

# Occurrence of patient safety incidents during cancer screening

## A cross-sectional investigation of the general public

Noor Afif Mahmudah, MD, MSc<sup>a</sup>, Dasom Im, MC<sup>b</sup>, Jeehee Pyo, PhD cand<sup>c</sup>, Minsu Ock, MD, PhD<sup>b,c,d,\*</sup>

#### Abstract

This study aimed to explore the various types and frequency of patient safety incidents (PSIs) during a cancer screening health examination for the general public of Ulsan Metropolitan City, South Korea. Furthermore, the associated elements and responses to PSIs during a cancer screening were examined. The survey, conducted in the five districts of Ulsan, was completed by residents aged 19 years and older who agreed to participate. Descriptive analysis, Chi-square or Fisher exact test, and multivariable logistic regression were performed to analyze the data. A total of 620 participants completed the survey, with 11 (1.8%) individuals who experienced PSIs themselves and 11 (1.8%) by their family members. The highest type of PSIs was those related to procedures. The multivariable logistic regression analysis showed no significant variables associated with experiencing PSIs during cancer screening. However, there was a significant association between the judgment of medical error occurrence and level of patient harm both in experience of PSIs disclosure (P < .001). This study comprehensively analyzed the types and extent of PSIs experienced by Korean individuals and their family members in Ulsan. These findings suggest that patient safety issues during cancer screening should not be overlooked. Furthermore, an investigation system to regularly monitor PSIs in cancer screening should be developed and established.

Abbreviations: CI = confidence interval, OR = odds ratio, PSIs = Patient Safety Incidents, SD = standard deviation.

Keywords: adverse event, early detection of cancer, medical error, patient safety, patient safety incident

## 1. Introduction

The World Health Organization (WHO) defines patient safety as "the absence of preventable harm to a patient during the process of healthcare and reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum".<sup>[1]</sup> This definition embodies patient safety as a task that encompasses the comprehensive healthcare service and is not limited to administration, surgical procedures, and other specific treatment processes.<sup>[2]</sup> Providing safe healthcare services involves various healthcare domains, such as thriving and safe advanced surgeries and surgical procedures at tertiary hospitals to primary health care, emergency care, long-term care, rehabilitation, and other settings.<sup>[3–6]</sup> This notion is also applied to periodic health examinations for the entire population.

A health examination is a widely employed strategy to prevent premature death and decreased quality of life from disease through early diagnosis and treatment.<sup>[7]</sup> Specialized health

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

Supplemental Digital Content is available for this article.

examinations of particular diseases, such as various cancers (cervical, breast, and colorectal) and diabetic retinopathy, and specific populations, such as infants, expectant mothers, and laborers, have been conducted worldwide.<sup>[8]</sup> However, unintended harm may incur from health examinations, such as additional medical resource consumption, anxiety caused by a false positive,<sup>[9,10]</sup> delayed diagnosis due to a false negative,<sup>[11]</sup> and overdiagnosis.<sup>[12]</sup> Furthermore, medical practice from a health examination may cause harm.<sup>[13,14]</sup>

The prospect of harm from a health examination outweighs the benefits with good intentions could decrease the intent of undergoing health examinations. Thus, it is essential to incorporate the value of patient safety in health examinations.<sup>[8]</sup> First, an extensive evaluation of the possible harm during health examinations, such as patient safety issues,<sup>[15]</sup> should be conducted. The evaluation should compromise test performance as well as various circumstances of patient safety, such as adverse drug reactions, surgical procedure complications, diagnosis-related

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NAM and DI contributed equally to this work.

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<sup>&</sup>lt;sup>a</sup> Department of Family and Community Medicine, Faculty of Medicine, Public Health and Nursing, Universitas Gadjah Mada, Yogyakarta, Indonesia,

<sup>&</sup>lt;sup>b</sup> Department of Preventive Medicine, Ulsan University Hospital, University of Ulsan College of Medicine, Ulsan, Republic of Korea, <sup>c</sup> Task Forces to Support Public Health and Medical Services in Ulsan Metropolitan City, Ulsan, Republic of Korea, <sup>d</sup> Department of Preventive Medicine, University of Ulsan College of Medicine, Seoul, Republic of Korea

