International Journal of Basic & Clinical Pharmacology
Nasir M et al. Int J Basic Clin Pharmacol. 2020 Oct;9(10):1497-1502
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20203994

Original Research Article

Acquaintance, approach and application of pharmacovigilance: questionnaire based study at a tertiary care teaching hospital in Dhaka

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Received: 24 July 2020
Revised: 08 September 2020
Accepted: 09 September 2020

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ABSTRACT

Background: Pharmacovigilance is proven as an effective monitoring mechanism for safety and efficacy of pharmaceutical products with the assistance of physicians, pharmacists, nurses, and other healthcare professionals to avoid undue physical, mental and financial suffering of patients. Thus, this study was conducted to assess awareness of pharmacovigilance among the healthcare service providers to evaluate the acquaintance, approach application (3A) of judicial reporting of ADRs and pharmacovigilance in a tertiary care teaching hospital in Dhaka.
Methods: A pre-tested questionnaire-based study was done among the 5th year medical students, interns, doctors and nurses of Holy Family Red Crescent Medical College, Dhaka, Bangladesh to assess the overall status of acquaintance (knowledge), approach (attitude) and application (practice) pharmacovigilance. Total 417 questionnaires were distributed and 389 were included as valid, compiled and analysed using SPSS version 25.0.
Results: Among the respondents, almost 78% of the nurses responded the right answers and doctors responded the lowest 29% on average. The average percentage of approach and application of pharmacovigilance was low in all the respondent groups. The poorest outcome was observed about reporting an adverse drug reactions (ADR) form by all respondents as 01% to 08%.
Conclusions: The overall status of pharmacovigilance in a tertiary teaching hospital was found paradoxically low, that revealed the necessity of much more initiatives at the undergraduate and postgraduate academic curriculum and intensive motivation, training, monitoring should be addressed to ensure the safety of medication, rationality of drug use and accomplish the national pharmacovigilance programs.

Keywords: Pharmacovigilance, ADR, Rational drug use, Drug safety, ADR reporting

INTRODUCTION

Pharmacovigilance is also termed as drug safety is defined by the WHO as the study of science and activity related to collection, assessment, detection and knowledge about the long term and short term adverse effects of a drug or any other drug related problems and also the prevention of these adverse effect particularly long-term and short-term adverse effects.[1] Drugs are the mainstay of treating diseases in this modern era. Various groups of drugs are used abiding the rationality. Recently, concerns have been broadening to include: Herbals, Traditional and complementary medicines, blood products, biologicals, medical devices, vaccines.[2] The burden on public health of ADRs remains significant. Adverse reactions tend to be viewed, incorrectly, as 'side effects' and thus as distractions from patients' and doctors' priorities.

Excessive use of medications leads to adverse effects. Drug errors and ADRs in hospitalized and out-patients are well known, and contribute significantly to morbidity, mortality. Most are inevitable, and can be avoided.

Pharmaco-economic research on the effects of adverse reactions show that governments spend large sums from health budgets to cover the resulting effects. In most countries the extent of this expenditure has not been measured.[3] To make rational and judicious selection of drugs, it is important for the prescriber to get aware of the amount and commonness of possible undesirable risks.

Safety and efficacy are two parameters that influence the rationality of drug use. No drugs are devoid of side effects. To make a therapeutic agent more acceptable, three phases of clinical trial and lastly, very critical post-marketing surveillance is done. Based on clinical trial, some of these are rejected from the market, some are accepted for use. To provide safest drugs, larger target population with longer time is required.[4] Pharmacovigilance aims at comparing the safety of various drugs, specifically recognizing the risk factors and leading to the evaluation of both the efficacy and the risk of pharmaceutical products. It provides timely communication and recommendations to regulatory authorities, clinicians, and conveying the selective information to users for ensuring the safe and the best use of medicines and monitoring the outcome of action previously undertaken. Pharmacovigilance is one of the essential components of patient care and the rational medication practice.[5] The major key of a successful pharmacovigilance relies on the involvement, understanding and reporting ADRs by all healthcare professionals including doctors, nurses, and pharmacists. The healthcare professionals must be aware of what to, how to and whom to report ADRs for the greater benefit of the patient.[6] Recognition of less apparent adverse effects requires professional alertness, accurate evaluation and a knowledge of the causality assessment concepts.

Health care practitioners are more likely to recognize and record important ADRs if they trust their ability to detect, control and avoid these reactions. Local pharmacovigilance centers and educational facilities play vital role in this by promoting the implementation of pharmacovigilance standards and methods. 7 With a relatively high number of recent high-profile drug recalls, the issue of monitoring for ADR has been posed by both the pharmaceutical industry and numerous regulatory agencies worldwide. No degree of care and vigilance, as a medication is sold and administered to large populations, may guarantee full safety at the clinical trial level. Thanks to the fact that clinical trials include at most several thousand patients; less common side effects and ADR are still unknown before a medication reaches the market. Some very severe ADR, such as liver damage, are often undetected for small size of study populations.

