

ORIGINAL ARTICLE

Impact of knowledge, attitude and preceptor behaviour in pharmacovigilance education

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Abstract

This study aimed to determine the level of pharmacovigilance (PV) education in pharmacy programmes and to evaluate the predictive factors for the intent to report adverse drug reactions (ADRs) by pharmacy students in South Korea. Self-administered questionnaires were collected from a regionally stratified nationwide convenience sample of pharmacy students in September 2017. The association between students' intent to report ADRs and their knowledge and attitude was evaluated by using multivariate logistic regression analysis. In total, 303 pharmacy students participated in the survey; the average age of students was 26.7 (standard deviation 2.9) years and 40.6% were males. Eighty-eight students (29%) marked the degree of their intent as "strongly high." Increased knowledge of ADR reporting methods and positive attitude towards the need for ADR reporting were significant predictors of the intent to report ADRs. Further, witnessing reporting by the preceptor (adjusted odds ratio, 2.37; 95% confidence interval, 1.26–4.46; $P < 0.01$) was significantly correlated with the knowledge on and attitude towards ADR reporting of pharmacy students. The findings of our study indicated the need for improvements in PV curriculum, such as educational content focused on ADR reporting methods and demonstration of a preceptor's reporting in pharmacy practice experiential rotation, within Korean college of pharmacy curriculum.

KEYWORDS

adverse drug reaction, education, intent, pharmacovigilance, student

1 | INTRODUCTION

Spontaneous reporting (SR) of adverse drug reactions (ADRs) is a critical activity for healthcare professionals, as ADRs are one of the leading causes of morbidity and mortality¹ and a threat to public health.^{2,3} The identification of pharmacovigilance (PV) activities as common objectives in the global community triggered international collaborations to enhance patient safety.⁴ The successful operation of the SR system relies heavily on vigilant reports made by various healthcare professionals, as well as consumers. Among healthcare professionals, pharmacists are most accessible to patients; therefore, appropriate counselling by the

pharmacists could prevent ADRs and resolve the adverse outcomes encountered by the patients, and SR activities could further protect patients from medication-related harm.⁵

The World Health Organization and the International Pharmaceutical Federation have reported the significance of pharmacists' engagement in the improvement of public health, health promotion and patient safety.⁶ Accreditation standards for pharmacy programmes have emphasized on public safety, PV and population-based care.^{7,8} Professional expectations and educational goals are similar in South Korea, with recently revised legal responsibilities clearly

denoting the role of pharmacists in the improvement of public health care.⁹

After a six-year programme was launched in 2009, the pharmacy curriculum was created and implemented to educate pharmacy students, with emphasis placed on training pharmacists who could demonstrate competencies in three areas of pharmacy: drug development, drug manufacturing and drug utilization, with the recognition for providing public services.⁹ Despite the establishment of the Pharmacovigilance Research Network and the Korean Pharmaceutical Association (KPA) as one of 27 Regional PV Centres for nationwide SR activities by pharmacists in the retail setting since January 2013,¹⁰ the reported rates of SR by pharmacists in South Korea remained low, between 13.5% in 2016 and 15.3% in 2017.¹¹

A number of published studies have indicated that knowledge and attitude are predictors of SR^{12–15} and are improved through continuation of education through structured educational programmes and educational resources.^{5,16} However, these studies were focused on the characteristics of health-care professionals as ADR reporters, and only a very limited number of studies investigated the associations of knowledge and attitude with the reporting intent of pharmacy students as professional pharmacists in their near future, and evaluated the effect of PV education programme in a college of pharmacy.^{17–19} Therefore, this study aimed to describe the level of PV education, relative to the knowledge of and the attitude to ADR reporting in pharmacy students and to evaluate the predictive factors for the intent to report ADRs.

2 | METHODS

2.1 | Study design

A cross-sectional survey was conducted by using a self-administered questionnaire with a nationwide convenience sample which included participants who could be easily contacted. Online recruitment was conducted via the social networking service of the Korean Pharmacy Students' Association, which is the national representative body of undergraduate pharmacy students in South Korea. For a regionally stratified survey, we restricted the percentage of required number of respondents reflecting the distribution profile of sixth-year pharmacy students in the capital, metropolitan and rural areas. Data collection was done in September 2017.