<sup>\*</sup> Correspondence: Minsu Ock, Department of Preventive Medicine, Ulsan University Hospital, University of Ulsan College of Medicine, 877 Bangeojinsunhwando-ro, Dong-gu, Ulsan 44033, Republic of Korea (e-mail: ohohoms@naver.com).

events, and others. Nonetheless, there is a scarcity of inclusive studies on the frequency and types of patient safety incidents (PSIs) during health examinations.<sup>[8,16]</sup>

This study explored the various types and frequency of PSIs during a cancer screening health examination for the general public of Ulsan Metropolitan City (hereafter termed Ulsan), South Korea. Furthermore, the associated elements and responses of PSIs during the cancer screening were examined.

## 2. Methods

#### 2.1. Study design

This study adopted a cross-sectional survey design. The survey was conducted by Ulsan Regional Cancer Center with cooperation from a professional research company, Gallup Korea, from March 18 to 21, 2021, to identify the experiences and perceptions of Ulsan residents regarding cancer screening and prevention rules. The survey comprised sociodemographic characteristics, whether they had cancer screening experience, perception regarding actual and hypothetical patient safety incident experience during a cancer screening, and awareness of cancer preventive measures. This study focused on patient safety incident experiences during cancer screening.

#### 2.2. Setting and participants

Participants were recruited from five districts of Ulsan using a multi-stage stratified quota sampling method based on sex, age group, and region. This study included 620 Ulsan residents with inclusion criteria of age over 19 years old. The sampling data was based on the national resident registration population data of the Ministry of Government Administration and Home Affairs as of 2021.

For the participant recruitment process, a surveyor approached a potential participant on the street of a designated area based on the predefined quota. Every participant was informed of the study purpose, voluntary participation, withdrawal opportunities without disadvantages at any point of the survey process, anonymous data storage period, and the disposal process. Only participants who provided informed consent were recruited. The surveyor enquired regarding the participant's eligibility based on gender, age, and place of residency. The participant proceeded if they met the eligibility criteria.

#### 2.3. Development of the survey items

The survey enquired about participants' sociodemographic factors, the type of PSIs experienced, and the characteristics of the incident both at individual and family levels. The sociodemographic factors consisted of seven questions: resident district, age, gender, self-rated health status, education level, occupation, and household income level. Next, one question about the type of incident participants experienced was asked, and no limitation were set for the recall period as in previous studies.<sup>[17-19]</sup> It further identified the following characteristics of the incident the frequency, type, elapsed time since the incident, damage level, the judgment of medical error occurrence, and medical professionals' responses (25 questions).<sup>[17,20]</sup> The survey also identified the type of incident the participants' family members experienced (1 question) and defined family members as parents, siblings, and children, as in a previous study.<sup>[17]</sup> The characteristics of each type of incident (25 questions) the participants' family members experienced were also investigated. Three general people reviewed the word appropriateness of the questionnaire, and modifications were made to reflect their opinions. The questionnaire used in the survey has been attached in the Supplement (Supplement 1, Supplemental Digital Content, http://links.lww. com/MD/H704).

#### 2.4. Conducting the survey

Prior to the survey execution, a one-and-a-half-hour surveyor training session was held on February 19, 2021. The training involved the survey's criteria, the definition of PSIs-related terminology, survey correspondence methods, and others.

The survey was conducted face-to-face using a PC table in a self-administrated style. In the beginning, a surveyor explained a definition of patient safety, medical error, adverse event, and PSIs to the participant via a supplementary definition card. The PSIs included PSIs related to diagnosis, drug administration, procedure, infection, and others (Table 1). Participants with limited vision were assisted with a physical scale card to answer the questions. Those who completed the survey received a gift worth approximately 3000 KRW (USD 3).

#### 2.5. Analysis and ethical approval

Data were analyzed via SPSS version 23.0 (IBM Corp, New York, NY). First, descriptive analysis was performed to define the survey responses. Further, a Chi-square test or Fisher exact test was used to identify the proportional differences between the current and previous study<sup>[17]</sup> regarding patient safety incident experiences at personal and family levels according to the following variables: had experiences of PSIs, type and harm level of a patient safety incident, and judgment of medical error occurrence. Furthermore, multivariable logistic regression was performed to determine participants' features related to PSI experience. For logistic regression, the associations were demonstrated as odds ratio (OR) with 95% confidence intervals

 Table 1

 Definition of the terminology used in the questionnaire.

