

ORIGINAL RESEARCH ARTICLE

ASSESSMENT OF KNOWLEDGE, AWARENESS, AND ATTITUDE REGARDING PHARMACOVIGILANCE AMONG HEALTH CARE PROFESSIONALS (HCP) OF KARACHI: A CROSS SECTIONAL STUDY

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ABSTRACT

Objective: The objective of this study was to assess the knowledge and attitude of Health care Professionals (HCP) towards Pharmacovigilance.

Methodology: A set of 20 Questionnaires distributed randomly to a total of n=150 Health Care Professionals of Government, Private Hospitals and Clinics.

Results: Out of 150 Prescribers (107) responded the questionnaire. Among Responded samples only n= (94) (87.8%) were know the term "Pharmacovigilance n= (63) (58.8%) were know National Pharmacovigilance center & its location in Islamabad Pakistan n = (37) (34.5%) Responded that they have Pharmacovigilance department in their Hospitals and Clinics. n=101 (94.3%) not experienced Pharmacovigilance training during their graduation studies or continuous medical education.

Conclusion: The study demonstrated that the information of Health care professionals by and large was less about the National Pharmacovigilance center and its location in Pakistan, International center and the WHO online database of observing and reporting ADRs. To avoid adverse drug related hospitalization and mortality an evaluation mechanism to ensure safety and monitoring of the medicines are needed. Health care professionals are strongly suggested the need of training thorough frequent continuous medical education sessions to improve ADR Reporting.

Keywords: ADR Reporting, Pharmacovigilance, Attitude, HCP (Health Care Professionals)

INTRODUCTION

Pharmacovigilance derived from Greek word Pharmakon which means Drug and vigilance from Latin word "vigilare" To keep watch for safety of Drugs" defines by world Health organization (WHO) as, "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problem" PV Plays a vital role throughout the life cycle of a medicine from the pre-approval to post approval stages (Organization, 1972), (Mann and Andrews, 2007). An untoward effects of Drugs

describe by world Health Organization (WHO) as harmful response of the drug that occur at normal doses used for humans for detection, protection, and remedy of disease for mitigation of physiological Activity " (World Health Organization %J Geneva, 1975). Drug Harmful Events are defined as harms caused by the Drug overdoses and harms from the use of drug either by Dose Reduction and Discontinuation of drug therapy (Nebeker et al., 2004).Pharmacovigilance is needed in every country, Globally mortality figure and disorders are elevated due to detrimental effects of drugs that are the most fearsome situation because practi-

tioners has inadequate knowledge/awareness of any aspect of Pharmacovigilance (ARAIN et al., 2015). The ADR affects quality of patient life's but also increases rate of mortality and morbidity globally (Shakeel et al., 2014). In early 60s, reporting of incidence of babies with deformed limbs due to Thalidomide (Kim and Scialli, 2011) following this occurrence, In 1971, the WHO, under their responsibility officially built a plan for the rapid spotting of Harmful effects of Drugs called International Drug monitoring with more supporter countries now called as Pharmacovigilance center (Organization, 2014). Unintended effects of Drugs cause death, comorbidities are crucial source of patient's hospitalization and can influence the position of general Population Health. Since 1978 the program has been carried out by Uppsala Monitoring Centre (UMC) in Sweden. UMC has managed primary aspects of the expanding worldwide Pharmacovigilance network of now more than 134 countries, known as the WHO program for International Drug monitoring. The supporter countries in collaboration with WHO officially set up International Drug Monitoring program and send details of ADR to the WHO International Data Base "vigiBase" govern by Uppsala Monitoring Centre (UMC). ADR Records are critically evaluated and documented guidance sent to the member states (Center, 2018). It was raised in National Drug Policy of Pakistan in 2003 to establish a set up to keep an eye and inspect any Harmful effect of Drug (Atif et al., 2017). Although, did not start until 2012, when mortality of greater than 200 patients in Lahore owing to locally fabricated Isotab 20 mg (Isosorbide mononitrate, batch number J093) (Hussain et al., 2018). After subsequent event Supreme Court of Pakistan by the ordered officially set an independent Drug Regulatory Authority (WHO, 2018), Thenceforth, in 2012 Drug Regulatory DRAP was established. As a sixth Administrative Division of National Health services Regulation and Coordination (NHSRC) DRAP serves to monitor the standard, accessibility and protection, of medical apparatuses and therapeutic goods in the region (DRAP, 2019). A frame work for monitoring of drugs after it has been released in the market with the partnership of United States Pharmacopoeia and Promoting Quality Medicines (USP-PQM). In 2017 DRAP established Pakistan National Pharmacovigilance center (PNPC) under the Division of Pharmacy service in Islamabad and other regional Pharmacovigilance center. In 2018 by these endeavors, Pakistan got membership of UMC. To report any harmful or un-intended effect of drugs (DRAP in 2018) launched an online reporting form Label as "Med Vigilance" on DRAP'S official Database, convenient for patients, Pharmaceutical industries and Primary health care providers. An active role can be played by HCP in exposing, recording and reporting ADR if they are motivate to implement adequately by filling ADR forms available in their organizations and connect these formats to central and national ADR and Pharma-

