



Importance of Pharmacovigilance (Review Article)

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Abstract

According to WHO, pharmacovigilance is defined as “science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problem.”^[1]

WHO defines "Adverse Effect" as “any undesirable or unintended consequence of drug administration”^[2].

The term Side Effect is often used synonymously but it precisely means unintended additional action of a drug which may even be therapeutically useful.

There is no drug without some or other adverse effect .It may develop either immediately or after prolonged use or even after stoppage of drug. Adverse effects are sometimes very rare. Even then, they play an important role in determining the therapeutic use of the drug.

It has been estimated that ADRs are responsible for death for nearly 50 out of every 1000 patients admitted to hospitals & cause nearly 5-7% of all hospital admissions.[3].The job of recording & studying these adverse effects is done by pharmacovigilance committee. Unfortunately, In India not all the clinicians & healthcare professionals are aware of this term and its importance.

This article enlightens the importance of pharmacovigilance among various health care professionals and some methods to increase its awareness.

Keywords—*pharmacovigilance (PhV), adverse drug reactions(ADRs), side effects*

Introduction

Unfortunately many of the registered medical practioners are not aware of the pharmacovigilance centres which are meant for receiving reports from medical practioners about various untoward reactions happened to the patient during drug therapy. They know what is pharmacovigilance but are not interested in submitting adverse effects occurring due to drugs.This may be due to lack of time or because they are not interested to interact with pharmacovigilance centres or some may not know about contact centres or communication ways

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assessment, understanding and prevention of adverse effects or any other drug related problem.”^[1].

Adverse drug reaction means an unintended & undesirable reaction. Actually any drug possesses so many actions .Because the drug not only acts on specific system .After entering into the body, it is distributed to various compartments and reaches various systems viz nervous system, cardiovascular system, respiratory system etc. So suppose a drug is taken for suppressing cough ,at the same time it also decrease the motility of the GIT so it not only suppresses the cough but produces constipation as side effect which is undesirable. This is only

revealed adverse effect. There may be so many unrevealed effects and in these unrevealed side effects, some may be converted into useful. For eg:-the constipation effect is converted to therapeutic effect (useful effect) in Traveler’s diarrhoea using same codeine. So our aim is to inspire the physicians, Nurses, Dental surgeons & other legal practitioners to cooperate with pharmacovigilance people to help in evaluating the Drug effects. Hypersensitivity reactions occur sometimes immediately viz reaction to penicillin, analgin etc. But certain reactions occur on long term use for eg:-chronic use of NSAIDs produce Analgesic nephropathy & Chronic use of Chloroquine for R.A produces retinopathy. So whatever may be the side effect the physician must have the habit of informing them to concerned Phys.

