Journal of Pharmaceutical Research International

33(7): 78-86, 2021; Article no.JPRI.64598
ISSN: 2456-9119
(Past name: British Journal of Pharmaceutical Research, Past ISSN: 2231-2919, NLM ID: 101631759)

Exploration of Perception, Need and Barriers against Pharmacovigilance and Adverse Drug Reactions Reporting: Healthcare Professionals' Insight

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Authors' contributions

This work was carried out in collaboration among all authors. Authors QL and SS designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors SKC, RB, MR, MK and RN managed the analyses of the study. Authors SM, IA, RM and SB managed the literature searches. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2021/v33i731204
Editor(s):
(1) Dr. Prabakaran Nagarajan, The Ohio State University, USA.
Reviewers:
(1) Subina Narang, Government Medical College & Hospital, Chandigarh, India.
(2) Fei Yee Lee, Clinical Research Centre, Malaysia.
Complete Peer review History: http://www.sdiarticle4.com/review-history/64598

Original Research Article

Received 15 November 2020
Accepted 20 January 2021
Published 05 March 2021

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ABSTRACT

Objective: The present study was designed to assess the perception, need and the barriers of PV and ADRs reporting in the hospital settings of Karachi, Pakistan.
Methods: A cross-sectional survey was conducted from October 2019 to February 2020 by the random sampling in the healthcare professionals including physicians, pharmacists and nurses. Questionnaire was distributed to 525 participants (n=175 from each group) being serving for one or more year in hospitals and clinics. Overall, 425 participants were responded having 138 physicians, 143 pharmacists and 145 nurses.
Results: Perception of pharmacovigilance was found to be 81.02%, 73.40% and 35.17% respectively in physicians, pharmacists and nurses. Overall, 80.70% of respondents were felt the need of drug monitoring system in each hospital to improve patients' responses against treatment. The main hindrance for PV in our society was the lacking/ absence of the ADRs monitoring and reporting system marked by the physicians and pharmacists.
Conclusion: ADRs reporting and pharmacovigilance are not practiced properly in our region. It's a time to pay attention to this neglected area not only to strengthen the infra structure of healthcare units but also to increase the patient compliance and to avoid any drug associated disaster in future.

Keywords: Pharmacovigilance; adverse drug reaction (ADRs); ADRs reporting; healthcare workers; physician; pharmacist.

1. INTRODUCTION

According to the World Health Organization (WHO), adverse drug reactions (ADRs) are the noxious, unintended and undesired responses of drug that occurs routinely at standard therapeutic doses [1]. ADRs are very frequent with variable intensity of severity leading to the hospitalization and may even to deaths. The ADRs affect not only the quality of life quality of the patients but also contributing massive rise in mortality and morbidity globally [2]. Many of the ADRs occurring routinely while drug therapy are usually minor and preventable with proper management. Spontaneous reporting of ADRs is consider to be the best tool for monitoring of medicines which comes under post marketing surveillance or Pharmacovigilance [3]. Pharmacovigilance, involves detection, assessment, understanding and prevention of adverse drug effects. PV actually opens the new horizon for the patient and drug safety for the last 2 decades. However; it has taken many other disciplines into it including research, product development and pharmaceuticals [4,5]. Drug safety and monitoring activities were first launched by WHO after the world worst disaster of thalidomide in 1960s [6]. World health organization (WHO) set an international regulatory program in 1971, to identify various adverse drug reactions in initial stages of drug utilization. This initiation of WHO provides information regarding secured utilization of medicines, increase patient safety, prevention and treatment of any ADRs. Robust pharmacovigilance systems are currently available in technologically advanced countries of the world. But many low to middle income countries are still striving for such settings in hospitals. Pakistan is one of these developing country with 207.8 million population who are deprived of established Medical and healthcare facilities [6]. It drags many disasters due to the lack of quality surveillance system. Due to weak process/system of Pharmacovigilance the definite figure of casualties related to ADRs is not identified. The actual number of deaths related to ADRs is not known due to an underdeveloped process of pharmacovigilance. Thereafter, an independent regulatory body "Drug Regulatory Authority of Pakistan (DRAP) in 2012 was established for critical evaluation of drug safety, quality and availability of medical devices and medicines in the country [7]. Globally, healthcare professionals including physicians, pharmacist and nurses are responsible to fill the ADR forms available in their organization and also to connect these formats to a central and national ADRs and pharmacovigilance systems [8]. Past studies revealed that knowledge, attitude and perception affect the professional behavior of the practicing health professionals [9]. Underreporting of ADR is still a big challenge that needs to be addressed especially in developing countries where incentives and time constraints are the logistic hindrances in establishing and implementing the pharmacovigilance system. Number of studies has been reported covering the knowledge, perception, significance,

