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Pharmacovigilance Activities

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Abstract: *Pharmacovigilance (PV) is an important area for the safety and ensuring that the patients are safe in every aspect of the drugs being taken or injected. India is still in its nascent stage; there is a lot to be done and to learn, in the field of PV, in ensuring that the safe implementation of the activities and work done is achieved. The major problem in India is the under-reporting of adverse drug reaction (ADR). There is an increasing number of hospitalization of patients owing to adverse effects of drugs and it becomes a challenge to find out the exact cause the ADRs when a patient in treated with multiple drugs simultaneously. In the review, we will explore the different types of assessment scale to do the ADR assessment and to find its causative agents.*

Keywords: *Pharmacovigilance*

I. INTRODUCTION

DEFINITION

The branch of science who`s activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug related problem

Pharmacovigilance Overview

Pharmacovigilance encompasses proactive surveillance, identification, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

It's fundamental in ensuring patient safety and public health by minimizing risks associated with pharmaceutical interventions while maximizing therapeutic benefits.

Pharmacists' Role in Pharmacovigilance:

Pharmacists play a pivotal role in pharmacovigilance, going beyond traditional responsibilities to detect, evaluate, and mitigate adverse drug reactions (ADRs).

Their direct patient interactions and specialized knowledge of medications equip them to recognize, assess, and manage medication-related risks effectively

Improvement of patient care and safety inrelation to the use of medicines with medical and paramedical interventions remains to be an important parameter. The main objectives of pharma covigilance involve exhibiting the efficacy of drugs by monitoring their adverse effect profile for many years from the lab to the pharmacy; tracking any drastic effects of drugs improving public health and safety in relation tothe use of medicines; encouraging the safe, rational and cost-effective use of drugs promoting understanding, education and clinical training in pharmacovigilance; and effective communication to the generic public. In addition, providing information to consumers, practitioners and regulators on the effective use of drugs along with designing programs andprocedures for collecting and analyzing reports from patients and clinicians conclude to the objectives of pharmacovigilance studies

Significance of Pharmacovigilance:

Pharmacovigilance serves as a proactive mechanism for continuous monitoring of drug safety in real-world clinical settings, complementing insights gained from clinical trials.

By detecting safety signals early, pharmacovigilance facilitates informed decision-making regarding medication use, prescribing practices, and regulatory interventions.

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Objective of the Project:

- The project aims to provide an insight into the intricate dynamics of pharmacists' roles in pharmacovigilance, exploring their responsibilities, challenges, and opportunities within this critical domain of healthcare
- Aims of PV
- PV has an important role in the assessment of side effects caused by the drugs whether it is caused by oral drugs; parenteral drugs or I.V. drugs.
- These drugs are pretested for ADRs before it is being marketed worldwide.
- PV has a key role in assessment, detection and identification of drugs which caused a particular ADRs and the mechanism by which it caused the injury.
- But to fulfill these requirements of finding and eliminating, a side effect is the responsibility of the doctors involved in the case; nurses, health workers, residents and proper guidance of the patients themselves help it to alleviate the root cause of ADR.
- Pharmacovigilance constitutes a multifaceted discipline integral to the overarching framework of healthcare delivery. At its core, pharmacovigilance encompasses a systematic approach to monitoring, detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems associated with pharmaceutical products. It represents a proactive endeavor aimed at ensuring the safety and efficacy of medications throughout their lifecycle, from preclinical development to post-marketing surveillance.
- Regulatory interventions, thereby minimizing potential harm to patients and optimizing therapeutic outcomes.

Key components of Pharmacovigilance include:

- Monitoring: The ongoing surveillance of adverse events and other drug-related problems through various data sources, including spontaneous reporting systems, healthcare databases, literature reviews, and signal detection algorithms.
- Detection: The identification of potential safety signals or deviations from expected patterns of drug response through rigorous data analysis and epidemiological studies.
- Assessment: The systematic evaluation of reported adverse events to determine their causality, severity, frequency, and potential risk factors, utilizing standardized algorithms and assessment criteria.
- Understanding: The in-depth analysis of underlying mechanisms, risk factors, and patient characteristics contributing to adverse drug reactions, aimed at elucidating the root causes and informing targeted preventive measures.
- Prevention: The implementation of risk mitigation strategies, regulatory interventions, and public health initiatives to minimize the occurrence and impact of adverse drug reactions, fostering a culture of medication safety and vigilance.

