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KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE IN BASAVESHWAR TEACHING AND GENERAL HOSPITAL, GULBARGA

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ABSTRACT: CONTEXT: Adverse Drug Reactions (ADRs) are a growing problem throughout the world causing significant patient morbidity and mortality, therefore, its monitoring has become exceedingly important in today's practice of medicine. In a country with limited medical and financial resources such as ours, eliminating or even reducing this potential source of morbidity and mortality is a worthy challenge. The primary source of information for pharmacovigilance is from spontaneous reporting by health care professionals. Spontaneous reporting of ADRs has played a major role in the detection of unsuspected, serious and unusual ADRs previously undetected during the clinical trial phases. The Pharmacovigilance Program of Indian (PvPI) was started with an aim of generation of ADR database in the Indian population subset. One of the major hurdles faced by PvPI was the under-reporting of ADRs. India, with its sizeable population and varied diseases and treatments, is still not a major contributor to the international ADR database. **AIMS:** The aim of our study is to deduce by a survey the knowledge, attitude and practice of pharmacovigilance amongst the various cadres of medical healthcare professionals (interns, postgraduate students and teaching faculty) in a tertiary care hospital. As spontaneous reporting forms the backbone of pharmacovigilance, especially in developing countries like India which lack a more structured approach, proper training in the know-hows of ADR reporting is mandatory for the healthcare professionals at the grass root level. We intend to investigate whether our healthcare professionals are inclined to, and are properly equipped to spontaneously and properly report ADRs. **METHODS AND MATERIALS:** This questionnaire based survey was conducted in Basaveshwar Teaching and General Hospital (BTGH), attached to M.R Medical College, Gulbarga, Karnataka. The study was conducted in the month of March-April 2014 on a total of one hundred (100) participants, comprising of interns, postgraduate students and teaching faculty of various clinical departments of BTGH. The study instrument was a pre designed questionnaire which was structured to obtain information on the knowledge of the ADRs reporting, the attitudes towards the reporting, and the factors that in practice could hinder the reporting among the doctors. **RESULTS AND CONCLUSION:** Our study revealed that the doctors in this tertiary care hospital were inadequately aware about the aim and methods of pharmacovigilance. Moreover, the primary tool of pharmacovigilance, that is spontaneous ADR reporting, was poorly understood by a vast majority of the participants. The International landscape of pharmacovigilance has changed from "reactive" nature, where it looked into safety as a mere regulatory requirement, to a more "proactive" approach which helps get safer drugs in the market.

KEYWORDS: Pharmacovigilance, ADR monitoring, spontaneous reporting, KAP survey.

INTRODUCTION: Every drug has an effect and maybe a side effect. It is only the dose and the situation that determines it. Adverse drug reaction (ADR) as defined by WHO is "a response to a drug

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which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.”¹

According to the WHO Collaborating Centre for International Drug Monitoring, “Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems”.

ADRs are a growing problem throughout the world causing significant patient morbidity and mortality, therefore, its monitoring has become exceedingly important in today's practice of medicine. In a country with limited medical and financial resources such as ours, eliminating or even reducing this potential source of morbidity and mortality is a worthy challenge.

Pharmacovigilance is applicable to both marketed products and even those under clinical development.² Data collection; processing and analysis form the pillars of classical pharmacovigilance. The primary source of information for pharmacovigilance is from spontaneous reporting by health care professionals. Spontaneous reporting of ADRs has played a major role in the detection of unsuspected, serious, and unusual ADRs previously undetected during the clinical trial phases.³

This has led to the withdrawal of many drugs in the recent past, i.e., rofecoxib, rosiglitazone, cisapride, terfenadine. When data communication and risk assessment are added to the equation of classical pharmacovigilance, we enter the field of advanced pharmacovigilance.

The Uppsala Monitoring Centre (UMC, WHO), Sweden, maintains the international database of the adverse drug reaction reports. The Pharmacovigilance Program of India (PvPI) was started with an aim of generation of ADR database in the Indian population subset.⁴ One of the major hurdles faced by PvPI was the under-reporting of ADRs. India, with its sizeable population, varied diseases and treatments, is still not a major contributor to the international ADR database.

It is estimated that only 7-10% of ADRs are actually reported to the regulatory authorities.⁵ This under-reporting presents a serious challenge to pharmacovigilance as ADR reporting, whether spontaneous or structured, forms the backbone of the pharmacovigilance program.

