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Review Article

A Review On: Pharmacovigilance Important And Its Future Perspectives

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ABSTRACT

Pharmacovigilance, a vital component of the healthcare system, has evolved over 170 years to become a structured activity aimed at monitoring the risks and benefits of drugs. This article explores the historical milestones in the evolution of pharmacovigilance, from early clinician warnings in scientific journals to the establishment of electronic registries. Through vigilant monitoring of drug side effects, pharmacovigilance has made substantial contributions to preventing and addressing potential problems promptly. However, emerging challenges necessitate ongoing evolution in data collection and analysis methods to identify new side effects and drug interactions. Global pharmacovigilance systems aim to regulate the risk-to- benefit ratio of medicinal drugs, enhancing patient safety and overall quality of life. The article highlights the significant transformation in European Pharmacovigilance with the establishment of the European Medicines Agency (EMA) in 1995 and the introduction of Surveillance in 2001. Directive 2010/84/EU in 2012 brought crucial changes, including modified adverse drug reaction definitions, increased patient involvement, and enhanced transparency. A literature survey emphasizes the global perspective on pharmacovigilance. Studies from India underscore the importance of implementing Good Pharmacovigilance Practice (GPP) to improve regulatory compliance, clinical trial safety, and post-marketing surveillance. The challenges and future perspectives of pharmacovigilance in India are discussed, emphasizing the need for a well-functioning system. The historical evolution of pharmacovigilance in India is detailed, starting with revisions to Schedule Y in 2000 and the establishment of the National Pharmacovigilance Program in 2004-05. Despite India's growing prominence in clinical trials and pharmaceuticals, challenges like low ADR reporting rates persist. Case studies illustrate the practical application of pharmacovigilance, showcasing its role in identifying adverse drug events, conducting thorough reviews, and ensuring patient

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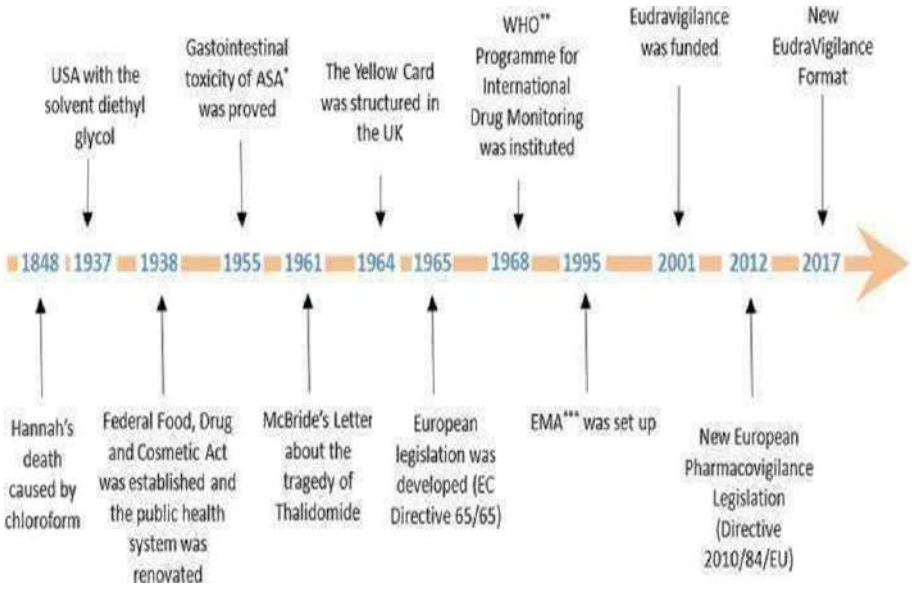
safety. The article concludes with recommendations for strengthening India's pharmacovigilance system, addressing challenges, and emphasizing the importance of integrating patient perspectives. In the future, the focus should be on developing a robust pharmacovigilance system that identifies emerging adverse drug reactions, integrates patient perspectives, and incorporates good pharmacovigilance practices into regulatory processes.

