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Knowledge of and Perspectives on Pharmacovigilance among Pharmacists in the Miyagi and Hokkaido Regions of Japan

Taku Obara[1,2]*, Hiroaki Yamaguchi[1], Yutaro Iida[8], Michihiro Satoh[1], Takamasa Sakai[3], Yoshiko Aoki[4], Yuriko Murai[1,5], Masaki Matsuura[1], Mayumi Sato[1], Takayoshi Ohkubo[6], Ken Iseki[7] and Nariyasu Mano[1]

[1]*Department of Pharmaceutical Sciences, Tohoku University Hospital, Sendai, Japan*
[2]*Department of Preventive Medicine and Epidemiology, Tohoku Medical, Megabank Organization, Tohoku University, Sendai, Japan*
[3]*Pharmaceutical Information Center, Faculty of Pharmacy, Meijo University, Nagoya, Japan*
[4]*National Institute of Health Sciences, Tokyo, Japan*
[5]*Pharmacy Education and Research Center, Tohoku University Graduate School of Pharmaceutical Sciences, Sendai, Japan*
[6]*Department of Hygiene and Public Health, Teikyo University School of Medicine, Tokyo, Japan*
[7]*Department of Pharmacy, Hokkaido University Hospital, Sapporo, Japan*
[8]*Department of Pharmacy, Iwakiri Hospital, Sendai, Japan*

Abstract

The aim of the present study was to clarify the knowledge of and perspectives on pharmacovigilance among pharmacists in the Miyagi and Hokkaido regions of Japan. In this cross-sectional, self-administered questionnaire-based study, we contacted 3,164 pharmacists who belonged to the Miyagi Prefecture Hospital Pharmacists Association or the Hokkaido Society of Hospital Pharmacists during the 3-month period between January and March 2013. Of the 1,851 respondents (<30 years, 22.2%; ≥ 50 years, 25.8%; women, 41.9%), 6.9%, 22.1%, and 71.0% answered "I understand what it is", "I have heard of it, but I do not understand what it is", and "I do not know what it is", respectively, to the question "Have you ever heard of the term 'pharmacovigilance'?". Multivariate logistic regression analysis revealed that being ≥ 50 years old (odds ratio [OR]: 6.10, 95% confidence interval [CI]: 1.99-18.72), having a doctoral degree (OR: 6.33; 95%CI: 3.19-12.57), and having ≥ 10 pharmacists in the workplace (OR: 2.08; 95%CI: 1.20-3.60) were ifica3.60) were significantly and independently associated with understanding "pharmacovigilance." Pharmacists who understood "pharmacovigilance" also tended to know more related terms and actions. Furthermore, 76.2% of the respondents thought that pharmacists should be responsible for pharmacovigilance in the clinical setting, and even though most of the pharmacists in Japan had insufficient knowledge of pharmacovigilance, 71.9% wished to acquire more.

Keywords: Pharmacovigilance; Pharmacist; Questionnaire

Abbreviations: WHO: World Health Organization; ADR: Adverse Drug Reaction; MHLW: Ministry of Health, Labour and Welfare; RMP: Risk Management Plan; MIHARI: Medical Information for Risk Assessment Initiative; JADER: Japanese Adverse Drug Event Report Database PMDA: Pharmaceutical and Medical Devices Agency

Introduction

The World Health Organization (WHO) defines "pharmacovigilance" as a term that describes the "science and activity related to the detection, evaluation, understanding and prevention of adverse effects or other problems of pharmaceutical products" (http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.8.pdf). The concept of pharmacovigilance has been widely accepted around the world. One of the traditional pharmacovigilance systems is the spontaneous adverse drug reaction (ADR) reporting system. However, the ADR reporting system has some limitations, such as not being able to know the prevalence of an ADR due to unknown drug use denominator data and the presence of reporting bias resulting from the spontaneous reporting system. To compensate for these limitations, several systems, such as secondary claims databases, medical chart reviews, and surveillance registry systems, have been developed and used for pharmacovigilance in number of countries [1].

