International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 6, June 2025 ijppr.humanjournals.com ISSN: 2349-7203

A Review Article on "Challenges of Pharmacovigilance in Developing Nations"

Aditya Sinha[1], Alok Kumar[2]

[1] student, Bachelor of pharmacy, Innovative College of Pharmacy, Greater Noida, U.P. India.

Received: 2025-04-29 Revised: 2025-05-15 Accepted: 2025-05-25

ABSTRACT

pharmacovigilance is required to find, assess, and avoid harmful drug reactions (ADRs) so that drugs can be used effectively and in a secure way. developed Countries have had strong pharmacovigilance programs in place for a long time, while developing countries are experiencing challenges in establishing efficient programs. Such problems like gaps within the health care infrastructure, training and awareness gaps, regulatory framework defects, and socioeconomic and cultural barriers are thoroughly discussed in this article. The paper presents practical, evidence-based suggestions to enhance pharmacovigilance in resource-constrained environments, drawing on case studies in Asia and Africa. The review provides a roadmap for bolstering drug safety systems worldwide, ensuring that no disadvantaged populations are left behind in the pursuit of safe pharmacotherapy.

Keywords: Continuing professional development, Low- and middle-income countries, Periodic Safety Update Report, Drug safety legislation

INTRODUCTION

Based on the Latin word vigilare (to watch) and the Greek word pharmakon (drug), pharmacovigilance is the methodical, scientific process of tracking, identifying, assessing, and averting adverse drug reactions (ADRs) and drug-related issues. It is of crucial value in ensuring patient safety, rational drug use, and public faith in the health system [1]. Although nations with well-established healthcare systems have made considerable strides in this area, most developing countries still experience systemic vulnerabilities that prevent the effective implementation of pharmacovigilance programs [2]. In these environments, underreporting of ADRs, insufficient trained staff, fragmented reporting structures, and weak regulatory enforcement all play a role in poor drug safety surveillance [3]. With increased access to new therapies globally—particularly in the case of generics, vaccines, and traditional herbal medications—the need for strong pharmacovigilance systems in LMICs is even greater [4]. This paper attempts to analyse the precise structural, educational, cultural, and regulative obstacles deterring pharmacovigilance in developing countries and suggests purpose-specific recommendations deriving from global expertise and local dynamics.

Pharmacovigilance as regulatory body.

Pharmacovigilance would have to be implemented when a new therapy or drug is being researched and put onto the market. It can then allow any adverse effect to be identified and tracked. Monitoring for adverse effects also needs to occur after a drug or therapy has been on the market for a while because new ones could develop.

Pharmacovigilance consists of three phases: pre-clinical, clinical trial, and post-marketing. All these phases play their significant role in the safety of medicines.

Pre-Clinical Pharmacovigilance

It encompasses detection of risks related to medicine prior to approval to use by regulatory bodies. This is accomplished via animal testing and clinical trials.

Clinical Pharmacovigilance

This stage evaluates the safety and effectiveness of a drug within a controlled environment. Clinical trials are carried out prior to a drug being licensed for use.

1 Post-marketing Pharmacovigilance

This stage tracks the long-term safety of a drug once it has been licensed for use and is available for purchase on the market. This is achieved through voluntary reporting of adverse events from patients, physicians, and pharmacists.

