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Original Research Article

Knowledge, Practices & Attitudes Towards Adverse Drug Reaction Reporting among Public Healthcare Professionals in West Pahang

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ABSTRACT

Background: The World Health Organization identifies adverse drug reactions (ADRs) as unintentional and harmful reactions to drugs, which are among the leading causes of death in many nations. ADR under-reporting is a threat to pharmacovigilance. **Objective:** The objectives of this study were to evaluate the knowledge, practices & attitudes towards ADR reporting among public healthcare professionals and to determine factors that lead to underreporting of ADR in public health facilities (hospitals and clinics) in West Pahang, Malaysia. **Methods:** This was a cross-sectional, questionnaire-based observational study conducted in 2021 with respondents consisting of healthcare professionals from all hospitals and health clinics in West Pahang. Data was collected from March 2021 to April 2021 via a validated questionnaire. **Results:** A total of 400 questionnaires were distributed and 344 healthcare professionals took part in the study, with an 86% response rate. The majority of survey respondents selected positive responses in the area of knowledge and attitude, but not in the area of practice for ADR reporting. It was found that 95.3% of respondents had good knowledge, 11% had good practices and 52% had good attitudes towards ADR reporting. Over half of respondents (53.2%) believed that it is nearly impossible to conclude that a drug is the cause of a particular adverse event. Fifty percent of respondents believed they would be held accountable for the ADR which occurred once they reported it. The majority of the respondents (68%) thought that really serious ADRs were already documented when the drugs were marketed. **Conclusion:** The majority of healthcare professionals in West Pahang showed good knowledge and attitude, but poor practice in ADR reporting. Insecurity, fear of admitting harm, complacency, and ignorance were the discouraging factors that led to the underreporting of ADR among healthcare professionals from West Pahang.

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INTRODUCTION

The World Health Organization identifies adverse drug reactions (ADRs) as unintentional and harmful reactions to drugs, which are among the leading causes of death in many nations [1]. ADRs may cause a loss of confidence or evoke negative emotions towards physicians, leading patients to seek self-treatment options, which, in turn, can compromise patients' health further [2]. Approximately 5% of all hospital admissions are attributed to ADRs, and around 10%-20% of those admitted into wards will experience at least one ADR during their hospital stay [2]. In the United States, the full adverse reaction profile of a new drug approved by the Food and Drug Administration (FDA) for marketing may not be known due to limitations in pre-approved clinical trials [3]. Therefore, all drugs that are approved for sale are subject to safety monitoring through the post-marketing surveillance (PMS) program, and timely reporting of ADRs by healthcare professionals is essential to ensure the success of the program [3]. PMS is a part of pharmacovigilance, an activity associated with detecting, evaluating, understanding, and preventing occurrences of ADRs or other problems associated with drugs or vaccines [2,3].

However, ADR under-reporting is a threat to pharmacovigilance [4] and is known as a major obstacle to the success of pharmacovigilance programs attributed to factors related to the knowledge, practices and attitudes of healthcare professionals [5]. As proposed by Inman [6] in 1976, the 'seven deadly sins' which lead to underreporting of ADR include Ignorance, Diffidence, Complacency, Fear and Guilty, Lethargy, Greed, as well as Indifference [6,7].

Healthcare professionals should consider ADR reporting as their professional responsibility because the efficient ADR reporting scheme is important in improving patient care and safety [4]. According to a study by Sen S et al. in evaluating knowledge, attitude, and practice with regards to pharmacovigilance among physicians in India, approximately 89.62% of public practitioners correctly identified the WHO definition of pharmacovigilance, whereas only 77.5% of private practitioners achieved the same accuracy [8]. Among public practitioners, only 19.81% documented a suspected ADR using any surveillance form, while the percentage was even lower for private practitioners at 3.75% [8]. Around 59.43% of physicians in government hospitals published ADR case reports in medical journals, and this figure was much lower in private practice settings, a mere 18.75% did so [8].

