Adverse Drug Reactions Reporting and Monitoring

PHARMACY PRACTICE
Semester: VII
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Introduction

“ one 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 ”

Introduction

The terms ‘adverse drug event’ and ‘adverse drug reaction’ are not synonymous

Why Monitor Adverse Drug Reactions

- **Worldwide, the incidence of occurrence of ADRs is steadily increasing**
  - **Up to 35% of hospitalised patients experience an ADR**
  - **Approximately 5% to 10% of all hospital admissions are due to ADRs**
  - **The incidence of fatal ADRs is estimated to be 0.23% to 0.41%**

Need for Monitoring Adverse Drug Reactions

- Major clinical problem in terms of human sufferings and increased healthcare costs
- Adversely affect patients' quality of life
- ADRs are one of the leading causes of morbidity and mortality

Traditional Classification

As proposed by Rawlins and Thompson (1977)

Type A (Augmented)

Type B (Bizarre)

Newer Classification

As proposed by Rene J Royer (1997)

Type A (Augmented)

Type B (Bizarre)

Type C (Continuous)

Type D (Delayed effects)

Predisposing Factors

- **Age**
- **Gender**
- **Polypharmacy**
- **Multiple and intercurrent diseases**
- **Race and genetics**
- **Drug characteristics**
- **Previous history of allergy / intolerance**
- **Inappropriate dosing and prolonged therapy**

Detection of ADRs

- **Detection of an ADR is crucial in the management of any patient**

- **Always suspect a drug as cause of symptoms in a patient**

How do we detect ?

- **By patient interview**
- **Reviewing prescriptions containing drugs like anti-histamines and corticosteroids**
- **Checking for abrupt cessation of any medications**
- **Obtaining previous medical history**

How do we detect ?

- **Firstly, find out whether a patient taking a medicinal product**

- **Obtain complete details of the patient pertaining to both event and medications and other relevant information**

How do we detect ?

- **Details pertaining to suspected reaction**

  - **Nature and severity of suspected reaction**
  - **Time of onset of suspected reaction**
  - **Duration of suspected reaction**
  - **Previous report on reported reaction**

How do we detect ?

- **Details pertaining to suspected drug**
  - **Name of the suspected drug**
  - **Time of administration**
  - **Complete dosing regimen**
  - **Previous report on suspected drug**

How do we detect ?

- Other relevant information

  - Patients demographic data
  - Presenting complaints
  - Past medication history
    - Current drug therapy details including OTC medications
  - Treatment with any other system of medicine
  - Risk factors

How do we detect ?

- **Correlate the collected information with the event**

- **To find out whether the effect could be due to a medicine consider the following**

  - **The temporal time relationship between the administration of the suspected drug and the reaction**

How do we detect ?

- **Background frequency of the event**
- **Possible involvement of other causes (non – drug causes)**
- **Previous exposure / allergy**
- **Outcome of the reaction upon dechallenge and rechallenge**

Reporting of an ADR

- **To report an ADR you need not be certain just be suspicious**
- **Make sure that sufficient/adequate information is available**
- **The most commonly adopted method is spontaneous reporting**

Spontaneous reporting

- **It was, and still is, the main way of detecting early drug safety signal**
- **Widely accepted method of ADR reporting worldwide**
  - **Simple to operate, easy to report and cheap**

Spontaneous reporting

Limitations

- **Under reporting**
- **Reporting bias**
- **Incidence cannot be studied**

Who can report ?

Reports can be completed by

- **Doctors**
- **Dentists**
- **Pharmacists**
- **Nurses**
- ***Consumer reporting is the need of the hour***

Reporting - What should be the minimum information ?

- **patient identity**
- **description of reaction**
- **exposure to the drug**
- **temporal time relationship between the exposure and the reaction**
- **other possible causes** (disease or concomitant therapy)
- **reporter's identity**

What to report ?

- **Serious and or life threatening reactions**
- **Fatal reactions**
- **Reactions resulted in disabilities/ permanent harm**
- **Reactions resulted in increased healthcare costs**

What to report ?

- **Severe reactions of any type**
- **Any reactions to newer drugs**
- **Newer reactions to any drugs in the market**
- **Rare and uncommon adverse reactions**

How to report ?

- **Reporting can be made through reporting forms**
- **Can be reported through telephone**
- **Can be reported directly to WHO database through 'vigiflow' on-line program**

How to report ?

- **You may report by filling the ADR notification form with following details**

  - **Patient's demographic details**
  - **Prescriber's details**
  - **Suspected drug(s)**
  - **Date of suspected drug started and stopped**
  - **Date of ADR started**
  - **Brief description of the reaction**
  - **Name and address of the reporting community pharmacist with date of reporting**

Where to report ?

- **Local / peripheral centre**
- **Regional pharmacovigilance centre**
- **National pharmacovigilance centre**
- **WHO collaborating centre**
- **Manufactures** **(in case of trial drugs, newly marketed drugs)**

Management of an ADR

Rapid action is sometimes important

- **First and foremost step is withdrawal of suspected drug (s)**

- **If the reaction is likely to be dose related, dose reduction should be considered**

Management of an ADR

- **Treatment for suspected reaction**
  - **Symptomatic**
  - **Specific**

- **While managing an ADR,**

  Always have a clear therapeutic objective in mind, do not treat for longer than is necessary, and review the patient regularly and look for ways to simplify management

Role of Pharmacist

- **Monitor the patients who are at greater risk of developing ADRs**

  compromised ability to handle drugs

  previous documentation of allergy or ADR

  those with multiple disease process

  geriatric or pediatric patients

Role of Pharmacist

- **Monitor the patients who are prescribed with drugs highly susceptible to cause ADRs**

  high incidence of adverse effects

  low therapeutic index

  potential for multiple interactions

Role of Pharmacist

- **Assess and document the patient's previous allergic status**
- **Assess the patient's drug therapy for its appropriateness**
- **Create awareness about ADRs amongst patients, HCP and public**

Role of Pharmacist

- **Assist HCP in detection and assessment of ADRs**
- **Educate and encourage the HCPs and patients in reporting of an ADR**
- **Document the reported ADR in the patient's medical record**
- **Communicate the reported ADRs to appropriate concerned**

Role of Pharmacist

- **Present the reports in meetings and conferences**
- **Conduct workshops or seminars on ADRs for HCPs**
- **Disseminate the signals generated through publication of reports in bulletins/journals**

Conclusion

- **ADRs are inevitable risk associated with drug therapy**

- **Prompt recognition of potential ADRs, and early detection and intervention may prevent**

    - **morbidity and mortality**
    - **unnecessary investigations and treatments**
    - **unnecessary human suffering and healthcare costs**