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Original Article

Dawn of Community Pharmacovigilance-A Scope and Opportunity in India

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ABSTRACT

Background: Pharmacovigilance plays a crucial role in safeguarding public health by detecting, assessing, and preventing Adverse Drug Reactions (ADRs) and related drug problems. Despite the establishment of the Pharmacovigilance Programme of India (PvPI), ADR underreporting remains a critical challenge, particularly in rural and underserved regions. **Objectives:** This review introduces the concept of Community Pharmacovigilance® (CP) as a proactive, community-based approach aimed at expanding pharmacovigilance activities into the community at large. **Materials and Methods:** CP advocates the integration of ADR monitoring into the routine duties of community-level healthcare workers, including ASHA, ANM, MPHW, and medical students, through the Family Adoption Program (FAP). These stakeholders, through regular interactions with families, identify ADRs, educate beneficiaries on safe medication practices, and strengthen ADR reporting mechanisms. The approach utilizes existing national health programs and mobile technology to bridge gaps in awareness and assessment. **Results:** The CP model has the potential to substantially enhance drug safety monitoring, particularly in resource-limited settings, by improving ADR identification, awareness, and reporting at the community level. **Conclusion:** Although challenges such as training of healthcare workers, integration of ADR reporting systems for wider coverage, and data validation need to be addressed, Community Pharmacovigilance® offers a transformative opportunity to improve health outcomes and establish a more inclusive, grassroots pharmacovigilance framework in India.

Keywords: Adverse Drug Reactions, Adverse Drug Reaction Reporting Systems, Healthcare Workers, Health Services, Health Education, Pharmacovigilance.

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INTRODUCTION

Pharmacovigilance is the "science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems" (World Health Organization, 2002). It encompasses not only reporting of Adverse Drug Reactions (including pediatric and geriatric population), but also errors in medication, reporting of substandard formulations or spurious drugs, errors in medication, off label use of drugs, drugs abuse, misuse or overdose of drugs, therapeutic failure, exposure of drugs during pregnancy and lactation (Peters *et al.*, 2021).

African and Asian countries face difficulties in successful implementation of pharmacovigilance programs so as to recommend change in healthcare policy and practice (Kiguba *et al.*, 2023). One of important reason being shortage and inequitable distribution of health care resources, especially in rural areas (Mehta *et al.*, 2024). Moreover, pharmacovigilance system in India is behind developed countries. There is a dire need for a well-structured system that integrates Good Pharmacovigilance Practice (GPP) into the regulatory processes (Kiguba *et al.*, 2023).

Pharmacovigilance was initiated in India in 1986. In 1998, India also participated in the WHO Programme for International Drug Monitoring. However, the programme could not achieve its intended objectives. The National Pharmacovigilance Programme, launched in 2005, was renamed as the Pharmacovigilance Programme of India (PvPI) in 2010 (Kalaiselvan *et al.*, 2016). The program witnessed many milestones like launching of Haemovigilance Programme of India (HvPI) (National Institute of Biologicals, n.d.), Materiovigilance Programme of India (MvPI) (Indian Pharmacopoeia Commission, n.d.-a), publishing monthly

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Drug Safety Alerts (DSAs) and providing a helpline (Kalaiselvan *et al.*, 2016; Rajesh & Thejaswini, 2023). PvPI was redesignated as WHO Collaborating Centre for Pharmacovigilance as a part of Regulatory Services as well as Public Health Programmes (World Health Organization, n.d.). Year 2021 witnessed the initiation of National Pharmacovigilance Week observation every year from September 17 to 23 to raise awareness about medicine safety (Rajesh & Thejaswini, 2023). PvPI has collaborated with Central Drugs Standard Control Organisation (CDSCO) and national programs like Revised National Tuberculosis Control Programme (RNTCP), National Vector Born Diseases Control Programme (NVBDCP), and National AIDS Control Organization (NACO) for integration of pharmacovigilance activities (Kalaiselvan *et al.*, 2016). The updated figures indicate increase in the number of Adverse Drug Reaction (ADR) monitoring centres in India to 1025 (National Coordination Centre - Pharmacovigilance Programme of India, 2024). In addition, nine Regional Training Centers (RTCs) across India conduct training programmes of healthcare professionals for better ADR reporting (Kumar *et al.*, 2024).