covigilance systems (Upadhyaya et al., 2012). ADR reporting system in Pakistan still in its infancy, and need to introduce many reforms by the government regulatory bodies for the betterment of system (Hussain et al., 2019). Pakistan needs multi stake holder's endeavors and systematize techniques to point out the reasons, intensity and prevention of potential ADRs. It is necessary to implement different plans of action to remove conversation gap between Pakistan Pharmacovigilance center and Primary health care providers, which includes daily medical news bulletin and informative pamphlets to Health care Professionals (Organization, 2004). Past studies revealed that Health care professionals are un-aware about Pharmacovigilance guidelines and drug regulatory bodies of their respective countries responsible for accessing ADR (Vallano et al., 2005). This study will help in analyzing the factors to determine lack of practice, awareness of Pharmacovigilance, its importance in safety of patient and communication gap between patient and health care professionals. It improves the safety in relation to the use of medicines and tracks any drastic effects of Drugs.

METHODOLOGY

Study Design

A Cross sectional study was carried out to evaluate Knowledge of (Healthcare Professionals) which includes Physician, Pharmacist & Nurses working in Government, Private Hospitals and clinics towards ADRs and Pharmacovigilance. Data were collected through random sampling technique.

Study Duration

6 months (November 2020–April 2021)

Study population and sample size

All recruited Participants were entirely volunteer. A set of 20 Questionnaires distributed to a total of n=150 HCP (Health care professionals) consist of closed ended questions in Hard copy Language of questionnaires were in English. Informed consent was given and assurance for Confidentiality of Data were maintained.

Inclusion and Exclusion criteria

Among n= (150) HCP, n= (107) were responded the questionnaires are included, the Healthcare professionals n= (43) were not willing to participate in the study are excluded.

RESULTS

Out of 150 Prescribers, n= (107) were filled questionnaires, with response rate of 71.3% while n= (43) 28.6% not responded because lack of time and busy schedule. The Demographical data of all Participants are shown in Table1: n=35 male & n=7 female Physicians, n=25 male & n=15 female Pharmacist while n=05 male & n=20 female Nurses.

Table-1 Demographic Details of Participants

Health care Professionals	Categories		Age	Male (n=35)	Female (n=07)
Physician	Male (n=35)	Female (n=7)	25-30	17	5
			31-35	15	2
			36-40	3	-
Pharmacist	Male (n=25)	Female (n=15)	25-30	15	10
			31-35	10	5
Nurses	Male (n=05)	Female (n=20)	25-30	7	10
			31-35	3	3
			36-40	-	2

Results showed that 87.8% n= (94) participants were familiar with the term Pharmacovigilance while n= (13) (12.1%) were not familiar. (82.24%) n= (88) gave correct answer that science of reporting ADR is Pharmacovigilance, while 17.7% (n=19) answered incorrectly, n=63(58.8%) HCP had knowledge that DRAP established National Pharmacovigilance center and its location in Islamabad. While n= (44) (41.1%) responded did not know. n= (37) (34.5%) HCP has Pharmacovigilance department in their Hospitals/Clinics while n= (108) (73.4%) gave response that they do not have Pharmacovigilance department in their Hospitals/Clinics. n= (65) (60.7%) responded that both terms Adverse drug reaction and adverse drug event can be used vice versa

while n= (42) (39.25%) gave correct answer that both ADR reaction and ADR Events are not same. Among responded only n= (6) (5.6%) experienced Pharmacovigilance training in their CME while n= (101) (94.3%) not experienced any PV training. Among respondent n= (19) (17.7%) gave incorrect answer of Augmented ADR. n= (62) (57.9%) HCP incorrectly answered UMC is Uppsala Monitoring Center and its location in Africa while n = (12), (11.2%) participant responded that UMC is urgent monitoring core located in Sweden and only limited number of Health care Professionals n= (33) (30.8%) gave correct answer that UMC is Uppsala Monitoring Center and its location in Sweden as shown in table-2.

