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Systematic Approach in Reporting and Monitoring of Adverse Drug Reaction

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Abstract:- Adverse Drug Reactions (ADRs) are a significant public health concern, and the reporting and monitoring of these events is essential for the identification of potential safety issues with medications. A systemic approach to reporting and monitoring of ADRs includes a comprehensive evaluation of all aspects of the process, including the collection and analysis of ADR data, the reporting mechanisms in place, and the follow-up and response to the reported events. This approach should involve collaboration between healthcare providers, patients, and regulatory agencies, and should leverage technology to enhance the efficiency and accuracy of the process. A robust and systematic approach to ADR reporting and monitoring is critical for ensuring patient safety and improving the quality of healthcare.

I. INTRODUCTION

The pharmaceutical science of detecting, evaluating, comprehending, and preventing harmful effects, particularly long-term and short-term side effects of medications, is known as pharmacovigilance (PV), sometimes known as drug safety. PV is a crucial and essential component of clinical research. The biggest problem in the world is the under-reporting of adverse drug reactions (ADRs), which can be linked to a lack of time and report forms. It is well known that the World Health Organization (WHO) has started a programme to record any adverse drug responses. Additionally, its concerns now extend to biologicals, medical devices, vaccines, traditional and complementary medicines, blood products, and herbal medication items. PV also performs a variety of responsibilities, including the detection, measurement, and reporting of drug-related issues that lead to drug-related injuries. Additionally, nationwide PV programmes have been launched, which play a crucial part in raising public knowledge of medication safety. The necessity for PV in the daily lives of doctors, patients, and the pharmaceutical business is explained in this review paper.

Pharmaceutical companies must perform clinical trials in accordance with ICH GCP principles in order to create new pharmaceuticals for the market. Clinical trials include pharmacovigilance as a crucial and essential component.

W. McBride, an Australian physician who first suggested a causative connection between thalidomide, a medication taken during pregnancy, and significant foetal abnormalities (Phocomelia), published a case report in the Lancet in December 1961, which led to the formal introduction of pharmacovigilance. Thalidomide was employed by pregnant women as a sedative and antiemetic. The World Health Organization (WHO) developed "Programmed for International Medication Monitoring" in 1968 as a pilot initiative with the goal of aggregating global data on adverse drug responses (ADRs). The "WHO Programmed" was specifically designed to locate the first PV signs. A French group of toxicologists and pharmacologists coined the word PV in the middle of the 1970s to describe the actions supporting "The evaluation of the risks of side effects that may be connected with drugs.

"Pharmacovigilance is one of the most important and crucial elements of clinical research. Safety in clinical trials and post-marketing pharmacovigilance potential (also known as Post-marketing studies or Phase IV clinical trials) are both crucial throughout the whole life cycle of a product. With a sizable number of high-profile medication withdrawals in recent years, both the pharmaceutical industry and numerous regulatory bodies worldwide have increased the bar. In order to discover the risks associated with their treatments as soon as possible, major pharmaceutical firms have recently implemented early identification of signals from the early phases of clinical trials and post-marketing monitoring studies. If such a risk exists, it is necessary to properly manage it by using effective risk management strategies throughout the product's life cycle. These risk management strategies are also frequently referred to as risk mitigation strategies. Adverse drug responses (ADRs), which are unpleasant and undesirable drug reactions that occur at doses commonly utilized for disease prevention, diagnosis, or therapy, or for the modification of physiological function, are of particular concern to PV. Continuously assessing

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pharmaceutical effects, side effects, contraindications, and unfavorable adverse events that may cause severe morbidity and mortality is essential to maximise benefits and minimise dangers. No amount of care and caution taken during the pre-clinical and clinical testing phases can ensure total safety when a product is sold and prescribed to large populations both inside and outside of the country. As clinical trials only involve at most a few thousand people, less prevalent side effects and adverse drug reactions (ADRs) are typically unknown when a product is first put on the market. To determine the connections between medications and ADRs, post-marketing PV use methods including data study of case reports. Drug regulatory organisations are expected to have a reliable PV system in place in order to monitor ADRs both during the medication development stage and later on over the life cycle of a marketed product.

