

# Knowledge and attitude of pharmacy students about pharmacovigilance in Semarang, Indonesia

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**Abstract.** To assure pharmacovigilance must be applicable in the future, knowledge and attitude of pharmacy students have to be examine. Therefore, the study objective was to correlate the knowledge and attitude toward pharmacovigilance of pharmacy students in Semarang, Indonesia. A cross sectional study was carried out using valid and reliable questionnaire. The questionnaire was design to asses knowledge and attitude regarding pharmacovigilance. Pharmacy students of undergraduate program and pharmacist students of Profession Program studying in STIFAR, Wahid Hasyim University and Sultan Agung Islamic University during the study period were included. The data was analyzed by Chi square test to identified the correlation between the knowledge and attitude. Three hundred and twelve pharmacy students {219(70,19%) undergraduate program and 93 (29,8%) pharmacist profession program} participated. Among pharmacy students, 51% (n=158) had good level of knowledge and attitude toward pharmacovigilance. We found significant correlation between knowledge and attitude pharmacy student regarding pharmacovigilance ( $p=0,000$ ). There is correlation between the knowledge and attitude related to *pharmacovigilance* in pharmacy students. Developing a right attitude towards pharmacovigilance may be a key determinant to improving their practice in the future.

**Keyword:** knowledge, attitude, pharmacovigilance, pharmacy students

## 1 Introduction

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem is defined as pharmacovigilance (PV) [1]. Adverse drug reactions (ADRs) are an important cause of morbidity and mortality and are responsible for a significant number of hospital admissions ranging from 0.3% to 11%[2]. In simple definition, adverse drug reactions (ADRs) are one of the major problems associated with medicines and are recognized hazards of drug therapy. Therefore, adverse reaction monitoring and reporting are very important in identifying the adverse reaction trends and to minimize or prevent harm to patients arising from their drugs

Indonesia has national centre of pharmacovigilance, namely National Agency of Drug and Food Control

and was accepted as the member of World Health Organization (WHO) programme for International Drug Monitoring in 1990. Under this programme, all ADR reports that have been received and screened by the National Agency of Drug and Food Control (NADFC) are submitted to the monitoring centre in WHO database[3]. PV has been recommended for every country due to variation in drug response among individuals. However, Application of PV in many country remain to be underreporting [4,5] and those activity still rarely to be done in Indonesia[6]

Previous study shows, majority of healthcare professional in Kuwait and India have poor behaviour in reported and monitor adverse drug reaction (ADR) [5,7]. Being one of key health care professional, pharmacists have immense responsibility in pharmacovigilance. Pharmacists work in community and hospital are the most closest to the ADRs effect on patients every day. Majority pharmacist in India have

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good attitude about pharmacovigilance but have poor knowledge toward it [8,9]. Pharmacists who are have good knowledge in Kuwait, majority never reported ADR[7], Hence, educational intervention programs and curriculum concept are needed to increase pharmacist's role in the reporting process and training pharmacy student for reporting ADR are vital in safe guarding the public health[10].

Similar studies have been also conducted among pharmacy students in different countries[10].The pharmacy student in India had strong intentions and favourable attitudes toward ADR reporting but they had inadequate knowledge of how to report serious ADR[11]. In spite of studies conducted among different health professionals and students, there is a lack of information about pharmacovigilance study from pharmacist perspective in Indonesia. To assure PV must be applicable in the future, knowledge and attitude of undergraduate pharmacy student and pharmacist profession student has to be examine because widening the teaching programs for students during their undergraduate training might provide a solution to strengthen ADR reporting system. Therefore, the study objective was to correlate the knowledge and attitude toward pharmacovigilance of pharmacy students in Semarang Indonesia.

## 2 Methodology

### Setting

Final semester of Pharmacy students of undergraduate program and pharmacist students of Profession Program studying in STIFAR, Wahid Hasyim University and Sultan Agung Islamic University during the study period (February-March 2018) were included.

