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Knowledge, Attitude and Practice Regarding Adverse Drug Reaction Monitoring & Reporting Amongst Physicians in a Tertiary Care Teaching Hospital, Ahmedabad

KEYWORDS: Pharmacovigilance, adverse drug reaction, KAP study

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ABSTRACT *The aim of the study was to assess the knowledge, attitude and practice of physicians regarding pharmacovigilance and spontaneous reporting of ADR with a view to identify the reasons for under-reporting and the methods for its improvement. The study was a questionnaire based study involving physicians. The study was conducted at Civil Hospital Ahmedabad. We visited the physicians personally, distributed the questionnaire and collected the duly filled questionnaire on the same day. The questionnaire contained 14 questions, 5 to evaluate knowledge, 4 to assess their attitude and 5 to judge the practice regarding pharmacovigilance and ADR reporting. Total 230 physicians were served the questionnaire but 207 physicians submitted the duly filled questionnaire (response rate 90%). About 83% physicians were aware about the term "Pharmacovigilance". About 48% physicians knew how to report ADRs. Only 11.1% physicians said that all ADRs should be reported while 55.5% physicians said only serious ADRs should be reported. About 44% physicians knew about existing setup of ADR reporting in this hospital and 34.7% physicians were aware about CDSCO program. Majority of the physicians (89.8%) thought that ADR monitoring should be made mandatory. Major reasons for not reporting ADR were-lack of availability of ADR forms (57.9%), lack of time (71.9%), doubtful diagnosis (30.4%) and fear of legal issues (20.3%). Majority of the physicians reported that they inform the patients about possible adverse effects of prescribed drugs. Almost all (95%) physicians asked and took feedback from patients after treatment. Half of the physicians had not filled ADR form during last 1 year. Despite good knowledge the rate of reporting ADRs was low among doctors. Active participation of physicians is a key to enhance the spontaneous reporting of ADR. To change the attitude and to improve participation of physicians in ADR reporting, educational measures like awareness programs, CMEs etc should be held at regular intervals.*

Introduction

WHO defines adverse drug reaction as a response to a medicine which is noxious and unintended and which occurs at a dose used in humans for prophylaxis, diagnosis, therapy or modification of physiological functions. ADRs are global problem of major concern (Rehan Hs et al. 2005)

India is a developing country with large drug consuming population. Many diseases are prevalent so exposure to drugs was larger (Amrita S, Singh SP, 2011). ADRs have medical as well as economic consequences, leading to increased patient morbidity and mortality (Upadhyay P et al. 2012). This has given rise to "pharmacovigilance", which is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects of drugs, or any other drug-related problems (WHO 2002). ADRs are the cause of hospital admission in 3% to 6% of patients of all ages (Onder G et al. 2005), while in elderly patients it is 3% to 24% . ADR incidence has been reported to range from 5.9% to 22.3% of all emergency department admissions (Amrita S et al. 2011). Thus it is essential that the drug treatment should be safe, efficacious and cost effective. It is also emerging as a clinical trial hub exposing larger population to newer drug treatments. It is the need of the hour to identify adverse drug reactions as early as possible and to prevent them if possible, to ensure the well-being of the patient at reasonable cost.

To improve the pharmacovigilance activities in India, the Ministry of Health and Family Welfare had initiated the National Pharmacovigilance Program (NPP) on 1st January 2005 which was further revived in July 2010 (Pharmacovigilance programme India, PvPI). This program is overseen by Central Drugs Standard Control Organization (CDSCO), New Delhi (Gupta YK, 2010).

One of the important factors of an efficient pharmacovigilance system is contribution by healthcare professionals in the form of spontaneous reporting. This study was aimed at investigating the knowledge, attitude and practice of spontaneous ADR reporting among physicians in a tertiary care teaching hospital.

Aims and objectives

1, To assess the knowledge, attitude and practice of physicians regarding pharmacovigilance and spontaneous reporting of ADR
2, To identify the reasons for under-reporting among physicians and the methods for its improvement.

Methodology

This study was a questionnaire based study carried out amongst physicians including resident doctors and Professors at Civil Hospital Ahmedabad. Study duration was 2 months from December 2012 to January 2013 .We visited the physicians personally, distributed the validated questionnaire and collected the duly filled questionnaire in 24 hours. The questionnaire had total 14 questions, 5 questions to evaluate knowledge, 4 questions to assess their attitude and 5 questions to judge their practice about pharmacovigilance and ADR reporting and monitoring.

Five questions on knowledge revealed information regarding their knowledge about pharmacovigilance, awareness about ADR reporting, address of pharmacovigilance centre in Delhi, awareness about other ADR reporting programme

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out of India, awareness about WHO Uppsala ADR monitoring programme, national monitoring centre, CDSCO ADR form.