Post-marketing pharmacovigilance uses methods like data mining and case reports analysis to classify the product interactions and ADR. It is the duty of the regulatory agencies to provide a well-established pharmacovigilance program for tracking ADR during the process of drug production and during the lifetime of a marketed drug.[8] After the occurrence of Thalidomide catastrophe in 1961, WHO first established the pharmacovigilance program for international drug monitoring. Now, the WHO promotes this at the country level. More than 134 countries became part of this program now-a-days.[9] The Uppsala Monitoring Centre (UMC) in Sweden maintains the international database of the ADR reporting.

More than 94 countries throughout the world were technically supported by the WHO-UMC located in Sweden. Neighbouring country, India established National Pharmacovigilance Program with the help from the World Bank on 2004, which was re-modelled in 2010 with the long-term goal to establish a “Centre of Excellence” through collaboration with the WHO and UMC. In the year2013, India's contribution to the WHO-Uppsala Monitoring Centre's global drug safety database (Vigibase) was 2%.[10] In England, USA and Germany, the prevalence rate of ADRs was 3.22%, 5.64% and 4.78% respectively. About 3.6% of all hospital admission were due to ADRs, of which 0.5% ended in fatality9. Around 80 percent of older people taking antipsychotic medications do not have dementia or other disorders that warrant the use of these potent drugs, and many of these patients experience significant side effects from medicines that have been mistakenly administered. Drug-induced Parkinsonism has developed in 61,000 older adults also due to the use of other atypical or classical antipsychotic drugs such as haloperidol, chlorpromazine, thioridazine etc.[11] Pharmacovigilance is proven to be an effective monitoring mechanism for the protection of medicines in a country with the assistance of the country's doctors, pharmacists, nurses and other health professionals to prevent any undue physical, mental and financial distress of patients. In 1996, a cell was established in Bangladesh to support WHO in DGDA. An ADR advisory committee (ADRAC) of 10 members had been created by the Ministry of Health and Family Welfare in 1997. The objective of this was to evaluate and propose how to solve problems of ADRs.

Bangladesh became the 120th member country of WHO pharmacovigilance programs in December 2014, after reporting their 1st adverse reaction case report to Vigibase through Vigiflow.10. To build community understanding, insight into the gaps in information, attitudes and practices regarding pharmacovigilance is necessary. A very few base line studies were done in the past in Bangladesh on pharmacovigilance comprising a mixed group or multiple groups of people.

The importance of pharmacovigilance is safety and monitoring of medicinal products, drug monitoring, pharmaceutical preparations, adverse effects, adverse drug reaction reporting, product surveillance, post marketing, legislation is utmost. Thus, this study was conducted to assess awareness of pharmacovigilance among doctors, interns, 5th year students and stuff nurses

and to evaluate the acquaintance, approach towards judicial reporting of ADRs and application (3A) of pharmacovigilance in Holy Family Red Crescent Medical College and Hospital, Dhaka, Bangladesh.

METHODS

The study design was qualitative with a mix of descriptive, cross sectional and exploratory research design tools. The descriptive study design helps the researcher to collect information on the current state of the phenomenon while the exploratory design familiarizes the researcher with basic data, settings and observations about the issue not yet studied.

The a pre-tested questionnaire composed of both quantitative and qualitative variables was developed from previous studies by Thangaraju et al, Datta S et al and Ajoy et al validated through face and content validity techniques.[2,4,6] The face validity was achieved by giving the draft questionnaire to a few of the respondents (interns, doctors, nurses) in Holy Family Red Crescent Medical College and Hospital to assess whether the response looks meaningful, well designed and basic concepts of the construct. Information gathered from this exercise was used to refine and modify the questionnaire further.

The content validity was done by two independent scholars from public health and pharmacology to assess its appropriateness, extent, clarity and relevance to the study. The incorporated draft questionnaire was recast for ambiguity. The reliability of the validated questionnaire was ascertained by test retest method. The questionnaire was tested twice at two weeks' interval on five respondents from October 2019 to November 2019 in the institute who were involved in healthcare services. The responses were compared and the reliability coefficient determined (r=0.85). Ethical considerations were fulfilled by obtaining verbal consent and maintaining the confidentiality.