### Sample Calculation

Three hundred and twelve pharmacy students {219(70,19%) undergraduate program and 93 (29,8%) pharmacist profession program} participated. Sample was calculated by Slovin Formula for each faculty in different university.

$$n = \frac{N}{Nd^2 + 1} \quad (1)$$

N : total population

n : number of samples

d : error tolerance (level)

#### a. STIFAR

1) Undergraduate Program (397 population)

$$n = \frac{397}{397 \times 0,1^2 + 1}$$

n = 80 students

2) Pharmacist Profession Program(122 population)

$$n = \frac{122}{122 \times 0,1^2 + 1}$$

n = 55 students

b. Wahid Hasyim University

1) Undergraduate Program(342 population)

$$n = \frac{342}{1+342(0,1)^2}$$

n = 77 students

2) Pharmacist Profession Program(61 population)

$$n = \frac{61}{1+61(0,1)^2}$$

n = 38 students

c. Sultan Agung Islamic University

1) Undergraduate Program (164 population)

$$n = \frac{164}{164 + 0,1^2 + 1}$$

n = 62 students

### 1. Study Design

A cross sectional study was carried out using valid and reliable questionnaire. This study was approved by the faculty ethical commites and have prior permission from the deans of each faculty. The questionnaire was design to asses knowledge and attitude regarding pharmacovigilance, adapted from the previously published article[12] and modified according to the need of the present study. In order to test the validity and reliability of the survey form, the revised questionnaire was tested by administering it to a sample of 30 pharmacy students. The overall cronbach's alfa value was 0,884.

The questionnaire survey consists of demographic characteristics of participants, their knowledge of pharmacovigilance (12 questions), attitude towards ADR reporting (9 questions). Five levels likert scaling (1=strongly agree, 2=agree, 3=neutral, 4=disagree, and 5=strongly disagree) was used to analyze the attitude of the respondents. Scoring was done for sections on knowledge and attitude. Each correct answer on knowledge towards pharmacovigilance was scored "1". From the participants' response result, the score are categorize by good, fair and poor.

### 2. Data Collection

Written consent was taken from the participants prior the data collection. The participants were given 20 mins to provide the necessary information. their responses were dealt with high level of confidentiality and anonymity. Participants were briefed about the objectives and the significance of research prior to data collection.

### 3. Statistical Analysis

The completed questionnaire information was recorded using Microsoft Excel spreadsheet

(Microsoft Office 2007). The information from the returned questionnaire was coded and entered into Statistical Package for Social Sciences (SPSS)

version 21.0 software for analysis. The data was analyzed by Chi square test to identified the correlation between the knowledge and attitude.

### 3 Results

#### 3.1 Demographic Data

Table 1 presents three hundred and twelve pharmacy students {219(70%) undergraduate program and 93 (30%)

pharmacist profession program} participated. A total of 76 respondents were males (24%), while 236 were females (76%) and most participants (58%) were within the age group of 21–23 years. Details of demographic are shown in Table 1.

**Table 1.** Demographic details of pharmacy students in Semarang, Indonesia

Characterization	Frequency	%
Gender		
Male	76	24
Female	236	76
Age Distribution(in years)		
18-20	118	38
21-23	183	58
24-26	11	4
Status		
Undergraduate student	219	70
Pharmacist profession	93	30

#### 3.2 Knowledge Of Pharmacy Student Toward Pharmacovigilance

Table 2 shows knowledge of pharmacovigilance among pharmacy students, it is good to see 94% pharmacy students could tell the definition of pharmacovigilance, but only 60% of students were able to tell that International Centre for Reporting ADR is Uppsala. However, only 64 % of students had knowledge that doctors, nurses, and pharmacists are the health-care professional responsible for ADR

reporting. Overall, 75% students could tell that National Agency of Drug and Food Control (NADFC) is the regulatory body for drug safety issues in Indonesia and could identify that time limitation to report ADR is one day, but only 60% of students could answer that rarely ADR on clinical trial can be identified in phase 4, and among the students, only 77% students could answer that thalidomide was example of drug that caused ADR. From this study, it was found that 81% of them were able to make out that yellow card is use to report ADR in Indonesia.

**Table 2.** Knowledge related questions and percentage of correct and incorrect responses of pharmacy students in Semarang, Indonesia

Knowledge related questions	Correct	Response	Incorrect	Response
	n	%	N	%
1. Pharmacovigilance definition	294	94	18	6
2. Purpose of pharmacovigilance	290	93	22	7
3. Healthcare professionals who responsible for report ADR in hospital	199	64	113	36
4. Organization that responsible for ADR monitoring in Indonesia	236	75	76	25
5. Location of ADR monitoring centre in the world	188	60	124	40
6. Time limitation to report ADR	234	75	78	25
7. Stage of clinical trial test rarely ADR can be identified	188	60	124	40
10. Drug that caused ADR	240	77	72	23
11. ADR Reporting in Indonesia	254	81	58	19

### Attitude of Pharmacy Students Toward Pharmacovigilance

Table 3 describes assessment of attitude by Likert's-type scale regarding ADR reporting among students. It was good to see that 48-49% of students strongly agreed to the fact that ADR reporting is important and obligate. When asked whether establishing ADR monitoring center should be made compulsory in every hospital, 38% of them strongly agreed to the fact. Overall, 37 % of students agreed to the fact that ADR

reporting is a professional obligation to them. Pharmacovigilance should be taught in detail to healthcare professional is strongly agreed among 53% of students, but only 27% of students strongly agreed that they have time to read any article about ADR prevention. When asked whether they have seen ADR reporting form, only 27% of students that they have seen ADR reporting form but it was good to know that 96% of student have taught about pharmacovigilance in their study.

