a more quantitative examination of the effects of PSIs. For 4) socio-demographic items, the participants' sex, age, and elapsed time since license acquisition were collected. The full questionnaire can be found in the supplementary information ('Supplementary file 1').

PTSD and PTED Scales

PTSD[27] and PTED[28] scales used in previous studies were adopted. The PTSD scale, designed to measure the past and present effects of trauma, is composed of 30 items. Responses for the PTSD scale were defined as follows: 1 point for "Strongly Disagree," 2 points for "Disagree," 3 points for "Slightly Disagree," 4 points for "Slightly Agree," 5 points for "Agree," and 6 points for "Strongly Agree." The PTED scale, on exceptionally negative incidents in life, is composed of 19 items, used after modifying them to check the effects of the participants' most memorable PSI. Responses on the PTED scale were defined as follows: 1 point for "Strongly Disagree," 2 points for "Disagree," 3 points for "Slightly Disagree," 4 points for "Agree," and 5 points for "Strongly Agree."

Participants and Questionnaire Administration

Participants were nurses who had experienced patient safety incidents and provide direct care

in hospitals. The sample size of this study was determined in consideration of the study budget and the sample size of similar preceding studies.[22–25] Because this study focused on the analysis of current status rather than hypothesis testing, we did not set up parameters to determine sample size, such as effect size, alpha error, beta error, etc. Furthermore, the sampling error was not available because the non-probability sampling method was used, but it was intended to overcome the representativeness problem by recruiting as many participants as possible.

Online self-assessment questionnaires were administered over approximately 2 months, from April 2019 to May 2019. Since nurses may be unfamiliar with terminology related to patient safety, definitions of such terms, including *patient safety*, *medical error*, *adverse event*, and *patient safety incident*, were provided prior to the survey.[23,29,30] The survey was promoted via online blog posts and word-of-mouth among colleagues, and participants were gathered through snowball sampling. Participants were blocked from responding to the questionnaire more than once from the same IP address, to prevent possible repeated participation in the survey.

Analysis

First, the socio-demographic factors and experienced PSI characteristics were examined through a frequency analysis. A chi-squared test was conducted to determine whether there was a difference in responses on difficulties due to PSIs by direct versus indirect experiences. To analyze the results of the PTSD and PTED scales, total scores derived by aggregating the item responses for each scale were used for analysis. The range of total scores of the PTSD and PTED was from 30 to 180 and from 19 to 95, respectively. A linear regression analysis was conducted to examine the factors related to the PTSD and PTED scores, which were used as dependent variables. Socio-demographic factors (sex, age, and career stage), type of PSI

experience (direct and indirect), level of harm, elapsed time since PSI, and opinion on medical error relatedness of the PSI (Yes, No, I do not know) were included as independent variables. Participants who had experienced PSIs both directly and indirectly were classified under direct experience.

Microsoft Excel 2007 was used to organize data, and all data analysis was conducted with Stata/SE13.1 (StataCorp, Texas, TX). Results were deemed statistically significant at a p-value under 0.05.

Patient and Public Involvement

Patients or the public were not involved in the study design.

RESULTS

Socio-demographic Characteristics

A total of 492 nurses responded to the survey (Table 1). The absolute majority of the participants were female (470, 95.5%). The largest number of participants were in their 30s (244, 49.6%) in terms of age, with the greatest number having acquired their license between 10 and 20 years previously (183, 37.2%), followed by 5 to under 10 years (173, 35.2%) and under 5 years (112, 22.7%).

Characteristics of PSI Experiences

A total of 492 nurses provided responses regarding the characteristics of their PSI experiences. 297 nurses (60.4%) responded that they had directly experienced PSIs, while 195 (39.6%) had indirectly experienced them, through seeing or hearing of a coworker's incident. The largest number of memorable PSIs had occurred within 1 to under 5 years (205, 41.7%). For types of memorable PSIs (multiple responses possible), most were related to transfusion or IV injections (334, 67.9%), followed by PSIs related to patient care (269, 54.7%), and PSIs related to surgical procedure or treatment (104, 21.1%). Most PSIs were unharmful, according to 219 responses (44.5%), while incidents that resulted in permanent disability and in death were 23 (4.7%) and 41 (8.3%) respectively. A total of 297 participants (60.4%) believed that there had been medical error involved in the PSI, while 119 (24.2%) and 76 (15.4%) believed that medical error was not present and was uncertain respectively (Table 2).

