Pharmacist's Knowledge of Adverse Drug Reactions Reporting: Narrative Review

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Abstract. Adverse drug reactions can increase morbidity and mortality in hospitals and the community. Monitoring the incidence of adverse drug reactions can prevent or reduce the harm experienced by patients and can improve public health. Pharmacists have an important role in drug monitoring, starting from the manufacturing process to marketing, so pharmacists must have knowledge about adverse drug reactions and how to solve them. This study aims to determine the knowledge of pharmacists on reporting adverse drug reactions using the literature study method. This research is qualitative research with descriptive analysis using literature review method obtained through Google Scholar, Pubmed, Sciencedirect based on inclusion and exclusion criteria. The journal search results found 774 studies, namely 160 in science direct, 212 in Pubmed, and 402 from Google Scholar. Then deletion of articles was carried out based on inclusion and exclusion criteria so that nine journals met the inclusion criteria. This literature review study concludes that pharmacists' knowledge of reporting adverse drug reactions can be categorized as poor knowledge. This poor pharmacist knowledge is influenced by education, age, sense of responsibility, and pharmacist attitude. Variables such as education level, age and sense of responsibility, and attitude towards the problem are important and can be changed. So that training is needed on reporting adverse drug reactions and collaboration between healthcare professionals, authorities, and government authorities to implement a learning system for reporting adverse drug reactions.

Keywords: Knowledge · Pharmacist · Reporting adverse drug reactions

1 Introduction

Before being circulated in the market, pharmaceuticals must meet the requirements for efficacy and safety first, and they must go through research and clinical trials. Research and clinical trials have limitations, so they cannot identify all possible adverse drug reactions. The recall of several pharmaceutical preparations circulating in the market is due to the risk of undetected adverse drug reaction [1]. The efficacy and safety of pharmaceutical preparations are continuously supported by data collection and analysis of pharmaceuticals until the drug begins to be circulated. To assist in collecting and analyzing

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data, monitoring from various parties is needed, one of which is healthcare professionals. This monitoring activity is called pharmacovigilance, namely science and activities related to collecting, detecting, assessing, monitoring, and preventing undesirable events in pharmaceutical preparations [2].

In recent years, significant developments in pharmacovigilance have benefited health care systems worldwide [3]. The pharmacovigilance reporting system relies on establishing a detection signal, i.e., the communication of an Adverse Drug Reaction (ADR) or Adverse Drug Event (ADE) made by the patient, manufacturer, or healthcare provider to a pharmacovigilance center. The incidence of adverse drug reactions has a relationship with a significant increase in morbidity and mortality. Increased morbidity and mortality can occur in hospitals and the community. The incidence of adverse drug reactions as morbidity in hospitals is the main cause of hospitalization, which is 10%. It is estimated that 10–20% of hospitalized patients experience unwanted adverse drug reactions [4]. Thus, monitoring the incidence of adverse drug reactions is carried out to prevent or reduce losses experienced by patients to improve public health [5].

Reporting spontaneous adverse drug reactions is an important component of the pharmacovigilance system. Optimization of knowledge, attitudes and behavior related to pharmacovigilance is important in formulating strategies to encourage the reporting of adverse drug reactions. Pharmacists have a role in reporting adverse drug reactions because they can have a direct impact on patient care [6]. The pharmacist's role is to identify patients, assess, research, refer and monitor adverse drug reactions reporting systems [7].

Pharmacists also play an important role in drug monitoring, starting from manufacturing to marketing, so pharmacists must have good knowledge about adverse drug reactions and how to solve them [8]. Knowledge of other healthcare professionals regarding reporting adverse drug reactions will also increase if pharmacists have sufficient knowledge about the process of reporting adverse drug reactions. Pharmacists think that the development of measures in reporting pharmacovigilance will increase the compliance of pharmaceutical professionals for reporting adverse drug reactions and will imply an increase in the quality of care, rational use of drugs, and patient safety [9]. So this review is used to review pharmacists' knowledge of reporting adverse drug reactions carried out through literature studies.

2 Materials and Methods

The method used in this article is a literature review to evaluate and determine pharmacist knowledge of reporting adverse drug reactions. The intended knowledge is the pharmacist's knowledge of the definition of the adverse drug reaction reporting system and the incidence of adverse drug reactions, reporting of adverse drug reactions, and identification of adverse drug reactions.

