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Evaluation of the awareness, knowledge and application of pharmacovigilance among the health professionals from Bihar region

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Abstract

Pharmacovigilance Programme of India (PvPI) was initiated to monitor ADRs in 2010 by Government of India. The primary goal of the program is to protect and to safeguard health of the public by assuring the safety of medicine. Health professionals like Doctors, nurses, and pharmacists involved in prescribing, dispensing, administering, storage, and disposal of medicines play a key role in the success of the programme. Attitude, and practice (KAP) about pharmacovigilance from various studies have revealed that ADR reporting by healthcare providers is linked to their awareness and knowledge about ADRs. Hence based on above finings the present study was planned for Evaluation of the Awareness, Knowledge and Application of Pharmacovigilance among the Health Professionals from Bihar Region.

The present study was planned in Anugrah Narayan Magadh Medical College, Gaya, Bihar, India. In the present study 25 Pharmacist, 25 Nurses, 25 Doctors and 25 Medical students were evaluated for the pharmacovigilance awareness. All the groups were underwent the given set of question. Based on that questions the Awareness, Knowledge and Application (Practice) were presented based on Poor, Average, Good and Excellent parameters.

The data generated from the present study concludes that A positive attitude toward pharmacovigilance exists among the healthcare providers and students of the institution. More continuous medical education programs need to be conducted to educate all healthcare providers about the importance of a pharmacovigilance program, the role of all healthcare providers in ensuring its success and the various facilities available in the institution for reporting ADRs.

Keywords: awareness, knowledge, application, pharmacovigilance, ADR, etc

Introduction

Pharmacovigilance (PV or PhV), also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products [1]. As such, pharmacovigilance heavily focuses on adverse drug reactions, or ADRs, which are defined as any response to a drug which is noxious and unintended, including lack of efficacy (the condition that this definition only applies with the doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological disorder function was excluded with the latest amendment of the applicable legislation) [2]. Medication errors such as overdose, and misuse and abuse of a drug as well as drug exposure during pregnancy and breastfeeding, are also of interest, even without an adverse event, because they may result in an adverse drug reaction [3].

Information received from patients and healthcare providers via pharmacovigilance agreements (PVAs), as well as other sources such as the medical literature, plays a critical role in providing the data necessary for pharmacovigilance to take place. In fact, in order to market or to test a pharmaceutical product in most countries, adverse event data received by the license holder (usually a pharmaceutical company) must be submitted to the local drug regulatory authority.

Ultimately, pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients. Companies must conduct a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations, and guidance [4].

The activity that is most commonly associated with pharmacovigilance (PV), and which consumes a significant amount of resources for drug regulatory authorities (or similar government agencies) and drug safety departments in pharmaceutical companies, is that of adverse event reporting. Adverse event (AE) reporting involves the receipt, triage, data entering, assessment, distribution, reporting (if appropriate), and archiving of AE data and documentation. The source of AE reports may include: spontaneous reports from healthcare professionals or patients (or other intermediaries); solicited reports from patient support programs; reports from clinical or post-marketing studies; reports from literature sources; reports from the media (including social media and websites); and reports reported to drug regulatory authorities themselves. For pharmaceutical companies, AE reporting is a regulatory requirement in most countries. AE reporting also provides data to these companies and drug regulatory authorities that play a key role in assessing the risk-benefit profile of a given drug.

Spontaneous reports are termed spontaneous as they take place during the clinician's normal diagnostic appraisal of a patient, when the clinician is drawing the conclusion that the drug may be implicated in the causality of the event.

Spontaneous reporting system relies on vigilant physicians and other healthcare professionals who not only generate a suspicion of an ADR, but also report it. It is an important source of regulatory actions such as taking a drug off the market or a label change due to safety problems. Spontaneous reporting is the core data-generating system of international pharmacovigilance, relying on healthcare professionals (and in some countries consumers) to identify and report any adverse events to their national pharmacovigilance center, health authority (such as EMA or FDA), or to the drug manufacturer itself [10]. Spontaneous reports are, by definition, submitted voluntarily although under certain circumstances these reports may be encouraged, or "stimulated", by media reports or articles published in medical or scientific publications, or by product lawsuits. In many parts of the world adverse event reports are submitted electronically using a defined message standard [5].

