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Review Article

Pharmacovigilance in rural India: challenges, opportunities and the way forward

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ABSTRACT

Pharmacovigilance (PV) plays a crucial role in safeguarding drug safety, yet its reach in rural India, home to approximately 65% of the population, remains markedly limited compared to urban centres. Drawing from our experiences in adverse drug reaction (ADR) monitoring at peripheral health centres, this article explores key barriers, including inadequate awareness, infrastructural deficits, and sociocultural hurdles, that hinder effective PV implementation. It highlights opportunities through community health workers (CHWs), low-bandwidth mobile technologies, and innovative models such as Delay-Tolerant Networking (DTN) for offline reporting. Recommendations include embedding PV within existing national programs like the National Health Mission (NHM) and Ayushman Bharat Digital Mission (ABDM), enhancing contextualised training, and pursuing policy reforms through the PV Programme of India (PvPI). By systematically addressing these gaps, India can acheive more equitable drug safety, reduce preventable ADRs, and strengthen public health in its most underserved communities. This review offers practical, field-informed insights for policymakers, practitioners, and program implementers.

Keywords: Pharmacovigilance, Rural India, Adverse drug reactions, Community health workers, Delay-tolerant networking, PvPI, mHealth

INTRODUCTION

Pharmacovigilance (PV), defined by the World Health Organisation (WHO) as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, constitutes an indispensable pillar of post-marketing drug safety surveillance.[1] The significance of this discipline extends well beyond urban hospital corridors: globally, ADRs account for a substantial burden of preventable morbidity and mortality, with studies from hospital settings across low- and middle-income countries demonstrating that ADR-related admissions constitute between 0.5% and 12.8% of total hospital admissions.[2-4] In India, where nearly 1.4 billion people rely on a diverse pharmacopoeia spanning allopathic, traditional, and over-the-counter medicines, this burden carries particular weight.

India's national PV infrastructure, the PvPI, was launched in 2010 under the Indian Pharmacopoeia Commission (IPC) with technical support from WHO.[2] Since then, the programme has expanded to a network of over 300 ADR Monitoring Centres (AMCs), predominantly situated in urban tertiary care institutions. By mid-2025, PvPI has amassed over 500,000 ADR reports, a milestone that reflects improved reporting culture in these institutional settings.[3] Yet, a critical and often overlooked reality persists: fewer than 10% of these reports originate from rural areas, despite rural India housing nearly two-thirds of the national population.[8,9] This is not merely a statistical curiosity. It reflects structural gaps in how PV is conceived, implemented, and resourced in the country.

As pharmacologists with over a decade of combined involvement in ADR monitoring at primary and peripheral health centres across southern India, we have observed this disparity with growing concern. Step into a rural Primary Health Centre (PHC) in Uttar Pradesh or Tamil Nadu, and the contrast with an urban AMC becomes stark: erratic power supplies, overburdened staff managing immunisation drives and outbreak responses simultaneously, an almost complete absence of trained PV personnel, and patients who attribute drug side effects to seasonal ailments rather than medications they have been prescribed. In communities where polypharmacy is common, self-medication is prevalent, and concurrent use of traditional Ayurvedic or herbal preparations is the norm, the absence of systematic ADR monitoring creates significant blind spots in national drug safety data.[9-11]

The consequences of this gap are more than academic. When a rural patient experiences a hypersensitivity reaction to a first-line antibiotic, and the healthcare worker at the PHC lacks the awareness or the tools to document and report it, a potential safety signal is lost. Repeated across thousands of such facilities and millions of patients, this silence distorts the national PV landscape, potentially delaying recalls, safety alerts, or regulatory action for drugs with disproportionate rural exposure, particularly antimalarials, antitubercular drugs, and vaccines deployed under national health programmes.[8-12] Several challenges have been well-described in the literature, including healthcare provider knowledge deficits, logistical barriers to form submission, and poor community health literacy.[8-12] However, systematic, field-tested solutions contextualised to the Indian rural setting remain sparse. This article draws on available evidence and our direct field experience to delineate the challenges, identify emerging opportunities, and propose a pragmatic way forward, with particular attention to innovations such as community-based CHW-led reporting networks, low-bandwidth digital tools, and the novel application of DTN to offline ADR data capture.

