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In recent years pharmacovigilance has grown as companies have to track pharmaceutical safety after launch. Pharmaceutical surveillance is now expected to produce transparent, open results. It showed a growing concern about the safety of newly developed and approved drugs for regular use. The innovative technologies in pharmacovigilance help the world of threatening and ravishing disease in a life-long struggle to clean. Pharmaceutical surveillance is becoming more and more important worldwide, especially for the prevention of serious and costly industrial damage. Drug monitoring seeks to provide vital information on the functioning of medications, from short to long-term, in medical practice. Current research has arisen from a clinical and scientific viewpoint, including the methods of 'Omics' and novel biomarkers correlated with the emergence of unusual and idiosyncratic ADRs, and integrates these rapidly evolving pharmacovigilance strategies.
INTRODUCTION:
From the data, drug monitoring started around 170 years ago. It is a systematic medical practice with important social and business implications for tracking the medicines risk-benefit ratio enhances patient health and improves the quality of life. In addition to monitoring the medicines risk/benefit ratio, it helps in improving patient safety and quality of life, development of international PV systems. The tasks in PV include: Gathering and monitoring drug safety data, peer view of case reports for the identification of new "indications," constructive risk management to reduce potential pharmaceutical risk, interacting and providing stakeholders and patients with information. On 29th Jan 1848, 169 years ago, the history of pharmacovigilance was began.[1]

US and FDA Sources
With the enactment of the Pure Food and Drugs Act of 1906 the US Federal Food and Drugs Act was created on 30th June 1906. The law banned interstate commerce in adulterated and misbranded food & drugs followed by provided the basic consumer protection elements. Consequently, the corporation started governing in 1911 against false indications on therapeutic medicines. In 1937, a solvent in a sulfanilamide elixir had more than 100 deaths. The Federal Act on Foods, Drugs and Cosmetics was therefore introduced in 1938 with the aim that the public health system should be renewed. None the less, the new program expected before their markets launch that product protection must be demonstrated and that factory inspections must be necessary.[2]

WHO and EMA Sources
The catastrophe of thalidomide is a landmark in drug surveillance's history and development. Thalidomide was introduced in 1957 and was commonly used as an apparently innocuous morning disease and nausea remedy. The dosage form has been tested without toxicity in around 300 patients. It soon became associated with a congenital phocomelia, which caused serious birth defects in children of women who were prescribed this treatment during pregnancy. World Health Organization (WHO) supports PV at country level with the WHO Coordinating Center for International Drug Monitoring, Uppsala. The WHO's International Drug Monitoring Program (IPM) was initiated in 1968 to combine existing data on adverse drug reaction (ADRs). The network has since been greatly extended as more countries around the world are implementing a pilot project in 10 countries with developed ADR national reporting systems. Post-marketing PV uses techniques such as data mining to classify drug ADRs relationships. It is the responsibility of the drug regulatory agencies, during the drug development process and later during the life of a commercial medicinal product, to provide a defined PV program to control ADRs. Throughout the field of drug safety surveillance a wide number of partners including government, industry, health centers, clinics, academies, medical and pharmacy associations, poison centers, healthcare providers, patients, customers and the media, have a dynamic and critical partnership.[3]

Discussions
The effectiveness and overall safety of marketable medications are in suspicion as newly developed drugs are becoming the standard treatment for pharmaceutical companies around the world. The modification of pharmacovigilance for institutions of pharmaceutical origin must be supervised in order to provide the best available medication with minimal harm as far as toxicity and degrading outcomes such as death are concerned in order to control and rule drug’s efficacy. The need for a comprehensive information system or database is crucial because of limited public access to global safety databases and that regulatory compliance leading to patient accountability of pharmaceutical companies which stand by their drugs and propensity to blame customer. In order to address this issue, the strict technologies of pharmacovigilance have been used to track and control the dispersal of these substances, their effects and indications. Pharmacovigilance can be defined as tools and strategies for identifying, elucidating, monitoring and avoiding the adverse drug effects (ADRs) of any medications or infectious diseases from the perspective of the WHO.[4] Pharmacovigilance is primarily designed for the identification of the safety signals of medications in addition to concomitant product usage in relation to their anticipated effects as
realistic approaches are unique for various organizations.
In addition to the global concern regarding ADRs, pharmacovigilance also tracks other key elements, such as traditional medication causes, medical errors, lack of information on effectiveness, drug use with no indications, acute and chronic poisoning case-based records, mortality assessment due to a medicine-induced disease and medicinal intake errors as well as other major concerns. Specifically, the practices of pharmacovigilance functions are as follows:

- Improve patient health and general treatment with the use and development of medicines;
- Enhance public health and safety for overall use,
- Successful risk evaluation of medicines for safety and economic effectiveness, and
- Facilitate drug behavior based education and public awareness.