Difficulties Following Direct and Indirect Experience of PSIs

Examining difficulties due to PSIs based on experience type, a statistically significant difference was observed, as 42.4% of those with direct experience but only 21.0% with indirect experience responded that they had experienced sleeping disorder due to the PSI.

33.3% of nurses with direct experience and 18.5% with indirect experience claimed to have experienced eating disorders. Statistically significant differences were also observed in experience of symptoms of nausea, dyspnea, cold sweats, or body tension when exposed to a similar situation, affecting 31.3% with direct experience and 21.5% with indirect experience. The difference between the 34.3% with direct experience who had considered changing duties or job (resignation) compared to the 21.1% with indirect experience who had was also found to be statistically significant (Table 3).

PTSD- and PTED-Related Factors

Linear regression results to find factors related to total PTSD and PTED scores of survey participants can be found in Table 4. PTSD scores were around 12.98 points (95% confidence interval: -25.68–-0.29) lower for females compared to males, and 11.73 points (95% confidence interval: 3.50–19.97) higher for nurses in their 30s and 13.60 points (95% confidence interval: 1.58–25.63) higher for those in their 40s or older compared to nurses in their 20s. Furthermore, total PTSD score was 11.97 points (-17.31–-6.63) lower for indirect experience compared to direct experience, and tended to decrease with increased elapsed time since the PSI. Finally, total PTSD score was 10.20 points (95% confidence interval: -16.52–-3.88) lower for nurses who did not believe that there had been a medical error compared to those who did.

PTED showed similar trends to PTSD: scores were around 6.51 points (95% confidence interval: -12.21–-0.81) lower for females than males, increased with age, and decreased with time elapsed since PSI. Additionally, PTED scores were 4.39 points (95% confidence interval: -7.23–-1.55) lower for those who did not think that there had been a medical error compared to those who did.

DISCUSSION

In this study, a questionnaire was administered to nurses who had experienced PSIs to investigate the impacts of PSIs, the difference in difficulties resulting from PSIs between direct and indirect experience, and factors related to post-PSI experience of PTSD and PTED. The characteristics of and difficulties resulting from PSIs experienced by 492 nurses were explored and the effects of incidents examined from various perspectives using the scores and factors affecting PTSD and PTED. While there have been previous studies in South Korea that examined the experiences of medical personnel who experienced error,[17] the coping process of medical personnel after experiencing PSIs,[26] and nurses' 2- and 3-dimensional experiences of PSIs,[18] almost no studies have been conducted on the topic of this study, that is, measuring factors relating to post-trauma and the difference between direct and indirect experience on the effects of PSI from various angles. A notably significant aspect of this study is that it verifies the need for support for nurses who experience PSIs and establishes base data and factors that can be considered when developing and implementing such support programs.

In this study, the most memorable type of PSI according to nurses was PSI related to transfusion or IV injection (67.9%), followed by PSI related to patient care, such as the occurrence of falls and pressure ulcers. According to the Korea Patient Safety Reporting & Learning System (KOPS), falling followed by medication error was reported to be the most frequent PSI by type, and in medication error reports, nurses appeared the most frequently under related personnel.[31] Despite the need to focus while administering medication given its potentially dangerous nature, interruption and disturbances during its measurement and administration are common due to inhibitors such as receiving telephone calls, patient and guardian reception, and communication with other health and medical personnel.[20] Previous

research reports that the risk of medication error increases due to such disturbances,[32] and that such medication error negatively affect nurses personally and professionally.[4,33] There is a necessity to reduce the negative effects of such PSIs by recognizing the common PSI experiences of nurses, analyzing their causes, and re-educating nurses based on the results.[33]