II. VARIOUS TERMS ASSOCIATED WITH REPORTING OF ADVERSE DRUG REACTION:

Adverse event: Any unfavorable medical occurrence that may occur when taking a drug but does not necessarily have a connection to its use is referred to as an adverse event.

Adverse drug reaction: Any unpleasant, unplanned, and unwanted effects of a medication that occur when it is administered to a human for prevention, diagnosis, treatment, or alteration of physiological function are known as adverse drug reactions (ADRs).

Post marketing surveillance: Post-marketing surveillance (PMS) is the process of keeping track of a medicine or device's safety after it has been put on the market.

Clinical trials: Clinical trials are a class of tests used in medical research and drug development to determine the safety and effectiveness of health interventions. They also provide data on adverse drug reactions and unfavorable consequences of other therapies (e.g., drugs, diagnostics, devices, therapy protocols).

Safety signal: Safety signals, which can come from post-marketing data as well as other sources like pre-clinical data and events linked to other products in the same pharmacological class, refer to a worry about more adverse events than one may anticipate being connected to the usage of a product.

Pharmacoepidemiology: Study of the effects and usage of medications in huge populations.

Pharmacology: Study of drug usage, effects, and mechanisms of action

Pharmacovigilance: The knowledge and methods used in the detection, assessment, comprehension, and reduction of adverse effects or any other drug-related problem.

Side effect: Any unanticipated side effect of a medication that results from taking it as prescribed and is connected to its pharmacological characteristics.

Poly-pharmacy: The simultaneous use of many drugs, sometimes with multiple doctors' advice

Most common two types of ADRs:

- Predictable (Type-A) Reactions- They are based on pharmacological characteristics such as an increased but quantitatively normal reaction to the medication, which includes toxic effects, side effects, and withdrawal symptoms. Examples of these dose-dependent effects include bleeding while using anticoagulants.
- Unpredictable (Type- B) Reactions - They are based on the patient's indications rather than the drug's known side effects, such as allergies and idiosyncrasy. They require drug withdrawal because they are more severe, such as an allergic reaction to penicillin.

The first goal of pharmacovigilance is to better safeguard the public from new medications.

- To contribute to the evaluation of the efficacy, safety, and risk of pharmaceuticals.
- Encourage community members to communicate well.
- To encourage the prudent and secure use of medication.
- Drug effectiveness and monitoring of unfavorable effects.
- Pharmacovigilance prevents any negative side effects from medications.

Increase public health and safety in relation to the application of pharmacovigilance through promoting knowledge, instruction, and clinical training.PV plays a significant part in the evaluation of pharmacological side effects, whether they are brought on by oral, parenteral, or intravenous medications. Before they are sold globally, many medications are pretested for ADRs. In assessing, detecting, and identifying the medicines that produced a specific ADR and the mechanism by which it caused the harm, PV plays a crucial role.

The rate of suspected ADRs among hospitalised patients has been estimated by studies to be between 2% and 3%, depending on the region of India. A recent systematic investigation assessed the typical incidence of ADRs that led to hospitalisation and those that occurred while in the hospital to be 2.85(%) percent and 6.34(%) percent, respectively. ADRs cost the hospital a total of Rupees 1567397, according to research. ADR patients who are hospitalised often incur management expenditures of about Rupees 5000 (115 in dollar). The costs were revealed to be rather high for a country where the annual per capita health spending is close to 109 US dollar.ADRs lengthen hospital stays, raise the expense of care, and place a load on the healthcare system of an nation.

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III. SUGGESTIONS ABOUT REPORTING

Inform the public of adverse drug reactions:

- Report a significant adverse response: A reaction is serious when the patient's outcome is one of the following: death, life-threatening illness, hospitalisation, or the need for an intervention to stop long-term harm or disability.
- Any healthcare practitioner may file a report (doctors including dentists, nurses, and pharmacists) Please send the completed form to the National Coordinating Center or the Adverse Drug Reaction Monitoring Center that is closest to you.
- What happens to the supplied information? All information is treated with absolute confidentiality. At ADR monitoring centres, the causation evaluation is done using the WHO-UMC scale. The ADR database was used to send the evaluation can be made to national centres.
- National Coordinating Centers examine the report on an ongoing basis. The data produced based on this study aids in ongoing evaluation of the benefit-risk ratio of pharmaceuticals. The data is given to the PvPI steering group, which was established by the Ministry of Health and Family Welfare.

