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Review Article on Importance of Pharmacovigilance Programs in India

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ABSTRACT

Pharmacovigilance defined by the world Health Organization as "the science and activities relating to the detection, assessment, understanding, assessment and prevention of adverse effect or any other drug related problems" it plays a key role in ensuring that patients receive safe drugs. Our knowledge of a drug's adverse reactions can be increased by various means, including spontaneous reporting, intensive monitoring and database studies. The major problem in India is the under- reporting of adverse drug reactions.

Keywords: Drug regulation, Drug safety, intensive monitoring, pharmacovigilance, adverse drug reaction, ADR assessment, Spontaneous reporting, Transparency

INTRODUCTION

Pharmacovigilance also known as drug safety, is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term, and short term side effects of medicines. Pharmacovigilance is an integral part of clinical research. These adverse drugs reactions (ADRs) not only add to suffering of patients but also increase morbidity and mortality along with a financial burden on society. The overall incidence of ADRs in hospitalized patients is estimated to be 6.7% (range 1.2-24.1) and that of fatal ADRs 0.32%(0.1-0.85).Data indicates that in patients who experience ADRs, death rates are 19.18% higher and the length of hospital stay is 8.25% higher. Total medical cost for patients with ADRs are increased by an average of 19.86%. The lack of ability of clinicians to suspect or detect such adverse events related to drugs might lead to inappropriate management of adverse events, thus exposing the patients to additional drug hazards. National pharmacovigilance programmes have been introduced which occupies a prime role in increased the public awareness about drug safety. This review article explains the need and importance of pharmacovigilance in daily lives of doctors patient and the pharmaceutical industry.

METHODS USED IN PHARMACOVIGILANCE

Many research developed different of causality assessment of ADRs by utilizing different criteria like chronological relationship between the administration of the drug the and the occurrence of the ADR, screening for non- drug related causes, confirmation of the reaction by in vivo Or in vitro tests, and antecedent information on homogenous events attributed to the suspect drug or to it's therapeutic class, etc. to defined ADRs in different categories.

1. Kramer et al. Method

This method applies when the offending drug is administered and a single adverse drug events has taken place. Each adverse event is assessed independently and assessment is prepared. One of the advantages of this algorithm is it's transparency

2. Naranjo et al. Method

It is utilized to verify causality in a variety of clinical situations utilizing the categories and definitions of definite, probable, possible ,and doubtful. It consists of ten questions which are answered as yes, no and unknown The event is assigned to a probability category predicated on the total score after totaling . A total score of greater than 9 is definite, probable is 5-8 possible is 1-4 and doubtful greater than 0.

3. Ciba –geigy method

Expert consensus meeting have resulted in Ciba- geigy method. Experts used their clinical judgement to assess adverse drug events and assign causality on a VAS. This method uses a checklist which is composed of 23 questions, which is split into 3questions 1) present patient adverse reaction history 2) past patient adverse reaction history 3) monitoring physicians experience

4. Balanced assessment method

This method evaluate a case report on visual analog scale (VAS) models that each criterion is fulfilled individually. It has an added advantage that it considers an alternative causative factor as a possibility and not just a separate factor.

5. Loupi et al. Method

This method develop to assess the teratogenic potential of drug. The first sections of the algorithm sanction for the drug to be omitted if not implicated in the inception of the abnormality. The second section weigh the bibliographic data.

6. Australian method

Australian method involves the evidence which helps in to draw the conclusion. Such as timing, and laboratory information from case reports presented and the antecedent cognizance on the suspect drug profile.

7. Rousseluclaf causality assessment method

The method is used in disease states such as liver and dermatological problems.

ADVERSE DRUG REACTION

Any noxious change which is suspected to be due to a drug, occurs at doses normally used in man, requires treatment or decrease in dose or indicates caution for in future use of the same drug.

Adverse drug event

Any untoward medical occurrence that may present during treatment with medicine, but which may not have causal relationship with the treatment

ADVERSE DRUG REACTION REPORTING TOOLS

Adverse drug reactions reporting tools or monitoring is a process of continuously monitoring of undesirable effect suspected to be associated with use of medical products. ADR reporting covers all pharmaceutical products, biological, herbal drugs, cosmetics and medical device.

SPONTANEOUS REPORTING SYSTEM

1) Standardized evaluation of causality and significance
2) Regionalization
3) Detailed drug utilization data.
4) Repossession of further data
5) Access to all important pre and post marketing information

DOCUMENTATION OF ADRs

It takes interests on reports of the following

A) Every adverse effect suspected or occurred by nee drugs and drugs of current issue
B) Documentation of various drugs that causes ADRs, which include death, life- threating conditions, disability, hospitalization and congenital abnormalities

The ADR form can be collected through any pharmacovigilance centre. After reviewing the form, the centre forwards it to the regional centre and after that, it is propelled to the zonal centre (goldman 1988: palaian et al. 2006: Ravi shankar et al. 2010) The details are then statistically inspected and forwarded to WHO – uppsala monitoring committee (UMC)

MONITORING OF ADVERSE DRUG REACTIONS

Adverse drug reaction monitoring is the practice of continuously monitoring the undesirable effects caused using any drug. Pharmacovigilance plays an impersonation in monitoring Adverse drug reactions.