The study participants were 5th year medical students (66), interns (112), doctors of all faculties (90) and stuff nurses (149) in the hospital. Prior written informed consent was gathered from all participants explaining about the study and questionnaire, in brief. A sum total of 15 (nine related to acquaintance, two about approach and four related to application) validated and pretested 3A questionnaire was designed to evaluate the knowledge (acquaintance with pharmacovigilance), attitude (approach towards pharmacovigilance) and their practice (application of ADR reporting). Total 417 questionnaires were distributed, of which 389 were returned and included in the study as valid and completed response. The study protocol was approved by the Institutional Ethical Review Committee (IERC) of Holy Family Red Crescent Medical College, Dhaka, Bangladesh.

RESULTS

Out of 417 questionnaires, 389 were satisfactorily filled and were included for statistical analysis. Thus, the response rate was 93.28%. In the present study, a total of 389 health care professionals were assessed with 3A questionnaire about pharmacovigilance, of which males and females were 106 (27.3%) and 283 (72.7%), and the median age was 35.77 and 35.10 respectively. Among the respondents, 16.9% were 5th year students with median age of 24.20 years, interns 27.5% with median age 28.09, doctors 21.8% with median age 46.97 and nurses 33.6% with median age of 41.69 years as shown in Table 1.

Table 2 shows the details of the respondents' acquaintance with pharmacovigilance in nine questions and 78% of the nurses responded the right answers and doctors responded the lowest 29% on average. The average percentage of approach and application of pharmacovigilance was low in all the respondent groups. The poorest outcome was observed about reporting an ADR form by all respondents as 01% to 08%.

Statistically significant difference was observed by analysing the mean score of the respondents of four groups on the acquaintance with pharmacovigilance domain with p=0.00281 (significant at p<0.05) as shown in Table 3.

The overall comparative status in figure 1 shows that the doctors have low acquaintance but moderate application of pharmacovigilance, whereas nurses have high responses on acquaintance and moderate in application. Lowest average (29%) of acquaintance with pharmacovigilance was observed among doctor, approach was lowest.

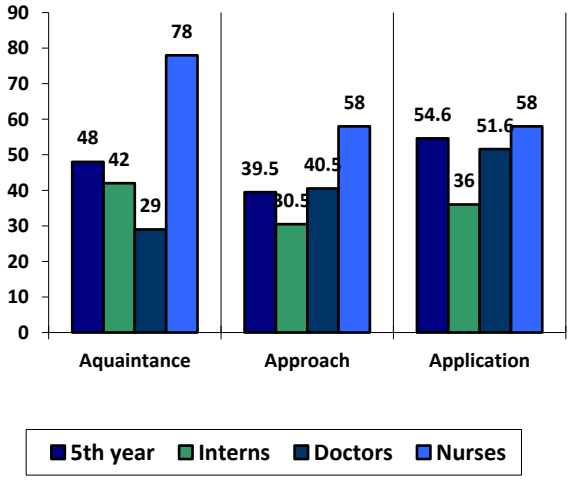

Figure 1: Comparative status of 3A of pharmacovigilance among different respondent groups.

Table 1: Details of the respondents.

Gender	n=389	Frequency (%)	Median age (years)	IQR
Male	106	27.3	35.77	24
Female	283	72.7	35.10	
Respondents				
Students	66	16.9	24.20	08
Interns	107	27.5	28.09	09
Doctors	85	21.8	46.97	22
Nurses	131	33.6	41.69	18

Table 2: Percentage of correct answers of the respondents in different domains.

Questions	Students (n=66) (%)	Interns (n=107) (%)	Doctors (n=85) (%)	Nurses (n=131) (%)
Acquaintance with pharmacovigilance				
Have you ever heard of pharmacovigilance?	90	67	73	99
Do you know what to report	54	35	32	93
Do you know how to report	44	05	31	86
Do you know whom to report	48	33	03	94
Is there any ADR monitoring center in your institution	10	03	01	61
Is there any National PV guideline in BD	45	42	21	83
Is there any International center for ADR monitoring	51	66	23	94
What you understand about PV is, to assess medication?	42	61	18	06
Who regulates the PV in Bangladesh?	48	74	67	88
Average percentage	48	42.8	29	78
Approach to pharmacovigilance				
Have you ever trained to report ADR form?	04	01	01	20
Do you think ADR reporting is your professional obligation?	75	60	80	96
Average percentage	39.5	30.5	40.5	58
Application of pharmacovigilance				
Do u know what is ADR reporting?	69	44	56	86
Have you ever reported any ADR form?	01	01	05	08
Should pharmacovigilance be taught to every healthcare professionals?	94	63	94	80
Average percentage	54.6	36	51.6	58

Table 3: Average mean score of acquaintance in different groups.

