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Pharmacovigilance: An Essential Tool for Drug Safety Monitoring

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Abstract—Pharmacovigilance(PV) is the science and activities relating to the detection , assessment, understanding and prevention of adverse effects. Adverse effects means the abnormal conditions occurs in the body due to the drugs which are consumed by the peoples. The main process of pharmacovigilance is reporting about the safety and quality of the drugs. It makes the treatment for patients as worthy as possible. This process makes the subject of chemical compositions of the drugs worthy and correctly. This is one of the major process in drug industries. The proposed system use an ideal tool for this process is the reporting by means of forms which are available under medical bodies also by means of web applications for pharmacovigilance process. This paper presents the better results in clinical trials. The success or failure of pharmacovigilance activity depends on the reporting of suspected adverse reactions. Reports made by a health professional are an interpretation of information originally provided by a patient who has experienced the actual benefit or harm of a medicine taken.

Keywords:-***a***dverse reactions, adverse effects, drugs, pharmacovigilance.

I. INTRODUCTION

Data Pharmacovigilance (PV) can be defined as the act of assessing the drugs and adverse effects caused by a drug. It can also be defined as, the pharmacological sciencerelatingto thecollection,assessment, detection, understanding and prevention of adverse effects. The reason behind the monitoring of adverse reactions is the rapid increase in introduction of new drug entities and pharmacy products. The pharmaceutical industries are introducing many new drug entities which lead to good economic profit. The major role of Pharmacovigilance is determining the side effects or adverse reaction caused by the drugs. Every drug has side-effects some are known by clinical trials and some are unknown until the drug is in clinical use. Moreover it is necessary to determine the known and unknown side effects for better assessment of risks involved in drug entities. It also concentrates on record keeping functions to ensure the processing and submitting the reports.

The objective of the system is to: timely collection of data, recording and notification Appropriate assessments (data completeness, seriousness) expedited and periodic reporting and Creates appropriate structures for communication. The different methods of pharmacovigilance are:

1. Individual case safety reports
2. Clinical review of case reports
3. Cohort event monitoring
4. Longitudinal electronic patient records
5. Spontaneous reporting
6. Periodic Safety Update Reports (PSUR)
7. Expedited report
8. Record linkage

The proposed system use Spontaneous Reporting[2]: -The reporting might be directly to the company. The main limitation is under reporting. However, their key purpose is not the quantification of the rate, but identification of indicators. When becoming aware of a severeadversarial drug reaction, health care providers, pharmacies, pharmaceutical companies shall report to the health authority. Time frame of recording,shot within a specific time frame (ex: 7days) upon knowing of any serious ADR.

Aim of Pharmacovigilance

- To promote safe usage of medicines.
- Taking care of public health in proactive manner.
- Ensuring healthy communications to the peoples.
- To promote education and clinical training.

Pharmacogenomics

It is a part of Pharmacovigilance. For the treatment of different type of diseases, different classes of medicines are available. A major problem in clinical world is that why particular person with particular disease respond to a particular drug well and other patient does not respond the same. It is due to the difference in genetic pattern, patient may respond differently to drugs consumed. The difference in drug response and drug tolerability can be understood by use of pharmacogenomics and pharmacogenetics[1]. Many

types of assumed ADRs are complex and depend on several factors which cause disease. For instance, the metabolic syndrome, suicidality, hepatic dysfunction and cardiac abnormalities.Pharmacogenomicsand Pharmacogenetics are clinically substantial and are frequently associated with drug therapies, but they cannot be easily or completely recognized to a drug exposure. Individual who are susceptible to ADRs and has a potential to reduce the personal and population costs of drug related morbidity can be helped byPharmacogenetics. Although promising, the eventual impact of pharmacogenomics profiling foridentification of ADR susceptibility among individuals would depend upon incidence of drug toxicity, prevalence of variants severity of consequenceand also the availability of rapid, reliable and cost effective as says. Several researchers have proposed the integration of genomic information with the pharmacovigilance database, which can not only enhance signal detection but also aid in determining whether genotypic examination should be performed prior to initiation of drug therapy.ADR [3] is measured based on the following reactions.