IV. PROGRAMME COMMUNICATION

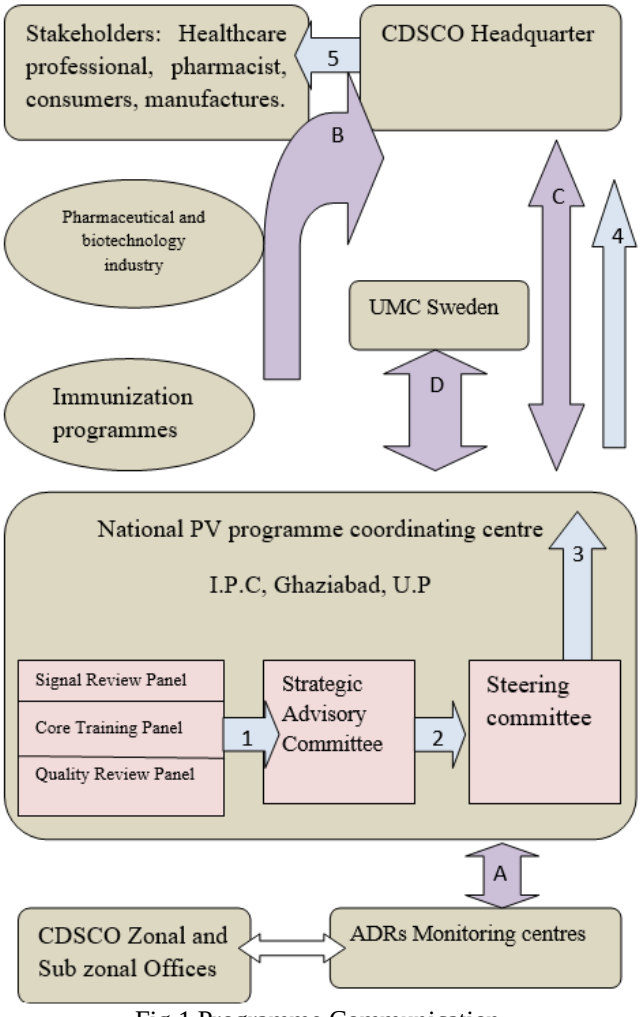

Fig 1 Programme Communication

A. *What to report?*

The National Pharmacovigilance Programme (NPP) would encourage reporting of all alleged adverse medication reactions, including those that could have been caused by herbal, conventional, or alternative therapies. It would be crucial to record adverse responses that appear to be minor or frequent because they might draw attention to a widespread prescription issue. The initiative specifically requests reports of:

- All adverse events thought to be brought on by novel medications and "Drugs of Current Interest" (List to be published by CDSCO from time to time)
- Any conceivable drug interactions
- Reactions to any other medications that may have a major impact on a patient's care, including those that may: Death Life-threatening (actual risk of dying) (real risk of dying) Hospitalisation (initial or protracted) (initial or prolonged) Disability (severe, chronic or permanent) (significant, persistent or permanent) Congenital defect Intervention that is necessary to stop lasting harm or impairment

B. *Who can report?*

Any health care provider, including doctors, dentists, nurses, and pharmacists, may report possible medication side effects. Reports from laymen or anybody else who is not a healthcare professional are not acceptable for the Programme.

C. *Where to report?*

The completed form must be delivered back to the original pharmacovigilance Centre where it was first obtained. Any of the country's pharmacovigilance entrées that are close to the reporter can receive reports. (A complete list of pharmaceutical surveillance facilities may be found at www.cdsco.nic.in) If in doubt, the form can be forwarded to the Central Drugs Standard Control Organization in New Delhi, the country's pharmacovigilance Centre.

