Journal of Advances and Scholarly Researches in Allied Education
Vol. 18, Issue No. 3, April-2021, ISSN 2230-7540

Assessment of Knowledge, Attitude and Practice of Pharmacovigilance and Adverse Drug Reaction

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Abstract – Adverse Drug Reactions (ADRs) underreporting is a great challenge to pharmacovigilance. Healthcare professionals should consider ADR reporting as their professional obligation because the effective system of ADR reporting is important to improve patient care and safety. This study was designed to assess the knowledge, attitude, practice and factors associated with ADR reporting by healthcare professionals (physicians and pharmacists) in secondary and tertiary hospitals of India.

Keywords – Adverse drugs Reactions, Attitude, Knowledge, Pharmacovigilance, Practices and Spontaneous ADR Reporting.

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INTRODUCTION

WHO characterizes adverse drug reaction (ADR) as any reaction to a medication which is harmful and unintended, and which happens at measurements typically utilized as a part of man for prophylaxis, analysis or treatment of illness or for the alteration of physiological capacity. Antagonistic medication responses are negative outcomes of medication treatment. They are one of the main sources of grimness and mortality. It has been assessed that around 2.9-5.6% of all clinic affirmations are because of ADRs and upwards of 35% of hospitalized patients encounter an ADR amid their hospitalization. An unconstrained revealing of ADRs has remained the foundation of pharmacovigilance and is imperative in keeping up tolerant wellbeing. In India, all social insurance experts including specialists, medical caretakers, and drug specialists can report an ADR by filling an ADR type of the Central Drugs Standard Control Organization. The dynamic interest of social insurance experts in the pharmacovigilance program can enhance the ADR revealing.

The ADR revealing rate in India is underneath 1% contrasted with the overall rate of 5%. One reason for low reporting rate in India might be an absence of learning and sharpening towards pharmacovigilance and ADR among health care professionals (HCPs). The examination likewise demonstrated that the normal cost associated with treating these ADRs was INR 900/ - per patient. In India, Pharmacovigilance is still in early stage and there exists very limited knowledge about this discipline. Inadequate funds, lack of trained staff, and lack of awareness about detection, communication, and spontaneous monitoring of ADRs may be the reason; gross underreporting of ADRs is a cause of concern.

The market today is flooded with an enormous number of drugs for various ailments. The Pharmaceutical industries are busy innovating testing and manufacturing new drugs day in and day out, such that 45 drugs gained FDA approval in 2015 and 41 new drugs were launched in 2014 every year on an average. Before the drugs are marketed, they undergo stringent measures to assess their safety profile; still, certain unusual, rare, serious adverse drug reactions may go undetected at this level. This applies more to newer drugs which may lead to severe adverse drug reactions which may not have come to light yet owing to a short span of their use. ADRs (adverse drug reactions) are responsible for about 5 % to 20% of hospital admissions. About 2.9% ADRs lead to hospitalization and approximately 6.3% ADRs develop while one is in the hospital. One third of these ADRs are preventable.

In India, National Pharmacovigilance Centre (NPC) has been formed which is an active participant in the on-going activities of UMC and in the past years, the PV programme has gained momentum such that the reporting rates from India have increased from 0.5% to 2%, still these figures are very low as compared to other countries. All healthcare professionals can report an ADR by filling an ADR reporting form provided by CDSCO (Central Drug Standard Control

Organization). Still, under reporting is highly prevalent. An important part in this under reporting is played by the lacunae in the knowledge (especially lack of knowledge of how and whom to report about ADRs) and attitude of various health care professionals towards monitoring and reporting of ADRs. The success of a PV program depends upon the active involvement of the healthcare professionals such as doctors, pharmacists, nurses and can greatly reduce the burden on limited health care resources in developing countries like India.

Increasing health professional and student participation in national medication reporting programs remains an important goal in promoting safe health care practices. Opportunities for improvement in pharmacy curricula and practice sites toward interactive experiences with reporting programs should be continually evaluated. Thus, early identification of ADRs is extremely important for both government and non-government health care organizations.

Pharmacovigilance (PV)

Pharmacovigilance is concerned with only two outcomes: safety and efficacy. Does a drug work and is it safe? It touches on almost every aspect of the drug lifecycle - from preclinical development to post-market surveillance - making it one of the most fundamental functions within a life science company.

Pharmacovigilance – also known as drug safety - is a broad term that describes the collection, analysis, monitoring and prevention of adverse effects in drugs and therapies. It is a completely scientific and process-driven area within pharma.

The definition of an adverse event is any reaction within a patient's body caused by a drug/candidate molecule – a side effect. A serious adverse event is a life-threatening side effect that causes hospitalisation, incapacity, permanent damage or, in extreme cases, the death of a patient. Adverse event reporting is mandatory for all clinical research investigators, even if the side effects are only suspected.