All survey participants provided their written informed consent prior to participation in the study. The study protocol was approved by the Institutional Review Board (IRB) of Seoul National University (IRB No. E1410/001-011). The study was conducted in accordance with the Basic & Clinical Pharmacology & Toxicology policy for experimental and clinical studies.²⁰

2.2 | Survey design

The survey was developed based on a mixed theoretical model,^{15,21} which accounted for the knowledge-attitude-practices model²² and the theory of satisfaction of needs.²³ The survey was designed to assess both extrinsic and intrinsic factors.²¹ The extrinsic factors included environmental variables related to pharmacy programmes, preceptors and family members, whereas the intrinsic factors were the personal and educational variables, knowledge of ADR reporting, attitude towards ADR reporting and intent to report ADRs. Questions regarding the environmental variables related to pharmacy programmes consisted of the type and the location of pharmacy schools. The questions related to preceptors evaluated the students' experiences of their preceptor's ADR reporting and monitoring. Students were also asked questions related to prior experiences of ADRs by themselves or their family members. The questions related to personal information and variables related to PV education evaluated age, gender, hours of education on ADR reporting conducted in-class, at required experiential sites, and at an advanced experiential site.

Questions regarding the knowledge of ADR reporting methods were focused on knowledge of the SR system, reporting website, reporting forms, causality assessments and agencies related to PV reporting and tools, including the Korean Institute of Drug Safety & Risk Management (KIDS) and World Health Organization-Uppsala Monitoring Centre (WHO-UMC). Questions were included on the laws related to serious adverse events and reportable items. Students were also asked whether they felt they had sufficient knowledge and skills to report ADRs.

The questions addressing the attitude of students were related to the importance of the SR system and training and the professional duty of pharmacists to report and monitor ADRs. Eight questions assessed obstacles against ADR reporting; these were based on Inman's seven reasons²⁴ and the available literature on pharmacists' attitude towards ADR reporting.^{15,25} The obstacles considered in the questionnaire included the following: "not a serious ADR," "well-known ADR," "uncertain causality," "risk of disrupting the normal workflow and requiring too much time," "risk of damaging relationships with doctors," "risk of damaging relationships with patients," "liability of the pharmacy" and "no impact on improving drug safety."

The questions related to the obstacles against ADR reporting utilised a five-point Likert-type scale, with 5 points allocated to "strongly agree," 4 points to "agree," 3 points to "neutral," 2 points to "disagree" and 1 point to "strongly disagree." For analytical purposes, the data were converted to binary data; "strongly agree" and "agree" were combined into answers denoting agreement and "neutral," "disagree" and "strongly disagree" were combined

into answers denoting disagreement or neutral. Similarly, the questions regarding participant attitude towards ADR reporting and intent to report ADRs utilised the five-point Likert-type scale; however, the conversion into binary data was completed by dividing the responses into “strongly agree” and other responses of “agree,” “neutral,” “disagree” and “strongly disagree” to distinguish students with a strong positive attitude towards ADR reporting and intent to report ADR, because we would like to assess the predictive factors for strong intent, which is highly relevant in actual ADR reporting behaviour.²⁶

2.3 | Sample size

A sample size of 300 students was calculated as adequate to detect a 15% difference in the intent to report ADRs with 90% power and 5% α -error; this calculation was based on a report that the indicated 60% of students had taken courses on ADR reporting, and 87% of students had a strong positive attitude towards the need for education on ADR reporting.²⁷ The sample size calculation was performed using MedCalc Statistical Software version 17.1 (MedCalc Software byba, Ostend, Belgium). The proportion of the number of students who needed to be recruited was calculated to reflect the regional distribution of sixth-year pharmacy students in the capital (31%-36%), metropolitan (23%-27%) and rural areas (40%-45%).²⁸

2.4 | Statistical analysis

The internal consistency reliability of the questionnaire in the knowledge and attitude domains was assessed, and a Cronbach's α coefficient ≥ 0.7 was considered adequate for internal consistency.²⁹ The construct validity of the questionnaire was also assessed by using exploratory factor analysis: the number of factors was determined by eigenvalues > 1 as the reference and based on examination of the scree plot. Items that indicated a loading ≥ 0.4 were considered as the corresponding factors.³⁰ To verify the fitness of the data, a cut-off of 0.5 was set in the Kaiser-Meyer-Olkin measure of the sampling adequacy and a P -value of < 0.001 in Bartlett's test of sphericity was adopted.¹⁵

