Pharmacovigilance Training for Health Professional

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Abstract

The problems with patients now the new disease by drugs during therapy called adverse drug reaction needs great attention and reporting to both regulators and manufacturers for further data. The mechanism of adrs needs great evaluation by pharmacologist and R&D to work on SAR(structure activity relationship with molecular activity and biomarkers for disease and drug adverse reactions difference for its benefits in early detection is called as Pharmacovigilance Every health workers should be trained.

KEYWORDS-Pharmacovigilance, Adverse drug reaction, adverse drug event, challenges, dechallange, Bio marker

Introduction-We define an adverse drug reaction as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product." Such reactions are currently reported by use of WHO's Adverse Reaction Terminology, which will eventually become a subset of the International Classification of Diseases. Adverse drug reactions are classified into six types (with mnemonics): dose-related (Augmented), non-dose-related (Bizarre), dose-related and time-related (Chronic), time-related (Delayed), withdrawal (End of use), and failure of therapy (Failure). Timing, the pattern of illness, the results of investigations, and rechallenge can help attribute causality to a suspected adverse drug reaction. Management includes withdrawal of the drug if possible and specific treatment of its effects. Suspected adverse drug reactions should be reported. Surveillance methods can detect reactions and prove associations.

Aim: To protect serious adverse drug reaction and assess incidence, predictability, preventability and severity of adverse drug reactions (ADRs) in hospitalised patients. Medical records were reviewed. Causality, predictability, preventability and severity may be assessed for each ADR. Ninety percent of ADRs were predictable. Of these, 2% is classified as definitely preventable and 50% probably preventable. The most common ADRs are constipation, nausea, vomiting, fatigue, alopecia, drowsiness, myelosuppression, skin reactions, anorexia, mucositis and diarrhea, some sever toxicity like hand foot syndrome (neurotoxicity), pulmonory fibrosis, haemorrhagic cystitis, ototoxicity, nephrotoxocity, cardiotoxocity, hepatoxicity, cerebellarataxia, arthralgia, thrombotic events, hypersensitivity reactions, venous thromboembolism,

pure red-cell aplasia, acute myeloid leukemia, myelodysplastic syndrome, thrombotic thrombocytopenic purpura, etc and death.

Safety information and adverse event reporting program pharmacovigilance, notes that all serious adverse events should be reported. A serious adverse event is defined as being one that is life-threatening, requires hospitalization, results in a disability or congenital defect, permanent impairment or damage, or results in death. Suspected ADRs should be classified according to a four-tiered system, ranging from "certain" to "probable," "possible" to "unlikely" based on evidence and timing.

 An ADR may be defined as certain: If the time frame of the reaction can plausibly be linked to the drug; patient responds positively to the removal of the drug and a rechallenge results in the reappearance of the initial reaction.
 An ADR may be defined as probable: If no rechallenge information is available.
 An ADR may be defined as possible: If time frame is reasonably related to the administration of the drug in question and its occurrence might also be the result of other drugs or diseases.
 An ADR may be defined as unlikely: If other chemicals, drugs, and diseases provide likely explanations.

Pharmacovigilance in its broadest terms can be defined as monitoring medicines to determine unrecognized adverse effects or changes in the patterns of their adverse effects. In other words pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions or any other drug-related problem. India is the fourth largest producer of pharmaceuticals in the world, It is emerging as an important Clinical trial hub in the world.

IMPORTANCE OF PHARMACOVIGILIANCE : IS early detection of ADR on functional & physiological system including Peripheral Nervous System, Central Nervous System, Cordiovascular System, Respiratory System, Renal & GIT System etc. ADR could be managed by well trained organized drug management service team from, pharmacist Nurses, Professional Doctors from different specialties to prevent unnecessary suffering and financial loss sustained by patient due to unsafe and inappropriate use of medicine.