One of the major weaknesses of spontaneous reporting is that of under-reporting, where, unlike in clinical trials, less than 100% of those adverse events occurring are reported. Further complicating the assessment of adverse events, AE reporting behaviour varies greatly between countries and in relation to the seriousness of the events, but in general probably less than 10% (some studies suggest less than 5%) of all adverse events that occur are actually reported. The rule-of-thumb is that on a scale of 0 to 10, with 0 being least likely to be reported and 10 being the most likely to be reported, an uncomplicated non-serious event such as a mild headache will be closer to a "0" on this scale, whereas a life-threatening or fatal event will be closer to a "10" in terms of its likelihood of being reported. In view of this, medical personnel may not always see AE reporting as a priority, especially if the symptoms are not serious. And even if the symptoms are serious, the symptoms may not be recognized as a possible side effect of a particular drug or combination thereof. In addition, medical personnel may not feel compelled to report events that are viewed as expected. This is why reports from patients themselves are of high value. The confirmation of these events by a healthcare professional is typically considered to increase the value of these reports. Hence it is important not only for the patient to report the AE to his health care provider (who may neglect to report the AE), but also report the AE to both the biopharmaceutical company and the FDA, EMA. This is especially important when one has obtained one's pharmaceutical from a compounding pharmacy.

The principle of international collaboration in the field of pharmacovigilance is the basis for the WHO Programme for International Drug Monitoring, through which over 150 member nations have systems in place that encourage healthcare personnel to record and report adverse effects of drugs in their patients [6]. These reports are assessed locally and may lead to action within the country. Since 1978, the programme has been managed by the Uppsala Monitoring Centre to which member countries send their reports to be processed, evaluated and entered into an international database called VigiBase. Membership in the WHO Programme enables a country to know if similar reports are being made elsewhere [6]. When there are several reports of adverse reactions to a particular drug, this process may lead to the detection of a signal, and an alert about a possible hazard communicated to members countries after detailed evaluation and expert review.

The ICH is a global organization with members from the European Union, the United States and Japan; its goal is to recommend global standards for drug companies and drug regulatory authorities around the world, with the ICH Steering Committee (SC) overseeing harmonization activities. Established in 1990, each of its six co-sponsors—the EU, the European Federation of Pharmaceutical Industries and Associations (EFPIA), Japan's Ministry of Health, Labor and Welfare (MHLW), the Japanese Pharmaceutical Manufacturers Association (JPMA), the U.S. Food and Drug Administration (FDA), and the Pharmaceutical Research and Manufacturers of America (PhRMA)—have two seats on the SC. Other parties have a significant interest in ICH and have been invited to nominate Observers to the SC; three current observers[when?] are the WHO, Health Canada, and the European Free Trade Association (EFTA), with the International Federation of Pharmaceutical Manufacturers Association (IFPMA) participating as a non-voting member of the SC [7, 8].

The Pharmacovigilance exertion in India is organized by The Indian Pharmacopoeia Commission and conducted by the Central Drugs Standard Control Organization (CDSCO). The main responsibility of the IPC is to maintain and develop the pharmacovigilance database consisting of all suspected serious adverse reactions to medicines observed. Indian Pharmacopoeia Commission (IPC) is functioning as a National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI). National Coordination Centre is operating under the observation of steering committee which recommends procedures and guidelines for regulatory interventions. The main duty of National Coordination Centre is to monitor all the adverse reactions of medicines being observed in the Indian population and to develop and maintain its own pharmacovigilance database. Pharmacovigilance Programme of India (PvPI) The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of Ministry of Health & Family Welfare, Government of India in association with Indian Pharmacopeia commission, Ghaziabad is initiating a nation-wide Pharmacovigilance Programme for protecting the health of the patients by promising drug safety. The Programme shall be coordinated by the Indian Pharmacopeia commission, Ghaziabad as a National Coordinating Centre (NCC). The center will operate under the supervision of a Steering Committee. The Pharmacovigilance Programme of India (PvPI) was started by the Government of India on 14th July 2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordination Centre for monitoring Adverse Drug Reactions (ADRs) in the country for safe-guarding Public Health.

In the year 2010, 22 ADR monitoring centres including AIIMS, New Delhi was set up under this Programme. To safeguard implementation of this programme in a more effective way, the National Coordination Centre was shifted from the All India Institute of Medical Sciences (AIIMS), New Delhi to the Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh on 15th April 2011. Before registration and marketing of medicine in the country, its safety and efficacy experience is based chiefly on the use of the medicine in clinical trials. These trials primarily detect common adverse reactions. Some important reactions, such as those, which take a long time to develop, or those, which

occur rarely, may not be detected in clinical trials.

