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A Review on Importance of Pharmacovigilance

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ABSTRACT

In the labyrinth of healthcare, Pharmacovigilance (PV) serves as the beacon of safety, navigating through the intricate web of drug interactions and effects on human health. As pharmaceutical and biotechnological marvels strive to diagnose, prevent, or cure diseases, the significance of PV cannot be overstated, especially in a country as populous as India, where over a billion individuals stand as potential recipients of medicinal interventions. Despite India's involvement in the Uppsala Monitoring Center (UMC) program, its contribution to the global PV database remains modest, underscoring the need for a more robust and participatory approach. Signal assessment, utilizing tools such as the World Health Organization (WHO) scale and the Naranjo scale, emerges as a crucial yet intricate process in discerning causality amidst the complex tapestry of drug effects.This article embarks on a systematic exploration of PV in India, tracing its journey from inception to the contemporary landscape. It delves into various strategies and propositions aimed at fortifying the PV framework and enhancing the culture of adverse drug reaction (ADR) reporting nationwide.In the realm of PV, the paramount concern lies in the under-reporting of ADRs, a challenge exacerbated by the escalating instances of patient hospitalization due to adverse drug effects. Unraveling the intricacies of causation becomes a formidable task, particularly in scenarios where patients are subjected to a confluence of multiple medications simultaneously. This review ventures into the diverse arsenal of assessment scales employed in ADR evaluation, each offering a unique vantage point in the quest to identify causative agents. From the intricate dance of pharmacokinetics to the subtle nuances of drug interactions, every facet of PV is scrutinized with meticulous attention, echoing the imperative of safeguarding patient well-being in every therapeutic endeavor. As India treads the path of PV, it stands at the threshold of discovery and innovation, poised to unravel the mysteries of drug safety with diligence and resolve. With each stride forward, the nation inches closer to a future where the promise of pharmaceutical advancements is matched only by the assurance of patient safety.

Keywords: Adverse Drug Reactions, Pharmacovigilance, Spontaneous Reporting System, Uppsala Monitoring Centre, Causality Assessment System, ADR assessment.

I. INTRODUCTION

Delving into the realm of pharmacovigilance (PV), also recognized as drug safety, we uncover a vital pharmacological science dedicated to detecting, assessing, comprehending, and preventing adverse effects, spanning both short and long-term impacts of medications. Integral to clinical research, PV confronts a significant global challenge: the underreporting of adverse drug reactions (ADRs), often stemming from constraints such as time limitations and documentation procedures. To address this, the World Health Organization (WHO) has launched initiatives mandating the reporting of all drug-related adverse reactions, extending its purview to encompass herbal products, traditional medicines, and vaccines, among others.In elucidating the necessity and significance of PV in the daily lives of medical practitioners, patients, and the pharmaceutical industry, it becomes evident that while drugs revolutionize disease treatment, they also entail inherent risks. Adverse drug reactions (ADRs) represent a prevalent and frequently preventable source of illness, disability, and mortality. A comprehensive definition characterizes an ADR as an adverse, harmful, or unpleasant reaction resulting from medicinal product usage, necessitating preventive measures, specific treatments, dosage adjustments, or product withdrawal.Rooted in the fundamental principles of detecting, assessing, understanding, and averting drug-related adversities, PV plays a multifaceted role. It facilitates the identification, quantification, and documentation of drug-related issues accountable for injuries, thereby bolstering drug regulation systems, public health endeavors, and clinical practices. By fostering the discovery of previously unknown ADRs, interactions, and variations in known ADR frequencies, PV enhances risk factor identification and facilitates quantitative benefit-risk analyses.The historical trajectory of drug safety monitoring unveils significant milestones, including the establishment of systems to scrutinize drug safety, such as the Lancet committee formed in response to anaesthesia-related mortalities and the subsequent initiatives following the thalidomide tragedy. Thalidomide's catastrophic impact underscored the imperative of rigorous drug safety monitoring, precipitating the formation of national drug monitoring centers and international collaborations under the WHO.The inception of PV in 1961, catalyzed by Dr. William McBride's Lancet publication linking thalidomide to severe congenital deformities, marked a pivotal moment in drug safety surveillance. Subsequent initiatives, including the WHO Programme for International Drug Monitoring, epitomize the global commitment to proactively identify PV signals.In the contemporary landscape, PV serves as the cornerstone of post-marketing surveillance, aiming to quantify recognized ADRs, uncover unrecognized ones, evaluate real-world medication effectiveness, and mitigate ADR-associated mortality and morbidity. Coordinated by the Uppsala Monitoring Centre (UMC), the International Drug Monitoring program encompasses over a hundred official member countries, yet challenges persist, notably in countries like India, where robust ADR monitoring systems and reporting awareness among healthcare professionals remain wanting.Recognizing ADRs as a leading cause of morbidity and mortality in India underscores the imperative of galvanizing medical communities to prioritize PV initiatives. As approximately 8% of hospital admissions and 8-19% of hospitalized patients are attributed to ADRs, fostering awareness and strengthening surveillance mechanisms are paramount for safeguarding public health.

