

PHARMACOVIGILANCE AND ADR REPORTING IN PERAK

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Background: Healthcare professionals, particularly pharmacists, play a crucial role in adverse drug reaction (ADR) reporting and pharmacovigilance activities. Despite retail pharmacies being the most accessible point of care for the patients to report mild ADRs, ADR reporting by community pharmacists in Malaysia remains low. Hence, increasing reporting rate among community pharmacists is crucial to promote medication safety. **Objective:** This study aimed to assess the knowledge, attitudes, and barriers related to ADR reporting and pharmacovigilance among community pharmacists in Perak, Malaysia, and explore associations between their sociodemographic characteristics with their good knowledge, positive attitudes and high barriers level. **Methods:** A cross-sectional study design was employed through both physical and online survey, involving 179 community pharmacists in Perak. Data were collected using a 38-item self-administered online structured questionnaire. Statistical analyses were subsequently conducted. **Results:** This study revealed that community pharmacists exhibited good knowledge (82.1%), positive attitudes (68.7%) and low barriers (86.1%) towards ADR reporting and pharmacovigilance. However, several significant barriers hindered their reporting efforts, including the time-consuming nature of the reporting process (37.4%) and doubts about the causality of ADRs (29.7%). Remarkably, gender and CPD programmes participation were associated with good knowledge. While female gender, younger age and recent pharmacovigilance course exposure were associated with positive attitudes, higher education level was inversely associated with positive attitudes. **Conclusion:** Despite possessing good knowledge and

positive attitudes, several barriers prevent community pharmacists in Perak from effectively reporting ADRs. Targeted interventions are necessary to address these barriers and improve ADR reporting rates among community pharmacists.

Keywords: ADR, adverse drug reactions, attitude, barriers, community pharmacists, knowledge, pharmacovigilance.

Introduction

The acceptance of Malaysia as the 30th member of the International Drug Monitoring Programme (PIDM) marked the establishment of the first Malaysian World Health Organization (WHO)-endorsed pharmacovigilance centre called National Centre for Adverse Drug Reaction Monitoring (NPRM, 2019). Pharmacovigilance (PV) refers to the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems (World Health Organization, 2002). The benefits of PV extend from detecting and preventing adverse drug reactions (ADRs) that may not be identified in pre-marketing trials to providing evidence-based information for healthcare professionals, patients, and policymakers on drug safety (Trifirò & Crisafulli, 2022; WHO, 2002). PV relies on collaboration from many types of healthcare professionals, including community pharmacists who are often first points of contact for patients. Pharmacists' active participation in ADR reporting is crucial, yet community pharmacists frequently submit few reports. For

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instance, in Malaysia only 0.97% of ADR reports in 2020 originated from community pharmacists (NPRA, 2020). Studies in other countries like Sudan, Nigeria and Lithuania also show similarly low reporting by community pharmacists, underscoring a regional trend of underreporting (Mohammed Tahir & Hussein, 2020; Usifoh, *et al*, 2018; Valinciute-Jankauskiene & Kubiliene, 2021). Despite the rising needs of community pharmacists in PV in Malaysia, very little is known regarding their current knowledge, attitudes and barriers towards PV and ADR reporting which may explain such low level of ADR reporting practice.

In Malaysian landscapes, a cross-sectional survey in Selangor circa 2015 found that while community pharmacists demonstrated sufficient knowledge and positive attitudes to report ADR, the practice of ADR reporting was low (Zin, *et al*, 2019). They highlighted barriers such as inadequate clinical knowledge hindered them from reporting ADR. Another Malaysian study in northern region of Malaysia reinforced this narrative, revealing a lack of awareness among pharmacists regarding PV activities (Elkalmi, *et al*, 2014). The low reporting rate further highlighted barriers, including a lack of knowledge on reporting procedures and the unavailability of reporting forms. This study will address crucial gaps in understanding the current knowledge, attitudes, and barriers related to PV and ADR reporting among community pharmacists in Perak, Malaysia. The findings can inform interventions, educational programmes, and policy changes, empowering community pharmacists as vigilant guardians of patient safety and optimising healthcare resources. Additionally, the study findings

could serve to align Malaysian pharmacovigilance practices with international standards.

Therefore, this work aimed to evaluate the knowledge, attitudes and barriers of PV and ADR reporting among community pharmacists in Perak, Malaysia and explore the potential association between their sociodemographic characteristics with the level of knowledge, attitude and barriers toward PV and ADR reporting.

Methods

This cross-sectional study employed convenience sampling to assess the knowledge, attitudes, and barriers related to PV and ADR reporting among community pharmacists in Perak, Malaysia, from March to May 2024. The study targeted pharmacists with a valid license in Malaysia, must work as community pharmacists in the state of Perak, at least one year of experience, and proficiency in English. The population size was estimated at 331, aligning with the number of registered retail pharmacies in the state (*Program Perkhidmatan Farmasi*, 2020). The required sample size, calculated using Raosoft software at a 95% confidence level and a 5% margin of error, was 179 participants (Raosoft, 2004). All participants who meet the inclusion criteria were recruited into the study. Participants who do not satisfy the inclusion criteria or fulfil the defined exclusion criteria were excluded from participation. The defined exclusion criteria are as follows; a) Participants who do not possess a valid license to practise as a pharmacist in Malaysia, b) Participants who practise in settings other than community pharmacy, c) Participants who work as community pharmacists but do not practise in

the state of Perak, Malaysia, d) Participants with less than one year of practice experience, e) Participants who are not able to read and understand English language.

Data were collected via a self-administered online questionnaire using Google Form distributed through e-mail, social media, and physical visits. The questionnaire, adapted from various sources (Alam, *et al*, 2021; Alnawaiseh & AL-Oroud, 2022; Alsaleh, *et al*, 2017; Elkalimi, *et al*, 2014; Mustafa, *et al*, 2021; Syed, *et al*, 2018), consisted of five sections: sociodemographic characteristics, knowledge of PV and ADR reporting, attitudes towards PV, barriers to reporting, and recommendations for improvement. The first section comprised six questions, with one multiple selection answer question. The second section comprised ten multiple choice questions. The third and fourth section consisted of ten closed-ended statements, structured on a 5-point Likert scale. The fifth section concluded with one open-ended question. Questions were adapted from validated Knowledge, Attitude, Practice & Barriers (KAPB) studies in similar contexts. The specific adaptation process was guided by relevance to Malaysian community pharmacy practice. The complete final questionnaire is included as an Appendix for reference.