D. *What happens to the information submitted?*

The data in the form must be treated with absolute confidentiality. The form must be sent by peripheral pharmacovigilance entrées to the corresponding regional pharmacovigilance entrées so they may conduct the causality analysis. These details must be sent to the Zonal Pharmacovigilance Centers. The information will be statistically analysed before being sent to the WHO Uppsala Monitoring Center in Sweden's worldwide pharmacovigilance database. The National Pharmacovigilance Advisory Committee, which was established by the Ministry of Health and Family Welfare, will regularly evaluate the final report based on the analysed data. The Committee is charged with reviewing data and recommending any regulatory measures that could be necessary either regard to the medicine.

E. *Importance of PV and its governance structure in India*

It is research that deals with the difficult process of comprehending and outlining the nature of adverse drug reactions (ADR) that occur when a patient receives either oral, parenteral, or intravenous (I.V.) medications to treat a condition. To determine if a treatment is safe for use in

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treating a particular ailment and to determine the precise side effects connected with it, the pharmaceuticals now on the market across the world have undergone a wide range of testing as well as clinical studies on both human and animal subjects. Even yet, a sizable portion of it escapes unreported, and some ADR are found through post-marketing surveillance. According to estimates, there are a considerable number of ADRs, which lower quality of life, lengthen hospital stays, and raise mortality. According to a seminal research by Lazarou in 1998, ADRs are between the fourth and sixth largest cause of mortality in the US and are responsible for between three percent and seven percent of all hospital admissions.

V. GOVERNANCE STRUCTURE

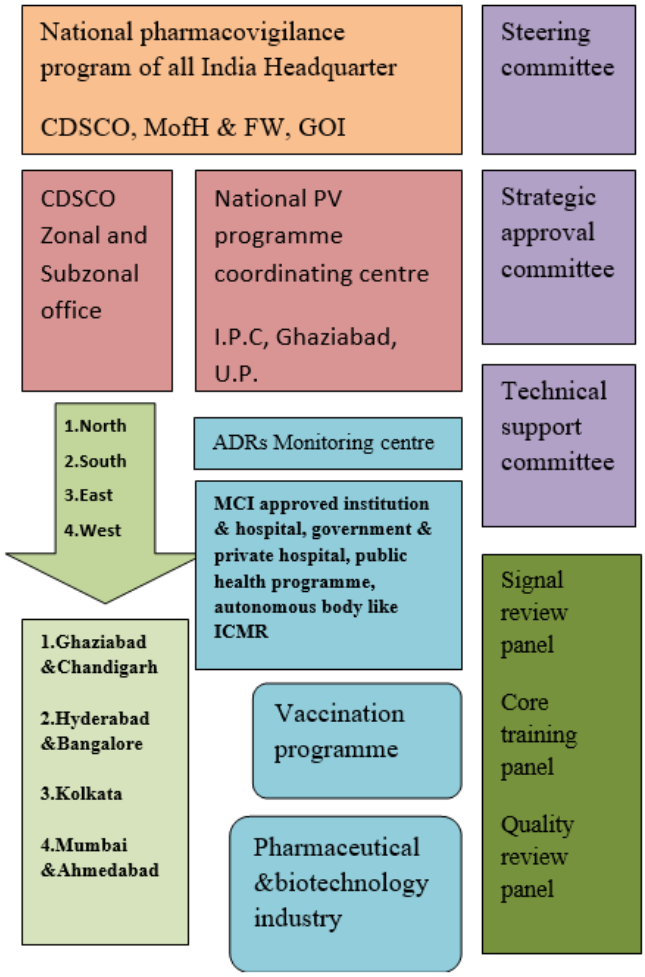

Fig 2:- Governance Structure

A. *PvPI Programme:*

The Indian government's Pharmacovigilance Programme of India (PvPI) is a body that finds and fixes drug safety issues. Receiving reports of adverse medication occurrences and taking the appropriate measures to address issues are among its activities.

Its components:

- Administrative Body: Steering committee, Technical support committee, Strategic advisory committee.
- National Pharmacovigilance center: Zonal Pharmacovigilance center, regional Pharmacovigilance center, peripheral Pharmacovigilance center.
- ADRs monitoring center: MCI approved medical college, private hospital\health center, and autonomous institution.