The importance of pharmacovigilance in Japan has been gradually recognized after the serious incidence of drug-induced hepatitis was reported in the 1980s. In addition to the spontaneous ADR reporting system for pharmaceutical companies and medical institutions, a spontaneous ADR reporting system was developed for patients and consumers in 2012. The development of an infrastructure to adequately utilize medical databases, including a national receipt database, is ongoing. In particular, pharmacists who play a role in the gathering, evaluating, and releasing of drug information in the clinical setting are more increasingly expected to participate in pharmacovigilance activities. To promote the development of an infrastructure for pharmacovigilance, the Ministry of Health, Labour and Welfare proposed the Japanese Sentinel Project, started the Medical information Database Infrastructure Development Project, developed guidelines for the Drug Risk Management Plan (RMP), compelled all pharmaceutical companies to adopt the RMP, started the Medical Information for Risk Assessment Initiative (MIHARI) Project, and recently made the Japanese Adverse Drug Event Report (JADER) Database, the database for the spontaneous ADR reporting system in Japan, available for download through the Pharmaceutical and Medical Devices Agency (PMDA) website (http://www.pmda.go.jp/english/index.html). However, Japanese pharmacists' knowledge of and perspectives on pharmacovigilance remain unclear. Therefore, the aim

***Corresponding author:** Taku Obara, Department of Pharmaceutical Sciences, Tohoku University Hospital, Aoba-ku, Sendai, Japan, Tel: +81-22-717-7548; Fax: +81-22-717-7545; E-mail: obara-t@hosp.tohoku.ac.jp

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of the present study was to assess the knowledge of and perspectives on pharmacovigilance among Japanese pharmacists.

Methods

This was a cross-sectional, self-administered questionnaire-based study involving pharmacists who belonged to the Miyagi Prefecture Hospital Pharmacists Association or the Hokkaido Society of Hospital Pharmacists [2]. The questionnaire was developed based on previous studies [3-5], and was pre- tested on a sample group composed of 10 pharmacists and five pharmacovigilance professionals to whom the purpose of the study was explained. Based on the comments received during the pilot testing, slight modifications were made to the wording of the questionnaire prior to its use in this study. Data from the pilot study were not included in the final analysis.

The final questionnaire consisted of the following five sections: (a) characteristics of the pharmacists (age, sex, workplace, experience as a pharmacist, postgraduate degree, and number of pharmacists in the workplace); (b) knowledge of the ADR reporting system; (c) personal history of ADR reporting; (d) reasons for not having reported an ADR; (e) personal opinions on pharmacovigilance (preference for receiving information on pharmacovigilance and the responsible party regarding pharmacovigilance in their clinical practice); and (f) knowledge of recent developments in pharmacovigilance in Japan and of terminology related to pharmacovigilance with explanations for each term or action (the payment system for medical services, the pharmacovigilance database, "pharmacovigilance per se," and "regulatory science"). Questionnaires were distributed and collected by mail over the 3-month period between January and March 2013. Parts of the responses were used for this article.

Pharmacists were divided into three groups based on the following three responses to the question "Have you ever heard of the term 'pharmacovigilance'?": "I understand what it is"; "I have heard of it, but I do not understand what it is"; and "I do not know what it is." Next, the numbers of pharmacists who were aware of terms and actions related to pharmacovigilance, and of those who had perspectives on pharmacovigilance, were compared between the three groups using the chi-square test or Fisher's exact test. Determinants of understanding the term 'pharmacovigilance' was identified through the use of multilevel and multivariate logistic regression analyses to estimate odds ratios (ORs) with 95% confidence intervals (CIs) for understanding the term 'pharmacovigilance'. Multivariate logistic regression analysis was adjusted for variables that were significantly related to understanding the term 'pharmacovigilance' on univariate analyses. All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). A P value less than 0.05 was considered to indicate statistical significance.

Results

Of the 3,164 pharmacists who were sent the questionnaire, 1,862 (58.8%) responded. After excluding responses with incomplete data regarding age, sex, or knowledge of pharmacovigilance, data from a total of 1,851 pharmacists (<30 years, 22.2%; ≥ 50 years, 25.8%; women, 41.9%) were eligible for analysis (Table 1). Regarding the characteristics of the respondents, 3.0% had a doctoral degree, 35.1% had ≥ 20 years of experience as a pharmacist, 88.3% worked in a hospital, and 43.3% worked in a workplace that had ≥ 10 pharmacists (Table 1).

The percentage of pharmacists who answered "I understand what it is", "I have heard of it, but I do not understand what it is", and "I do not know what it is" to the question "Have you ever heard of the term 'pharmacovigilance'?" was 6.9%, 22.1%, and 71.0%, respectively. Compared to pharmacists who answered "I have heard of it, but I do not understand what it is" or "I do not know what it is", pharmacists who answered "I understand what it is" were more likely to be male, to be ≥ 50 years of age, to have a doctoral degree, to have ≥ 20 years of practical experience as a pharmacist, to have worked at places other than hospitals, doctor's offices, or clinics, and to work in a workplace with ≥ 10 pharmacists (Table 1). Multivariate logistic regression analysis revealed that being ≥ 50 years of age (OR: 6.10, 95% CI: 1.99-18.72), having a doctoral degree (OR: 6.33, 95%CI: 3.19-12.57), and working in a workplace with ≥ 10 pharmacists (OR: 2.08, 95%CI: 1.20-3.60) were significantly and independently associated with understanding the term "pharmacovigilance" (Table 2).