Variables	Students	Interns	Doctors	Nurses	Total
Σx	432	386	269	704	1791
Mean	48	42.88	29.88	78.22	49.75
Σx^2	24050	22154	13107	61908	121219
SD	20.3531	26.4549	25.1667	29.2394	30.2923
Statistical analysis					
Different groups	**SS**	**Df**	**MS**	**Inference**	
Between groups	11297.4167	3	3765.8056	The f-ratio=5.78817, p=0.002801	
Within groups	20819.3333	32	650.6042	The result is significant at p<0.05	
Total	32116.75	35			

DISCUSSION

Pharmacovigilance is a major and inseparable part of clinical research. The core principle is formed by vast knowledge of adverse effects. So far, we found, this is the first study involving the different levels of respondents related to healthcare service in a tertiary care teaching hospital in Bangladesh, as it included medical students, interns, doctors and nurses altogether in same set of questionnaires. The foremost thing to be noted in these types of studies is the response of the participants.

Few previous studies on knowledge, attitude and practice had reported a response rate of 55.33%, 61% and 83.5% among the healthcare professionals in India.[12,13] In this study, the rate of overall response was 93.28% in the tertiary care teaching hospital, which is a good sign and reflection of the keenness among the respondents which is comparable to other similar studies as Pimpalkhute et al and Ajay et al reported the response rate of 93.33% and 83.5% respectively.[14,6] On the other hand response rate were much less in studies done by Gupta et al (67.33%) and Hema et al (70%).[15,16] This high rate of response in present study might be due to inclusion of the 5th year medical students who tends to be more aware about pharmacovigilance.

The acquaintance level with pharmacovigilance was found to be poor in this study. Only 29% of the doctors were found to have overall knowledge of pharmacovigilance, whereas 78% of nurses showed better acquaintance with the knowledge. The overall level of knowledge was good in nurses. Whereas relatively poor in 5th year students, less in interns and poor in doctors.

In case of 5th year students, they are taught ins and out about pharmacovigilance in Pharmacology lectures and tutorial classes, so their response is relatively good. On the other hand, interns almost forgot about theoretical knowledge of pharmacovigilance, and due to under-reporting of ADRs, their knowledge gets poorer. In doctors due to lack of practice and not attending CME and workshops and of course owing to their reluctant attitude, their performance was the poorest. Similarly, a study conducted by Dikshit et al. reported that 70% of the respondents were unaware of where to report.[17] In this study most of the respondents don't know what to report, how to report and whom to report. In another study done by Bepari et al showed that higher number of the respondents do not know what to report and whom to report.[18] The present study revealed that students, interns and doctors were unaware of ADR monitoring center of their respective institution.

As a medication is sold and administered to large populations, no defined level of care and vigilance can guarantee full safety at the pre-clinical and clinical test levels. Thanks to the fact that clinical trials include at most several thousand patients; uncommon side effects and ADRs are still unknown before a medication reaches the market. Also, very serious ADR, such as damage to the liver, are often undetected as the sample population is limited.

It is the immense responsibility of doctors, nurse, pharmacist, interns, post-graduate, even the patients to report ADRs. But unfortunately, Bangladesh is lacking the formal targeted teaching and training to detect and report ADRs as well as no research to monitor ADRs among health professionals.

In this context, to increase the overall awareness about pharmacovigilance, educational intervention may play a vital role for acquaintance with pharmacovigilance by attending educational workshops, CME's (continuous medical education), seminars and clinical meetings at on regular basis.[19] The task of pharmacovigilance centers is intended to enhance the capacity of national pharmacovigilance centers (PVCs) to detect, evaluate and provide recommendations for preventing or minimizing patient-damaging medication errors. This is also intended to model collaboration between national pharmacovigilance centers and patient safety organizations (PSOs) to coordinate together to mitigate preventable medicinal harms.

CONCLUSION

Academic knowledge of pharmacovigilance, the national pharmacovigilance program and its activities should be given more weightage in undergraduate and postgraduate curriculum to be acquainted with pharmacovigilance at student level. Visiting the pharmacovigilance centers during training, the hands-on reporting of ADRs can be much helpful to sensitize the doctors to feel comfortable with the approach and application of pharmacovigilance in practice.

ACKNOWLEDGEMENTS

Author would like to thank all the respondents including the 5th year students (HF-17) for their voluntary participation in the study. Also extend gratitude and thanks to all the faculty staff including Dr. Khandaker Abu Talha and Dr. Mithila Ahmed for their extended co-operation and support.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Nasir M, Zahan T, Farha N, Chowdhury ASM S. Acquaintance, approach and application of pharmacovigilance: questionnaire based study at a tertiary care teaching hospital in Dhaka. Int J Basic Clin Pharmacol 2020;9:1497-502.