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RESEARCH ARTICLE

Knowledge and perception of pharmacovigilance among pharmacy students and pharmacy professional students

Fivy Kurniawati[1], Arief Rahman Hakim[1], Pradipta Dwinisa Novitasari[2], Pratiwi Dian Kumalasari[2], Lulu Wana Hamidah[2]

[1] Pharmacology and Clinical Pharmacy Department, Faculty of Pharmacy, Universitas Gadjah Mada, Indonesia
[2] Faculty of Pharmacy, Universitas Gadjah Mada, Indonesia

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Correspondence
Arief Rahman Hakim
Pharmacology and Clinical Pharmacy Department
Faculty of Pharmacy
Universitas Gadjah Mada
Indonesia
hakim_ar@ugm.ac.id

Abstract

Background: Adverse Drug Reaction (ADR) contributes to high morbidity and mortality rate worldwide. This can be minimised through pharmacovigilance. It is important to evaluate the level of knowledge and perception of pharmacovigilance among pharmacy students. **Objective**: To describe the level of knowledge and perceptions of final-year pharmacy students and students of pharmacy professional programs in Yogyakarta regarding pharmacovigilance. **Method**: A cross-sectional study involved 437 pharmacy students from five different universities in Yogyakarta, who were selected using a convenience sampling technique. Data were analysed to describe the characteristics of the respondents and their level of knowledge and perceptions about pharmacovigilance. **Result**: The majority of final year students in pharmacy and pharmacy professional programs had acquired a high level of knowledge about pharmacovigilance with a percentage of 54.0%. They also shared a positive perception of the implementation of pharmacovigilance with a percentage of 55.6%. **Conclusion**: Final-year pharmacy students and students of the pharmacy professional program have good knowledge and perceptions towards pharmacovigilance.

Introduction

Drugs are commonly used to treat a disease, reduce symptoms, and improve a patient's health and quality of life. However, drugs can also produce unwanted reactions known as Adverse Drug Reactions (ADR) (WHO, 2006). This ADR-related problem needs attention because it is associated with increased mortality, morbidity, and cost of hospital stay (Lovia *et al*., 2019).

The World Health Organization has recommended that every country carry out pharmacovigilance programs to identify and detect drugs that are likely to cause ADR (WHO, 2002). It is important to understand pharmacovigilance in detecting, monitoring, and reporting ADR because it can affect the attitudes and roles of each health professional in pharmacovigilance activities (Rajiah *et al*., 2016). Therefore, pharmacists have a vital role in pharmacovigilance activities to ensure safety in drug use.

A study by Rajiah et al. (2016) showed that pharmacy students had adequate knowledge about pharmacovigilance and a positive perception of ADR reporting. Related research by Febrinasari et al. (2018) in Indonesia found that most respondents had good knowledge and attitudes about pharmacovigilance. Several studies regarding the level of knowledge and perceptions related to pharmacovigilance have been conducted in several countries (Rajiah *et al,* 2016; Musdar *et al*., 2021; Alwhaibi *et al*., 2020; Elkalmi *et al*., 2011; Farha *et al*., 2015; Othman *et al*., 2017; Osemene & Afolabi, 2017). However, no recent similar studies have been found in Indonesia, especially in Yogyakarta. This study aims to describe the level of knowledge and

perceptions of final-year pharmacy students and students of pharmacy professional programs in Yogyakarta regarding pharmacovigilance.

Methods

Design

This is an online questionnaire-based cross-sectional study involving final-year pharmacy students and students of pharmacy professional programs from five universities in Yogyakarta, Indonesia. The study protocol was approved by the Medical and Health Research Ethics Committee (MHREC) Faculty of Medicine, Public Health and Nursing at Gadjah Mada University (No. KE/FK/0270/EC/2022). Every student was informed about the objectives of the study and consented before participating in the study.

