



ALGORITHMS FOR DETECTING, ASSESSING, REPORTING AND AVOIDANCE OF ADVERSE DRUG REACTIONS

N.Kanaka Durga Devi*, G.Lakshmi Suneetha, P.Nikhitha

KVSR Siddhartha College of Pharmaceutical Sciences, Vijayawada-520010, Andhra Pradesh, India.

*Corresponding author's E-mail: nelluriss@gmail.com

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ABSTRACT

The present study is aimed at assessing the knowledge, attitude and perception of physicians from various fields in Vijayawada, towards adverse drug reactions reporting, to get an in-sight into the causes of under-reporting of ADRs and to suggest possible ways of improving this method of reporting. Detection assessment and understanding of adverse drug events towards prevention has become indispensable perspective of modern drug therapy. This essentially guides appropriate use of drugs and interpretation of safety information by health care providers. Reporting adverse drug reactions spontaneously is considered as a cornerstone of pharmacovigilance. However, its success depends on co-operative and motivated health care professionals. Under-reporting of the ADRs by the prescribers is a common problem. The study was cross-sectional and questionnaire-based involving only medical doctors working in different fields. It was observed that the knowledge of ADRs and how to report them are inadequate among doctors. More awareness should be created on the ADR reporting system.

Keywords: ADRs, Pharmacovigilance, Physician, prescribers.

INTRODUCTION

An adverse drug reaction (ADR) is described by the World Health Organization as a, response to a medicine which is noxious and unintended, and which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function. Detection assessment and understanding of adverse drug events towards prevention has become indispensable perspective of modern drug therapy¹⁻⁵. This essentially guides appropriate use of drugs and interpretation of safety information by health care providers. Preventing and detecting adverse effects from medicines is termed pharmacovigilance. Health professionals play an important role in monitoring the safety of medicines by reporting any suspected adverse drug reactions (ADRs) to the Therapeutic Goods Administration. Spontaneous reporting has contributed significantly to successful pharmacovigilance. In spite of these benefits, under-reporting remains a major drawback of spontaneous reporting. Assessment of awareness of pharmacovigilance among the healthcare professionals is very important due to under reporting^{6,7} of adverse drug reactions.

Examples of ADRs include⁸ :

Medicines	Reactions
Amidopyrine (for inflammation)	white blood cell disorder
Clioquinol (for skin infections)	visual impairment
Erythromycin estolate (antibacterial)	hepatitis (liver disorder)
Oral contraceptives	Thromboembolism (blood clots)
Statins (for controlling cholesterol)	muscle degeneration
Thalidomide (for managing morning sickness)	Phocomelia (disfigured infants)

Risks

- Wrong diagnosis of the patient's condition.
- Prescription of the wrong drug or wrong dosage of the right drug.
- Reactions with other drugs (including traditional medicines) and certain foods.
- Self-medication with prescription medicines.

Recognition of ADRs

The ADRs produced by a certain new drug are often recognized when the medication^{9,10} is undergoing its phase three randomized controlled trials. A clinician may have problems recognizing the scenario as an ADR, because of the background symptoms of the patient's original illness. Clinicians might also be wary of reporting an ADR, because of worries of inducing a complaint, even in this no blame culture NHS. In recognizing an ADR there are a number of important factors. One is identifying those individuals in whom ADRs are most likely to occur. This includes the aged and the premature, those with liver and renal dysfunction, those on polypharmacy and patients with certain individual conditions¹¹⁻¹⁷, such as Human Immunodeficiency Virus infection (HIV).

MATERIALS AND METHODS

Reporting of Adverse drug reactions

The study was a cross-sectional, observational, questionnaire-based study¹⁸⁻²⁷ involving only medical doctors, working in different fields such as clinical research, industry, hospital, medical colleges, general practitioners and post graduate students. A total of 120 questionnaires were distributed to medical doctors. A



KAP questionnaire containing 15 questions was designed, to obtain the information regarding demographics of the respondents, knowledge regarding ADR reporting system, attitude and perception of ADR reporting.

1] Your Profession?

1. General Physician 2. Specialist 3. Industry 4. Research 5. Academician

2] Do you believe all the drugs available in the market are safe?

1. Yes 2. No 3. Don't know

3] Have you ever experienced an adverse drug reaction (ADR) in patients during your practice?

1. Yes 2. No

4] With which class of drugs do you frequently experience ADRs?

Write 'Not Applicable' if answer to above question is 'No'.

5] How many percent of your patients complain about ADRs?

1. Nil 2. 10-20% 3. 30-40% 4. 40-50% 5. More than 50%

6] Do you think that pharmacist could be the right person to assist physician in ADR reporting?

1. Yes 2. No 3. Don't know

7] Is ADR reporting form available when you are at the job of prescribing medicines to the patients?

1. Yes 2. No 3. Don't know

8] Do you think that ADR reporting and monitoring system would benefit the patient?

1. Yes 2. No

9] What are the sources of ADR information to you?

10] ADRs should be reported only when they are- (you may select more than one option)

1. Serious and life threatening. 2. Severe and cause disability. 3. Mild and cause less inconvenience. 4. All the above. 5. None of the above. 6. Don't know. 7. Others (please specify).

