

Knowledge and Perception towards Pharmacovigilance among Healthcare Professionals in Tertiary Care Teaching Hospital in Aden, Yemen

Mohammed Alshakka^{1*}, Huda Bassalim², Khaled Alsakkaf³, Marwa Mokhtar¹, Mustafa Alshagga⁴, Sami AL-Dubai⁵, Nisha Jha⁶, Ahmed Abdoraboo⁷, P. Ravi Shanker⁸

¹Assistant Professor, Department of Clinical Pharmacy, Faculty of Pharmacy, Aden University, Yemen.

²Associate Professor, Department of Community Medicine and Public Health, Faculty of Medicine and Health Sciences, Aden University, Yemen.

³Assistant Professor, Epidemiologist in the Department of Community Medicine and Public Health, Faculty of Medicine and Health Sciences, University of Aden.

⁴Assistant Professor, School of Biomedical Sciences, Faculty of Science, University of Nottingham Malaysia Campus, Semenyih, Malaysia.

⁵Professor of Community Medicine, SEGi University, Selangor, Malaysia.

⁶Lecturer, Department of Clinical Pharmacology and Therapeutics, KIST Medical College, Imadol, Nepal.

⁷Professor of Pharmacology, Faculty of Medicine and Health Sciences, Sana'a University, Yemen.

⁸Professor of Pharmacology, Xavier University School of Medicine, Aruba, Kingdom of the Netherlands.

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*Correspondence to:

Dr. Mohammed Alshakka, PhD,
Department of Clinical Pharmacy,
Faculty of Pharmacy,
Aden University, Yemen
Email: alshakka400@gmail.com

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Abstract

Reporting adverse drug reactions (ADRs) is considered the essence of pharmacovigilance practice. Physician and nurse are among health care providers who extensively take part in reporting. However, underreporting is a malpractice worldwide. This study aimed to determine physicians and nurses' knowledge and perception toward pharmacovigilance in general, and consumer's related pharmacovigilance. **Method:** A cross-sectional study was conducted in Al-Gamhouria Teaching Hospital at Aden, Yemen. The study conducted from September to October 2014. Target populations were physicians and nurses. A 40-item self administered questionnaire was administered among participants. Descriptive and Chi square analysis were used to analyse to express the results. **Results:** 130 health care professionals were participating in the study with a mean age of 42.9 (SD 7.93) years and a mean experience period of 20.3 (SD 9.73). Females comprised 63.1% of the participants and majority of them are nurses (68.5%). Although, Physicians and nurses showed varied statistically significant differences in knowledge toward pharmacovigilance. However, nurses showed a positive attitude and perception. Meanwhile, regarding consumer pharmacovigilance, again nurses showed positive attitude compared to physicians but physicians were more positive with the consumer reporting. Both physicians and nurses were highly scored for the importance of pharmacovigilance in Yemen as well as to be part of health education curriculum. **Conclusion:** A relatively good level of pharmacovigilance knowledge has been encountered among physicians and nurses. Nurses had had optimistic attitude and higher perception toward pharmacovigilance compared to physicians who more valued consumer reporting.

Key words: Knowledge, Perception, ADRs reporting, pharmacovigilance, physician, nurses, Yemen.



INTRODUCTION

Adverse drug reactions (ADRs) represent a serious health problem.^[1] Despite all their benefits, evidence continues to mount that ADR are common, yet often preventable cause of illness, disability and even death. ADR are responsible for a significant number of hospital admissions ranging from 0.3% to 11%.^[2] Over 770,000 people are injured or die each year from adverse drug events.^[3] A commonly quoted meta analysis performed in the United States indicated that ADRs were between the 4th and 6th most common cause of death in 1997.^[4] The World Health Organization (WHO) defines an ADR as 'any response to a drug that is noxious and unintended, and that occurs at doses used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose'.^[5]

Pourseyed *et al.*, showed in their study in Iran that 11.75% of the patients had experienced at least one ADRs^[6] In an another researcher from Iran showed that 16.8% of the patients had at least one ADRs and 2.9% of the ADRs was identified as lethal.^[7] Another study from South India reported an overall incidence of 9.8%. This included 3.4% ADRs related admissions and 3.7% ADRs occurring during the hospital stay.^[8] In Nepal, the prevalence of ADRs was 0.86% and male to female ratio was 0.85 and 10.81% of the ADRs to be were severe.^[9]