In all, 60.4% of the nurses who participated in this study had experienced PSIs. They can be seen to have frequent exposure to PSIs, as they are generally the medical professionals who work most closely with patients.[34] Harrison et al.[35] also found that nurses report more negative emotions after medical error, and this result was attributed to the nursing culture and the fact that nurses are in direct contact with the patients. In this regard, difficulties due to direct and indirect PSI experiences were examined separately in this study, and statistically significant differences between those with direct and indirect experience were seen for sleep disorder, eating disorder, symptoms such as nausea and dyspnea when exposed to a similar situation, and consideration of job or duty changes. There was a difference between direct and indirect experience on PTSD and PTED scale scores as well, with the PTSD scores for those with indirect experience being statistically significantly 11.97 points lower than for those with direct experience. As such, it was found that nurses who directly experience PSIs are affected to a greater degree in terms of psychological and physical symptoms as well as consideration of job changes. This is similar to the findings of Van Gerven et al.[36] in which medical personnel who had experienced a PSI in the past 6 months showed higher problematic medication use, burnout risk, and intention to change jobs compared to those who had not. In another study, physicians who had experienced an adverse event or a near miss were reported to have lower confidence, sleep disorder, and tension regarding the occurrence of PSIs.[37] Sleep disorder and symptoms of nausea, dyspnea, and body tension in particular directly influence patient safety, as they may cause additional PSIs.[38] Therefore,

psychological and administrative support must be provided to nurses exposed to PSIs, to minimize the negative effects on the psychological state of nurses and, by extension, on patient safety; in particular, nurses who directly experienced the incident should be prioritized for support and aid.

PTSD and PTED scores tended to significantly decrease as more time passed after a PSI. However, existing studies indicate that second victims actively try to overcome trauma after its occurrence and that such efforts may heal the wound but leave a scar.[2,26] In a study by Vanhaecht et al.[39] symptoms such as hypervigilance, flashbacks, shame, and doubts about one's knowledge and skill continued for over 6 months in some cases. Such results can be interpreted to mean that while post-incident trauma and frustration fade with time, they are not completely resolved, and that the type of difficulties varies across the stages. Thus, temporal factors such as whether it is immediately after the incident, medium-term, or long-term must be considered in developing second victim support programs,[26] and second victims must be managed so that such aid is seamlessly provided.

Existing research shows increased emotional difficulty when there is a possibility of medical malpractice,[40] which was also seen in this study, as PTSD and PTED scores were found to be higher when there was belief that medical error was present. On this note, a qualitative study on second victims expressed the need for institution-level support relating to medical malpractice and administrative processes that could result from PSIs.[26] Scott et al.[1] also proposed that long-term support and risk management directions should also be provided during legal proceedings stemming from PSIs if necessary. Medical malpractice cases are on the rise in South Korea, and nurses face increased risk of being involved in medical malpractice as their scope of work has expanded with the revisions to the *Medical Service Act*. As such, administrative and legal support, in addition to psychological support, should be

provided if necessary.

The limitations of this study are as follows. First, this was a cross-sectional study on the PSI experiences and difficulties of the participants, and we promoted participants through online blog posts and snowball sampling. Therefore, it is limited in its ability to assess change over time. According to existing research on the coping process of second victims, their experiences of PSIs and their impacts must be studied longitudinally as they undergo change over time.[2,26] Also, many of the study participants were female and younger nurses. In particular, with fewer male participants, the interpretation of gender comparisons should be careful, and further research that is designed to compensate for limitation is needed. Second, in this study, we did not identify the participants' work setting. According to Lewis et al, characteristics of the work unit such as the overall environment of the nursing unit, nurse manager, and so on were important to nurses' experiences of PSIs,[41] further research that includes the characteristics of the nursing unit is needed. Third, as participants were asked about their most memorable PSI, the possibility of recall bias regarding the characteristics and difficulties of their PSI experiences in their responses should be kept in mind when interpreting the data. Besides, follow-up studies should identify and analyze in detail the number and range of PSIs experienced by nurses. Fourth, the response rate was not obtained due to the methodological limitations of anonymous self-report online survey. Accordingly, information on the characteristics of those who refused to participate in the survey was not collected to ensure the anonymity of the participants. This limitation may restrict the representativeness of this study, but this study sought to overcome this problem by taking as many nurses as possible into the survey.

