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ATTITUDE AND PRACTICE OF ADVERSE DRUG REACTION REPORTING AMONG PRESCRIBERS:

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Abstract:

Aim and Objectives:

The present study was undertaken to evaluate the knowledge, attitude, and practices (KAP) regarding ADR reporting among prescribers.

Materials and methods:

A pretested KAP questionnaire comprising of 17 questions was administered to 63 prescribers. The questionnaires were assessed for their completeness and the type of responses regarding ADR reporting.

Result and discussion:

A total of 63 prescribers completed the survey. ADR reporting was considered important by 51.9 % of the respondents; primarily to share Information about ADR with colleagues(37.3%). A majority of the respondents opined that they would like to report serious ADRs (31.1%). 93.3% of the prescribers had reported ADRs in their practise. Preferred methods for reporting were post(32.2%).

Conclusion:

The prescribers are aware of the ADRs and the importance of their reporting. However, under reporting and lack of knowledge about the reporting system are clearly evident. Creating awareness about ADR reporting and devising means to make it easy and convenient may aid in improving spontaneous reporting.

Introduction

Pharmacovigilance deals with drug safety and focuses on adverse drug reaction (ADR) which is defined as “a response to a drug 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” (7)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(4).Adverse drug reactions (ADRs) affectirrespective of the age group of patients worldwide with varying magnitude of causing morbidity and mortality.(1)Most important things are more and more new drugs are being introduced, which include new chemical entities (NCE), vaccines and new dosage forms, new routes of drug administration, and new therapeutic claims of existing drugs.(2) The success of a pharmacovigilance program depends upon the involvement of the healthcare professionals and reporting the ADRs. Being the key healthcare professionals, the doctors, nurses and pharmacists have immense responsibility in reporting ADRs and strengthening the pharmacovigilance mechanisms that exists in their vicinity. Although pharmacovigilance programs are successful in improving drug use patterns, under- reporting of ADRs is felt as a major problem.10 There is also strong evidence of significant and widespread under-reporting of ADRs to spontaneous reporting systems including serious or severe ADRs.(5) One reason for the lack of awareness about the detection, communication, and reporting of ADRs, because there is no intensive teaching about ADR reporting in the undergraduate curriculum and no periodic reinforcement of ADR monitoring in internship and postgraduate studies.(6) Each country has set their own set of guidelines on pharmacovigilance for detection, collection, assessment of adverse events in their corresponding regions.(8)Problems of motivating reporters, commitment, and lack of clarity about what should be reported and fear of recrimination for errors may be some of the factors responsible. The success of a pharmacovigilance program depends upon the involvement of the healthcare professionals and reporting the ADRs.(9)

Various methods of detecting an adverse event include spontaneous reporting, prescription event monitoring (PEM) and others.(10) ADRs have a major impact on public health by imposing a considerable economic burden on the society and the already- stretched health-care systems.(14) Several studies have been conducted to evaluate the knowledge, attitude and practice (KAP) towards pharmacovigilance activity among doctors, pharmacists or nurses in various countries [21, 22]. Further, Rehan, et al. [22]concluded in their study that resident doctors and nurses had good knowledge and awareness on ADR reporting; however there is need of improvement in their practices. Amrita and Singh, [23] concluded in their study that the rate of reporting to ADR monitoring centres (AMC) by doctors was low despite having good observation and knowledge of ADR. Subish, et al. [24] conferred in their study that majority of the health care professionals felt ADR monitoring to be important, but only a few had ever reported an ADR to the pharmacovigilance centre. The authors have reported that, the reasons for under-reporting were either they did not come across an ADR or a few were unaware of the existence of a pharmacovigilance centre at the hospital. Hajebi, et

al.[25] concluded that, it is necessary to offer continuous ADR related educational programs. The study was a humble attempt taken in that direction and it was endeavoured to assess the level of knowledge, attitude, and the practices of pharmacovigilance among the doctors.The burden of ADRs may be due to the deficits in the practice of ADR reporting by health care professionals. And these deficits include the factors which influence the under-reporting of ADR like, lack of awareness on reporting, extra work and the lack of time .

The specific objectives of Pharmacovigilance

i. To improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions.

ii. To improve public health and safety in relation to the use of medicines.

iii. To contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more cost-effective use.

iv. To promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public(13)

Materials and Methods:

A pretested KAP questionnaire comprising of 17 questions was administered to 63 prescribers. The questionnaires were assessed for their completeness and the type of responses regarding ADR reporting.