It is essential to monitor ADRs in order to reduce or prevent harm to patients from their drugs, to detect of ADR before they are manifested clinically, obtain much more knowledge to ensure safety of drugs and to assess the harm, benefits and risk of available drugs.^[10] WHO defines pharmacovigilance as the 'science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problems'.^[11] The pharmacovigilance program in Yemen has been functioning under the national pharmacovigilance center located at Aden city. Although this National ADR Monitoring Program in Yemen has been successful to a certain extent, there are a few major challenges left unsolved. Furthermore, there are big challenges to make drug safety among the top priorities of the health programs in this developing country. The major problem is believed to be under reporting. Other major reasons for the weaknesses of the drug safety system in Yemen, in brief range from the health care providers' (HPs) lack of awareness to the limited role of the non-governmental organizations (NGOs) in issues pertaining to drug safety.^[12] In summary, the major limitations are lack of awareness concerning drug safety among health professionals; the existence, function and purpose of national ADR reporting have not been made

known widely; inability to involve pharmaceutical industries on drug safety issues; lack of information on genetic effects, social practice and drug interaction and contra indication associated with the use of drugs; only few reports are present regarding the traditional and herbal drugs which are widely used; involvement of nursing staffs and consumers reporting of ADRs is still in infancy; the limited role of NGOs in drug safety issues; and the limited role of mass media in public drug safety education.

It is assumed that involvement of consumers can be an important approach towards ensuring medicine safety. Consumers are active players in drug safety and key stakeholders with relation to pharmacovigilance and can actively contribute through an integrated and efficient reporting system. In addition, direct reporting is an essential tool to empower consumers and improve their involvement in the management of their own health. With consumer reporting, ADRs will be detected earlier, thus reporting more ADRs especially to over the counter medicines. Similarly, consumer reporting is able to serve as a useful method to overcome under reporting. It can also be a good solution to mitigate the limitations of the existing system based on health professionals' reports as well as promoting consumer rights. However, it is worth noting that consumer reporting cannot replace the existing system but can instead complement and strengthen it.

Furthermore many studies are conducted in both developed and developing countries and showed poor knowledge among healthcare professionals about ADRs reporting. This is due to the fact that drug safety has not been taken seriously and is not one of the top priorities in healthcare programmes worldwide. However, this is not a global phenomenon; Green *et al* (2001) confirms this by studying the attitudes of the UK hospital pharmacists and their understanding of adverse ADR reporting.^[13]

They conclude that this type of professionals have a reasonable knowledge, which plays a part in them being supportive of the Yellow Card spontaneous ADR reporting schema. They also see education and training as two aspects that should not be abandoned in order to keep maintaining and increasing the number of ADR reports from the pharmacists. Similarly, Backstrom *et al* (2000) have investigated attitudes of general practitioners and hospital physicians in Sweden towards spontaneous reporting of ADRs. The physicians in particular have proven their good knowledge about the existing rules for reporting ADRs in the country.^[14] However, there is a hint of under-reporting to take place because of the matters which relate mainly to the medical impact of the reaction and of reporting it, but also

the scientific ‘myth’ of reporting only based on suspicions and due to the lack of time in the healthcare setting.

METHODS

Study Design and Setting:

A prospective, cross-sectional study was conducted among physicians and nurses at Al-Gamhouria Teaching based Hospital for the period of two months from September to October 2014. The hospital is a referral teaching hospital opened in 1958 under the name Queen Elizabeth hospital with a capacity of 500 beds. The total health care workers are working presently near about 1200.

Study Population and Sampling:

According to the hospital statistical department; there are 467 nurses and 246 physicians. The sample size was calculated by using the following formula.^[15]

$$n = k^2(pq)/d^2$$

Where:

n = required sample size;

k = standard of 1.96 at 95% certainty;

p = the prevalence of (50%).

q = 1 - p

d = Precision or error allowable, which be in our study is 0.10

We assumed a prevalence of 50% for unknown prevalence and to maximize the required sample size. The calculated sample size was 96 (rounding to 100). With a non-response estimation of 30% representing 30 in this study, the needed sample size was 130.

Referring to the statistics of the hospital:

All nurses are 467 which represents 65% of the targeted community

All physicians are 246 or 35% of the targeted community

According to the proportional allocation technique, the required numbers of respondents were 85 nurses and 45 physicians.