**Table 3.** Attitude related question and anticipated response of pharmacy student in Semarang, Indonesia

Attitude related questions	Anticipated response	
	n	%
1. ADR are important to report	150	48
2. ADR are obligate to report	153	49
3. ADR reporting are obligation for pharmacist	116	37
4. Pharmacovigilance should be taught in detail to healthcare professional	165	53
5. I know national ADR centre monitoring	55	18
6. I have time to read any article about ADR prevention	79	25
7. ADR monitoring centre should be established in every hospital	119	38
8. I have seen ADR monitoring form	85	27
9. I have taught about pharmacovigilance in my study	299	96

### 3.3 Level of Knowledge of Pharmacy Students

Table 4 indicates, among pharmacy students, 57% (n=125) undergraduate program and 61% (n=57) pharmacist profession program, had good level of knowledge regarding pharmacovigilance and 43% (n=94) undergraduate program and 39% (n=36) pharmacist profession program, had fair level toward it. Knowledge frequency distribution of pharmacy students are shown in Table 4.

**Table 4.** Knowledge frequency distribution of pharmacy students toward pharmacovigilance in Semarang, Indonesia

Knowledge	Undergraduate		Profession	
	Student		Pharmacist	
	N	%	N	%
Good	125	57	57	61
Fair	94	43	36	39
Total	219	100	93	100

### 3.4 Attitude Frequency Distribution of Pharmacy Students

Among pharmacy students, 73% (n=159) undergraduate program and 71% (n=66) pharmacist profession program, had good level of attitude regarding pharmacovigilance and 27% (n=60) undergraduate program and 29% (n=27) pharmacist profession program, had fair level toward it. Attitude

frequency distribution of pharmacy students are shown in Table 5.

**Table 5.** Attitude frequency distribution of Pharmacy Students toward Pharmacovigilance in Semarang, Indonesia

Attitude	Undergraduate		Profesion	
	Student		Pharmacist	
	N	%	N	%
Good	159	73	66	71
Fair	60	27	27	29
Total	219	100	93	100

### 3.6 Correlation of Knowledge and Attitude of Pharmacy Student toward Pharmacovigilance

Table 6 describes, 51% (n=158) pharmacy students, had good level of knowledge and attitude regarding pharmacovigilance and 18% (n=56) pharmacy students, had fair level of knowledge and attitude toward it. From this study, despite the good knowledge among pharmacy students, it was found 8% (n=26) had fair level of attitude and 23%(n=72) had fair level of knowledge but with good level of attitude toward pharmacovigilance. We found significant correlation between knowledge and attitude pharmacy student regarding pharmacovigilance (p value 0,000).

**Table 6.** Correlation of Knowledge and Attitude of Pharmacy Student toward Pharmacovigilance in Semarang, Indonesia

Knowledge of Pharmacy Student	Attitude						p value
	Fair	%	Good	%	Total	%	
Fair	56	18	72	23	128	41	0,000
Good	26	8	158	51	184	59	
Total	82	26	230	74	312	100	

## 4 Discussion

The present study is the first study reporting knowledge and attitude toward pharmacovigilance of pharmacy students in Indonesia. This study is questionnaire-based survey conducted to assess the knowledge and attitude of pharmacovigilance towards ADR reporting among undergraduate pharmacy students and pharmacist profession students in STIFAR, Wahid Hasyim University and Sultan Agung Islamic University. The questionnaire had 18 questions in total. From this study indicates, that majority of students know WHO standard definition of pharmacovigilance which are opposite to studies done earlier [13,14]. 37% of students felt ADR reporting is a professional obligation to them which is similar to other studies [13]. The majority of students could tell NADFC is the regulatory body for drug safety issues in Indonesia; the result of which is similar to other studies [13,14]. The majority felt that pharmacovigilance should be taught in detail to health-care professionals and practicing it will bring improvement in the quality of life, which correlates with another study [14]. From this study, it was found that the result is opposite with the study conducted in Malaysia and Nigeria, it were reported that pharmacovigilance and ADR reporting among final year pharmacy students in Malaysian public universities and also undergraduate pharmacy students in Nigeria have poorly understands and insufficient knowledge about the concept of pharmacovigilance[15]. However, from this study it was found that only 25% pharmacy students have time to read any article about ADR prevention, indicating that this behaviour must be initiate since early semester. It was seen that a majority of students have not seen the ADR reporting form at all, from this study, 27% pharmacy students who have seen ADR reporting form are at the pharmacist profession group, suggesting that this topic is not cover sufficiently in undergraduates curriculum all all study institutes