A lack of knowledge was observed in Southern India where 28.3% of respondents reported having heard the name pharmacovigilance, while only 3.3% knew the meaning of pharmacovigilance [9]. In Hospital Sikkim, 37% responded to the definition of pharmacovigilance correctly, the majority by the professors were the most accurate (71.4%), and lower by postgraduates or residents (19.2%) [10]. Most of the respondents knew that doctors, pharmacists, and nurses could report ADRs, while 63% of the respondents could correctly identify the spontaneous reporting system as the most commonly employed method to monitor ADRs [10]. Among interns at a tertiary healthcare centre in India, 52.0% of the respondents did not know about the reporting system in the hospital [11]. Only 20.0% had reported an ADR and 97.0% had never filled out the ADR notification forms [11].

Apart from that, a study in Pakistan showed that most of the respondents (83.1%) indicated poor ADR reporting knowledge [12]. The majority of respondents (78.2%) expressed a positive attitude towards ADR reporting, but only a few hospitals (12.3%) demonstrated good ADR reporting practices. Factors such as the seriousness of ADR, unusualness of reactions, involvement of new drugs, and confidence in diagnosing ADR encouraged respondents to report ADR [12]. However, lack of knowledge regarding where and how to report ADR, limited access to ADR reporting forms, prioritizing patient management over-reporting ADR, and concerns about legal liability were the major factors that discouraged respondents from reporting ADR [12].

In a study conducted in Saudi Arabia, 95.0% of the respondents stated that ADRs should be reported for both newly marketed and already marketed agents [13]. When it came to the types of ADRs that should be reported, 75.0% of the respondents believed that all reactions should be reported, while 16.0% stated that only serious reactions should be reported [13]. Physicians and pharmacists had nearly identical responses (80.0%) in favour of reporting all reactions [13]. However, 20.0% of nurses believed that serious ADRs should be reported for more than one type of reaction, which differed from the views of physicians (10.0%) and pharmacists (15.0%) [13].

Locally, a study conducted in the Klang Valley involving private practitioners reported that almost half (46.2%) of the participants believed that only confirmed reactions needed to be reported. In comparison, only 58.6% provided the correct response that all suspected reactions to established drugs in new combinations or for new indications should be reported [14]. Concerning new products, 45.5% of the participants held the opinion that only serious reactions needed to be reported, and 89.7% responded that all serious reactions to both new and established products should be reported [14]. On the other hand, another study involving community pharmacists in Selangor reported a positive attitude towards ADR, but less than half (34.2%) had ever reported an ADR [15]. The main obstacles to ADR reporting were lack of patient information, inadequate

clinical knowledge, and uncertainty regarding the relationship between the adverse reaction and the drug [15].

According to a study conducted by Belton et al. to evaluate the attitudes of European Union (EU) healthcare professionals towards their national spontaneous reporting system, issues that appeared to discourage reporting included the lack of available report forms, absence of contact details for the reporting agency, insufficient information on the reporting process, and limited time to report [16]. On the contrary, issues that did not seem to discourage reporting included concerns about patient confidentiality, fear of legal liability or embarrassment, hesitation to acknowledge the harm caused to a patient, and a desire to accumulate and publish personal case series [16].

Previous studies have shown ADR to be under-reported globally [8,9,12,16]. It was therefore worth investigating the level of knowledge, attitude, and practice in ADR reporting among healthcare professionals in West Pahang. To our knowledge, no research related to the assessment of knowledge, attitude, and practice in ADR reporting was conducted for a combination of public hospitals and public health clinics in Pahang State. The primary objective of this study was to evaluate the knowledge, practices, and attitudes towards ADR reporting among Public Healthcare Professionals (hospitals and clinics) in West Pahang while the secondary objective was to determine factors that lead to underreporting of ADR in public health facilities (hospitals and clinics) in West Pahang.

MATERIAL AND METHOD

West Pahang consists of 4 districts including Kuala Lipis, Bentong, Raub and Cameron Highlands. Each district has a hospital and a district health office, which is the headquarters of several primary health clinics. Approvals were obtained from the National Medical Research Registry (NMRR) and Medical Research Ethics Committee (MREC) before data collection (Registration number: NMRR-20-2615-57129). Consent forms were signed by respondents before filling out the questionnaires.

