Effect of Educational Interventions on Adverse Drug Reaction Reporting in a Cancer Institute in Japan: A Questionnaire Study

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Abstract

Background: Limited data regarding knowledge and factors related to understanding the adverse drug reaction (ADR) reporting system of health care professionals are available in Japan. **Objective:** The objective of this study was to identify factors related to understanding the ADR reporting system in Miyagi Cancer Center and to find ways to increase the number and quality of ADR reports. **Methods:** Self-administered questionnaire surveys were administered before and after the educational meeting among health care professionals who were working in our hospital during the study period. Subanalyses restricted to nurses were also performed. **Main Outcome Measure:** Understanding ADR reporting system among healthcare professionals. **Results:** The percentage of respondents who understood the ADR reporting system in the questionnaire after the educational meeting was significantly higher than that in the questionnaire before the educational meeting. In the questionnaire after the educational meeting, multivariate logistic regression analysis found that having over 30 years of practical experience (odds ratio [OR], 3.852; 95% confidence interval [CI], 1.228–12.081 for 20–29 years, 7.695; 1.650–35.881 for over 30 years), being a physician (8.071; 1.923–33.878), being a pharmacist (18.357; 3.847–87.585), and participating in the educational meeting (5.111; 1.700–15.365) were factors associated with understanding the ADR reporting system. Multivariate logistic regression analysis of the questionnaire results before the educational meeting among nurses showed that working at outpatient departments (8.330; 3.008–23.069) was significantly and independently associated with understanding the ADR reporting system. **Conclusions:** The present study demonstrated that many years of practical experience, profession (physicians, pharmacists), and educational interventions were associated with good understanding of the ADR reporting system among health care professionals.

Keywords

drug information, medication safety, pharmacy education

Introduction

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.^{1,2} Data from spontaneous adverse drug reactions (ADR) reporting systems are used for signal detection of unexpected ADRs and detecting rare ADRs that have not been observed in the development phase. For this reason, collecting spontaneous ADR reports plays an important role in the proper use of medicines.

The “Drugs and Medical Devices Safety Information Reporting System” is a system to collect postmarketing safety information on drugs from medical institutions in Japan. Currently, health care professionals such as physicians, nurses, and pharmacists are responsible for directly

reporting information on adverse health outcomes (ie, ADRs, infections, and malfunctions) that occur with use of drugs or medical devices in the health care environment to the Minister of Health, Labor and Welfare (MHLW).³

Recently, with the facilitation of multinational clinical trials, the approval review of new drugs such as anticancer agents has been accelerated to solve “the drug lag problem”

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in Japan. As a result, such drugs have often been launched without sufficient safety profiles in Japan. To have adequate postmarketing safety profiles of drugs like anticancer agents, it is important to report ADRs from cancer institutions, such as our hospital. Because nurses are more likely to be the first to encounter ADRs, they are known to have an important role in monitoring ADRs.⁴

Limited data regarding knowledge and factors related to understanding the ADR reporting system are available in Japan. It was suggested that educational interventions and provision of information about ADR reporting systems to health care professionals should be done efficiently.⁵ Furthermore, they are expected to increase the number, improve the quality of spontaneous ADR reporting, and contribute to enrich the safety profiles of new drugs. Several studies reported that there is a positive correlation between quantitative and qualitative improvement of reporting of ADRs and educational interventions improving knowledge about pharmacovigilance.⁶⁻¹⁰

In our hospital, Miyagi Cancer Center, Miyagi, Japan, we reported 35 ADR cases to the Pharmaceuticals and Medical Devices Agency (PMDA) in 2015, of which 16 (45.8%) reports were from physicians and 19 (54.2%) were from nurses with pharmacists' support. They included drug allergies or anaphylaxis symptoms, and the suspected drugs were anticancer drugs (22 cases), antiemetic drugs (2 cases), and contrast medium (11 cases). The number of spontaneous ADR reports from our hospital is insufficient. Therefore, the aim of the present study was to identify the factors related to understanding the ADR reporting system in our hospital and to find a way to increase the number and quality of ADR reports.