Adverse drug reactions can occur by use of various pharmaceutical products, herbal drug, cosmetics, medical devices, biological etc. Introducing this monitoring procedure intends at warranting patients to receive safe and beneficial medicinal products.

Benefits of ADR Monitoring

ADR Monitoring and reporting programme can following benefits
It prevents the predictable adverse effects and helps in measuring ADR incidence.
It initiative risk- management plans.
It caters information about quality and safety of pharmaceutical products.
It instruct health care team, patients, pharmacist and nurses about adverse drug effects and creates awareness regarding ADRs.

ROLE OF PHARMACOVIGILANCE PROGRAMM OF INDIA

Many incidents occurred that caused the need of laws and regulations regarding the safe use of drugs. After rofecoxib with drawl from the European market, the FDA rules on post market surveillance were criticized and a new system of pharmacovigilance was introduced that provided information on identified risks.

Throughout the early post – marketing period, the product might be used in different groups of people from those used in clinical trials and much larger population might be exposed in a relatively short time. The post marketing product is required to develop new information, which can focus on the benefits as well risks of the product pharmacovigilance produces detailed information of marketed products to ensure their safe use.

Serious Adverse event
Serious adverse events include adverse events
Result in death
Require either in patients hospitalization or the prolongation of hospitalization
Are life threating
Result in a persistent Or significant disability
In capacity or result in a congenital anomaly And birth defect
Other important medical events, based upon appropriate medical judgement, may also be considered serious adverse events if a trail participants health is at risk and intervention is required to prevent an outcome mentioned

PHARMACOVIGILANCE IN INDIA

India has more than half a million Qualified doctors and 15,000 hospital having a bed strength of 6, 24,000 . It is the fourth largest producer of pharmaceuticals in the world. It is emerging as an important trial hub in the world. Many new drugs are introduced in our country. Therefore, there is a need for a vibrant pharmacovigilance system in the country to protect the population from the potential harm that may caused by some of these new drugs.

In 1986

1.ADR monitoring system for india proposed with 12 regional centres
2.Oversaw areas with population size of approximately 50 million each

In 1977

1.India joined WHO- ADR reporting program based in uppsala, sweden
2.3 centres viz, AIIMS, KEM, and AME
3.A national pharmacovigilance centre located located in the department of pharmacology, All india institute of medical sciences (AIIMS) new delhi and two Who special centrea in Mumbai (KEM Hospital) and aligarh (JLN hospital aligarh) . These centres were to report ADRs to the drug regulatory authority of india. The major role of these centres were to report ADRs to medicines marketed in India.

NATIONAL PHARMACOVIGILANCE PROGRAMM (NPP)

2004

The national pharmacovigilance program (NPP) officially inaugurated by the centre health minister as new delhi.

2005

The ministry of health and family welfare in India initiated the NPP, coordinated by the central drugs standard control organization (CDSCO)

Programme was started with 2zonal, 5 regional and 24 peripheral centres

FUTURE ASPECTS OF PHARMACOVIGILANCE IN INDIA

In India there is an immense need to understand the importance of pharmacovigilance and how it impacts the life cycle of product.

It will benefit all patients including health care professionals, regulatory authorities, pharmaceutical companies and the consumers.

The proposal that have to be followed
High level discussion with various stake holders
Making pharmacovigilance reporting compulsory and introducing pharmacovigilance inspections.
Creating a single country specific adverse event reporting form to be used by all
Building and maintaining a robust pharmacovigilance system
Education and training of medical students, pharmacist and nurses in area of pharmacovigilance.
Building a network of pharmacovigilance and pharmaco epidemiologists in India.
Pharmacovigilance developments
Education is the appropriate use of drugs
Drug safety information
All the evidence needed to assess and understand risks and benefits must be openly available

IMPORANTCE OF PHARMACOVIGILANCEAS FOLLOW

A. Case report
B. Analysis of case series
C. Developing case series
D.Clinical trails
E. Safety and monitoring products
F. Spontaneous reporting
G. Steps in pharmacovigilance program me
H. Pharmacoepidemiological study
I. Clinical trails
J. Find the risk of drug
K. Case report
L. Use of data mining to identify product- event combination
M. Spontaneous report

PARTNERS IN PHARMACOVIGILANCE

1.Hospital and academia
2.Government
3.Healthcare professionals
4.Patients
5.World Health Organization
6.Media
7.Consumer

CONCLUSION

The pharmacovigilance in India has become an important public health issue as regulators, drug manufactures, consumers, and healthcare professionals are faced with a number of challengers . The pharmacovigilance in India continues to grow, evolve, and improve India is the largest producer of pharmaceuticals and new emerging as an important clinical trial hub in the world

The pharmacovigilance programme India is coordinated at IPC through NCC under the control of indian government to generate an independent data on safety of medicines, which will be at par with global drug safety monitoring standard.

National and regional pharmacovigilance systems are well- adapted bodies, attuned to the intricate collection and analysis of ADR data that leads to timely alerts and interventions to protect population health.

Every reporting by health care professional is important, even though focus on the serious unlabelled types of ADRs is more important.

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