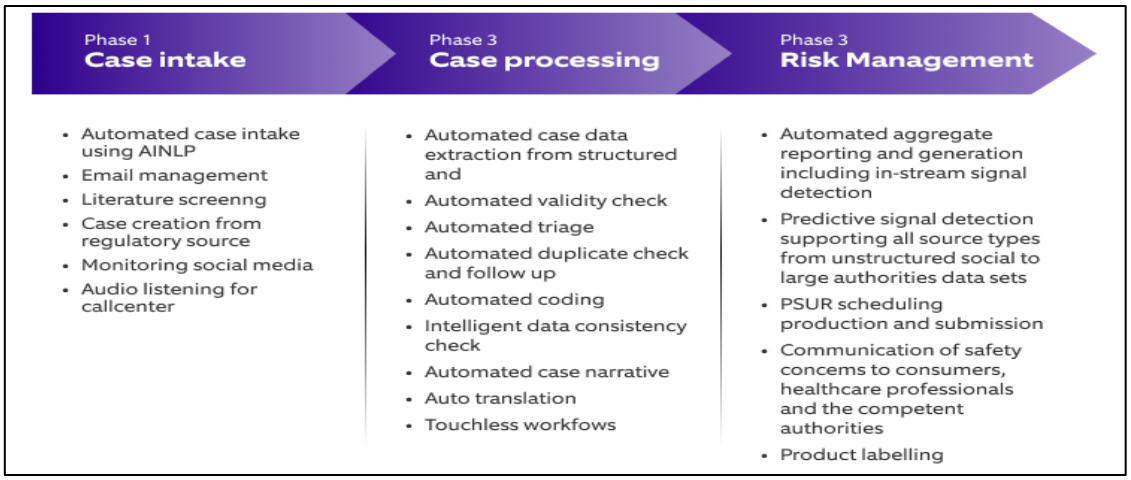

Fig. 1 Case Filing Procedure

2. Limited Healthcare Infrastructure

A proper functioning and healthy system of healthcare is the key for a strong pharmacovigilance system. However, most of the developing countries are also besieged by problems of poor health infrastructure, which seriously hampers their monitoring, recording, and management of adverse drug reactions (ADRs) in a timely and orderly fashion. Where even basic healthcare centres are overburdened, pharmacovigilance is the forgotten child. This is a long-term under-emphasis, with serious shortcomings in the reporting of ADRs, absence of evidence-based regulatory choice, and therefore increased risks to patients.

2.1 Lack of Technological Support and Digital Reporting Systems

One of the significant barriers in pharmacovigilance effectively working is lack of access to use of digital technology for the monitoring and documentation of adverse drug reaction (ADRs) in low- and middle-income countries (LMICs). In the majority of healthcare facilities of developing country, especially those found in rural or underserved communities, patient data are predominantly kept in manual paper-based systems. These traditional systems are prone to errors, physical degradation, and inefficiencies in data storage. The absence of digital platforms not only impedes timely processing of ADR data but also impedes timely detection of safety signals that would neutralize public health risks [5].

Based on the World Health Organization (WHO) survey conducted recently, less than 20% of health facilities in sub-Saharan Africa use digital reporting systems. This is a big technological gap compared to developed countries, where electronic health records and unified databases for monitoring medication safety are the norm. Since most healthcare providers lack access to these systems, reporting adverse drug reactions is difficult, and national agencies lack the capacity to analyse data or provide alerts based on real-time data. In addition, unstable power supply and poor internet connectivity exacerbate the process of setting up online reporting systems.

2.2 Shortage of Skilled Health Professionals

The persistent shortage of trained health professionals in the majority of developing countries severely retards the development of effective pharmacovigilance systems. Pharmacists, being the habitual first contact point for drug-related information, are especially under-represented. The World Health Organization suggests that the majority of sub-Saharan African countries have fewer than one pharmacist in every 10,000 population, placing an inordinate burden on the already limited available resource [6].

The consequences of this shortage go beyond numbers; they go to continuity and quality of care. Both doctors and nurses, already burdened with clinical responsibility, seldom have time or are trained to detect and report ADRs. A Kenyan survey found that only 38% of health staff had a correct definition of pharmacovigilance, and only 25% had ever generated an ADR report submitted [11].

This figure shows that even if ADRs do occur, they will not be entered into the national safety monitoring system, and the data will be incomplete and unreliable for public health action.

2.3 Poor Integration with National Health Systems

Among the most important obstacles in low-income nations is the weak incorporation of pharmacovigilance—i.e., surveillance of drug safety—into overall health systems. In most low- and middle-income countries (LMICs), these surveillance programs are in silos, with weak linkages to drug regulatory authorities, ministries of health, or national health information systems. This fragmentation leads to dispersed data collection, duplicate reporting activities, and eventually towards an uncoordinated overall response.

Nigeria is a case in point. Both the Federal Ministry of Health and the National Agency for Food and Drug Administration and Control (NAFDAC) are mandated to ensure drug security, yet their mandate overlaps without clear boundaries. This has led to a poor exchange of data as well as interagency communication issues among the stakeholders. This means that critical safety information may be delayed and even left out, thus compromising patient health and eroding the faith of the public in the healthcare system.

In addition, issues such as outdated data systems and untrained health workers endanger advances in drug safety monitoring in the LMICs. To counter this, we must invest in information technology, develop the workforce, and make policy efforts more aligned so monitoring adverse drug reactions becomes part of the healthcare services.