Pharmacovigilance stands as a linchpin in the ongoing quest for safe and efficacious medication usage, underpinning public health policies, regulatory frameworks, and clinical decision-making globally.
Typically, clinical trials for new drugs are not of short durations and are conducted in populations that number up to 5000, therefore, the most common dose related ADRs are usually detected in the premarketing phase.

Types of ADR :

ADR is a response to a drug which is noxious and unintended, and which occurs at doses normally used in human being for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

Table.1 : Types of ADR's

Type	Type Of Effect	Characteristics	Example
A	Augmented	Dose dependent predicted from the known pharmacology of the drug.	Hypoglycemia-insulin
B	Bizarre	Unpredictable, dose independent, rare, Fatal	Anaphylaxis to penicillin
C	Chronic	Prolonged treatment	Analgesic neuropathy
D	Delayed	After years of treatment	Antipsycotic - turdlvedyskinesia

Table.1 : Types of ADR's

Historical background of PV

In the annals of pharmaceutical history, the paramount importance of drug safety was not always apparent. It took the tragic thalidomide episode of the 1960s to awaken drug regulators and healthcare professionals worldwide to the imperative of ensuring the safety of medications. However, an earlier pivotal moment in drug safety discourse occurred in 1893 with the publication in The Lancet journal of the first documented chloroform-related fatality, underscoring the nascent concerns in this realm.The landscape of drug safety underwent significant transformations following various global initiatives aimed at safeguarding public health. The enactment of the US FDA Act in 1906 marked a seminal step, albeit primarily addressing misbranding and false advertising. It wasn't until the sulphanilamide elixir tragedy, claiming 107 lives due to the use of diethylene glycol as a solvent, that amendments were made to incorporate stringent measures against such egregious lapses.However, it was the far-reaching repercussions of the thalidomide catastrophe that reshaped the paradigm of drug safety. Dr. William McBride's seminal report in December 1961, linking thalidomide to severe congenital deformities, catalyzed a global awakening to the imperative of comprehensive safety assessments. The tragic aftermath, affecting thousands in West Germany alone, underscored the imperative of going beyond mere efficacy evaluations.In the aftermath of the thalidomide tragedy, regulatory frameworks underwent profound revisions worldwide. The US FDA Act was swiftly amended in 1962 to mandate the compulsory submission of both efficacy and safety data prior to marketing approval. Similarly, the enforcement of the UK Medicines Act in 1968, coupled with the introduction of safety monitoring mechanisms like the 'yellow card system' in 1964, reflected the global resolve to fortify drug safety protocols.The establishment of the WHO Programme for International Drug Monitoring (IDM) in 1968 represented a watershed moment, heralding a concerted global effort to systematize and strengthen drug safety surveillance. This collaborative endeavor aimed not only to mitigate the immediate aftermath

of tragedies but also to proactively anticipate and address emerging safety concerns on a global scale.In essence, the evolution of drug safety discourse underscores a collective commitment to prioritize public health and safety, transcending mere efficacy considerations. The tragic lessons of history have spurred a global resolve to fortify regulatory frameworks, enhance surveillance mechanisms, and foster a culture of vigilance to safeguard against future calamities.