INTRODUCTION

Pharmacovigilance is an essential part of the healthcare system. It refers to the structured activity employed in the healthcare industry to monitor the risks and benefits of drugs. The ultimate goal is to ensure the safety of patients and improve the quality of life. The term 'pharmacovigilance' may be relatively new, but the practice dates back to around 170 years. In this article, we explore significant milestones in the evolution of pharmacovigilance. The first reports were actually warnings or letters sent by clinicians to scientific journals. It was not until much later that electronic registries were developed. These successive phases reveal the historical evolution of pharmacovigilance and high its significance in promoting public health. Through pharmacovigilance, significant strides have been made in ensuring the safety and efficacy of drugs. By closely monitoring side effects, we have been able to prevent and respond to potential problems promptly. However, new challenges are continuously emerging, and pharmacovigilance must continue to evolve to meet them. It is essential to develop new ways of collecting and analysing data to identify new side effects and drug interactions. In accordance with the European Commission (EU), PV is defined as the systematic process and scientific practice of monitoring the safety of medicines, while also taking necessary actions to mitigate the risks associated with their usage and maximize their potential benefits. 0The global PV systems aspire to effectively regulate the risk-to-benefit ratio of medicinal drugs, with the additional objective of enhancing the safety and overall quality of life for patients. The core activities encompassed within PV involve the systematic collection and management of data pertaining to the safety profile of medicines. This data is meticulously examined, giving special attention to individual case reports, in order to detect any emerging signals that might indicate potential safety concerns. By actively engaging in risk management initiatives, PV seeks to proactively minimize and address any risks that may be associated with the utilization of medicines. Communication and continuous information dissemination form an integral part of PV, serving to keep stakeholders and patients informed regarding the latest advancements in medicine safety. The seamless post-marketing surveillance conducted by PV primarily aims to safeguard the welfare of the public. Through this surveillance, Controlling Authorities (CAs) are able to make necessary modifications to the Summary Product Characteristics (SPC) of new medicinal products based on newly identified signals. The SPC provides comprehensive information about the medicine and its authorized use, and is initially released by the Marketing Authorization Holder (MAH) when a new medicine is introduced to the market. In this short article, we describe the milestones (as in Fig. 1) that led to the evolution of Pharmacovigilance activities in the last century.



Specifically, these tragedies brought about a transformation in the Pharmacovigilance system, as it shifted from sporadic and unstructured reporting of adverse drug reactions to a methodical, well-organized, and regulated process. This correspondence already encompassed all the essential components required for initiating spontaneous reporting and for establishing a clear cause-and-effect correlation between the adverse incident and the medication."

- **Establishment of surveillance**

"In 1992, the establishment of the European Society of Pharmacovigilance (ESoP) marked the beginning of what later evolved into the International Society of Pharmacovigilance (IsoP). The primary objectives of this organization were to advocate for Pharmacovigilance and to advance all facets of the safe and appropriate utilization of pharmaceuticals. Subsequently, in 1995, the European Medicines Agency (EMA) was founded, and in 2001, the inception of EudraVigilance took place. EudraVigilance serves as the official European repository for the collection and analysis of data concerning suspected adverse reactions to medicines that have received authorization for market distribution or are under investigation in European clinical trials . A significant transformation in European Pharmacovigilance occurred in 2012 with the introduction of new legislation, Directive 2010/84/EU. The principal alterations within this new legal framework included:"

The main changes in the new legislation were :

- Modification of the definition of adverse drug reactions (ADR)
- Greater involvement of patients and citizens in Pharmacovigilance activities
- Strengthening of the Eudravigilance database containing reports of suspected reactions reported by all EU Member States
- Increasing transparency and timeliness of important information on Pharmacovigilance problems
- Obligation of "additional monitoring" for the products contained in the specific list kept by the EMA
- Possibility to impose further safety and/or efficacy studies on the certificates of marketing authorization at the time of granting the trust

- Establishment within the EMA of the Pharmacovigilance Risk Assessment Committee (PRAC)

In November 2017, a revised EudraVigilance format was introduced. Notably, marketing authorizations will be granted increased access to the EudraVigilance database to aid them in meeting their Pharmacovigilance responsibilities. These responsibilities encompass the ongoing surveillance of EudraVigilance data and the reporting of validated alerts to both the Agency and relevant national regulatory authorities, as specified in the Commission Implementing Regulation.