CHALLENGES

Implementing PV in rural India is not a single-barrier problem; it is a web of interconnected challenges that reinforce one another, each rooted in the broader socio-economic realities of rural life.

Awareness and knowledge deficits

Among healthcare providers, awareness of PvPI protocols and the categories of reportable ADRs remains strikingly low. A study by Sood et al., conducted in a rural tertiary care hospital in North India, found that only 30% of staff could correctly identify ADRs that warranted formal reporting.[8] This gap is not simply a matter of individual negligence; it reflects systemic under-investment in PV education at undergraduate and postgraduate levels, and an almost complete absence of in-service training at peripheral health facilities. AYUSH practitioners, who serve as the first point of contact for a large proportion of rural patients, remain less informed about PV systems, despite being expected to report ADRs from traditional and herbal medicines.[9] At the community level, patients with low health literacy routinely attribute drug-related symptoms, such as nausea, skin rashes, or unusual fatigue, to seasonal changes, dietary factors, or unrelated illness, seldom connecting them to medicines they are taking.[9]

Infrastructure deficits

Physical and digital infrastructure in rural health facilities is ill-suited to PV implementation as currently designed. Unreliable electricity supply disrupts digital tools, while internet connectivity in many PHCs and sub-centres remains intermittent or non-existent, rendering smartphone-based reporting platforms like the PvPI mobile application less feasible.[11] Paper-based Yellow Cards, while available in principle, frequently do not reach facilities, and when they do, the logistical challenge of physically transporting completed forms to the nearest AMC, often located in a district town hours away, means that most reports are never submitted.[11] Human resource constraints compound these difficulties. PHCs routinely operate below sanctioned staffing norms, with overworked medical officers and nursing staff who, understandably, prioritise immediate patient care over documentation. Unlike urban AMCs, which may have a dedicated pharmacologist or clinical pharmacist, rural facilities rely entirely on generalist staff with little to no PV training.[8-12]

Sociocultural barriers

Beyond the structural, sociocultural factors create a persistent layer of resistance. Trust in local traditional healers, village practitioners, and faith-based medicine remains high in many rural and tribal communities, while trust in formal biomedical systems is qualified at best.[9] In tribal areas of Odisha and Jharkhand, for instance, discussing side effects from prescribed medicines openly may carry a social stigma, with patients fearing that reporting an adverse reaction implies that they or their healthcare provider have done something wrong. Language barriers further complicate matters, as standard PV forms and educational materials are predominantly available in English and major scheduled languages, leaving speakers of regional dialects without accessible reporting pathways.[9-12] These challenges collectively produce a profound underrepresentation of rural ADR profiles in national data, with potentially serious consequences for signal detection in drug classes heavily used in rural endemic contexts, including antimalarials, antifilarials, antitubercular agents, and anti-snake venom preparations.

Table 1: Comparison of urban vs. rural PV performance indicators.

Indicators	Urban settings	Rural settings
ADR reporting frequency	High (>80% from AMCs)	Low (<10% of national total)
Staff training coverage	Regular CMEs (70–90% trained)	Sporadic (20–40% trained)
Access to reporting forms	Digital + Paper (readily available)	Mostly Paper (often unavailable)
Infrastructure support	Reliable internet and power supply	Intermittent or absent connectivity
Community engagement	Moderate (structured awareness campaigns)	Low (significant cultural barriers)
Dedicated PV personnel	Present (pharmacologist/ clinical pharmacist)	Absent (generalist staff only)

*Data adapted from PvPI Annual Reports, Sood et al and Sulakhiya et al[8,9]

OPPORTUNITIES AND INNOVATIVE APPROACHES

Despite these formidable challenges, rural India offers considerable untapped potential for PV innovation. Several models, some already piloted in limited settings and others conceptually developed, point toward a future where geographic and infrastructural barriers no longer define the limits of drug safety monitoring.