Table 1. General Comparison of Pharmacovigilance Systems in Different Regions

Aspect	High-Income Countries	Low-Income Countries
Pharmacovigilance Infrastructure	Well-established, centralized systems	Fragmented, often paper-based systems
Technology Use	Electronic health records, digital ADR reporting	Limited or no digital reporting; heavy reliance on paper-based methods
Staffing	Adequate number of trained professionals (pharmacists, clinicians)	Shortage of trained personnel, especially pharmacists
Regulatory Support	Strong, well-funded regulatory agencies	Weak or poorly coordinated regulation

3. Inadequate Training and Awareness

The effectiveness of pharmacovigilance systems relies not just on policy mechanisms and technology but also on the proficiency and interest of healthcare workers. In most LMICs, though, there is a stark lack of both initial training and ongoing continuing professional education in drug safety. Unawareness—among healthcare personnel and the public at large—is a major cause of underreporting of adverse drug reactions and delay in the detection of safety signals. This section explores the systemic perceptual and education barriers hindering pharmacovigilance activity in low-resource environments.

3.1 Absence of Pharmacovigilance in Medical and Pharmacy Curricula

In developing countries Poor pharmacovigilance is partly results from no formal teaching of pharmacovigilance in medical, pharmacy, and nursing schools during undergraduate and postgraduate levels of education. Although the subject of pharmacology is universally taught, elements of ADR reporting, signal detection, and post-marketing surveillance either receive superficial reference or remain unmentioned altogether. As a result, healthcare workers are introduced into the working environment lacking both the training and proficiency to make effective contributions to pharmacovigilance [7].

A wide-ranging study carried out across pharmacy schools in India found that only 28% of these schools had particular modules on ADR monitoring as part of their academic curriculum, and even fewer schools assessed students on this subject in exams [8]. This absence of standardization indicates a larger problem in which drug safety is not regarded as a core component of patient care. Without early introduction to the principles of pharmacovigilance, health professionals are less likely to make reporting of ADRs a priority in their practice, hence sustaining the culture of underreporting. An updated, competency-based curriculum that integrates pharmacovigilance as an essential learning objective would go a long way towards better preparing future health professionals in LMICs.

Table 2. Impact of Educational Gaps in Pharmacovigilance

Area	Effect of Educational Gaps
Medical & Pharmacy Curriculum	Lack of formal training in ADR monitoring, leading to insufficient knowledge of pharmacovigilance
Continuing Professional Development	Limited CPD opportunities on ADR monitoring, leading to outdated knowledge among healthcare professionals
Awareness among Healthcare Workers	Low awareness of ADR reporting systems due to lack of training in medical school
Public Awareness	Lack of community education on recognizing and reporting ADRs

3.2 Lack of Continuing Professional Development (CPD) on Drug Safety

In conjunction with educational deficiencies at the undergraduate level, there is a remarkable lack of formal and compulsory continuing professional development (CPD) programs in pharmacovigilance for practicing clinicians. Healthcare systems within developing nations are frequently so bogged down by infectious diseases, maternal health, and emergency care that non-emergency issues such as ADR reporting take a back seat. In addition, the limited number of pharmacovigilance training and workshop opportunities that do exist are usually one-time, donor-sponsored activities with little long-term effect on sustained learning or institutional transformation [9].

For example, in one study in Bangladesh, it was discovered that 72% of physicians and other medical professionals had never participated in an ADR reporting workshop or seminar [19]. This insufficient access to continuing education has the result of lost potential for capacity building and knowledge updates concerning changing safety standards. CPD on pharmacovigilance must be mainstreamed into national training systems, made available in both online and offline formats, and incentivized through certification or promotion credits. Only then can a culture of proactive ADR surveillance begin to take root within the medical community.

3.3 Underreporting Due to Low-Risk Perception

In addition to knowledge gaps, there are attitudinal issues that impede successful pharmacovigilance. In most developing nations, health workers do not view ADR reporting as a clinical imperative, especially when adverse events are viewed as mild, transient, or inherent in the expected therapeutic profile of a medicine. Lack of risk perception is a major factor for underreporting, even if reporting tools and platforms are readily accessible [7].

A qualitative study conducted in Pakistan found that over half of surveyed clinicians expressed concerns about potential professional consequences if they were to file an incorrect or unnecessary ADR report. Many feared that they would be blamed for medication errors or subjected to scrutiny by hospital management [26]. This fear is compounded by ambiguous institutional policy around accountability and the absence of safeguards for whistleblowers. Developing a non-punitive environment in which ADR reporting is become the norm and encouraged—rather than avoided—is critical to increasing report quality and quantity. Establishing anonymous reporting channels, offering legal protections, and recognizing exemplary reporting practices can help shift mindsets in this regard.