2.1 Search Strategy

The literature search was conducted based on the Pubmed, Google Scholar, and Science Direct electronic databases for articles published between 2011 and 2021. All searches were conducted on November 20, 2021, using the keywords "Knowledge," "Adverse Drug Reaction," "ADR," "Reporting," "Pharmacist," and in combination.

2.2 Article Selection

Inclusion criteria

Articles that will be included in this literature review meet the inclusion criteria. The inclusion criteria are:

- Articles aimed at evaluating, assessing, knowing pharmacists' knowledge of reporting adverse drug reactions
- Articles in English
- Full text
- Surveyor interview method
- Using self-made questionnaires or using existing questionnaires
- Pharmacist respondents
- Articles published in the last ten years, namely between 2011 and 2021

Exclusion criteria

- Articles published in this study are incomplete articles or contain only abstracts, editorials, clinical studies, review articles
- Respondents in the survey are healthcare professionals other than pharmacists
- Published before 2011.

3 Results

3.1 Literature Study Search Results

Based on the search for articles from all databases, 774 studies were obtained, namely 160 in science direct, 212 in Pubmed, and 402 from Google scholar. Then the process of deleting duplicate articles, irrelevant articles such as editorials, clinical studies and review articles, published articles was carried out, under 2011, articles that are not in English and incomplete articles. Research journal reduction was carried out based on title screening. Then a feasibility study was carried out based on the abstract by first removing articles that did not meet the inclusion criteria. Then a literature study was carried out by looking at the entire journal so that nine research articles were reviewed. The Fig. 1 briefly describes the flow of the selection of the literature study used (Fig. 1).

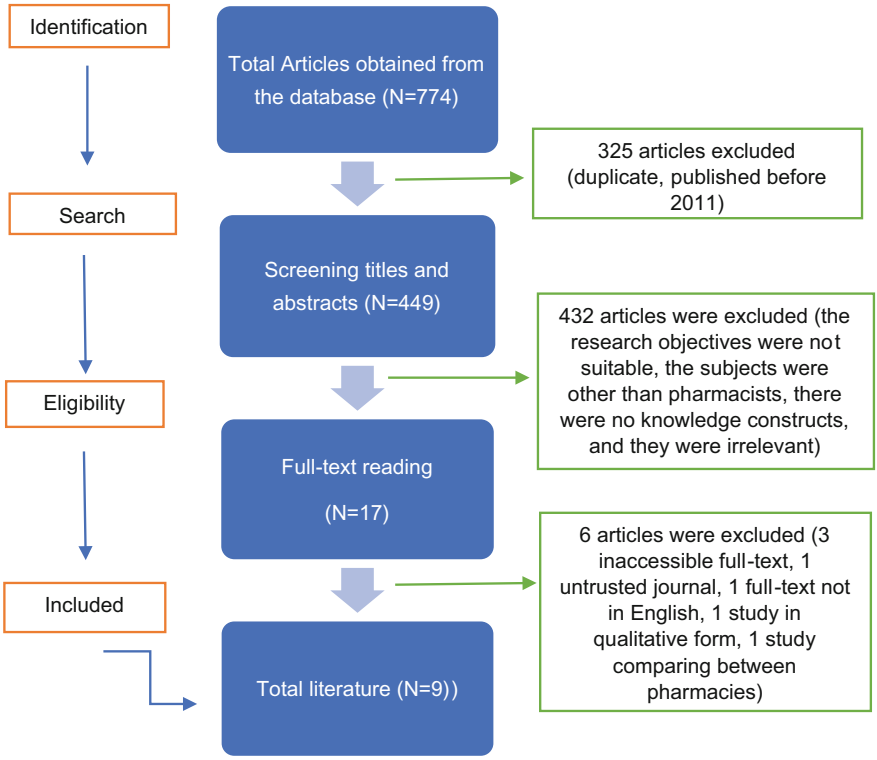

Fig. 1. Study selection flow chart

3.2 Study Characteristics

All studies included in this study varied from sample size to location. This study's response rate and sample size ranged from 41.8% to 83.3% and from 70 to 522 respondents. The characteristics of the study can be seen in full in Table 1.