CHWs as PV sentinels

India's network of over 900,000 Accredited Social Health Activists (ASHAs) and Auxiliary Nurse Midwives (ANMs) represents perhaps the most underutilised resource in rural PV.[13] These workers have direct, trusted relationships with communities, visit households regularly as part of maternal and child health programmes, and have demonstrated their capacity to take on expanded roles when adequately trained and supported. Structured pilots in Tamil Nadu, drawing on field data compiled by the National Health Systems Resource Centre (NHSRC), have shown that brief, focused training sessions using simplified ADR checklists can enable ASHAs to identify and preliminarily document reportable reactions during routine home visits, with one such initiative reporting a 40% increase in ADR reports from targeted areas over a six-month period.[14]

Extending causality assessment responsibilities to nurses and pharmacists at block-level facilities, under pharmacologist supervision, would further decentralise PV without requiring entirely new cadres or resource infusions.

Low-bandwidth digital solutions

While smartphone applications have received considerable attention in the mHealth literature, their practical utility in areas with poor connectivity is limited.[15,16] For rural India, purpose-designed, low-bandwidth solutions present a more realistic pathway. Interactive voice response (IVR) systems operating on toll-free numbers allow healthcare workers and even literate patients to report ADRs verbally in their regional language, with responses converted to structured data through natural language processing pipelines. Unstructured supplementary service data (USSD) platforms, accessible on even the most basic feature phones without internet access, can guide CHWs through simple symptom-drug correlation prompts. Such approaches sidestep the dual barriers of digital literacy and connectivity, and have precedents in related health domains, including immunisation tracking and maternal health monitoring programmes in Sub-Saharan Africa and Bangladesh.

DTN for offline ADR capture

Perhaps the most innovative approach being explored in this domain is the application of DTN to rural PV. Originally developed for communication in environments where continuous end-to-end connectivity cannot be assumed, such as disaster zones, deep-sea exploration, and remote military operations, DTN operates on a store-carry-and-forward paradigm: data is captured locally, held until a communication opportunity arises, and then transmitted to the next node toward the destination.[17,18]

Translated to rural PV, a DTN-based framework would operate as follows: CHWs use basic mobile phones with a lightweight offline application to capture ADR data during community visits. This data is stored locally in structured form. When the CHW subsequently travels to the block PHC or encounters a supervisor or mobile health team (the "data mule"), the data is transferred via Bluetooth or Wi-Fi Direct to a device that does have, or will have, internet access. The consolidated data is then uploaded to the PvPI portal in a batch upload. Figure 1 illustrates proposed ADR reporting pathway for rural India using this framework.

We are in the process of conceptually piloting this model in low-connectivity zones across Puducherry and Tamil Nadu, with a proposed six-month mixed-methods study assessing usability, data quality, and CHW acceptability among approximately 85 CHWs.

Early stakeholder engagement has been encouraging, with ASHAs expressing comfort with the basic phone interface and supervisors endorsing the data mule concept as compatible with their existing field supervision schedules.

Artificial intelligence and blockchain for signal enhancement and supply chain integrity

Emerging technologies offer complementary value at the backend of the PV pipeline. AI-driven signal detection tools can process the relatively sparse and heterogeneous data from rural reports more effectively than conventional disproportionality analysis methods designed for large, uniform datasets.[19-22] Machine learning models trained on community-level data can flag unexpected symptom clusters associated with specific drug batches, manufacturing units, or seasonal prescribing patterns, potentially uncovering signals that would be invisible in aggregated national data.[21] Blockchain-based supply chain traceability, while still nascent in Indian healthcare, offers the potential to link an ADR report to a specific drug batch, enabling targeted recall and regulatory action rather than broad product withdrawals.[23-25] Figure 2 illustrates the reported disparity in ADR volumes between urban and rural settings, underscoring the magnitude of the gap that these innovations aim to address.

