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Review on Concept of Pharmacovigilance and their Opportunity in India

Rakesh R. Tarare , Rashmi Sonkusare, Chandrashekhar M. Deotale,
Jayesh D. Nil, Piyush G. Ashtankar
New Montfort Institute of Pharmacy, Ashti, Wardha, Maharashtra, India

Abstract: *Adverse drug reactions (ADRs) can cause serious health problems, as shown in studies about drug-related hospitalizations. To build knowledge of and raise awareness about ADRs among healthcare professionals, more educa tion in the field of ADRs and pharmacovigilance (PV) is needed. No standard exists for teaching PV at universities for medical, pharmacy, dentistry and nursing students, so a core curriculum needs to be developed to teach important aspects of PV to students. In September 2016, a stakeholders' meeting was initiated on behalf of the World Health Organization (WHO) and organized by the Netherlands*

Keywords: Adverse drug reactions

I. INTRODUCTION

Pharmacovigilance is not limited to pharmaceutical medicines but also concerns herbal and other traditional medicines. Pharmacovigilance practices and tools though have developed in the context of conventional medicine and have rarely considered the complexities of monitoring the safety of medicines sourced from plants Medicines help us treat many diseases, but adverse drug reactions (ADRs) cause serious health problems. Studies indicate that ADRs account for approximately 5% of all acute hospitalizations Pharmacovigilance is defined by the WHO as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects, or any other problem in the field of medicine".

Competence in handling ADRs in clinical practice is important, not only for patient safety in individual patient care but also for drug safety monitoring at a population level. The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem is called pharmacovigilance (PV)

History and definitions

Pharmacovigilance was officially born in December 1961 with the publication of a letter (case report) in the Lancet by W. McBride, the Australian doctor who first suspected a causal link between serious fetal deformities (phocomelia) and thalidomide drug used during pregnancy: Thalidomide was used as an antiemetic and sedative agent in pregnant women In 1968, the World Health Organization (WHO) promoted the "Programme for International Drug Monitoring", a pilot project aimed to the centralization of world data on ADRs. In particular, the main aim of the "WHO Programme" is to identify the earliest possible pharmacovigilance signals. Italy joined this international program in 1975. As of April 2013, 112 countries have joined the WHO Programme for International Drug Monitoring, and in addition 32 'associate members' are awaiting full membership

Pharmacovigilance is defined

by the WHO as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects, or any other problem in the field of medicine". The monitoring of spontaneous suspected ADRs reports represents the key component of the integrated systems of pharmacovigilance

Adverse drug reaction

is an expression that describes harm associated with the use of given medications at normal dose. The meaning of this expression differs from the meaning of "side effect", as this last expression might also imply that the effects can be

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beneficial. Adverse effects may be local, due to abnormal pharmacokinetics such as Comorbid disease states, Genetic factors, Phase I reactions, Phase II reactions. Interaction swith other drugs are increased with polypharmacy, Protein binding and Cytochrome P450

Examples of adverse effects associated with specific medications

1. Abortion, miscarriage or uterine hemorrhage associated with misoprostol (Cytotec), a Labor-inducing drug (this is a case where the adverse effect has been used legally and illegally for performing abortions).
2. Addiction with many sedatives and analgesics such as diazepam, morphine,etc.
3. Birth defects associated with Thalidomide and Accutane
4. Bleeding of the intestine associated with aspirin therapy.
5. Cardiovascular disease associated withCOX-2 inhibitors (i.e. Vioxx).
6. Deafness and kidney failure associated with gentamicin (an antibiotic)
7. Death, following sedation in children using propofol (Diprivan).
8. Dementia associated with heart bypass surgery.
9. Depression or hepatic injury caused by interferon.
10. Diarrhoea caused by the use of orlistat (Xenical).

II. FRAMEWORK FOR PHARMACOVIGILANCE IN INDIA

various Zonal, Regional and Peripheral Centers will be supervise by the National Pharmacovigilance Advisory Committee (NPAC) and will perform the functions of "Review Committee" for this program. A countrywide Pharmacovigilance programmed is initiating by the Central Drugs Standard Control Organization (CDSCO) under the guidance of Ministry of Health & Family Welfare and Government of India. Th The National Pharmacovigilance Program established in January 2005, New Delhi and the performance e National Pharmacovigilance Centre shall coordinate the program at CDSCO. The National Centre will operate under the supervision of the National Pharmacovigilance Advisory Committee to recommend procedures and guidelines for regulatory services

Pharmacovigilance program for india [PvPI]requirement for ADR reporting in India

Constitution And Objectives of Pharmacovigilance Program of India (PvPI)
India's pharmacovigilance

1. CSCA, Central Drug Standard Control Association – Ministry of Health and Family Welfare, DGHS
2. PV in India: Legislative Requirements –The Drug and Cosmetic Act of 1945, Schedule Y

III. METHODS TO GENARETE SAFETY DATA DRUGE PRE CLINICAL POST CLINICAL DRUG LIFE

1] Drug Discovery

Typically this involved highly parallelized processes for making new compounds and testing them in high-throughput screens. From this, a certain number of hits will be obtained and these will be whittled down by further analysis into a set of leads.

2] Pre-clinical Trials

This includes in vitro and in silico testing of the compounds to identify the best members of a series to take into Clinical Trials. This is also where the first stages of safety assessment are undertaken via toxicity testing in animals. If a drug shows promise in preclinical trials, a pharmaceutical company can request permission from the FDA to begin testing in humans (known as First-in-Man or FIM trials). This is called an Investigational New Drug (IND) application. In Europe, the European Medicines Agency (EMA) equivalent is an Investigational Medicinal Product Dossier (IMPD).

3] New drug application (NDA)

Once the Phase 3 clinical trials are finish, a pharmaceutical company can appeal FDA approval to market the drug within the USA. This is called a New Drug Application (NDA). The NDA hold all the scientific data that the company

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has accumulated during clinical trials. Within the EU, pharmaceutical companies yield a Marketing Authorization Application (MAA).

4] Regulatory (GLP) Toxicology

Good Laboratory Practice (GLP) standards contain those required by local regulatory authorities or ethics committees prior to a drug can be given to human subjects for the first time. Regulatory toxicology also balance to learn the required for supportig a New Drug Application (NDA).

Major Challenges are

1) Globalization.
2) Web-based sales and information
3) Broader safety concerns
4) Public health versus pharmaceutical industry economic growth
5) Monitoring of established products
6) Developing and emerging countries

OPPORTUNITIES IN PHARMACOVIGILANCE

1) Audits and vendor management
2) Technology services
3) Literature monitoring
4) QPPV services
5) Safety content services
6) Safety information management.
7) Safety operations
8) Aggregate reports
9) Risk management

IV. CONCLUSION

If every member of the healthcare industry, including doctors, nurses, pharmacists, and others like patients, reports all ADRs, the regulatory body can act quickly and potentially prevent the availability of illegal drugs in India. Systems for pharmacovigilance are required to protect the public's health. Information creation that can support healthcare processes has received only minor significance. One of the main responsibilities of pharmacovigilance is the gathering and dissemination of this data.

The ability to identify which people are at risk from drug use is a requirement for pharmacovigilance types. The objective of India's pharmacovigilance programme, also known as adverse drug reaction observation and reporting programmes,

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