Table-2 Evaluation of knowledge About Pharmacovigilance

Question	Physician (n=42)		Pharmacist (n=40)		Nurses (n=25)		Total (n=107)	
	Yes	NO	Yes	NO	Yes	NO	Yes	NO
1. Do you know the term Pharmacovigilance	36 (85.71%)	6 (14.28%)	38 (95%)	2 (5%)	20 (80%)	5 (20%)	94 (87.8%)	13 (12.1%)
2. Science to report serious adverse drug reaction is Pharmacovigilance and its professional obligation	34 (80.9%)	8 (19.04%)	36 (90%)	4 (10%)	18 (72%)	7 (28%)	88 (82.24%)	19 (17.7%)
3. Are you aware DRAP established National Pharmacovigilance center which is located in Islamabad	28 (66.6%)	14 (33.3%)	33 (82.5%)	7 (17.5%)	2 (8%)	23 (92%)	63 (58.8%)	44 (41.1%)
4. Do you have Pharmacovigilance Department in your Hospital/clinic	10 (23.8%)	32 (76.1%)	22 (55%)	18 (45%)	5 (20%)	20 (80%)	37 (34.5%)	70 (65.4%)
5. Adverse drug reaction and adverse drug event both terms can be used vice versa	14 (33.3%)	28 (66.6%)	36 (90%)	4 (10%)	15 (60%)	10 (40%)	65 (60.7%)	42 (39.25%)

6. Do you experience Pharmacovigilance training during undergraduate studies or CME (Continuous Medical Education)	2 (4.76%)	40 (95.25%)	3 (7.5%)	37 (92.5%)	1 (4%)	24 (96%)	6 (5.6%)	101 (94.3%)
7. Do you know about DUPV in Pakistan	3 (7.14%)	39 (92.8%)	5 (12.5%)	35 (87.5%)	2 (8%)	23 (92%)	10 (9.34%)	97 (90.6%)
8. Augmented ADR is	Physician(n=42)		Pharmacist(n=40)		Nurses(n=25)		Total (n=107)	
a) Dose related type A ADR	25 (59.5%)		37(92.5%)		15(60%)		77(71.9%)	
b) Dose related type B ADR	10(23.8%)		2(5%)		7(28%)		19(17.7%)	
c) Augmented ADR not exist	7(16.6%)		1(2.5%)		3(12%)		11(10.2%)	
9. Do you know WHO PIDM stand for								
a) Professional institute of doctors monitoring.	25(59.5%)		5(12.5%)		15(60%)		45(42.0%)	
b) International Program for Adverse Drug Reaction monitoring	17(40.4%)		35(87.5%)		10(40%)		62(57.9%)	
10) Where "UMC" located and what it stands for								
a) Uppsala monitoring center located in "Africa"	38(90.4%)		10(25%)		14(56%)		62(57.9%)	
b) Urgent monitoring core located in Sweden	1(2.38%)		5(12.5%)		6(24%)		12(11.2%)	
c) Uppsala monitoring center located in Sweden	3(7.14%)		25(62.5%)		5(20%)		33(30.08%)	

Studies showed that n=11 (10.2%) Professionals has ADR recording system, n=98 (91.5%) Professionals believed that Poly Pharmacy are major cause of ADR, n= (40) (37.3%) responded that there should be collective efforts of HCP to report ADR and n=

(11) (10.2%) HCP believed that Geriatric are more susceptible to ADR. Whereas n= (9) (8.41%) believed that Pediatrics are at high risk of ADR but majority of HCP n= (87) (81.3%) had believed that it is independent of Age as shown in Figure-1 and 2; Table-3.