The aim of our study is to deduce by a survey the knowledge, attitude and practice of pharmacovigilance amongst the various cadres of medical healthcare professionals (interns, postgraduate students and teaching faculty) in a tertiary care hospital. This assessment will aid us to aptly identify any glaring discrepancies which have led to our lack lustre pharmacovigilance reporting system.

As spontaneous reporting forms the backbone of pharmacovigilance, especially in developing countries like India which lack a more structured approach, proper training in the know-hows of ADR reporting is mandatory for the healthcare professionals at the grass root level. We intend to investigate whether our healthcare professionals are inclined to, and are properly equipped to spontaneously and properly report ADRs.

MATERIALS AND METHODS: The questionnaire based survey was conducted in Basaveshwar Teaching and General Hospital (BTGH), attached to M R Medical College, Gulbarga, Karnataka, after obtaining prior permission from the Institutional Ethics Committee. The study was conducted in the month of March-April 2014 on a total of one hundred (100) participants, comprising of Interns, Postgraduate students and Teaching faculty of various clinical departments of BTGH.

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The study instrument was a pre designed questionnaire which was structured to obtain information on the knowledge of the ADRs reporting, the attitudes towards the reporting, and the factors that in practice could hinder the reporting among the doctors. The survey questionnaire was provided to the doctors and was collected the same day so as to avoid any missing forms/dropouts. To exclude any potential bias, the name disclosure on the questionnaire was made optional.

STATISTICAL ANALYSIS: The KAP (Knowledge, attitude and practices) questionnaire was assessed and analyzed and data was presented as percentages.

RESULTS: A total of 100 survey questionnaires (with 12 questions each) were reviewed. Since all forms were duly collected back the same day of distribution, we observed a 100% feedback response.

Figure 1: Deals with the demographic aspects, out of a total 100 contributors, the majority (48%) were interns.

Figure 1

Figure 2: This sought information regarding the basic definition of pharmacovigilance. A majority (64%) of the doctors had a basic idea about pharmacovigilance and what it deals with.

Figure 2

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Figure 3: This investigated the meaning of post-marketing surveillance. 59% of the respondents rightly answered the implication of post-marketing surveillance.

Figure 3

Figure 4: This question investigated the knowledge of the respondents about PvPI. A majority (70%) stated that they were knowledgeable about its existence.

Figure 4

Figure 5: This question sought information regarding location of headquarters of PvPI. Interestingly, most of the responders answered this question wrong as AIIMS, New Delhi rather than CDSCO, New Delhi.

Figure 5

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Figure 6: This question sought responders' reply on the existence of pharmacovigilance centre in their states. 46% of the responders were not sure of the answer.

Figure 6

Figure 7: This question investigated the knowledge of responders about the reporting time of ADRs to the regulatory authority. 40% of the people replied as 7 days, which pertains to the earlier set guidelines. The new regulation involving reporting of ADR by investigator within 24 hours was correctly mentioned by a mere 23 people.

Figure 7

Figure 8: This question investigates the availability of Suspected ADR reporting forms in BTGH. A majority (43%) of the responders were unaware of such a form.

Figure 8

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Figure 9: To establish further whether the responders had actually seen and dealt with this form, it was asked which body issues this form. An equal number of responders (43% each) replied AIIMS and CDSCO.

Figure 9

Figure 10: The next 3 questions pertain to the attitude towards pharmacovigilance. This question asks whether or not PV reporting should be compulsory. 90% of the replies indicated that yes it should be mandatory.

Figure 10

Figure 11: This question asks whether a pharmacovigilance monitoring centre should be set up in BTGH, Gulbarga. A majority (85%) stated that yes they wanted a monitoring centre should be set up in this institution.

Figure 11

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Figure 12: This question asks how many centers in their opinion are apt for any city/town. 65% of the responders wanted establishment of 1-3 centers/city or town.

Figure 12

Figure 13: This question deals with the practice of pharmacovigilance. It asks about the factors discouraging participation in the pharmacovigilance program. 41% of the responders replied that bureaucratic hassles were the biggest deal breaker in their opinion.

Figure 13

DISCUSSION: The science of pharmacovigilance has come a long way from the ignominious thalidomide tragedy in the late 1950s to the more recent rofecoxib and rosiglitazone controversy. Though the developments in this field have been stupendous, much work needs to be done at the grass root level. Education of doctors, nurses, pharmacists and other healthcare professionals is a must.