A “principal investigator at the site” was nominated in each hospital and district health office. These on-site principal investigators were responsible for collecting data from healthcare providers at their respective sites. The healthcare professionals who participated in the study were doctors (specialists/ medical officers/ houseman officers), dentists, pharmacists, medical assistants, pharmacy assistants and nurses. Stratified systematic sampling was used to select the participants in each study site. All health professionals in West Pahang were stratified by occupational group, and then every fifth person (5th, 10th, 15th and so on) from the list was selected to participate in the survey. The inclusion criteria were West Pahang public healthcare professionals who were available to participate in the study and were able to complete the English version of the questionnaire. Individuals who were off duty during the study period were excluded from the study.

There were 2,326 public health professionals working in the West Pahang area entitled to this study. The sample size needed for this study was 330 and was calculated using the Raosoft sample size calculator (with a margin of error of 5%, a confidence interval of 95% and a response distribution of 50%) [17]. Another 70 participants were intentionally added to account for missing data or dropouts, with the final target sample size for this study being 400 participants. Data collection was conducted from March 2021 to April 2021, using a validated questionnaire previously used in a similar study in Klang Valley, Malaysia [14]. Written permission was obtained from the Malaysian Journal of Medical Sciences to utilize the questionnaire and protocol from the study [14].

The questionnaire was divided into two sections. The first section consisted of questions on demographic characteristics. The second section had three domains, in which two questions with 11 sub-items, two questions with 7 sub-items, and three questions with 22 sub-items were used to evaluate knowledge, practices, and attitudes towards ADR reporting, respectively [14]. Each favourable answer for each sub-item was scored as 1, and participants who obtained a domain score of 70% or more were assessed as having good knowledge, attitude, and practice, respectively [14]. In addition, participants with a score of 70% or higher across all sub-items in all three domains were considered to have a good overall knowledge, attitude and practice (KAP) towards ADR reporting. The self-administered questionnaires were distributed to the participants by principal investigators at their respective sites. Each respondent took approximately 30 minutes to complete the survey.

Statistical Package for Social Sciences (SPSS) program version 26 was used to analyse the collected data in this study. The data were analysed using descriptive statistics as well as the chi-square test. This study was conducted in compliance with the ethical principles outlined in the Declaration of Helsinki and the Malaysian Good Clinical Practice Guidelines.

Ethical Approval and Consent to participate

Approvals were obtained from the National Medical Research Registry (NMRR) and Medical Research Ethics Committee (MREC) before data collection (Registration number: NMRR-20-2615-57129). Consent forms were signed by respondents before filling out the questionnaires.

Table I: Demographic Data of the Study Participants (n = 344)

Characteristics	n (%)
Gender	
Male	111 (32.3)
Female	233 (67.7)
Age (years)†	31 (7.8)
District	
Lipis	120 (34.9)
Bentong	116 (33.7)
Raub	78 (22.7)
Cameron Highlands	30 (8.7)
Facility	
Hospital	167 (48.5)
Health Clinics (PKD)	177 (51.5)
Department	
Outpatient	114 (33.1)
Emergency	32 (9.3)
Pharmacy	53 (15.4)
Inpatient	73 (21.2)
Others	72 (20.9)
Professional Status	
Doctors	86 (25.0)
Medical Assistants	61 (17.7)
Pharmacists	34 (9.9)
Pharmacy Assistants	22 (6.4)
Nurses	127 (36.9)
Dentists	14 (4.1)

† ***Data are shown as median (IQR)***

RESULT

A total of 400 questionnaires were distributed and 344 healthcare professionals took part in the study, with an 86% response rate. The majority of the participants were female, 67.7% (n=233), from the outpatient department, 33.1% (n=114) and nurses, 36.9% (n=127). The data are presented in (Table I).

The majority of the study participants chose favourable answers to the questions regarding knowledge in ADR reporting as shown in Table II. However, most of them chose unfavourable answers regarding practices of ADR reporting. More than half of the participants had suspected an ADR before. Out of 180 participants who had ever suspected an ADR, 80% of them sent an ADR report to the national reporting agency (Table III). Concerning the attitude of participants towards ADR reporting, most participants chose favourable answers in this domain. The factors discouraging ADR reporting among participants in West Pahang include the perception that serious ADRs are already well established by the time a drug is marketed (68.0%) and it is nearly impossible to determine the causal relationship between a drug and a particular adverse event (53.2%, Table IV). In terms of scoring, it was found that 95.3 per cent of participants had good knowledge, 11 per cent had good practices and 52 per cent had good attitudes towards ADR reporting.