1. **Renu Tapadiya et.al :**

Pharmacovigilance(PV) is defined by the World Health Organization (WHO) as "the research and practices associated to the detection, evaluation, comprehension, and prevention of adverse effects or other important issues caused by drugs. To enhance regulatory compliance, clinical trial safety, and post- marketing surveillance, the Drugs Controller General of India (DCGI) should act fast to improve PV by implementing Good Pharmacovigilance Practice (GPP) into processes and procedures. If medicines are to be used safely, a well- functioning PV system is essential. This article summarized introduction, history, current status and future aspects of Pharmacovigilance in India.

2. **D. Nagarjuna Reddy et.al :**

The PV databases help in the promotion of safe drug use and protection of public health safety. This article compares the PV system in the USA, Europe, and India, highlighting the challenges and future perspectives to be adapted to widen the horizon of the existing PV structure in India. In India, PV programs are still at the dawning stage when paralleled to the other countries. The National Pharmacovigilance Program and the Pharmacovigilance Program of India are the most recent advancements in this field in the country.

3. **Harsha Negi et.al :**

Pharmacovigilance (PV) plays a key role in the healthcare system through assessment, monitoring and discovery of interactions amongst drugs and their effects in human. Pharmaceutical and biotechnological medicines are designed to cure, prevent or treat diseases; however, there are also risks particularly adverse drug reactions (ADRs) can cause serious harm to patients. Thus, for safety medication ADRs monitoring required for each medicine throughout its life cycle, during development of drug such as pre-marketing including early stages of drug design, clinical trials, and post-marketing surveillance. PV is concerns with the detection, assessment, understanding and prevention of ADRs. Pharmacogenetics and pharmacogenomics are an indispensable part of the clinical research.

4. **Naveen Goyal et.al :**

Pharmacovigilance is an important and integral part of clinical research. Pharmacovigilance is "defined as the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term adverse effects of medicines. This addresses what exactly is pharmacovigilance. What do we know of its benefits and risks, challenges and the future hold for pharmacovigilance in Indian medicine. Here the main focus on the aims and role of pharmacovigilance in medicines regulation and their Partners.

5. **Praveen V. Pati et.al :**

The present global network of pharmacovigilance centres, which is supervised by the Uppsala Monitoring Center, would be strengthened by an independent review procedure. This would consider disputed and important pharmaceutical safety problems that might have a detrimental effect on public health across international borders. Recently, the main goal of pharmacovigilance has been to identify previously

unrecognised or poorly understood adverse drug reactions. Clinical research must include pharmacovigilance, which is becoming more and more popular in many countries. To improve drug safety and monitoring, pharmacovigilance faces significant obstacles at the turn of the millennium.

6. Janmejeva samal :

The Concept of Pharmacovigilance: Pharmacovigilance is the science of detection, understanding, assessment and prevention of adverse drug reactions and related untoward effects. Concepts and Regulations of Pharmacovigilance in Ayurveda: Given the current scenario of the usage of the traditional and alternative medicine at a global scale, it becomes imperative to ensure the safety of the patients consuming these medications. This makes the science of pharmacovigilance, a significant domain in the field of medicine and public health as well. Nevertheless, the adverse drug reaction of traditional Ayurvedic medicine may range from trivial effects to serious fatal outcomes leading to the death of a patient.