assessing and monitoring methodologies of PV globally [10]. But in low to middle income countries inadequate literature are found which explain the exact picture of PV. The intrinsic factors (Knowledge, attitude and practices) and extrinsic factors (Relationship between health professionals and their patients, the health system and the watchdogs) can improve spontaneous reporting of ADRs by healthcare professionals In this context, the current study was aimed to evaluate the knowledge, attitude and practices of pharmacovigilance and ADRs reporting by physicians, clinical pharmacists and nurses working in different hospital facilities in Karachi, Pakistan.

2. METHODOLOGY

2.1 Design and Period

A cross-sectional study was designed to assess the perception and need of pharmacovigilance among healthcare professionals. It was conducted from June to October 2019 in various hospital settings of Karachi, Pakistan. Physicians, pharmacists and nurses were targeted for data collection through systemic random sampling.

2.2 Study Tool and Protocol

After the relevant literature review a questionnaire was construed and validated to collect the required variables. One part of questionnaire contained the demographic information of the participants while the second part has the questions thought to be necessary for assessing their ideas, attitude and vision for the pharmacovigilance and ADRs reporting. Overall, 20 close ended questions were given to the respondents with multiple options. Questionnaire were printed in English language however it was explained before the filling and provided them in hard copy or mailed electronically upon demand. Participation of healthcare professionals was entirely volunteer. Consents were taken and assure them all about their data confidentiality. Data collectors were briefly provided the details to the willing participants on the cover page.

2.3 Sample Size estimation

Sample size for the present study was calculated by Danniel expression (Daniel WW 1999) using 43% prevalence of pharmacovigilance awareness [5]. 95% confidence interval was taken with 0.05 level of significance. The sample size was also estimated with Raosoft calculator using 100,000 population size of healthcare personals, 5% margin error, 50% response distribution and 95% of confidence interval (Raosoft, 2004). Sample size of 376 and 383 were computed by Danniel and Raosoft calculator respectively. However larger sample size was taken to obtain higher result accuracy therefore 525 individuals having equal number of physicians (n=175) pharmacist (n=175) and nurses (n=175) working in private and public sector hospitals were initially approached. These hospitals were located in different districts of the city. Respondents were given two weeks for the completion of questionnaire with two soft reminders after every 7days. Out of 525 respondents, 138 physicians, 143 pharmacists and 145 nurses return the filled forms. Finally, 425 healthcare professionals were selected with response rate of 80.95%. Only those healthcare professionals (male and females) having at least one year of experience in their respective organization were included. Results are expressed in descriptive statistics using frequency, percentages and bar graphs.