In essence, Pharmacovigilance embodies a collaborative effort involving healthcare professionals, regulatory agencies, pharmaceutical manufacturers, and patients to safeguard public health and optimize medication safety. By fostering transparency. accountability, and evidence-based decision-making. Pharmacovigilance serves as a cornerstone of patient-centered care, ensuring that the benefits of pharmaceutical interventions outweigh their potential risks in real-world clinical practice.

Pharmacist's role in pharmacovigilance

Pharmacists occupy a central position in the healthcare ecosystem, serving as trusted advisors and frontline guardians of medication safety. Their roles extend far beyond the traditional dispensing of medications, encompassing a spectrum of responsibilities that are instrumental in Pharmacovigilance efforts.

First and foremost, pharmacists serve as educators, empowering patients with comprehensive information regarding their medications, including potential side effects and adverse reactions. Through one-on-one counseling sessions, pharmacists enhance patients' understanding of their treatment regimens, fostering a proactive approach to medication management and adverse event reporting. By promoting patient engagement and shared decision-making, pharmacists

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play a pivotal role in facilitating the early detection and reporting of adverse drug reactions, thereby contributing to pharmacovigilance initiatives.

Furthermore, pharmacists function as vigilant observers, leveraging their expertise to detect and assess potential adverse events in real-time clinical practice. Armed with specialized knowledge of pharmacology and therapeutics, pharmacists are uniquely positioned to recognize subtle changes in patients' health status and medication responses. Whether through medication reconciliation processes, medication therapy management services, or routine patient consultations, pharmacists play a crucial role in identifying and triaging adverse drug reactions, ensuring timely intervention and follow- up as warranted.

Moreover, pharmacists serve as active participants in Pharmacovigilance reporting systems, serving as conduits for the timely and accurate submission of adverse event reports to regulatory authorities. Through established reporting channels such as the FDA Adverse Event Reporting System (FAERS) the World Health Organization's Vigibase, pharmacists contribute valuable data that inform post-marketing surveillance efforts and regulatory decision-making processes. By maintaining meticulous documentation and adherence to reporting guidelines, pharmacists uphold their professional duty to prioritize patient safety and public health in Pharmacovigilance endeavors.

Challenges faced by Pharmacists

Despite the invaluable contributions pharmacists make to Pharmacovigilance, they encounter a myriad of challenges that impede their ability to fulfill this crucial role effectively. These challenges stem from various factors, including organizational constraints, resource limitations, regulatory complexities, and cultural barriers within the healthcare system.

One significant challenge pharmacists face in Pharmacovigilance is time constraints. The demanding nature of pharmacy practice, characterized by high patient volumes, administrative responsibilities, and workflow pressures, often leaves pharmacists with limited time to devote to Pharmacovigilance activities. As frontline healthcare providers, pharmacists must balance competing priorities while ensuring the safe and effective use of medications, creating a perennial challenge in allocating sufficient time and attention to Pharmacovigilance endeavors.

Moreover, pharmacists encounter barriers related to the awareness and understanding of Pharmacovigilance principles and reporting processes. Despite their specialized training in pharmacotherapy and medication management, pharmacists may lack comprehensive knowledge regarding the scope and significance of Pharmacovigilance in healthcare.

Inadequate education and training on Pharmacovigilance topics, coupled with limited. access to relevant resources and guidelines, hinder pharmacists' ability to recognize. document, and report adverse drug reactions effectively.

Furthermore, reporting barriers pose significant challenges to pharmacists' engagement in Pharmacovigilance activities. Complex reporting systems, cumbersome documentation requirements, and perceived legal implications associated with adverse event reporting may deter pharmacists from reporting ADRs promptly and accurately. Fear of liability, confidentiality concerns, and uncertainty regarding the consequences of reporting can contribute to underreporting and the underrepresentation of medication safety issues in Pharmacovigilance databases.