7. Kumar Sumit et.al

In the scenario of ever-increasing range and potency of medicines, safety of medicines is one of the key parameters along with therapeutic efficacy for success of any drug. India is now a preferred clinical trials destination for to be launched drug entities. By keeping in view the increasing incidences, dug related mortality, proper identification, reporting, evaluation and understanding of adverse drug reaction lead to development of pharmacovigilance. It is a branch of pharmacological science critical to effective clinical practices and public health with immense capability for growth. These necessities the utmost need of effective regulations for drug approval and conscious pre and post approval vigilance of undesired effect especially in India.

- **Historical development**

The Indian government has made revisions to Schedule Y of the Drug and Cosmetics Rules of 1945, fulfilling its commitment to advancing clinical research for novel therapies. Schedule Y serves as the framework for clinical trial guidelines and prerequisites. In 2000, the Indian Council of Medical Research (ICMR) introduced the Ethical Standards for Biomedical Research Involving Human Subjects, and in 2001, the Central Drugs Standard Control Organization (CDSCO) issued the Indian Good Clinical Practice (GCP) guidelines .Back in 1986, when a formal Adverse Drug Reaction (ADR) monitoring system with 12 centre's was conceived, there was limited development and focus on Pharmacovigilance activities. In 1997, India actively participated in the World Health Organization's ADR Monitoring Program, held in Uppsala, Sweden .India boasts a population of approximately 1.21 billion people, making it the world's second-most populous country according to the 2011 census. The pharmaceutical industry in India is valued at 18 billion dollars, with an expected annual growth rate of 12-14%. India is gaining recognition as a global hub for clinical trials, drug discovery, research, and development. The primary strategy to prevent or mitigate ADRs is the immediate reporting of such events by healthcare professionals. However, in India, the ADR reporting rate is less than 1%, in contrast to the global rate of 5%. One potential explanation for the lower rate in India could be the heightened awareness of Pharmacovigilance and ADR monitoring among Indian healthcare workers .In 2002, more than 65 countries established their own pharmacovigilance systems. The World Health Organization Collaborating Centre for International Drug Monitoring, commonly known as the Uppsala Monitoring Centre, oversees WHO's involvement in global drug monitoring (UMC). Pharmacovigilance is now firmly grounded in sound scientific principles and is an

integral component of effective therapeutic strategies. To meet the expectations of the public and address current public health challenges, the field must continue to evolve. A resolution was adopted at the Sixteenth World Health Assembly

Table 1. The development of pharmacovigilance over time, with a focus on India

Developments	Year
James Lind conducted the first documented clinical research establishing the effectiveness of lemon juice in scurvy prevention	1747
More than 100 children have died as a result of sulphanilamide poisoning.	1937
Chloramphenicol poisoning has been associated to aplastic anemia.	1950
Toxicity to thalidomide has caused a worldwide tragedy.	1961
The 16th World Health Assembly recognizes the importance of quick action on adverse drug reactions (ADRs).	1963
The WHO is conducting research for international drug surveillance on a small Scale	1968
In India, clinical trials at the global standard level have started.	1996
India has joined the Adverse Drug Reaction Monitoring Program of the World Health Organization	1997
Pharmacovigilance is started in India.	1998
In India, the 67th National Pharmacovigilance Center was formed	2002
The National Pharmacovigilance Program was established in India	2004-05
Structured clinical trials have been completed in India.	2005
PvPI (Pharmacovigilance Program) has started.	2009-10