3. RESULTS

Overall, 425 respondents (Table 1) were participated. All respondents had at least two years of working experience in the same institution from where they recruited. It was found that majority of the physicians and the pharmacists had grown concept of pharmacovigilance and majority of them felt the urge to develop the adverse drug reporting systems in lined with the pharmacovigilance units in each and every small and large hospital settings. Regrettably; nurses had confused and inadequate knowledge about the pharmacovigilance conception. However; majority of healthcare providers recommended incorporating the contents of adverse drug events, their reporting and significance in their respective undergraduate curriculum. This would not only improve the theoretical knowledge but will also benefits the candidate to boost their practicing skills. The details of above-mentioned items are presented in Table 2 and 3. Respondents were asked to mark the similarity of ADRs and pharmacovigilance using 6-points Likert scale. Overall, 40.30% of the health professionals were “strongly agreed” that ADRs are come under the head of the pharmacovigilance. However, only few nursing staff was in opinion of the “strongly agreed” option. This finding was critical as nurses had not

presented the clear vision of PV. Details are given in Table 4. Majority of healthcare professionals accepted that ADRs reporting is their professional obligation but even though they had many concerns with it. Table 5 lists the various factors that make obstacles in ADRs reporting. Although physicians realize the need and significance of ADRS documentation and PV in healthcare units but owing to the lack of appropriate reporting and monitoring systems they were failed to perform this duty. Same thoughts were also presented by pharmacists. While nurses being a low paid employee, blamed the administration for this lacking as they are not providing incentives for this additional work.

Healthcare professionals including physicians, pharmacists and nurses are consider being the key reporter for ADRs. According to the present analysis, physicians (42.82%) and pharmacists (29.41%) were thought to be the key persons for addressing of ADRs. Nurses and patients were ranked as low as shown in Fig. 1 and Fig. 2 shows the various modes of communication for reporting ADRs in studied clinical settings. It was found that the most likely way to report ADRs by patients is through verbal communication as they felt more comfortable to explain the underlying clinical conditions. Fig. 3 indicates different events that have to be documented to improve the treatment. Physicians and pharmacists were in favor to document any response that appears like ADRs including mild to severe reactions.

4. DISCUSSION

Public health and their well-being are the primary concerns of both developed and under developing countries. New and old drug alone or in combinations are prone to induce many unwanted responses in the body. The present study deals with the perception of pharmacovigilance among healthcare professionals working in various hospital settings of Karachi city. It was found that nurses were not fully understand the term PV exactly while majority of the physicians and the pharmacists had grown concept of PV. This reflects the need of informative sessions of PV and ADRs that should be conducted in their working institution. The categorical responses of perception and need of the present study are given in Table 2. Similar responses were also observed in an investigation performed in Japan where only 44.7% of healthcare professionals had an idea of PV with 23.3% of the professionals were known about the correct definition of it. Especially the nurses and midwives were found to have extremely insufficient understanding of pharmacovigilance [11]. Table 3 provides the responses dealing with the routine practices and beliefs of health professionals regarding ADRs. In past, many lives threatening issues and disasters were faced by patients in different countries due to the lack of adverse drug monitoring. It was found that 97% of the healthcare professionals were believed that ADR reporting is necessary to improve not only the patient conditions but also increase the patient compliance and adherence to any particular treatment and also being taught in under graduate study [12]. Many past studies documented that the healthcare professionals working all over the world realized that the ADR monitoring and reporting are their key responsibilities and professional obligation [13]. Responses of physicians, pharmacist and the nurses were separately presented against each item in Table 3. Pharmacovigilance mainly incorporates the close monitoring of ADRs of different therapeutic moieties. The role of nurses in developing country is very crucial as they are the persons come in immediate and frequent contact with the patients. Nursing staff are spending more time with the patients and able to observe any kind of ADRs occurring at that time. Short tutorials, small group seminars and workshop should be arranged in the working setting to motivate and groom their professional skills. Details are given in Table 4. The acceptance of nurses to be an ADR reporter is less in physicians [12], nurses as well are also not fully aware of their role in ADR reporting. It has been estimated that many problems are due to under reporting of ADRs; about 5 to 10% of ADRs had been found to be documented. In one of the study carried on addressing the ADRs reporting practices, clinical pharmacists were found to be the most practiced and well aware healthcare providers regarding pharmacovigilance and drug monitoring. In this finding researcher evaluated that 60.5% of Pharmacist and 18% nurses while 12.1% of physician have awareness of PV [14]. Overall, healthcare personals are thought to be responsible for ADRs documentation but patients could also be involved in adverse event reporting if motivated. The knowledge that patient can report ADRs is very least established healthcare units [15]. Various modes of ADRs reporting exists and utilized all over the world however; online systems are now launching to save the time and expenditure [16]. China has developed online spontaneous self-reporting Adverse Drug