1. Side effects: - unwanted and unavoidable things of drugs due to their pharmacological things at suggested doses. Ex-dry mouth from atropine therapy.
2. Secondary effect: -Incidental effects of drug due to its majoract. Ex-occurrence of TB in corticosteroid therapy.
3. Toxic effect: -It is a pharmacological action due to over dose or lengthy usage. Ex-coma with barbiturates.
4. Mutagenicity & carcinogenicity: -metabolites from drugs can cause structural variations in chromosomes to produce alterations. Ex-anti-cancer drugs.

The use of medicines is an important aspect of many PHPs that are designed to improve the health of a target population. Their cost to the health budget is between 6% in developed countries and 45% in some developing countries, but there are huge variations between both developed countries and developing countries. Medicines are important at only because of their capacity to treat and prevent disease and to support PHPs, but also because the confidence of the public in the health policies of their countries is inextricably linked to their confidence in the availability of medicines that are safe and effective. All medicines carry some risk of harm and it is important to monitor their effects, both intended and unwanted, so that good evidence is available upon which to base an assessment of risk versus effectiveness or risk versus benefit. Furthermore, particularly with new medicines, the early identification of unexpected adverse reactions and their risk factors is essential, so that the medicines can be used in an informed manner with the least chance of harm. This is the role of pharmacovigilance. Information gathered during pharmacovigilance may also assist in selecting the most appropriate medicine for future use.

II. ORIGINS OF PHARMACOVIGILANCE

The history of pharmacovigilance goes back more than 40 years. In 1965 the eighteenth World Health Assembly, WHA 18.42, drew attention to the problem of adverse drug reaction monitoring and following further resolutions in 1966, 1967 and 1970 the International Drug Monitoring Programme[8] came into being. In 2005, 78 member countries are participating in this Programme and the last decade has seen the participation of numerous developing countries. The programme functions on the basis of national pharmacovigilance centres coordinated by the WHO Programme for International Drug Monitoring, which consists of the WHO Collaborating Centre for International Drug Monitoring, Uppsala and the Pharmacovigilance Department of WHO,Geneva[6].

Recently, the concerns of pharmacovigilance have been widened to include herbal, traditional and complementary medicines, blood products, biologicals, medical devices and vaccines. Many other issues are also of relevance to the science of pharmacovigilance. These include substandard medicines, medication errors, lack of efficacy, use of medicines for indications that are not approved and for which there isinadequate scientific basis, case reports of acute and chronic poisoning, assessment of medicine-related mortality, abuse and misuse of medicines, and adverse interactions of medicines with chemicals, other medicines and foods and drinks.

III. WHO PROGRAMME FOR INTERNATIONAL DRUG MONITORING

National pharmacovigilance centres are functioning as an international network coordinated by the WHO Programme for International Drug Monitoring[4]. The Programme has achieved much in improving the activities, support and recognition of individual national pharmacovigilance centres. It plays a key role as a communication and training centre and clearing-house for information on the safety of medicines. The WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden manages the international database of adverse reaction reports received from national centres. In 2005 this database held over 3.5 million case reports. The majority of contributing national centres have ready electronic access to these. The Centre has established standardized reporting by all national centres and has facilitated communication between countries to promote the rapid identification of signals. The terminologies developed within the WHO programme for coding adverse reactions to medicines have been widely adopted by national centres, manufacturers and medicine regulators.
More effective communication of information is being promoted and encouraged through the WHO Programme for International Drug Monitoring

IV. THE COST ADVANTAGE

A medicines monitoring system is an essential and cost-efficient means of detecting and minimizing injury to patients and averting potential disaster. Pharmacovigilance can help to better assess and communicate information on the effectiveness and risks of medicines and to educate and inform patients. It is also an insurance against the undetected use of ineffective, substandard or counterfeit medicines, thus minimizing the possibility of wastage of resources.

