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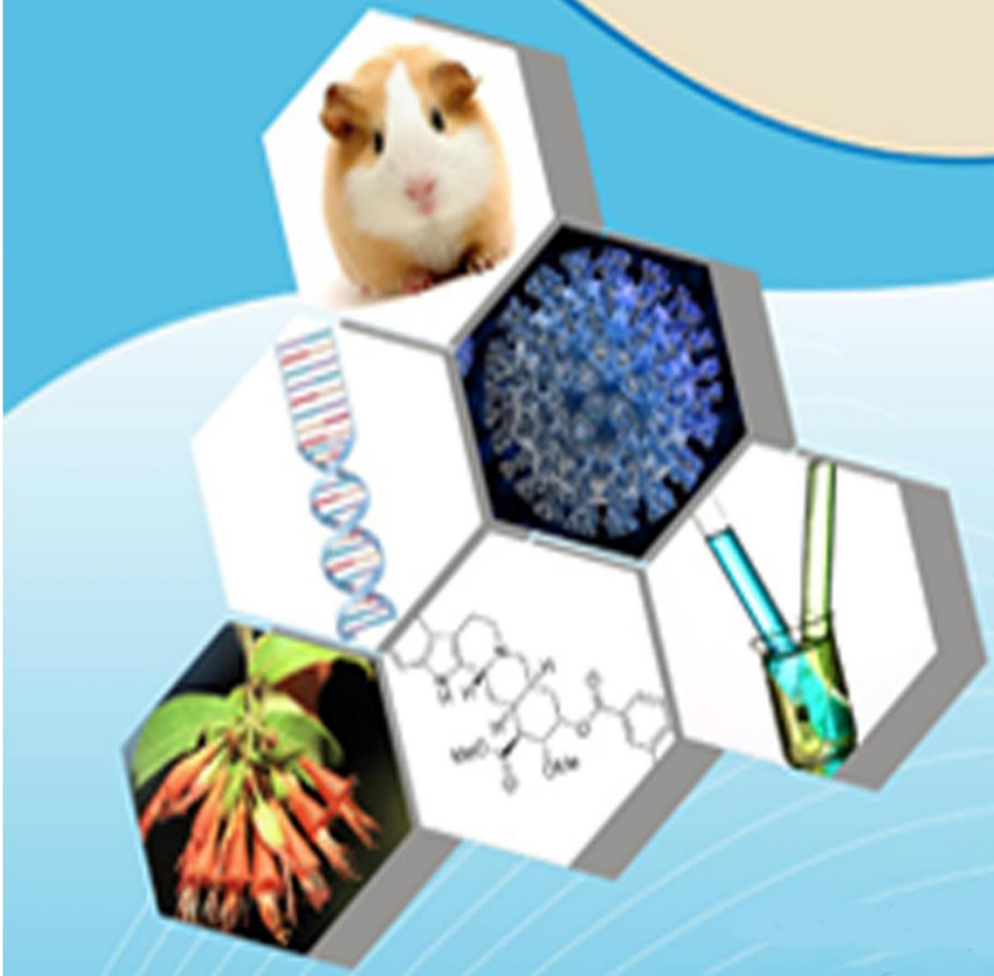

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Community Pharmacists' Pharmacovigilance Knowledge and Attitudes: A Cross-Sectional Survey

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ABSTRACT

As part of their post-marketing monitoring efforts, all national and regional governments are obligated to establish a system for reporting adverse drug reactions, often known as pharmacovigilance. Consequently, it was crucial to optimize one's attitude and understanding of the system. The purpose of this research was to survey rural public healthcare pharmacists on their pharmacovigilance knowledge and attitudes. From July to December 2021 in Bantul Regency, Yogyakarta, Indonesia, 48 pharmacists from both hospitals and community pharmacies participated in this cross-sectional analytical observational study. We used chi-square to look for relationships between the variables, and descriptive statistics and frequency distribution analysis to get a feel for people's levels of understanding and sentiment about the pharmacovigilance system. Among those who took part, 60.4% had solid understanding and 52.1% felt positively about the system. A p-value of 0.045 further demonstrated the existence of a correlation between attitude and knowledge. Thus, among rural public healthcare pharmacists, there was a correlation between pharmacovigilance knowledge and attitude. Research like this strongly suggests that all healthcare providers, but notably pharmacists, should educate themselves on pharmacovigilance and incorporate it into their daily work.