Four questions on attitude regarding pharmacovigilance helps us to know their opinion on essentiality of ADR monitoring and to assess possible reasons for non- reporting of an ADR such as ADR is well known, not sure about the drug causing ADR. Further their perception about 'whether ADR monitoring should be made mandatory' was probed.

Five questions on practice covered various activities or inputs given by physicians to strengthen pharmacovigilance and ADR reporting like – informing patients about possible side effects, noticing ADRs in patients, getting feedback of discomfort experienced by patient after drug treatment, availability of ADR form, reporting/non-reporting of observed ADR, existence of set procedure of reporting ADR

The collected data was entered in Microsoft excel 2007 version and analysed.

Results

For this study, we approached 240 physicians out of them 207 completed and returned the duly filled questionnaire. So response rate was 86%.

Knowledge of physicians:

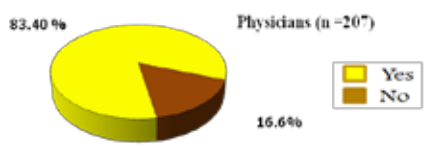

Figure 1: Awareness about pharmacovigilance

Out of the total (207) physicians, 172 (83.40%) reported that they were aware of the term pharmacovigilance (figure-1), 35 (16.6%) physicians did not know the term pharmacovigilance .Almost 86% physicians did not know address of pharmacovigilance centre in India.

Only 44.4% physicians (92 out of 207) knew about existing ADR reporting centre in this hospital. Nearly 50% physicians (99 out of 207) did not know how to report ADRs at the centre. Table-1 shows that awareness of physician about ADR reporting programmes in different countries. Many times physicians were aware about more than one programme.

ADR reporting program	No of physicians	Percentage
CDSCO form for India	72	34.7%
Yellow card for UK	50	24.1%
WHO Uppsala monitoring	28	13.5%
Blue card for Australia	22	10.9%
Form FDA 3500 for USA	12	5.7%
CIOMS for Canada	2	0.9%

Table 1 : Awareness about ADR reporting programmes (n=207)

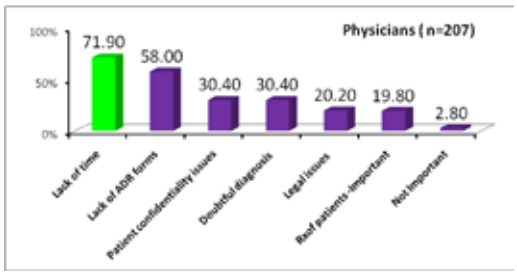

Figure 2: Reasons for under reporting of ADRs

Attitude of physicians:

82.6% (171 out 0f 207) physicians felt ADR reporting was important even though when they asked regarding reasons for under reporting of ADRs only 2.8% physicians said it was not important . 89.8% physicians (186 out of 207) felt that the ADR monitoring should be made mandatory. However 20.3% physicians (42 out of 207) felt that there is no need to report the ADR as it is well known. 45.4% physicians (94 out of 207) believed that ADR reporting was professional obligation. Figure 2, shows various possible reasons for under reporting of ADRs. Major reasons for not reporting ADR were- lack of time (71.9%), lack of availability of ADR forms (57.9%), doubtful diagnosis (30.4%), patient confidentiality issues (30.4%) and fear of legal issues (20.2%). Figure -3 shows opinion of physicians regarding ADRs to be reported. 55.5% physicians were of the opinion that only serious ADRs should be reported while only 11.1% physicians were of the opinion that all ADRs should be reported.

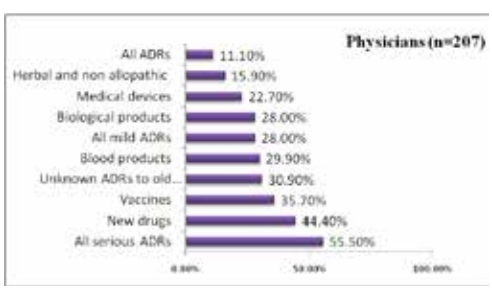

Figure-3: Attitude towards ADRs to be reported

Practice of physicians:

97.5% physicians (202 out of 207) said that they informed their patients about the possible side effects/adverse effects of the prescribed drug. 88.9% physicians (184 out of 207) observed ADRs in patients (184 out of 207). However, 63.2% physicians (131 out of 207) had neither reported any ADR nor filled any ADR form in last 1 year .Only, 43.9% physicians (91 out of 207) had filled ADR form in last one year. Around 95% physicians had taken feedback from the patients regarding ADR of prescribed drug (figure 4).