The inclusion criteria were "*final-year pharmacy undergraduate students*" and "*students of pharmacy professional program*" who were willing to participate in this research. Meanwhile, the exclusion criteria were respondents giving incomplete information. The questionnaire was designed based on the researcher's literature review of previous studies that used similar questionnaires. It was then developed and adapted to the research conditions that were used to assess the level of knowledge and perceptions related to pharmacovigilance.

It had a total of 32 items of survey instruments grouped into three domains, such as characteristics of respondents, knowledge, and perceptions related to pharmacovigilance. The first part contained four-item questions on respondents' characteristics, such as age, gender, current university, and supporting courses related to pharmacovigilance. The second part contained 13-item questions to measure the basic knowledge about pharmacovigilance. Respondents were asked to determine the answer choices based on their knowledge. There are three answer options in multiple-choice format. The correct answer was scored with one, while the incorrect and the "*I don't know*" (IDK) answers were scored zero. The third part included 15 items designed to evaluate the perceptions of students toward pharmacovigilance activities. Students' perceptions of pharmacovigilance were measured on a four-point Likert scale (one = strongly disagree, two = disagree, three = agree and four = strongly agree).

Assessment

The questionnaire was tested to measure its face value and content validity. Four pharmacy lecturers with experience in drug-use research and ADR reporting studies were asked to evaluate the relevance, clarity, conciseness of the items, and ease of understanding of the questions. The observations and comments of the lecturers were considered. To test the validity and reliability of the survey form, the revised questionnaire was pilot-tested by administering it to a sample of 30 final-year pharmacy undergraduate students and 20 pharmacy professional students in Yogyakarta. The pilot test obtained the overall Cronbach's Alpha value of 0.70. Data were analysed using the Statistical Package for Social Sciences (SPSS, Version 25).

Results

Out of 437 respondents, three hundred seventy (84.67%) were female, 298 (68.19%) of them were aged more than or equal to 22 years, 91 (20.82%) of them were from Gadjah Mada University and 351 (80.32%) respondents had previously taken a supporting course on pharmacovigilance. The characteristics of the respondents are presented in Table I.

Table I: Characteristics of the respondents

Characteristics	Final year pharmacy N (%)	Pharmacy profession N (%)
Gender		
Male	33 (15.1)	34 (15.5)
Female	185 (84.9)	185 (84.5)
Age (years)		
< 22	119 (54.6)	20 (9.1)
≥ 22	99 (45.4)	199 (90.9)
Current university		
UGM	46 (21.1)	45 (20.6)
UAD	45 (20.6)	41 (18.7)
UMY	42 (19.3)	43 (19.6)
UII	42 (19.3)	44 (20.1)
USD	43 (19.7)	46 (21.0)
Supporting course		
Pharmacotherapy	165 (75.7)	186 (84.9)
Pharmacoepidemiology	140 (64.2)	141 (64.4)
Pharmaceutical care	156 (71.6)	132 (60.3)
Pharmacology	165 (75.7)	154 (70.3)
Pharmacokinetic	136 (62.4)	138 (63.0)
Others	18 (8.3)	17 (7.8)

Abbreviations: UGM=Gadjah Mada University, UAD=Ahmad Dahlan University, UMY=Muhammadiyah Yogyakarta University, UII=Islam Indonesia University, USD=Sanata Darma University

The mean knowledge score of pharmacovigilance for the final year pharmacy students was 9.12 and for the students of pharmacy professional program was 9.97. Most of the respondents gave the correct definition of pharmacovigilance (97.48%) and of ADR (92.22%) as shown in Table II.

They also answered correctly the statement regarding the fact that vaccine development is one of the fields within the scope of pharmacovigilance (82.38%) and recognised the Indonesian FDA as the body that regulates ADR reporting in Indonesia (66.13%) and they were aware that reports related to ADR must be filled in the ADR reporting form or the yellow form (94.28%).