Terminology	Definition
Patient safety	Based on World Health Organization: "Preventing medical
	errors and adverse events that occur to patients."
Error	Failure to complete planned actions as intended (error in
	execution) or poorly planning to achieve goals (error
	in planning)
Adverse event	According to the United States Institute of Medicine:
	"Injury resulting from medical practice and not due to
	the patient's underlying disease."
Medical accident	All personal accidents that occur in the entire process
	of medical care, including diagnosis, examination,
	and treatment of patients at medical institutions,
	regardless of the doctor's negligence
Patient safety	Any incident, including adverse events and medical
incidents	errors related to the diagnosis, such as incorrect
related to the	diagnosis, delayed diagnosis, etc.
diagnosis	
Patient safety	Any incident, including adverse events and medical
incidents	errors related to the drug administration, such as
related to	overdose, contrast agent allergy, dyspnea due to
the drug	sedatives, etc.
administration	
Patient safety	Any incident, including adverse events and medical errors
incidents	related to the procedures, such as persistent pain and
related to the	bleeding or intestinal perforation after endoscopy; or
procedures	Patient safety incidents related to theexamination, for
	instance, radiation-related harm, pain, etc.
Patient safety	Any incident, including adverse events and medical
incidents	errors related to the infection, for example, infection at
related to the	the procedure or test site, etc.
infection	
Other patient	Any incident, including adverse events and medical
safety	errors related to other than diagnosis, drug adminis-
incidents	tration, procedures, and infection.

(CI). The presented OR was the result of logistic regression of each predictor variable after adjusting for all predictors in the model. The predictor variables selected were based on the earlier study.<sup>[17]</sup> Dependent variables were both PSIs experienced by personal and by family. Independent variables were socio-demographics, which included age group (19-29, 30-39, 40-49, 50-59, or ≥60 years), gender (male or female), education level (middle school or lower, high school or attending college, or college or higher), and household income level (<KRW 3 million, KRW 3-5 million, or > KRW 5 million).

This study was approved by the Institutional Review Board of Ulsan University Hospital (Serial number: 2021-02-017-003). All participants provided informed consent. This study was conducted in accordance with the code of ethics set by the Declaration of Helsinki and its future amendments or comparable standards.

## 3. Results

Initially, 1824 people were contacted to complete the survey. Of these, 620 respondents (response rate: 34.0%), who completed the survey, were included. The sociodemographic characteristics of the participants are shown in Table 2. Participants' mean age was 47.6 years (standard deviation [SD]  $\pm$  15.1). The proportion of either age groups or sex between our survey participants and the Ulsan general population was not significantly different based on the national resident registration as of mid-2021, as published by the Korean Statistical Information Service.<sup>[21]</sup>

Among 620 participants, 11 (1.8%) individuals experienced PSIs themselves. The mean age was 56.3 years (SD ± 15.7), the majority being in the 50 to 59 years (n = 4, 36.4%) and more than 60 years (n = 4, 36.4%) age groups. Females experienced more PSIs compared to males (Table 3). The type of PSIs mainly was related to procedures (n = 8, 72.7%), followed by one case (9.1%) each of diagnosis, drug, fluid or blood, and others. Among the PSIs, 10 cases (90.9%) reported no harm, and one case (9.1%) reported recovery in less than a month. Participants thought medical errors occurred for three PSIs (27.3%). From the comparison with the previous study,<sup>[17]</sup> we observed a significant difference (P = .01) between the characteristic of medical error in participants' own experience of PSIs (Table 4).

Furthermore, 11 (1.8%) individuals reported their family members also experienced PSIs. The mean age was 49.7 years (SD  $\pm$  12.2), the majority in the 50 to 59 years age group (n = 5, 45.5%). In contrast to the PSIs' of one's own experience, the male reported more PSIs experienced by family than by personal (Table 3). The type of PSIs was mainly related to procedures (n = 6, 54.5%), followed by diagnosis (n = 3, 27.3%) and drug, fluid, or blood (n = 2, 18.2%). Three PSIs (27.3%) left permanent impairment, and one (9.1%) required more than a month to recover. Participants thought medical errors occurred for five PSIs (45.5%). Compared to the previous study,<sup>[17]</sup> we also observed a significant difference (P < .01) between the characteristic of medical error in PSIs experienced by the family of participants (Table 4). The description of the PSIs' experience at the individual and family level is provided in Supplement (Supplement 1, Supplemental Digital Content, http://links.lww.com/MD/H705).