3.3 Pharmacist Knowledge

Based on nine literature reviews, one study [18]. Did not categorize the results of pharmacist knowledge on reporting adverse drug reactions. Eight literatures gave different results, namely [12, 17] moderate and [10, 11, 13]–[16] low. The results of pharmacists' knowledge of reporting adverse drug reactions can be seen in Table 2. From the results of the literature study, it was found that the average knowledge of pharmacists on reporting adverse drug reactions ranged from 19.45%, 51.13%, 52.04%, 52.47%. 58.75% for each identification of adverse drug reactions, definitions of pharmacovigilance, pharmacist professionalism in reporting adverse drug reactions, differences in adverse drug reactions, medication errors and adverse events, reporting systems and national regulations, and the highest percentage is regarding the definition of adverse drug reactions. Pharmacists' knowledge of reporting adverse drug reactions can be seen in Table 3.

Table 1. Study Characteristics

No. Author	Sample Size	Studi design	Response rate (%)	Year	Research sites
1. Alharbi *et al.* [10]	103	*Cross sectional*	79	2016	Saudi Arabia
2. Atia *et al.* [11]	408	*Cross sectional*	87,61	2021	Tripoli, Libya
3. Tahir *et al.* [12]	201	*Cross sectional*	NA*	2020	Sudan
4. Li *et al.* [13]	232	*Cross sectional*	61,9	2018	Australia
5. Ali *et al.* [14]	101	*Cross sectional*	67,33	2020	Dammon, Saudi Arabia
6. Kopciuch *et al.* [15]	522	*Multicenter study*	58	2019	Poland
7. Mahmoud *et al.* [16]	104	*Cross sectional*	70,7	2013	Riyadh, Saudi Arabia
8. Jose *et al.* [17]	107	*Cross sectional*	72,3	2014	Muscat dan South Sharqiyah
9. Khan [18]	70	*Cross sectional*	71,43	2013	Eastern Region, Alahsa

Table 2. Category of Pharmacist Knowledge of Adverse Drug Reactions Reporting

Author	Pharmacist Knowledge of Adverse Drug Reactions Reporting
Alharbi *et al.* [10]	Poor
Atia *et al.* [11]	Poor
Tahir *et al.* [12]	Moderate
Li *et al.* [13]	Poor
Ali *et al.* [14]	Poor
Kopciuch *et al.* [15]	Poor
Mahmoud *et al.* [16]	Poor
Jose *et al.* [17]	Moderate

Table 3. Pharmacist Knowledge of Adverse Drug Reactions Reporting

No	Description	Alharbi *et al.* [10]	Atia *et al.* [11]	Tahir *et al.* [12]	Li *et al.* [13]	Ali *et al.* [14]	Kopciuch *et al.* [15]	Mahmoud *et al.* [16]	Jose *et al.* [17]	Khan [18]
1	Definition of Adverse Drug Reactions	54.4%	-	70,1%	81,9%	-	32%	22.1%	-	92%
2	Definition of Pharmacovigilance	51,5%	28,9%	-	-	-	73%	-	-	-
3	Difference between Adverse Drug Reactions and Medication Errors, Adverse Even	64,7%	-	84,1%	8,6%	-	-	-	-	-
4	National Regulations and Reporting System	-	14,7%	49,3%	-	88.11%	-	20,2%	88.8%	90%
5	The importance of reporting Adverse Drug Reactions in pharmacist professionalism	-	-	-	-	46.53%	19%	-	90,6%	-
6	Identifying Adverse Drug Reactions	-	-	30,3%	-	8,6%	-	-	-	-

3.4 Barriers to Pharmacists in Reporting Adverse Drug Reactions

Five studies assessed the barriers felt by pharmacists to reporting adverse drug reactions. Reported barriers such as lack of access to forms, unavailability of forms, too complex forms, no time to report adverse drug reactions, need extra time, wasting time, no remuneration, fear of reports made, and lack of motivation in reporting, and others. All the obstacles in the five literature studies can be seen in full in Table 4.

