PERCEPTIONS OF MEDICAL RESIDENTS REGARDING ADVERSE DRUG REACTION REPORTING IN TEACHING HOSPITAL IN MUMBAI, INDIA.

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Summary

The study was aimed to determine level of awareness amongst medical residents regarding Adverse Drug Reactions (ADRs) reporting and to ascertain the reasons for under reporting of ADRs. Following approval from the Institutional Ethics Committee, a questionnaire based survey was carried out among medical residents. The written inform consent was taken from all the participants. The questionnaire (both open and close ended questions) aimed at ascertaining the level of awareness among medical residents regarding ADR reporting and documenting the reasons for under-reporting. The questionnaire was given to 200 medical residents and their responses were analyzed and expressed as percentages. Ninety eight residents responded to the questionnaire. Only 27% of the residents report ADRs. Out of these, only 47% of residents said that they report ADRs to the Pharmacovigilance centre. The main reasons for not reporting ADRs were lack of awareness of the need to report, the method of reporting, not knowing which ADR to report and lack of time due to heavy patient load. Most of the residents are not aware of the need to report ADRs, which ADRs to be reported, to whom to report and the correct method of reporting. Thus educating them about details of ADR reporting is important and can be started at undergraduate level and reinforced at postgraduate level.

Key Words: Attitudes, ADR, Pharmacovigilance, Questionnaire

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Introduction

Adverse Drug Reactions (ADRs) are considered to be a leading cause of morbidity and mortality [1]. They are responsible for about 2-6% of all hospital admissions [2, 3]. Lazarou *et al* have shown that the overall incidence of serious ADRs was 6.7%, of which 0.3% ADRs were fatal [1].

Conventional clinical studies on efficacy and safety are suitable for recognizing frequent ADRs and are required for the approval of a new drug; they often fail to detect rare ADRs [4]. As a result, a number of spontaneous reporting systems have been developed in recent decades to help detect serious, rare, and unexpected ADRs. These systems are characterized, however, by a high rate of underreporting [5]. A systematic review about determinants of under-reporting found that a large proportion of physicians did not report ADRs because they felt that these were well known or too trivial [6].

India has a large drug consuming population. There is a plethora of counterfeit and substandard drugs [7], drugs belonging to alternative systems of medicine like Ayurveda, Unani, Siddha, Homeopathy and drugs which have been banned/withdrawn in other countries [8]. Because of these factors, it was imperative that a system of adverse drug reaction (ADR) reporting is established in the country. Therefore the National Pharmacovigilance Programme was established in November 2004 [9]. Under this programme, the Central Drugs Standards Control Organization (CDSCO), New Delhi officiated as the central co-ordinating body under which 2 zonal, 5 regional and 24 peripheral centres had been established. It was terminated in late 2009 for various reasons [10]. The program is now renamed as The Pharmacovigilance program for India (PvPI) and has been operational with effect from July 2010 [11]. The enormity of the problem of ADR reporting and poor post marketing surveillance by pharmaceutical companies in India is well documented [12]. India rates below 1% in terms of ADR reporting against the world rate of 5% [13].

Medical residents will be the future physicians. They actively need to report the ADRs. It is important to find out the degree of their knowledge regarding the ADR reporting, identify the lacunas and train them accordingly. Thus we planned a study to understand the level of awareness amongst medical residents regarding ADR reporting and reasons for underreporting in a tertiary care hospital.

Material And Methods

The study was conducted in a teaching hospital in Mumbai, India and involved the residents of clinical specialities. A questionnaire was prepared [Appendix 1]. It contained both open and close ended questions. It aimed at ascertaining the level of awareness regarding adverse drug reaction reporting among medical residents. The clarity and level of understanding of the questionnaire was confirmed by testing it initially on 5 medical residents and their comments were used to improve the questionnaire (prevalidation).

Following approval from the Institutional Ethics Committee, a questionnaire based survey was carried out. Written informed consent was taken from all the participants. The questionnaire was given to 200 medical residents and their responses were analyzed and expressed as percentages.

Results

Out of the 200 residents approached 49% (98 residents) responded. 87% (86) residents reported that they come across at least 1 ADR per 10 patients. 66% (59) of residents said that they came across unexpected ADRs.

1. ADR reporting: whom and how?

Only 27% (26 residents) of the residents said they reported ADR reports. Only half of them, i.e. 47% (14 residents), reported to the local Pharmacovigilance centre, 40% (6 residents) reported to their respective Departmental Head or to the Pharmacology department and 13% (4 residents) reported to the respective company medical representatives. 30.76% (8 residents) of the respondents said that they reported by phone calls, 7.09% (2 residents) of the respondents reported via email and 7.09% (2 residents) of the respondents reported through letter. 15.38% (4 residents) of the respondents reported using other means such as ADR surveys, through the Pharmacology department.

2. Type of ADR reported:

69.23% (18 residents) of the respondents said that they reported any ADR that they came across. 38.46% (10 residents) of the respondents reported ADRs to drug that were life threatening and needed urgent hospital admission. 7.69% (2 residents) of the respondents reported ADRs due to new drugs only (drugs that are in the market since the last two years).

3. Reasons for not reporting:

Out of the 72 residents who did not report ADRs, 50 responded to this question.

28% (14 residents) of the respondents said that they were not aware of the need to report. The remaining 72% (36 residents) were aware of the nedd to report ADRs but the various reasons quoted by them for not reporting ADRs are as shown in Table1tions'.