The multivariable logistic regression analysis showed no significant variables related to experiencing PSIs during cancer screening (Table 5). Meanwhile, the proportion of judging that a medical error had occurred was higher for PSIs experienced by the family (n = 5, 62.5%) compared with one's own experiences (n = 3, 37.5%), as shown in Table 6. In total, 100% (4) of diagnosis-related PSIs were regarded as medical errors, and 28.6% (4) of procedure-related PSIs were considered as medical errors. Furthermore, although 42.9% (6) of PSIs without any harm were suspected of having been associated with medical error, 100% of PSIs that took more than a month to recover or resulted in permanent impairment were regarded to be caused

by medical error. There was a significant association between the judgment of medical error occurrence (P = .038) and level of patient harm (P = .032) both in experience by family members and total experience of PSIs.

Table 7 shows how the general public, with direct or indirect experience with PSIs, experienced PSI disclosure. Two items of PSI disclosure, namely being truthful about the incident and expressing empathy and regret before requested by a patient and caregiver, had higher experience than other items. We also observed a significant difference between whether they had a PSI disclosure experience (P < .001).

## 4. Discussion

This study used a survey to identify the frequency, characteristics, and risk factors of PSIs during cancer screening of the general Korean population of Ulsan. A total of 3.6% (22) participants responded that they or their family members had experienced PSIs during a cancer screening. There have been limited comprehensive studies regarding the types and frequency of PSIs in cancer screening, contrasting to the necessity of providing safe healthcare services during health examinations, such as cancer screenings. The findings of this study imply significance in understanding the scale of PSIs in cancer screening.

An individual's lifetime experience rate of PSIs related to cancer screening is 1.8 cases per 100 populations. There are six types of national cancer screening programs in Korea, such as for stomach and liver cancers, and approximately six million people were screened per year as of 2020.<sup>[22,23]</sup> Extrapolating the scope of possible PSIs from the national cancer screening based on this information, approximately 108,000 people will experience PSIs during a cancer screening in their lifetime (1.8 cases \* 60,00,000 people/100 people). Furthermore, approximately 3600 people per year would experience PSIs during the cancer screening (108,000 people/30 years), assuming one person undergoes cancer screening for 30 years in their lifetime. Therefore, it is essential to improve the quality of cancer screening at the national level by regularly monitoring the occurrence and identifying the causes of PSIs during cancer screening.

It is challenging to interpret the extent of PSIs in cancer screening from this study due to the limited comparability caused by differences in the research method, participants, scope, and indicators of previous studies. However, compared with a previous study conducted in Korea,<sup>[17]</sup> likely to have high comparability due to similarity in the research method, the PSI rate of cancer screening was relatively lower than that of hospitalization in this study. Furthermore, based on the type of PSIs, the procedure-related PSI rate (individual rate 72.7%, family member rate 54.5%) was higher than that reported by the previous Korean study. This discrepancy might be due to the characteristics of cancer screening which uses various types of invasive procedures, such as gastroscopy. Most were bleeding or sedative-related side effects that could occur during gastric and colorectal cancer screening.

Nonetheless, the degree of harm during cancer screening was relatively low, and the proportion of judging whether a medical error had occurred was lower than in the previous Korean study.<sup>[17]</sup> The PSIs' degree of harm and the ratio of judging whether a medical error had occurred were higher at the family level than the individual level. However, they were lower than the findings of the previous Korean study.<sup>[17]</sup> A statistically significant relationship was identified between the type of PSIs, the degree of harm, and the judgment of medical error occurrence, similar to the previous Korean study.<sup>[17]</sup> Mainly, all diagnosis-related PSIs were judged to have medical errors. Hence, to enhance patient safety in cancer screening, it is essential to have strategies to minimize diagnosis-related PSIs, such as delay in diagnosis and diagnostic error, which could result in medical litigation.<sup>[24]</sup>