Importance of PV

Within the realm of pharmacovigilance lies a nuanced science dedicated to unraveling the intricate processes underlying adverse drug reactions (ADRs) manifesting in patients undergoing oral, parenteral, or intravenous (IV) drug therapies for various ailments. Despite the rigorous battery of tests and clinical trials conducted on drugs marketed globally to ascertain their safety profiles and delineate associated side effects, a significant portion of ADRs evades detection. It is during post-marketing surveillance that many of these adverse events come to light.The impact of undetected ADRs is profound, diminishing the quality of life, prolonging hospitalization stays, and contributing to mortality rates. A seminal study by Lazarou in 1998 shed light on the staggering toll of ADRs, identifying them as the fourth to sixth leading cause of death in the US. Furthermore, ADRs are estimated to precipitate 3-7% of all hospital admissions, underscoring their pervasive impact on healthcare outcomes.In essence, pharmacovigilance serves as a critical linchpin in navigating the complexities of drug safety, striving to mitigate the adverse consequences of medication use through vigilant monitoring and proactive intervention.

Aims of PV

1. Pharmacovigilance (PV) plays a pivotal role in assessing and identifying side effects induced by drugs, irrespective of their administration route—be it oral, parenteral, or intravenous (IV). Prior to global marketing, drugs undergo meticulous pretesting for adverse drug reactions (ADRs) to ensure safety.
2. PV is instrumental in scrutinizing, detecting, and pinpointing the drugs responsible for specific ADRs, along with elucidating the underlying mechanisms of injury. However, the onus of identifying and mitigating side effects lies not solely on PV professionals but also on the collective effort of healthcare stakeholders including doctors, nurses, health workers, and residents.
3. Effective patient engagement and guidance are indispensable in addressing the root causes of ADRs, fostering a culture of safety and empowerment among patients themselves. This collaborative approach enhances patient care and safety concerning medication usage and all medical interventions.
4. The overarching objectives of PV encompass enhancing public health and safety vis-à-vis medication utilization. This entails contributing to the comprehensive assessment of the benefits, harms, effectiveness, and risks associated with medicines, thereby promoting their judicious and cost-effective utilization.
5. A fundamental aspect of PV involves fostering understanding, education, and clinical training in pharmacovigilance practices, facilitating effective communication of safety information to the public. This dissemination of knowledge empowers both healthcare professionals and patients to make informed decisions regarding medication usage.
6. The evolution of pharmacovigilance is dynamic, responding to the evolving needs and leveraging the unique strengths of stakeholders within the WHO Programme and beyond. Encouraging and nurturing active involvement and influence fosters innovation and sustains international best practices and standards in drug safety surveillance.

Methods used in PV

Numerous researchers have devised diverse methodologies for assessing the causality of adverse drug reactions (ADRs), leveraging varied criteria such as the temporal relationship between drug administration and ADR occurrence, exclusion of non-drug-related causes, confirmation of reactions through in vivo or in vitro tests, and analysis of antecedent information on similar events associated with the suspect drug or its therapeutic class. These approaches aim to categorize ADRs based on their likelihood and severity.However, despite the proliferation of algorithmic methods for causality assessment, there remains a lack of consensus on a universally accepted standard. Each algorithm exhibits its own strengths and limitations, leading to discrepancies and inconsistencies among them. Consequently, no single algorithm has emerged as the definitive "gold standard" for evaluating ADR causality.The absence of a universally endorsed methodology underscores the complexity inherent in assessing causality, given the multifactorial nature of ADRs and the intricacies involved in establishing definitive causal relationships. Hence, ongoing research endeavors seek to refine existing algorithms and develop novel approaches that enhance the accuracy and reliability of causality assessment in pharmacovigilance practices. We would explicate them in short as listed below.