Attitude, knowledge, rural, pharmacovigilance, pharmacist

INTRODUCTION

Improving the quality of public health is intimately tied to increasing the consumption of pharmaceutical products; hence, it is imperative that these products be both effective and safe. Proper use of pharmacological drugs delivers more advantages than hazards, but their effectiveness and safety rely on careful monitoring and attention (Aruru et al., 2021). Because of this, it is critical to adequately monitor pharmaceutical medication safety. To do this, pharmacovigilance—a mechanism for reporting Adverse Drug Reactions (ADRs)—must be put in place (Edrees et al., 2022; Liu et al., 2019). When it comes to pharmaceutical products, the World Health Organization (WHO) defines pharmacovigilance as "the science and activity concerned with the detection, assessment, understanding, and prevention of adverse reactions or other events" (Beninger, 2018). The goal of thisapproach is to make healthcare safer and better by reducing hazards associated with prescription medication usage. Healthcare providers, particularly in underdeveloped nations, have not fully contributed to the system since its inception in 1961 by the World Health Organization (WHO) (Yawson et al., 2022). As part of their post-marketing monitoring efforts, all national and international governments are obligated to engage in pharmacovigilance (Beninger, 2018).

Pharmacovigilance has expanded greatly over the last decade and is now facing many new difficulties. The public's expectations about the safety and efficacy of pharmaceutical medication usage will rise as a result of the fast distribution of information, which will further enable access to diverse medicines (Thomas, 2018). But this approach can only work if doctors and nurses report potential adverse drug reactions in their patients as part of routine patient care. Medical professionals in Indonesia have an ethical obligation to report any adverse drug reaction (ADR) they suspect to the country's pharmacovigilance center or the Monitoring Efek Samping Obat (MESO) facility. The Yellow Form, a tool for reporting medication side effects, may also be used to conduct

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pharmacovigilance events; it can be accessible at https://e-meso.pom.go.id/. Pharmacists primarily engage in spontaneous reporting as a kind of pharmacovigilance to help uncover adverse drug reactions (ADRs) that are not detectable during clinical studies. A variety of issues, such as a lack of information, uncertainty about the ADRs, and trouble comprehending the system, might impact reporting in the real clinical context (Thomas, 2018). A number of prior research have shown that in order to enhance the system, it was crucial to optimize knowledge and attitude towards pharmacovigilance (Edrees et al., 2022; Güner & Ekmekci, 2019; Liu et al., 2019). Further research has shown that pharmacists' attitudes and levels of knowledge can have a major impact on the pharmaceutical services they offer to patients, particularly when it comes to discussing medication use and potential adverse effects (Alshayban et al., 2020; Reddy et al., 2014).