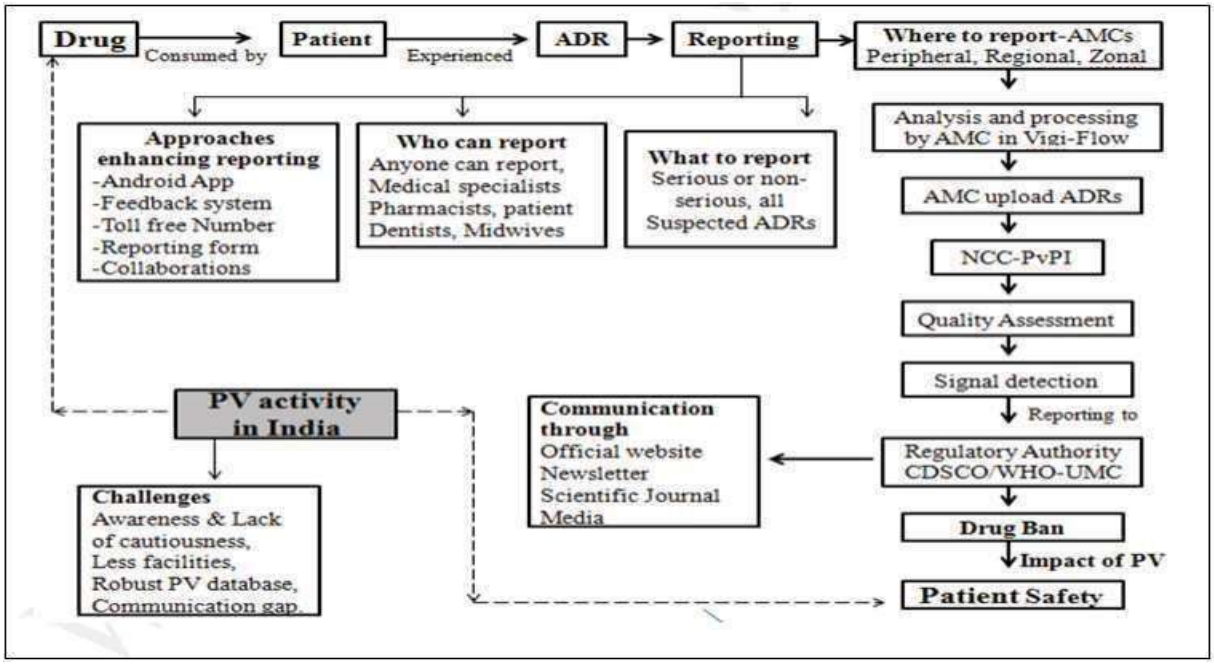
The establishment The National Pharmacovigilance Advisory Committee took place in January 2005 with the aim of overseeing the National Pharmacovigilance Program. It is situated at the Central Drugs Standard Control Organization in New Delhi. The collection of data from various locations in the country is done by the South-West zonal center and the North-East zonal center, after which it is sent to the Committee and the Uppsala monitoring center in Sweden. Reporting responsibilities are divided among the regional centers, with the Mumbai center reporting to three regional centers and the New Delhi center reporting to two. Each regional center is in charge of a number of peripheral centers. As of now, there are 26 peripheral centers (17). In July 2010, the Ministry of Health and Family Welfare, Government of India, launched a nationwide pharmacovigilance program to monitor adverse drug reactions and protect global health. The All-India Institute of Medical Sciences in New Delhi serves as the National Coordinating Center(NCC) for this program. As part of this initiative, 22 ADR monitoring centers (AMCs) were established in 2010, including AIIMS in New Delhi. Subsequently, in April 2011, the National Coordination Center was moved from All India Institute of Medical Sciences in New Delhi to the Indian Pharmacopoeia Commission in Gaziabad, Uttar Pradesh, with the objective of ensuring more successful implementation of the program. Over 60,000 trademarked formulations and over 6,000 licensed medication makers can be found in the large nation of India.India, the fourth-largest pharmaceutical producer in the world, is fast becoming as a hub for clinical trials. But in recent memory, the interval between when a medicine is authorized for sale and when it's made available in India, it's become so little that long-term security Data is not accessible anymore. Furthermore, by use of independent study, Indian pharmaceutical Businesses are now more equipped to create and market novel products, emphasizing the setting up appropriate internal pharmacovigilance standards

is crucial for identifying adverse medication happenings t was previously suggested by the Drugs Technical Advisory Board (DTAB) that pharmaceutical companies be forced to disclose side effects of their promoted medications. Even if the proposals are proactive, the requirement law was also created in March 2016.Given that several Pharmaceutical firms consider periodic communications and ADR reporting to be industry practices. and fruitful discussions between PvPI and its stakeholders have led to advancements in obtaining report ADRs. Consequently, the ADR reporting rate to PvPI for the pharmaceutical industry in 2015 was 18.80 ratio.