In addition, 5.0% of pharmacists had heard the term "regulatory science", 19.1% knew that medical information databases are used for safety evaluations of pharmaceutical products in other countries, 1.3%

Have you ever heard of the term "pharmacovigilance?"						
		Total	**I I understand what it is**	**I have heard of it, but I do not understand what it is**	**I I do not know what it is**	
n (%)		1,851 (100)	127 (6.9)	409 (22.1)	1,315 (71.0)	P
Sex						
	Female, %	41.9	31.5	38.6	43.9	0.008
	Male, %	58.1	68.5	61.4	56.1	
Age, Years						
	20–29, %	22.2	10.2	18.6	24.4	<0.0001
	30–39, %	30.3	24.4	25.9	32.2	
	40–49, %	21.7	19.7	23.5	21.4	
	≥ 50, %	25.8	45.7	32.0	22.0	
Highest level of education						
	Bachelors, %	65.4	58.3	64.1	66.5	<0.0001
	Masters, %	16.7	18.9	16.1	16.7	
	Doctorate, %	3.0	17.3	5.1	0.9	
	No answer, %	14.9	5.5	14.7	15.9	
Years of practical experience as a pharmacist						
	<5, %	15.9	12.6	15.6	16.3	<0.0001
	5–9, %	22.0	13.4	14.7	25.1	
	10–19, %	25.2	23.6	26.4	24.9	
	≥ 20, %	35.1	48.8	41.1	31.9	
	No answer, %	1.8	1.6	2.2	1.8	
Workplace						
	Hospital, doctor's office, or clinic, %	88.3	83.5	87.5	89.0	<0.0001
	Community pharmacy or drugstore, %	9.6	9.4	9.0	9.8	
	Other, %	1.9	7.1	3.5	0.9	
	No answer, %	0.2	0.0	0.0	0.3	
Number of the pharmacists in the workplace						
	<5, %	32.2	31.5	32.8	32.1	0.07
	5–9, %	24.4	15.0	22.2	25.9	
	≥ 10, %	43.3	53.5	44.7	41.9	
	No answer, %	0.1	0.0	0.3	0.1	
Region						
	Miyagi, %	25.9	32.3	26.2	25.2	0.21
	Hokkaido, %	74.1	67.7	73.8	74.8	

Table 1: Characteristics of participants by awareness of pharmacovigilance.

had knowledge of the "Japanese Sentinel Project", 7.2% knew that the MHLW utilizes health insurance claims data (national database) to conduct research for the public interest and has undertaken an initiative to improve the quality of medical services, 2.5% had knowledge of the "MIHARI Project", 5.6% were familiar with the development of an infrastructure for a medical information database, 2.7% knew about the "ICH E2E Guideline: Pharmacovigilance planning", 4.1% had knowledge of the "RMP", and 1.7% knew that "signal detection" is used to explore unknown adverse reactions to drugs (Table 3). Pharmacists who understood the term "pharmacovigilance" more frequently understood terms and actions related to "pharmacovigilance" than those who did not.

	Variables	Odds ratio	95% confidence interval
Sex			
	Female	0.76	0.51-1.15
	Male	1.00	
Age, Years			
	<30	1.00	
	30-39	2.22	0.89 – 5.52
	40-49	2.76	0.95 – 8.01
	≥ 50	6.10	1.99 – 18.72
Highest level of education			
	Bachelors	1.00	
	Masters	1.53	0.91-2.56
	Doctorate	6.33	3.19-12.57
Years of practical experience as a pharmacist			
	<5	1.79	0.73-4.37
	5-9	1.00	
	10-19	1.14	0.56-2.31
	≥ 20	1.20	0.48-2.98
Workplace			
	Hospital, doctor's office, or clinic	1.00	
	Community pharmacy or drugstore	1.15	0.60-2.23
	Other	1.57	0.60-4.09
Number of pharmacists in the workplace			
	<5	1.25	0.70-2.25
	5-9	1.00	
	≥ 10	2.08	1.20-3.60

The odds ratios for "no answer" are not shown.