Despite the above limitations, a major source of significance of this study is that it analyzed the impacts of PSI experiences of nurses and the factors related to subsequent

trauma from various angles. It showed that nurses who experienced PSIs face difficulties such as sleep disorder, eating disorder, and nausea and dyspnea in similar situations, an impact that was more prominent in nurses who directly experienced PSIs. Furthermore, the examination of PTSD- and PTED-related factors for PSIs revealed their differential relation to direct and indirect experiences, elapsed time, and presence of medical error. Second victim support programs that can provide realistic help to nurses who have experienced PSIs must be developed, reflecting the results of this study. Moreover, to fully support second victims there need to be efforts to create a broader patient safety culture, with the active participation of the government and medical institutions.

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Table 1. Socio-demographic Information

		Frequency	%
Sex	Male	22	4.5
	Female	470	95.5
Age group	20s	195	39.6
	30s	244	49.6
	40s	40	8.1
	50 and older	13	2.7
Career after license acquisition	Under 5 years	112	22.7
	5 to under 10 years	173	35.2
	10 to under 20 years	183	37.2
	20 years or longer	24	4.9
Total		492	100.0

Table 2. Characteristics of PSIs Experienced by Research Participants

	Item	Frequency	%
PSI experience	Direct experience	115	23.4
	Indirect experience via seeing or hearing an incident experienced by a coworker at the same medical institution	195	39.6
	Both direct and indirect experiences	182	37.0
Elapsed time since PSI	Under 1 month	35	7.1
	1 to under 6 months	68	13.8
	6 months to under 1 year	65	13.2
	1 to under 5 years	205	41.7
	5 years or longer	119	24.2
Types of memorable PSIs (multiple responses)	PSIs related to diagnosis (misdiagnosis, delayed diagnosis, etc.)	63	12.8
	PSIs related to transfusion or IV injection (drug and transfusion complications, etc.)	334	67.9
	PSIs related to patient care (occurrence of falls, pressure ulcers, suicides, etc.)	269	54.7
	PSIs related to surgical procedure or treatment (post-endoscopy enterobrosia, etc.)	104	21.1
	PSIs related to infections (surgical site infections, catheter-associated urinary tract infection, etc.)	87	17.7
	Other PSIs	26	5.3
PSI level of harm	No harm	219	44.5
	Under 1 month required for harm recovery	138	28.0
	1 to under 6 months required for harm recovery	50	10.2
	6 months or longer required for harm recovery	21	4.3
	Resulted in permanent disability	23	4.7
	Death	41	8.3
Medical-error-relatedness of PSIs	Yes	297	60.4
	No	119	24.2
	I do not know	76	15.4
Total		492	100.0

Table 3. Difficulties Following Direct and Indirect Experience of PSIs

	Direct (N=297)		Indirect (N=195)		P-value	95% confidence interval for difference	
	n	%	n	%		Lower	Upper
Experienced sleep disorders	126	42.4%	41	21.0%	<0.001	13.4%	29.4%
Experienced eating disorders	99	33.3%	36	18.5%	<0.001	7.2%	22.5%
Experienced symptoms of nausea, dyspnea, cold sweats, or body tension when exposed to a similar situation	93	31.3%	42	21.5%	0.017	2.0%	17.6%
Hypervigilance toward a similar situation	120	40.4%	68	34.9%	0.217	-3.2%	14.2%
Considered changing duties or job (resignation)	102	34.3%	43	22.1%	0.003	4.4%	20.2%

Table 4. Regression Analysis of Factors Related to PTSD and PTED Instrument Scores

	PTSD			PTED		
	Coefficient	95% confidence interval		Coefficient	95% confidence interval	
		Lower	Upper		Lower	Upper
Gender						
Male	Ref			Ref		
Female	-12.98	-25.68	-0.29	-6.51	-12.21	-0.81
Age group						
20s	Ref			Ref		
30s	11.73	3.50	19.97	5.83	2.13	9.52
≥40s	13.60	1.58	25.63	9.70	4.30	15.10
Career						
<5	Ref			Ref		
5-10	5.18	-2.69	13.05	2.16	-1.37	5.70
≥10	-4.64	-15.15	5.87	-3.08	-7.80	1.64
Level of harm						
Under 1 month	Ref			Ref		
1 month or longer	5.18	-2.38	12.74	4.77	1.38	8.17
Permanent disability or death	-3.64	-11.50	4.23	-0.97	-4.50	2.56
Experience of PSIs						
Direct experience	Ref			Ref		
Indirect experience	-11.97	-17.31	-6.63	-1.48	-3.88	0.92
Elapsed time since PSIs						
Under 6 months	Ref			Ref		
6 months to under 5 years	-7.64	-14.42	-0.86	-5.12	-8.17	-2.08
5 years or longer	-11.02	-19.60	-2.44	-6.64	-10.49	-2.79
Medical-error-relatedness of PSIs						
Yes	Ref			Ref		
No	-10.20	-16.52	-3.88	-4.39	-7.23	-1.55
I do not know	-4.70	-12.08	2.68	-3.81	-7.12	-0.49