Despite these achievements, India has a long way to go for implementation of the practices of Pharmacovigilance at all health care centres and reaching global scenario of reporting ADR. Currently less than 1% ADRs are reported in country. The big hurdle was identified as poor awareness of physicians and pharmacists about PvPI programme and the objectives of programme (Nadig *et al.*, 2025).

The current ADR reporting process is through doctor or hospital and somewhat extended to pharmacist. Community pharmacovigilance is a new concept and conceptualized by team of medical college professors. The team feels that there is an urgent need to explore for benefits of Indian community. Currently on a daily basis, patients pick up medications at the pharmacy without asking any questions as patients are not aware of adverse drug reactions. Pharmacists don't spend time explaining common ADRs to patients. There is a reluctance of health care providers/pharmacists to discuss ADRs prior to treatment. This has caused potentially serious adverse drug reactions, lack of proper reporting and management of ADRs. The current concept of pharmacovigilance in the community is restricted to the community pharmacist training and reporting of ADR through community pharmacist (Hadi *et al.*, 2017).

The present review article introduces the broader concept of Community Pharmacovigilance, that encompasses involvement of all the health care stakeholders, who are in continuous contact with the community, to proactively participate in the pharmacovigilance program.

Community Pharmacovigilance (CP)

Community Pharmacovigilance® is a copyrighted concept coined by team of authors (Pandit, 2024). It is a proactive approach to ADR monitoring and drug safety education, which expands the role of healthcare workers beyond traditional clinical settings. This concept aims to integrate pharmacovigilance into routine community healthcare activities, allowing healthcare workers to monitor drug use, detect ADRs, report, and educate the public about safe medication practices during their regular interactions at the community level. This can play a critical role in preventing drug-related harm, particularly in rural or underserved areas in developing countries, where healthcare access and awareness are often limited.

CP includes proactive ADR monitoring, integration of pharmacovigilance into routine healthcare, and education and awareness activities for the beneficiaries during visits of healthcare professionals in the community.

Proactive ADR Monitoring

Rather than relying on patients to report ADRs themselves, healthcare workers actively seek out information about drug use and potential side effects. This reduces underreporting and allows for early detection of harmful drug effects.

Integration of CP into Existing Community Programs

CP integrates ADR monitoring and reporting into existing healthcare programs, ensuring that drug safety is monitored during routine health visits. The community pharmacovigilance may be integrated into various programs after training and sensitization of the health care workers, Medical students in Family Adoption Program (FAP), Accredited Social Health Activists (ASHA), Urban Social Health Activists (USHA), Auxiliary Nurse Midwives (ANM), and Multipurpose Health Workers (MPHW) in identification, recognition and reporting of suspected adverse drug reactions. Some of the levels of healthcare where the integration can be done are shown in Figure 1.

FAP

FAP is recommended as a part of curriculum of Community Medicine subject under revised curriculum of NMC for MBBS teaching training. It is begun from 1st professional year and remain throughout the curriculum till third year. This program includes mandatory adoption of villages which are not covered under PHC, are adopted by medical college. Each medical student is allotted 3 to 5 families for learning community health (National Medical Commission, 2022). As a part of Community Pharmacovigilance, Medical students shall be trained for ADR monitoring and reporting in collaboration with Pharmacology department. Students can apply CP during their family visits by asking about drug history and monitoring ADRs. This is a part of their broader responsibility to understand and manage the family's overall health. There are over 700 Medical colleges and yearly admission of over 1,10,000 MBBS seats in India (National Medical Commission, n.d.). If the CP is integrated with FAP from second year of graduation, approximately 2,20,000 students will

adopt 6,60,000 families (considering three families adopted by every student). This FAP alone will cover approximately 6.5 lakh families, benefitting nearly 32.5 lakh people.

ASHA Workers

In a randomized trial by Modi *et al.*, an online mobile application (Innovative Mobile-phone Technology for Community Health Operations- ImTeCHO) was tested for its applicability as a job aid to the government's Accredited Social Health Activists (ASHAs) and Primary Health Center (PHC) staff to improve coverage of Maternal, Neonatal and Child health services (MNCH) in rural tribal communities of Gujarat, India. This application was found to improve the coverage and quality of MNCH services in hard-to-reach areas by facilitating the scheduling of home visits, screening for complications, counselling during home visits, and supportive supervision by PHC staff (Modi *et al.*,2019). Such an application, in modified form can be used for ADR reporting and its causality assessment. ASHA workers are community health workers who are responsible for providing basic healthcare facilities and educating the community. They regularly visit homes as part of HBYC and other national health programme (Ministry of Health and Family Welfare, n.d.). They can be trained to inquire about medication use, particularly for vulnerable populations like children and pregnant women, and report any adverse reactions they encounter. ASHA workers can include questions about drug use and possible side effects in their checklist during home visits. With simple training, they can identify basic ADRs, report them to higher authorities, and encourage families to be more vigilant about drug use. The same may be implemented during the Home Based New Born Care (HBNC) and other national programmes (Ministry of Health and Family Welfare, n.d.) as well as other additional activities that are run at grass root level by ASHA workers.