Table II: The respondents' knowledge of pharmacovigilance

No.	Questions	Correct answers N (%)	Wrong answers N (%)	Don't know answers N (%)
1.	Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of drug side effects or other problems related to drug use	426 (97.48)	5 (1.14)	6 (1.37)
2.	Drug safety data at the time of drug development is sufficient to provide information regarding serious but rare side effects	223 (51.03)	188 (43.02)	26 (5.95)
3.	Vaccine development at the Adverse Events Following Immunization (AEFI) is one of the areas within the scope of pharmacovigilance	360 (82.38)	41 (9.38)	36 (8.24)
4.	An Adverse Drug Event (ADE) is an unwanted medical event that occurs during drug therapy and is certainly caused by the drug	301 (68.88)	127 (29.06)	9 (2.06)
5.	Adverse Drug Reaction (ADR) is a response to an unwanted drug that occurs at doses normally used for the prophylaxis, diagnosis, or therapy of a disease	403 (92.22)	24 (5.49)	10 (2.29)
6.	Type A ADR is dose-dependent and predictable	352 (80.55)	11 (2.52)	74 (16.93)
7.	Type B ADR is predictable and independent of dose	208 (47.60)	142 (32.49)	87 (19.91)
8.	The Indonesian Food and Drug Authority (Badan POM) does not function as a national pharmacovigilance centre	96 (21.97)	289 (66.13)	52 (11.90)
9.	Reports related to ADR are filled in the ADR reporting form or yellow form	412 (94.28)	5 (1.14)	20 (4.58)
10.	One of the information that must be included in the ESO/ADR reporting is patient data such as age and sex	397 (90.85)	31 (7.09)	9 (2.06)
11.	All suspicious drug side effects, even if they are mild, need to be reported for "*new*" drugs (newly discovered drugs)	402 (91.99)	19 (4.35)	16 (3.66)
12.	Patients or the general public are involved in reporting unwanted events/ADR to health professionals	360 (82.38)	54 (12.36)	23 (5.26)
13.	Suspicion of a drug product quality defect or lack of efficacy of a drug should not be reported.	111 (25.40)	311 (71.17)	15 (3.43)

Data revealed that the overall perceptions toward pharmacovigilance among final-year pharmacy students and students of the pharmacy professional program were positive. Almost all respondents strongly agree or agree with the statement that pharmacovigilance should be included as a core topic in pharmacy education, information on how to report ADR should be taught to pharmacy students, and the purpose of the ADR spontaneous reporting system is to measure the incidence of ADRs as shown in Table III.

Discussion

The knowledge of final-year pharmacy students and students of pharmacy professional programs on the reporting of ADRs and pharmacovigilance activities is adequate, with a percentage of 54.0%. This result agrees with the findings of previous studies conducted in Indonesia (Musdar *et al*. 2021), Saudi Arabia (Alwhaibi *et al*., 2020), and Malaysia (Rajiah *et al*., 2016).

Most of the respondents (51.03%) gave incorrect answers to the second statement in Table II. One of the limitations of safety information at the drug development stage is that it has not been able to provide information about serious but rare side effects, chronic toxicity, and drug safety data in a special population (BPOM, 2019).