Additionally, pharmacists navigate evolving regulatory frameworks and documentation requirements that shape their pharmacovigilance practices. Compliance with regulatory

BASIC DRUG INFORMATION RESOURCES

Drug information is current, critically examined, relevant data about drugs and drug use in a given patient or situation.Current information uses the most recent, up-to-date sources possible.Critically examined informationRelevant information must be presented in a manner that applies directly to the circumstances under consideration(e.g. patient parameters, therapeutic objectives, alternative approaches).

TYPES OF RESOURCES:-

(I) Primary resources

(II) Secondary resources

(III) Tertiary resources

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Once the complete feed of data has been established, it will be the largest database of its kind in the world. It will become an extremely useful resource for academic and commercial research once full access to data mining and statistical evaluation can be provided. Information resources in pharmacovigilance.

ORIGIN OF PHARMACOVIGILANCE

The Thalidomide disaster in 1956 - Thalidomide launched in market and in 1956-61 report of foetal abnormalities (20000 cases) maximum in Germany. In 1962 USA revised law requiring proving the safety and efficacy before issuing marketing authorization.

In 1963 British committee on safety of drug monitoring. In 1964 UK starts the "YELLOW CARDS" system.

In 1964-65 National ADR reporting system UK, Australia, New Zealand, Canada, West Germany, Sweden .

in a hospital and national OBJECTIVE:

1- To know what are the various sources of drug information.

2- To select the appropriate source depending on the information.

Establishing pharmacovigilance programme

Established pharmacovigilanace program

PV is a major post-marketing tool to ensure the safety of a medicinal product.

Apart from the respective drug regulating authorities in each country,

International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use, Pharmacovigilance Planning ICH E2E and World Health Organization-Uppsala Monitoring Centre (WHOUMC) also play key roles towards developing, enhancing and monitoring global

PV system. A PV system is defined as a system used by an organization to fulfill

its legal tasks and responsibilities in relation to PV that monitors authorised medicinal products' safety and detect if any change to risk benefit balance.

After the thalidomide disaster in the year 1961, WHO worked along with its Collaborating Centre to establish a programme for International Drug Monitoring and through this programme, WHO promoted PV at the country level.At the end of 2010, 134 countries were part of the WHO-PV Programme

Minimum requirements for a functional national pharmacovigilance system

The following are the minimum requirements that WHO and partners agreeshould be met in any national pharmacovigilance system.

1. A national pharmacovigilance centre with designated staff (at least one fulltime), stable basic funding, clearmandates, well-defined structures androles, and collaborating with the WHO Programme for International Drug Monitoring;

2. A national spontaneous reporting system with a national individual case safety

report (ICSR) form, i.e. an ADR reporting form;

3. A national database or system for collating and managing ADR reports;

4. A national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management, including crisis communication;

5. A clear communication strategy for routine communication and communication during crises.

The Manpower and the machinery

a) Adequate qualified and experienced man power to run the system - PV staff should have complete knowledge regarding data collection and verification, coding of drugs and adverse events, causality assessment, signal detection, risk management, interpreting the data obtained etc.

*Staff

The expertise desirable in the routines of a pharmacovigilance centreincludes:

Clinical medicine, pharmacology, toxicology, epidemiology. However, a new

pharmacovigilance centre often starts with only a part-time expert

* usually a physician or a pharmacist

* and some secretarial support.

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Planning the basics

A blueprint should be drawn up to establish and get a PV system to work. Care needs to be taken to establish the following:

a) Advisory Committees

A multi-disciplinary advisory committee is desirable, to support the pharmacovigilance centre with regard to the quality of the procedures in:

1. Data collection and assessment
2. Data Interpretation
3. Information publication

A network of experienced advisors in various specializations is helpful

b) Communication process

Getting in conversation with health authorities and local, regional, national bodies and groups engaged in clinical medicine, pharmacology, toxicology, epidemiology, briefing them about the importance of the project and its applicability in modern therapeutics. A bulletin or newsletter distributed to all healthcare professionals or a regular column in reputed (medical and pharmaceutical) journals are good means for the dissemination of information. Prompt data-sheet amendments are important, but data-sheets may be printed infrequently and their educational impact may not be large. In urgent cases of sufficient importance 'Dear Doctor' letters may alert the profession

c) Data acquisition

Designing a template for ADR reporting and making available ADR reporting forms at all times, to hospital departments and general practitioners, on which they can furnish relevant information to the data bank of the center.

