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Research Article

Evaluating The Functioning and Significance of The Pharmacovigilance Programme of India

Mehak Chandhok*[1], Sarita Gautam[2]

[1]*Masters of Public Health, School of Global Affairs, Dr B. R. Ambedkar University, Karampura Campus, New Delhi, India.*
[2]*Department of Social Sciences, National Institute of Health and Family Welfare, Munirka, New Delhi, India.*

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ABSTRACT

Pharmacovigilance (PV) is very important in safety surveillance of drugs and Adverse Drug Reaction (ADRs) with greater public health benefits. According to WHO, pharmacovigilance is a branch of pharmacoepidemiology concerned with the epidemiology of adverse effects or other drug related problems. The current demand for improved health and extended access to needed medical care and the steadily rising global consumption of drugs demonstrate the need for durable PV systems. In 2010, Pharmacovigilance Programme of India, PvPI was started under the Ministry of Health & Family Welfare, initially run by AIIMS and then migrated to Indian Pharmacopoeia Commission (IPC). PvPI is concerned with reporting, documentation, assessment, and sharing of ADR information to enhance drug safety and hence supportive authorities' decision making. The paper assesses the relevance and performance of PvPI employing the context analysis approach, where data have been obtained from the 2012–2023 scientific production database. They quote that within three years of its operation, PvPI has recorded vital progress in ADR monitoring with 256 Adverse Drug Reaction Monitoring Centres (AMCs). Nevertheless, threats like under-representation, training of healthcare workers, and structural difficulties are still there. All the same, the displayed problems do not overshadow the efforts made in the PvPI framework to improve the situation concerning drug safety, for example, training, creating public awareness, and performing technological developments. Comparing the situation with other PV systems, existing in the USA and EU, it can be stated that India ranks lower in integration and ADR reporting statutory requirements. Solutions proposed for future studies are independent ADR reporting, integrating artificial intelligence and electronic records, extension of network coverage, and international cooperation. Improving the

***Corresponding Author:** Mehak Chandhok
Address: Masters of Public Health, School of Global Affairs, Dr B. R. Ambedkar University, Karampura Campus, New Delhi, India.
Email ✉: mehakchandhok@gmail.com
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understanding of PvPI's framework may improve patient safety, consonant regulations and approach to rational use of drugs. Therefore, with its compliance to the best practices globally, PvPI has the potential to elevate India's pharmacovigilance system to international standards, ultimately contributing to safer pharmaceutical practices and improved healthcare outcomes.

INTRODUCTION

According to WHO, pharmacovigilance means the editorial and scientific disciplines involved in the surveillance of, and monitoring of adverse effects or other drug-associated issues. The growing necessity for effective health care services and the tendency toward enhancing the frequency of the pharmaceuticals consumption worldwide defined the great significance of pharmacovigilance in a modern society. ADRs involve noxious and unintended effects of drugs in the therapeutic dose, therefore poses a massive clinical practice challenge since patients' outcomes and general health of people are affected by these effects. Consequently, proper pharmacovigilance systems are required for signal identification, reporting, and risk management in relation to medication use, as well as for the continuous population confidence in pharmaceutical products. Pharmacovigilance has several essential objectives that are as follows: It encourages the rational and cautious administration of drugs, oversees drug utilization patterns as well as the adverse effects related to them and determines novelty ADRs known as 'signals'. Such knowledge can be used to revise patient records and the instructions on the package insert to include new words of caution, advice on changed dosages or new indications of the contraindication to use of the product. Pharmacovigilance also helps regulatory bodies make informed decisions, enhancing the quality of health care in general. This system enhances safe medication use by healthcare practitioners in that it provides information and training relevant to the practitioners. Further, improving the systematic monitoring of medications will play a crucial role in managing the benefit/risk as the base, which is important for the formation of public confidence in pharmaceutical products. In India, The Pharmacovigilance Programme of India (PvPI) was launched in 2010 under the Central Drugs Standard Control Organization (CDSCO), working under the Ministry of Health & Family welfare. Firstly, to facilitate the reporting of ADRs across the country the programme selected the AIIMS in New Delhi as the NCC. Subsequently, the NCC functions were devolved upon Indian Pharmacopoeia Commission (IPC) at Ghaziabad, Uttar Pradesh. Since then, the PvPI initiative has grown from strength to strength, with the 250 Adverse Drug Monitoring Centres (AMCs) running throughout medical institutions as well as hospitals across the nation to 2017. The main focus of PvPI is to review and monitor that the therapeutic values of the drugs outweigh the health risks to the Indian population.