The content validity of the questionnaire was rigorously evaluated by three expert panels from Universiti Kuala Lumpur Royal College of Medicine Perak with extensive expertise in the fields of pharmacovigilance and pharmacy practice. A pilot test with ten pharmacists verified its reliability, achieving a Cronbach's alpha of 0.84, indicating strong internal consistency (Bujang, *et al*, 2018). Since the pilot study

respondents met all inclusion criteria and only minor revisions were made to the questionnaire, their data were included in the main study. Ethical approval was granted by the Universiti Kuala Lumpur Royal College of Medicine Perak (UniKL-RCMP) Ethical Committee (UniKLRCMP/MREC/MARCH-JULY 2024/FPHS/BACH.PHARM/FYP-010).

The scoring system in knowledge, attitudes and barriers evaluation sections (second, third and fourth sections) was aligned with the categorisation based on Bloom's cut-off points: 80.0%-100.0% for good/positive/high knowledge/attitudes/barriers; 60.0%-79.0% for moderate/neutral knowledge/attitudes/barriers; 0.0%-59.0% for poor/negative/low knowledge/attitudes/barriers, respectively (Alzahrani, *et al*, 2022).

For the section assessing the knowledge of community pharmacists toward PV and ADR reporting, a binary scoring system was applied. A score of 1 was assigned for each correct answer, while a score of 0 was given for incorrect/uncertain responses (Mutagonda, *et al*, 2022). The maximum total score for this section was ten, indicating a perfect knowledge score, and the minimum was 0. To enhance interpretability, the total scores for this section are trichotomised into three levels: Poor Knowledge (<6); Moderate Knowledge (6 – 7); Good Knowledge (>7).

Meanwhile, the attitude evaluation utilising 5-point Likert scale was transformed to binary scale using established methods from other past studies (Mouhieddine, *et al*, 2015; Mutagonda, *et al*, 2022; Zajmi, *et al*, 2017). Each positive response (agree or strongly agree) was assigned a score of one, while

each negative response (neutral, disagree, or strongly disagree) was given a score of 0 (Mutagonda, *et al*, 2022). There were two negative statements provided, hence the positive response (in this case, strongly disagree, or disagree) is assigned a score of one, while each negative response (neutral, agree, or strongly agree) is given a score of 0. The maximum score for this section is ten, indicating a highly positive attitude. The scoring breakdown is as follows: Positive Attitude (>7); Neutral Attitude (6 – 7); Negative Attitude (<6). The same scoring system was applied to barriers evaluation section.

Data analysis for this study was conducted using IBM SPSS version 29 (IBM Corp, Armonk, NY, USA). Descriptive analysis was conducted to evaluate knowledge, attitudes, and barriers, with categorical variables presented in frequencies and percentages. Median and interquartile ranges were calculated for continuous variables as they were not normally distributed. For bivariate analyses, pharmacists were categorised into “good” vs “not good” knowledge

(combining moderate and poor knowledge categories) and “positive” vs “not positive” attitudes (combining neutral and negative attitude categories) for chi-square tests, due to small cell counts in lower categories. Similarly, they were also categorised into “high” and “not high” barriers (combining moderate and low barrier categories). Associations between good knowledge, positive attitudes, and high barriers levels with sociodemographic characteristics were assessed using Pearson’s Chi-squared or Fisher’s Exact Test when appropriate, with Phi and Cramer’s V Test applied in cases of significant associations to express the strength of existing association (Akoglu, 2018; Kim, 2017). We interpret the strength of association results from the Cramer’s V values as suggested by Akoglu (2018), see Table I. The Spearman correlation test was used to examine the relationship between the outcomes of knowledge and attitude levels, with statistical significance set at $p < 0.05$.

Table I: Interpretation of Phi and Cramer’s V Value.

Phi and Cramer’s V value	Interpretation
More than 0.250	Very strong
0.151 – 0.250	Strong
0.101 – 0.150	Moderate
0.051 – 0.100	Weak
0 – 0.050	No or very weak

(Akoglu, 2018)

Results

A total of 179 community pharmacists completed the survey and were analysed (no participants were excluded). Table II presents the sociodemographic characteristics of the respondents, including gender, age, highest education level, length of practice, participation in CPD programmes (in hours), and exposure to a PV course within the past one year. As these data are categorical variables, they are represented using frequencies and percentages.

Table II: Community Pharmacists' Sociodemographic Information.

Variable	Category	Frequency (N)	Percent (%)
Gender	Male	73	40.8
	Female	106	59.2
Age	21 – 30 years	91	50.8
	31 – 40 years	48	26.8
	41 – 50 years	28	15.6
	≥ 51 years	12	6.7
Education Level	Undergraduate (Bachelor's degree)	165	92.2
	Postgraduate (Master's degree or PhD)	14	7.8
Length of practice as a community pharmacist (in years)	≤ 5	106	59.2
	6 – 10	31	17.3
	11 – 15	14	7.8
	16 – 20	14	7.8
	≥ 21	14	7.8
Participation in CPD programmes per year (in hours)	None	14	7.8
	1 – 5	34	19.0
	6 – 10	55	30.7
	≥ 11	76	42.5
Exposure in pharmacovigilance course or seminar for the last one year	No	134	74.9
	Yes	45	25.1

Note: N=179

A slight majority of the participants were female (106 respondents; 59.2%), while males constituted 40.8% (73 respondents). The age distribution indicated that more than half of the respondents were between 21–30 years old (91 respondents; 50.8%), with the smallest group being those older than 50 years (12 respondents; 6.7%). A substantial majority of the respondents were undergraduates (165 respondents; 92.2%), with postgraduates representing only 7.8% (14 respondents). Since majority of the respondents are among younger demographic, most respondents (106; 59.2%) had less than five years of practice, and a minority (14; 7.8%) had more than 21 years of experience. 42.5% (76 respondents) participated in more than 11 hours of CPD programmes annually, while 7.8% (14 respondents) did not participate in CPD programmes at all. Lastly, 74.9% (134 respondents) had not attended any PV courses or seminars in the past one year, whereas 25.1% (45 respondents) had such exposure.

Knowledge, Attitudes and Barriers Domains

The knowledge domain comprised ten questions as presented in Figure I. For the first question defining “Pharmacovigilance”, 81% (145 respondents) answered correctly, while 19% (34 respondents) were uncertain or answered wrongly. The second question regarding the purpose of PV saw 92.2% (165 respondents) responding accurately. Defining an ADR was correctly done by 84.4% (151 respondents), whereas 15.6% (28 respondents) were uncertain or answered incorrectly. Identifying reportable ADR examples was achieved by 87.7% (157 respondents),

while 12.3% (22 respondents) failed to identify the correct answer. Recognising the existence of an ADR reporting system in Malaysia was known by 94.4% (169 respondents). When asked about the channel of ADR reporting in Malaysia through email, 38% (68 respondents) answered incorrectly, making only 62% (111 respondents) able to choose the correct answer. For the seventh question, 95.5% (171 respondents) correctly identified the ADR form as a channel to report ADRs in Malaysia. The existence of an official standardised form to report ADRs was known by 88.8% (159 respondents). The ninth question about reporting side effects like headache, fever, and vomiting had 63.1% (113 respondents) answering correctly. Lastly, 91.1% (163 respondents) correctly identified Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) as the reporting organisation in Malaysia.