Factors connected to the learning process of a professional pharmacist at the levels of knowing, comprehending, applying, analyzing, and evaluating include knowledge and attitude. Bepari et al. (2019) noted that a variety of variables, such as education, experience, age, environment, and socio-cultural knowledge, might impact these aspects. Finding out how pharmacists' pharmacovigilance knowledge and attitudes relate to ADR prevention was the primary goal of Halijah's (2019) research. The study was carried out in a specific time and place with a specific set of research aims, which may not align with the current study. Halijah found that her research participants were quite knowledgeable about pharmacovigilance (72%), and they were also very committed to preventing adverse drug reactions (74%). The results show that the pharmacists who took part in the study really care about avoiding negative medication responses and have a good understanding of pharmacovigilance concepts. Furthermore, the research found a strong link between pharmacists' pharmacovigilance expertise and their attitudes toward reducing adverse drug reactions (ADRs), suggesting that pharmacists' attitudes toward ADR prevention are positively correlated with their pharmacovigilance knowledge. A number of variables may impact pharmacists' understanding and perspectives in different locations, thus it's possible that Halijah's study's findings won't apply there either. Furthermore, it was noted that healthcare practitioners in poor nations, such as Indonesia, have not yet optimally, passively, and willingly integrated pharmacovigilance operations into their everyday clinical practice (Yakubu et al., 2020; Zhang, 2018). According to Maylani et al. (2021), type 2 diabetes patients at the local public healthcare facility in Bantul Regency, Indonesia, had 20.7% of their suspected medication-related issues validated by the reporting profile of adverse drug reactions. These considerations highlight the need of studying the impact of pharmacovigilance on rural public healthcare pharmacists. The purpose of this research was to look at how public healthcare pharmacists in Bantul, Yogyakarta, Indonesia, felt about pharmacovigilance and how much they knew about the topic.

MATERIALS AND METHODS

Study Design and Participant

It was a cross-sectional analytical observational research of 48 hospital and community pharmacists working at healthcare facilities (e.g., hospitals, pharmacies, and public health centers). This study took place at Bantul Regency, Yogyakarta, Indonesia, that was carried out from July to December 2021. In addition, the participant recruitment process in this study utilized accidental sampling – a sampling model involving the sample being drawn from that part of the population that is close to hand (Edgar & Manz, 2017). There were two criteria in this research. First, the eligibility criteria of this research include the professional pharmacists working at public healthcare services (e.g., hospitals, public health centers, medical clinics, and pharmacies) in Bantul, Yogyakarta, Indonesia, and willing to fulfill the questionnaire. Second, the exclusion criteria were participants on leave or sick and those who did not complete the questionnaire. To achieve the maximum number of target respondents, a public announcement, consisting of the purpose of the study and a link to the questionnaire, was roughly distributed to potential participants through WhatsApp and direct calling.

Research Instrument

The instrument used in the study was a questionnaire adopted from a previous study (Gupta et al., 2015; Halijah, 2019; Othman et al., 2017; Reddy et al., 2014), which had been translated into Bahasa and tested for validity and reliability (Halijah, 2019). The questionnaire has three main parts. First, section A consists of the research participant's characteristics, such as age, gender, education, and length of work experience. Second, section B consists of 10 question items related to pharmacovigilance knowledge (Supplement 1). Third, section C consists of 10 statement items related to pharmacovigilance attitudes (Supplement 2).

Knowledge Regarding Pharmacovigilance

A frequency distribution analysis was used to obtain an overview of participants' pharmacovigilance knowledge. Before the analysis, it was necessary to understand the scoring system of the participants'

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knowledge by assigning a value to each question item using Microsoft Excel. The correct answers were given a value of 10, while 0 for the wrong answers. To determine the participant's knowledge, it was categorized into two types (Gupta et al., 2015; Halijah, 2019): (a) Tscore >75% = good knowledge; (b) Tscore ≤ 75% = poor knowledge.

Attitude Regarding Pharmacovigilance

A descriptive analysis was conducted to examine the participants' attitudes regarding pharmacovigilance. First, it was carried out by calculating the score for participants' attitude variables using a 5-item Likert scale, and then categorizing the total score with the following formula: (a) Tscore > Tmean = positive attitude; (b) Tscore ≤ Tmean = negative attitude;

Tmean of this study, referring to the previous studies, was 50 (Gupta et al., 2015; Halijah, 2019).

Relationship between Knowledge and Attitude regarding Pharmacovigilance

A Chi-square statistical analysis was employed to determine the relationship between knowledge and attitude regarding pharmaco-vigilance among research participants.