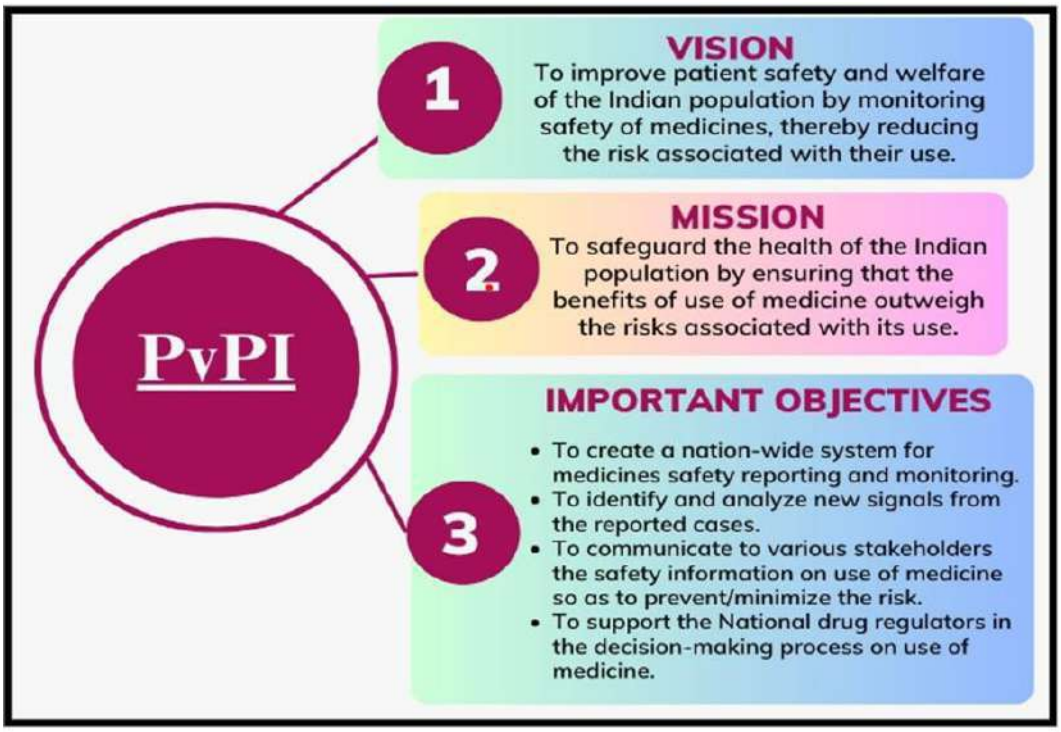

Figure 1 PVPI Vision, Mission, Objectives

There is no abbreviation for the term 'PvPI' itself, but the objectives are clear: the development of an efficient and specialized ADR reporting system across the country, contribution to the regulatory decision-making process and safety promotion among healthcare workers concerning the medications used. Basic features and goals of the future are to extend cooperation with global PV centres, develop a strategy for the progress of patient safety, and contribute to the resolution of more extensive challenges like AMR, falsified medicines, and the monitoring of safety during mass immunization drives. PvPI will also look to widen its reporting structure by considering the implementation of electronic reporting systems to capture and input data – this would better the understanding and function of adverse event reporting. Lastly, for developing its long-term goals and objectives, PvPI seeks to make the reporting of ADRs one of the cultures among the health care practitioners as a way of achieving good risk management.

The function of PvPI is essential in a health system of India due to the fact that pharmacovigilance not only speaks about the clinical aspect of ADRs but additionally discusses the sociological facet. Considering the wide range of tasks and difficulties inherent in pharmacovigilance in India, including the absence of real-time data on drug safety, the goals of PvPI's development are closely connected with the general perspective of patient safety. In its endeavors and association with different organizations, PvPI envisions changing the face of the Indian pharmacovigilance to a new high of par excellence to safeguard the therapeutic products for all patients.

Objective

The primary objective of the study is to assess the functioning and importance of the Pharmacovigilance and Pharmacovigilance Programme of India.