Table-1: Reasons For Not Reporting Adverse Drug Reactions

Percentage of residents (number of residents)	Reason for not reporting ADR
28% (14)	Not aware of the need to report
52% (26)	Not aware of which ADRs to report
52% (26)	Observed ADRs are well known or common
40% (20)	Observed ADRs are too trivial to report
36% (18)	Address of the concerned authority unavailable
32% (16)	Lack of time due to heavy patient load
16% (8)	Fear of legal implications
16% (8)	ADR form filling too time consuming

The different ways suggested by the residents to improve ADR reporting were: simple ADR reporting forms provided with self addressed stamped envelopes 71.11% (64 residents), easy access to computers and internet 40% (36 residents), provide them with the details of contacting persons 35.55% (32 residents), ADR monitoring centre to offer therapeutic advice to manage ADRs 22.22% (20 residents).

Discussion

The survey showed that the occurrence of ADR is common. 87% of the residents observe at least 1 ADR in 10 patients. Almost 66% of residents come across unexpected ADRs. Unexpected ADRs are those which are not well documented or not seen very frequently with a particular drug. These are the ADRs which need to be reported so as to generate more information about a drug.

However, only 27% of the residents reported ADRs. Further when asked to whom they report, only 47% of residents reported to the local pharmacovigilance centre. This shows the lack of knowledge regarding the authority to which the ADR should be reported. The knowledge regarding which ADRs should be reported is also poor. The national Pharmacovigilance program encourages reporting of all suspected drug related adverse events. It particularly solicits report of all adverse events suspected to have been caused by new drugs and 'Drugs of current interest' (List to be published by CDSCO from time to time), all suspected drug interactions, reactions to any other drugs which are suspected of significantly affecting a patient's management, including reactions suspected of causing death, life-threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent or permanent), congenital anomaly, required intervention to prevent permanent impairment or damage[14].

The method of reporting is also poorly understood by the residents. Common methods are through medical representatives, phone call or email to the pharmaceutical company. The ideal procedure of reporting ADR is filling the CDSCO (Central Drugs Standard Control Organization) 'Suspected Adverse Drug Reaction Reporting Form' and sending it to the ADR Monitoring centre.

While going through the reasons for not reporting it becomes clear that most the prescribers are not aware of the correct methodology of ADR reporting such as to whom to report, which ADRs to report and how to report.

The results of our study are parallel to the previously reported studies. The studies conducted in many countries across Africa [15, 16], Europe [17, 18, 19, 20], America [21, 22] and Asia [23, 24] also showed lack of awareness amongst medical residents and practitioners about ADR reporting and the proper methodology.

This data points out towards the need for making the prescribers aware of the importance of ADR reporting. This could be done by educational intervention as early as undergraduate level and can be reinforced at postgraduate and post-PG levels. Educational intervention has been shown to improve ADR reporting in Portugal [25] and Rhode Island in the USA [26]. The intervention could be by the means of regular seminars, workshops, distance learning programmes, etc. This would improve the understanding of the residents regarding the need and methods for reporting. Also future studies comparing the attitudes of residents before and after training in ADR reporting would be useful.

Conclusions

ADR reporting is an important aspect of drug therapy and pateint care. Most of the residents are not aware of ADR reporting. They do not know which ADRs to be reported, to whom to report and the correct method of reporting. Thus educating them about details of ADR reporting is important and can be started at undergraduate level and reinforced at postgraduate level.

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Appendix I: Questionnaire

The following questionnaire contains 10 questions. Please tick-mark your choice of answer(s) in objective type questions. You can add your views to support your response to any question in the space provided after each question.

1. How many cases of adverse drug reactions do you come across per ten patients?
2. How many of them are potentially life threatening and need urgent admission?
3. How many of them are unexpected?
4. Have you ever reported any ADRs to authorities? Yes / No

   If yes, to whom did you report?

   a. FDA
   b. Company personnel
   c. DCGI Office
   d. Regional pharmacovigilance centre
   e. Any other (please specify)
5. What types of ADR's do you report? (Please tick one or more)

   a. Any ADR's that you have seen

   b. ADR's due to new drugs only (drugs that are in the market since the last 2 years)
   c. ADR's due to old drugs (drugs that are in the market since more than the last 2 years)
   d. ADR's due to any drug that is life-threatening or requires admission of the patient to hospital.
6. How do you report?

   a. Through the Company medical representative
   b. Phone call
   c. By letter
   d. By Email
   e. Any other means (please specify)
7. If the answer to question no. 4 is no, then please give a reason for not reporting ADRs?

a. Not aware of the need to report
b. Not aware to whom to report ADRs
c. Any other reason (please specify)

8. If you are aware of the need to report adverse drug reactions, what are the reasons of not reporting them?
   a. Too time consuming to fill the form
   b. Not interested
   c. Heavy patient load
   d. Address of concerned authority not available
   e. Fear of legal implications
   f. ADR observed is too trivial to report
   g. Not aware of which ADR's to report
   h. ADR observed is well known or commonly observed
   i. Fear regarding patient confidentiality
   j. Reluctance to admit that harm has been caused to a patient
   k. Any other reason, please specify
9. What according to you are the best and practical measures to be taken by the ADR reporting authorities so as to increase the reporting of ADRs? Please tick one or more
   a. If therapeutic advice is offered to manage the ADR
   b. Details of contacting persons provided
   c. Simple ADR reporting forms provided with self addressed stamped envelopes
   d. Easy access to computers and internet

Thank You