The cost of a pharmacovigilance system, compared with the cost of ADRs to a nation and to the total national expenditure on medicines, is small. The idea that pharmacovigilance is a luxury, affordable only in the developed world, should be replaced by the realization that a reliable system of pharmacovigilance is essential for the rational, safe and cost-effective use of medicines in all countries and consequently for public health, and should produce clear advantages in relation to cost.

Pharmacovigilance has developed and will continue to develop in response to the special needs and according to the particular strengths of members of the WHO Pharmacovigilance Programme. The ultimate benefit is the safe, rational and effective use of medicines by patients.

V. RELATED WORK

Pharmacovigilance Inspection has two types –
1.Routine inspection 2. Targeted inspection.
1. Routine inspections - To make sure that pharmaceutical companies have the ability in performing Pharmacovigilance activities.

2. Targeted inspections are classified into 2 types:
a) Reviews unconnected to drug safety -companies that have not yet been inspected -companies that launch their first product -companies which are newly combined

b) Reviews related to drug safety -companies that delay or fail to take their obligations on safety monitoring -companies that delay to submit or submit incomplete and insufficient periodic safety update reports -companies that unsuccessful to report drug safety related matters

Adverse Drug Reactions: Adverse event reporting – comprises four elements are 1..An identifiable patient, 2. An identifiable reporter, 3. A suspect drug, 4. A Suspected contrary incident in the proposed system.
The following figure I shows the block diagram of Pharmacovigilance. The steps of pharmacovigilance process is given in figure-i.

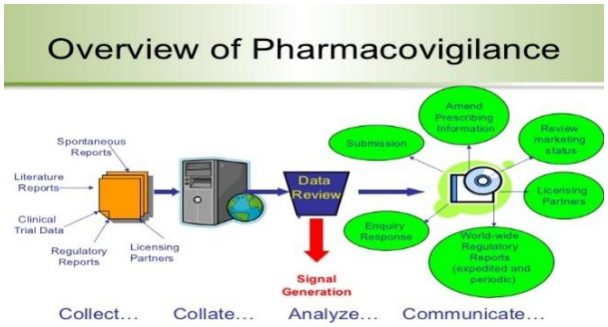

Figure 1 :Overview of pharmacovigilance system

VI. METHODOLOGY

An Adverse Event is not inter-related with the patient's body conditions. It is an unexpected reaction occurs in the body due to the drug intolerance. On the other hand, Adverse Reactions are similar to the adverse events which may harm the patient's body conditions at a normal dose of some medications. It is different from side effects.

Chart of ADR
The below given chart shows the impacts of Adverse Drug Reaction (ADR).

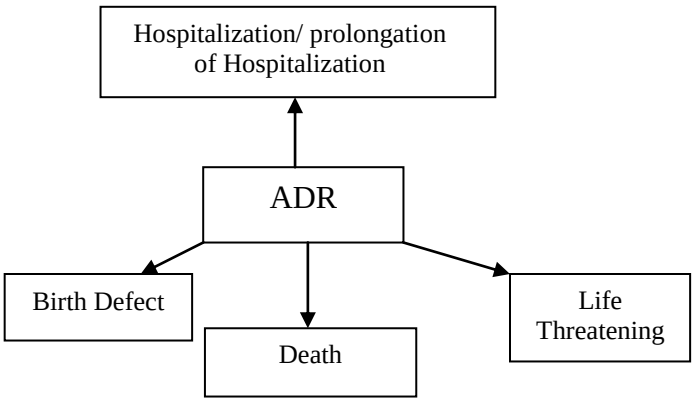

Figure 2 : impacts of Adverse Drug Reaction (ADR)