The preferred source of information about PV and ADR reporting is presented in Figure II. This question accepted multiple answers from each respondent. The main source of information was social media/internet (n=100; 37.9%), followed by university courses (n=68; 25.8%) and CPD programmes (n=68; 25.8%). Journals were the least preferred source of information (n=8; 3%), with others (n=20; 7.6%). Among those selected “Other” sources of information, no further details were provided as the participants were not able to specify others. The total number of answers collected was 264.

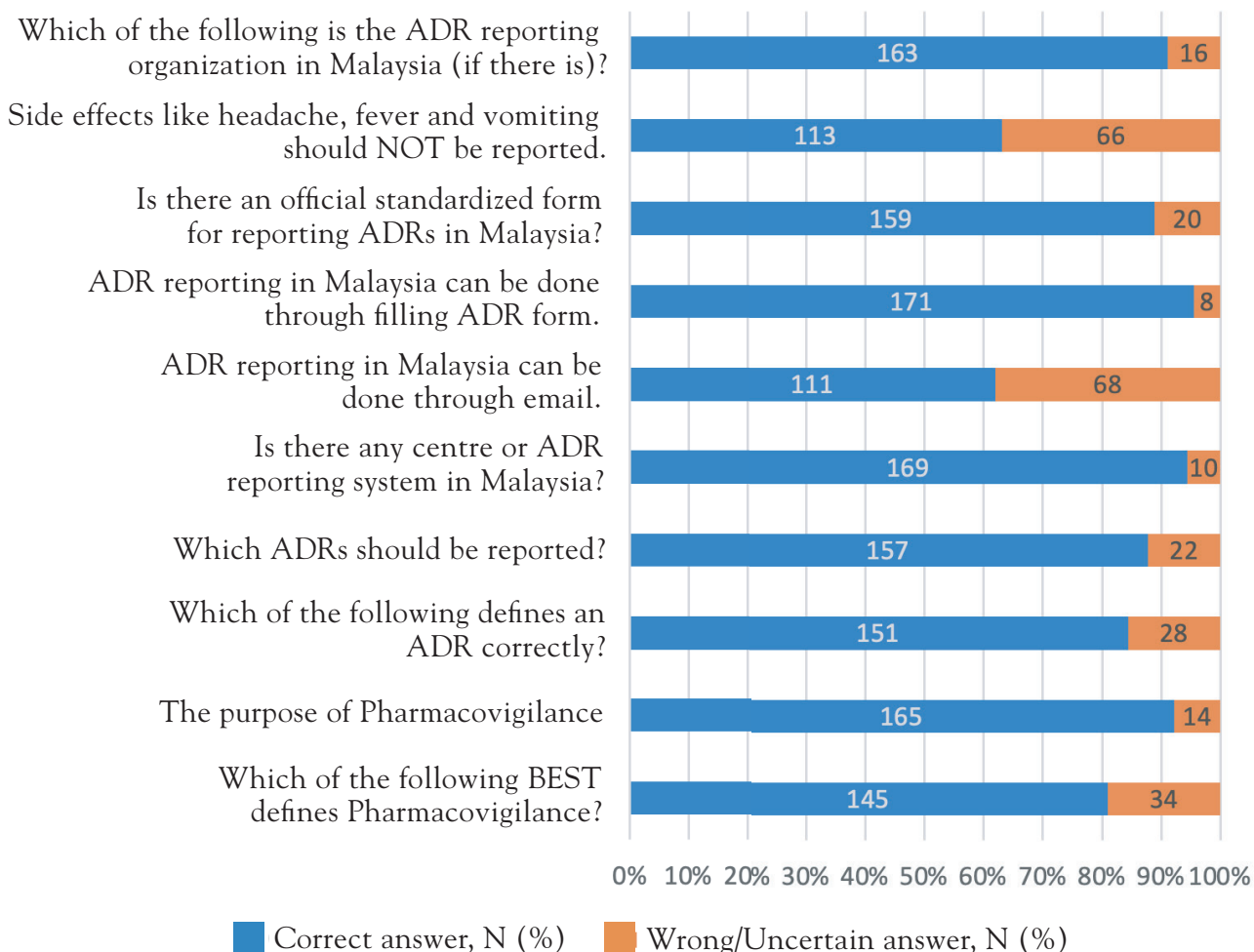


Figure I: Responses of the community pharmacists on knowledge domain about PV and ADR Reporting.