B. *Goals of pvpi*

➢ *Short term goals*

- To create and execute an Indian pharmacovigilance system
- To persuade medical professionals to disclose any negative effects from medications, vaccinations, medical equipment, or biological products
- Gathering data and case reports.
- All medical colleges that received approval from MCI implemented the programmes.

➢ *Long term goals*

- Adding all hospitals and public health initiatives in India to the pharmacovigilanceprogramme
- Making ADR reporting necessary for medical practitioners.
- To create an online reporting system.

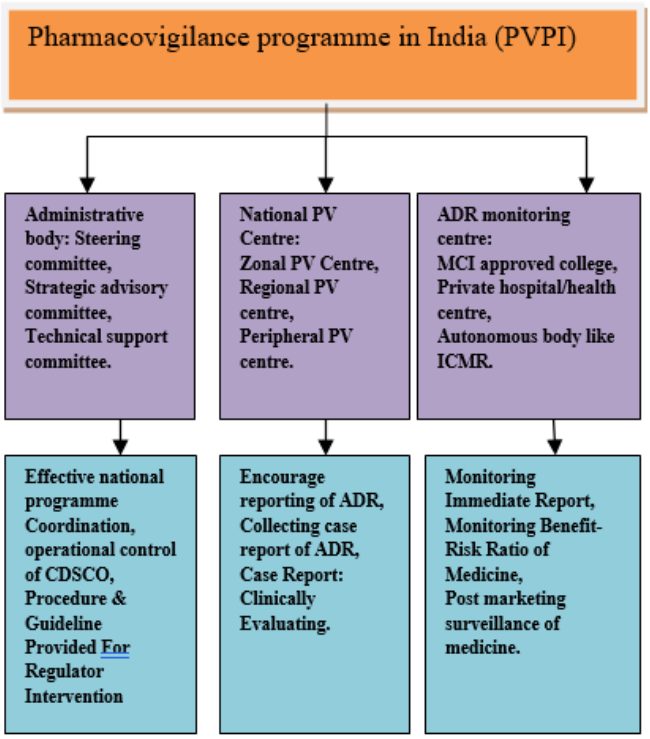

Fig 3:- Pharmacovigilance programme in India (PVPI)

VI. ADVERSE REACTION REPORTING CHALLENGES

A. *Opinions of healthcare experts on ADR reporting:*

A common challenge throughout most investigations has been the absence of suspicion surrounding the emergence of ADRs. It's a common fallacy that ADRs don't need to be reported unless there is solid proof demonstrating a connection between the medicine and the adverse event. It is

problematic when spontaneous reporting is ignored. Medical professionals frequently think that one case cannot possibly add to the corpus of knowledge. There is a common misconception that since only safe medications are licenced for marketing, they must be safe. Prospective reporters frequently struggle to pick up the phone and figure out if an ADR actually occurred.

B. Knowledge gaps and insufficient training:

There is still a major ignorance regarding the existence, function, and use of national pharmacovigilance programmes and ADR monitoring systems, despite the fact that doctors and other healthcare professionals are rapidly becoming more aware of them. The specifics of what has to be reported are unclear to healthcare providers, who also lack knowledge of how to do so. Although doctors and other healthcare professionals are gradually becoming aware of national pharmacovigilance programmes and ADR monitoring systems, they still have little knowledge of their existence, function, and functioning. The information that healthcare professional's need to report and how to accomplish so are unclear to them. Lack of formal training in ADR diagnosis, reporting, and recommended protocols among medical personnel is another hurdle. Both the general public and the medical community feel that the spontaneous reporting of ADRs has not been adequately promoted. The impression of the danger associated with over-the-counter, herbal, and relatively older medications as well as the information and experience necessary to accurately detect ADRs are both insufficient.

C. Potential conflict problems:

Potential conflict problems have also been said to affect the reporting of healthcare practitioners. Many respondents worry that they would become mired in legal problems brought on by the reporting of ADRs. Since patients are frequently reluctant to provide their personal information, it is difficult to manage them and handle their confidentiality concerns when reporting.