The role of pharmacovigilance is to determine which adverse events cross the line of a drug's efficacy. In other words, analysing which side effects are worth the risk to patients compared with how effective they are at treating a disease. For instance, chemotherapy is known to cause some very serious side effects but when faced with life-threatening cancer, these side effects are considered acceptable given the potential to cure a patient. However, if a drug used to cure a headache caused similar side effects, the risk to the patient would be considered too great and the benefit not substantial enough to justify the potential damage.

Main areas of pharmacovigilance

Pharmacovigilance is a huge and encompassing discipline, but we can broadly divide pharmacovigilance into four main sub-specialisms:

Operations:

This sector is where many life science professionals interested in drug safety jobs will begin their career. Typical jobs within drug safety operations include case processor, drug safety officer/associate and drug safety manager, and of course team lead and directorships. These professionals will collect and record information during preclinical development and clinical trials, in addition to gathering real world evidence (RWE) of adverse events reported by doctors and patients post-market. Operations are also usually responsible for creating standard operating procedures (SOPs), individual case study reports, literature screening and regulatory expedited reporting.

Surveillance:

Professionals who focus more within surveillance tend to look towards risk management and signal detection jobs. This also involves performing analysis of the data collated by the wider division. Professionals in this area can hold an array of titles, the most common of which are pharmacovigilance scientist and drug safety physician, but like in all teams, there are many degrees of seniority and remit available. These professionals perform analysis on the drug safety information gathered by the wider department and assist with the creation and review of aggregate reports. They also create development safety update reports (DSURs) for drugs in clinical research, and periodic benefit risk evaluation reports (PBRER) for post-market drugs. These reports ultimately help the team to draw conclusions around the safety and efficacy of a drug or candidate molecule.

Systems

This division is concerned with the building and ongoing development of a fully robust and innovative system, charged with the responsibility for housing and is usually collated by those working in operationally focused roles, but is accessed by all. The systems division constantly has to improve, and stay in line with, changing regulations and requirements for the business/ health authorities, making this a very challenging and vital aspect of drug safety.

Qualified Person for Pharmacovigilance (QPPV)

QPPVs jobs are mainly concerned with marketed drugs and those about to be authorised, but as QPPVs are considered by many to be subject matter experts, their expertise is utilised across the

discipline and wider business. These senior pharmacovigilance roles will only be held by very experienced professionals and their focus is to understand, plan for and advise upon the regulations and requirements that companies must adhere to across the EU. This is a highly strategic appointment and one of great importance.

Fortunately for drug safety professionals, there are several pharmacovigilance jobs available to them due to the different types of companies within life sciences, including global pharmas, small pharmas, generics companies, drug safety consultancies and health authorities. Each offers slightly different opportunities but in every case, there is plenty of scope for professionals to progress their pharmacovigilance career.

Importance of pharmacovigilance

Pharmacovigilance is arguably the most essential function within a life science company. To develop, manufacture and commercialise a drug a company must adhere to strict regulations. Many of these regulations will focus on the patient's safety and the added benefit to the patient derived from the drug. This, in a nutshell, is the mission of drug safety and highlights why this discipline plays such a central and important role within pharmaceuticals.

Patient safety and continuous vigilance

By definition, drug safety ensures that a patient's safety and wellbeing is safeguarded throughout the entire drug development lifecycle, including when the drug is readily available on the market. Indeed, drugs are continuously monitored for other side effects on patients, and any new data is collected and reported to health authorities on a regular basis. While other areas focus on improving patient lives in everything that they do, no other department has such a sharp focus on patient safety as an end-point.

Power and authority

This continuous vigilance does mean that, alongside others in the business, senior leaders within a drug safety team have the responsibility and authority to recommend that a development process is stopped, or that an approved drug is pulled from the market. EU QPPVs are especially important in this process, and again this goes to demonstrate the importance and central role of drug safety.

Keeping it moving

In many ways, drug safety helps to keep the wheels of a pharmaceutical company moving. The nature of drug safety means that it works on a very cross- functional basis. Therefore, the influence and value which the division can add to other aspects of the business is tremendous.

Adverse event reporting

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. The following are several facets of AE reporting:

Individual Case Safety Report (ICSR)

One of the fundamental principles of adverse event reporting is the determination of what constitutes an Individual Case Safety Report (ICSR). During the triage phase of a potential adverse event report, it is important to determine if the "four elements" of a valid ICSR are present: an identifiable patient, an identifiable reporter, a suspect drug, and an adverse event.

If one or more of these four elements is missing, the case is not a valid ICSR. Although there are no exceptions to this rule there may be circumstances that may require a judgment call. For example, the term "identifiable" may not always be clear-cut. If a physician reports that he/she has a patient X taking drug Y who experienced Z (an AE), but refuses to provide any specifics about patient X, the report is still a valid case even though the patient is not specifically identified. This is because the reporter has first-hand information about the patient and is identifiable (i.e. a real person) to the physician. Identifiability is important so as not only to prevent duplicate reporting of the same case, but also to permit follow-up for additional information.