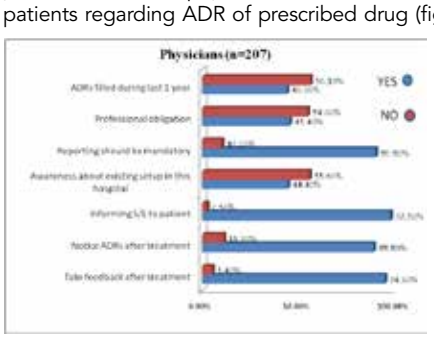

Figure 4 :Practice about ADRs amongst physicians

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Discussion

Countries like Australia, Brazil have well established spontaneous ADR reporting systems with participation from all healthcare professionals (Yadav S, 2008). In India, very few studies have looked at ADRs as the cause of hospital admissions and fewer still have looked at costs associated with ADRs. ADR monitoring and reporting activity is in its developing stage in India. This survey helps in knowing the actual participation of physicians in spontaneous reporting to ADR monitoring centres. The overall response rate of this survey was (86.0%) which is somewhat higher than the 50% response rate reported by Hasford et al in his study. Physician's expertise in informing patient about expected side effects of prescribed drugs and noticing ADRs in patient was very good. Physicians have extended their role beyond diagnosing and prescribing. The physicians are informing patients about the expected therapeutic effects, dosage regimen, directions for use and possible side effects. Patient's feedback to doctors about experienced discomfort due to drug was also good. Such data indicates that physicians have good communication skills and they have been successful in developing healthy doctor-patient relationship which is essential for patient safety. Significant percentage (57.9%) of physicians did not have ADR reporting form. This is against the finding of Cosentino M that only 16% of physicians of Northern Italian district were devoid of ADR reporting form. Surprisingly 63.2% physicians did not report the ADRs which they had come across which is almost similar with the study of J. Hasford et al., which found that 68.2% physicians did not report the suspected adverse drug reaction. But our percentage is much higher than the finding of Cosentino M that 50% medical practitioners did not report observed ADRs. In a study conducted by J. Hasford et al. in 2002, 66.3% physicians were found to be uncertain of definite causality thereby did not report it while in our study 30.2% physicians were found to be uncertain about drug causing the ADR. The reason for such finding could be enhancement in physician's ADR assessment ability over the period of 9 years (J. Hasford et al.2002). Although the PvPI states that all suspected reactions to any drug in the market must be reported, half of the physicians felt that the observed ADR need not be reported as they were well known. This is lower than the findings of J. Hasford et al. which observed that 75.6% of suspected ADR went unreported by physicians as they were considered to be well known. Almost all physicians felt that the ADR monitoring is essential which is similar to study of Consentino M that where no doctor seemed to believe that ADR reporting was useless. (50.0%) physicians felt that they did not report ADR because they did not know where to report. Thus we can say that majority of the physicians considered ADR reporting to be essential but were ignorant about the existence of ADR monitoring centers.

Under-reporting of ADR by doctors is well known, and in India also, the spontaneous ADR reporting system has produced lower rates of reporting. Clinical pharmacy was introduced to the hospital in 1998 but the ADR monitoring and reporting programme was not introduced until 2004 because pharmacovigilance was poorly developed in our country. At the same time, as part of the routine clinical pharmacy services, ADR monitoring was done by the clinical pharmacists in the hospital without further documentation and reporting (Arunmali S et al. 2007) .

In our study, only 11% of the physicians believed that all ADRs should be reported while in another study (Pimpalkhute SA et al. 2012) 63% physicians believed that all ADRs should be reported.

Low awareness among health care professionals toward ADRs may reflect lack of basic knowledge and lack of vigilance. This finding was also observed by Elnour AA et al. 2009.

Suggestions for Improvement in ADR Reporting:

1. Each hospital should build local 'Pharmacovigilance Unit' for collection of ADR reporting forms.
2. Unit should periodically supply ADRs forms to physicians and collect ADR forms from hospitals by sending representatives.
3. Periodical meetings of experts from PvPI with doctors should be arranged to boost reporting.
4. ADR drop boxes should be introduced at strategic locations in hospitals.
5. Pharmacovigilance workshops for health care professionals should be initiated.
6. Facilitate ADR reporting by SMS, e-mail, fax and phone.
7. Incorporation of pharmacovigilance in the syllabus of UG and PG courses of medicine.
8. Associating ADR reporting with incentives.
9. Felicitation of physicians for maximum ADR reporting in a year.
10. Assurance of non-involvement in legal matters, if they arise.
11. Positively changing the mindset of physicians, so that ADR reporting becomes an accepted and understood routine.
12. The Government of India may pass a law for making ADR reporting mandatory for physicians.

Conclusion

Despite good observation and knowledge of ADR among doctors, the rate of spontaneous reporting to ADR monitoring centre in this hospital was low. The overall awareness of doctors about ADR reporting centers of existing setup, CDSCO form, their phone number, address and availability of ADR reporting forms was very low. The actual reporting of ADRs by physicians to monitoring centers designated by PvPI was very low. Sensitization and orientation of physicians towards spontaneous reporting of ADRs to monitoring centers is essential to improve reporting rate. Implementing the suggestions would significantly change the attitude of physicians and improve ADR reporting. Proactive participation of physicians is a key to enhance spontaneous reporting of ADR.

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