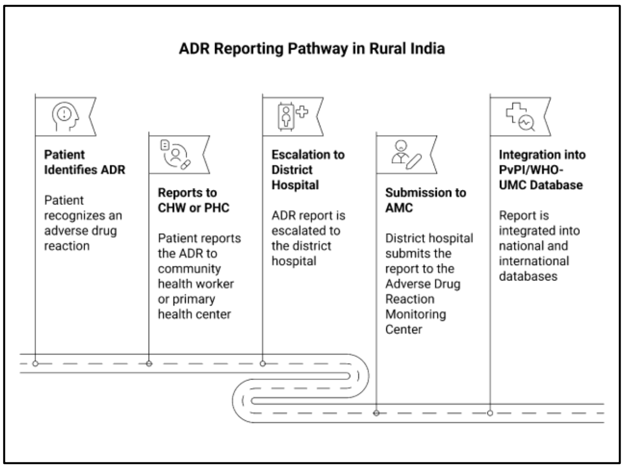

Figure 1: Proposed ADR reporting pathway in rural India using a DTN framework.

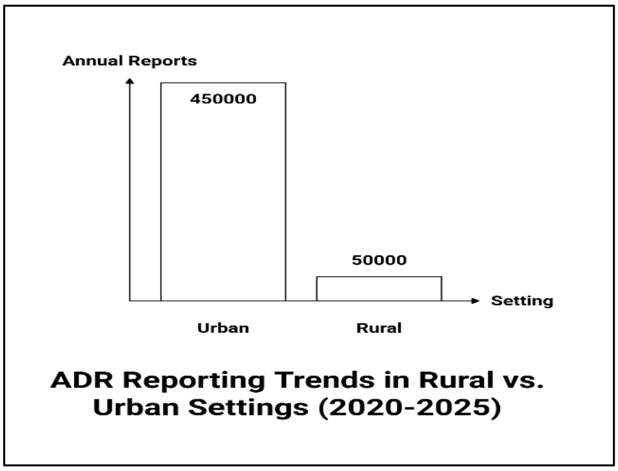

Figure 2: ADR reporting trends in rural vs. urban settings (2020–2025), highlighting the urban–rural disparity.

RECOMMENDATIONS: THE WAY FORWARD

Translating the above opportunities into sustainable change requires deliberate policy action, institutional investment, and community engagement. We propose the following prioritised recommendations, informed by field evidence and grounded in India's existing health systems architecture.

Embed PV within NHM and ABDM frameworks

The NHM and ABDM represent the two most expansive and resource-rich platforms in rural Indian healthcare.[27,28] Embedding PV activities within these frameworks, rather than operating PV as a parallel vertical programme, would achieve enormous gains in reach and sustainability. Specifically, linking ADR reporting to beneficiary Health IDs under ABDM would allow longitudinal tracking of drug safety events at the individual level, creating a passive surveillance layer within routine clinical workflows. PV metrics, including ADR reporting rates and staff training completion, should be incorporated into PHC performance evaluation frameworks under NHM, thereby creating institutional accountability.

Contextualised training for rural healthcare providers

Training programmes for rural healthcare providers must be redesigned around the practical realities of PHC-level practice. Short, modular continuing medical education (CME) sessions focused on the ADRs most commonly encountered in rural settings, including those from antimicrobials, antitubercular drugs, vaccines, and antimalarials, can be delivered by district PV officers during existing outreach visits. Simulation-based approaches, in which providers practise completing a Yellow Card for a scripted case scenario, have demonstrated measurable improvements in reporting confidence and accuracy in small-scale evaluations. [8] Training for ASHAs and ANMs should be visual, vernacular-language based, and integrated into their existing job-aid tools rather than introduced as an entirely new module.