Chi-square tests of homogeneity were conducted to check a difference in proportion between each group of sociodemographic characteristics and Overall KAP in ADR Reporting. All expected cell frequencies were greater than five, and post hoc analysis involved pairwise comparisons using the z-test of two proportions with a Bonferroni correction. In total, 52.9 per cent of all healthcare professionals in West Pahang had good overall KAP towards ADR reporting. A breakdown of the data is presented in (Table V).

DISCUSSION

Knowledge

The current study found that 65% of the participants showed good knowledge of ADR reporting as the majority chose favourable answers. This finding is consistent with a local study conducted in northern Malaysia, where 72.1 per cent of healthcare professionals demonstrated good knowledge of ADR reporting [18]. However, it was found that over 40% of participants felt that only proven responses should be reported. This is in line with the previous study by Belton et al., which found that more than 20% of respondents in Italy, Portugal and Spain were unwilling to report suspected reactions (as opposed to proven ones) [16]. According to the Malaysian Adverse Drug Reaction (ADR)/ Adverse Event Following Immunization (AEFI) Reporting: Manual for Healthcare Providers, all suspected ADRs should be reported for all products registered with the Drug Control Authority (DCA), even if the products are not used following the authorised dosage. [19].

Attitude

According to the result in Table IV, 64.5% of respondents knew how to report an ADR and 72.1% of respondents knew where the form is available from. This is contrary to the study by Adegbuyi et al., where only 38.3 percent of those surveyed had ever seen an adverse drug reaction reporting form [20]. According to a study by Survase et al. involving nurses in a tertiary care centre, 65% of the participants responded that the non-availability of forms was one of the major factors that have deterred nurses from reporting ADRs [5].

More than two-thirds of the respondents in this study disagreed that reporting ADR is time-consuming or too busy to report. This is encouraging as the attitude survey on the reporting of adverse reactions to medicinal products by health professionals in the European Union in 1997 showed that lack of time was one of the key issues that prevented suspected ADRs from being reported [16].

Table II: Responses about Knowledge in ADR Reporting (n = 344)

Variable	Yes, n (%)	No, n (%)
Regarding type of ADR to be reported:		
All suspected reactions to established drugs in new combination or for new indication should be reported.	334 (97.1)	10 (2.9)
All suspected reactions to new products should be reported.	329 (95.6)	15 (4.4)
Only serious reactions to new products should be reported.	75 (21.8)	269 (78.2)
All serious reactions to old & new products should be reported.	336 (97.7)	8 (2.3)
Only proven reactions should be reported.	146 (42.4)	198 (57.6)
Following is/are the purpose(s) of the national ADR reporting scheme in Malaysia:		
For identification of previously unrecognized ADRs.	328 (95.3)	16 (4.7)
To recognize factors predisposing to ADRs.	327 (95.1)	17 (4.9)
To characterize ADRs.	324 (94.2)	20 (5.8)
To enable toxicity of drugs in similar therapeutic classes to be compared.	303 (88.1)	41 (11.9)
To identify safe drugs.	312 (90.7)	32 (9.3)
To measure the incidence of ADRs.	329 (95.6)	15 (4.4)

More than half of the respondents (53.2%) believed that it is nearly impossible to conclude that a drug is the cause of a particular adverse event thus resulting in low practice in ADR reporting. This is following findings from a systematic review of 45 articles, where 67% of the studies identified insecurity as one of the factors related to under-reporting [21]. Notably in this section, half of the respondents believed they would be held responsible for the ADR that happened once they reported it. This is much higher than the findings from a study by Belton et al., where only under 10% of respondents in each European Union countries agreed on the fear of admitting harm as a deterrent for ADR reporting [16].

The majority of the respondents (68%) thought that really serious ADRs were already documented when the drugs were marketed. This is also consistent with results from two-thirds of studies with a higher level of evidence in a systematic review, where complacency was found to be a factor associated with ADR under-reporting [21].