D. Organizational issues with the pharmacovigilance system in hospitals and with patients:

It has been noted that there is insufficient awareness of the goals and possible benefits of ADR monitoring. Lack of understanding of the available ADR reporting forms. There are logistical problems, such as the shortage of ADR forms at pharmacies and hospitals or the inability to get them when needed. Due to the patient's inability to provide the necessary information, pharmacists believe that the information needed to report the ADR is insufficient.

E. Health care practitioners' perspectives on reporting ADRs:

Healthcare professionals commonly bemoan their lack of time, interest in, or access to the appropriate reporting form. It has been said that professionals might not be as eager to disclose a negative reaction they observe. This is made worse by the requirement that they complete extra paperwork in order to disclose ADRs. Lethargy and procrastination in reporting are the outcomes of this. Moreover, several studies have highlighted the notion that handling individual ADRs is more important than reporting them. Lack of incentives for healthcare workers to complete this activity, which is already a strain given their heavy workloads, is another potential barrier. There is a belief that running into ADRs are a regular aspect of patient treatment and do not require reporting.

VII. OBSTACLE REMOVAL STRATEGIES

Eventually, insufficient ADR reporting causes a number of critical signals to be missed or needlessly delayed in being gathered, enabling potentially hazardous drugs to remain on the market and endangering patient safety. Based on the data currently at hand, including surveys of medical experts, a number of potential steps to improve the in-situ adverse event reporting system in India have been identified.

A. Greater participation of all parties involved in reporting ADRs

➢ *Nurses and Pharmacist*

Despite evidence that suggests nurses are frequently unsure of their role in spontaneous reporting of adverse drug reactions (ADRs), studies have shown that increased involvement of nurses in not only gathering and managing ADRs but also reporting and documenting them contributes to the improvement of the system. The statistical and subjective analysis of nurses' reports of ADRs was done in a Swedish research. According to the statistics, the rate rose from 2–3% in the middle of the 1990s to 12% in 2004. For identifying and reporting adverse medication reactions, nurses are a valuable supplementary resource. Additional studies have revealed that there was a considerable increase in the proportion of severe and unlabeled ADRs as well as the reporting rates of ADRs after integrating nurses who had received adequate training in reporting ADRs. Customers must be included in ADR reporting alongside doctors since they regularly contact with pharmacists, whose reports may be supplemented by reliable and relevant information from pharmacists. The reports also take into account any potential worries the patients may have regarding the ADRs they encounter. Despite the common belief that pharmacists don't have a lot of room in India's drug delivery system, offering consumer reporting forms through pharmacies can greatly enhance direct patient reporting of ADRs.

➢ *Patients/Consumers:*

Expanding the use of patients or consumers as reporters is a very important step that can help to overcome the issue of under reporting of ADRs. Hunzel et al assessments of 11 nations highlighted the significance of allowing members of the public to report adverse reactions in order to increase the scientific value of the pharmacovigilance data that has been gathered. According to findings from a previous study on patient reporting, individuals are more likely than healthcare professionals to recognise and report the negative reactions they experience. Additionally, patient reporting sheds information on potential novel responses, giving expert reports of ADRs significance and relevance. Patients and consumers have so far had excellent experiences in countries that have included them as reporters. By incorporating patients, we may gain a better understanding of their thoughts

and broaden our perspective on ADR5 reporting. In terms of India, this addition is recent and is expected to strengthen and improve the present programme. Less than 12% of ICSRs submitted to PvPI are believed to be directly from consumers at this time.

B. Making the reporting process more time-efficient, comfortable, and easy:

➢ *Promoting eHealth tools for reporting:*

Many polls among healthcare professionals on how to improve spontaneous ADR reporting have advised the creation of techniques to make the reporting process faster and more convenient. Regulatory organisations are increasingly leveraging data collected through social media and mobile applications to speed ADR reporting and enhance consumers' capacity to report unfavorable situations instantly. Although these initiatives have already begun in India, acceptance rates are still modest at less than 1%. In 2015–16, mobile platforms were used to receive individual case safety reports (ICSRs). Using a website that allows for online form completion and submission can speed up the ADR filing process and make it more efficient. According to a French study, this strategy significantly reduced the reporting duration and boosted the quantity of reports by around 50%. It has also been recommended that the reporting status be improved by automatically filling up some elements of the reporting form (if it is online). At hospitals with the option for electronic patient records, especially in the critically underserved private sector, a hyper link to an online ADR reporting form can be included to the record. A Portuguese study found that after including a hyperlink, the number of ADR reports increased from an earlier average of 1 to 4.