District nodal PV officers and structured supervision

Establishing district-level nodal PV officers with specific mandates for rural outreach would address the chronic gap in dedicated PV human resources. These officers, ideally trained clinical pharmacologists or pharmacists, would be responsible for supervising CHW-based reporting networks, conducting data quality checks, facilitating the batch upload of DTN-captured reports, and providing feedback to field workers. The latter point, feedback to reporters, is a particularly undervalued driver of reporting culture: when ASHAs and ANMs receive acknowledgement that their reports have been received, processed, and acted upon, they are significantly more likely to continue reporting.[13,14]

Community-level awareness and trust building

Building community trust in PV requires meeting people where they are, culturally and linguistically. Radio programmes, puppet theatre, and community health camps framed around medicine safety rather than side-effect reporting, a term that carries unintended implications, can shift public perception. Involving local AYUSH practitioners as co-reporters, rather than excluding them from the PV ecosystem, would leverage their existing patient trust and extend coverage to the substantial proportion of the population receiving traditional medicines. Incentivising reporting through non-monetary mechanisms, such as CHW recognition certificates, skill-building opportunities, or digital data top-ups, has shown promise in other community health programmes in India and could be adapted for PV. Figure 3 summarises this proposed multi-pronged intervention framework for improving PV in rural India.

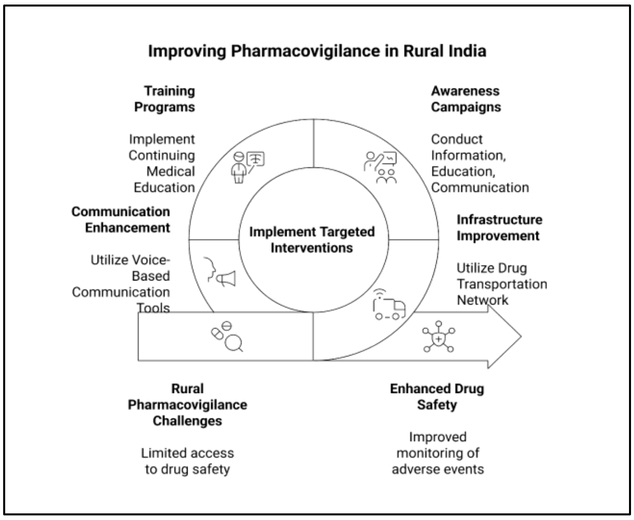

Figure 3: A multi-pronged intervention framework for improving PV in rural India.

CONCLUSION

PV in rural India is not an intractable problem. It is a design problem, and one that is, with sufficient will and ingenuity, solvable within the country's existing health systems infrastructure. The challenges are real and layered: awareness gaps among providers and communities, physical infrastructure that was never built for data-intensive surveillance, sociocultural dynamics that make self-reporting difficult, and a chronic shortage of dedicated PV personnel beyond urban AMCs. Yet within these constraints lie equally real assets: a vast, trusted CHW workforce, an expanding digital health architecture under ABDM, a national PV programme with established data systems, and an emerging global evidence base on technology-enabled surveillance in low-resource settings.

What is needed now is a shift in approach, from urban-centric, institution-anchored PV to community-embedded, context-adapted surveillance. The DTN model, ASHA-led ADR identification, low-bandwidth reporting tools, and district-level nodal oversight structures we have described here are not aspirational concepts; they are actionable interventions, each with precedents in analogous health domains, that can be piloted, evaluated, and scaled within India's existing NHM framework. Ensuring that every patient in rural India, whether a farmer in Rajasthan or a plantation worker in Assam, has the same access to the protections that PV offers is not only a matter of equity. It is a prerequisite for the integrity of India's national drug safety system itself.

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