Table 4. Barriers to Pharmacists in Reporting Adverse Drug Reactions

No	Description	Alharbi *et al.* [10]	Li *et al.* [13]	Ali *et al.* [14]	Kopciuch *et al.* [15]	Khan [18]
1	Lack of access to the Adverse Drug Reactions reporting form	22%	-	22,72%	12%	88%
2	Adverse Drug Reactions reporting form is too complex	-	-	21,78%	-	18%
3	Lack of time to report Adverse Drug Reactions	33%	43,5%	27,72%	87%	-
4	Reporting Adverse Drug Reactions Wasting time		24,75%			34%
5	Requires extra work in reporting Adverse Drug Reactions				67%	
6	Lack of training on pharmacovigilance systems	48%		2,97%		
7	Lack of motivation to report Adverse Drug Reactions	25%		17,82%		
8	Afraid that the reports given regarding the occurrence of Adverse Drug Reactions will cause legal problems	13%		22,72%	32%	
9	No remuneration		65%		25%	

(*continued*)

Table 4. (*continued*)

No	Description	Alharbi *et al.* [10]	Li *et al.* [13]	Ali *et al.* [14]	Kopciuch *et al.* [15]	Khan [18]
10	There are no reported events of Adverse Drug Reactions		22,4%	20,79%		
11	Not confident			19,80%		2%
12	Lack of knowledge of pharmacotherapy in detecting Adverse Drug Reactions			19,80%	76%	2%
13	There is no place for professional discussion to discuss Adverse Drug Reactions			15, 74%		86%
14	There is no need to report the incidence of adverse drug reactions reported by the patient				37%	
15	do not know how to report					44%
16	Believe that only safe drugs are on the market					66%

4 Discuss

Adverse Drug Reaction (ADR) is an unwanted drug effect on animals and humans, causing morbidity and mortality in hospitalized patients. Adverse drug reactions can be predicted in part, but many other side effects will be found [19]. The preparation formulation will experience improvements in testing, but the causative drug is still difficult to identify. Monitoring adverse drug reactions that appear in the circulation is known as reporting adverse drug reactions [20]The spontaneous reporting system is one hope for detecting potential adverse drug reactions such as the Yellow Form in the UK, which is operated by the Medicine and Healthcare Product Regulatory Agency (MHRA) and the Commission on Human Medicine (CHM) [21].

Reporting spontaneous adverse drug reactions is the mainstay of pharmacovigilance because it is very helpful in identifying adverse drug reactions that occur rarely or take time. The lack of reporting of adverse drug reactions by health professionals is a global problem. Healthcare professionals have an important role in reporting adverse drug reactions during their practice activities. Lack of knowledge and awareness about

pharmacovigilance and reporting adverse drug reactions among healthcare professionals may contribute to underreporting [22]. Healthcare professionals have the role of detecting, recording adverse events and conducting causality assessments, reporting any serious and non-serious adverse events due to drug use, and conveying information to the pharmacovigilance center. The active participation of health professionals directly determines the effectiveness of national pharmacovigilance programs and reporting of adverse drug reactions. Healthcare professionals occupy the most strategic role in reporting suspected adverse drug reactions during the daily practice of patient care [23]. Healthcare professionals may include doctors, specialists, dentists, pharmacists, midwives, nurses, and other healthcare professionals [24].

Factors influencing reporting are not knowing how to report adverse drug reactions 53.8%, lack of time 37.1%, increase in workload 22.0%, uncertainty of reporting results 32.6%, and lack of confidence to discuss adverse drug reactions with colleagues 22.0% [25]. Meanwhile, according to other studies, the factors that influence the reporting of adverse drug reactions are poor knowledge, work experience, and lack of training regarding reporting adverse drug reactions [26]. Reporting the incidence of adverse drug reactions is an important component in the pharmacovigilance system. Attitudes and behaviors related to pharmacovigilance are important in formulating strategies to encourage adverse drug reaction reporting activities. Pharmacists play an important role in monitoring drugs from the research process, manufacture to marketing, so they must have knowledge about adverse drug reactions and how to solve them.

Knowledge is important to increase pharmacist awareness of reporting adverse drug reactions because the knowledge possessed by pharmacists will provide interventions to other healthcare professionals [25]. Based on the results of the review literature, it is known that the knowledge of pharmacists and patients regarding adverse drug reactions is quite high, namely 93% of pharmacists and 75% of patients have high knowledge. However, the awareness of pharmacists and patients to report adverse drug reactions is very low [27]. Research [15] states that pharmacists have a good basic knowledge of pharmacovigilance and adverse drug reactions, namely 73% and 69%, but pharmacists do not know how and where to report adverse drug reactions. This relates to the level of education [17, 28] age, sense of responsibility, and attitude of the pharmacist [15].