➢ *Increasing the accessibility and usefulness of forms for spontaneous ADR reporting:*

One important aspect of the pharmacovigilance programme that can have a good impact on the process is the design and content of the spontaneous reporting forms. ADR forms should be more widely accessible, which is equally important. Reports forms can be updated to be less complicated and more user-friendly, as well as to include all the essential information. The healthcare providers may be discouraged from voluntarily reporting an adverse occurrence if the form is overly complicated. A study evaluating the effectiveness of ADR reporting forms from other countries found that Malaysia's form is the most detailed and capable of capturing the necessary data. Due to diverse designs, the data collection methods used by the others differed. Synchronizing the forms and producing a comprehensive form is essential to streamline the filing procedure and lessen confusion.

C. Instruments to strengthen the pharmacovigilance system and promote clinicians for reporting:

An education campaign for boosting understanding and awareness of PV as well as ADR notification drop boxes were established in a research conducted in India. These boxes, which also included straightforward reporting forms, were placed in every OPD and ward in the hospital. Physicians were required to complete the form and place it in the drop box when they encountered an ADR. These forms were then delivered to the national pharmacovigilance Centre as a group. Due to this, the number of ADR reports in the three months nearly doubled. To improve reporting outcomes, these novel strategies may be evaluated and used in medical settings. Drop boxes and telephone contact are the most favored ways of communication, according to a survey of resident physicians and nurses. As low-cost and effective ways to urge clinicians to routinely report the ADRs they observe in their patients, both within and in the OPD, periodic emails and/or SMS alerts have also been suggested. Economic enticement may be viewed by some as a motivator to promote ADR reporting among healthcare providers. However, a survey revealed that almost 80% of participants did not believe that financial incentives might improve the process. Additionally, using financial incentives to prevent biased and excessive reporting is not generally recognised. For the programme to be successful in the long run, building positive relationships with stakeholders like physicians and pharmacovigilance entrées and changing how ADR reporting is seen are crucial. It is essential that physicians make reporting of adverse reactions an integral part of their daily tasks and that all healthcare workers view it as their duty. Regular feedback for ADRs reported to specific healthcare professional's (HCPs) or groups of HCPs can help to strengthen the voluntary reporting culture.

D. Medical students and professionals can benefit from educational programmes and training.

The majority of participants in several researches on improving spontaneous reporting of adverse events across India supported adding training programmes and continuing medical education (CME) series. According to a randomised controlled trial (RCT) conducted among physicians to see if educational interventions for pharmacovigilance could improve spontaneous reporting of adverse events, the reporting rate (RR) increased by about 65% in the intervention group, indicating the significant impact of the intervention. Another RCT found that the intervention group was almost 10% more likely to report adverse drug reactions than the controls (adjusted RR 10.23%). This RCT also included a multifaceted educational intervention for doctors that included a weekly outreach visit, a card of reminders, and an ADR report form. . In the first four months, there was a sharp increase in ADR reporting, and the effect remained for the first year. It is evident that targeted outreach programmes like this one can boost the number of ADRs that doctors report. As a result of awareness-raising training seminars, the amount and quality of spontaneous reporting from healthcare practitioners has consistently increased. Workshops that include concise explanations on the basic terms used in PV and the necessity of ADR monitoring, followed by the presentation of a clinical case and hands-on form filling, have produced notable and long-lasting benefits.

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VIII. CONCLUSIONS AND WAY FORWARD

In an effort to make it simpler for patients, customers, and healthcare professionals to report suspected adverse reactions that could be connected to a drug that was consumed, the PvPI established a toll-free hotline service in 2014.A mobile application was also introduced in May 2015 to give healthcare workers in the public and private sectors a platform to quickly submit ADRs. A consumer reporting form for drug adverse effects has also been established and made accessible in ten local languages. While the opening of additional channels for reporting adverse drug reactions by patients and healthcare professionals is encouraging, more needs to be done to ensure that these channels are successfully adopted by the appropriate groups in order to facilitate better ADR reporting by all significant stakeholders. Importantly, the PvPI has consistently received outstanding ratings for the thoroughness of individual case safety reports, and efforts are being made to establish effective connections with national TB, HIV, and immunization programmes.