Educational intervention is very much essential to these undergraduate students to get a good grasp of pharmacovigilance. Hence, this topic must be dealt separately during their theory classes and initiation must be made for inclusion how to fill ADR form and causality assessment of ADR in our practical syllabus. With regard to attitude toward ADR reporting, students response was satisfactory.

The present study indicates that only more than half (59%) of participants have good knowledge and

attitude about pharmacovigilance. However there was significant correlation ( $p=0,000$ ) with regard to knowledge and attitude of it, among pharmacy students. Pharmacy students who have real knowledge of pharmacovigilance are likely to provide more adequate health services in their future practice. So with a positive attitude toward ADR reporting, many interventions can be made in the students curriculum such as continued pharmacy education, seminars, and workshops to strengthen the system and to improve the ADR reporting culture in our country so that students realize that all medicines can cause ADRs. The students can get an actual practical knowledge by visiting a pharmacovigilance center and by observing its functioning carefully[13].

In this study, of the total pharmacy students in Semarang region, only 312 students were studied. Thus, the findings might or not represent the overall perspectives of the pharmacy students about pharmacovigilance. Moreover, this study was conducted in only one city and hence difficult to extrapolate the study findings to the entire country. Success of Pharmacovigilance programme depends on prompt reporting of ADRs. Hence, it is important to raise an awareness of pharmacovigilance since at undergraduate study. Also our current curriculum has little space for the one of the important aspect of pharmacotherapy, i.e. adverse drugs reactions, which in turn achieves the goals of pharmacovigilance programme. Therefore it is important to develop a habit of being vigilant on ADR and reporting the same among students [14], especially at early part of pharmacy education.

## Conclusion

Underreporting of ADR is a major threat to the success of pharmacovigilance program. Regarding the study, there was significant correlation to knowledge and attitude toward pharmacovigilance. It is a need for providing continuing education programs for pharmacist on pharmacovigilance in Indonesia. It is anticipated that our study results will help in future for curriculum designing to strengthen pharmacovigilance.

## References

- [1] WHO. The importance of pharmacovigilance. World Health Organization, Geneva, 146-157(2002)
- [2] A. A. Khobrani, M. S. Almilki, F. T. Alotaibi, H. A. Aljabri, The Egyptian Journal of Hospital Medicine, **70 (7)**, 1224-1227 (2018)
- [3] National Agency of Drug and Food Control, available from <http://e-meso.pom.go.id/web/index.php?act=newsdet3&newsId=90&lang=0&action=>
- [4] S. Shalini and S.Mohan, Journal of Young Pharmacists, **7(2)**,118-125 (2015)
- [5] Srinivasan V, Sheela D. Biomed Pharmacol J. **10(3)** (2017)
- [6] G. Wangge, W. Akbar, Health Science Journal of Indonesia. **7(1)** (2016)
- [7] S.K Gupta, R.P. Nayak, R. Shiravanjani, S.K Vidyarthi, Perspect clin res, **6(1)** (2015)
- [8] F.M.Alsaleh, S.W.Alzaid, E.A.Abahussain, T.Bayoud, J.Lemay, Saudi Pharm J, **25(6)**: 830–837, 2017
- [9] M.Suyagh, R. A. Farha, D.G. Farah, Saudi Pharmaceutical Journal, **23(2)**, 2014
- [10] M.E. Isfahani, S. Mousavi, A. Rakhshan, M. Assarian, L. Kutti, K.Eslami, Journal Of Pharmaceutical Care, **1(4)**:145-148 (2013)
- [11] S. Shivadasan, M. Sellapan, International Journal Of Current Pharmaceutical research, 7(2015)
- [12] V. Srivinasan, D. Sheela, D. Mridula, Biomed Pharmacol J, 10(3) (2017)
- [13] V. Rani, R. Shyamala, G. B.Simpson, Asian Journal of Pharmaceutical and Clinical Science, **10- 7** ( 2017)
- [14] S. Kumbar, P.Khrisna, Indian Journal of Pharmacy and Pharmacology, **4(1);45-48** (2017)
- [15] A.Raz a and H.Jamal, Journal of pharmacovigilance, **3:173**(2015)