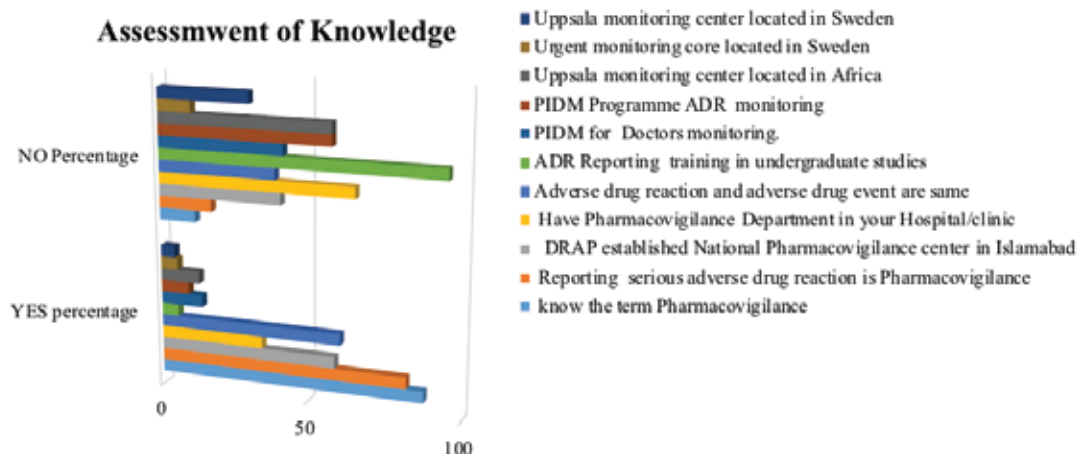


Figure-1 Knowledge Assessment of Health care Professionals

Table-3 Attitude of Health care Professionals towards Pharmacovigilance

Question	Physician(n=42)		Pharmacist(n=40)		Nurses(n=25)		Total(n=107)	
	Yes	NO	Yes	NO	Yes	NO	Yes	NO
11. If you are not reporting ADR, so do you have any record regarding ADR	4 (9.52%)	38 (90.4%)	5 (12.5%)	35 (87.5%)	2 (8%)	23 (92%)	11 (10.2%)	96 (89.7%)
12. Do you believe that Poly pharmacy is the factor of ADR	40 (95.2%)	2 (4.76%)	38 (95%)	2 (5%)	20 (80%)	5 (20%)	98 (91.5%)	9 (8.4%)
13. Do you have any discussion regarding unlabeled reaction with medical raps	7 (16.6%)	35 (83.3%)	23 (57.5%)	17 (42.5%)	2 (8%)	23 (92%)	32 (29.9%)	75 (70.0%)
14. Who should report ADR	Physician (n=42)		Pharmacist(n=40)		Nurses(n=25)		Total(n=107)	
a) Physician	20(47.6%)		2(5%)		8(32%)		30(28.0%)	
b) Pharmacist	10(23.8%)		5(12.5%)		10(40%)		25(23.36%)	
c) Nurses	2(4.76%)		7(17.5%)		3(12%)		12(11.2%)	
b) All of them	10(23.8%)		26(65%)		4(16%)		40(37.3%)	
15. Which age group is more susceptible to ADR								
a) Geriatrics	5(11.9%)		2(5%)		4(16%)		11(10.2%)	
b) Pediatric	2(4.76%)		1(2.5%)		6(24%)		9(8.4%)	
c) it is independent of age	35(83.3%)		37(92.5%)		15(60%)		87(81.3%)	