d) Dissemination

Producing printed handouts as well as conducting meetings or workshops in hospitals and academia to acquaint health care professionals about the definitions, goals, scope, and methodology of the PV system to create awareness about its relevance in present times.

e) Establishment

Hiring the right qualified and interested staff, getting suitable place for accommodating them as well as the center, making arrangements for telephones, computers, printers, word processors, database management, bibliography support services and an internet.

f) Internal education

Ensuring proper education and frequent updating of the staff belonging to the PV centers by training them in data collection, filtration, mining, verification, interpretation and coding of ADRs, medicines coding, causality assessment, signal detection, risk management, and action in case of serious/fatal adverse drug events (ADE). Data mining is a relatively nascent interdisciplinary area which involves finding correlations and patterns among many fields in large databases with the aim of categorizing the data and summarizing identified relationships.

g) Database and information serivce

Creating a safely stored, classified database which is retrievable and guarded by required degrees of confidentiality. The provision of a high quality information service to healthcare professionals is a basic task of a pharmacovigilance centre and a major instrument in the stimulation of reporting. For this purpose and for the assessment of case reports the centre should have access to a comprehensive and up-to-date literature source and information database.

Location of the centre in a large hospital usually has the advantage of a library within reach. National pharmacovigilance centres can have online access to the database of the UMC and be on the mailing lists of adverse drug reaction and drug bulletins produced by the World Health Organization and many national or regional centers.

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h) Promotion

To inculcate and promote the habit of reporting ADRs to the higher center, medical journals, health bulletins and other professional healthcare publications.

I) Networking

To encourage healthcare professionals to contact institutions working on a global scale in PV e.g. Uppsala Monitoring Centre (UMC) WHO department of Essential Medicines and Medicines Policy, Geneva, and net groups like International Network for the Rational Use of Drugs (INRUD), E-drug, and Network for Rational Use of Medicines (NetRUM)

3. Data

Pharmacovigilance at present thrives heavily on a regional/country wide reporting of suspected ADRs throughspontaneous reporting system from motivated reporters. It usually picks up signals of rare, serious, unprecedented ADRs. Reports of suspected ADRs are taken in case report forms (CRF) which in PV is defined as a notification relating to a patient with an ADE (or laboratory test abnormality) suspected to be induced by a medicine. The CRF should be distributed to health care professionals across the area covered by a particular PVcenter regularly, and a suitable system has to be developed to ensure that the filled forms are either collected or could be posted free, or sent by e mail/FAX to the center, so that there is an uninterrupted and free flow of data.A CRF should contain minimum following information

* Patient: Age, gender, medical history in brief, ethnic origin (in some countries)
* ADE monitoring: Detailed description (nature, localization, severity, characteristics), reports of investigations and tests, date of appearance, course, outcome
* Suspected medicines: Name (brand, formulation, ingredient, concentration, manufacturer), dose, route of administration, date of initiation of therapy/date of withdrawal of therapy, indications for use, and rechallenge in case of non serious ADEs
* Other medicines: All other medicines used by the patient (including self medication) including their name, dose, route, date of initiation and withdrawal
* Risk factors: e.g. impaired renal function, past exposure to suspected medicines, history of allergy, and social drug use
* Reporter: Name and address of the reporter (confidential and to be used for data completion, verification, and follow up)

Health care professionals e.g. practicing physicians, pharmacists, nurses, dentists, and midwives are reliable sources of information. Pharmacists and nurses can illuminate on concomitant medication and history of medicine usage. It is imperative for pharmaceutical companies to report any ADRs of their products to regulatory authorities. In the event of patients directly reporting ADRs, it is always better to communicate with their physicians for better understanding and verification of data.