i) Dangaumou's French method

Since 1977, the French government agency has adhered to a guiding principle in assessing causality, which distinguishes between intrinsic imputability (the potential connection between a substance and an impartial event) and extrinsic imputability (drawn from bibliographical data). This assessment is conducted through the application of seven criteria, divided into two distinct tables.The first three criteria are connected and revolve around the concepts of drug challenge, dechallenge, and rechallenge, each contributing to an overall score categorized into four possible levels. The remaining four semiological criteria include the evaluation of clinical signs (semiology) as either suggestive or inconclusive, consideration of any favoring components, assessment of non-drug-related factors (none or potential), and scrutiny of laboratory test results, which can yield positive, negative, or inconclusive outcomes for the event-drug pair.Scores derived from these criteria are then consolidated into two main groups: those indicating a possible causal relationship and those suggesting doubt. This methodical approach serves as a structured framework for discerning the likelihood of a drug's involvement in adverse events, providing valuable insights into pharmacovigilance practices.

ii) Kramer et al. method

This methodology is applicable in scenarios where a specific drug is administered, and a singular adverse drug event occurs. Each adverse event is meticulously evaluated in isolation, with a dedicated assessment crafted for each instance. Notably, one of the key strengths of this algorithm lies in its transparency, offering a clear and structured framework for causality assessment.However, the effective utilization of this method necessitates varying levels of experience, expertise, and time commitment. Skilled professionals with a nuanced understanding of pharmacovigilance principles and clinical judgment are required to navigate the intricacies of the assessment process effectively. Moreover, the thorough evaluation of individual adverse events demands a significant investment of time and resources to ensure comprehensive analysis and accurate conclusions.

iii) Naranjo et al. method (Naranjo scale)

In diverse clinical contexts, this method serves to ascertain causality utilizing distinct categories: definite, probable, possible, and doubtful. It entails the use of a structured questionnaire comprising ten questions, each requiring responses of yes, no, or unknown. Based on the cumulative score derived from these responses, the adverse event is categorized

into one of the predetermined probability levels.A total score of nine or higher indicates a definite causal relationship, while scores ranging from 5 to 8 suggest a probable connection. Events scoring between 1 and 4 are deemed possible, whereas scores of 0 or below are categorized as doubtful.However, while this scale excels in pinpointing the causative agent when only one drug is involved, its efficacy diminishes in cases of polypharmacy or drug interactions. When multiple drugs are implicated or interactions occur, the scale may struggle to accurately identify the offending agent, necessitating a more nuanced approach to causality assessment.

iv) Balanced assessment method

In this method, a case report undergoes evaluation using several visual analog scale (VAS) models, with each criterion assessed individually. What sets this approach apart is its inclusion of alternative causative factors as potential contributors, rather than treating them as separate entities. This nuanced perspective enhances the comprehensiveness of the assessment, allowing for a more holistic consideration of potential causative factors.Furthermore, each case is subjected to independent assessment by different evaluators, introducing a layer of diversity and perspective into the analysis. The effectiveness of this method hinges significantly on the expertise and acumen of the assessors, underscoring the importance of their skills and knowledge in accurately interpreting the data and arriving at informed conclusions.

v) Ciba-Geigy method

Through a collaborative effort of expert consensus meetings, the Ciba-Geigy method emerged as a comprehensive approach for assessing adverse drug events. Drawing upon the collective clinical judgment of seasoned professionals, this method employs a visual analog scale (VAS) to gauge causality. Notably, it employs a structured checklist comprising 23 questions, categorized into three sections: (i) History of present adverse reaction, (ii) Patient's past adverse-reaction history, and (iii) Monitoring physician's experience.his updated methodology represents a significant advancement in causality assessment, reflecting a synthesis of clinical expertise and methodological rigor. Its introduction of a detailed checklist facilitates a systematic and thorough evaluation of adverse events, enhancing the accuracy and reliability of causality determinations.Moreover, validation studies have demonstrated the efficacy of the Ciba-Geigy method, with a notable 62% agreement observed when compared with evaluator's assessments. This high degree of concordance underscores the robustness and utility of this approach in clinical practice, affirming its value as a trusted tool for pharmacovigilance professionals.