The concept of identifiability also applies to the other three elements. Although uncommon, it is not unheard of for fictitious adverse event "cases" to be reported to a company by an anonymous individual (or on behalf of an anonymous patient, disgruntled employee, or former employee) trying to damage the company's reputation or a company's product. In these and all other situations, the source of the report should be ascertained (if possible). But anonymous reporting is also important, as whistle

blower protection is not granted in all countries. In general, the drug must also be specifically named. Note that in different countries and regions of the world, drugs are sold under various trade names. In addition, there are a large number of generics which may be mistaken for the trade product. Finally, there is the problem of counterfeit drugs producing adverse events. If at all possible, it is best to try to obtain the sample which induced the adverse event, and send it to either the EMA, FDA or other government agency responsible for investigating AE reports.

If a reporter can't recall the name of the drug they were taking when they experienced an adverse event, this would not be a valid case. This concept also applies to adverse events. If a patient states that they experienced "symptoms", but cannot be more specific, such a report might technically be considered valid, but will be of very limited value to the pharmacovigilance department of the company or to drug regulatory authorities.

Coding of adverse events

Adverse event coding is the process by which information from an AE reporter, called the "verbatim", is coded using standardized terminology from a medical coding dictionary, such as MedDRA (the most commonly used medical coding dictionary). The purpose of medical coding is to convert adverse event information into terminology that can be readily identified and analyzed. For instance, Patient 1 may report that they had experienced "a very bad headache that felt like their head was being hit by a hammer" [Verbatim 1] when taking Drug X. Or, Patient 2 may report that they had experienced a "slight, throbbing headache that occurred daily at about two in the afternoon" [Verbatim 2] while taking Drug Y. Neither Verbatim 1 nor Verbatim 2 will exactly match a code in the MedDRA coding dictionary. However, both quotes describe different manifestations of a headache. As a result, in this example both quotes would be coded as PT Headache (PT = Preferred Term in MedDRA).

NEED OF THE STUDY

The most serious ADRs lead to hospitalization, and hospital stays can lead to further ADRs. Hence, HCPs and hospitals can play a significant role in minimizing ADR-related morbidity and mortality. HCPs can play multiple roles by carefully reviewing the full patient history, particularly the drug allergy and drug-drug interaction history, to avoid any unwanted ADRs. In addition, reporting ADRs to the responsible office at their hospital or the regulatory authority is a pharmacovigilance approach that can be used to minimize ADRs because reporting ADRs can increase HCPs' awareness of reactions, which could result in the avoidance of particular drugs, thus reducing the harm associated with reactions to particular drugs.

Several drugs have been withdrawn from the market as a result of HCPs reporting ADRs. However, understanding the knowledge and practice of health care professionals regarding ADR reporting is very important for enhancing the reporting of ADRs.

Therefore, the present study is undertaken to determine the current status of ADR reporting and also to investigate knowledge and attitude of particularly nursing staffs towards pharmacovigilance and ADR reporting.

AIM ANDOBJECTIVES

AIM

- To assess the knowledge, attitude and practice of pharmacovigilance and adverse drug reaction reporting among nursing staffs.

OBJECTIVES

- To assess the knowledge of pharmacovigilance towards adverse drug reaction reporting
- To assess the attitude and practice towards adverse drug reaction reporting
- To determine the factors that encourages the study subjects to report adverse drug reaction
- To evaluate the factors that discourages the study subjects not to report adverse drug reaction

METHODOLOGY

Study site

- The study was conducted in 3 different multi-speciality hospitals, at Chennai.

Study design

- Cross sectional, questionnaire based study

Study setting

- This study was conducted from December 2017 to August 2018 for a period of 10months.

Study sample

- The study sample size was300.

Inclusion criteria

- Nurses

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- Any age group

Exclusion criteria

- Other health care professionals
- Study participants with unwillingness are excluded

Study tools

The study questionnaire was prepared for incorporating participant's demographic details like age, gender and designation and working experiences. In KAP, Knowledge part of the questionnaire included sixteen questions that were used to measure the knowledge of nurses related to ADR and pharmacovigilance such as definition, awareness, purpose of ADR, PV, reporting system, regulatory body etc. The attitude part comprised of eight questions about their thoughts and views related to ADR and reporting. Attitudes related questions were developed in 5-point likert scale. The practice part of questionnaire included three questions such as type, nature, methods for ADR reporting. Finally the fifth section was limited to two questions with the help of which factors encouraging and discouraging to nurses to report ADR were determined.

DATA COLLECTION

A structured pretested questionnaire was prepared. After pilot-scale testing, the questionnaire was modified. After obtaining approval from IEC and hospital authority, a questionnaire was distributed to nursing staffs. Participants were explained about the purpose of the study. Those who showed interest to participate in the study were requested to fill the questionnaire in 30 min with ensured confidentiality. The responses to the questionnaire were analyzed, categorized and presented in percentages.

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