The reporting can be done from peripheral to the regional PV centers, which sweep a particular region, which in turn pool into the zonal database, the analysis of which reflects a gross national overview. The entire national data should be reported to UMC.

4. Bringing a reporting culture

Reporting of ADR is a continuous process and important to cultivate and sustain the attention and interest of healthcare workers so that it gets incorporated as a routine procedure in healthcare. The following measures may be adopted to give a fillip to reporting:

* Easy and free availability of prepaid reporting forms and other modes of reporting
* Duly acknowledging the receipt of ADR reports telephonically or through personal communication
* Providing journal articles, ADR bulletins, newsletters to reporters
* Actively involving the PV center staff in scientific meetings, undergraduate and postgraduate education
* Collaborating with other PV committees, It is always ideal to look out for other organizations that may be able to collaborate with your PV Centre to reduce the financial and logistic burden. For example, poison control and drug

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information centres share similar PV interests. It may be useful to develop a PV system in conjunction with these centres.

* Collaborating with professional associations
* Utilizing PV data for development of clinical pharmacy and clinical Pharmacologypharmacovigilance

a) Information service

One of the primary responsibilities of a center is to make high quality credible and latest medicine information available to health care professionals. For this, the center should have access to up-to-date and comprehensive literature database. The national centers should preferably have an online access to UMC database and be on the mailing list of ADR bulletins of WHO.

b) Reaching out

Newsletters, medicine bulletins, columns from reputed medical or pharmaceutical journals may be chosen as routes of effective propagation of latest developments in medicine research and therapy to the healthcare professionals.

c) Appraisal

The ADR case reports obtained are evaluated by the center staff, employing the collective know-how of clinical medicine, pharmacology, toxicology, and epidemiology.

d) Secondary prevention of ADRs

Secondary prevention of ADRs can be attempted by distribution of "patient alert cards" which are pocket size cards and could be carried around by patients. They provide relevant information about the medicines including ADRs and go a long way in preventing ADRs.

e) Data processing

Data is best managed electronically by computer, wherein, data is entered in a hierarchical format according to product name, medicine name or therapeutic category. This facilitates recording detailed case information and easy retrieval. Internationally accepted terminologies regarding classification of medicines (Anatomical Therapeutic Chemical [ATC], International Nonproprietary Names [INN]) and ADRs e.g. WHO Adverse Reaction Terminology (WHO ART), Medical Dictionary for Regulatory Activity (MedDRA) should be used, so that the data can be globally shared.

f) Hypothesizing

This is one of the chief goals of PV center. Based on the case reports, the center should be able to generate hypothesis or detect a signal with regard to probable ADRs.

e) Medicine regulation

It is PV center's duty to keep a close eye on the new medicines launched in the market and follow them up to look for newer ADEs, issue warnings, unmask newer indications or changes or to advocate withdrawal of medicines in extreme cases. A center should actively take up activities towards furthering the role of PV with periodic safety update reports (PSURs), registries, risk management minimization plans, and improved communication with changes in label of medicines.

The PV system needs to deal with large population and the rate of reporting the estimation of the money needed to run the complete system. Huge investment is required in terms of collection of data from the actual source to transforming it into a Regulatory reportable format. Funding can be obtained from various parties, such as drug Regulatory authority, university departments, health insurance companies, and professional associations

II. CONCLUSION

PV remains a dynamic part of the clinicians and the general population.

After the appearance of these adverse drugs effects, it is very essential that these are reported timely and analyzed. Not only the doctors should be aware of the PV programme but the patients themselves should be made aware of this so

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self-reporting is increased and the burden on the clinicians is also reduced. India is still in the growing phase of PV and more reporting is necessary to reach the world's standard of reporting these adverse events to provide effective drug use in children's and pregnant women which is one of the most vulnerable populations of all. The PV programme must be able toidentify these adverse events timely in the coming years with the help of clinicians, patients, and the pharmaceutical industry to help shape the safety of patients themselves

DISCUSSION

As far as we are concerned, this research is the primary of its type, accomplished in Iraq/Basra area, which evaluates the KAP of the subject of pharmacovigilance and reporting of adverse drug reactions (ADRs) among final year pharmacy students studying in the public university of Basra