Survey on the Patient Safety Incident Experience

Department of Preventive Medicine, Ulsan University Hospital

Dear participants,

In this survey, we are attempting to understand the magnitude and impact of trauma injuries in Korea. The results of this survey will be used as a practical resource for the future development of a patient safety incident trauma recovery support program. Securing your personal information will be our utmost priority. The results of this study will be used only for academic purposes, and your personal information will be anonymized to prevent verification even for academic usage. The survey will take about 15 minutes, and you will receive two complimentary coffee coupons if you leave your cell phone number when you complete the survey.
Thank you for taking the time to cooperate and help our research.

September 2018

1. Characteristics of Patient Safety Incident

<Term Verification>

• Patient safety
- World Health Organization: "The prevention of errors and adverse effects to patients associated with health care."
• Error
- Failure to complete the intended action as planned(error in execution) or failure to construct a plan to achieve goals(error in planning)
• Adverse event
- American International Organization of Migration: "Damage resulted by an act of medical practice rather than by the underlying disease of the patient."
• Patient safety incident - Incidents of adverse event and medical error
• Medical accident
- Physical incidents during the entire process of medical practices, such as patient diagnosis, examination, and treatment, at a medical institution regardless of a doctor's error.

1. Have you ever experienced a **patient safety incident (PSI)**?

① I have a direct experience of a PSI. ☞ **Go to item 3**

② I have an indirect experience of a PSI, such as witnessing or hearing a PSI of a colleague in the same medical institution. ☞ **Go to item 3**

③ I have both direct and indirect experiences of PSIs. ☞ **Go to item 3**

④ I have never experienced a PSI. ☞ **End of the survey**

2. **How long is the elapsed time** since your experience of **the most memorable patient safety incident**?

① Less than a month

② More than a month to less than six months

③ More than six months to less than a year

④ More than one year to less than five years

⑤ More than five years

3. Please select **all types** of **patient safety incidents (PSI),** which were **the most memorable** to you. (Select all that apply).

① Diagnosis-related PSI (e.g., diagnosis error, delayed diagnosis, etc.)

② Medication, fluid administration and transfusion-related PSI (e.g., side effects of medication and transfusion, etc.)

③ Patinet care-related PSI (e.g., fall, pressure ulcer, suicide, etc.)

④ Surgery or procedure-related PSI (e.g., enterobrosia from an endoscope, etc.)

⑤ Infection-related PSI (e.g., surgical site infection, catheterization-related urinary tract infection, etc.)

⑥ Other PSI (Please describe:)

4. **How much harm** did **the most memorable patient safety incident** of your cause?

* **"Harm recovery"** means discharge or termination of treatment.

① No harm

② It took less than a month to recover from the harm

③ It took more than a month to less than six months to recover from the harm

④ It took more than six months to recover from the harm

⑤ It left permanent disability

⑥ Death

5. Do you think your most memorable **patient safety incident** has **a medical error**?

① There was a medical error

② There was not a medical error

③ I do not know

6. Have you experienced the following **difficulties** from your **most memorable patient safety incident** (PSI)?:

Difficulties from PSI	Yes	No
6-1. Experienced s**leep disorder** (insomnia, Insomnia, excessive sleep, nightmares, etc.)	①	②
6-2. Experienced **eating disorder** (anorexia, overeating)	①	②
6-3. Experienced symptoms such as **dizziness, dyspnea, cold sweating, or stiffness** at the time of the exposure of a similar incident	①	②
6-4. **Became excessively vigilant** at the time of the exposure of a similar incident (avoidance, asking colleagues to complete the task, etc.)	①	②
6-5. Considered **change of profession** or **job (resignation)**	①	②