In conclusion, there is a considerable knowledge, attitude, and behavior gap in relation to pharmacovigilance efforts. According to the review, the biggest obstacles are healthcare personnel' poor knowledge and training, their attitudes and views, and issues with the facility-level organisation of reporting systems. By making effective efforts to involve all stakeholders, ensuring a better, simpler, and more comfortable means of reporting, along with focused capacity building activities, the potential of pharmacovigilance may be more completely realised.

It is challenging to set up a trustworthy system for reporting ADRs and supporting the growth of drug safety systems, especially in emerging countries like India. It is a challenging task that can only be completed by carefully considering the limitations, meticulously planning how to get around them, and developing solutions that make sense, are practical, and are affordable in the Indian context, where the patient oversupply is enormous and the health professionals are overworked. By first attempting to change the mindset through knowledge transfer and raising awareness, followed by gradual but significant behavioural change and general attitude, it is possible to achieve a more effective pharmacovigilance system that is well-equipped to not only capture ADRs but is also capable of making informed and evidence-based decisions for ensuring the safety of patients as well as the community at large.

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REFERENCES

[1]. Campbell, J. E.; Gossell-Williams, M.; Lee, M. G. A Review of Pharmacovigilance. West Indian Medical Journal 2014.
[2]. International Journal of Advance Research, ArticleDOI:10.21474/IJAR01/10289DOIURL:http://dx.doi.org/10.21474/IJAR01/10289, RESEARCH ARTICLE; PHARMACOVIGILANCE: A REVIEW; Sangita Fulchand Pawar and Vikram Limbaji Musale; M. Pharmacy, Dept. Of Pharmaceutics, Government Collage of Pharmacy, Aurangabad- 431001.
[3]. [No title found] Online journal of public health informatics.
[4]. Mandal, S. C.; Mandal, M. Evolution of Pharmacovigilance Programme : Present Status in India Evolution of Pharmacovigilance Programme : Present Status in India. 2017, No. June.
[5]. Kumar, S.; Baldi, A. Pharmacovigilance in India: Perspectives and Prospects. Journal of Drug Delivery and Therapeutics2013, 3 (4), 237–246.
[6]. Naman M Singh, K.; Kanase, H. R. Pharmacovigilance Programme of India: The Beginning, Current Status and Recent Progress. Advances in Pharmacoepidemiology and Drug Safety2017, 06 (04), 4–6.
[7]. Suke, S. G.; Kosta, P.; Negi, H. Role of Pharmacovigilance in India: An Overview. Online Journal of Public Health Informatics2015, 7 (2).
[8]. IFPMA. Pharmacovigilance of bio therapeutic Medicines: Identifying Global Case Studies.
[9]. Wanmali, V. V; Brahmane, R. I.; Gupta, R. Review Article PHARMACOVIGILANCE.
[10]. Laporte, J. The Case-Population Strategy in Pharmacovigilance. 2013,
[11]. WHO. The Importance of Pharmacovigilance, Safety Monitoring of medicinal products. World Health Organization 2002.
[12]. Report E. Effective communications in Pharmacovigilance. International Conference on Developing Effective Communications in Pharmacovigilance, Erice, Sicily 1997; 24-27
[13]. Reporting of adverse drug reactionsin India: A review of the current scenario, obstacles and possible solutions, Rubina Mulchandaniaand Ashish Kumar Kakkarb, An Indian Institute of Public Health, Gurgaon, India Department of Pharmacology, Postgraduate Institute of Medical Education and Research, Chandigarh, India
[14]. Jobin Jose, Naziya Refi Rafeek. "Pharmacovigilance in India in Comparison With the USA and European Union: Exclude quotes Off Exclude bibliography On Exclude matches Off Challenges and Perspectives", Therapeutic Innovation & Regulatory Science, 2018