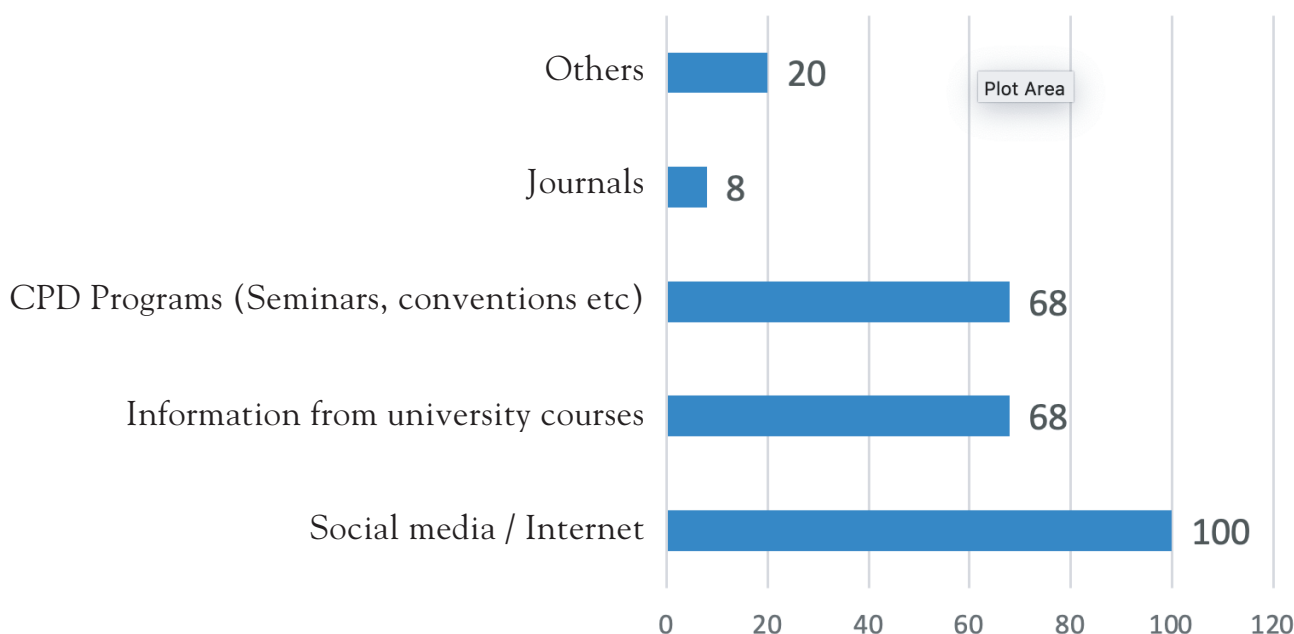


Figure II: Sources of information about PV and ADR reporting.

Figure III presents data related to attitude. Regarding attitudes towards ADR reporting, 93.3% (167 respondents) believed it to be part of a pharmacist’s duty, and 94.4% (169 respondents) considered monitoring drug safety as important. Only a small minority (7.8%; 14 respondents) did not think it necessary to confirm an ADR’s relation to a specific drug before reporting. The necessity to report ADRs related to OTC products was acknowledged by 76% (136 respondents). Additionally, 93.3% (167 respondents) recognised the importance of reporting ADRs leading to hospitalisation, and 85.5% (153 respondents) deemed reporting life-threatening ADRs as important. Discussing ADRs with a trained physician or academician was considered important by 76.5% (137 respondents), while 62% (111 respondents) believed that non-serious adverse reactions should be reported.

Table III exhibits data related to barriers. The majority (72 respondents; 40.2%) strongly disagreed that the unavailability of reporting forms was a barrier. The complexity of the reporting form was strongly disagreed upon by 32.4% (58 respondents). Although 32.4% (58 respondents) were neutral on the time-consuming nature of reporting ADRs, 20.1% (36 respondents) agreed, and 17.3% (31 respondents) strongly agreed it was time-consuming. Besides, confidential handling of reports was not seen as a barrier by 34.6% (62 respondents). Furthermore, insufficient clinical knowledge was strongly disagreed upon as a barrier by 38% (68 respondents), meanwhile lack of knowledge on how to report ADRs was strongly disagreed upon by 43.6% (78 respondents). Finally, while 29.1% (52 respondents) were neutral on being not convinced that the ADR is caused by the drug as a barrier to report ADRs, 29.7% (53 respondents) collectively agreed or strongly agreed it was ... (truncated?)

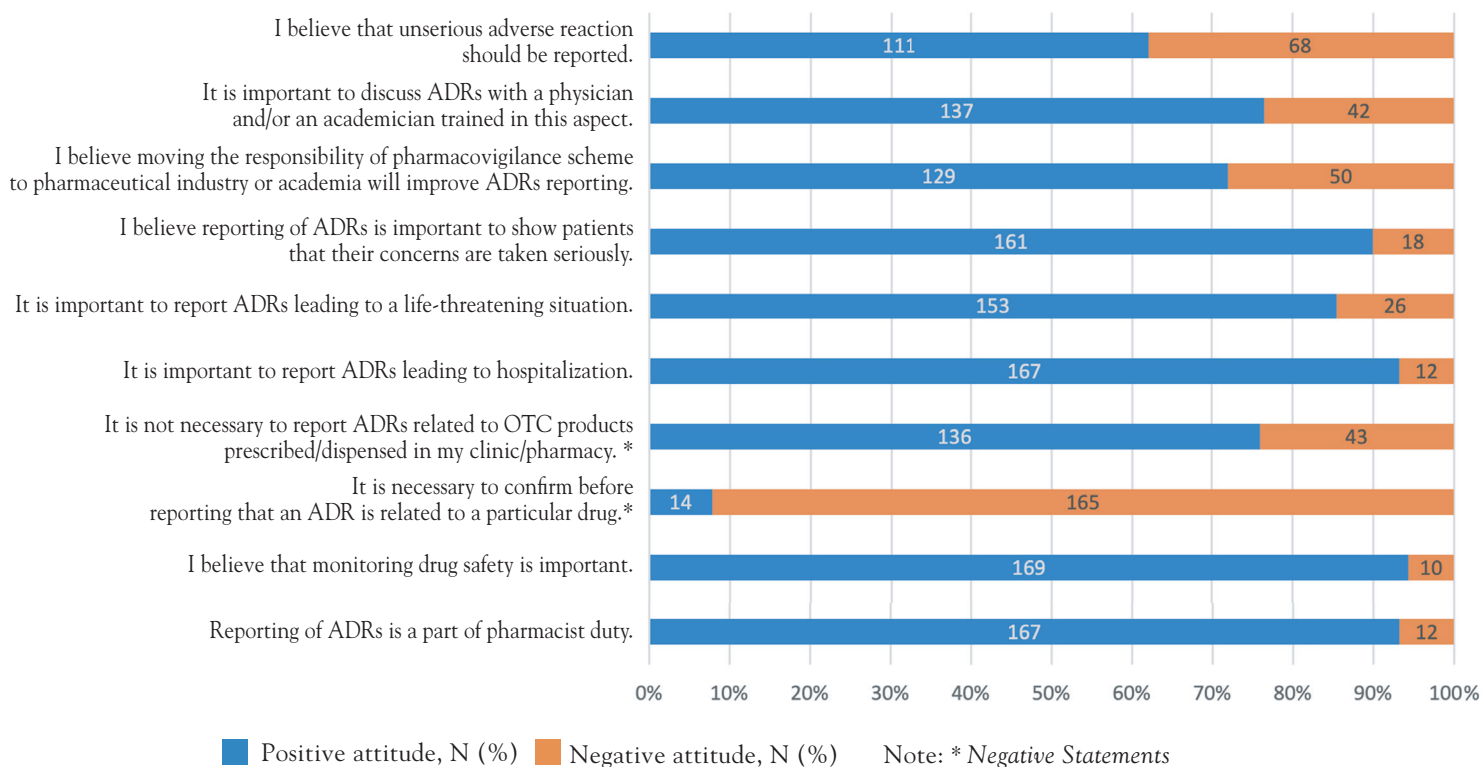


Figure III: Responses of the community pharmacists on attitude domain about PV and ADR Reporting.