Research Procedures

The research procedure was carried out through the following phases: preparation, implementation, and data analysis. The preparation phase consists of the research proposal preparation, instrument modification, the questionnaire on knowledge and attitude regarding pharmacovigilance from previous studies (Gupta et al., 2015; Halijah, 2019), validity and reliability test for the questionnaire, and ethical clearance at the Health Research Ethics Committee (KEPK), Faculty of Medicine and Health Sciences, Universitas Muhammadiyah Yogyakarta, Indonesia. In the implementation phase, the data collection was carried out through many phases, such as providing explanations to participants through a small group related to the aims and objectives of the study and asking them to complete the questionnaire through Google Form. The ethical considerations and approval procedure for the study were described, taking into account the potential risks and benefits of participation, the preservation of the participants' privacy and confidentiality, and any potential conflicts of interest. The provision of compensation to participants, including the nature and determination of compensation, was also discussed. Specifically, monetary incentives were distributed via a variety of electronic payment platforms, including Shopee Pay, OVO, and Gopay. It was ensured that the compensation did not influence the participants unduly or compromise the ethical principles of the study. Finally, in the data analysis phase, after the participants sent their questionnaire back, obtained data were statistically processed using Microsoft Excel and IBM® SPSS® Version 22.0 through editing, coding, data entry, and tabulating.

Ethical Consideration

This study was officially approved by the Health Research Ethics Committee (KEPK) of the Faculty of Medicine and Health Sciences, Universitas Muhammadiyah Yogyakarta, Indonesia (Number. 245/EC-KEPK FKIK UMY/VIII/2021).

RESULTS AND DISCUSSION

Pharmacovigilance plays a crucial role in ensuring patients' safe use of pharmaceutical drugs. One of the primary reasons for morbidity and mortality is ADRs; therefore, healthcare practitioners, especially pharmacists, contribute to monitoring drug safety by preventing, identifying, documenting, and reporting adverse drug reactions. All the practitioners have a role in maintaining a balance between the benefits and risks of drug use.

Table I. A Summary of Participant Background and Demographic Information (n=48)

Demographic Variables	Categories	Frequency (%)
Sex	Male	8 (16.7)
	Female	40 (83.3)
Age	23 - 33	25 (52.1)
	34 - 43	18 (37.5)
	44 - 54	5 (10.4)
Education	Bachelor	37 (77.1)
	Master	11 (22.9)
Work Experience	< 1 year	5 (10.4)
	1 - 10 years	28 (58.3)
	> 10 years	15 (31.3)

Research Participants' Profiles

The overall population of this study consisted of 193 pharmacists who were employed in the Bantul regency, which is located within the Special Region of Yogyakarta. The following formula was utilized in this investigation to get the required size of the sample: n = (N.e2) / (N.e2 + z2.p.q), where n represents the sample size, N represents the population size (in this case, N equals 193), e represents the margin of error (the study used 0.05, which is equivalent to 5%), z represents the z-score corresponding to the desired level of confidence (this study used 1.96 for a 95% confidence level), p represents the proportion of the population expected to have the characteristic of interest (the study assumed 0.5 for maximum variability), and q represents 1 minus p. The necessary sample size of 44.55 was calculated for the research project by applying the procedure above and then replacing the numbers. Because the study cannot have a sample size that is a fraction, the researchers rounded the

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number of participants up to 45 in order to achieve the desired sample size. For this reason, the research would require a sample size of 45 people from the total population of 193 in order to obtain a confidence level of 95% while maintaining a margin of error of 5%. The study increased the minimum required sample size by 10%, which resulted in a final sample size of 50, which was intended to prevent sample depreciation. Because of the higher sample size, the study ought to produce results that are more accurate and trustworthy.

As the result of recruitment, this study involved 50 professional certified pharmacists. Due to some reasons, unfortunately, 2 participants decided to resign from the study, meaning the response rate was 96%. Finally, 48 participants were involved in this study (Table I), the study was dominated by female (n=40; 83.3%), aged between 23-33 years old (n=25; 52.1%), holding bachelor degree with certified pharmacist (n=37; 77.11%), and with 1-10 years of work experience (n=28; 58.3%).