vi) Loupi et al. method

Developed specifically for evaluating the teratogenic potential of drugs, this method encompasses two primary sections aimed at rigorously assessing causality. The initial phase of the algorithm mandates the exclusion of the drug if it is not implicated in the onset of the abnormality, ensuring a focused evaluation. Subsequently, the second section scrutinizes bibliographical data, with three key questions probing into alternative etiological factors besides the drug, the chronology of the suspected drug administration, and other pertinent bibliographical evidence.Known as the Roussel Uclaf causality assessment method, this approach finds application in diverse disease states, including liver and dermatological issues. Notably, its retrospective assessment by four experts revealed a varying agreement rate ranging from 37% to 99%, reflecting both the complexity of causality assessment and the subjectivity inherent in expert judgments.This method underscores the importance of a comprehensive and systematic approach to evaluating drug-induced adverse events, particularly in scenarios where teratogenicity is of concern. While it may yield varying levels of agreement among experts, its structured framework provides valuable insights into the potential causative role of drugs in adverse outcomes, contributing to informed decision-making in clinical practice.

vii) Australian method

The Australian method for causality assessment diverges from traditional approaches by focusing solely on the evidence presented within case reports. Notably, it deliberately excludes antecedent knowledge regarding the suspect drug profile during the assessment process. Instead, emphasis is placed on factors such as timing of the adverse event and pertinent laboratory information.This distinctive methodology underscores a commitment to impartiality and objectivity, ensuring that assessments are based solely on the evidence at hand rather than preconceived notions about the drug in question. By prioritizing the information gleaned from case reports, this approach facilitates a thorough and unbiased evaluation of causality, enabling clinicians to make informed decisions regarding drug safety.While the Australian method may yield unique insights, its reliance solely on case report evidence may present limitations in cases where comprehensive data is lacking. Nonetheless, its emphasis on empirical evidence serves as a valuable contribution to the field of pharmacovigilance, promoting rigorous and evidence-based assessment of adverse drug events.

The WHO-UMC causality assessment system

The WHO-UMC system for assessing adverse drug reactions (ADRs) was devised through collaboration with National Centres participating in the Programme for International Drug Monitoring. It serves as a pragmatic tool for evaluating case reports, integrating both clinical-pharmacological considerations and the quality of documentation. Given the focus of pharmacovigilance on detecting unknown and unexpected ADRs, factors such as prior knowledge and statistical probability play a subordinate role in this system.Recognizing the critical importance of semantic clarity, the WHO-UMC system emphasizes the need for consistency in interpretation, acknowledging the potential for variability in individual judgments. While alternative algorithms may exist, some prove overly intricate or overly specialized for widespread application. In contrast, the WHO-UMC system offers guidance on selecting the most appropriate category based on general arguments, facilitating consistency and comparability in assessments.The system delineates various causality categories, each defined with specific assessment criteria detailed in a structured manner. This approach, developed for practical training during UMC Training courses, aims to equip practitioners with the requisite skills for accurate and consistent causality assessment in pharmacovigilance practice.

Causality term	Assessment criteria
Certain	Event or laboratory test abnormality, with plausible time relationship to drug intake Cannot be explained by disease or other drugs Response to withdrawal plausible (pharmacologically, pathologically) Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) Rechallenge satisfactory, if necessary
Probable /Likely	Event or laboratory test abnormality, with reasonable time relationship to drug intake Unlikely to be attributed to disease or other drugs Response to withdrawal clinically reasonable Rechallenge not required
Possible	Event or laboratory test abnormality, with reasonable time relationship to drug intake Could also be explained by disease or other drugs Information on drug withdrawal may be lacking or unclear