Table III: Barriers on Pharmacovigilance and ADR Reporting (N=179).

Statement	Strongly Disagree		Disagree		Neutral		Agree		Strongly Agree	
	N	%	N	%	N	%	N	%	N	%
I don't report ADRs because reporting form is not available.	72	40.2	40	22.3	38	21.2	14	7.8	15	8.4
The reporting form is too complicated.	58	32.4	26	14.5	54	30.2	20	11.2	21	11.7
Reporting ADRs is time consuming.	22	12.3	32	17.9	58	32.4	36	20.1	31	17.3
I don't report ADRs because I am not convinced about the confidential handling of the reports.	62	34.6	60	33.5	46	25.7	4	2.2	7	3.9
I don't report ADRs because I fear it may harm the confidence of my patients.	66	36.9	54	30.2	34	19.0	10	5.6	15	8.4
I don't report because I find it difficult to admit that the patients have been harmed.	54	30.2	60	33.5	34	19.0	14	7.8	17	9.5
I don't report because I fear legal liability for the reported ADRs.	66	36.9	52	29.1	42	23.5	8	4.5	11	6.1
I don't report because I have insufficient clinical knowledge.	68	38.0	50	27.9	32	17.9	18	10.1	11	6.1
I don't report because I don't know how to report ADRs.	78	43.6	44	24.6	32	17.9	14	7.8	11	6.1
I don't report because I am not convinced the ADR is caused by the drug.	36	20.1	38	21.2	52	29.1	18	10.1	35	19.6

The median knowledge score was 9 (IQR: 8-9). The attitude scores were similarly analysed, with the median score being 8 (IQR: 7-9). The median barriers score was found to be 0 (IQR: 0-3). The summarisation of knowledge and attitude levels among the respondents is detailed in Table IV.

Table IV: Summary of the knowledge, attitude and barrier level of the community pharmacists.

Variable (median, IQR)	Categories	N	%
Knowledge (Median 9, IQR 8–9)	Poor	6	3.4%
	Moderate	26	14.5%
	Good	147	82.1%
Attitude (Median 8, IQR 7–9)	Negative	20	11.2%
	Neutral	36	20.1%
	Positive	123	68.7%
Barrier (Median 0, IQR 0–3)	Low	155	86.1%
	Moderate	18	10.0%
	High	7	3.9%

Association between sociodemographic characteristics and good knowledge, positive attitudes and high barriers

Gender was significantly associated with knowledge with 88.7% of females and 72.6% of males had good knowledge ($\chi^2=7.61$, $p=0.006$, Cramer's $V=0.206$). A Cramer's V of 0.206 corresponds to a small-to-moderate effect size (Akoglu, 2018). In addition, those who had not participated in CPD programs showed the least percentage of good knowledge level (28.6%), with 82.4%, 85.5%, and 89.9% of 1–5 hour(s), 6–10 hours, and more than ten hours CPD programmes groups showed good knowledge level, respectively.

Hence, the Chi-square Test revealed significant result ($\chi^2(1) = 30.561$, $p = <0.001$, $V = 0.413$). These results shows that there is a significant association between annual CPD programmes and good knowledge level, indicating moderate association. Participation in CPD programmes was also significantly associated with knowledge ($\chi^2=30.56$, $p<0.001$, $V=0.299$), indicating a moderate effect size. Furthermore, 82.4% of the pharmacists in the age bracket of 21-30 years old had good knowledge level. Likewise, 79.2%, 92.9% and 66.7% of the pharmacists demonstrated good knowledge level in the age bracket of 31-40, 41-50 and ≥ 51 years old respectively. The Chi-

square Test yielded no significant result ($\chi^2(3) = 4.441, p = 0.218$). Despite obvious differences, these results imply that there is no significant association between age and good knowledge level, possibly due to small numbers in some age groups. Education level (undergraduate 81.8% vs postgraduate 85.7%) also showed no significant association ($p=1.000$, Fisher's Exact). The association between PV course exposure and knowledge was not significant ($p=0.069$).

Meanwhile, relationship between sociodemographic characteristics and high barriers level showed no significant association for all characteristics except for length of practice and participation in CPD programmes ($p = 0.038, V = 0.219$ and $p < 0.001, V = 0.299$, respectively) as stipulated in Table V.

Table V: Sociodemographic characteristics and their correlation with good knowledge, positive attitudes and high barriers.

Characteristics	Good Knowledge				Positive Attitudes				High Barriers			
	%	χ^2 value (df)	p-value	Phi & Cramer's V value	%	χ^2 value (df)	p-value	Phi & Cramer's V value	%	χ^2 value (df)	p-value	Phi & Cramer's V value
Gender												
Male	72.6	7.610	0.006	0.206	53.4	13.407	<0.001	0.274	4.1	-	0.062*	-
Female	88.7	(1)			79.2	(1)			3.8			
Age (years)												
21–30	82.4				69.2				3.3			
31–40	79.2	4.441	0.218	-	83.3	13.515	0.004	0.275	8.3	-	0.121*	-
41–50	92.9	(3)			57.1	(3)			0.0			
≥ 51	66.7				33.3				0.0			
Education Level												
Undergraduate	81.8		1.000*	-	70.9		0.038*	-0.162	4.2	-	0.518*	-
Postgraduate	85.7	-			42.9	-			0.0			
Length of practice (in years)												
≤ 5	81.1	4.577†	0.331†	-	71.7	5.924†	0.197†	-	3.8	-	0.038*	0.219
6–10	80.6				74.2				9.7			
11–15	100.0				57.1				0.0			
16–20	85.7				71.4				0.0			
≥ 21	71.4				42.9				0.0			

CPD programmes per year (in hours)												
None	28.6				57.1				0.0			
1–5	82.4	30.561	<0.001	0.413	70.6	1.174	0.759	–	11.8	–	<0.001*	0.299
6–10	85.5	(3)			67.3	(3)			1.8			
≥ 11	89.5				71.1				2.6			
Pharmacovigilance course or seminar for the last one year												
No	79.1	3.308	0.069	–	64.2	5.102	0.024	0.169	4.5	–	0.140*	–
Yes	91.1	(1)			82.2	(1)			2.2			

Note:

* Fisher–Freeman–Halton Exact Test

† Fisher’s Exact Test for cases when more than 20% of the cells have expected count less than 5

Spearman’s correlation revealed a significant positive correlation (Spearman’s rho = 0.288, p < 0.001) between the knowledge and attitudes domains as stipulated in Table VI. In contrast, attitudes and barriers domains noted no significant correlation.

Table VI: Spearman’s correlation across knowledge, attitude and barrier scores.