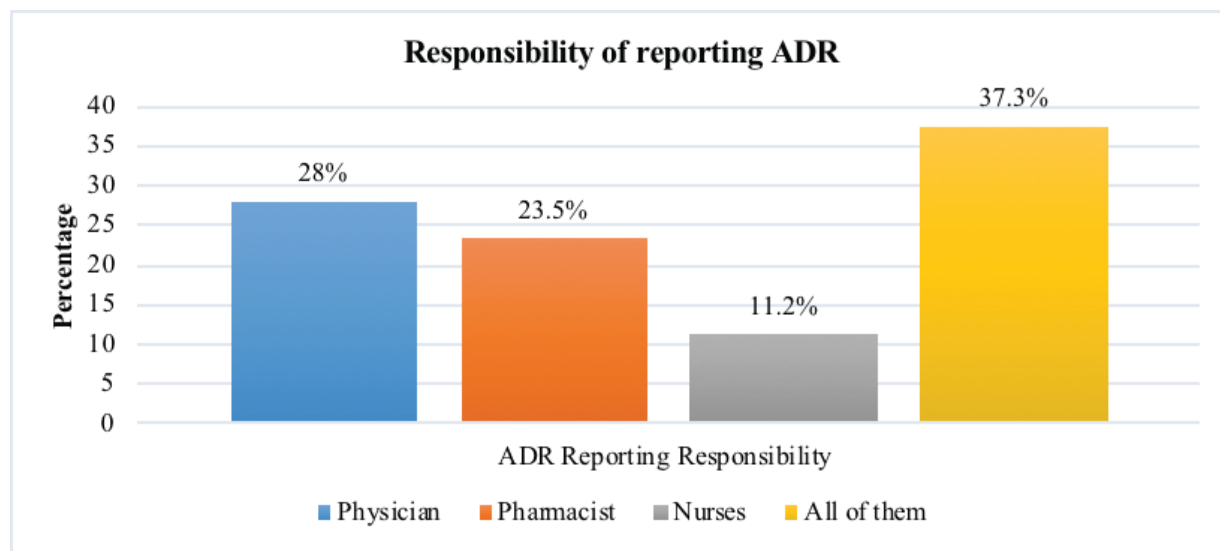


Figure-2 Adverse Drug Reaction Reporting Responsibility

The study also evaluated the unfavorable factors discouraging ADR Reporting like scale were used as shown in Figure-3. In our study Results showed (60.7% n= 65) HCP were strongly agreed that Less Establish Role of Community Pharmacist in Pakistan is factor for under reporting while (4.67%, n=5) HCP were strongly disagreed. This study reveals another factor that n= (40) (37.3%) HCP strongly agreed that no feedback response from patient discourages them to report ADR. This study results shows that n= (90) (84.1%) HCP strongly agreed that lack of time and

increase number of patients stops them for asking ADR from patients only n= (7) (6.54%) were strongly disagree. In our findings results were found that HCP n= (70) (65.4%) agreed that providing incentives to Physician or Health care professionals can be sixfold beneficial for ADR reporting & HCP n= (15) (14.0%) were strongly disagreed. In our studies we found n= (65) (60.7%) participants were strongly agreed their unawareness about how to report ADR while only n=2(1.86%) was sure where to report ADR shown in Table-4.

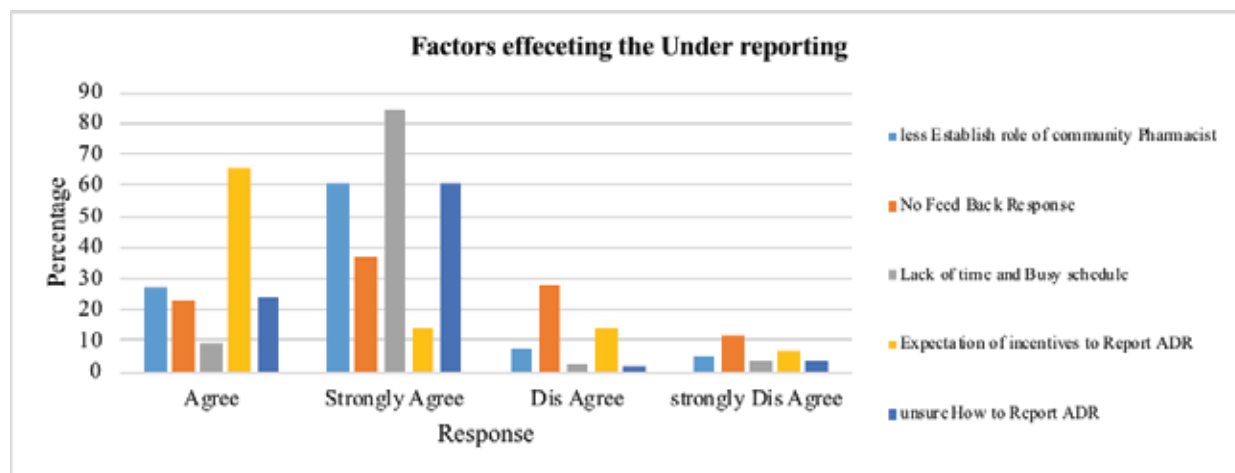


Figure-3. Unfavorable Factors of ADR Reporting

Table-4 Evaluation of unfavorable Factors for Reporting ADR

Questions	Agree (n=107)	Strongly Agree (n=107)	Disagree (n=107)	Strongly disagree (n=107)
16. Less establish Role of Community Pharmacist in Pakistan	29 (27.1%)	65 (60.7%)	8 (7.47%)	5 (4.67%)
17. NO feedback response discourages me from reporting ADR	25 (23.3%)	40 (37.3%)	30 (28.03%)	12 (11.2%)
18. Lack of time and increase number of patients stops me from asking ADR from patient	10 (9.34%)	90 (84.1%)	3 (2.8%)	4 (3.73%)
19. Providing incentives to Physician or health care professionals beneficial for ADR reporting	70 (65.4%)	15 (14.0%)	15 (14.0%)	7 (6.54%)
20. Adverse drug reaction not reported usually because of the Unsure how to report	36 (33.6%)	65 (60.7%)	2 (1.86%)	4 (3.73%)