Pilot Test

Prior to data collection, a pilot test involving 20 pharmacists working in many private hospitals (outside of the Bantul Regency) was conducted to ascertain the validity and reliability of the research instrument and to demonstrate the consistency of the obtained results. This study's instrument was a questionnaire adapted from previous research, namely the questionnaires of Gupta et al. (2015) and Othman et al. (2017). Because of the validity test results provided (Table II), all 20 questions have a significant positive correlation with the construct being measured, indicating good validity. The R-values range from 0.361 to 0.737, all of which are above the critical R-value of 0.361, indicating that all items are valid. Therefore, it is possible to conclude that the questionnaire has high validity and can be used to measure the intended construct. The reliability test (Table III) indicates that both variables, pharmacist knowledge and attitude, have satisfactory internal consistency, with Cronbach's alpha values of 0.70 and 0.76, respectively. In general, Cronbach's alpha values of 0.7 or higher are regarded as having good internal consistency, indicating that the items within each variable consistently measure the same underlying construct.

Table II. Validity Test Results of the Pharmacovigilance Knowledge and Attitude Questionnaire (n=20)

Question Items	R_{value}	R_{table}	Note
PK 1	0.519	0.361	Valid
PK 2	0.532		Valid
PK 3	0.467		Valid
PK 4	0.528		Valid
PK 5	0.610		Valid
PK 6	0.509		Valid
PK 7	0.610		Valid
PK 8	0.361		Valid
PK 9	0.454		Valid
PK 10	0.610		Valid
PA 1	0.703		Valid
PA 2	0.684		Valid
PA 3	0.582		Valid
PA 4	0.636		Valid
PA 5	0.619		Valid
PA 6	0.717		Valid
PA 7	0.733		Valid
PA 8	0.737		Valid
PA 9	0.709		Valid
PA 10	0.679		Valid

PK: Pharmacist Knowledge; PA: Pharmacist Attitude

Table III. Frequency Distribution of Respondents' Knowledge on Pharmacovigilance

Levels of Knowledge	n (%)
Good	29 (60.4)
Poor	19 (39.6)

Knowledge Regarding Pharmacovigilance

Almost all the questions (90%; n=9) (Table IV), were correctly answered by study participants. It was only one question (number 2: the most important purpose of pharmacovigilance is) that was not correctly answered. This finding aligned with a previous survey, which found 80.2% of healthcare practitioners (e.g., doctors, nurses, and pharmacists) stating that reporting ADRs was the practitioners' responsibility. In terms of pharmacist, a study confirmed that pharmacists were the healthcare practitioners responsible for reporting the ADRs (Günter & Ekmekci, 2019). However, other studies found that almost all participants did not know pharmacists were healthcare practitioners responsible for reporting ADRs (AlShammari & Almoslem, 2018; Alshayban et al., 2020). Based on these findings, it could be confirmed that pharmacists have a role in the pharmacovigilance system in detecting drug safety signals to identify ADRs and reporting them to the system; therefore, ADRs reported by the practitioners, especially pharmacists, would have good quality as they knew and understood pharmacology. Regarding the frequency distribution of respondents' knowledge, as shown in Table III, more than half (60.4%; n=29) of the participants had a score of more than 75, which was included in the good category. It describes those participants knew, understood, and were aware of the definition of the pharmacovigilance system, including its objectives, pharmacovigilance centers, healthcare practitioners and authorities, sources of ADRs information, reporting time of serious events, and how to report the events, pharmacovigilance department, also

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ADR description. The study findings aligned with a previous cross- sectional survey, which found that pharmacists had good knowledge among other health practitioners since pharmacovigilance was a part of the pharmacy curriculum (Hussain *et al.*, 2021).