Auxiliary Nurse Midwife (ANM)

ANM are instrumental in the execution of various national health programmes, more importantly, those related to maternal and child health, immunization, family welfare, and disease surveillance. ANMs deliver essential services concerning Reproductive, Maternal, Newborn, Child and Adolescent Health, National Immunization Programme, and Mission Indradhanush (Ministry of Health and Family Welfare, 2010; Tripathy, n.d.). Acknowledging their role in the community and immunization activities, ANMs can play pivotal role in identifying and reporting

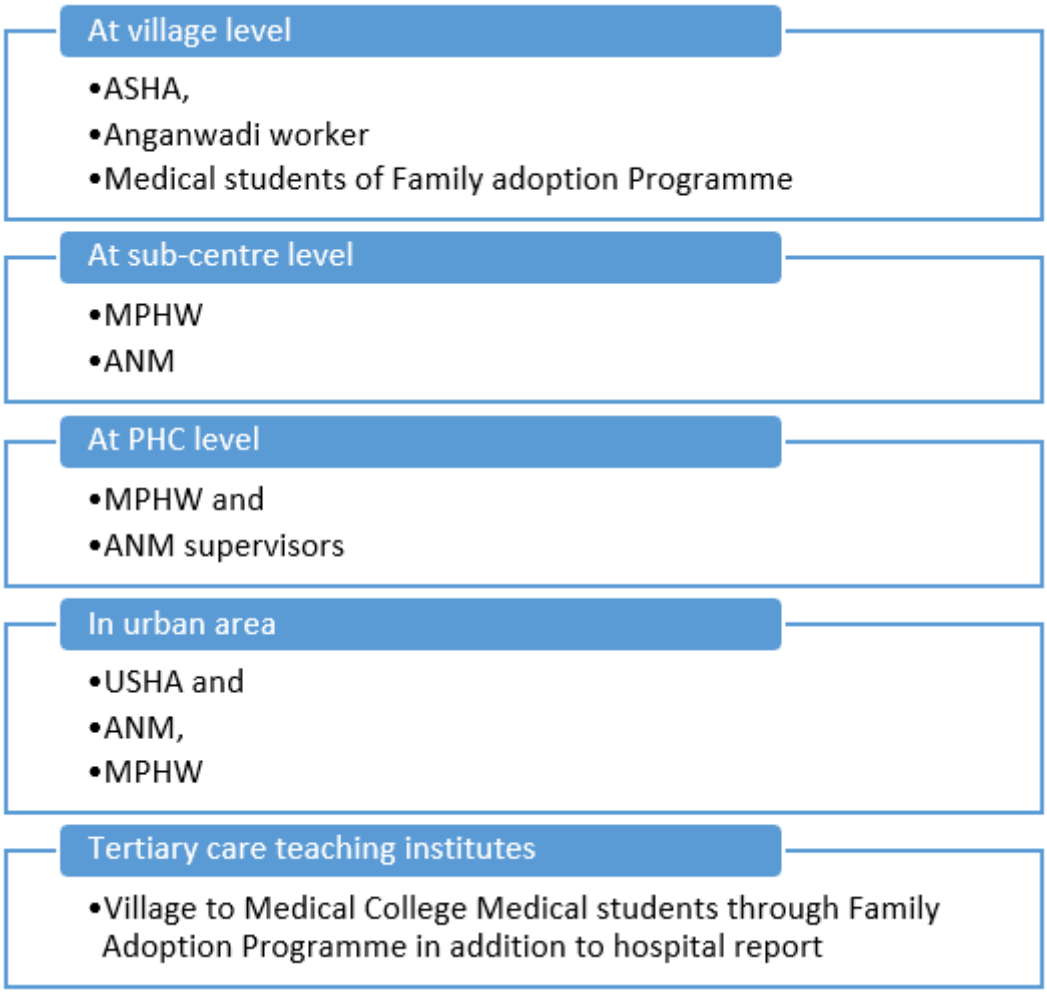

Figure 1: Possibilities of Integration of Community Pharmacovigilance at various Health care levels.