DISCUSSION

Past studies suggests that under-reporting of ADRs is one of the main problems associated with Pharmacovigilance program several studies conducted to create awareness among Health care Professionals in the interest or reporting ADR (Abidli et al., 2019). In Japan only 23.3% Health care Professionals were Know the correct definition of Pharmacovigilance Nursing staff had not sufficient familiarity and under-

standing of Pharmacovigilance (Inácio et al., 2017). Past studies reveals that unawareness of HCP towards the existence of a National ADR Reporting system (Hashmi et al., 2020). In our findings we found (87.8%) had sufficient knowledge of HCP about definition that science to Report ADR is Pharmacovigilance but (41.1%) had insufficient knowledge about National Pharmacovigilance center and its location in Pakistan. It is the responsibility of each provisional administrative authority to supervise

Health care services in their own Province. The most common barrier against ADR reporting is the nonexistence of strict reporting system in their respective settings (Leghari et al., 2021). The current study reveals that most of the Health care professionals (65.4%) do not have any Pharmacovigilance services in their Hospitals/ clinics. ADR Reporting is necessary to improve not only patient quality of life but also patient adherence to any particular treatment (Santosh et al., 2013). Past studies reveals that there is a great need for the introduction of Pharmacovigilance education and training in the curriculum (Alwhaibi et al., 2020). In our studies (94.3%) HCP did not received any Pharmacovigilance training. It can be overcome by informative intervention program like training workshop & internship on Pharmacovigilance at undergraduate level can enhance ADR Reporting activities. A number of e-learning or digital lessons should be available on ADR Reporting for all Health care professionals (Hussain et al., 2018). It is an obligation of Health care professionals to report all predictable ADR that are common and related to Pharmacological Action of drug such as sedation with antihistamine, diarrhea with antibiotic and drug interaction theophylline with erythromycin all these are Augmented Type A ADR (Parthasarathi et al., 2012). In our study we found majority of the respondent had (71.9%) had sufficient knowledge of Augmented ADR. With each passing day new medicines are introduced in the market thus stake holders must play their role in order to improve quality of health. Training of Health care Professionals must be needed to hierarchize medication protection in health care systems involving deep knowledge of core areas of ADR Reporting. Studies shows that negative health outcomes increased due to polypharmacy which can lead to drug interactions, decreased functional status in geriatric patients (Sr et al., 2018) New and odd drug either alone or combination polypharmacy are the major cause of unwanted effect. In our study majority of Health Care professionals believed that it is their collective responsibility and professional obligation of all HCP to Report ADR (Fig 2) Pharmacist can contribute their role in Drugs safety by identifying, documenting and reporting ADR (Granás et al., 2007). As with other Health Care Professionals community Pharmacist working in individual or chain pharmacies is the prime source of valid information regarding appropriate use of medication (Newlands et al., 2018). As community Pharmacist provides recommendation to patients and other Health care Professionals improved Health and Patient safety thus major responsibility of ADR reporting lying on community Pharmacist (Newlands et al., 2018). In our study (60.7%) responded were agreed that less established role of community Pharmacist can be a major factor for Adverse Drug reaction. Pharmacist should performed their duties in monitoring and providing counselling to the public regarding the use of over-the-counter medicine (Janaki et al.,

2011). Past studies showed that ADR encountered by HCP during their work are never reported as lack of time to actively look and may generate extra work (Gurung et al., 2019). Lack of consultation time with patients, increased work load and time consuming documentation were the factors of reporting ADR (Valinciute-Jankauskiene and Loreta, 2021) In our studies (84.1%) respondent agreed that lack of time and work load of clinical activities another major cause of under reporting ADR which are similar with past studies that work load and busy schedule limits HCP to report ADR (Hazell and Shakir, 2006). Several studies revealed interventions that improve reporting regular reminder, educational sessions with financial incentives improves ADR reporting (Chang et al., 2017). In our findings we found majority of HCP (65.4%) agreed that providing incentives to HCP encourages them to report ADR. Other factors that can lead to the poor reporting of ADR ignorance of importance of Pharmacovigilance, complex ADR Reporting form, fear of litigation & fear of loose of reputation (Aziz et al., 2007) and unawareness of reporting. Pharmacovigilance is one of the most extreme requirements for encircling the arrangements in regards to the component of reporting ADRs with the correct customary preparing to all the medical practitioner. The procedure of ADRs reporting in a professional perspective is troublesome because of their substantial OPDs, deficiency of time and absence of learning appeared to be the primary purpose behind not reporting ADRs.

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