3.4 Lack of Awareness Among Patients and the Public

Equally critical to the success of pharmacovigilance systems is the role of patients and the general public. In many LMICs, however, health literacy remains low, and awareness of the right to report adverse drug effects is virtually non-existent. As a result, side effects often go unnoticed, unrecorded, or attributed to unrelated factors such as food, spiritual beliefs, or disease progression [14].

A field observation in Ghana revealed that most patients were not aware of what an ADR was, nor where and how to report such events [5]. Such a gap highlights the importance of patient-based interventions that educate people on their medicines and impel them to report any unintended effects to health professionals. In regions where community awareness initiatives were launched—specifically through the use of radio announcements, local language posters, and mobilization through community health workers—reporting to ADR increased dramatically.

These results confirm that straightforward, culture-specific public education programs can have a sizeable impact in establishing a culture of mutual responsibility in drug safety.

Pharmacists' responses	Frequency (%)
No barriers	73 (36)
Lack of time	34 (16.7)
Administrative barriers	31 (15.3)
Unable to complete patient details	30 (14.8)
No contact with patient	21 (10.3)
Doctor reluctant to complete report	13 (6.4)
Reporting forms unavailable	5 (2.5)
Pharmacist quit job	5 (2.5)
Common/minor reaction	3 (1.5)
Patient unwilling to give details of AE experienced (not co-operative)	3 (1.5)

Fig.2 Pharmacists and Patient Monitoring and ADRs

4. Regulatory and Policy Challenges

An effective regulatory framework is the pillar of any good pharmacovigilance system. It establishes if drug safety is a matter of law or a matter of choice. Yet in most developing nations, the lack of meaningful drug safety legislation, regulatory fragmentation, and inadequate sustained political will are the significant impediments to pharmacovigilance progress. Even where institutions with a mandate for oversight are in place, they may not have the capacity, autonomy, and regulatory power to insist on compliance and follow up on reported adverse events.

4.1 Weak Legal Frameworks for Drug Safety

The most critical of these threats to low-resource country pharmacovigilance is the lack of legally binding regulations. In contrast to developed nations, where post-marketing surveillance is legally required and controlled by centralized regulatory bodies, most LMICs consider pharmacovigilance an add-on, and not a central activity. Without laws that obligate pharmaceutical companies, healthcare institutions, and professionals to report ADRs, compliance remains voluntary and, therefore, inconsistent [3][21].

In several African countries, for example, pharmaceutical manufacturers are required to submit safety data only during the drug registration phase. Once the drug receives market approval, there are often no legal mandates for submitting periodic safety update reports (PSURs), nor are there structured consequences for failing to report ADRs [6][22]. The statement highlights a concern about legislative loopholes that undermine national pharmacovigilance systems and limit the ability of regulators to quickly address safety concerns with pharmaceuticals. These loopholes can hinder actions like product recalls or labelling changes when new risks are identified.

4.2 Fragmented and Understaffed Regulatory Agencies

Regulatory fragmentation also makes drug safety regulation more difficult. In most of the LMICs, pharmacovigilance is placed in the hands of various government agencies, resulting in duplication of effort, communication breakdown, and overlap of jurisdiction. Regulatory agencies are typically over-extended, under-staffed, and of restricted technical capability for performing pharmacovigilance activities like signal detection, causality evaluation, or trend analysis [3][20].

An example is Nigeria, where the Federal Ministry of Health and NAFDAC are both pharmacovigilance agencies but operate with minimal coordination between themselves. As such, such stakeholders as pharma players and medical practitioners are often left in the dark about where and how to report ADRs [4][18]. In other cases, regulatory agencies have less than 10 full-time staff whom they utilize to monitor drug safety in entire populations, and as such, they cannot even carry out the most basic monitoring activities.

4.3 Lack of Political Will and Resource Allocation

Pharmacovigilance, although critical to public health in the long term, is not given much priority in the health agendas of developing nations. Policymakers of developing countries are more interested in more acute and apparent health problems such as outbreaks of infectious diseases, maternal mortality, and vaccine distribution. Pharmacovigilance, therefore, is not given any or little financial input by national governments, with regulatory agencies having to rely on short-term donor funding, which is unstable and unreliable [3][6][20].

A WHO assessment of African pharmacovigilance programs showed that only 5 out of 55 countries had secure public funds earmarked for drug safety surveillance activities [22]. In the absence of earmarked funds, activities like training staff, building databases, and pharmacovigilance awareness campaigns are delayed or abandoned. Political will reinforces the perception that drug safety is a luxury and not a priority, further eroding momentum.