Methods

Study Design

A self-administered questionnaire survey was completed before and after the educational meeting among health care professionals (physicians, nurses, pharmacists, medical technologists, and radiological technologists) who were working in Miyagi Cancer Center during the study period. Questionnaire was developed based on the previous study,⁵ in which it was pre-tested on a sample group that consisted of 10 pharmacists and 5 pharmacovigilance professionals to whom the purpose of the study was explained. This study was approved by the ethics review board of Miyagi Cancer Center (approval number: 2016-070).

Questionnaire Before the Educational Meeting

In November 2016, the first questionnaire (sex, age, profession, years of practical experience, understanding the ADR reporting system, knowledge of how to report ADRs, experience submitting ADR reports, reasons for no experience submitting ADR reports) about the ADR reporting system was

distributed and collected over a 1-week period to all health care professionals in our hospital. In addition, to give respondents information on the spontaneous ADR reporting system, an explanation about the concept of the Japanese ADR reporting system and the way to report were included in the questionnaire.

Questionnaire After the Educational Meeting

In early December, the third questionnaire (sex, age, profession, years of practical experience, understanding of the ADR reporting system, knowledge of how to report ADRs, experience submitting ADR reports, reasons for no experience submitting ADR reports, whether you knew about the educational meeting, whether you participated in the educational meeting, reasons for not participating) was distributed after the educational meeting to all health care professionals in our hospital. Each questionnaire was distributed to each section and collected from each section.

Statistical Analysis

Univariate analysis was conducted to determine factors associated with understanding the ADR reporting system using the chi-squared test or Fisher exact test. Determinants of understanding the ADR reporting system were identified by multivariate logistic regression analysis, estimating ORs with 95% CIs for understanding the ADR reporting system. Multivariate logistic regression analysis was adjusted for profession (physician, nurse, pharmacist, other) and years of practical experience (1-4 years, 5-9 years, 10-19 years, 20-29 years, over 30 years). In addition, subanalyses restricted to nurses were performed. Multivariate logistic regression analysis was adjusted for profession, years of practical experience, and department (inpatient or outpatient). Data are shown as means $\pm$ standard deviation (SD). A *P* value less than .05 was considered to indicate significance. All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc, Cary, North Carolina).

Results

Questionnaire Before the Educational Meeting

Of the 427 health care professionals who received the questionnaire before the educational meeting, 355 (83.1%) responded. Thirty-three of 77 (42.9%) physicians, 266 of 277 (96.0%) nurses, 17 of 23 (73.9%) pharmacists, and 39 of 50 (78.0%) other health care professionals completed the questionnaire.

Questionnaire After the Educational Meeting

Of the 427 health care professionals who received the questionnaire after the educational meeting, 327 (76.6%) responded.

Table 1. Characteristics of All Participants.

	Before the educational meeting (n = 355)	After the educational meeting (n = 327)	P value ^a
Gender (%)			
Male	18.3	17.1	.69
Female	81.7	82.9	
Profession (%)			
Physician	9.3	7.0	.46
Nurse	74.9	77.4	
Pharmacist	4.8	6.4	
Others	11.0	9.2	
Years of practical experience ^b (%)			
<5 years	17.2	18.4	.99
5-9 years	14.7	13.8	
10-19 years	37.0	37.0	
20-29 years	25.1	25.4	
≥30 years	5.9	5.5	
ADR reporting system ^c (%)			
Understanding	13.5	19.2	.045
Not understanding	86.5	80.8	
How to report ADRs ^d (%)			
Knowing	35.2	43.0	.04
Not knowing	64.8	57.0	

Note. ADR = adverse drug reaction.

^aChi-squared test.

^bOne value was unavailable in “before intervention” group.

^cThree and four values were unavailable in “before the educational meeting” group and in “after the educational meeting” group, respectively.

^dFour values were unavailable in “after the educational meeting” group.

Twenty-three of 77 (29.9%) physicians, 253 of 276 (91.7%) nurses, 21 of 24 (87.5%) pharmacists, and 30 of 50 (60.0%) other health care professionals completed the questionnaire.