Table IV. A Summary of the Score of Participant's Knowledge on Pharmacovigilance (n=48)

Statements and Questions	Correct (%)	Incorrect (%)
Define Pharmacovigilance	42 (87.5)	6 (12.5)
The most important purpose of pharmacovigilance is	21 (43.8)	27 (56.2)
The healthcare professionals responsible for reporting ADRs in a hospital is/are	29 (60.4)	19 (39.6)
In Indonesia which regulatory body is responsible for monitoring ADRs?	35 (72.9)	13 (27.1)
Where are the sources of ADR information?	45 (93.8)	3 (6.2)
What is your opinion about establishing ADR monitoring center in every hospital?	38 (79.2)	10 (20.8)
A serious adverse event should be reported to the regulatory body within	32 (66.7)	16 (33.3)
How to get the ADR reporting measurement instrument?	40 (83.3)	8 (16.7)
Pharmacovigilance includes	45 (93.8)	3 (6.2)
Which statement best describes ADR?	48 (100.0)	0 (0.0)

The research also explained that a person's level of good knowledge was influenced by various factors, including education, age, experience, environment, socio-culture, and sources of information (Hussain et al., 2021).

Pharmacist's Attitude

The option of "strongly agree," (Table IV), dominated in participant's responses, followed by "agree," "neutral," "disagree," and "strongly disagree." According to the results, ADR reporting played a key role for healthcare practitioners, especially pharmacists. The participants also agreed that pharmacovigilance should be included in the pharmacy curriculum and should be regularly updated. It was similar to a previous cross-sectional study in Pakistan, which affirmed that 93.4% of pharmacists stated that they had been involved in reporting ADRs activities. In comparison, 60% said that ADR reporting should be mandatory, and pharmacovigilance should be taught in detail to healthcare practitioners, notably pharmacists (Hashmi et al., 2020). On the other hand, other studies found that pharmacists would practice pharmacovigilance if they received training (Terblanche et al., 2018). According to the National Agency of Drug and Food Control of the Republic of Indonesia, monitoring the aspect of drug safety by healthcare practitioners was still voluntary reporting. It means that reporting on the safety of drug use was carried out spontaneously without planning or being part of a study or research (Rachmawati et al., 2022). Of these results, pharmacists perceive that the ADR reporting system is essential and must be carried out by health workers. Based on the attitude variables, the distribution of participants is the frequency indicating the participant's positive or negative response to pharmacovigilance. Therefore, descriptive analysis was carried out first by calculating the participant's attitude variables score. The results (Table V) confirmed that pharmacists with a positive attitude toward pharmacovigilance were 25 people (52.1%), while the negative ones were 23 (47.9%). A previous cross-sectional survey stated that the pharmacist's positive attitude regarding pharmacovigilance could encourage the quality of the ADR reporting system (Hussain et al., 2021). Meanwhile, another study found that pharmacists with a positive attitude toward ADR reporting increase patient safety in medication usage, thus encouraging drug safety monitoring in daily clinical practice (Green et al., 2001).

Relationship between Knowledge and Attitude

The chi-square statistical test was used to know the possible relationship between pharmacist's knowledge and professional attitude regarding pharmacovigilance. The result showed a significant relationship with a p-value of 0.045 (Table VI). As a previous study affirmed, the increasing level of pharmacists' knowledge would affect pharmacists' awareness of being positive or supportive to be responsible for monitoring the pharmacovigilance system in their daily practice.

Table V. Frequency Distribution of Professional Attitudes on Pharmacovigilance

Professional Attitudes	n (%)
Positive	25 (52.1)
Negative	23 (47.9)

Table VI. Hypothesis Test Results of the Relationship Between Knowledge and Attitude

Level of Knowledge	Professional Attitudes		Significance
	Positive	Negative	
Good	19	10	0.045
Poor	6	13	

Providing pharmacists with professional and ongoing education and training would change behavior and attitudes toward ADR reporting. The provided education improved knowledge and changed the pharmacist's attitude regarding ADR reporting. Additionally, the theoretical and practical knowledge in the undergraduate pharmacy curriculum needed to be carried out carefully (Venkatasubbaiah et al., 2021).