11] Which types of ADRs are usually reported? (You may select more than one option)

1. Serious, unexpected and suspected. 2. any ADR of old drug. 3. any adverse event. 4. ADR to a new product. 5. only proven ADRs. 6. all of above. 7. None of above. 8. Don't know 9. Others

12] Do you feel that proper training should be provided to the physicians for ADR reporting?

1. Yes 2. No 3. Don't know

13] Do you support 'Direct ADR reporting' by the patients instead of physicians?

1. Yes 2. No

14] Has this system created awareness of ADR reporting in you?

1. Yes 2. No

15] Do you expect feedback from ADR monitoring centre?

1. Yes 2. No

RESULTS AND DISCUSSION

Only 94 out of 120 respondents filled and returned the questionnaire within the stipulated time frame giving a response rate of about 78.33%. 88 (93.61%) doctors were of the opinion that all the drugs available in the market are not safe. 74 (78.72%) doctors had experienced ADRs in patients during their practice. 70 (74.46%) said that only 10-20% of their patients complain about ADRs. 90 (95.74%) were in favor of ADR reporting by the physicians. 40 (42.55 %) doctors supported pharmacists as the right persons to assist physicians in ADR reporting. 88 (93.61%) agreed that ADR reporting form is not available at their job place. 88 (93.61%) of them believed that ADR reporting and monitoring system would benefit the patients. 54 (57.44%) doctors were not satisfied with the ADR information provided to them. 76 (80.85%) physicians agreed that they were not adequately trained in ADR reporting. 90 (95.74%) doctors stated that proper training should be provided to physicians for ADR reporting. 62 (65.95%) respondents feel that patient confidentiality should be maintained while ADR reporting. 42 (46.49%) doctors admitted that they were worried about legal problems while ADR reporting. Factors for under reporting of ADRs are depicted in table 1 and in figure 1.

Reasons cited by doctors for reporting adverse drug reactions:

- To improve the patient safety.
- To improve the quality of drugs.
- To identify and detect new ADRs.
- To measure the incidence of ADRs.
- To identify relatively safe drugs.
- To avoid future medical mishaps

Table 1: Factors for under reporting of adverse drug reactions

Reason	Number (n=94)	Percentage (%)
Don't know whom to report.	58	61.70
Busy schedule.	54	57.44
Think that one report doesn't matter.	48	51.06
Difficult to pin point suspected drug.	48	51.06
Insufficient clinical knowledge.	46	48.93
Lack of incentives.	38	40.42
Difficult to admit harm to the patients.	22	23.40
ADR is already known to physician.	20	21.27



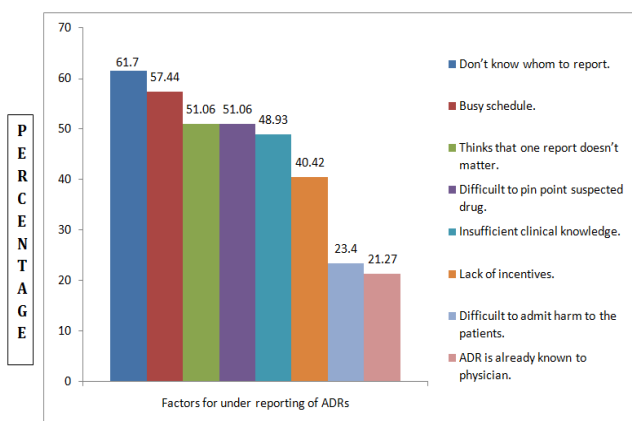


Figure 1: Factors for under reporting of adverse drug reactions

Suggested methods for improving adverse drug reactions reporting:

- Continuous medical education, training and refresher study.
- Instituting and encouraging feedback between patients prescribers and dispensers of drugs.
- Reminders and increased awareness from the ADR monitoring Committee.
- Increasing awareness among other professionals that they could report ADRs.
- Increased collaboration with other healthcare professionals.
- More publicity about reporting scheme in local journals.
- Encouragement from the ADR Monitoring Committee and various head of departments.
- Alerting all outpatients to watch out for possible ADR when prescribing new drugs.
- Remuneration for every reported case of ADR.
- Spending more time on the wards with patients.
- Making reporting a professional obligation.
- Incentives to every outpatient that report.

Sources of ADR information used by the respondents:

- Patients
- Hospitals
- Friends/Colleagues
- Drug information sheets(in drug packs)
- Internet
- Scientific journals
- Text on drugs and therapies
- Medical representatives of drug companies
- Direct mail brochures

- Continued Medical Education (CME), Seminars.

These included creating awareness about ADR monitoring among health care professionals and consumers, through appropriate educational interventions [e.g. seminars, CMEs], making ADR reporting forms easily available and simplifying the process of reporting. Feedback from ADR monitoring centers about the causality and severity of ADRs reported by physicians would also encourage them to continue reporting.

CONCLUSION

Adverse drug reaction reporting is low among the medical professionals. There is a need for regular training and re-enforcement of guidelines for ADR reporting among health care personnel. ADR reporting by nurses, pharmacists and patient self-reporting should also be encouraged. There are gaps between knowledge and ADR reporting among the doctors. These gaps need to be filled by improved training in pharmacovigilance. Attitudinal changes, whereby ADR reporting should be seen as an integral part of clinical activities of the doctors are very necessary for long term improvement of ADR reporting. Further studies needed to strengthen effectiveness of pharmacovigilance activities are necessary.

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