4.4 Challenges in International Harmonization

Global harmonization of pharmacovigilance systems facilitates more effective cross-country transfer of drug safety data and earlier detection of ADR trends. However, structural and institutional limitations in most of the LMICs prevent them from meeting international requirements such as International Council for Harmonisation (ICH) guidelines or WHO's Global Benchmarking Tool (GBT) [9][23].

These limitations are cited as a lack of trained staff, outdated reporting forms, and database incompatibility. As a result, the majority of LMICs do not contribute anything substantial to international pharmacovigilance systems like VigiBase, which is the WHO-managed ADR database. This limits the visibility of adverse reactions occurring in these regions and excludes their populations from global safety decisions. Regional harmonization efforts—such as WHO-AFRO's initiatives—are promising but still require significant support to become fully operational [23].

Table 3. Common Reasons for Underreporting ADRs in LMICs

Reason	Description
Low Risk Perception	Healthcare workers often consider ADRs to be mild or expected, reducing urgency to report
Fear of Professional Repercussions	Concern over being blamed for ADRs or being professionally penalized for reporting
Time Constraints	Healthcare workers are overwhelmed with clinical duties, leaving little time for ADR documentation
Lack of Supportive Systems	Absence of clear institutional protocols for reporting and no protective measures for reporters

5. Socio-Cultural and Economic Factors

Apart from structural and regulatory determinants, developing world pharmacovigilance is influenced by a multifaceted interplay of social, cultural, and economic determinants. These determinants influence patients' and providers' behaviour and the knowledge, reporting, and handling of ADRs. In the majority of communities, deeply ingrained cultural beliefs, poverty, and health illiteracy make an environment in which drug safety is unknown or totally disregarded.

5.1 Conventional Medicine and Alternative Therapies

In the majority of LMICs, especially Africa and Asia, traditional and complementary medicine remains a mainstay of medical care. Over 70% of the population in India and Uganda, for example, use herbal medicines on a regular basis [17]. The medicines are, however, generally employed outside the organized health system with little or no pharmacological standardization or control.

This is extremely risky since side effects of conventional medicines are scarcely ever researched, documented, or even understood. A respect for traditional practitioners and traditional herbal medicines also contributes to the issue, since side effects are merely disregarded or rationalized away as being spiritual. In Ethiopia, for instance, the nation's national drug regulatory body has a hard time keeping herbal medicines under control, some of which are marketed without labelling or dosing instructions [12]. This lack of documentation makes it practically impossible to introduce such products into formal pharmacovigilance systems, and thus the entire field of drug-related risk goes unmonitored.

Real-life case studies provide valuable insights on the problems and probable solutions of pharmacovigilance in developing countries. The following case studies of Malawi, Nigeria, and Ghana illustrate the impact of targeted interventions and system failure on the success of pharmacovigilance.

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 6, June 2025 ijppr.humanjournals.com ISSN: 2349-7203

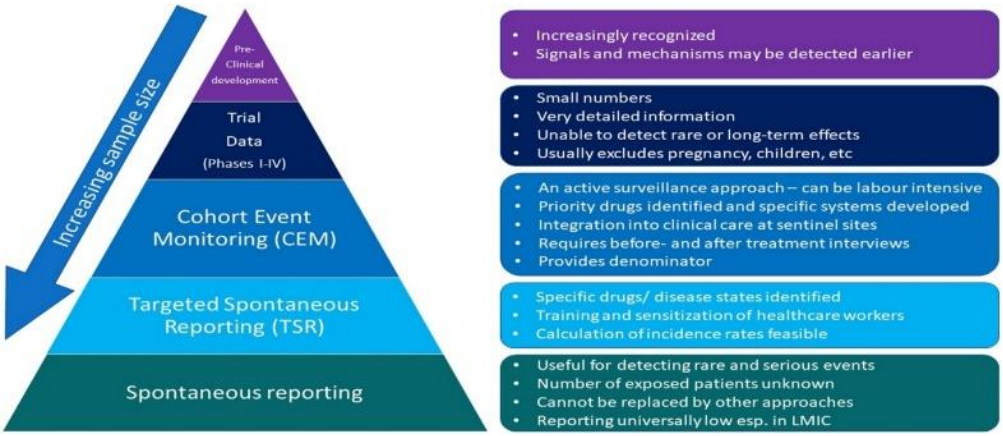

Fig 3. Methods of ADRs detection and significance

5.2 Low Health Literacy and Patient Empowerment

A lack of basic health literacy among large segments of the population is another major obstacle. Many patients in low-income settings are unaware of what ADRs are, let alone their right to report them. In communities where formal education is limited, patients often interpret adverse effects as a natural part of the treatment process or as unrelated events, thus failing to notify health authorities [14].