Understanding the ADR Reporting System

There were no significant differences in characteristics (sex, profession, years of practical experience) between before and after the educational meeting (Table 1). The percentage of respondents who understood the ADR reporting system and knew how to report ADRs in the questionnaire after the educational meeting was significantly higher than that in the questionnaire before the educational meeting (13.5% before to 19.2% after the educational meeting, $P = .045$, 35.2% to 43.0%, $P = .04$, respectively) (Table 1). In the questionnaire before the educational meeting, the multivariate logistic regression analysis showed that having over 20 years of practical experience (OR, 6.40; 95% CI, 1.59-25.77 for 20-29 years, 22.0; 4.31-111.81 for over 30 years), being a physician (5.41; 1.34-21.90), and being a pharmacist (18.78; 3.71-95.15) were significantly and independently associated with understanding the ADR reporting system. In the questionnaire after the educational meeting, the multivariate logistic regression analysis showed that participating in the

educational meeting (5.11; 1.70-15.37) was a factor related to understanding the ADR reporting system in addition to the factors found in the questionnaire before the educational meeting (Table 2).

Reasons for Not Participating in the Educational Meeting

Among 289 health care professionals who did not participate in the educational meeting, the most common reason for not participating in the meeting was “I was working at that time” (117 respondents, 40.5%), followed by “I was off-duty on that day” (79, 27.3%). There was no difference in reasons among professions.

Experience Submitting ADR Reports

Only 9% of health care professionals had submitted reports in the questionnaire before the educational meeting. Among 320 health care professionals who had never submitted ADR reports, the most common reason was “Did not know how to report” (115 respondents, 35.9%), followed by “It was a well-known ADR” (89, 27.8%). There was no difference in reasons among the professions (Figure 1).

Table 2. Multivariate Logistic Regression Analyses for Understanding the ADR Reporting System.

	Odds ratio	95% CI	p value
Before the educational meeting			
Profession			
Others	1.000		
Physician	5.415	1.339-21.895	.02
Nurse	1.626	0.462-5.724	.45
Pharmacist	18.784	3.708-95.153	<.01
Years of practical experience			
<5 years	1.000		<.01*
5-9 years	2.032	0.422-9.781	
10-19 years	2.678	0.675-10.631	
20-29 years	6.402	1.590-25.769	
≥30 years	21.953	4.310-111.810	
After the educational meeting			
Participation in the educational meeting			
Not participated	1.000		
Participated	5.111	1.700-15.365	<.01
Profession			
Others	1.000		
Physician	8.071	1.923-33.878	<.01
Nurse	1.716	0.498-5.919	.39
Pharmacist	18.357	3.847-87.585	<.01
Years of practical experience			
<5 years	1.000		<.01*
5-9 years	1.648	0.436-6.227	
10-19 years	1.777	0.569-5.546	
20-29 years	3.852	1.228-12.081	
≥30 years	7.695	1.650-35.882	

Note. ADR = adverse drug reaction; CI = confidence interval.

*p value for trend.

Figure 1. Reasons for no experience submitting ADR reports ($n = 320$).

Note. ADR = adverse drug reaction.

Table 3. Multivariate Logistic Regression Analysis of Understanding the ADR Reporting System Among Nurses in the Questionnaire Before the Educational Meeting.

	Odds ratio	95% CI	p value
Department			
Inpatient	1.000		<0.01
Outpatient	8.330	3.008-23.069	
Years of practical experience			
<5 years	1.000		0.03*
5-9 years	1.251	0.158-9.904	
10-19 years	0.722	0.121-4.302	
20-29 years	3.907	0.777-19.649	
≥30 years	4.960	0.271-90.713	

Note. ADR = adverse drug reaction; CI = confidence interval.

*p value for trend.

Subanalyses Restricted to Nurses

There were no significant differences in the characteristics (sex, department, years of practical experience) of nurses between before and after the educational meeting. The percentages of nurses working at outpatient departments who understood the ADR reporting system (30.0% outpatient vs. 5.1% inpatient) and who knew how to report ADRs (60.0% vs. 29.3%) were significantly higher than among those working at inpatient departments in the questionnaire before the educational meeting. The multivariate logistic regression analysis of the questionnaire before the educational meeting showed that working in outpatient departments was significantly and independently associated with understanding the ADR reporting system (8.33; 3.01-23.07) (Table 3).

Discussion

Factors Related to Understanding the ADR Reporting System

Physicians and pharmacists. Although physicians and pharmacists were more likely to understand the ADR reporting system compared to other professions, nurses were not. The OR for nurses was 1.626, but it was not significant. Nurses could play an important role in spontaneous ADR reporting, because they are close to the patient and record the symptoms of suspected ADRs. Therefore, subanalyses of nurses were conducted to determine their understanding and knowledge of ADR reporting and to find ways to improve them.