Data collection:

A self-administered structured questionnaire was specially prepared from different sources^[16] to meet the study objectives. The questionnaire consists of two sections. The

first section consists of five questions about the personal characteristics of the respondents whereas the second section consists of 40 questions designed to five level Likert scale (1=strongly disagree and 5=strongly agree) and single choice. This section covers pharmacovigilance-related knowledge and perception and consumer's pharmacovigilance-related knowledge and perception. The questionnaires were distributed among physicians and nurses in the different departments of the hospital by a trained pharmacy student.

Statistical analysis:

The coded data were systematically verified and checked for errors. The Statistical Package for Social Sciences (SPSS) programme, version 20.0 was used for data entry and analysis.

Results were presented as mean \pm standard deviation (SD) for quantitative variables and number with percentages for categorical variables. Percentage on each category, median and mode were presented for the likert scale. The chi-square test was performed to compare the level of knowledge and perception between doctors and nurses. Significance level of $P < 0.05$ was used, where the test was relevant.

Ethical Approval:

The study protocol was approved by the Ethics Research Committee of the Faculty of Medicine and Health Sciences, Aden University. Written consent was taken from the participants prior the data collection. Participation of respondents was voluntary and their responses were dealt with high level of confidentiality and anonymity. Participants were briefed about the objectives and the significance of research prior to data collection.

RESULTS

130 HCPs were encountered and agreed to participate in the study with a mean age of 42.9 (SD7.93) years and a mean experience period of 20.3 (SD 9.73). Females comprised 63.1% of the participants and nurses (68.5%). PhD holders constituted only 7.7% and 50% were diploma holders. Details of the respondents' demographic profile are illustrated in Table 1.

Pharmacovigilance related eight knowledge statements are displayed in Table 2; There is significant difference between physicians and nurses in all statements except “many ADRs are preventable”. Physicians had significantly better knowledge compared to nurses regarding the statements:

Table 1: Characteristics of HCP (n=130)

Demographic Characteristics (n)		N (%)	95% CI	Mean \pm Sd
Age in years	20 – <30	9 (6.9)	2.5 – 11.3	42.9 \pm 7.93
	30 – <40	31 (23.8)	16.5 – 31.1	
	40 – <50	63 (48.5)	39.9 – 57.1	
	≥ 50	27 (20.8)	13.8 – 27.8	
Sex	Male	48 (36.9)	28.6 – 45.2	-
	Female	82 (63.1)	54.8 – 71.4	
Professional Status	Physician	45 (31.5)	23.5 – 39.5	-
	Nurses	85 (68.5)	60.5 – 76.5	
Qualifications	PhD	10 (7.7)	3.1 – 12.3	-
	Masters	16 (12.3)	6.7 – 18.0	
	Diploma post BSc	16 (12.3)	6.7 – 18.0	
	BSc	3 (2.3)	-0.3 – 4.9	
	Diploma	65 (50)	41.4 – 58.9	
	Secondary school	20 (15.4)	9.2 – 21.6	
Years of experience	< 5	15 (11.5)	6.0 – 17.0	20.3 \pm 9.73
	5 – <10	9 (6.9)	2.5 – 11.3	
	10 – <15	13 (10)	4.8 – 15.2	
	15 – <25	26 (20)	13.1 – 26.9	
	≥ 25	67 (51.5)	42.9 – 60.1	

Table 2: Pharmacovigilance–Related Knowledge (n=130)

Questions	Category	Incorrect	Correct	χ^2
ADRs are one of the major causes of death in the world	Physician	16 (35.6)	29 (64.4)	15.091
	Nurses	7 (8.2)	78 (91.8)	P<0.001
Many ADRs are preventable	Physician	12 (26.7)	33 (73.3)	0.301
	Nurses	19 (22.4)	66 (77.6)	P=0.366
OTC medications don't cause any ADRs	Physician	30 (66.7)	15 (33.3)	10.112
	Nurses	76 (89.4)	9 (10.6)	P=0.002
A good no. of ADRs can be prevented if appropriate measures are taken	Physician	6 (13.3)	39 (86.7)	FEP
	Nurses	3 (3.5)	82 (96.5)	P=0.045
Hartwig scale is used to establish the severity of ADRs	Physician	12 (26.7)	33 (73.3)	FEP
	Nurses	83 (97.6)	2 (2.4)	P<0.001
The international center for ADRs monitoring is located in Sweden	Physician	14 (31.1)	31 (68.9)	46.948
	Nurses	76 (89.4)	9 (10.6)	P<0.001
Pharmacovigilance started in Yemen in the year 2011	Physician	12 (26.7)	33 (73.3)	41.215
	Nurses	71 (85.5)	14 (16.5)	P<0.001
The National Pharmacovigilance Center in Yemen is located in the Dept of Drug Administration	Physician	12 (26.7)	33 (73.3)	25.694
	Nurses	62 (72.9)	23 (27.1)	P<0.001