Table III: The respondents' perception toward pharmacovigilance

No.	Question	Strongly Disagree N (%)	Disagree N (%)	Agree N (%)	Strongly Agree N (%)
1.	In my opinion, pharmacovigilance should be included as a core topic in pharmacy education	4 (0.92)	5 (1.14)	218 (49.89)	210 (48.05)
2.	In my opinion, information on how to report ADR should be taught to pharmacy students	6 (1.37)	1 (0.23)	160 (36.61)	270 (61.78)
3.	In my opinion, the reason for not reporting suspected ADR is because of the uncertainty of the relationship with the drug	28 (6.41)	165 (37.76)	206 (47.14)	38 (8.70)
4.	In my opinion, the purpose of the ADR spontaneous reporting system is to measure the incidence of ADR	3 (0.69)	14 (3.20)	302 (69.11)	118 (27.00)
5.*	In my opinion, serious and unexpected reactions that are not fatal or not life-threatening during clinical trials should not be reported	165 (37.76)	212 (48.51)	40 (9.15)	20 (4.58)
6.*	In my opinion, any serious or non-serious ADR should not be reported voluntarily (*spontaneous reporting*)	100 (22.88)	142 (32.49)	122 (27.92)	73 (16.70)
7.*	In my opinion, adverse reactions caused by cosmetics should not be reported	213 (48.74)	181 (41.42)	32 (7.32)	11 (2.52)
8.	In my opinion, the incidence of ADR caused by herbal medicine should be reported	6 (1.37)	24 (5.49)	259 (59.27)	148 (33.87)
9.*	In my opinion, only reactions to new products should be reported	119 (27.23)	242 (55.38)	43 (9.84)	33 (7.55)
10.*	In my opinion, there is no need to report an unreported adverse reaction (ADR) for a particular drug	193 (44.16)	120 (27.46)	26 (5.95)	98 (22.43)
11.*	In my opinion, patients should not be given ADR-related counselling every time they get medication	169 (38.67)	207 (47.37)	48 (10.98)	13 (2.97)
12.*	In my opinion, ADR reporting is not mandatory for pharmacists	169 (38.67)	220 (50.34)	35 (8.01)	13 (2.97)
13.	With my current knowledge, I am prepared to report any ADR occurrences in my practice in the future	2 (0.46)	8 (1.83)	246 (56.29)	181 (41.42)
14.	In my opinion, ADR reporting is part of pharmaceutical services	4 (0.92)	3 (0.69)	222 (50.80)	208 (47.60)
15.	In my opinion, pharmacist involvement in reporting ADR will have a positive impact on pharmacovigilance activities	4 (0.92)	2 (0.46)	168 (38.44)	263 (60.18)

*Unfavourable statement

About 92.22% of respondents correctly defined ADR. However, 68.88% of respondents could not define ADE. The results showed that most respondents presumably did not understand the difference between ADR and ADE. ADR is a type of ADE whose causes can be directly attributed to the drug and its physiological properties (Schatz & Weber, 2015).

In the statement regarding the ADR classification, most respondents (80.55%) correctly answered the question regarding ADR type A. However, only 32.49% of the respondents were able to correctly answer the question related to ADR type B. This suggests that some respondents may have insufficient knowledge regarding the classification of ADR. According to MSH and WHO (2007), type B ADR is unpredictable and dose-independent.

The perceptions of final-year pharmacy students and students of pharmacy professional programs on the reporting of ADRs and pharmacovigilance activities have been relatively positive, with a percentage of 55.61%. This result agrees with the findings of previous studies conducted in Malaysia (Elkalmi *et al.,* 2011; Rajiah *et al*., 2016), Jordan (Farha *et al*., 2015), Yemen (Othman *et al*., 2017), and Nigeria (Osemene & Afolabi 2017).

The statement on the aspects of the curriculum stated in items number one and two of Table III insinuates that most of the respondents agreed and strongly agreed with the given statements. This indicates their positive perception of the importance of pharmacovigilance and ADR reporting.

The statement about the causality aspects of ADR stated in item number three of Table III demonstrates that respondents had various answers, but most of them shared a positive perception that the reason for not reporting suspected ADR is due to the uncertainty of its relationship with the drug. The causal relationship between the drug and the suspected event of ADR is

one of the reasons that create uncertainty about whether the event was caused by a drug, which causes the absence of the need to report to ADR (Khan, 2013).

The majority of respondents disagreed with the administration of ADR-related counselling to patients every time they get medical treatment. This means that most respondents have a positive perception. Such counselling is necessary to ensure that the patient is well informed about the possible adverse reactions after taking the drug.

Regular curriculum reviews to improve the content of pharmacovigilance courses can increase students' knowledge about PV. It is also necessary to increase training and provide lecture-based workshops about pharmacovigilance and ADR reporting. This is highly essential considering the importance of understanding and preventing drug-related problems, and improving the knowledge, attitude, and practice of pharmaceutical students.

Conclusion

The study revealed that final-year pharmacy students and students of pharmacy t professional programs have a high level of knowledge and positive perceptions of pharmacovigilance.

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