METHODS AND MATERIALS

The present study utilized the Context Analysis method to evaluate the effectiveness and relevance of pharmacovigilance in India, with a particular focus on the Pharmacovigilance Programme of India (PvPI). A systematic search of published literature was performed. The search included ResearchGate, Google Scholar and PubMed with the search type of articles published between 2012 and 2023. 11 articles were included in the study. English language was used only when conducting the research and only published documents in the form of research articles, scientific reports and documents found on the Internet were used. To reduce publication bias and increase the range of literature selected, further papers and grey literature were sought by manually hand-searching the bibliographies, forward citation chaining, and backward citation checking. The final selected articles delivered essential and pertinent information on the current and potential status of pharmacovigilance in India. In the analysis phase these articles were reviewed and data was pulled from them, noting overall findings and main results. To achieve the aim and objectives of the study, the data collected were systematically reviewed, categorized, and consolidated systematically. However the study faced several limitations. Firstly, only published articles were reviewed, which may increase the risk of publication bias, as unpublished research was not included. Although a wide range of articles was sought, the selection is not exhaustive, which may limit the generalizability of the findings. Secondly, the studies included various perspectives, which may result in some inconsistency in the general interpretation of results. Additionally, as this study relied on secondary data, there is a possibility that some information obtained may lack accuracy, as the primary data sources may have reporting biases or other errors.

Findings

The findings in the present research study indicates that the Pharmacovigilance (PV) framework including the Pharmacovigilance Programme of India (PvPI) is important in the Indian healthcare system for improving patient and public health safety. Initiated under the Ministry of Health & Family Welfare in 2010, PvPI has come a long way in drug safety surveillance and ADR reporting, overtime showing a newfound interest in public health. Nevertheless, as it will be understood, PvPI faces a number of issues that diminish its effectiveness and that require fine-tuning and further development on par with international counterparts (Kalaiselvan et al., 2016). The main activity of PvPI is centered on the collection, analysis and distribution of information concerning ADRs. This is done through a network of Adverse Drug Reaction Monitoring Centres (AMCs), functionalized in various medical colleges and hospitals across India. These AMCs collect ADR reports from health care professionals and patients which are compiled at the Indian Pharmacopoeia Commission in Ghaziabad. The IPC is a crucial part of warning detection, evaluating risk/benefit balance of pharmaceuticals, and providing recommendations for regulatory actions to protect marketed medicines' safety (Kalaiselvan et al., 2016).

Key Functional Aspects of PvPI

1. Data Collection: The AMCs are the main sources for ADR data collection for PvPI, as it is the case with D undertaking them. Reporting can be done via clinical and ward staff, patients, and drug manufacturers on physical forms, by email, or an Online Reporting System. This is because the latter follows a multi-channel approach aiming at both increasing ADR capture and enhancing the number and variety of returned data.

2. Data Analysis: These ADR reports after being compiled go through rigorous analysis at IPC to determine signals and trends that may show that certain safety concerns are emerging. These analyses are also important in assessing the effect between drugs and the adverse effects in such a way that new risks may be detected (Kalaiselvan et al., 2016).

3. Regulatory Action: According to the result of ADR analysis, PvPI works with some organizational bodies such as the Food and Drug Administration to apply certain actions like continuing safety information, limiting use of drugs or even removing drugs from the market if it is severe.

4. Feedback and Communication: PvPI communicates its information to the healthcare workers and other stakeholders through newsletters, safety alerts, health promotion education. This feedback loop makes sure that information gathered from ADR monitoring is communicated to the necessary stakeholders (Gupte et al., 2020).

Challenges in PvPI's Implementation

Despite PvPI's achievements, the pharmacovigilance landscape in India still faces significant hurdles:

1. Under-Reporting of ADRs: There has been identified an important limitation of PvPI, which is the bias arising from under-reporting of ADRs, an issue that discourages a sound appraisal of drug safety. It has been found that there is low awareness and low motivation among the HCPs leading to this problem that has the HCPs lacking the right knowledge of reporting the ADRs stating that only the serious ADRs have to be reported (Kumar et al., 2015). This perception reduces the amount and quality of data that may be used in safety evaluation.

2. Inadequate Training: A large proportion of healthcare professionals are not well trained in pharmacovigilance and the frequency and quality of ADR reports evaluated for this study are consequently affected. The literature review indicates that between 41% and 80% of medical personnel are still ignorant of correct ADR reporting practices, and only report serious cases that limit data coverage (Gupte et al., 2020).