Table 2: Multivariate logistic regression analyses for understanding pharmacovigilance.

Have you ever heard of the term "pharmacovigilance?"						
		Total	I I understand what it is	I have heard of it, but I do not understand what it is	I I do not know what it is	
n (%)		1,851 (100)	127 (6.9)	409 (22.1)	1,315 (71.0)	P
Have you ever heard of the term "regulatory science?"						
	I understand what it is, %	5.0	36.2	8.1	1.1	<0.0001
	I have heard of it, but I do not understand what it is, %	16.9	43.3	35.9	8.4	
	I do not know what it is, %	77.6	20.5	55.5	90.0	
	No answer, %	0.5	0.0	0.5	0.5	
Do you know that medical information databases are used for safety evaluations of pharmaceutical products in other countries?						
	I understand what it is, %	19.1	58.3	28.6	12.3	<0.0001
	I have heard of it, but I do not understand what it is,%	30.3	33.1	45.0	29.2	
	I do not know, %	47.4	8.6	25.4	58.0	
	No answer, %	0.5	0.0	1.0	0.5	
Do you know what the "Japanese Sentinel Project" is?						
	I understand what it is, %	1.3	16.5	0.5	0.1	<0.0001
	I have heard of it, but I do not understand what it is, %	10.3	44.9	24.9	2.4	
	I do not know what it is, %	88.1	37.8	73.8	97.4	
	No answer, %	0.3	0.8	0.8	0.1	
Do you know that the MHLW utilizes health insurance claims data (national database) to conduct research for the public interest and has undertaken an initiative to improve the quality of medical services?						
	I understand what it is, %	7.2	42.5	8.1	3.5	<0.0001
	I have heard of it, but I do not understand what it is, %	23.2	37.0	43.3	15.6	
	I do not know what it is, %	69.4	19.7	48.2	80.8	
	No answer, %	0.2	0.8	0.4	0.1	
Do you know about the "MIHARI Project" carried out by the PMDA?						
	I understand what it is, %	2.5	17.3	3.9	0.7	<0.0001
	I have heard of it, but I do not understand what it is, %	12.0	40.2	26.4	4.9	
	I do not know what it is, %	85.0	40.9	69.4	94.1	
	No answer, %	0.5	1.6	0.2	0.4	
Do you know about the "Medical information database infrastructure development" carried out by MHLW and PMDA?						
	I understand what it is, %	5.6	34.6	6.8	2.4	<0.0001
	I have heard of it, but I do not understand what it is, %	19.4	39.4	35.5	12.5	
	I do not know what it is, %	74.6	26.0	57.2	84.6	
	No answer, %	0.4	0.0	0.5	0.5	
Do you know about the "ICH E2E Guideline: Pharmacovigilance planning" indicated by MHLW in 2005?						
	I understand what it is, %	2.7	25.2	2.4	0.6	<0.0001
	I have heard of it, but I do not understand what it is, %	15.3	42.5	34.0	6.9	
	I do not know what it is, %	81.7	32.3	63.1	92.3	
	No answer, %	0.3	0.0	0.5	0.2	
Do you know about the "Drug Risk Management Plan" indicated by MHLW in 2012?						
	I understand what it is, %	4.1	26.8	4.4	1.7	<0.0001
	I have heard of it, but I do not understand what it is, %	24.2	47.2	43.3	16.0	
	I do not know what it is, %	71.5	26.0	51.8	82.0	
	No answer, %	0.2	0.0	0.5	0.3	
Do you know that a method called "signal detection" is used to detect unknown adverse reactions to drugs?						

	I understand what it is, %	1.7	16.5	1.5	0.3	<0.0001
	I have heard of it, but I do not understand what it is, %	15.3	47.2	31.3	7.2	
	I do not know what it is, %	82.7	36.3	66.7	92.2	
	No answer, %	0.3	0.0	0.5	0.3	

MHLW: Ministry of Health, Labour and Welfare, MIHARI: Medical Information for Risk Assessment Initiative; PMDA: Pharmaceutical and Medical Devices Agency.

Table 3: Awareness of terms and actions related to pharmacovigilance by awareness of pharmacovigilance.