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Knowledge and attitude play a significant influence in the reporting profile of adverse drug reactions (ADRs) (Nisa et al., 2018). Healthcare personnel with adequate knowledge and positive attitudes toward ADR reporting, such as recognizing the significance of ADR reporting and a sense of duty to report ADRs, are more likely to report it. Improving the knowledge and attitudes of healthcare professionals regarding the reporting of ADRs is therefore essential for increasing the incidence of ADR reporting.

A theory related to knowledge, attitude and practice is known as Health Belief Model (HBM). It describes how people's thoughts and feelings influence their health-related actions, such as taking their medications as prescribed (Jose et al., 2021) – in this study, type 2 diabetes. According to this theory, a patient's likelihood of taking their prescribed medications as directed is affected by how seriously they take their condition, the benefits they derive from their prescription, and any potential drawbacks they may encounter. If patients believe their medication will improve their glycemic control, they are more likely to take it as prescribed. The theory suggests that improving knowledge and attitudes related to the disease can lead to positive changes in diabetes management practices. Interventions targeting the HBM components, such as increasing awareness of the disease, emphasizing the severity of the consequences of the disease, highlighting the benefits of engaging in diabetes management behaviors, and providing cues to action, may improve the health outcomes of type 2 diabetic patients. After knowing the knowledge and attitude, according to the HBM, healthcare professionals can provide recommendations to enhance medication adherence in type 2 diabetic patients (Osterberg & Blaschke, 2005). The recommendations consist of increasing perceived susceptibility, highlighting perceived benefits, addressing perceived barriers, encouraging patient engagement, and providing ongoing support. By addressing all the factors, the professionals can foster patient engagement and empowerment, resulting in increased medication adherence and enhanced health outcomes (Shakya et al., 2023; Sweileh et al., 2014). The results of this study can have significant implications and effects on clinical practice. First, the study's findings can help identify areas where rural community pharmacists require additional training and education by highlighting deficiencies in their knowledge and practice. This can enhance the quality of care provided by pharmacists, resulting in improved patient outcomes. Second, the research can aid in educating pharmacists about the significance of pharmacovigilance and their role in ensuring drug safety. This can enhance the reporting of adverse drug reactions, thereby contributing to the development of a more comprehensive database of drug safety information. The study also has implications for policymakers, as it can provide evidence to support the development of policies and guidelines to enhance pharmacovigilance practices among rural community pharmacists. This can result in a more standardized approach to pharmacovigilance across various settings, which will ultimately benefit patients and the healthcare system as a whole.

Limitation of the Research

This research confirmed a significant relationship between the pharmacists' knowledge and attitude regarding pharmacovigilance. However, it needed to be evaluated in the research limitations context. First, the data collection process was carried out online using a Google Form due to the COVID-19 physical distancing policy; therefore, respondents' assistance in filling out the questionnaire might not run optimally, and the results might not reflect the results actual situation. Second, the researchers only focused on using the questionnaire as a research instrument, so it might be influenced by the situation and conditions when participants filled out the questionnaire. Additionally, the study findings might also be influenced by the participant's misunderstanding regarding the intent of the questions in the questionnaire. Third, this study was still limited to only studying common factors (i.e., knowledge and attitude). The further study highlighted other pharmacovigilance variables with different instruments. In the data collecting process, participants sometimes did not give accurate opinions due to many uncontrolled factors, such as honesty, mindset, and understanding in filling out the questionnaire.

CONCLUSION

There was a significant relationship between knowledge and attitude regarding pharmacovigilance among professional pharmacists working in rural public healthcare services at Bantul, Yogyakarta, Indonesia, with a p-value of 0.045. Meanwhile, the total research participants were 60.4% and 52.1% for positive attitudes.

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