7. Have you encountered any of the following **countermeasures** for your most memorable **patient safety incident**?

Disclosure of PSI	Yes	No
7-1. A medical professional **honestly disclosed the incident** to patients before the request of **patients and their caregivers**	①	②
7-2. A medical professional **shared empathy and regret** the incident before the request of patients and their caregivers	①	②
7-3. A medical professional promised an inquiry before the request of patients	①	②
7-4. A medical professional **delivered the fact** that there was no medical error from a completed inquiry to **patients and their caregivers**	①	②
7-5. A medical professional **delivered a sincere apology to patients and their caregivers** as a medical error was confirmed through an inquiry	①	②
7-6. **Offered adequate compensation** for the harm of patients	①	②
7-7. A medical professional made a **promise of preventing similar recurring incidents** to patients and their caregivers	①	②

2. Impacts of Patient Safety Incident – 1

Item	Strongly disagree	Disagree	Slightly disagree	Slightly agree	Agree	Strongly agree
11. At the time of the incident, it had an extreme impact on me.	①	②	③	④	⑤	⑥
12. After the incident, I had difficulty carrying out my daily life in the following days.	①	②	③	④	⑤	⑥
13. After the incident, I was suffered from nightmares.	①	②	③	④	⑤	⑥
14. After the incident, I was distressed by the painful memories of the incident.	①	②	③	④	⑤	⑥
15. After the incident, I felt as if I were re-living the incident.	①	②	③	④	⑤	⑥
16. After the incident, it was very painful every time I saw places, things, or people reminding me of the incident.	①	②	③	④	⑤	⑥
17. After the incident, it was very painful to see anything symbolizing or similar to the incident.	①	②	③	④	⑤	⑥
18. After the incident, I was withdrawn from others for a long time.	①	②	③	④	⑤	⑥
19. After the incident, I was very much afraid of experiencing a similar incident.	①	②	③	④	⑤	⑥
20. After the incident, I spent much time distracted and confused.	①	②	③	④	⑤	⑥
21. After the incident, I felt intense negative emotions.	①	②	③	④	⑤	⑥
22. After the incident, I did not feel positive emotions, such as joy, for a long time.	①	②	③	④	⑤	⑥
23. After the incident, I felt isolated from others.	①	②	③	④	⑤	⑥

24. After the incident, I felt as if my future life was shortened.	①	②	③	④	⑤	⑥
25. After the incident, I felt that I could not manage to live a healthy life.	①	②	③	④	⑤	⑥
26. I still live with the impacts of the incidents.	①	②	③	④	⑤	⑥
27. When the memory of the event occurs to me, I have a hard time taking care of my daily tasks.	①	②	③	④	⑤	⑥
28. Although a long time has passed, I sometimes still suffer from nightmares.	①	②	③	④	⑤	⑥
29. Although a long time has passed, I am often still distressed by the painful memories of the incident.	①	②	③	④	⑤	⑥
30. Although a long time has passed, I sometimes still feel as if I were reliving the same incident.	①	②	③	④	⑤	⑥
31. It is still very painful every time I see places, things, or people reminding me of the incident.	①	②	③	④	⑤	⑥
32. It is still very painful to see anything symbolizing or similar to the incident.	①	②	③	④	⑤	⑥
33. I am still withdrawn from people.	①	②	③	④	⑤	⑥
34. I am still very much afraid of experiencing a similar incident.	①	②	③	④	⑤	⑥
35. I still spend much time distracted and confused.	①	②	③	④	⑤	⑥
36. I sometimes still feel intense negative feelings since the incident.	①	②	③	④	⑤	⑥
37. I still feel less of positive emotions, such as joy, since the incident.	①	②	③	④	⑤	⑥
38. I sometimes still feel isolated from others.	①	②	③	④	⑤	⑥

39. I sometimes still feel as if my future life is shortened.	①	②	③	④	⑤	⑥
40. I still feel that I cannot manage to live a healthy life.	①	②	③	④	⑤	⑥