Functional pharmacovigilance, in collaboration with others, will ensure cooperative citizenship so that it can produce positive outcomes, while monitoring a person or population level involves a correlation between the individual's duty and the alertness.[7]

**European Union (EU) and United States (US) Pharmacovigilance Regulations recent changes**

Two phenomena are illustrated by changes in the regulations of EU and US pharmacovigilance. The first is to improve human health safety instruments by constant monitoring of the risk-benefit product ratio, increased transparency and the potential to penalize pharmaceutical firms for their failure to meet pharmacovigilance standards. The second pattern is that the different pharmacovigilance schemes are partly harmonized. However this goal is still far.[6]

**European Union**

With four different Acts over the last two years, the EU has introduced several changes. For example, now:

- The definition of ADR has changed to make sure it covers noxious and unintended effects, including abuse and abuse of the medication, which are also due to medication errors and use outside the terms of the marketing authorization. There is ample justification for disclosing a fair chance of causal association between a drug and an adverse event;
- As a condition of the marketing authorization, the competent authorities are allowed to require MAHs to perform post-authorization protection and effectiveness studies;
- Many medicinal products are approved subject to additional supervision, such as newly activated and biologic medicinal products; the EMA maintains a list of such medicinal products that must be marked by a black mark accessible to the general public.[7]
- A new “Pharmacovigilance System Master File” Program tool is designed to help enhanced prepare and perform MAH audits as well as supervise pharmacovigilance by the skilled individual in the field of pharmacovigilance;
- Appropriate and efficient quality framework, allowing for effective monitoring of compliance, correct and reliable documentation of all the steps taken, must be developed for MAHs, national authorities and EMA. The quality program also ensures that adequate skilled, eligible and educated personnel is available to MAHs, national competent authorities and EMA;
- MAHs, national competent authorities and EMA have to continuously monitor the data in the Eudravigilance database.[8]

**United States**

Article IX of the FDA Amendments Act of 2007 has substantially changed US regulations.[9]

As a result, FDA:

- Conduct a two-week review of the data base of the Adverse Event Reporting System and post any new safety details or possible risk signal online on an electronic quarterly report.
- Empowered that the company submits a REMS, if the advantages of its product do not prevail over the risks.
- Entitled to allow post-approval studies or testing in order, if current knowledge is not
sufficient to adhere to that assessment, to evaluate a known risk or signal of serious risk and to recognize unexpected serious risk from the available data;

- Have the power to penalize all the applicants who are in breach of the responsibilities of REMS or post approval studies / trials with civil penalties and product misbranding.\[10\]

**ADR reporting:**

“Adverse drug reaction” or an "adverse reaction" means a response to a medicine in the humans or animals, which is noxious and unintended, including lack of efficacy, and which occurs at any dosage and can also result from an overdose, misuse or abuse of a medicine.

Several studies worldwide have reported that the adverse drug reaction reduces the quality of life, hospitalization, hospital staying and mortality substantially.

Early in 1993 when Med Watch, the FDA's safety information and adverse event reporting scheme were created, the FDA acknowledged the need of an effective risk management plan. The FDA Division, Pharmacovigilance and Epidemiology Division (Center for drug assessment and research) is currently carrying out the assessment and risk assessment of medicines.

In 1996, FDA stated that the success or failure of any pharmacovigilance activity depends on the reporting of suspected adverse reactions.

In order to determine the drug information obtained from the reported cases and published literatures collect information about pharmaceutical health worldwide, create input channels by distributing newsletters and undertake an education campaign. The purpose of the ADR monitoring system is to obtain adversities suspected of being linked to using medicines. The final aim is to promote the ethical use of medicines, thus enhancing the health of the population (DOH, 1998).

In 2002, the WHO notes those physicians, nurses, pharmacists and any other health workers reports on ADRs. The declaration intonated the reports could be sent to each country's pharmacy department, hospital or pharmacovigilance Centre. Information of suspected patients name, intensity, dosage and length of the treatment should be included in the documentation of ADRs. The report should also cover information on additional concurrent drugs, ADRs, e.g. New ADRs, ADRs for risk groups, such as pregnant women, women breastfeeding, the elderly and children drug reactions, serious / unexpected ADRs, other drug-related issues like regardless of the content, inappropriate use, etc.\[11\]

**Pharmacovigilance development in India:**

**National pharmacovigilance centre:**

The Central Drugs Standard Control Organization (CDSCO) has initiated a country-wide Pharmacovigilance programme under the aegis of DGHS, MoHFW, Government of India.

The programme is coordinated by National Pharmacovigilance Centre at CDSCO. The National Center is responsible for developing protocols and recommendations for regulatory action under the oversight of the National Pharmacovigilance Consultative Committee.

**National pharmacovigilance’s programme (NPP):**

National Pharmacovigilance Program officially inaugurated by the Honorable Health Minister Dr. Anbumani Ramadoss in New Delhi on 23rd November 2004. Supported by the World Health Organization (WHO) and sponsored by the World Bank, India's National Pharmacovigilance System came into existence fully in January 2005.