Have you ever heard of the term "pharmacovigilance?"						
		Total	**I understand what it is**	**I have heard of it, but I do not understand what it is**	**I do not know what it is**	
n (%)		1,851 (100)	127 (6.9)	409 (22.1)	1,315 (71.0)	P
In your opinion, who should be responsible for "pharmacovigilance" in the clinical setting?						
Pharmacist, %		76.2	88.2	79.7	74.0	0.003
Physician, dentist, %		13.1	8.7	12.7	13.6	
Nurse, %		0.6	0.8	0.0	0.8	
Other, %		5.3	2.3	3.4	6.2	
No answer, %		4.8	0.0	4.2	5.4	
Would you like to obtain more knowledge and information regarding "pharmacovigilance?"						
I strongly think so, %		7.2	23.6	4.9	6.4	<0.0001
I somewhat think so, %		64.7	67.7	75.6	61.0	
Neither, %		23.3	7.1	17.6	26.7	
I do not quite think so, %		2.8	0.0	1.0	3.6	
I do not think so at all, %		1.1	0.8	0.0	1.5	
No answer, %		0.9	0.8	0.9	0.8	

Table 4: Perspectives of pharmacovigilance by awareness of pharmacovigilance.

Regardless of the extent of understanding of the term "pharmacovigilance", more than 74.0% of pharmacists answered that they should be responsible for pharmacovigilance in the clinical setting (Table 4). Among pharmacists who understood the term "pharmacovigilance", knew but did not understand, and did not know, 91.3%, 80.5%, and 67.4%, respectively, wished to acquire more knowledge and information.

Discussion

We found that only 6.9% of pharmacists understood the term "pharmacovigilance", and these pharmacists tended to be ≥ 50 years of age, have a doctoral degree, and work in a workplace with ≥ 10 pharmacists. Use of databases for the evaluation of drug safety in other countries was the most popular action related to pharmacovigilance among Japanese pharmacists. To our knowledge, this is the first study to clarify the knowledge of and perspectives on pharmacovigilance among Japanese pharmacists.

Prevalence and determinants of understanding pharmacovigilance

Over 90% of the respondents did not understand the term "pharmacovigilance", and the determinants of understanding "pharmacovigilance" were working in a relatively large hospital and in a managerial position. The finding that a large proportion of Japanese pharmacists did not understand the term "pharmacovigilance" was similar to results from previous studies conducted in other countries [6-8]. However, many pharmacists likely participate in pharmacovigilance activities in daily practice, and therefore might have working knowledge of pharmacovigilance even though they are not familiar with the actual term.

Knowledge of terms and actions related to pharmacovigilance

Pharmacists' knowledge of terms and actions related to pharmacovigilance was not widespread in Japan. Compared with pharmacists who did not understand the term "pharmacovigilance", those who did more often had knowledge of related terms and actions. However, even among those who understood the term "pharmacovigilance", the prevalence of those who had such knowledge was less than 50%, and the degree of the understanding was inadequate. Although using the ADR reporting system to evaluate drug safety was the most popular pharmacovigilance activity, knowledge of special terms and the names of projects (e.g., MIHARI, RMP, and signal detection) were relatively low. However, these proportions are expected to increase because RMP was introduced in the clinical setting in Japan in 2014, and an increasing number of studies using the signal detection method and JADER are being conducted.

Perspectives of pharmacovigilance

Even among pharmacists who did not understand the term "pharmacovigilance", more than 74% of the respondents believed that pharmacists are responsible for pharmacovigilance, and 65% wished to obtain more information. Previous studies in foreign countries found that many pharmacists consider pharmacovigilance to be important and want to receive pharmacovigilance training [6,9,10] reported that although its overall impact was mild, pharmacovigilance training was associated with improved knowledge and practice of pharmacovigilance among various health care providers. Therefore, additional knowledge and information regarding pharmacovigilance should be encouraged in undergraduate and postgraduate pharmacy curriculum in Japan.

Limitations

This study did have a few limitations. First, our results were based on data from pharmacists in only two of 47 prefectures in Japan. Whether larger differences in knowledge regarding pharmacovigilance exist among pharmacists in different prefectures of Japan remains unclear. In addition, pharmacists who had a prior interest in pharmacovigilance may have been more likely to respond to the questionnaire. Therefore, the actual proportion of pharmacists who understand the term "pharmacovigilance" may be even lower in the general pharmacist population. Nonetheless, since the response rate for this study was approximately 60%, the results appear to accurately reflect pharmacists' knowledge of and perspectives on pharmacovigilance within the study region.

Conclusion

Most Japanese pharmacists did not understand the term "pharmacovigilance", and their knowledge of terms and actions related to pharmacovigilance was insufficient. However, among both pharmacists who did not know, and among those who knew but did not understand what "pharmacovigilance" was, more than

74% thought that pharmacists should be responsible for pharmacovigilance in the clinical setting, and more than 65% wished to obtain further knowledge and information.

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