Reaction (ADR) Monitoring System in 2003. Although still the ADR reporting is not mandatory but even though extensive improvement in practicing ADRs monitoring and PV has shown great progress [17,18]. Similarly many countries have started active pharmacovigilance programs at their national level and also in collaboration with international authorities of WHO for drug safety and risk management [19]. In the current study, respondents experienced during their duty timings that patients are comfortable to communicate various drug associated complaints verbally. Patients and their relatives were habitual to converse their ADRs to the physicians and the paramedical staff orally. They felt hesitation to fill the ADR formats as they found difficulties in completion of written formats. Henceforth they just want to convey or record their complaints to the staff present at their ward counter. Verbal communication (48.94%) and written formats (36.94%) were still found to be the best systems for the ADRs reporting. However; electronic communication has also now gaining popularity and established mode of ADRs documentation.

According to the physicians, common barriers against ADRs reporting were the lack of reporting system and also the free time to look into this side. While pharmacist blamed the non-existence of the strict reporting system in their settings, other factors included the incentives and the time constraints as well. Nursing staff however; considered this part of ADRs reporting as an extra burden and the core discouraging factor was the low or no incentives paid for this additional load. Additionally, healthcare professionals were also mentioned absence of national pharmacovigilance center and related activities in their vicinity. Various obstacles for healthcare professionals against ADRs reporting is given in table 5. These findings were in concordance of the previous study where the main reasons of non- documentation of ADRs were the staff negligence, extra burden, the short of time, legal liability, training of risk of under reporting [2,20].

It is a well-established reality that all medicines are chemicals and no chemical would be devoid of side effects. However; the consumption of such chemicals is basically a compromise between the beneficial and adverse responses that are supposed to be induced upon administration. Many commonly utilized drugs including paracetamol, NSAIDs and anti-hypertensive agents are documented to cause hepatotoxicity [19], gastro-intestinal ulcers [20] and renal damage respectively. Nevertheless, the mentioned drawbacks, these agents are still being highly utilized all over the world. ADRs of new moieties whether predicted or unpredicted, are desired to be monitored vigilantly from its premarketing to post marketing phases. In past, many drug stocks were withdrawn after/during the post market surveillance from the commercial market owing to unavoidable associated ADR including terfenadine, cisapride, phenylpropanolamine, rofecoxib, cerivastatin, gatifloxacin, cisapride, sibutramine and tegaserod [19,21]. For this purpose, pharmacovigilance centers are supposed to launch successful programs for close monitoring of presumed or unexpected adverse effects as the same drug is being given to different sets of patients, elder, adults and the children. This will surely improves the underlying treatment and eventually the patients' health profile. In the present study physicians and the pharmacists were in opinion that ADRs of all kinds of drugs whether new and existing must be documented. Additionally, all the responses that appeared like an ADR or any suspected reaction of drug interaction is not only be monitored intensely but should be reported as well. It is also documented in past that ADRs of even OTC products should also be documented [5]. The responses of each group of healthcare are presented graphically in Fig. 3.

Table 1. Participation of healthcare professionals in the survey

Healthcare Professionals	Participants (n=525)	Respondents	
		Accepted (425)	Rejected (99)
Physicians	175	138	37
Pharmacists	175	143	32
Nurses	175	145	30

Table 2. "True Perception "and "Need" of Pharmacovigilance in health care facility

Response	Pharmacists (n=143)	Physicians (n=137)	Nurses (n=145)
Perception	105 (73.40%)	111 (81.02%)	51 (35.17%)
Need	125 (87.41%)	113 (82.48%)	56 (38.62%)