Table 3: Consumer Pharmacovigilance–Related Knowledge (n=130)

Questions	Category	Incorrect	Correct	χ^2
Consumers can report for herbal medicines as equal as allopathic medicines	Physician	24 (53.3)	21 (46.7)	25.715
	Nurses	78 (91.8)	7 (8.2)	P<0.001
Patients can themselves report ADRs to the doctors and other HCPs	Physician	18 (40)	27 (60)	17.206
	Nurses	8 (9.4)	77 (90.6)	P<0.001
There is a separate form developed for consumers reporting of ADRs	Physician	20 (44.4)	25 (55.6)	41.215
	Nurses	66 (77.6)	19 (22.4)	P<0.001
The ADRs reporting form for consumers should be in a single page	Physician	13 (28.9)	32 (71.1)	16.168
	Nurses	56 (65.9)	29 (34.1)	P<0.001
Consumers Pharmacovigilance is already established in Yemen	Physician	26 (57.8)	19 (42.2)	8.188
	Nurses	69 (81.2)	16 (18.8)	P=0.004

Questions	Category	Incorrect	Correct	χ^2
ADRs reporting will waste my time	Physician	33 (73.2)	12 (26.7)	13.055 P<0.001
	Nurse	80 (94.1)	5 (5.9)	
Pharmaceutical industries should also report ADRs	Physician	9 (20)	36 (80)	FEP P=0.008
	Nurse	4 (4.7)	81 (95.3)	
Chemists and druggists Associations should be involved more on drug safety issues	Physician	2 (4.4)	43 (95.6)	FEP P=0.118
	Nurse	0 (0.0)	85 (100)	
Pharmacovigilance should be included in the curriculum of all HCP	Physician	12 (26.7)	33 (73.3)	2.450 P=0.118
	Nurse	13 (15.3)	72 (84.7)	
Remuneration should be given to the HCP to report ADRs	Physician	16 (35.6)	29 (64.4)	FEP P<0.001
	Nurse	2 (2.4)	83 (97.6)	
Reading articles on ADRs will be beneficial to HCP	Physician	4 (8.9)	41 (91.1)	FEP 0.013
	Nurse	0 (0.0)	85 (100)	
Pharmacovigilance is essential in a developing countries like Yemen	Physician	7 (15.6)	38 (84.4)	FEP 0.003
	Nurse	1 (1.2)	84 (98.8)	
ADRs reporting should be made mandatory in Yemen	Physician	10 (22.2)	35 (77.8)	7.696 P=0.006
	Nurse	5 (5.9)	80 (94.1)	
The Pharmacovigilance program in Yemen is successful	Physician	35 (77.8)	10 (22.2)	FEP P<0.001
	Nurse	84 (98.8)	1 (1.2)	
Dept. of Drug administration should take steps for strengthening Pharmacovigilance in Yemen	Physician	8 (17.8)	37 (82.2)	FEP P<0.001
	Nurse	1 (1.2)	84 (98.8)	

Category	Disagree		Agree		χ^2
	No.	%	No.	%	
Consumers are not aware enough of ADRs of their own medicines					FEP
Physician	12	26.7	33	73.3	P<0.001
Nurse	2	2.4	83	97.6	
There should be emphasis for consumers reporting of ADRs					FEP
Physician	8	17.8	37	82.2	P=0.001
Nurse	1	1.2	84	98.8	
Consumer's ADR reporting should be encouraged					41.215
Physician	13	28.9	32	71.1	P<0.001
Nurse	5	5.9	80	94.1	
ADRs reporting should be made mandatory by consumers as well as HCP					1.071
Physician	12	26.7	33	73.3	P=0.208
Nurse	16	18.8	69	81.2	
Consumers can report through their HCP					15.091
Physician	9	20.0	36	80.0	P<0.001
Nurse	11	12.9	74	87.1	
Involvement of patients is important as well as HCP in ADRs reporting					1.456
Physician	10	22.7	34	77.3	P=0.158
Nurse	28	32.9	57	67.1	
Reports given by patients can be good source of information of ADRs					7.696
Physician	10	22.2	35	77.8	P=0.006
Nurse	5	5.9	80	94.1	