In addition, the controlled conditions under which medicines are used in clinical trials do not necessarily reflect the way they will be used in practice. For a medicine to be considered safe, its predictable benefits should be greater than any associated risks of harmful reactions. So, in order to gain a complete safety profile of medicine, a continuous post-marketing monitoring system i.e. pharmacovigilance is essential. In order to screen the safety of medicine, information from many sources is used for pharmacovigilance. These include spontaneous (ADRs) reporting mechanism; medical literature published worldwide, action taken by regulatory authorities in other countries, etc. Meanwhile there exist considerable social and economic consequences of adverse drug reactions and the positive benefit/cost ratio of employing appropriate risk management (there is a need to engage healthcare professionals and the public at large, in a well-structured programme to build synergies for monitoring adverse drug reactions in the country). The purpose of the PvPI is to collate data, process and analyze it and use the inferences to recommend regulatory interventions, besides communicating risks to healthcare professionals and the public.

Pharmacovigilance Programme of India (PvPI) was initiated to monitor ADRs in 2010 by Government of India. The primary goal of the program is to protect and to safeguard health of the public by assuring the safety of medicine. Health professionals like Doctors, nurses, and pharmacists involved in prescribing, dispensing, administering, storage, and disposal of medicines play a key role in the success of the programme [9]. Attitude, and practice (KAP) about pharmacovigilance from various studies have revealed that ADR reporting by healthcare providers is linked to their awareness and knowledge about ADRs [10]. Hence based on above finings the present study was planned for Evaluation of the Awareness, Knowledge and Application of Pharmacovigilance among the Health Professionals from Bihar Region.

Methodology

The present study was planned in Anugrah Narayan Magadh Medical College, Gaya, Bihar, India. In the present study 25 Pharmacist, 25 Nurses, 25 Doctors and 25 Medical students were evaluated for the pharmacovigilance awareness. All the groups were underwent the given set of question. Based on that questions the Awareness, Knowledge and Application (Practice) were presented based on Poor, Average, Good and Excellent parameters.

A descriptive cross-sectional approach was adopted for the study. It included collection of information and data directly from the subjects of the study through a structured close-ended questionnaire prepared using review of literature from books, journals and published research studies.

All the patients were informed consents. The aim and the objective of the present study were conveyed to them. Approval of the institutional ethical committee was taken prior to conduct of this study.

Results & Discussion

In a country like India, with a huge population and vast diversity, it is absolutely necessary to introduce a standard Pharmacovigilance programme in each medical college and hospitals across the country. Pharmacovigilance is by definition "the science and activities which are related to the detection, assessment, understanding, and the prevention of adverse effects or any other drug-related problems. [11] India ranks below 1% in terms of ADR reporting against the world rate of 5% [12]. To overcome this problem, the Ministry of Health and Family Welfare, Government of India, has initiated the National Pharmacovigilance programme.

The purpose of this program is to gather the data, analyse it, and to use inferences to propose informing regulatory interventions, besides communicating the risks to the health-care professionals and the public. This program is coordinated by the National Pharmacovigilance Centre at the Central Drugs Standard Control Organization in New Delhi. The National Centre is operating under the supervision of the National Pharmacovigilance Advisory Committee, to recommend procedures and guidelines for regulatory interventions. This committee oversees the performance of two zonal, five regional, and twenty-six peripheral Pharmacovigilance centers. The entire network works in coordination to improve the ADR reporting in our country [13].

India has become a destination for conducting clinical trials. During clinical trials, drugs are commonly studied in a safeguarded environment, for a relatively small number of patients, and usually for a limited duration. These trials at times exclude the elderly, the very young, and patients with comorbidities. Often patients on multiple drug therapy and patients with decreased renal and hepatic function are disqualified. For these patient populations, any susceptibility to ADRs may be missed. Adverse reactions may occur at such a low frequency that they are not being detected in the small numbers of patients included in clinical trials. Furthermore, it is very difficult to foretell how practitioners will really use medications in practice. Once the drug is commercially available, the exclusion criteria applied in clinical trials, no longer exist. Thus the use of drug in general population either short term or long term may increase the possibility of identifying unobserved adverse effects. In addition, widespread use of medicines in the general population can increase the chances for uncovering adverse reactions occurring at low frequency and thus not previously detected during the marketing approval process.

World Health Organization (WHO) defines, an adverse drug reaction (ADR) is any noxious, unintended and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or cure of a disease [14]. Long stay in hospital, increased cost burden and mortality in associated with adverse drug reactions [15].