Targets for the Pharmacovigilance Program in India

2010-11	Creating framework and method Enlist forty clinical establishment Begin information assortment from AEFI Laying out an instructional hub PV Human Asset Preparing Linkage with UMC Sweden and the World Wellbeing Association Begun creating programming for the NDSD. Zonal studio for drug security public mindfulness Bulletin distribution of medication wellbeing
2011-12	Training for Pharmacovigilance (PV) Personnel: Provide training to build the capabilities of PV professionals. Identify knowledge gaps and address them through appropriate training.
2012-13	Expand the enrollment of an additional one hundred medical institutions. Provide training to enhance the skills and knowledge of PV professionals Organize workshops at the zonal level to educate the general public about drug safety.
	Enroll again more hundred medical college Interaction with international PV bodies PV human resource training The publication of a drug safety bulletin
2014-15	Create a PV center of excellence in the Pacific.

Pharmaceutical companies are mandated by Good Pharmacovigilance Practices (GPPs) and relevant regulations to continually assess the benefits and risks of their medications. Throughout the year, the National Coordination Centre - Pharmacovigilance Programme of India (NCC-PvPI) actively engages in providing training to seasoned pharmacovigilance experts, imparting knowledge on the foundational principles and regulatory aspects of pharmacovigilance. This training initiative extends to young professionals from pharmacy, medicine, and paramedica backgrounds. Notably, the NCC-PvPI's Indian Pharmacopoeia Commission (IPC) located in Ghaziabad received recognition as a WHO Collaborating Center for Pharmacovigilance in Public Health Programs and Regulatory Services on October 30, 2017 .In 2015, the Pharmacovigilance Program of India (PvPI) established the Materiovigilance Programme (MvPI) to scrutinize adverse incidents associated with medical devices in the country. In May 2017, MvPI members convened at the IPC to strategize the monitoring of the program's ambitious goals. It was decided that experienced biomedical engineers would be recruited, with the necessary training to be provided by PvPI.



FUTURE ASPECT

In the future, there is a pressing need for a robust pharmacovigilance system that can identify emerging adverse drug reactions (ADRs) and implement regulatory measures to safeguard public health. Unfortunately, the development of data that can aid healthcare professionals and patients in decision-making has not received adequate attention. The primary mission of pharmacovigilance is to gather and disseminate this critical information, particularly concerning the safety of actively monitored drugs . Additionally, pharmacovigilance must broaden its focus beyond conventional stakeholders, such as healthcare practitioners, to include patients as a valuable source of information in the future. To enhance regulatory compliance, bolster clinical trial safety, and improve post-marketing surveillance, the Drug Controller General of India (DCGI) should take swift action to integrate Good Pharmacovigilance Practice (GPP) into its processes and procedures. A well-functioning pharmacovigilance system is indispensable for the safe use of medications, benefiting healthcare experts, regulatory authorities, pharmaceutical companies, and consumers alike .Considering the numerous clinical trials and other research activities transpiring in India, it is imperative to recognize the significance of pharmacovigilance and its impact on a product's lifecycle. The DCGI has invested substantial effort in establishing a dependable and efficient pharmacovigilance system. However, further efforts and strategic planning are essential to meet the needs of a growing population while ensuring comprehensive data collection and processing. To address the challenges posed by inexperience and a shortage of trained personnel, the DCGI could explore the possibility of collaborating with commercial firms to provide training and set up an effective pharmacovigilance system. After assessing the challenges and hurdles faced by India in developing an effective pharmacovigilance system, the following recommendations can be proposed:

1. Establish and Sustain an Effective Pharmacovigilance System: India should focus on creating a robust and sustainable pharmacovigilance system.