The characteristics of the study population were summarised by using descriptive statistics. Univariate and multivariate logistic regression analyses evaluated the associations between the independent variables of the knowledge and attitude domains (e.g. knowledge on ADR reporting methods and positive attitude on the need for ADR reporting) and the outcome variable (i.e. intent to report ADR). The association between intent and predictive factors, including personal, educational and extrinsic domains was also determined by using univariate and

multivariate logistic regression analyses. The degree of association was presented as odds ratios (ORs) with corresponding 95% confidence intervals (CIs). The data analyses were conducted by using SPSS version 22.0 (SPSS Inc., Chicago, IL), and the level of statistical significance was set at $P < 0.05$.

3 | RESULTS

3.1 | Population characteristics

In total, 303 undergraduate pharmacy students participated in the study between September 1 and 30, 2017. Considering the number of students enrolled in their pharmacy schools in South Korea, the response rate was 17.2%. The mean (\pm standard deviation, SD) age of participating students was 26.7 (± 2.9) years, and males constituted 40.6% of the population (Table 1). Approximately one-third of the students (35.0%) attended public pharmacy school; the remainder of students attended private pharmacy school. Further, 31.4% of students attended pharmacy schools in the capital of South Korea. The mean (\pm SD) time spent with respect to education on ADR reporting was 2.7 (± 3.2) hr for in-class instruction and 7.8 (± 12.9) hr for pharmacy practice experience. A total of 88 students (29%) expressed their intent to report ADR as strongly high.

TABLE 1 Population demographics (n = 303)

Characteristics	Value
Age, mean \pm SD, years	26.7 \pm 2.9
Gender, n (%)	
Male	123 (40.6)
Female	180 (59.4)
Prior experience of ADR, n (%) ^a	
Student	106 (35.0)
Family members	84 (27.7)
Type of pharmacy school, n (%)	
Public	106 (35.0)
Private	197 (65.0)
Location of pharmacy school, n (%)	
Capital	95 (31.4)
Metropolitan area	73 (24.1)
Rural area	135 (44.5)
Hours of education on ADR reporting, mean \pm SD	
In-class teaching	2.7 \pm 3.2
Pharmacy practice experience	7.8 \pm 12.9

ADR, adverse drug reaction.

^aNot mutually exclusive.

3.2 | Knowledge of and attitude to reporting adverse drug reactions

Overall, 67.7% and 69.6% of students were aware of the web-site for reporting ADRs and could fill out a report form for SR, respectively. Less than one-third of the participating students (30.7%) felt that they had gained sufficient knowledge and skills to report ADRs through their pharmacy education. The majority of students (78.2%) strongly agreed on the importance of the SR system and 44.9% strongly agreed that ADR reporting should be taught in a compulsory course. Approximately two-thirds (65% and 63.4%, respectively) of the students strongly agreed that reporting and monitoring ADRs were the professional duty of a pharmacist.

More than half of the students (55.4%) anticipated that reporting would disrupt the normal workflow and be time-consuming. Approximately 40% of students were concerned about the risk of damaging relationships with doctors and the liability of the pharmacy owing to ADR reporting. In addition, one in four students were concerned about the risk of damaging relationships with patients (24.8%) and the lack of observed impact on improvements in drug safety (26.4%). Less than one-tenth of the students agreed that not serious (5.9%) or well-known (6.6%) ADRs and ADRs with uncertain causality (9.6%) were not to be reported.

3.3 | Reliability and validity

The internal consistency reliability was analysed by using Cronbach's α for questions relating to the knowledge of ADR reporting methods and to the attitude towards obstacles against ADR and necessity of ADR reporting. The alpha values for questions regarding knowledge (0.68) and attitude towards obstacles (0.67) were below the 0.7 cut-off; however, the alpha value for the attitude towards the necessity questions was 0.72, which indicated moderate internal consistency.