## Table 2

Socio-demographic characteristics of the study participants

Variable	Cu	urrent study (n = 620)	Regist	P-value	
	N	%	N	%	
Age group					.282
19–29	102	16.5	152,388	15.8	
30–39	105	16.9	147,641	15.3	
40-49	124	20	184,713	19.1	
50–59	137	22.1	207,057	21.4	
≥60	152	24.5	274,914	28,4	
Sex			,	,	.771
Male	316	51	487,056	50.4	
Female	304	49	479,656	49.6	
Educational level					_
Middle school or below	61	9.8	_	_	
High school or attending college	382	61.6	_	_	
College or above	177	28.5	_	_	
Occupation					_
Blue collar	342	55.2	_	_	
White collar	111	17.9	_	_	
Others	167	26.9	_	_	
Household Income level					_
<krw 3="" million<="" td=""><td>109</td><td>17.6</td><td>_</td><td>_</td><td></td></krw>	109	17.6	_	_	
KRW 3–5 million	325	52.4	_	_	
>KRW 5 million	186	30	_	_	
Self-rated health					_
Excellent	119	19.2	_	_	
Very good	399	64.4	_	_	
Good	78	12.6	_	_	
Fair	23	3.7	_	_	
Poor	1	0.2	_	_	

KRW = Korean Won.

\*Data were from the Korean Statistical Information Service for Ulsan Population in mid-year 2021.[21]

## Table 3

Experience of patient safety incidents according to the socio-demographic characteristics.

			Own experience (n = 11)	Experienced by a Family member (n = 11)		
Variable	Total number of participants	N	% of total	Ν	% of total	
Age group						
19–29	102	1	1.0	1	1.0	
30–39	105	0	0.0	3	2.9	
40-49	124	2	1.6	1	0.8	
50-59	137	4	2.9	5	3.6	
≥60 years	152	4	2.6	1	0.7	
Sex						
Male	316	3	0.9	6	1.9	
Female	304	8	2.6	5	1.6	
Educational level						
Middle school or below	61	0	0.0	1	1.6	
High school or attending college	382	10	2.6	6	1.6	
College or above	177	1	0.6	4	2.3	
Occupation						
Blue collar	342	6	1.8	7	2.0	
White collar	111	0	0.0	0	0.0	
Others	167	5	3.0	4	2.4	
Household income level						
<krw 3="" million<="" td=""><td>109</td><td>3</td><td>2.8</td><td>1</td><td>0.9</td></krw>	109	3	2.8	1	0.9	
KRW 3–5 million	325	4	1.2	7	2.2	
>KRW 5 million	186	4	2.2	3	1.6	
Self-rated health						
Excellent	119	1	0.8	4	3.4	
Very good	399	6	1.5	6	1.5	
Good	78	4	5.1	1	1.3	
Fair	23	0	0	0	0	
Poor	1	0	0	0	0	

KRW = Korean Won.

## Table 4

#### Characteristics of patient safety incidents.

		Curre	nt study	1		Previous	study	t	P-value		
	Own experience		Experienced by a family member		Own experience		Experienced by a family member		Own experience	Experienced by a family mem	
Variable	N	%	Ν	%	Ν	%	N	%			
Experiences of patient safety incidents**									.062	.001*	
Yes	11	1.8	11	1.8	24	3.4	37	5.3			
No	609	98.2	609	98.2	676	96.6	663	94.7			
Type of patient safety incidents***									.097	.668	
Related to diagnosis	1	9.1	3	27.3	8	29.6	17	43.6			
Related to drug, fluid, or blood	1	9.1	2	18.2	8	29.6	8	20.5			
Related to procedures	8	72.7	6	54.5	10	37.0	12	30.8			
Related to infection	0	0	0	0	1	3.7	1	2.6			
Others	1	9.1	0	0	0	0.0	1	2.6			
Harm due to patient safety incidents***									.114	.797	
None	10	90.9	4	36.4	13	48,1	14	37.8			
Recovery: < 1 month	1	9.1	3	27.3	8	29.6	7	18.9			
Recovery: $\geq$ 1 month	0	0	1	9.1	4	14.8	9	24.3			
Permanent impairment	0	0	3	27.3	2	7.4	7	18.9			
Medical error***									.006*	.004*	
Yes	3	27.3	5	45.5	19	70.4	31	79.5			
No	5	45.5	3	27.3	8	29.6	8	20.5			
Do not know	3	27.3	3	27.3	-	-	-	-			

– = No data.