Our study revealed that the doctors in this tertiary care hospital were inadequately aware about the aim and methods of pharmacovigilance. Moreover, the primary tool of pharmacovigilance, that is spontaneous ADR reporting, was poorly understood by a vast majority of the participants. Underreporting of ADRs is a worldwide phenomenon and this has been established from previous

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studies.⁶ Thus, our aim as pharmacologists should be the imparting of accurate and precise knowledge about this program to all healthcare professionals involved in patient care.

Our study involved 100 participating doctors from BTGH, Gulbarga. Figure 1 of this study shows that a major chunk of the participants were Medical Interns (48%), and Teaching Faculty accounted for a mere 13%. As Interns are the primary communication bridge between patients and doctors, their enrolment in our study was very important.

Figure 2 of the study reflects that 64% of the respondents knew what pharmacovigilance actually deals with. However, a quarter of the participants confused it with drug cost monitoring. Ramesh et al⁷ and Gupta et al⁸ in their respective studies found adequate knowledge but poor practice of ADR reporting in Mysore and Mumbai respectively, however our study in Gulbarga finds a deficiency in both the criteria.

Figure 3 of the study concurs that 59% of the times the preferred method employed by drug companies for ADR monitoring was post-marketing analysis. Only 3 people acknowledged the role of spontaneous reporting in this regard.

Figure 4 of the study in concordance with the study by Pimpalkhute et al⁹ brings to our notice that 70% of the participants were aware of the existence of PvPI. Though it's a clear majority, we need to work harder so to better sensitize and that the awareness regarding PvPI is known by all healthcare professionals.

Figure 5 showed a prevalence of confusion regarding the headquarters of PvPI. The participants were almost equally confused about CDSCO, New Delhi and AIIMS, New Delhi.

Figure 6 tackled the awareness of the presence of a PV centre in the respondents' state. The most common answer received was not sure (46%) in this regard. Thus better dispensing of knowledge and information is of utmost importance.

Figure 7 deals with the time frame for reporting an ADR. 40% of the participants considered 7 days to be the stipulated time frame for reporting to regulatory authorities while only 23% correctly knew the new guidelines requiring reporting to be done within 24 hours. This being a recent amendment in the PvPI, it is expected that healthcare professionals will slowly but surely become aware of these changes and incorporated this knowledge to their ever increasing armamentarium.

Figure 8 duly reflects that a majority of the participants had either not seen (43%) or were unaware (24%) about the ADR reporting form. This shows a vital shortcoming in the current teaching pattern as spontaneous reporting can only be initiated if the healthcare professionals are well versed with the ADR reporting form. Since so many participants were not well versed with the ADR reporting form that's why, according to figure 9, they were confused regarding the authority issuing these forms in India.

Figure 10 shows a positive picture in the sense that 90% of the participants feel that PV reporting should be made compulsory. This shows a bright future for the field and is also highlighted by studies by Tabali et al and Hardeep et al.^{10,11}

Eighty five participants wanted the setting up of a pharmacovigilance monitoring centre in BTGH, Gulbarga as stated in figure 11. Figure 12 show that 65% participants felt that 1-3 monitoring centres should be present in all cities/towns.

Figure 13 deals with the practice of pharmacovigilance. Exactly, it tries to identify the hindrances faced by the doctors which prevent them from voluntarily and correctly reporting ADRs. A majority (41%) stated bureaucratic hassles as the biggest road bump in this regard. This was

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followed by time consuming and institutional restrictions. Lack of monetary remuneration was at the bottom of the list. These factors have also been documented in a study by Inman regarding attitudes to ADR reporting.¹²

In order to generalize our findings, it is imperative that similar studies be done in other teaching hospitals of the country as well. Such studies can give us a better picture regarding the prevailing scenario and can tell us about the necessary steps to be taken to alleviate the problems.

Limitations of the study: Due to time and financial constraints we were able to include a sample size limited to one hundred participants. Our study was limited to interns, postgraduate medical students and medical teaching faculty only, however, it would have proved even more beneficial if paramedical staff such as nurses and pharmacists also could have been included in it.

SUMMARY: Our study revealed that the doctors in this tertiary care hospital were inadequately aware about the aim and methods of pharmacovigilance. Moreover, the primary tool of pharmacovigilance, that is spontaneous ADR reporting, was poorly understood by a vast majority of the participants.

The International landscape of pharmacovigilance has changed from “reactive” nature, where it looked into safety as a mere regulatory requirement, to a more “proactive” approach which helps get safer drugs in the market. Currently, Pharmacovigilance is poised to overcome many hurdles in its path to become one of the most important bridges between patients, healthcare professionals and the pharmaceutical industry for a safer healthcare system.

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