Table 3. Beliefs and practices of healthcare professionals about ADRs and its reporting

S. No.	Response to question	Physicians (n=137)	Pharmacists (n=143)	Nurses (n=145)	Not Attempted
1	Is reporting of ADRs necessary?	112 (81.75%)	129 (90.20%)	98 (67.58%)	02
2	Is ADRs monitoring center required in every hospital?	119 (86.86%)	121 (84.61%)	103 (71.03%)	03
3	Should pharmacovigilance be included in the educational syllabus of healthcare professionals?	121 (88.32%)	119 (83.21%)	109 (75.97%)	0
4	Should common ADRs like fever, headache, abdominal discomfort, vomiting be reported?	97 (70.80%)	109 (76.22%)	98 (67.58%)	6
5	Is reporting ADRs a professional obligation	89 (64.96%)	117 (81.81%)	83 (57.24%)	8

Table 4. Association between ADRs and Pharmacovigilance (PV)

Association of ADR and PV	Pharmacists (n=138)	Physicians(n=130)	Nurses (n=129)
Don't know	7 (5.07%)	3 (2.30%)	19(14.72%)
Strongly disagree	2 (1.44%)	1 (0.76%)	26 (2015)
Disagree	0 (0%)	4 (3.07%)	30(23.25%)
Neutral	09 (6.52%)	0 (0%)	35(27.13%)
Agree	43 (31.15%)	54 (41.53%)	12 (9.30%)
Strongly Agree	77 (55.79%)	68 (52.30%)	7 (5.42%)
Not Attempted	5 (3.49%)	7 (5.10%)	16(11.03%)

Table 5. Discouraging factors of reporting ADRs

Discouraging Factors	Physicians(n=133)	Pharmacists(n=138)	Nurses(n=136)
Don't know the reporting Procedure	09 (6.76%)	7 (5.07%)	15 (11.02%)
Lack of time to look for ADRs	44 (33.08%)	31 (22.46%)	11 (8.08%)
Existance of the reporting system in institution	51 (38.34%)	64 (46.37%)	37 (27.20%)
Non-remuneration/ incentives	22 (15.78%)	31 (22.46%)	45 (33.08%)
Consider an additional work	7 (5.26%)	5 (3.62%)	28 (20.58%)
Not Attempted	4 (2.91%)	5 (3.49%)	9 (6.20%)