Variable	Spearman's rho	Knowledge	Attitude	Barrier
Knowledge Score	Correlation	1.000	0.288*	0.037
	Coefficient			
	p-value	–	< 0.001	0.624
Attitude Score	Correlation	0.288*	1.000	-0.053
	Coefficient			
	p-value	< 0.001	–	0.478
Barrier Score	Correlation	0.037	-0.053	1.000
	Coefficient			
	p-value	0.624	0.478	–

Note: * Correlation is significant at the 0.01 level (2-tailed).

Finally, the community pharmacists recommended a few significant measures to improve PV and ADR reporting through the provided open-ended question. These include provide training and exposure to PV, enforcing law, improvising reporting system, establishing guidelines or standard operating procedures, incentive system, instillation in undergraduate syllabus and making ADR forms available in all retail pharmacy stores.

Discussion

In the current study, we examined the knowledge, attitude, and barriers related to PV and ADR reporting among community pharmacists in the state of Perak, Malaysia. Our findings shed light on current knowledge and attitude levels and also barriers faced by pharmacists in ensuring drug safety and highlight areas for improvement in the reporting system.

Overall pharmacists' knowledge and attitude

Overall, our findings revealed that community pharmacists demonstrated a good understanding of PV and ADR reporting. Majority of the participants (82.1%) answered more than two third of the questions correctly, with an average score (median) of 9 (IQR 8-9). Additionally, most of the participants (68.7%) exhibited a positive attitude toward PV and ADR reporting. This aligns with previous research conducted in Selangor in 2015, which also indicated sufficient knowledge among community pharmacists (Zin, *et al*, 2019). Globally, community pharmacists in Saudi Arabia, South Africa and Yemen also appeared to have good knowledge with positive attitudes comparable to our findings (Abdulsalim, *et al*, 2023; Alsheikh & Alasmari, 2022; Gordhan & Bangalee, 2022).

Knowledge Domain

Furthermore, in knowledge domain, almost a quarter (19%) of our participants wrongly defined PV. Meanwhile, a previous study in Malaysia reported only 11.6% were able to define pharmacovigilance, suggesting that the knowledge on pharmacovigilance term had fairly improved over the years (Zin, *et al*, 2019). Furthermore, 91.1% were able to identify MADRAC as ADR reporting organisation in Malaysia. This notes a higher leap of percentage compared to other past studies done in Malaysia, possibly due to more outreach programmes done by MADRAC along the time (Elkalmi, *et al*, 2014; Zin, *et al*, 2019). Most of the source of information about PV and ADR reporting of the studied community pharmacists were from social media or internet. This proves the proactive role of relevant agencies in reaching the pharmacists. MADRAC annual bulletin on the internet might evident that internet plays a big role in disseminating PV information.

Attitude Domain

A substantial majority of our respondents believed that reporting ADR is a part of pharmacist duty, showing positive attitude. This finding is coherent with another study in Selangor, Malaysia where our finding showed an increase in percentage for the positive responses, indicating the increased awareness on PV role of pharmacists (Zin, *et al*, 2019). Subsequently, our study found a gap in attitude of the community pharmacists who underestimated the importance to report unserious ADRs. Unserious suspected ADRs should still be reported to establish causality relationship between the drugs and ADRs for an improved intervention. On the other hand, unlike

many studies, our study found that huge majority (92.2%) believed that it is necessary to confirm the causality between drugs and ADRs before reporting. In fact, any suspicion should be enough to report ADRs as the analysis of the causality would be performed by MADRAC instead. This finding is contradictory to a study in Lagos State which most of the community pharmacists showed positive attitude (Olugbake OA, *et al*, 2023). It is fair to note that our method utilising Likert scale has superior approach due to its ability to evaluate the degree of their attitudes in which the above contradicting study only utilised agree/disagree answer choices.

Barriers Domain

As for the barriers of ADR reporting, our study found that a noticeable amount of the respondents identified the inability to be convinced that ADRs was caused by the drug as a barrier to report ADRs. This barrier is coherent with the finding of a similar study in Malaysia (Elkalmi, *et al*, 2014). This underscores a widespread misconception. ADR reporting is encouraged even on suspicion alone, since causality assessment is handled by regulatory agency. More interventions should be done to instil awareness to the community pharmacists to ascertain them that there is no requirement to validate the causality before reporting ADRs. Future research should further explore the underlying reasons for this reluctance, such as lack of confidence, fear of inaccuracy or limited training to design more effective educational and policy interventions. Furthermore, the most significant barrier found from our study is ADR reporting was deemed to be time-consuming. The same finding was reported by several studies in Malaysia, Wales, United Kingdom, and Saudi Arabia

(Alsheikh & Alasmari, 2022; Hughes & Weiss, 2019; Zin, *et al*, 2019). More significant approach needs to be done to reduce the time consumption of ADR reporting. A study in Wales had found that by centralising the reporting forms with dispensing software would be great facilitator to report ADRs among community pharmacists (Hughes & Weiss, 2019).

Association between sociodemographic characteristics and good knowledge, positive attitudes and high barriers

Consistent with past studies in another region in Malaysia and Poland, our study found that knowledge about PV and ADR reporting is not significantly influenced by the length of practice of the pharmacists (Elkalmi, *et al*, 2014; Zimmermann, *et al*, 2016). This suggests that CPD might be more critical than years of experience alone. Related to that, a very strong association was found in our study between CPD programmes and good knowledge. This highlights the critical role of CPD in enhancing pharmacists' knowledge about PV and ADR reporting. While CPD programmes are effective in enhancing knowledge, they may not directly influence attitudes based on our study findings. Hence, more CPD programmes on PV should be implemented with inclusion of components that address attitudes and evoke motivation to report ADRs as suggested by previous studies (Valinciute-Jankauskiene & Kubiliene, 2021; Zin, *et al*, 2019). For instance, offering CPD points for each ADR report submitted could be an effective incentive to translate their knowledge into practice. On the other hand, interestingly, an inversely related association was found where pharmacists with undergraduate

degrees had more positive attitudes than those with postgraduate degrees, possibly due to more recent curricular exposure to pharmacovigilance. This suggests the need to reinforce pharmacovigilance education consistently across both undergraduate and postgraduate levels. Further research, particularly qualitative or comparative studies, is needed to explore the reasons behind this inverse relationship. Finally, the findings from our study revealed that exposure to PV courses is strongly associated with positive attitude, suggesting that targeted educational interventions can effectively improve the community pharmacists' attitudes towards these critical practices (Al-Worafi, *et al*, 2017). Meanwhile, no significant association was identified between sociodemographic characteristics and high barriers, likely due to pooled number of subjects who exhibited low barriers level. Less participants (n=7) with high barriers causes the differences between each characteristic difficult to appear in statistical tests. However, lower practice length and lower CPD programmes are associated with higher barriers, indicating that interventions like providing CPD programmes may lower the barriers to report ADRs.