3. Impacts of Patient Safety Incident – 2

Item	Not true at all	Hardly true	True	Very much true	Extremely true
41. During the last years, there was a severe and negative life incident that hurt my feelings and caused considerable embitterment.	①	②	③	④	⑤
42. During the last years, there was a severe and negative life incident that led to a noticeable and persistent negative change in my mental well-being.	①	②	③	④	⑤
43. During the last years, there was a severe and negative life incident that I see as very unjust and unfair.	①	②	③	④	⑤
44. During the last years, there was a severe and negative life incident of which I had repetitively thought over.	①	②	③	④	⑤
45. During the last years, there was a severe and negative life incident that causes that caused me to be extremely upset when I was reminded of it.	①	②	③	④	⑤
46. During the last years, there was a severe and negative life incident that triggered me to harbor thought of revenge.	①	②	③	④	⑤
47. During the last years, there was a severe and negative life incident for which I had blamed and was with myself.	①	②	③	④	⑤
48. During the last years, there was a severe and negative life incident that led to either strive my willingness or became lethargic.	①	②	③	④	⑤
49. During the last years, there was a severe and negative life incident that made me feel sullen and unhappy.	①	②	③	④	⑤
50. During the last years, there was a severe and negative life incident that impaired my overall physical well-bing.	①	②	③	④	⑤

51. During the last years, there was a severe and negative life incident that made me avoid certain places or people that reminded me of the people associated with the event.	①	②	③	④	⑤
52. During the last years, there was a severe and negative life incident that made me feel helpless and disempowered.	①	②	③	④	⑤
53. During the last years, there was a severe and negative life incident that triggered feelings of satisfaction when I thought that the responsible party having to experience a similar situation as mine.	①	②	③	④	⑤
54. During the last years, there was a severe and negative life incident that led to a considerable decrease in my physical strength and drive.	①	②	③	④	⑤
55. During the last years, there was a severe and negative life incident that made me easily irritated than before.	①	②	③	④	⑤
56. During the last years, there was a severe and negative life incident that forced me to distract myself with business in order to experience a normal mood.	①	②	③	④	⑤
57. During the last years, there was a severe and negative life incident that made me unable to pursue occupational activities or have an interaction with family as before.	①	②	③	④	⑤
58. During the last years, there was a severe and negative life incident that caused me to draw back from friends and social activities.	①	②	③	④	⑤
59. During the last years, there was a severe and negative life incident which frequently evoked painful memories.	①	②	③	④	⑤

4. Socio-demographic factor

DQ1. What is your sex?

① Male ② Female

DQ2. What is your age?

( ) years old

DQ3. How many years have you practiced medicine (On the basis of period after the license acquisition)?

( ) years

DQ4. If you write down your cell phone number, we will assume that you have agreed to provide personal information and will provide 2 complimentary coffee coupons for participating in the survey. If you do not agree, do not fill out this form.

( )

The survey is completed.

Thank you for taking the time to complete this survey.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Check (page number)
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	✓ **(3)**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	✓ **(3-4)**
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	✓ **(5-6)**
Objectives	3	State specific objectives, including any prespecified hypotheses	✓ **(6)**
Methods			
Study design	4	Present key elements of study design early in the paper	✓ **(7)**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	✓ **(7)**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	✓ **(8-9)**
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	✓ **(8)**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	✓ **(7-8)**
Bias	9	Describe any efforts to address potential sources of bias	✓ **(8)**
Study size	10	Explain how the study size was arrived at	✓ **(8)**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	✓ **(9)**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	✓ **(8-9)**
		(*b*) Describe any methods used to examine subgroups	

	and interactions
	(*c*) Explain how missing data were addressed
	(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
	(*e*) Describe any sensitivity analyses

Continued on next page

Results			**Check (page number)**
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	✓ **(11)**
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	✓ **(11)**
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	✓ **(11-12)**
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	✓ **(11-12)**
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	✓ **(12)**
Discussion			
Key results	18	Summarise key results with reference to study objectives	✓ **(13)**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	✓ **(16)**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	✓ **(14-15)**
Generalisability	21	Discuss the generalisability (external validity) of the study results	✓ **(16)**
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	✓ **(18)**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.