+ Data from a previous study by Ock et al<sup>[17]</sup>

\* = significant, P < .05,

\*\* = Chi-square test,

\*\*\* = Fisher's exact test.

## Table 5

Multivariable logistic regression model of the factors associated with reports of patient safety incidents by the general public.

Variable	Odds ratio (Cl 95%) of the total PSIs
Age group	
19–29	Reference
30–39	0.5 (0.08-3.26)
40–49	0.75 (0.13-4.33)
50–59	0.63 (0.12-3.29)
≥60 years	1.80 (0.46-6.66)
Sex	
Male	Reference
Female	0.66 (0.27-1.57)
Educational level	
Middle school or below	Reference
High school or attending college	0.35 (0.03-4.17)
College or above	1.10 (0.34–3.57)
Household income level	
<krw 3="" million<="" td=""><td>Reference</td></krw>	Reference
KRW 3–5 million	1.12 (0.24–5.15)
>KRW 5 million	0.81 (0.30-2.20)

CI = Confidence interval; PSIs = patient safety incidents, KRW = Korean Won.

In this study, understanding the characteristics of the survey as a study method is essential for interpreting the scale of cancer screening-related PSIs during health examinations. We chose a survey method with a face-to-face interview method, among various forms, such as medical record review and administrative data analysis.<sup>[15]</sup> A survey is a well-known representative method to identify the occurrence of PSIs, particularly diagnosis-related PSIs, through interviews with patients and healthcare professionals.<sup>[25,26]</sup> As diagnosis-related PSIs frequently occur during a health examination, it is imperative to use a survey method to investigate the PSI trend in health examinations, despite the low PSI rate found in this study. Selecting a representative sample within a certain period after a health examination could mitigate the limitation of complete reliance on participants' recall for future PSI studies.

Statistical significance was not observed in the relationship between cancer screening-related PSI experiences and risk factors, despite the association of higher education level and the likelihood of reporting PSI experience identified in a previous study.<sup>[17]</sup> This study could not confirm the statistical significance between the education level and PSI reporting rate of cancer screening. Limited studies have been conducted on socially disadvantaged groups in PSIs, regardless of their high disease incidence and mortality rate. Future studies should examine the risk factors of PSIs in cancer screening with an acknowledgment of underlying disease or degree of severity, reflecting that patients with a comorbid condition or severity experience more PSIs.<sup>[14]</sup>

This study also examined the responses of PSIs during cancer screening. It is known that appropriate responses to PSIs are crucial. Furthermore, performing a PSI disclosure - a series of processes that offer a concrete incident explanation, sympathy and regret, an apology, appropriate compensation, and a promise to prevent recurrence when errors and harms are detected through an incident investigation, has been emphasized.<sup>[27,28]</sup> In this study, through an inquiry of each disclosure experience, it was noted that the participants with individual or family level of PSI experience barely encountered a full disclosure. Specifically, healthcare professionals hardly promised to investigate the incident, explained error occurrence, or apologized to them. Considering that cancer screening is usually performed in primary care, it is assumed that the awareness of PSI disclosure among these health professionals is exceedingly low. Therefore, it is essential to develop measures to improve and enhance the low awareness of PSI disclosure.

This study has three limitations. First, the study was conducted in a singular city in Korea. The study used random sampling,

#### Table 6

Judgment of the occurrence of medical error by types of and harm resulting from patient safety incidents