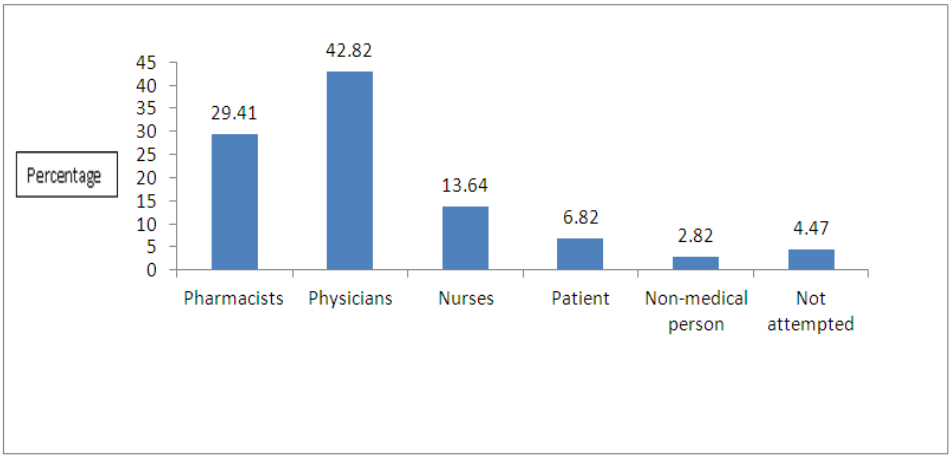

Fig. 1. Responsibility of ADR reporting

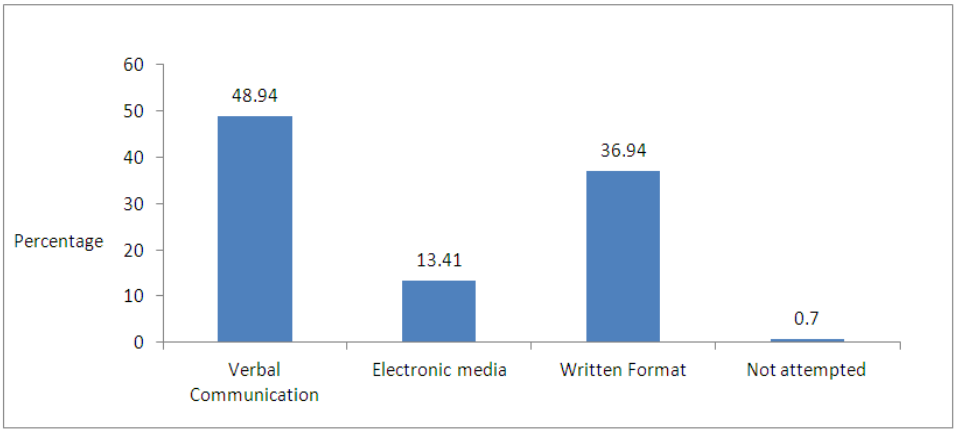

Fig. 2. Comparative values of the various modes available for ADRs recordings

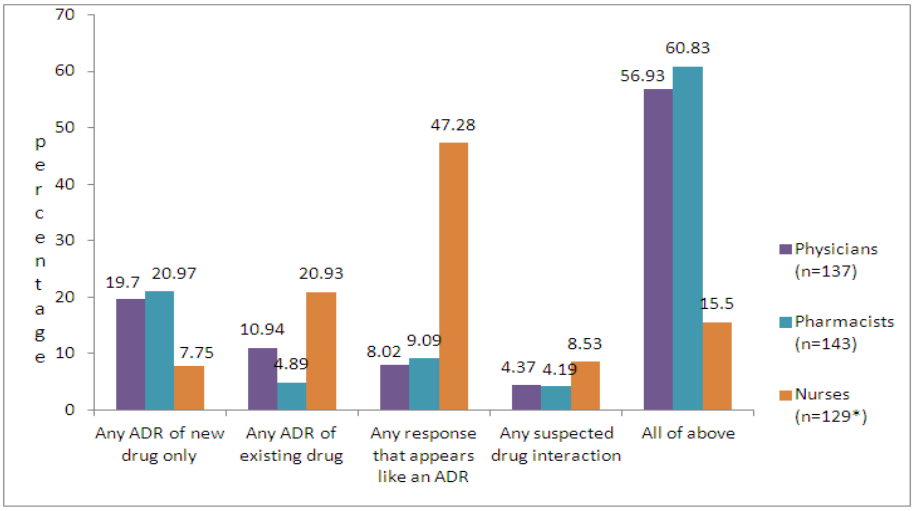

Fig. 3. Events included in ADRs reporting

5. CONCLUSION

Pharmacovigilance plays strategic role in improvement and enhancement of public health by curtailing various drug hazards. In the present study, healthcare professionals strongly believed upon the need of drug monitoring and ADRs reporting to increase the patients' safety and to minimize therapy crises/ failures. Physicians and the pharmacists were in opinion that ADRs of all kinds of drugs must be documented with recommendation of critical PV and ADRs surveillance for newly approved medicines in their post-marketing trials. Nurses are one of the major elements of health care networking system, but unfortunately in our country they need to be trained in all aspects come under the head of pharmacovigilance by conducting informative sessions, tutorials and seminars in their own institutes. Common barriers against ADRs reporting were found to be the non-existence of the strict reporting system in respective settings; other factors were monetary incentives and the time constraints as well.

CONSENT

As per international standard or university standard, respondents' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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DOI: 10.3390/pharmacy6020029;
PMID 29614725;

Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sdiarticle4.com/review-history/64598