Practice

While respondents demonstrated a good attitude, their practice of reporting ADR was not satisfactory. According to the 70% threshold rating for whether respondents had good practices, only 11% of respondents were considered to have good practices for ADR reporting. The low percentage of practice among respondents may be attributable to most health professionals in West Pahang who opted to report ADR only if the reaction is severe, unusual, caused by a new product, or had been observed previously. The reaction is confidently caused by the medication (Table III). These factors correspond to the findings of a study by Aziz et al., in which 'ADR considered to be too trivial or too well known to report' and 'uncertainty that the reaction had been caused by a drug' was among the top three predictors of physicians not reporting ADR in a multivariate logistic regression model [22]. It was nonetheless encouraging to note that, although most participants opted for

Table III: Responses regarding Practices of ADR reporting (n = 344)

Variable	Yes, n (%)	No, n (%)
Have you ever:		
1. *Sent an ADR report to your national reporting agency or a pharmaceutical company.*	144 (41.9)	200 (58.1)
2. *Suspected an ADR.*	180 (52.3)	164 (47.7)
I will report an ADR, only if:		
1. *The reaction is serious.*	241 (70.1)	103 (29.9)
2. *The reaction is unusual.*	263 (76.5)	81 (23.5)
3. *I have observed similar reactions to the drug class before.*	253 (73.5)	91 (26.5)
4. *The reaction is to a new product.*	256 (74.4)	88 (25.6)
5. *I am confident that the reaction is an adverse reaction to the drug.*	287 (83.4)	57 (16.6)

Table IV: Responses regarding Attitudes towards ADR reporting (n = 344)

Variable	Agree, n (%)	Disagree, n (%)
Attitudes towards ADR reporting.		
1. *The ADR form is not available and I do not know from where I can get the form.*	96 (27.9)	248 (72.1)
2. *The ADR form is too difficult to fill up.*	101 (29.4)	243 (70.6)
3. *The space provided in the ADR form to describe the ADR is too little or inadequate/insufficient.*	139 (40.4)	205 (59.6)
4. *It requires stating my identity, which I do not wish to provide.*	105 (30.5)	239 (69.5)
5. *It requires stating patient's identity, which I do not wish to provide.*	67 (19.5)	277 (80.5)
6. *Filling this ADR form will hold me responsible for ADR related harm to the patient.*	172 (50.0)	172 (50.0)
7. *I do not know the relevant phone numbers.*	130 (37.8)	214 (62.2)
8. *I do not know the address of the agency to which I should report.*	129 (37.5)	215 (62.5)
9. *I am not sure about how to report.*	122 (35.5)	222 (64.5)
10. *I am not sure whether the patient's confidentiality will be maintained.*	126 (36.6)	218 (63.4)
11. *I feel I will appear foolish.*	49 (14.2)	295 (85.8)
12. *I am worried about legal liabilities.*	131 (38.1)	213 (61.9)
13. *I am too busy to report.*	83 (24.1)	261 (75.9)
14. *I wish to publish a personal series of cases rather than reporting ADRs.*	53 (15.4)	291 (84.6)
15. *Really serious ADRs are well documented by the time a drug is marketed.*	234 (68.0)	110 (32.0)
16. *It is nearly impossible to determine if a drug is responsible for a particular adverse event.*	183 (53.2)	161 (46.8)
17. *The one case an individual physician might see cannot contribute to medical knowledge.*	127 (36.9)	217 (63.1)
18. *I should be financially reimbursed for providing the reports of ADRs.*	75 (21.8)	269 (78.2)
19. *I have a professional obligation to report ADRs.*	231 (67.2)	113 (32.8)
20. *Reporting ADRs puts my career at risk.*	45 (13.1)	299 (86.9)
21. *It takes too much time to report ADRs.*	120 (34.9)	224 (65.1)
22. *I will be asked to provide more information which I don't want to do because I am busy, it will take too much time (or other reasons).*	115 (33.4)	229 (66.6)

Table V: Difference in Overall KAP in ADR reporting by sample characteristics (n = 344)