Study design: The study conducted was a cross-sectional, questionnaire-based study.

Study setting:The study was conducted among general surgeons and dental surgeons in Chennai during a period of November 2016- January 2017.

Study procedure: Prior permission was obtained from the doctors for conducting the study. The purpose of the study was explained to the doctors and confidentiality was ensured. After obtaining informed consent, they were asked to fill up a printed, semi-structured questionnaire. The questionnaire contained questions regarding knowledge of pharmacovigilance, its definition, purpose, methodology of

reporting ADRs, Centres of PV. Attitude towards reporting ADRs and factors discouraging them from reporting ADRs, whether they have come across with any ADRs, awareness about ADR

format, any ADRs reported recently, any proper medication history taken and whether they give ADR information of the prescribed drug to the patient.

Statistical analysis: The returned questionnaires were checked for completeness of data. Descriptive data were expressed as percentages.

Result and Discussion:

A total of 63 prescribers completed the survey. ADR reporting was considered important by 51.9 % of the respondents; primarily to share Information about ADR with colleagues(37.3%). A majority of the respondents opined that they would like to report serious ADRs (31.1%). However, only 93.3% of the prescribers had reported ADRs previously. Preferred methods for reporting were post(32.2%).

1) Name
2) Speciality
3) Designation
4) Email id
5) Are you aware of pharmacovigilance program?
   a)Yes b)No
6)Have you reported an adverse Drug reaction(ADR)?
   a)Yes b)No
7)If yes, where have you reported?
   a) an ADR reporting centre b)the concerned pharmaceutical company c)others
8)How many ADRs do you encounter in a week?
   a)0-5/week b)6-10/week c)more than 10/week
9)List the common ADRs you have reported.
10)Are you aware of any medicines that is banned due to ADR?
11)If yes, name them along with the ADR
12)How important do you think is to report ADR?
   a)Very important b)Important c)Not very important
13)Why it is important to report ADR?
   a)To identify and detect new ADR b)To share information about ADRs with colleagues
   c)To improve patient safety d)To identify relatively safe drugs 3
   e)To measure the incidence of ADRs
14)What factors do you think are important whole deciding to report an ADR?
   a)Unusualness of the reaction b)Involvement of a new drug
   c)Confidence in diagnosis of an ADR
15)What are the factors that discourage you from reporting ADR?
   a)Did not know how to report. b)Not knowing where to report
   b)Lack of access to ADR reporting forms
16)In your view which ADRs should be reported?
   a)None. b)All ADRs. b)All serious ADRs c)ADRs to new drugs
   d)ADRs to vaccines. e) Others
17)Are you aware of any of the below reporting centers or systems in India where you can report ADR?
   a)Madras Medical College,Chennai. b)Christian Medical College,Vellore
   c)PSG institute,Coimbatore d)Govt. Kilpauk Medical College,Chennai
18)From which source do you gather information about ADR
   a)Text books. b)Journals c)Medical representatives d)Seminars e)Internet
19)Which method do you prefer to report ADR?
   a)Direct contact b)Telephone c)Post d)Email

The present study is a questionnaire-based survey conducted to assess the knowledge, attitude and practice of pharmacovigilance towards ADR reporting among doctors Worldwide, underreporting of ADR is a well-recognized problem associated with spontaneous ADR reporting system. Amongst various factors knowledge, attitude and practice of healthcare professionals play a significant role in spontaneous reporting of ADRs. Hence, the present study was undertaken to assess the knowledge, attitude and practice of healthcare professionals on ADR reporting. A total of 63 doctors from various specialties and super specialties had participated in the survey. The questionnaire had 19 questions in total. e knowledge based questions assessed, knowledge regarding various aspects of pharmacovigilance such as a location of local and national ADR monitoring centers, purpose, type of ADRs to be

reported, who can report and how ADR reporting done. e attitude based-questions assessed the view of the participants regarding the impact of ADR, current system of Pharmacovigilance, obligation towards ADR reporting. e practice based-questions determined practice concerning reading articles, attending the training program and reporting ADR.

Conclusion:

Today, the need for an efficientpharmacovigilance system has been realized more than ever, to ensure the safe use of medicines. Pharmacovigilance is being taught to some extent in theory, but the knowledge on the practical approach

is lacking. The present academic curriculum should be revised to include the application of pharmacovigilance in the medical practice. A culture of learning about pharmacovigilance should start early in the professional training of doctors. The medical students who are aware of pharmacovigilance are sure to realize that all medicines can cause ADRs.

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