Correlation across knowledge, attitude and barriers scores

Furthermore, our study found significant positive correlation between knowledge and attitude domains among community pharmacists. This finding aligns with a study in Yemen, highlighting that enhanced knowledge likely contributes to more favourable attitudes (Al-Worafi, *et al*, 2017). Therefore, comprehensive education and training programmes are crucial for fostering positive attitudes and

improving ADR reporting rates, ultimately enhancing patient safety and drug monitoring. Various recommendations were provided by the pharmacists to improve PV and ADR reporting, with the most recommended for training and exposures. This can be achieved through CPD programmes and exposure through internet. Besides, incentives system (which should not always be in monetary but could also be in the form of CPD points reward per report submitted) was also reported, consistent with several studies (Elkalmi, *et al*, 2011; Hughes & Weiss, 2019).

Karuppappan, *et al* (2022) reported that while most hospital and clinical pharmacists recently encountered ADRs, 81% of hospital/clinic pharmacists who encountered so reported the event compared to only 40% of community pharmacists. This disparity highlights that community pharmacists face distinct barriers to reporting and supports the need for previously discussed interventions tailored to the community setting.

Conclusion

The community pharmacists in Perak, Malaysia, exhibited good knowledge and positive attitudes towards PV and ADR reporting despite low ADR reporting rates. We found that the good knowledge and positive attitudes did not translate into practice due to several identified barriers. The barriers include the complexity and time-consuming nature of the reporting process and many of the retail pharmacists were not convinced that ADRs were caused by the drug. We also found a big misconception among community pharmacists where most believed that causality between drug and ADR is a prerequisite for

ADR reporting, when in fact causality assessment should only be done by the regulatory agency. This highlights the need for interventions to overcome the barriers between their knowledge and attitude with their ADR reporting behaviour.

Strengths and Limitations

Strengths of this study include achieving the pre-calculated sample size (n=179), use of a validated and pilot-tested questionnaire with good internal consistency (Cronbach's $\alpha=0.84$) and comprehensive assessment of knowledge, attitudes and barriers in the defined population. While this study provides valuable insights into the knowledge base, there are several limitations. The data collected were based on self-reported responses, which may be subject to response bias. Respondents might provide socially desirable answers regarding their attitudes and barriers. Besides that, the cross-sectional design of the study provides only a snapshot of the current state of knowledge, attitudes, and barriers. Longitudinal studies are needed to assess changes over time and the impact of interventions. Furthermore, the use of convenience sampling may limit the generalisability of the

findings, as the respondents may not fully represent the broader population of community pharmacists in Perak or Malaysia. Potential confounding variables (age, length of practice) may influence both exposures (CPD programmes participation) and outcomes (knowledge and attitudes). As the analysis relied primarily on bivariate tests, residual confounding cannot be excluded and should be considered when interpreting associations. Due to the cross-sectional design and small counts in some categories, analysis used bivariate methods. Future studies with larger samples should apply multivariable regression to adjust for potential confounders.

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Conflict of Interest

The authors declare no conflict of interest. No sponsorship was received to conduct this study.