	Own experience Medical error			Own experience Family member's experience						ice	Total				
					Medical error				Medical error						
Variable	Yes (%)	No (%)	Do not know (%)	<i>P</i> -value	Yes (%)	No (%)	Do not know (%)	<i>P</i> -value	Yes (%)	No (%)	Do not know (%)	<i>P</i> -value			
Type of patient safety incidents				1.000				.396				.051			
Related to diagnosis	1 (100)	0 (0)	0 (0)		3 (100)	0 (0)	0 (0)		4 (100)	0 (0)	0 (0)				
Related to drug, fluid, or blood	0 (0)	1 (100)	0 (0)		0 (0)	1 (50)	1 (50)		0 (0)	2 (66.7)	1 (33.3)				
Related to procedures	2 (25)	3 (37.5)	3 (37.5)		2 (33.3)	2 (33.3)	2 (33.3)		4 (28.6)	5 (35.7)	5 (35.7)				
Related to infection	0 (0)	0 (0)	0 (0)		0 (0)	0 (0)	0 (0)		0 (0)	0 (0)	0 (0)				
Others	0 (0)	1 (100)	0 (0)		0 (0)	0 (0)	0 (0)		0 (0)	1 (100)	0 (0)				
Harm due to patient safety incidents				.545				.038*				.032*			
None	2 (20)	5 (50)	3 (30)		0 (0)	1 (25)	3 (75)		2 (1.43)	6 (42.9)	6 (42.9)				
Recovery: < 1 month	1 (100)	0 (0)	0 (0)		1 (33.3)	2 (66.7)	0 (0)		2 (50)	2 (50)	0 (0)				
Recovery: ≥ 1 month	0 (0)	0 (0)	0 (0)		1 (100)	0 (0)	0 (0)		1 (100)	0 (0)	0 (0)				
Permanent impairment	0 (0)	0 (0)	0 (0)		3 (100)	0 (0)	0 (0)		3 (100)	0 (0)	0 (0)				

\* = Significant, P < .05 using Fisher's exact test.

Table 7										
Experience of patient safety incidents disclosures.										
Items	Yes N (%)	No N (%)	P-value							
Being truthful of the event before requested by patient/guardians	10 (45.5)	12 (54.5)	<.001*							
Expressing empathy and regret before requested by patient/guardians	12 (54.5)	10 (45.5)								
Promise to investigate the event before requested by patient/guardians	1 (4.5)	21 (95.5)								
Inform the result of no medical error	2 (9.1)	20 (81.9)								
Inform the result of medical error and apology	2 (9.1)	20 (81.9)								
Offer adequate compensation	1 (4.5)	21 (95.5)								
Promise to prevent a recurrence	4 (18.2)	18 (81.8)								

\* = Significant.

thus increasing the internal validity. Nevertheless, further studies should be conducted with a similar research design with more representative samples. Second, there was no additional process to verify the validity of participants' reported PSIs. This study could not partake in further verification processes, such as physician's review in previous studies that employed a patient survey to explore PSIs.<sup>[29,30]</sup> Also, checking whether to consult with the Medical Dispute Mediation and Arbitration Agency and whether to report to the Patient Safety Reporting and Learning System may be an alternative to verify the PSI experience. Therefore, the extent of PSIs in cancer screening might be overestimated in this study. Lastly, the details of the cancer diagnosis and severity that might influence the occurrence of PSIs were also not collected. Thus the association between the type and severity of cancer and PSIs could not be estimated.

## 5. Conclusion

This study comprehensively analyzed the types and extent of PSIs experienced by Korean individuals and their family members in Ulsan. The scale and responses of PSIs from these findings suggest that the patient safety issues in cancer screening should not be overlooked. It is fundamental to enhance the standard of patient safety in cancer screening to relish the ultimate effects and increase screening rates. Foremost, an investigation system to regularly monitor the occurrence and identify the causes of PSIs in cancer screening should be developed and established for quality improvement. Furthermore, awareness improvement and education are essential for proper responses to PSIs in cancer screening.

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### Author contributions

Conceptualization: Jeehee Pyo, Minsu Ock.

Data curation: Dasom Im, Minsu Ock, Noor Afif Mahmudah.

Formal analysis: Dasom Im, Minsu Ock, Noor Afif Mahmudah. Funding acquisition: Minsu Ock.

Investigation: Jeehee Pyo, Minsu Ock.

Project administration: Minsu Ock.

Supervision: Minsu Ock.

Validation: Dasom Im, Minsu Ock, Noor Afif Mahmudah.

- Writing original draft: Dasom Im, Minsu Ock, Noor Afif Mahmudah.
- Writing review & editing: Dasom Im, Jeehee Pyo, Minsu Ock, Noor Afif Mahmudah.

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