Variable	*Good Overall KAP*	*Poor Overall KAP*	
	n (%)	n (%)	$\chi 2$ (p)*
Gender			
Female	137 (58.8)	96 (41.2)	10.059 (**0.002**)
Male	45 (40.5)	66 (59.5)	
Age Group			
21-30	87 (54.4)	73 (45.6)	1.474 (0.479)
31-40	73 (54.1)	62 (45.9)	
>40	22 (44.9)	27 (55.1)	
Facility			
Hospital	89 (53.3)	78 (46.7)	0.019 (0.889)
PKD	93 (52.5)	84 (47.5)	
District			
Lipis	65 (54.2)	55 (45.8)	21.237 (<**0.0005**) [Δ]
Bentong	77 (66.4)	39 (33.6)	
Raub	32 (41.0)	46 (59.0)	
Cameron Highlands	8 (26.7)	22 (73.3)	
Professional Status			
Doctors	59 (68.6)	27 (31.4)	41.575 (<**0.0005**) [§]
Medical Assistants	17 (27.9)	44 (72.1)	
Pharmacists	29 (85.3)	5 (14.7)	
Pharmacy Assistants	12 (54.5)	10 (45.5)	
Nurses	57 (44.9)	70 (55.1)	
Dentists	8 (57.1)	6 (42.9)	

**Chi-square test. P < 0.05 indicates a statistically significant difference in proportions.*
*[Δ]Post hoc analysis showed statistically significant differences in proportion between groups of **Lipis vs Cameron Highlands**, **Bentong vs Raub**, and **Bentong vs Cameron Highlands**.*
*[§]Post hoc analysis showed statistically differences in proportion between groups of **Medical Officer vs Medical Assistant**, **Medical Officer vs Nurse**, **Pharmacist vs Medical Assistant**, and **Pharmacist vs Nurse**.*

unfavourable responses in the field of practice, 80% of those who previously suspected an ADR had submitted a report to the national reporting agency.

Overall KAP

The results showed that 52.9% of respondents had an overall score above 70% and were considered to have a good overall KAP concerning ADR reporting.

The proportion of doctors and pharmacists who have good overall KAP is significantly higher than that of nurses and medical assistants, which coincides with results from a study by Palaian S et al. in Nepal, where total KAP scores obtained by doctors and pharmacists were higher than those of nurses [23]. Another finding of this study was that the proportion of female respondents with a good overall KAP was significantly higher than that of male respondents. This is in line with the results from a study by Burud et al., where female respondents were 1.86 times and 2.74 times more likely to have satisfactory knowledge and desirable practices, respectively for ADR reporting than male respondents [24]. The study also showed that there were significantly fewer female respondents with perceived attitude barriers to the reporting process compared to male respondents [24].

In terms of comparison between the 4 districts, the Bentong and Lipis districts showed a greater proportion of health professionals with good overall KAP than the Cameron Highlands district. This could be due to the fact that the Cameron Highlands Hospital is a non-specialist hospital, whereas Kuala Lipis Hospital and Bentong Hospital are hospitals with specialists. According to findings from Agarwal et al., practitioners with a post-graduate degree demonstrated higher levels of knowledge with respect to ADR reporting than practitioners with only a basic medical degree because of greater clinical experience [14].

In order to further improve overall KAP among health professionals in West Pahang, educational interventions concerning pharmacovigilance may be necessary. According to Leena et al., ongoing educational interventions, especially with respect to how to identify and report ADRs, are often required to increase KAP scores in ADR reporting [11]. Further studies may be carried out to compare the KAP scores before and after educational interventions among healthcare professionals in West Pahang.

Limitations

Given that this was a self-reported survey, there might be response bias and the accuracy of the recall by respondents may be questioned. In addition, as this study was conducted only in Ministry of Health facilities, the results may not be generalized to other healthcare professionals in different practice contexts.

CONCLUSIONS

The majority of healthcare professionals in West Pahang showed good knowledge and attitude, but poor practice in ADR reporting. Insecurity, fear of admitting causing harm, complacency, and ignorance were found to be the discouraging factors that led to ADR underreporting among healthcare professionals in West Pahang. Proper education and training should be provided for healthcare professionals regularly to further improve their overall KAP in ADR reporting.

CONFLICT OF INTEREST

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