Medicine related morbidity & Morbidity in major problems due to Adverse Drug Reaction – 10-20% of Hospitalized Patient & ADR Health care budget – 15-20% of total Health care are required globally for medical insurance and persons for unnecessary spending money over ADR related

THESE ARE MINIMUM ADR OCCURS IN

IN NORWAY – 11.5%, INFRANCE – 13.0%, IN U.K. – 16.0%, IN INDIA – 25-27%,

Why ADR Occurs because

1. Wrong Prescription Practices, 2. Self Medication, 3. Genetics – G6PD Deficiency
4. Diet – High Carbo & Fat, 5. Traditional & complementary medicine, (Herbal, Unani, Homeopathic, Toxicological Substance
5. Blood Product, Vaccine, biological, medical devices,
6. Drug Related Problems
   Drug Manufacturing – size of particles, capsule, solution, solvent, Drug – distribution, Uses, Indication, Dose, Storage, Availability, Racial

difference – G-6-PD, Country to Country problem, (These ADR are excluded with others and established ADR by Drug, Over dose, Misuse, Poisoning, Medication error, Therapeutic failure

Method Reporting System: Many are concerned about the recent failure of the regulatory body to comprehensively report on serious ADRs. Even when ADRs are discovered early and are included in the drug's initial package insert, the comprehensiveness of the safety information disseminated by the regulatory body or pharmaceutical sponsor is frequently poor. Doctors can also report ADRs to independent pharmacovigilance organizations. Adverse Drug Events (ADEs) and adverse drug reactions (ADRs) are a significant source of morbidity and mortality among patients. ADRs account for more than 100,000 deaths in the United States annually and in India also .

Assessment of ADR

An assessment of whether the adverse event is related to the drug involves five categories viz. not related, unlikely, possibly, probably, definitely. Identifying the adverse effects of drugs, thus transforming adverse events into adverse drug reactions, is a useful and necessary but complicated task.

1. History taking
2 Time relationship ingestion / Administration & onset of reaction
3 Nature of reaction & known area ADR
4 Relocation resolve & cessation of drug
5 Any Condition explain the reaction
6 Dechallenge and rechallenge are very useful tools for attributing an adverse reaction to the drug in question.
7. Several means are at our disposal to achieve causal assessment: spontaneous reporting, clinical trials, epidemiological studies, cohorts with and without controls, and case-control studies, with each having advantages and limitations Intermediate reaction require further assessment testing Sever reaction – Anaphylactic, Steven Johnson Syndrome exfloative dermatitis & hepatotoxicity need rescreening test

Discussion

There are a number of reasons why efforts to rapidly report ADRs are hampered., because ADRs are particularly difficult to identify and distinguish from progression or comorbidity. There is a high rate of off-label drug use in settings for which drug safety profiles have not been sufficiently studied. Adverse events may be caused by the exacerbation of an existing problem such as already having side effect, medication error, or an adverse drug reaction (ADR). A drug may be considered the cause of the event if the event would not have occurred without the drug, if the drug resulted in the event occurring sooner than normal, or if the drug amplified the severity of the event as Dechallange& rechallange.

The evaluation of functional or physiological toxicities plays a key role in the safety assessment process. It should be viewed as complementary to traditional assessments of toxicity based upon morphological or biochemical lesions.

Pharmacovigiliance also develop good and effective methodology in the dynamic evaluation of new biological pharmacological and device technology in preclinical, clinical, biostatical and epidemiological discipline.

It also pertains to the activities of ADR effects of Drug at therapeutic doses and on animal & human beings.

The introduction of pharmacovigiliance into the environment is gaining the attention of both regulators and pharmaceutical industry it also include for purposes of the identification of relevant target species and – organ functions and the design of specific environment toxicology studies. The last decade has seen a growing awareness of the importance of Pharmacovigiliance for threatening effects e.g. cardiovascular functions.

Pharmacovigilance has also study over the adverse effects of new drug entities in animals and humans can be manifested by changes in the structural, biochemical or physiological status of the organism.

The organ systems and functions most frequently responsible in these events or the central nervous (seizure), cardiovascular (hypotension, hypertension, and arrhythmia), respiratory (asthma/bronchoconstriction), and renal (glomerular filtration) systems, and the result is almost always a critical care emergency.

The origins of pharmacovigiliance are grounded upon observations that organ functions & Investigation done in the specialized laboratories e.g., for cardiovascular and respiratory function, nephrology, blood coagulation, psychopharmacology, neuropharmacology, analgesic and anti-inflammatory research, gastroenterology, diabtology, atherosclerosis, and endocrinology, the potential new drug was studied according to internal rules for which the head of the department of pharmacology was responsible and drug monitoring & Signaling from pharmacovigiliance center should be conducted.

CLINICAL PRACTICE OF PHARMACOVIGILENCE IN TERTIARY CARE HOSPITAL

Phormacovigilance is “those studies that investing the potential undesirable pharmacodynamic effects of a substance on physiological function in relation ship to exposure in the therapeutic range and above”. There primary objectives are encompassed in these investigations.