Lack of pharmacist knowledge on reporting adverse drug reactions is considered a starting point for dealing with problems regarding reporting. Therefore, pharmacist knowledge strongly influences the adverse drug reaction reporting system [5]. Differences in pharmacist knowledge on reporting adverse drug reactions are related to the level of education [11, 16] age, sense of responsibility, and attitude of pharmacists [15]. Variables such as education level, age, sense of responsibility, and attitudes towards problems are important variables and can be modified [15]. Pharmacists who have received training in pharmacovigilance and have a higher level of education also have better knowledge about reporting adverse drug reactions and pharmacovigilance. Thus, educational training is needed and continuous efforts from the government and hospital authorities to ensure the implementation of an appropriate adverse drug reaction reporting system in all hospitals [29].

Pharmacists have several barriers in knowledge regarding the reporting of adverse drug reactions, such as differences in the level of clinical knowledge that make it difficult

for pharmacists to decide whether patients experience adverse drug reactions or not [30]. Barriers for pharmacists to detect and identify adverse drug reactions in patients [31]. Include the lack of cooperation and communication between health professionals and staff requirements to report adverse drug reactions [32] These barriers mean that pharmacists must have good skills and knowledge to identify and resolve drug-related problems and educate patients about the proper use [33]. The existence of obstacles also makes pharmacists have to improve education or re-learning programs as well as pharmacist training to increase pharmacists' knowledge of reporting adverse drug reactions in order to fulfill the quality and quantity of reporting [5, 16, 28, 31].

Research in Kuwait states knowledge and positive attitudes between doctors and pharmacists regarding pharmacovigilance and reporting adverse drug reactions. However, in practice, the reporting carried out by healthcare professionals is not optimal, so increased education and training are needed to improve the practice of reporting adverse drug reactions [34]. Other studies also show that knowledge and attitudes significantly correlate with reporting adverse drug reactions [35]. Research conducted in South Africa showed that the lack of practice of reporting adverse drug reactions has a relationship with the existence of gaps in knowledge, attitudes, and practices of respondents so that interventions and increased education and training of healthcare professionals regarding adverse drug reactions in South Africa are needed [30]. So that increasing education and training and simplifying the reporting process can overcome the barriers to the practice of reporting adverse drug reactions by pharmacists [13].

These results strengthen the hypothesis that not being aware of the incidence of adverse drug reactions and not knowing the pharmacovigilance system are the main causes of underreporting. A study of pharmacovigilance knowledge can form the basis for tailoring interventions specifically designed to address inappropriate concepts and may increase reporting rates at the national level [36].

The addition of pharmacovigilance topics in the pharmacy education curriculum training of pharmacy students in community pharmacies, such as internships, can also increase pharmacist awareness regarding monitoring, detecting, and reporting adverse drug reactions. The existence of general education or training regarding the importance of the pharmacovigilance system can provide more awareness for pharmacists to report adverse drug reactions. Awareness of pharmacists in increasing the reporting of adverse drug reactions is necessary to motivate and encourage pharmacists in pharmaceutical services, especially to monitor and report adverse drug reactions. Collaboration between academics and health authorities will be very important to achieve this goal. Educational institutions in line with health authority regulations can provide educational interventions according to the desired target [32].

Pharmacists have a role in patient identification, assessment, research, referral, and monitoring of adverse drug reaction reporting systems. Pharmacists submit reports of adverse drug reactions to provide information to doctors. This shows that pharmacists' reporting of adverse drug reactions is an important part of the spontaneous reporting system. Implicitly, we can conclude that a close relationship between pharmacists and the National Center for Pharmacovigilance can predict a remarkable increase in reporting rates [28].

5 Conclusion

Pharmacists' knowledge of adverse drug reaction reporting can be categorized as poor knowledge. This poor pharmacist knowledge is influenced by the level of education, age, sense of responsibility, and pharmacist attitude. Variables such as education level, age, sense of responsibility, and attitude towards the problem become important variables and can be modified. Therefore, training on adverse drug reaction reporting is needed, and collaboration between healthcare professionals, academics, and government authorities to implement a learning system regarding adverse drug reaction reporting.

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