In the construct validity analysis, the Kaiser-Meyer-Olkin measure of sampling adequacy (> 0.5) and Bartlett's test of sphericity ($P < 0.001$) demonstrated that the questions related to knowledge and attitude towards necessity and obstacles were pertinent for exploratory factor analysis. The factor loading for each question with regard to knowledge and attitude towards necessity and obstacles is detailed in Table 2. The factor analysis confirmed that six questions relating to knowledge of ADR reporting methods and four questions relating to attitude towards the necessity of ADR reporting were loaded onto a single factor; the question loadings were between 0.56 and 0.85. Furthermore, factor analysis indicated that the eight questions assessing the attitude towards the obstacles against ADR reporting were

TABLE 2 Internal consistency reliability and factor loading on the items for knowledge on and attitude towards adverse drug reaction reporting (n = 303)

	Total correlation coefficient	Factor	
Item		1	2
Knowledge of ADR reporting methods			
Knowledge on SR system	0.38	0.59	
Knowledge on reporting websites	0.49	0.67	
Knowledge on reporting forms	0.46	0.68	
Knowledge on causality assessment	0.44	0.65	
Knowledge on KIDS	0.42	0.62	
Knowledge on WHO-UMC	0.37	0.56	
Eigenvalue		2.37	
Cumulative variance explained (%)		39.46	
Attitude on the necessity of ADR reporting			
Importance of education on ADR reporting	0.39	0.61	
Importance of SR system	0.43	0.66	
Pharmacist's duty on ADR reporting	0.62	0.84	
Pharmacist's duty on ADR monitoring	0.64	0.85	
Eigenvalue		2.22	
Cumulative variance explained (%)		55.47	
Attitude on the obstacles against ADR reporting			
Not a serious ADR	0.40	0.17	0.80 ^a
Well-known ADR	0.35	0.10	0.82 ^a
Uncertain causality	0.28	0.05	0.78 ^a
Risk of disrupting the normal workflow	0.31	0.58 ^a	−0.002
Risk of damaging relationships with doctors	0.47	0.75 ^a	0.04
Risk of damaging relationships with patients	0.35	0.57 ^a	0.10
Liability of the pharmacy	0.50	0.75 ^a	0.11
No impact on improving drug safety	0.37	0.52 ^a	0.21
Eigenvalue		2.58	1.51
Cumulative variance explained (%)		32.27	51.10

ADR, adverse drug reaction; KIDS, Korean Institute of Drug Safety & Risk Management; WHO-UMC, World Health Organization-Uppsala Monitoring Centre.

^aItem loading > 0.4

bi-dimensional, explaining a cumulative variance of 51.1%. The two dimensions, as determined considering Inman's seven reasons, were related to ignorance or diffidence, and fear or indifference. We divided these two dimensions into concern about obstacles to ADR reporting system and damage-related obstacles against ADR reporting.

3.4 | Predictive factors for intent to report adverse drug reaction

The comparison of the factors related to knowledge and attitude and how these relate to intent to report ADR is presented in Table 3. For analytical purposes, the data on the number of questions indicating an accurate knowledge of

ADR reporting methods, positive attitude questions on the need for ADR reporting, and concern for damage-related obstacles against ADR reporting were divided into three groups of approximately equal proportions. Students who correctly answered 3-4 and 5-6 knowledge questions on ADR reporting methods were more likely to have an intent to report ADR than those who scored 2 or less (adjusted OR, 3.02 and 4.02; 95% CI, 1.11-8.23 and 1.44-11.23; $P = 0.031$ and $P = 0.008$ for 3-4 and 5-6 questions, respectively). Another predictive factor for the intent to report ADRs was a positive attitude with respect to the need for ADR reporting: students with 2-3 and 4 positive attitude answers on the need for ADR reporting were more likely to have an intent to report ADR than those with 1 or less

TABLE 3 Predictive factors for intent to report adverse drug reaction (n = 303)