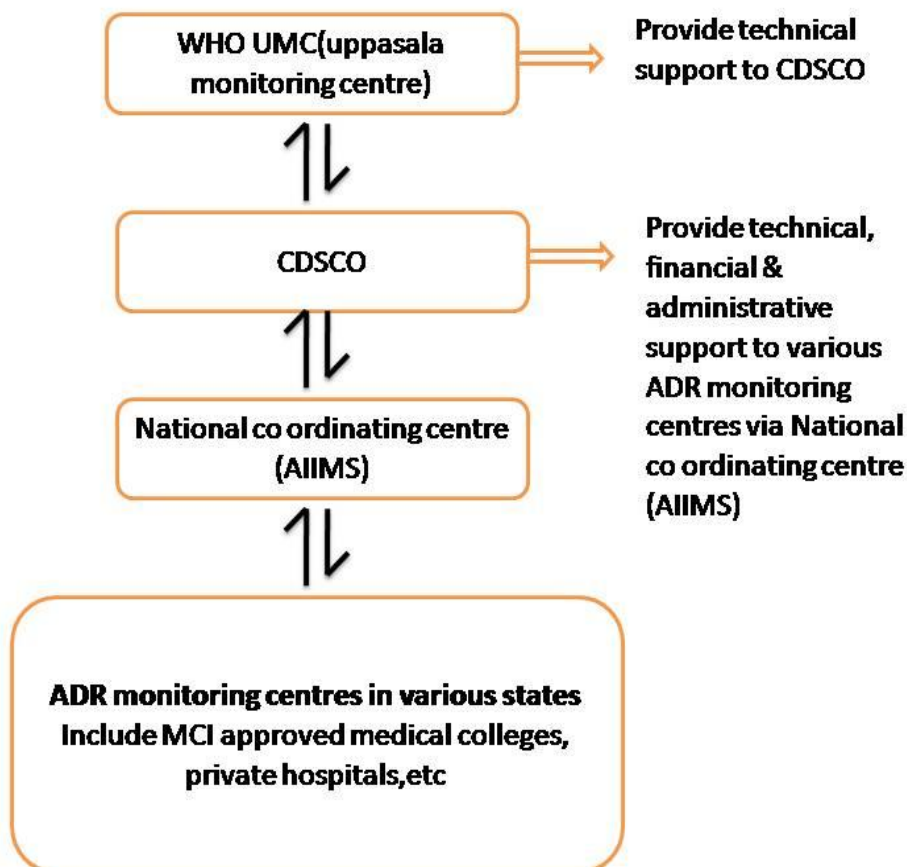
Materials & Methods

Registered Medical practitioners (of various departments), Nurses, Dental surgeons. Article

resources which are relevant to Pharmacovigilance and Adverse Drug Reporting process were searched from online papers (PubMed, Med IND, National & international online journals) using the key words pharmacovigilance, ADRs Reporting, side effect, old drug new use. About 30 articles were retrieved from these resources and 15 out of them are used for preparation of the review. Definitions are taken from official web sites of WHO. Information from official website of pharmacovigilance program in India is used. Few statistics are taken from two online news papers. All this data is gathered in this review article to enlighten the importance of Pharmacovigilance and some important methods to increase its awareness

Pharmacovigilance program in India

The following figure represents pharmacovigilance program in India.



Central drug standard control organization (CDSCO) in collaboration with WHO uppsala monitoring centre & NCC (national coordinating centre (department of pharmacology, AIIMS) launched pharmacovigilance program in India under which many ADR reporting centres are enrolled. These include various medical colleges of state, private hospitals, public health programs, autonomous institutes⁽⁴⁾

Importance of Pharmacovigilance

Pharmacovigilance involves in continuous monitoring of drugs for the benefit and safety of patients. Every drug is associated with some or other ADR. Very few ADRs are known when a drug has been introduced in market. It is several years after drug is marketed, many clinically significant ADRs are identified. Patients often get additional treatment for ADRs that are associated with drugs they have been using. There are instances when patients underwent surgeries because of these ADRs. Thus they incur an additional burden to patients. Some of these ADRs may be rare. Even then, reporting of ADRs is important because it may benefit patients belonging to particular race.(eg- incidence of hemolysis with primaquine is rare, but it is frequently seen in people with G6PD deficiency which is very common in Africans. So primaquine is cautiously used in African community.)

Thus ADR reporting is very important for the safety of patients.

PhV & ADRs reporting also helps in development of new treatment strategies using old drugs.

Awareness of Pharmacovigilance

Many researches were conducted to evaluate awareness of pharmacovigilance among health care professionals in India. Most of these researches have proved that PhV and ADRs Reporting systems in India to be improved. When I personally asked the physicians who are having leading practice in their local areas, it was revealed that they are not at all caring about reporting information to pharmacovigilance centres in areas like KPHB-Hyderabad, Bhimavaram, Tuni & Eluru etc in Andhra pradesh. It is supported by a research article-^[5] it is seen that 80% of respondents identified ADR as one of major cause for mortality and morbidity of patients. Though ADR reporting was considered important by 87.5% respondents but more than 85% wrote that they did not have enough knowledge about how to report an ADR." In another Research^[6] It was seen that more than 60% of doctors do not know how and where to report ADR though 77% were aware about the term pharmacovigilance. I feel that the clinicians must be regularly made to attend CME programmes and once in a year and importance of pharmacovigilance should be emphasized in CMEs. This point was emphasized in a study^[7] where it is seen that many doctors had less awareness about ADR reporting system but after some interventions(lecture, displaying posters, sending reminders as e mails, etc.) knowledge of ADR reporting system has significantly increased among doctors.