Unlikely	Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) Disease or other drugs provide plausible explanations
Conditional/ Unclassified	Event or laboratory test abnormality More data for proper assessment needed Additional data under examination
Unassessable/ Unclassifiable	Report suggesting an adverse reaction Cannot be judged because information is insufficient or contradictory Data cannot be supplemented or verified

Table.2 : Causality assessment criteria

WHO-UMC & India

The WHO Program for International Drug Monitoring (IDM) serves as a vital platform for collaboration among WHO member states, including India, in the surveillance of drug safety. Under this program, individual case reports of suspected adverse drug reactions (ADRs) are systematically collected and stored in a centralized database, which presently houses an extensive repository of over 3.7 million case reports. Since its inception in 1978, the Uppsala Monitoring Centre (UMC) in Sweden has spearheaded the program's operations, overseeing the collection, processing, evaluation, and entry of ADR data from member countries worldwide, including India.The aggregation of ADR reports from diverse geographic regions enables the identification of potential signals—a crucial mechanism for alerting member countries to possible hazards associated with specific drugs. However, the signaling process is contingent upon rigorous evaluation and expert review, ensuring that alerts are based on robust evidence and analysis.While ADR reporting holds immense potential for enhancing patient safety and public health, India, despite its substantial patient population and healthcare infrastructure, is still in the nascent stages of ADR reporting. Despite this, the country's participation in the WHO IDM program provides a framework for leveraging international collaborations and resources to strengthen pharmacovigilance initiatives. By tapping into the collective knowledge and experiences of other member countries, India can gain valuable insights and guidance to bolster its ADR reporting infrastructure and promote a culture of pharmacovigilance awareness among healthcare professionals and the public alike.

Pharmacovigilance Programme of India (PvPI)

A National PV Centre is located in the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi and two WHO special centres are located in Mumbai (KEM Hospital) and Aligarh (JLN Hospital). These centres were to report ADRs to the drug regulatory authority of India. The major role of these centres was to monitor ADRs to medicines marketed in India. The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of Ministry of Health & Family Welfare, Government of India in collaboration with Indian Pharmacopeia Commission (IPC), Ghaziabad, (U.P.) is initiating a nation-wide PV programme for protecting the health of the patients by assuring drug safety. The programme shall be coordinated by the IPC as a National Coordinating Centre (NCC). The centre will operate under the supervision of a Steering Committee. The PvPI was initiated by the Government of India on 14 July 2010 with the AIIMS, New Delhi as the NCC for monitoring ADRs in the country for safeguarding Public Health. In the year 2010, 22 ADRs monitoring centres including the All India Institute of Medical Sciences (AIIMS) New Delhi, were set up under this programme. To ensure implementation of this programme in a more effective way, the NCC was shifted from the AIIMS, to the IPC on 15 April 2011.

International Collaboration

The following organizations play a key collaborative role in the global oversight of PV.

The World Health Organization

At the heart of pharmacovigilance lies the principle of global cooperation, epitomized by the WHO Programme for International Drug Monitoring (IDM). This groundbreaking initiative has fostered collaboration among more than 150 nations, each equipped with systems to encourage healthcare professionals to meticulously document adverse drug reactions (ADRs) in their patients.Since its inception in 1978, this program has been entrusted to the capable hands of the Uppsala Monitoring Centre (UMC). Member countries diligently submit their reports to the UMC, where they undergo meticulous processing, evaluation, and integration into the esteemed VigiBase, an international repository of drug safety data.Participation in the WHO Programme not only empowers countries to locally address ADR concerns but also offers a broader perspective by revealing patterns and trends from across the globe. When multiple reports of ADRs linked to a specific medication surface, this collaborative effort may unveil a potential signal, prompting a thorough evaluation and expert review. Subsequently, a timely alert about potential hazards is disseminated to member nations, facilitating informed decision-making and safeguarding public health on a global scale.