Characteristics	Intent to ADR reporting, n (%)		OR _{unadj} (95% CI)	OR _{adj} (95% CI) ^a
	Yes (n = 88)	No (n = 215)		
The number of accurate knowledge on ADR reporting methods				
0-2	6 (6.8)	50 (23.3)	1.0	1.0
3-4	30 (34.1)	83 (38.6)	3.01 (1.17-7.74) ^b	3.02 (1.11-8.23)
5-6	52 (59.1)	82 (38.1)	5.29 (2.12-13.20) ^d	4.02 (1.44-11.23) ^c
Accurate knowledge on what to report				
No	76 (86.4)	185 (86.0)	1.0	1.0
Yes	12 (13.6)	30 (14.0)	0.97 (0.47-2.0)	0.69 (0.3-1.59)
Accurate knowledge on legal requirements				
No	43 (48.9)	130 (60.5)	1.0	1.0
Yes	45 (51.1)	85 (39.5)	1.6 (0.97-2.64)	1.51 (0.85-2.68)
Perception of having sufficient knowledge and ability to perform ADR reporting				
No	33 (37.5)	126 (58.6)	1.0	1.0
Either sufficient knowledge or ability to perform	13 (14.8)	38 (17.7)	1.31 (0.63-2.73)	0.95 (0.42-2.12)
Both sufficient knowledge and ability to perform	42 (47.7)	51 (23.7)	3.14 (1.80-5.51) ^d	1.61 (0.81-3.18)
Number of positive attitude items on the need for ADR reporting ^e				
0-1	7 (8.0)	77 (35.8)	1.0	1.0
2-3	33 (37.5)	87 (40.5)	4.17 (1.75-9.97) ^c	3.84 (1.56-9.41) ^c
4	48 (54.5)	51 (23.7)	10.35 (4.35-24.67) ^d	8.85 (3.57-21.9) ^d
Concern on obstacles against ADR reporting system				
No	77 (87.5)	184 (85.6)	1.0	1.0
Yes	11 (12.5)	31 (14.4)	0.85 (0.41-1.77)	1.36 (0.59-3.12)
Concern on damage-related obstacles against ADR reporting				
0	32 (36.4)	40 (18.6)	1.0	1.0
1-2	36 (40.9)	95 (44.2)	0.47 (0.26-0.87) ^b	0.57 (0.29-1.12)
3-5	20 (22.7)	80 (37.2)	0.31 (0.16-0.61) ^c	0.51 (0.24-1.1)

ADR, adverse drug reaction; CI, confidence interval; OR_{adj}, adjusted odds ratio; OR_{unadj}, unadjusted odds ratio.

^aMultivariate analysis adjusting for all variables listed in the table.

^b $P < 0.05$.

^c $P < 0.01$.

^d $P < 0.001$.

^eThe attitude towards the importance of ADR reporting training and ADR reporting system and the professional duty of pharmacists with respect to ADR reporting and monitoring were included.

(adjusted OR, 3.84 and 8.85; 95% CI, 1.56-9.41 and 3.57-21.9; $P = 0.003$ and $P < 0.001$ for 2-3 and 4 questions, respectively). Students' self-perception of having sufficient knowledge and the ability to perform ADR reporting, as well as low concern for damage-related obstacles against ADR reporting, were also significantly associated with the intent to report ADRs in the crude analysis; however, after adjustment of the remaining factors, the associations were not statistically significant. There was no difference in the specific knowledge about the laws related to serious adverse events and reportable items or concern of ADR reporting system obstacles between the two groups.

3.5 | Contributing factors to knowledge on and attitude towards adverse drug reaction reporting

To identify the factors contributing to the knowledge on and attitude towards ADR reporting of students, the

students were divided into two groups based on their degree of knowledge on ADR reporting methods and positive attitude towards the need for ADR reporting. Students with 3 or more accurate answer to knowledge questions on ADR reporting methods (i.e. SR system, reporting website, reporting forms, causality assessments and agencies related to PV reporting) and three or more positive attitude questions relating to the need for ADR reporting were assigned to the "high knowledge and attitude group" and the remainder were assigned to the "low knowledge and attitude group." Based on these groupings, a comparison of the personal and educational factors that affected the level of knowledge on and attitude towards ADR reporting is presented in Table 4. Notably, students who participated in a pharmacy practice rotation at an advanced experiential site with opportunities for real-time ADR reporting were more likely to fall within the high knowledge and positive attitude group than those who did not (adjusted OR, 2.1; 95% CI, 1.2-3.68; $P = 0.009$). The advanced experiential sites

TABLE 4 Contributing factors to knowledge on and attitude towards adverse drug reaction reporting (n = 303)

