ADR Monitoring: An essential need for better Health Care and Safety

Annu*, Priyanka
Department of Pharmaceutical Sciences,
Maharshi Dayanand University, Rohtak, Haryana, India.
*annu.gvm@gmail.com

ABSTRACT

Adverse drug reaction (ADR) is the noxious and unintended response that occurs at the dose of drug normally used for prophylaxis, diagnosis or therapy of disease. ADRs cause a huge burden on the modern society because of the increase incidence of the morbidity and mortality. ADRs can occur with any class of drugs and the availability of the more and more number of therapeutics increases the risk of ADRs consequently. It has been found that the maximum numbers of ADRs occur more among infants and children and also they are generally more severe as compared to adults. ADRs are of particular interest in today's practice because clinical trials are done in the limited number of the subjects and therefore the drug which is found safer in the clinical trial may produces serious ADRs. The most common reason for this is that the clinical studies generally have limited sample size and have low statistical power. Therefore the ADRs monitoring is an essential need for the better health care and therefore the health care centre should promotes the spontaneous monitoring, reporting, documentation and prevention of ADRs.

Keywords: Adverse drug reaction, Clinical Trials, Pharmacovigilance

INTRODUCTION [1] [2]

ADR is noxious or harmful and unintended response which occurs at doses normally used in human for prophylaxis, diagnosis or therapy of a disease or for the modification of physiological function.

Methods for Identifying ADRs [5]

- Case Record Review
- Drug Chart Review
- Laboratory Data
- Computerized ADR Reporting System
- Attendance at Ward Rounds
- Interviewing Patients

Adverse Drug Reactions Monitoring [6]

Adverse Drug Reactions monitoring is a process of continuously monitoring of undesirable effect suspected to be associated with use of medicinal products.

ADR Monitoring Systems [6]

- Collecting new information from reliable scientific resources
- Classifying and analyzing the above information.
- Circulating its contents as well as any action taken on specific drug to all health sectors

Rationale for ADRs Monitoring [3]

- Clinical Trials generally focuses on Safety and Efficacy of a Pharmaceutical Product
- Population in Clinical Trials is very Selective and Limited.
- Drug-Drug interactions are frequently not identified in Clinical Trials.

Objectives of ADRs Monitoring [1]

- To detect the nature and frequency of ADRs
- To assist the Drug Regulatory Authority, Public Health Programs, Scientists and Consumer Society to minimize ADRs.
- Providing updated Drug Safety Information to Health Care Professionals.
- To upgrade package insert and design appropriate package insert information and dissemination of information for marketing.
- Dissemination of information by designing proper education program to consumers

- To identify risk factors that may predispose, induce or influence the development, severity and incidence of ADRs.

Components of ADRs Monitoring [1]

- Information about the patient
- Description of ADRs
- Suspected drug(s)
- Reporter

Benefits of ADR monitoring [6]

- Proper information about the safety of drugs and medicines.
- Prevention of the adverse effects related to the pharmaceutical products.
- Instruction to the health care team, patients, pharmacists and nurses about ADRs and its management.

Procedure for Reporting ADRs [3]

- Only Suspected Associations that a Drug has caused a Particular Adverse Event.
- Reporting an ADR does not imply a causal association between the Drug and ADR.
- In a doubtful case it is better to report than not to report.

Information Required for ADR Reporting [3]

- Patient Information
- ADRs Description
- Information Related to Suspected Drug(s)
- Information on Management of ADR
- Information about the reporter

What to Report [3]

- All ADRs as a result of Prescription and Non-Prescription medicinal products.
- All suspected ADRs regardless of product information provided by the company
- Unexpected reaction with the product regardless of their nature or severity
- An observed increase in frequency of a given reaction
- A serious reaction, whether expected or not
- All suspected ADRs associated with drug-drug, drug-food or drug-food supplements interactions
- ADRs occurring from overdose or medication error
- Unusual lack of efficacy or when suspected pharmaceutical defects are observed

Who Should Report [3]

- Health care Professionals and Providers
- Manufacturers of Product
- Health care centers

When to Report [3]

- ADR should be reported as soon as possible
- Delay in reporting make the report inaccurate and unreliable

HOW TO REPORT [3] [4]

1. Report should be on a standardized ADR reporting form.
2. This form can be downloaded from http://www.ipc.gov.in/ and http://www.cdsco.nic.in/
3. Dully filled the ADRs in the reporting from when an ADR is encountered.
4. Use a separate from for each patient and filled with the complete information.
5. The completed ADR form is then returned to the nearest adverse drug reaction Monitoring Centre (AMC) or to National Coordinating Centre.]
6. Any follow-up information for an ADR case that has already been reported can be sent on another ADR form, or communicated by telephone, fax or e-mail.
7. Follow-up reports should be identifiable and the following should be indicated on the report
    a. Follow-up Information
    b. Date of Original Report
    c. Patient Identity

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Report Type ☐ Initial ☐ Follow up

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials _____

2. Age at time of Event or Date of Birth _____

3. M ☐ F ☐ Other ☐

4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent
☐ Hospitalization/Prolonged impairment/damage
☐ Disability ☐ Other (specify)

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
Iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____

_____

Pin:_____E-mail_____

Tel. No. (with STD code)_____

Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

PRINCIPLES OF REPORTING [3] [4] [7]

- Write legibly
- Report immediately
- Take decision to report whilst the patient is still with you
- Think about any other factors which may contribute in causing the event/ ADRs
- If something happens to the patients that increases suspicion then send a supplementary note immediately using ADRs reporting form with the patient identifiers.
- All reports must have the following four data elements: an identifiable patient suspected adverse effect name of suspected drug(s) and reporter.

WHAT HAPPENS TO SUBMITTED INFORMATION [4]

- The causality assessment is carried out at Adverse Drug Reaction Monitoring Centres (AMCs) by using WHO-UMC scale.
- The analyzed forms are forwarded to the National Coordinating Centre through the ADR database.
- Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.
- The reports are periodically reviewed by the National Coordinating Centre (PvPI).
- The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.

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