The International Council for Harmonisation (ICH)

ICH stands as a beacon of global collaboration, uniting members from the European Union, the United States, and Japan with the lofty ambition of establishing universal standards for pharmaceutical companies and regulatory authorities worldwide. Since its inception in 1990, the ICH Steering Committee (SC) has diligently overseen harmonization endeavors, ensuring coherence and efficacy in drug development and regulation.Comprised of six co-sponsors, including esteemed entities like the European Federation of Pharmaceutical Industries and Associations, Japan's Ministry of Health, Labour and Welfare, and the FDA, the SC boasts a balanced representation, with each co-sponsor holding two seats. Moreover, the SC extends invitations to other stakeholders of paramount interest, with current observers such as the WHO, Health Canada, and the European Free Trade Association actively contributing insights and perspectives.Beyond the purview of ICH, the Council for International Organizations of Medical Science (CIOMS), an integral component of the WHO, serves as a global intellectual powerhouse. Through its Working Groups, CIOMS provides invaluable guidance on drug safety matters, crafting reports that serve as foundational references for shaping future regulatory policies and procedures. From tackling contemporary challenges in pharmacovigilance to delineating pragmatic approaches for signal detection, CIOMS reports, including CIOMS V through VIII, exemplify the organization's unwavering commitment to advancing drug safety on a global scale .The CIOMS prepares reports that are used as a reference for developing future drug regulatory policy and procedures, and over the years, many of CIOMS proposed policies have been adopted. Examples of topics these reports have covered include: Current Challenges in PV: Pragmatic Approaches (CIOMS V); Management of Safety Information from Clinical Trials (CIOMSVI); the Development Safety Update Report: Harmonizing the Format and Content for Periodic Safety Reporting During Clinical Trials (CIOMS VII); and Practical Aspects of Signal Detection in PV: Report of CIOMS Working Group (CIOMS VIII).

II. FUTURE PERSPECTIVES

For, the problems & challenges facing the development of a robust PV system of India, the following proposals might be as follows:

1. Build & maintain a vigorous PV system.

2. Making PV reporting mandatory and introducing PV inspections.
3. High-level discussions with various stakeholders.
4. Creating a single country-specific ADRs reporting form to be used by all.
5. Strengthen the Drug Controller General of India (DCGI) office with trained scientific and medical assessors for PV.
6. Creating a clinical trial and post-marketing database for SAEs / SUSARs and ADRs for signal detection and access to all relevant data from various stakeholders.
7. Education and training of medical students, pharmacists and nurses in the area of PV.
8. List all new drugs/indications by maintaining a standard database for every pharmaceutical company.
9. Collaborating with PV organizations in enhancing drug safety with advancements in information technology, there has been the emergence of new opportunities for national and international collaborations that can enhance post-marketing surveillance programs and increase drug safety.
10. Building a network of PV and pharmacopeidemiologists in India.

III.CONCLUSION

Pharmacovigilance (PV) stands as a vibrant cornerstone in both clinical practice and public health consciousness. In the wake of adverse drug events, swift and comprehensive reporting is paramount, necessitating not only heightened awareness among healthcare practitioners but also active engagement from patients themselves. Empowering patients with knowledge about PV programs can foster self-reporting, alleviating the burden on clinicians and ensuring a more robust surveillance system.India, amidst its burgeoning PV landscape, recognizes the imperative of bolstering reporting mechanisms to meet global standards, particularly in safeguarding vulnerable populations like children and pregnant women. As the world's largest producer of pharmaceuticals and a burgeoning clinical trial hub, India's commitment to drug safety is underscored by the establishment of the National PV Program under the vigilant stewardship of the Drug Controller General of India (DCGI).The evolution of PV in India hinges not on a singular approach but on a mosaic of complementary strategies, including continuous training and retraining of personnel involved in PV activities to enhance the quality of reports. A robust PV system is indispensable for prudent medication use, benefiting healthcare professionals, regulatory bodies, pharmaceutical firms, and consumers alike.With concerted efforts and steadfast dedication, India is poised to cultivate a world-class PV infrastructure, emblematic of its commitment to patient safety and public health excellence.

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