Characteristics	High knowledge and attitude group ^a (n = 180), n (%)	Low knowledge and attitude group (n = 123), n (%)	OR _{unadj} (95% CI)	OR _{adj} (95% CI) ^b
Female	108 (60.0)	72 (58.5)	1.06 (0.67-1.69)	1.13 (0.66-1.93)
Student's experience of ADR	74 (41.1)	32 (26.0)	1.99 (1.2-3.27) ^c	1.7 (0.97-2.99)
Family member's experience of ADR	60 (33.3)	24 (19.5)	2.06 (1.2-3.55) ^c	1.67 (0.91-3.07)
Public pharmacy school	55 (30.6)	51 (41.5)	0.62 (0.39-1.0)	0.65 (0.38-1.09)
Location of pharmacy school				
Capital	54 (30.0)	41 (33.3)	1.0	1.0
Metropolitan area	44 (24.4)	29 (23.6)	1.15 (0.62-2.14)	1.68 (0.84-3.38)
Rural area	82 (44.6)	53 (43.1)	1.18 (0.69-2.0)	1.54 (0.83-2.86)
Hours of in-class teaching education on ADR reporting				
0	50 (27.8)	39 (31.7)	1.0	1.0
1-2	63 (35.0)	29 (23.6)	1.69 (0.92-3.11)	1.63 (0.85-3.15)
≥3	67 (37.2)	55 (44.7)	0.95 (0.55-1.65)	1.06 (0.58-1.95)
Hours of pharmacy practice experience education on ADR reporting				
0	18 (10.0)	16 (13.0)	1.0	1.0
1-4	83 (46.1)	55 (44.7)	1.34 (0.63-2.85)	1.06 (0.46-2.46)
≥5	79 (43.9)	52 (42.3)	1.35 (0.63-2.89)	0.94 (0.39-2.29)
Rotation at an advanced experiential site on ADR reporting education ^c	74 (41.1)	27 (22.0)	2.48 (1.48-4.18) ^c	2.1 (1.2-3.68) ^c
Preceptor's ADR reporting	146 (81.1)	76 (61.8)	2.66 (1.58-4.47) ^d	2.37 (1.26-4.46) ^c
Preceptor's ADR monitoring	139 (77.2)	84 (68.3)	1.57 (0.94-2.64)	1.01 (0.55-1.87)

ADR, adverse drug reaction; CI, confidence interval; OR_{adj}, adjusted odds ratio; OR_{unadj}, unadjusted odds ratio.

^aStudents with 3 or more accurate knowledge on ADR reporting methods and 3 or more positive attitude items on the need for ADR reporting were included.

^bMultivariate analysis adjusting for all variables listed in the table.

^c $P < 0.01$.

^d $P < 0.001$.

^eThe advanced experiential sites included hospital pharmacies, community pharmacies, regional pharmacovigilance centres, pharmaceutical manufacturers, and the Ministry of Food and Drug Safety.

included hospital pharmacies, community pharmacies, regional PV centres, pharmaceutical manufacturers and the Ministry of Food and Drug Safety. Further, witnessing a preceptor reporting an adverse event was a contributory factor to having knowledge of and a positive attitude to ADR reporting (adjusted OR, 2.37; 95% CI, 1.26-4.46; $P = 0.008$). In contrast, a student's prior personal and familial experience with ADR was significantly associated with the level of knowledge and attitude in the crude analysis but was not statistically significant after adjustment. Gender, the type and location of pharmacy school, and the instructional time spent on ADR reporting in-class did not significantly contribute to the knowledge of and attitude towards ADR reporting.

4 | DISCUSSION

To the best of our knowledge, this is the first nationwide survey of predictive factors for intent to report ADR in Korean pharmacy students. Undergraduate pharmacy education on PV and ADR reporting is important to foster the right attitude in pharmacists, who have an important role in patient safety. To date, very few studies have targeted students when evaluating the factors contributing to reporting intent.^{19,31,32} Importantly, this study determined the predictive factors for intent to report ADR with the aim of developing strategies to improve PV education. In addition, the survey was developed by using a conceptual framework, which helped to ensure the questions embodying the explanatory factors associated with reporting intent. In this study, only 29% of pharmacy students documented a strong intent to report ADRs, which suggested that current PV education, which focused on lecture-based instruction without compulsory training hours in Korean pharmacy schools, could be improved. The ultimate educational goal of PV education is to foster the students' knowledge, skills and perceptions on ADR reporting and prepare students to be pharmacists who can take charge of PV.