2. Introduce Mandatory PV Inspections and Reporting: Implement mandatory pharmacovigilance inspections and reporting procedures to ensure compliance and transparency.
3. Engage in High-Level Stakeholder Discussions: Conduct high-level discussions with a diverse range of stakeholders to gather input and expertise.
4. Increase the Number of Trained Scientific and Medical Assessors: Expand the pool of trained scientific and medical assessors within the Drug Controller General of India's office dedicated to pharmacovigilance.
5. Develop a Universal Adverse Event Reporting Form: Design a standardized adverse event reporting form that can be used universally, across countries.
6. Establish a Comprehensive Clinical Trial and Post-Marketing Database: Create a centralized database for Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSARs), and Adverse Drug Reactions (ADRs). This database should facilitate signal detection and allow access to relevant data from various stakeholders.
7. Maintain a Standardized Database for New Medications and Indications: Maintain a standardized database for every pharmaceutical company, tracking all new medications and indications.
8. Provide Pharmacovigilance Education and Training: Offer pharmacovigilance education and training to medical students, pharmacists, and nurses to enhance awareness and expertise in the field.
9. Collaborate with Pharmacovigilance Groups: Foster collaboration with pharmacovigilance groups to harness the potential of information technology for national and global partnerships, thereby improving post-marketing surveillance programs and enhancing drug safety

- **Case study 1st**

Patient:

Mr.abc , 60-year-old male

Medical history:

Mr.abc has a history of type 2 diabetes and hypertension for the past 5 years. He is currently taking metformin and amlodipine for his conditions.

Event:

Mr abc recently started experiencing episodes of dizziness and weakness. He also reported a decrease in his blood pressure readings. He visited his primary care physician who prescribed him a new medication, an alpha-blocker called doxazosin, to treat his hypertension.

Adverse drug event report: A week after starting doxazosin, Mr.abc was hospitalized for a syncopal episode. The medical team reported this adverse event to the pharmacovigilance department at the hospital.

Pharmacovigilance review:

The pharmacovigilance team reviewed Mr.abc's medical history and the medications he was taking. They discovered that doxazosin was the only recent addition to his medication regimen. The team then conducted a literature review and found that doxazosin can cause orthostatic hypotension, which can lead to syncope in some patients.

Outcome:

Based on the pharmacovigilance review, the medical team decided to discontinue doxazosin and switch 'abc' to another hypertension medication. abc's syncope resolved, and he did not experience any further episodes of dizziness and weakness.

- **Case Study 2 :**

Pancreatitis with a New Oral Antidiabetic Drug

Patient: Shubhangi , 21-year-old female

Medical history:

Shubhangi was recently diagnosed with type 2 diabetes and started on a new oral antidiabetic drug, sitagliptin, for glycaemic control.

Event:

Shubhangi presented to the emergency department with severe abdominal pain, nausea, and vomiting. She reported using sitagliptin as prescribed by her healthcare provider.

Adverse drug event report:

The attending physician reported a potential association between the use of sitagliptin and the development of pancreatitis in Shubhangi .

Pharmacovigilance review:

The pharmacovigilance team reviewed Shubhangi's medical records, including her diabetes diagnosis and prescribed medications. They investigated existing literature, case reports, and other sources for evidence of a link between sitagliptin and pancreatitis.

Outcome:

Based on the pharmacovigilance review, Shubhangi 's healthcare provider ceased sitagliptin and initiated appropriate management for pancreatitis. Shubhangi's condition gradually improved with treatment and cessation of the medication.

CONCLUSION:

As highlighted in case studies, pharmacovigilance plays a pivotal role in detecting and managing adverse events associated with medications. The continuous evolution of pharmacovigilance is necessary to meet the challenges posed by a growing diversity of pharmaceuticals and ensure the safety of the global population. The future demands a focus on a robust system that identifies emerging adverse reactions, integrates patient perspectives, and incorporates good pharmacovigilance practices into regulatory processes. The recommendations provided offer a roadmap for India to strengthen its pharmacovigilance system and contribute to global efforts in drug safety.

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