1. To provide a perspective of the potential pharmacodynamic risk posed to humans by exposure to a new therapeutic agent.
2. To investigate the underlying mechanism (s) of observed effects to refine and improve upon the integrated assessment of risk posed by the drug when adverse findings have been noted in non clinical or clinical investigations.
3. Peak blood levels of parent drug and any major metabolites.

FUTURE OF PHARMACOVIGILIANCE PRACTICE

The future of pharmacovigiliance will be contained within the vision of its current and future leaders, the issues and concerns that they face, and the solutions to the importanct problems that they generate.Inherent in the novelty of new targets is the risk of unwanted effects that may or may not be detected with current techniques. The scientific challenge facing pharmacovigiliance is to keep pace, to adapt, and to incorporate new technologies in the evaluation of new drugs in non-clinical models and identifying the effects that pose a risk to human volunteers and patients.

Pharmacovigilance's embracement of modern electrophysiological techniques to evaluate the effects of new drugs on the ionic components of the cardiac action potential, and telemetry techniques to permit the chronic monitoring of physiological functions in unstressed animals.

However, these tests may not appropriately detect specific response in humans at other ages (e.g., neonates, adolescents, and geriatrics) or those with underlying chronic diseases(e.g., heart failure, renal failure, and type II diabetes), conditions which may alter the pharmacodynamic response to a drug. In some cases, animal models that over express or are efficient in the unique targets.

If there is proper pharmacovigiliance practice done – the net morbidity and expense will become very low and PHV training will make less iatrogenic activity. The rationality of pharmacotherapy will be justified.

THERE ARE CERTAIN REQUIREMENTS IN PHARMA COVIGILANCE IN PRACTICE

1. Regularity Agency
2. Special Center for ADR Study & Maintenance of Activity and Rescrening.
3. Multidisciplinary Collaboration of different medical departments
4. Rational use of drugs.
5. National Pharma covigilance Center.
6. Regulation/Legislation for drug monitoring.
7. National policy for plans of action.
8. Education on safe and effective pharmaco Therapy.
9. Information of ADR to professional and consumers
10. Monitoring of the impact through process.
11. Trained staff in Hospital or regional area.
12. Control over OTC drugs & Internet selling drugs.

RESULT

Without details and careful documentation, it can be difficult to properly diagnose the event and monitor recurrences. Thus, it is imperative that doctors and nurses take extra care to record in a patient's medical charts any adverse events likely to have been caused by a drug. It is then necessary to distinguish between an ADE and an ADR. An ADE is defined as harm caused by the misuse of a drug, the likelihood of a suspected ADR according to introductory definition.

CONCLUSION

ADRs are common in hospitalised patients and are predictable and at least probably preventable in many instances. Improved use of preventive measures has the potential to contribute to reducing the incidence and severity of ADRs. Recognition and understanding of the discrepancy that exists between clinical severity and patient- perceived severity of ADRs will enable specific areas to be identified and targeted for vigourous intervention.

Many new drugs are being 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 be caused by some of these new drugs. The search for casualty in pharmacovigilance is a necessary scientific goal, but a high degree of suspicion may be all that is necessary to withdraw a drug from the market if it is suspected of causing serious adverse effects.

The single most important goal of pharmacovigiliance is to establish that how close is the relationship between drug and adverse event and whether the drug has actually caused the event. We have to be vigilant all the time during a clinical trial or clinical practice and always expect and suspect the probability and possibility of adverse reactions. Thorough date recording, analysis and reporting are the essential elements of pharmacovigilance. The conclusions must be based on our pharmacological knowledge, existing listing literature and databases. Ultimately we have to assess the strength of relationship between a drug and the event. The reports so generated serve the national and international drug regulatory agencies for determining their future course of action for approving, disapproving or withdrawing a drug. There are so many clinically experienced functional side effects due to ADR are because of toxic reaction due to morphological lesion which are not recognized by screening test previously need. Drug monitoring and ADR reporting in clinical medicine, Pharmacology & Toxicology Department. The PHV centre should play major role in , decision making, individual, regional, national & International for best benefit/risk assessment for safe & effective (cast also) rational pharmacotherapy & improve patient & public health education.

FUTURE CHALLENGES

JCI is covering 10-12% patient safety pharmacovigiliance safe patient for OPD & Indoor up 25-35% so pharmacovigiliance mandatory training for health professionals like nurses, chemist, health assistant & clinician (Doctor) are required.

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