The famous Chinese quotation of "Confucius"(Chinese philosopher) should be put in to practice ("*I hear and I forget, I see and I remember, I do and I understand*") to strengthen the foundation & bedrock of pharmacovigilance. Post graduate curricula of various clinical specialties should include mandatory visiting to local pharmacovigilance centre. Under graduates, Post graduate students, clinicians should be made to visit frequently to local pharmacovigilance centre so that their knowledge regarding drugs will be up dated and also become familiar with adverse drug reporting process

Social networking media and Pharmacovigilance

Social media is used by almost all doctors in US. Also, it is very common to see Indian doctors using social media. Organizations like IMA, should involve in educating clinicians regarding Pharmacovigilance using these social networking media. Such organisations can use powerful social networking media like facebook, google+, whatsapp, etc. to educate doctors regularly about ADR Reporting process. Social networking sites are used by a number of people, so they may play an important role in creating awareness about pharmacovigilance. Development of "Pharmacovigilance Application" for smart phones might also speed up ADRs reporting process. Any Suspicious ADR should be shared by clinician with other clinicians and pharmacovigilance centre with such an application.

ADR Reporting process should be made as simple as possible because many doctors hesitate to report ADR because of lengthy reporting process. Busy Clinicians should be appealed to report any ADR they come across. At least Some important basic information(drug and its usage, hospital name, patient name and address, photos) has to be sent to pharmacovigilance committee using such electronic application. These electronic applications and social media will definitely speed up the process of ADR reporting.

Pharmacovigilance among Allied Health Care Professionals

For Pharmacovigilance program to be successful, The allied health care practitioners should also be made aware of pharmacovigilance and ADR reporting system. Many allied practioners like dental surgeons prescribe drugs. For example, dentists regularly prescribe antibiotics & analgesics to their patients. The incidence of adverse reactions is common with antimicrobial drugs^[8]. There are some instances where these allied practioners experienced serious ADRs. Eg.- "Tetracycline induced psychosis" was seen by a dentist^[9], etc. Educating allied health care providers like dentists, physiotherapists, nurses can help pharmacovigilance program to be completely successful. Medical auxiliaries like pharmacists, nurses, physiotherapists can help pharmacovogilance to be outstanding. A number of doctors opined that pharmacists can assist in reporting Adverse drug Reactions and their involvement will increase ADRs reporting rate.^[10].This was proved in a research where TB Patients to a hospital were told to report any ADRs if they experience via a phone call where the clinical pharmacist of that hospital played an important role.^[11].

ADRs Reporting by Patients

It is suggested by few that even patients should be allowed to report ADRs. Now days, many patients are using internet to get information about treatments. Some of the patients are intelligent enough to report ADR independently. This may definitely help in identifying ADRs. But anonymous reporting of ADRs must not be accepted. There is every chance that some apprehensive patients report false ADRs. There is also a chance that some patients might wantedly report false ADR to spoil the name of a company. Report should only be considered when patient's identity and sufficient proof is provided .This prevents reporting of bogus ADRs which may downgrade reputation of a company name.

Discovery of New Drug

Discovering new drugs is a time taking procedure. It should undergo through a number of phases for it to be available for marketing. Moreover this may also be a financial burden. Reporting ADRs can help development of new treatment strategies using old drugs. Every drug has some unintended additional action which may be adverse reaction or side effect (that may be beneficial). Reporting of ADR can help in development of new treatment strategies which saves lots of money and time. Some examples of such drugs whose additional action is used for treating other disease are given below:-

- 1) **Escitalopram** is an Antidepressant its side effect converted to therapeutic action for irritable Bowel syndrome.^[12]
- 2) **Azithromycin** is originally an antibiotic & its other action used therapeutically for treating cancer.^[13]
- 3) **Chloroquine** is antimalarial drug is also now used for treating cancer.^[14]
- 4) **Doxycycline** is an antibiotic now used for treating Malaria in chloroquin resistant places.
- 5) **Acetazolamide** is a diuretic later used for preventing contrast induced nephropathy.^[15]

Conclusion

Clinicians and allied health care professionals should be made aware of ADR reporting process frequently. Social Networking media can be used for this purpose. This updates their knowledge of drugs. This also helps in development of new treatment strategies. Also further research has to be done regarding proper use social media to create awareness regarding pharmacovigilance.

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