Under reporting, the main problem of national program can be solved by consumer report					15.091
Physician	9	20.0	36	80.0	P<0.001
Nurse	20	23.5	65	76.5	
Consumer reporting will increase the knowledge about ADRs					FEP
Physician	0	0.0	45	100.0	0.654
Nurse	1	1.2	84	98.8	
Consumer reporting will ensure the safe use of medicines in Yemen					11.368
Physician	14	31.1	31	68.9	P=0.001
Nurse	7	8.2	78	91.8	
I'm optimistic about the success of consumer reporting of ADRs in Yemen					26.037
Physician	23	51.1	22	48.9	P<0.001
Nurse	9	10.6	76	89.4	
Consumers can write valid ADRs reports like HCP					5.568
Physician	20	44.4	25	55.6	P<0.001
Nurse	56	65.9	29	34.1	
The quality of consumers reports will be similar to HCP reports					2.049
Physician	25	55.6	20	44.4	P=0.108
Nurse	58	68.2	27	31.8	
Consumers need more education regarding reporting of ADRs of their medicines					FEP
Physician	10	22.2	35	77.8	P<0.001
Nurse	1	1.2	84	98.8	
Media may play a role in the success of consumer reporting in Yemen					FEP
Physician	9	20.0	36	80.0	P<0.001
Nurse	0	0.0	85	100.0	
NGOs in Yemen can help and play important role in the success of consumer reporting program					0.212
Physician	10	22.2	35	77.8	P=0.404
Nurse	16	18.8	69	81.2	
Consumer reporting will promote consumer rights in Yemen					15.091
Physician	6	13.3	39	86.7	P<0.001
Nurse	17	20.0	68	80.0	

“over the counter medications (OTC) medications don’t cause any ADRs”; “Hartwig scale is used to establish the severity of ADRs”; the international center for ADRs monitoring is located in Sweden”; Pharmacovigilance started in Yemen in the year 2011”; and “the National Pharmacovigilance Center in Yemen is located in the Department of Drug Administration”. On the other hand, nurses were significantly better in the knowledge about: ADRs are one of the major causes of death in the world”; and “a good number of ADRs can be prevented if appropriate measures are taken”.

The answers for five statements related to consumer pharmacovigilance knowledge are shown in Table 3. Physicians had significantly more correct answers with regards to the notions: “consumers can report for herbal medicines as equal as allopathic medicines”; “there is a separate form developed for consumers reporting of

ADRs”; “the ADRs reporting form for consumers should be in a single page”; and “consumers Pharmacovigilance is already established in Yemen”. Nurses had better knowledge only with regards to the statement “patients can themselves report ADRs to the doctors and other health care providers (HCP)”.

In Table 4, physicians are significantly different from nurses in eight out of ten pharmacovigilance–related perception statements. Nurses showed more positive perception in all statements compared to physicians.

There are 17 statements related to the consumer pharmacovigilance perception statements as shown in Table 5. No significant difference between physicians and nurses was observed in five of these statements. In nine of the remaining statements, nurses showed more positive perception compared to physicians. On the other hand,

physicians were more positive with the statements: “under reporting, the main problem of national program can be solved by consumer report”; “consumers can write valid ADRs reports like HCP”; and “Consumer reporting will promote consumer rights in Yemen”.

DISCUSSION

The pharmacovigilance programme can save lives and money. The costs in lives and money are great in high-income countries, but the situation in low- and middle-income countries is likely to be much worse because of the poorer health care system infrastructure, unreliable supply and quality of medicines and lack of adequately trained health care staff. In addition, the programme will improve patient care, public health, and safety in relation to the use of medicines and all medical and paramedical interventions. It will also help to detect problems related to the use of medicines and communicate the findings in a timely manner. It will contribute to the assessment of benefit, harm, effectiveness and risk of medicines leading to the prevention of harm and maximization of benefit. It can encourage the safe, rational and more effective (including cost-effective) use of medicines, as well as promoting understanding, education and clinical training in pharmacovigilance and its effective communication to the public. This is the first study in Yemen that evaluates the knowledge and perception towards pharmacovigilance and consumer's pharmacovigilance among doctors and nurses in a Teaching Hospital.