Table 1: Demographic Details

Parameters	Pharmacist	Nurses	Doctors	Medical Students
Total No.	**25**	**25**	**25**	**25**
Sex				
Males	18	0	20	13
Females	7	25	5	12
Age				
21 – 30 years	16	10	0	25
31 – 40 years	4	9	16	0
41 – 50 years	5	6	9	0

Table 2: Awareness, Knowledge & Application of Pharmacovigilance

Parameters	Pharmacist	Nurses	Doctors	Medical Students
Total No.	**25**	**25**	**25**	**25**
Awareness				
Poor	6	14	1	4
Average	16	8	5	3
Good	3	3	11	13
Excellent	0	0	8	5
Knowledge				
Poor	13	17	1	10
Average	10	6	4	2
Good	2	2	16	10
Excellent	0	0	4	3
Application				
Poor	15	18	4	12
Average	8	5	3	2
Good	2	2	15	8
Excellent	0	0	3	3

Tandon *et al*. in 2015 explained underreporting of ADRs in India. The results of the study suggest that lack of knowledge and awareness about PvPI, lethargy, insecurity, workload, and lack of proper training in PV were some factors responsible for underreporting [16]. In a similar type of study, ignorance in 95%; diffidence in 72%; lethargy in 77%; indifference and insecurity in 67%; and complacency in 47% of subjects were held responsible for under-reporting [17]. Jose & Rafeek in 2018 found that underreporting of ADRs is the major challenge related to PV in India [18]. There are several explanations for this including deficiency of medical professionals, inadequate nationwide awareness of PV. They suggested that all the health care providers including rural areas, should be given awareness about PV. ADR reporting was found to be on a higher percentage by physicians than pharmacists and health care providers.

An encouraging finding of this study was that the majority of participants (>90%) considered that ADR reporting is important and should be made mandatory. It should be taught during their training. Moreover, about 80% participants thought that ADR reporting is their professional obligation, which is more in the studies done in Nagpur and Tamil Nadu. [19-20] A study from India showed that 64% healthcare providers are reporting ADRs [21]. In this study, despite having a good attitude toward reporting of ADRs, only 45% healthcare providers had ever reported ADRs. Also, 32% participants want to report only serious ADRs which is lesser than the percentage observed in another study [22]. There is a need to emphasize to the healthcare providers that all adverse reactions must be reported whether mild or serious.

Many Indian studies have indicated that there is a gradual increase in the knowledge and attitude of the health-care professionals toward pharmacovigilance [23, 26], but unfortunately, it seems that the actual practice of ADR reporting is still deficient. It has been reemphasized that there is a positive correlation between training of Pharmacovigilance and reporting ADR by health-care professionals [27]. Factors like the unawareness about the method to decide the causal relationship between the ADR can only be removed by regular training [25]. The significance of adverse event monitoring and reporting can be increased through academic interference. This will ultimately help in improving the efficiency of pharmacovigilance program in India.

This study also revealed that the basic knowledge of pharmacists regarding pharmacovigilance was lesser than the other healthcare providers in all areas. This is similar to observation in another study from South India. [28] Pharmacists are key stakeholders involved in procurement, storage, dispensing, and disposal of medicines. They have a crucial role in the safe use of medicines. Thus, the concept of pharmacovigilance for patient safety needs to be emphasized during their professional training, and continued medical education programs should be organized regularly to update their knowledge.

One or the other reasons have been cited by participants for non-reporting of ADRs by health care professionals. The most important reason for non-reporting was “do not know how to report.” However, this issue can be tackled by delivering them a short and frequent hand on a training session with special emphasis on how to fill a standard ADR reporting form in a structured format available under PvPI. This will probably help in improving frequency as well as the quality of ADR reporting. Not only that, frequent exposure to such training session would dispel misconception, such as fear of litigation surrounding ADR reporting.

The major challenge related to pharmacovigilance in India is underreporting of ADRs. There are several explanations for this including deficiency of medical professionals, inadequate nationwide awareness of pharmacovigilance etc. In developing countries like India, lack of basic facilities and easy going procedures results in under-reporting of ADRs which is a serious concern. In India the existing system for monitoring ADRs depend on spontaneous reporting from health professionals which is the main source of information. Consumer‘s knowledge and perception towards adverse drug reactions & their reporting can play an important role in pharmacovigilance program of India & ensuring a healthy lifestyle with proper use of medicines.

Limitations of the study include; results are of only a single hospital (institution) and those inherent to questionnaire-based studies such as subjective response and recall bias. It would be logical to extend this study to other teaching hospitals, private practitioners, members of allied fields, students of medical and associated streams to enable us generalize our findings.

Conclusion

The data generated from the present study concludes that A positive attitude toward pharmacovigilance exists among the healthcare providers and students of the institution. More continuous medical education programs need to be conducted to educate all healthcare providers about the importance of a pharmacovigilance program, the role of all healthcare providers in ensuring its success and the various facilities available in the institution for reporting ADRs.

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