3. Infrastructure Limitations: Resources, including manpower and technical, required to support PvPI can be limited in the best of time and are most often inadequate to support the program.' Lack of staff, inadequate infrastructure required to manage the high number of reported ADRs put the efficiency of the pharmacovigilance system under threat in many AMCs (Jose et al., 2018).

Initiatives to Address PvPI's Challenges

PvPI has launched several initiatives to counter these challenges, notably:

1. Training Programs: Continuing education awareness has also been launched through consciousness programs by PvPI to healthcare workers. The author has pointed out that to increase the quality and quantity of received reports on ADRs, PvPI intended to organize the training session more frequently (Kalaiselvan et al., 2016).

2. Public Awareness Campaigns: To enhance patient involvement in pharmacovigilance, PvPI has embarked on awareness campaigns in media and print, electronic media. That is why these efforts are aimed at strengthening the ability of patients to notify about ADRs and their

contribution made to the database of pharmacovigilance (Rele et al., 2023).

3. Technological Integration: For that reason, technology has been embraced by PvPI as a means of enhancing ADR reporting. Of course, with the help of digital tools — mobile applications and web portals — PvPI has simplified the process of reporting ADRs for healthcare professionals and patients; this has done away with some of the barriers inherent in the traditional reporting system (Bhalkhe et al., 2023).

Global Comparisons: The United States and European Union

In comparison with the systems of pharmacovigilance in the USA and the European Union, the Indian PvPI is still rather recently developed. MedWatch and the FAERS are complex systems enhanced with data management and reporting technology of the U.S. Food and Drug Administration. These programs have the advantage of high level of public awareness and statutory mandate to report ADRs; thus, operates very effectively and are well integrated into the health system (Jose et al., 2018). Likewise, the European Union's EudraVigilance system works on a central computer system that requires ADR reporting in all Member States and gives a consistent as well as sound pharmacovigilance structure (Jose et al., 2018).

Future Perspectives for PvPI

To enhance its efficacy, PvPI has identified several future directions aligned with the best practices in international pharmacovigilance:

1. Expanding the Network: The ultimate vision of PvPI is to implement the project in all major healthcare facilities both governmental and private throughout the country. To increase the number of institutions reporting on ADRs, PvPI's objectives are to improve data coverage and further support drug safety surveillance (Kalaiselvan et al., 2016).

2. Mandatory ADR Reporting: Just like in the U.S and EU, PvPI calls for the reporting of all healthcare providers to ADR. In regards to legislative changes, at PvPI, it is hoped that such changes will bring about accountability and active ADR data reporting (Rele et al., 2023).

3. Technological Advancements: Namely, currently, PvPI is aimed at using technologies, such as artificial intelligence AI signal detection and electronic health record EHR analyses for the enhancement of the data accuracy and data processing velocities (Bhalkhe et al., 2023).

4. International Collaboration: PvPI aims to enhance its partnership with global PV organizations to harmonize with global safety monitoring of medicines and to exchange information sharing practices. Such affiliations including PvPI participation in WHO-UMC Pharmacovigilance Network will enhance formation of a stronger PV framework in India (Guidance Document for Pharmacovigilance 2022).

Benefits of Pharmacovigilance in India

The benefits of a robust pharmacovigilance system in India include:

1. Enhanced Patient Safety: PvPI facilitates early identification and prevention of drug risk thus protecting patients' health through constant observation of ADRs (Kalaiselvan et al., 2016).

2. Regulatory Support: The information collected through Density relies on developing laws regulating approval, restriction or withdrawal of drugs to prevent circulation of nausea drugs (Kalaiselvan et al., 2016).

3. Enhanced Client Outcomes: Implementing a good Pharmacovigilance system guarantees the public the use of safe and effective drugs that enhance the general health of the population demography and increases confidence in the healthcare sector. (Jose et al., 2018).