The present study has shown relatively good level of knowledge among HCPs about ADRs and pharmacovigilance not similar to previous studies in developed countries^[16] and developing countries.^[17-19] Poor knowledge of HCPs is most probably due to the fact that drug safety is not taken seriously worldwide, although it should be one of the top priorities in healthcare programs. Though the drug regulatory bodies have started paying more attention towards the drug safety issues, the pharmacovigilance activities are still inefficient.

Although, physicians and nurses showed varied statistically significant differences in knowledge toward pharmacovigilance, however, nurses showed positive perception. Regarding consumer ADRs reporting, again nurses showed positive attitude compared to physicians. Both physicians and nurses were highly scored for the importance of pharmacovigilance in Yemen as well as to be part of health education curricula.

The result of the study revealed that only 73% of the

HCPs were aware of the existence of the national pharmacovigilance program run by the Yemeni government. The present study results revealed that slightly higher percentage compared to the study conducted in Malaysia.^[20] which identified the awareness of the existence of the national pharmacovigilance program to be 40%. This problem not only exists in developing countries but also in developed countries. Studies in the US revealed that 57% of HCPs were not aware about the FDA pharmacovigilance program.^[21]

In our survey, 98 % of the HCPs stated that Pharmacovigilance is essential in a developing countries like Yemen. The study also found the main reasons for underreporting by HCPs to be the unawareness of the purpose and function of the ADRs program. Therefore, there is a need to educate the HCPs and emphasis should be given to create awareness about the national program. Eighty-six percent of HCPs were aware about the importance of reporting and the willingness to report to any pharmacovigilance centre. These results can be generalized because they are similar to others studies with the same results. In particular, the poor knowledge of HCPs towards Pharmacovigilance and ADR reporting is echoed in other studies. The finding indicates the urgent need for educational interventions among HCPs in Yemen. Steps can be taken to improve pharmacovigilance tools and methods among HCPs.

Educational interventions have been shown to improve ADRs programs in many countries. There is an urgent need to start interventions and awareness programs among HCPs about the existence, purpose and function of pharmacovigilance. Consumer reporting should be initiated to increase the information about ADRs, to overcome underreporting and improve patient safety. The involvement of nursing staff in reporting is a very important element to improve the reporting rate in clinics and hospitals.

Unlike previous studies including a small qualitative study by Ting *et al.* (2010) that shows low awareness among community pharmacists in Malaysia^[22] and a study with similar conclusions on the views of community pharmacists in the UK^[23] this study indicates that the perception of HCPs about the importance and benefits of consumer reporting is quite high. Most HCP thought that consumer reporting will add more benefits such as increasing the knowledge of and the information about ADRs, ascertaining safe use of medicines in Yemen and promoting consumers' rights. Most HCPs thought that patients should report ADRs through their healthcare providers because patients are not really aware of and knowledgeable about their medicines

and their hazards.

Involvement of patients is also important, as suggested by this study. Patients' reports can be a good source of information of ADRs because these reports are gathered from first-hand experience. Patients may not know the format in which the report is to be written but it is the content that matters. There are also voices of doubt regarding the reliability and trustworthiness of and also the validity of these reports, which help to explain why ADR reporting in countries like Yemen has not been as successful as it should be and why patients are not seen as important 'feedback providers' of the drugs prescribed to them.

Limitations of the study

Although several steps have been planned before conducting the survey, there are still certain aspects that need to be amend and improved in future studies. The major limitation of our study is that the findings could not be applied to the wider community because this study was done among the HCP in a teaching hospital in Aden. Thus, it is recommended that more studies have to be conducted to evaluate the knowledge, attitude and practices of HCP regarding medicine safety and adverse drug reaction reporting.

CONCLUSION

A relatively good level of pharmacovigilance knowledge has been encountered among physicians and nurses. Nurses had have optimistic perception toward pharmacovigilance compared to physicians who value consumer reporting.

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