The knowledge of ADR reporting methods was detected as a predictive factor for the intent to report ADR. This agreed with published studies, including those evaluating pharmacy and medical students^{31,32} and healthcare professionals,^{12-15,25} which demonstrated that a lack of knowledge about SR was a major barrier to reporting or reporting intent. Approximately 30% of the participating students did not know where to report or how to fill out a report form for SR, which was higher than that of pharmacy students (23.7%) and medical students (22%) in other countries.^{27,31} Considering the low level of knowledge on ADR reporting methods in our pharmacy students and the significance of the predictive factors for reporting intent, strengthening both in-class and experiential training content on the actual reporting methods may be a potential solution

for the improvement of students' intent to report. Moreover, more than two-thirds of students (69.3%) in this study felt that they lacked sufficient knowledge and skills to report ADRs, which was higher than that of sixth-year medical students (52%).³¹ Although not a significant factor after adjustment, the students' low perception of having sufficient knowledge and skills also supported the need for stronger education on this topic.

In this study, the attitude towards the necessity of ADR reporting was also a significant factor that affected the intent to report ADRs, which consisted of several sessions relating to the importance of the SR system and the training and professional duty of pharmacists to report and monitor ADRs. Our study confirms a number of previous studies, suggesting that pharmacy schools should embrace the attitude towards ADRs as an important determinant for pharmacists' reporting probability.^{15,33,34} In contrast, the finding that more than three-quarters of students supported the importance of the SR system, but less than half of students supported assigning classes for ADR reporting as required courses has important implications. Although the degree of strong agreement on the opinion that PV education should be a core educational topic was higher in this study than that for pharmacy students (18.0%) in a Malaysian study²⁷ and medical students (13.3%) in the Netherlands,³¹ we believe that the predominant discrepancy between the importance of SR system and PV education as a required course indicated a need for reassessment of educational policies in South Korea.

The high level of concern in our pharmacy students that ADR reporting interferes with the normal workflow and is time-consuming was also observed in previous studies on undergraduate pharmacy and medical students^{17,19,35} and healthcare professionals including pharmacists.²⁵ Streamlining the reporting process by sharing an online interface with the pharmacy's billing programme, which has been implemented by KIDS and KPA,¹⁵ simplifying the reporting tool for easy access, and providing feedback on the causality assessment to reporter might be valuable in overcoming the obstacles. In addition, to improve students' reporting skills, practical learning of and experience on the SR process should be strengthened in PV educational programme.

Training of ADR reporting in advanced experiential programmes and witnessing a preceptor's reporting correlated with the students' knowledge on and attitude towards ADR reporting, whereas the instructional time spent on ADR reporting in-class and at required experiential sites did not. These results indicated that hands-on practice using real-life situations, and exemplary behaviour of the preceptors in work environments is more effective than theoretical and didactic education. This result is consistent with a qualitative study on pharmacy students that

indicated that students' knowledge regarding professionalism was principally based on the student's work experience. Further, the study highlighted teacher practitioners as particularly valuable owing to their dual base in practice.³⁶ A systematic review of PV education in healthcare curricula also showed that real-life PV training improved the reporting skills and knowledge of healthcare students and increased their contribution to patient care.³⁷ Therefore, strategies for delivering PV education may be required with hands-on practice cases on ADR reporting during in-class sessions rather than heavily relying on lecture-based teaching methods, and with guided training sessions by the preceptor empowered with the advanced educational contents during advanced experiential programmes.

This study has some limitations. Firstly, we relied on voluntary participation and a convenience sample of students for this survey. This has the potential for selection bias with limited generalizability. However, this survey was regionally stratified for undergraduate pharmacy students, and there were no differences in the location of pharmacy school between respondents and non-respondents. Thus, we believe that the risk of selection bias was minimized. Secondly, Cronbach's α for items related to the knowledge of ADR reporting methods and items related to the attitude on the obstacles against ADR reporting was slightly below the acceptable value of 0.7, whereas items related to the attitude on the necessity of ADR reporting were above the cut-off.

In conclusion, our study found that less than one-third of sixth-year pharmacy students had the intent to report ADRs, showing the need for improvements in PV education in Korean pharmacy schools. The knowledge of ADR reporting methods and attitudes on the need for ADR reporting were key measures for indicating the reporting intent. In addition, hands-on practice in advanced experiential programmes and effective teacher practitioners were contributing factors to improve knowledge on and attitude towards ADR reporting.

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CONFLICT OF INTEREST

There are no conflicts of interest to declare.

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