Adverse Events Following Immunization (AEFIs) as well as other ADRs. Under the PvPI, ANMs can contribute by identifying ADRs, filling ADR reporting forms, and forwarding them to the nearest ADR Monitoring Centre or primary health centre (Indian Pharmacopoeia Commission, n.d.-b).

Multi-Purpose Health Worker (MPHW)

MPHW visit homes of their assigned villages house to house. They conduct activities which are related to disease control programs, treatment of minor illnesses, communication & counselling among others duties, at sub-centre. They also deal with national programme likes leprosy, tuberculosis, malaria and other communicable and non-communicable diseases (Ministry of Health and Family Welfare, 2010). Thus, they can also play an important role in implementation of pharmacovigilance at community level. The various opportunities of contact with the community include home visits as a part of various health care programs (under National Health Mission), can be exploited for inclusion of monitoring ADR in their work, educating families about drug safety and follow-up of any ADRs reported.

Education and Awareness

One of the most important aspects of Community Pharmacovigilance is **educating the public** about safe medication practices and the importance of reporting ADRs. Healthcare workers can provide simple, accessible information to families and individuals about:

1. Recognizing potential ADRs.
2. Proper storage and administration of medications.
3. The dangers of self-medication and drug interactions.
4. How and when to report ADRs to healthcare providers or local health authorities.

Data Collection and Reporting

Healthcare workers can serve as a crucial link between the community and healthcare systems. They can detect ADRs during their visits in the community and report them and also contribute to the understanding of drug safety in the community. The reporting systems embedded within various national programs as well as the existing ADR reporting system under PvPI can be utilized with any modifications, if required. One of the solutions is use of simplified multilingual reporting mobile applications, such as Epi collect software, Epi Info software or ADR forms. These ADRs can then be communicated to all healthcare stakeholders in the form of bulletins.

In Medical Colleges and Tertiary care centres, the ADR monitoring Centres (AMCs) gather the ADRs reported to them, estimate the causality of the ADR and further report it to Indian Pharmacopoeia Commission (IPC). However, for similar functioning of ADR detection and reporting at other health care levels, a process for data collection and validation needs to be defined. The respective Health Care Professionals- most often the medical officer and treating physician-may play a pivotal role for the same.

Benefits of implementing CP

By incorporating pharmacovigilance into routine community healthcare activities, underreporting of ADRs can be significantly reduced. This is particularly important in rural and underserved areas, where access to healthcare facilities is limited, and ADRs often go unnoticed. Healthcare workers in the community can detect ADRs early, and prevent serious health complications. Through education and awareness, families and individuals become more informed about the potential risks of medications, and are encouraged to actively participate in drug safety measures. Community Pharmacovigilance helps in preventing avoidable drug-related harm, contributing to improved overall health outcomes in the community. It also ensures that medication use is safer and more effective, particularly in vulnerable populations.

Challenges

Healthcare workers will need adequate training to recognize and report ADRs. This will require the development of simple, easy-to-understand pharmacovigilance training modules. Implementation should be integrated into health programs to avoid overburdening healthcare workers. A robust system must be in place for ADR data to be effectively reported, analysed, and acted upon at regional and national levels. When applied on a larger scale, verifying ADRs reported through ASHA, ANM and MPHW may pose challenges.

CONCLUSION

CP is an innovative and proactive approach to ensuring drug safety at the community level. By integrating ADR monitoring and education into routine healthcare visits, this model empowers healthcare workers and communities to play an active role in identifying and preventing drug-related harm. Through collaboration between healthcare providers, families, and pharmacovigilance authorities, this concept can significantly improve drug safety and health outcomes, especially in underserved areas. Implementation of CP will require changes in the policies of health care programs to integrate and incorporate the ADR reporting into all strata of health care centres. Pilot projects are required to ensure seamless integration of CP into the healthcare system and its broader implementation in society.

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ABBREVIATIONS

ADR: Adverse Drug Reaction; **ANM:** Auxiliary Nurse Midwife; **ASHA:** Accredited Social Health Activist; **CP:** Community Pharmacovigilance; **FAP:** Family Adoption Program; **MPHW:** Multipurpose Health Worker; **PvPI:** Pharmacovigilance Programme of India; **WHO:** World Health Organization.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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