REFERENCES

- Abdulsalim, S, Farooqui, M, Alshammari, M S, Alotaibi, M, Alhazmi, A, Alqasomi, A, & Altowayan, W M (2023). Evaluation of Knowledge, Attitudes, and Practices about Pharmacovigilance among Community Pharmacists in Qassim, Saudi Arabia. *International Journal of Environmental Research and Public Health*, 20(4). <https://doi.org/10.3390/ijerph20043548>.
- Akoglu, H (2018). User's guide to correlation coefficients. *Turkish Journal of Emergency Medicine*, 18(3), 91–93. <https://doi.org/10.1016/J.TJEM.2018.08.001>.
- Alam, K, Karki, B, Gupta, A K, Sarraf, D P, & Wagle, S (2021). Assessment of knowledge, attitude and practice of pharmacovigilance and adverse drug reactions reporting among the community pharmacies in Dharan. *International Journal of Scientific Reports*, 7(8). <https://doi.org/10.18203/issn.2454-2156.intjsci20212833>.
- Alnawaiseh, N A, & AL-Oroud, R Y (2022). Knowledge, Attitude and Practices of Pharmacovigilance and Adverse Drug Reaction Reporting Among Pharmacists Working at Alkarak Governorate, Jordan. *Biomedical and Pharmacology Journal*, 15(2). <https://doi.org/10.13005/bpj/2432>.
- Alsaleh, F M, Alzaid, S W, Abahussain, E A, Bayoud, T, & Lemay, J (2017). Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait. *Saudi Pharmaceutical Journal*, 25(6). <https://doi.org/10.1016/j.jsps.2016.12.004>.
- Alsheikh, M Y, & Alasmari, M M (2022). A National Survey of Community Pharmacists' Viewpoints About Pharmacovigilance and Adverse Drug Reaction Reporting in Saudi Arabia. *Frontiers in Pharmacology*, 13. <https://doi.org/10.3389/fphar.2022.819551>.
- Al-Worafi, Y M, Kassab, Y W, Alseragi, W M, Almutairi, M S, Ahmed, A, Ming, L C, Alkhashaiban, A S, & Hadi, M A (2017). Pharmacovigilance and adverse drug reaction reporting: A perspective of community pharmacists and pharmacy technicians in Sana'a, Yemen. *Therapeutics and Clinical Risk Management*, 13. <https://doi.org/10.2147/TCRM.S140674>.
- Alzahrani, M M, Alghamdi, A A, Alghamdi, S A, & Alotaibi, R K (2022). Knowledge and Attitude of Dentists Towards Obstructive Sleep Apnea. *International Dental Journal*, 72(3). <https://doi.org/10.1016/j.identj.2021.05.004>.
- Bujang, M A, Omar, E D, & Baharum, N A (2018). A review on sample size determination for cronbach's alpha test: A simple guide for researchers. *Malaysian Journal of Medical Sciences*, 25(6). <https://doi.org/10.21315/mjms2018.25.6.9>.
- Elkalmi, R M, Hassali, M A, & Ibrahim, M I M (2011). Impact of educational intervention for improving pharmacist knowledge in adverse drug reactions (ADR) reporting: Experience from Malaysia. *Open Drug Safety Journal*, 2(1). <https://doi.org/10.2174/1876818001102010047>.
- Elkalmi, R M, Hassali, M A, Ibrahim, M I M, Jamshed, S Q, & Al-Lela, O Q B (2014). Community pharmacists' attitudes, perceptions, and barriers toward adverse drug reaction reporting in Malaysia: A quantitative insight. *Journal of Patient Safety*, 10(2). <https://doi.org/10.1097/PTS.0000000000000051>.
- Gordhan, A, & Bangalee, V (2022). The current knowledge, attitude, perceptions and practice of pharmacovigilance amongst community pharmacists in Gauteng, South Africa. *Journal of Pharmaceutical Health Services Research*, 13(2). <https://doi.org/10.1093/jphsr/rmac012>.
- Hughes, M L, & Weiss, M (2019). Adverse drug reaction reporting by community pharmacists – The barriers and facilitators. *Pharmacoeconomics and Drug Safety*, 28(12), 1552–1559. <https://doi.org/https://doi.org/10.1002/pds.4800>.
- Kim, H-Y (2017). Statistical notes for clinical researchers: Chi-squared test and Fisher's exact test. *Restor Dent Endod*, 42(2), 152–155. <https://doi.org/10.5395/rde.2017.42.2.152>.
- Mohammed Tahir, R, & Hussein, M (2020). Knowledge, Attitude, and Practice of Community Pharmacists towards Pharmacovigilance and Adverse Drug Reactions: A Study from Sudan. *Journal of Scientific Research in Medical and Biological Sciences*, 1(2). <https://doi.org/10.47631/jsrmb.v1i2.118>.
- Mouhieddine, T H, Olleik, Z, Itani, M M, Kawtharani, S, Nassar, H, Hassoun, R, Houmani, Z, Zein, Z El, Fakhri, R, Mortada, I K, Mohsen, Y, Kanafani, Z., & Tamim, H (2015). Assessing the Lebanese population for their knowledge, attitudes and practices of antibiotic usage. *Journal of Infection and Public Health*, 8(1). <https://doi.org/10.1016/j.jiph.2014.07.010>.
- Mustafa, Z U, Salman, M, Asif, N, Rao, A Z, Khan, Q U A, Nawaz, A S, Mumtaz, M W, Masood, A, Khan, M F A, Shehzadi, N, & Hussain, K (2021). Knowledge, Attitude, Practices, and Barriers of Pharmacovigilance among Healthcare Workers: A Cross-sectional Survey from Lahore, Pakistan. *Bulletin of Faculty of Pharmacy Cairo University*, 59(1). <https://doi.org/10.54634/2090-9101.1023>.
- Mutagonda, R F, Marealle, A I, Nkinda, L, Kibwana, U, Maganda, B A, Njiro, B J, Ndumwa, H P, Kilonzi, M, Mikomangwa, W P, Mlyuka, H J, Felix, F F, Myemba, D T, Mwakawanga, D L, Sambayi, G, Kunambi, P P, Ndayishimiye, P, Sirili, N, Mfaume, R, Nshau, A, Bwire, G M (2022). Determinants of misuse of antibiotics among parents of children attending clinics in regional referral hospitals in Tanzania. *Scientific Reports*, 12(1). <https://doi.org/10.1038/s41598-022-08895-6>.
- National Pharmaceutical Regulatory Agency (NPR) (2020). 2020 ANNUAL REPORT NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING. <https://npra.gov.my/easyarticles/images/shared/FV/Annual%20Report/Annual-Report-2020.pdf>.
- NPR (2019, March 20). Introduction to MADRAC. National Pharmaceutical Regulatory Agency (NPR), Ministry of Health Malaysia (MOH). <https://www.npra.gov.my/index.php/en/about/malaysian-adverse-drug-reactions-advisory-committee-madrac/madrac-introduction>.

- Olugbake O A, Rufus A C, Joda A, & Balogun M (2023). Adverse drug reactions reporting by community pharmacists in Lagos State. *Ibom Medical Journal*, 16(2). <https://doi.org/10.61386/imj.v16i2.315>.
- Program Perkhidmatan Farmasi, K (2020, March 25). *Farmasi Komuniti di Malaysia*. Tableau. <https://public.tableau.com/app/profile/farmasi/viz/FarmasiKomunitidiMalaysia/Dashboard12>.
- Raosoft (2004). *Raosoft Sample Size Calculator*. Raosoft, Inc. <http://www.raosoft.com/samplesize.html>.
- Syed, A, Azhar, S, Raza, M, Saeed, H, & Jamshed, S (2018). Assessment of Knowledge, Attitude and Barriers towards Pharmacovigilance among Physicians and Pharmacists of Abbottabad, Pakistan. *Pharmacy*, 6(2). <https://doi.org/10.3390/pharmacy6020029>.
- Trifirò, G, & Crisafulli, S (2022). A New Era of Pharmacovigilance: Future Challenges and Opportunities. *Frontiers in Drug Safety and Regulation*, 2. <https://doi.org/10.3389/fdsfr.2022.866898>.
- Usifoh, S F, Aika, I N, Odili, V U, & Nwokoro, J O (2018). Community Pharmacists Knowledge, Behaviours and Practice of Adverse Drug Reactions Reporting in Lagos State, Nigeria. *Indian Journal of Pharmacy Practice*, 11(1). <https://doi.org/10.5530/ijopp.11.1.3>.
- Valinciute-Jankauskiene, A, & Kubiliene, L (2021). Qualitative study of community pharmacists' and general practitioners' views toward pharmacovigilance in Lithuania. *Healthcare (Switzerland)*, 9(8). <https://doi.org/10.3390/healthcare9081072>.
- World Health Organization. (2002). *The importance of pharmacovigilance*. World Health Organization. <https://iris.who.int/handle/10665/42493>.
- Zajmi, D, Berisha, M, Begolli, I, Hoxha, R, Mehmeti, R, Mulliqi-Osmani, G, Kurti, A, Loku, A, & Raka, L (2017). Public knowledge, attitudes and practices regarding antibiotic use in Kosovo. *Pharmacy Practice*, 15(1). <https://doi.org/10.18549/PharmPract.2017.01.827>.
- Zimmermann, A, Gaworska-Krzemińska, A, & Flis, A (2016). Adverse drug reporting in community pharmacy practice in the Pomeranian District in Poland. *Acta Poloniae Pharmaceutica*, 73, 1389–1396.
- Zin, R M, Hong, Y H, Ming, L C, Khan, T M, Dali, A F, & Neoh, C F (2019). Survey of knowledge, attitudes and practice regarding adverse drug reaction (ADR) reporting among community pharmacists in Selangor, Malaysia. *Journal of Pharmacy Practice and Research*, 49(3). <https://doi.org/10.1002/jppr.1495>.