The following steps are used for Adverse Drug Reaction monitoring:
1. Identifying adverse drug reactions
2. Assessing causality
3. Documentation of ADR
4. Reporting serious ADRs to PV centres/ADR regulatory authorities
The NARANJO algorithm is used for assessing the causality based on the Questionnaire. The output comes in any of the following range:
Definite = ≥9,
Probable = 5-8,

Possible = 1-4,
Doubtful = ≤ 0
Proposed system calculates only predictable type Adverse Drug Reactions.
Hartwig and Seigels scale is used for assessing the severity.[11] In order to improve the accuracy of our assessments, individual causality assessments were undertaken using the Naranjo's causality assessment scale which classifies drug reactions into definite, probable, possible and doubtful ADR[10]. Severity of the reaction was assessed using ADR Severity Assessment Scale (Modified Hartwig and Siegel [11] which classifies ADR into mild, moderate and severe. Preventability assessment was done by using Schumock and Thornton scale which classifies the ADRs into definitely preventable, probably preventable and not preventable. Figure III shows the relation between toxicity and ADR.

Figure 3 : relation between toxicity and ADR

VII. RESULTS AND DISCUSSION

ADR causality and severity are calculated and the output will be as follows
1. Minor ADRs-are self-limiting and do not donate to extension of length of hospital stay.
2. Reasonable ADRs- require therapeutic interference or hospital admission or prolonged hospital stay by at least one day.
3. Critical ADRs- life threatening, requiring serious medical care or produce disability or lead to death.

The success or failure of pharmacovigilance activity depends on the reporting of suspected adverse reactions. Reports made by a health professional are an interpretation of information originally provided by a patient who has experienced the actual benefit or harm of a medicine taken.

The mean age of the patients with the cutaneous drug reactions was 35 years. Most of them were in the age group of 30-37 years, with 49% females and 51% males. The most common reactions observed were urticaria, fixed drug eruptions, acneform eruptions, morbilliform eruptions , maculopapular rashes, and angio-oedema . The most common drugs which caused the reactions were Non Steroidal Anti-Inflammatory Drugs (NSAIDs)[5] , Quinolones , Amoxicillin and Corticosteroids. Most of the reactions were mild to moderate in severity and all of them were preventable.

VIII. GOOD PHARMACOVIGILANCE PRACTICE

To attain a coherent pharmacovigilance system it is vital that guidelines and standards are developed, which describe the practical details of the intended information flow.

Effective pharmacovigilance relies on contributions by many people with varying educational backgrounds. The concept of pharmacovigilance is normally not well understood, either by health professionals, patients or the general population. To attain a coherent pharmacovigilance system it is most important that guidelines and standards are developed, which describe the practical details of the intended information flow. Such standard operating procedures should include information on the following:

- What constitutes a reportable adverse reaction?
- Who is expected to report an observation of a suspected medicine-related problem?
- The availability and practicalities of filling in a reporting form.
- Procedures for submission or collection of reports.
- Routines for assessment, follow-up and processing of case reports at the pharmacovigilance centre.
- Procedures for analysis of aggregated information and options for action.
- Good communication practices.
- A description of indicators by which the progress of the monitoring system may be measured.

Pharmacovigilance guidelines are the main materials available for use in the training of peripheral health workers in pharmacovigilance

IX. CONCLUSION AND FUTURE SCOPE

It can be concluded that the pharmacovigilance is a versatile tool for taking care on public health also ensuring safety and quality of drug entities. In other words, pharamcovigilance is the ultimate key for maintaining drug safety and quality.Pharmacovigilance is used in the following areas. National drug policy, regulation of medicines, clinical practice, disease control public health programmes.The patterns of the cutaneous adverse drug reactions and the drugs which caused them varied in our study population according to the pattern of the drug intake, the associated illness and the susceptibility of the patients.

A sound knowledge of the adverse drugs reactions, a careful history taking and a cautious approach during the prescription of new drugs can prevent most of these adverse drug reactions.

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