The software aims to promote ADR notification culture in its first year of operation and is subsequently aimed at generating broad-based ADR data for India and at sharing the information through WHO-UMC with the global healthcare community. The function of NPP is to create and manage a database for ADR to make regulatory decisions regarding marketing authorization for drugs in India to ensure the security of drugs is supported and coordinated by the CDSCO of the country.

The network comprises of 26 centers in a regional center, five Regional Centers and two Zonal Centers. The outermost centers send the reports to the regional centers about the events that are unfavorable. The information obtained from the Peripheral Centers is gathered and analyzed in turn and sent to the Zonal Centers. The Zonal Centers must evaluate the data thoroughly and provide the detailed information to
National Pharmacovigilance Centre. Along with this the Zonal Centre provides training, general assistance and manage the regional Centre's operations.

In 1986, a standardized monitoring program of ADRs with 12 centers was introduced and the pharmacovigilance operation did not receive special attention.\[^{12}\]

In 1997, India took part in a program organized by the WHO in Uppsala-Sweden on ADR monitoring. This engagement was not enough to encourage pharmacovigilance. Consequently, a pharmacovigilance plan for India (PvPI) was launched by the Government of India on 14th July 2010. Within PvPI, New Delhi has been named as a National Coordinating Center (NCC) for the security of public health, validating the safety of drugs, by all India Institutes of Medical Sciences (AIIMS). Monitoring centers for ADRs were set up in 2010.\[^{13}\]

**Currently Developed Technologies of Pharmacovigilance**

The studies have paved the way to prepare effective drug monitoring protocols in the US and in EU, various countries around the world have started to emerge using avant-garde protocols, which provide a great insight into efficacious, previously unexpected methods of drug monitoring. Countries such as Sub-Saharan Africa are statistically spending 3.8-4.7 billion U.S. dollars for pharmaceutical production, including drug monitoring costs.\[^{14}\]

Globally about 41% of countries lack in national pharmacovigilance and medical safety policies, followed by 13% of countries accredited to no functional legal policies supporting the protocol of drug surveillance. Because of the large scatter of medications used to combat commonly eradicated diseases in the US which are now rampant, such as the Measles and the Rubella, the pharmacovigilance requirement is now more than ever confirmed.

Immunosuppressive diseases like HIV/AIDS lack established systemic bars necessary to control medicines used to treat these dangerous diseases as opposed to controlled drugs to treat widespread malaria cases with pharmacovigilance studies that promote medicinal products and protect the patients from serious contraindications that endanger their lives.\[^{15}\]

Recent reports showed preventable ADRs with a 14% prevalence due to medication errors that have led to the launch of a collaboration project with the World Alliance for Patient Safety (WAPS) with UMC, to improve the pharmacovigilance methodologies provided by the Moroccan Pharmacovigilance Centre. Recent experimental observations on French pharmacovigilance methods have been conducted to detect mechanism and the role of the various CYPs in a comparative pharmacovigilance database research to clinically characterize ADRs in terms of drug-drug interactions which are potentially caused by the induction or inhibition of human cytochrome P450 (CYP 450) enzymes.\[^{16}\]

The Democratic Republic of the Congo has recently used pharmacovigilance databases to correct the shortage of the second-stage patients obtaining clinical trial data for human African trypanosomiases, an infection of two forms of protozoan parasites: Trypanosoma brucei, which is the disease caused by an infection.

In a research conducted in Finland, a pediatric pharmacotherapy analysis was performed in a parental context to provide an appropriate insight into pediatric reasons for medications, resulting in definitive findings. ADR findings have been linked to therapeutic usage and dosing of most ADRs associated with anti infectious agents.\[^{17}\]

**CONCLUSION:**

Pharmacovigilance is a key approach in the detection of drug toxicities and safeguarding of the use of drug safety worldwide, but it is unbalanced application in development and developed country practice.

Clinicians, patients, drug manufacturers and regulatory officers must work closely together in order to develop reliable and highly efficient pharmacovigilant strategies to strengthen the ADR surveillance systems.

It is clear from all quarters that worldwide pharmacovigilance is becoming increasingly important, especially to avoid serious, costly industrial damage. Pharmacovigilance is structured to provide important details about how medications work from short to longer-term in medical practice. If used
correctly, this information can help the growth and marketing of drugs as a boon rather than an obstacle. Vision gain believes in particular that living licensing in the coming years will be important components of pharmaceutical regulations and drug development. Pharmacovigilance will underpin processes and developments such as these, as this report further explains.

In future, new established innovations should be taken to include translational research in clinical practice through pharmacovigilance. In the after growth age every one keep an eye on emerging developments such as systems pharmacology, if conventional methods are used in pharmacovigilance. All ADRs are impossible to be avoided, but many ADRs which can be reported with available testing methods, at least, can be prevented.

REFERENCES
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