Years of practical experience. Respondents who have many years of practical experience have more opportunities to encounter ADR cases during their work. Therefore, they are more able to understand the ADR reporting system. In addition, because managers such as head nurses often report ADRs in our hospital, there may be a relationship between understanding the ADR system and years of practical

experience. Previous studies found relationships between ADR reporting and age or years of practical experience among health care professionals.^{5,11-13}

Participating in the educational meeting. Respondents who participated in the educational meeting were more likely to understand the ADR reporting system than those who did not (OR, 5.11; 95% CI, 1.70-15.37 in the questionnaire after the educational meeting). Many previous studies reported that interventions such as training, meeting, and economic incentives were important in improving and increasing ADR reports from health care professionals.^{8,9,12,14,15}

On the contrary, although the proportion of respondents who participated in the educational meeting was low (11.6% of 327 respondents in the questionnaire after the educational meeting), the proportion of respondents who understood the ADR reporting system increased after the educational meeting compared with before. This suggests that taking part in this survey and reading the explanation about the ADR reporting system on the questionnaire paper made health care professionals in our hospital understand the ADR reporting system. A previous study also showed that taking part in a study of an educational program improved the knowledge of legislation, of how and when to report suspected ADRs, and how to easily access the report forms among pharmacists in Norway.¹⁶

Reasons for Not Participating in the Educational Meeting

The most common reason for not participating in the educational meeting was "I was working at that time," followed by "I was off-duty on that day." Because we conducted the educational meeting after business hours, some nurses or physicians who were on night shift or later could not participate.

Factors Related to Understanding the ADR Reporting System Among Nurses

Nurses working in outpatient departments were more likely to understand the ADR reporting system than nurses working in inpatient departments in the present study. A previous study showed that the proportion of ADR reports from outpatient departments was higher than that from inpatient departments.¹⁷ In our outpatient departments, anticancer drugs and contrast mediums are often used. Nurses working in outpatient departments have more opportunities to care for patients being administered these medications causing suspected ADRs than nurses working in inpatient departments. In addition, specialist nurses are more likely to be assigned to outpatient departments in our hospital. A previous study demonstrated that specialist nurses were more likely to report serious ADRs than other groups.¹⁸

Prevalence of Knowledge and Experience of ADR Reporting

In this study, approximately 14% understood the ADR reporting system, and only about 9% of health care professionals had reported an ADR. The most common reason for no experience submitting ADR reports was “Did not know how to report,” followed by “It was a well-known ADR.” These responses were similar to those reported in previous studies.^{11,16,19} Although almost every health care professional had already faced a suspected ADR once in their professional life, they could not submit reports because of their lack of knowledge of how to report or of the ADR reporting system. With regard to these situations, we should conduct educational meetings providing appropriate knowledge about the ADR reporting system at times when it is easy for staff to participate. An e-learning system might be appropriate for night shift professionals.^{16,20}

Limitations and Strengths of the Study

This study had a few limitations. First, the study was conducted in one cancer institute and therefore does not represent all health care professionals in Japan. It is necessary to examine whether there are differences among other type of institutes in Japan. In addition, only understanding and knowledge of the ADR reporting system were examined, and the effectiveness of the educational interventions in regard to quantitative and qualitative improvement of spontaneous ADR reports by health care professionals was not evaluated. Nonetheless, because the response rate for this study was approximately 80%, the results appear to accurately reflect health care professionals' understanding and knowledge of the ADR reporting system within our hospital. Although some studies in other countries reported that educational interventions enhanced the quantity and quality of spontaneous ADR reports, there was no previous study in Japan focusing on understanding and knowledge of the ADR reporting system among health care professionals. To the best of our knowledge, this is the first study to evaluate educational interventions for understanding the ADR reporting system among Japanese health care professionals.

Conclusion

The present study demonstrated that many years of practical experience, profession (physicians, pharmacists), and educational interventions were associated with good understanding of the ADR reporting system. It was expected that the educational meeting, which was available to every health care professional and provided knowledge about the ADR reporting system, could improve understanding of the ADR reporting system among health care professionals.

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Declaration of Conflicting Interests

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