4. Promotion of Rational Drug Use: As an organization that promotes medication safety, PvPI helps to prevent drug use to institutions and the public through education on safe use of medicines leading to a low-rate case of overprescribing medicines and the complications associated with it. The Pharmacovigilance Programme of India (PvPI) started in 2010 has demonstrated a good growth prospect; however, the findings of this study suggest that the strength of pharmacovigilance (PV) in India is still weaker than in developed countries such as the US and EU. There is some constant progression of the areas of concern that need focus for PvPI to meet the high set benchmarks by FAERS in the United States, as well as EudraVigilance in Europe. These systems are high tech, well integrated and are based on statutory requirements to make effective frameworks for reporting adverse drug reactions (Jose et al., 2018). While PvPI may only have moderate to high improvements needed in the infrastructure, training and awareness, PvPI has high improvements needed to address this gap. Current enhancements include software and hardware solutions like the use of artificial intelligence-based signal detection and implementation of Electronic Health Records, EHR that has been proven across the world to increase the performance accuracy in PV systems. Furthermore, to improve the efficiency of drug safety management and increase reporting rates from healthcare organisations, making reporting of ADRs mandatory along the principles of the US and EU legislation may be effective (Rele et al., 2023). Other measures are also important such as training of healthcare professionals, awareness and promotion of the principles of pharmacovigilance and the results obtained from the IE introduction in medical and pharmacy curriculum are positive (Guidance Document for Pharmacovigilance, 2022). PvPI can also gain additional advantages from international partnership, through joining the WHO-UMC Pharmacovigilance Network through which participating countries can exchange information and strive to harmonize their PV systems. Some of the objectives of PvPI include increased access to health care, compliance with the provisions of ADR reporting, integrated information technology in the PV system and improved international collaboration to ensure that the country's PV systems are on par with the best systems globally (Kalaiselvan et al., 2016). These findings underscore the need to build on the existing work that has gone into creating and deploying PvPI in order to have an effective pharmacovigilance system in India.

Recommendations

Based on the analysis, the Pharmacovigilance Programme of India (PvPI) should follow strategic objectives for input infrastructure, personnel training, mandatory methods of reporting, integration, global networks, and public understanding and practice of rational drug use. As a result, it is suggested that the forthcoming improvements in technology, for instance, better databases, signal recognition through AI, and EHR connection, should be adopted to improve the ADR reporting systems. This infrastructure requires systematic replenishments with resources for the upgrade of ADR monitoring centers in order to function optimally. Involving health care professionals and enhancing general public awareness in crusade, education awareness and campaigns will enhance the practice of ADR reporting. The additional reporting of ADRs and

non-ADRs, together with legislative changes and compliance monitoring, would facilitate improved data acquisition. The change in the management of ADR will lead to the creation of more standardized reporting forms as well as a central database which will help in collecting data and thus conduct proper risk assessment. Collaboration with international agencies such as WHO's UMC and replicating the experience of countries with advanced PV systems can build up further India's PV capacities. Last but not the least; encouragement of the culture of writing and receiving regular education on appropriate utilization of medicines, and having prospects of well-established structured feedback, will go a long way in creating a safer health atmosphere. By engaging on such measures, PvPI may easily work towards compliance with international benchmark from current standards; thus, increasing safer drugs available to the Indian populace.

CONCLUSION

In conclusion, with the help of PvPI, a strong protective network for received and analysed adverse drug reactions concerning ADRs has been set with the formally created Adverse Drug Reaction Monitoring Centres. Thus, it is noted that since its inception in the year 2010 under the Ministry of Health & Family Welfare, PvPI has made a groundwork in PV & relevant risk identification, role of the regulatory management actions on particular categories of medicines and general public awareness. Through its membership in the WHO-UMC Pharmacovigilance Network, PvPI has further strengthened commitment to the global standards of pharmacovigilance, has created conditions for the sharing of valuable information and international cooperation. Still, to achieve its goals and objectives, there are several challenges that need to be resolved by PvPI. The tried and tested methodologies of analysis could also be supplemented with fundamentally new approaches, such as artificial intelligence for analyzing large amounts of data and optimized databases to increase the accuracy of signals and exclude errors when assessing risks. In addition, getting consistent and mandatory reporting across all care settings for ADR, legislative and administrative reform to support complete data capture is also very significant. Other measures for developing a stronger PV culture within the healthcare system would include improvement of the existing infrastructure by enlargement of training for healthcare providers involved in the system and incorporation of pharmacovigilance into medical and pharmacy curricula. If PvPI is to meet its future objectives, it should target all healthcare organisations, develop interfaces and protocols for sharing and integration of data and leveraging the support from mass media instruments. Thus, by extending these numbers of efforts, PvPI can reinforce its function as the significant pillar of the public health protection by increasing the efficacy of pharmaceutical products monitoring and controlling to achieve desired pharmacovigilance of India's level with the worldwide one.

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