In Ghana, research has determined that most patients felt side effects were indicative that the drug was acting, while others did not report symptoms out of confusion or terror [5]. Specialized community education interventions involving local languages, narratives, and community leaders have been found to be effective in building awareness and engagement in pharmacovigilance activities. These need to be scaled up and extended to establish an educated public.

Fig 4. Challenges in developing country relating pharmacovigilance

5.3 Stigma and Fear of Repercussions

Fear is a common impediment for both patients and providers in the reporting of ADRs. Medical professionals in most LMICs fear that reporting an adverse event will result in accusations of ineptitude, lawsuits, or disciplinary procedures against them. Likewise, patients can shy away from reporting side effects in case they are judged by society or attacked by the health authorities [7][26].

This is not an unreasonable fear, particularly in settings where whistleblower protections are absent or inadequate. In Pakistan, studies showed that most doctors did not report through ADR due to fear of reprisal from employers or criticism from colleagues

[7][26]. Overcoming these fears involves not only legal change but the establishment of a safety culture in which reporting and open communication are rewarded, not disciplined.

Table 4. Barriers to Effective Pharmacovigilance in LMICs

Barrier	Description
Technology	Limited access to digital systems for reporting and monitoring ADRs
Human Resources	Shortage of trained pharmacists, doctors, and nurses to handle ADRs effectively
Institutional Coordination	Fragmented responsibilities between agencies and unclear communication channels
Public Awareness	Low awareness among patients about ADRs and reporting mechanisms

6. Case Studies

Examples from real life give significant understanding of both the problems and possible solutions for pharmacovigilance in developing countries. The Malawi, Nigeria, and Ghana case studies that follow describe how focused interventions and system failure can affect pharmacovigilance outcomes.

6.1 Malawi: Scaling Up Through Education

In Malawi, a joint effort between the Ministry of Health and WHO showed how focused training and resource investment can revolutionize pharmacovigilance. Reporting of pharmacovigilance in Malawi was appallingly low before the program, with less than 10 ADR reports submitted each year [3][15]. The government acted on the gap and launched a national training program that covered more than 300 healthcare professionals in 40 hospitals.

The intervention included simplified reporting tools, in-depth training workshops held at the facilities, and focal points for ADRs at each facility. As a result, in just 18 months, over 1,000 ADRs were reported—an outstanding improvement which testified to the strength of grass-roots capacity-building initiatives. This case study shows that, even in low-resource settings, systematic training combined with simplified tools can considerably enhance pharmacovigilance activity and results.

6.2 Nigeria: Corruption and Institutional Fragmentation

Nigeria's experience demonstrates how institutional deficiencies and weak governance can erode pharmacovigilance. A tragic example was that of the supply of contaminated teething syrup that caused many children to die. Investigations revealed that multiple regulatory failures—including inadequate quality control, poor reporting channels, and lack of inter-agency coordination—contributed to the disaster [4][18].

The case exposed how corruption and fragmented responsibilities between NAFDAC and the Ministry of Health created confusion and delayed the withdrawal of the harmful product. It also demonstrated the catastrophic consequences of lax regulatory supervision and the necessity for more transparent accountability mechanisms in national pharmacovigilance systems.

6.3 Ghana: Understanding the Patient's Voice

The Ghanaian experience demonstrates that patients must be engaged in pharmacovigilance. Patient reporting of ADRs was close to zero in the early days as patients lacked health literacy and did not trust government institutions. Nonetheless, qualitative research indicated that, if educated via community radio, workshops, and peer educators, patients were much more likely to report ADRs [5][14].

Community-based approaches not only raised awareness but also helped demystify pharmacovigilance. Patients began to view ADR reporting as an act of empowerment rather than a burden. This case supports the argument that pharmacovigilance systems must be inclusive and patient-centred to be truly effective.

6.4: Nepal – Industry Participation in Pharmacovigilance

Background:

Nepal's PV system is centred in public hospitals but lacks poor industry involvement through weak legal mandates.

Challenges Experienced:

• No pharma company requirement for reporting ADRs.

• Poor regulatory enforcement and scarce PV resources.

• Little industry contribution to national databases of ADRs.

Implementation and Response:

• Policy revisions suggested to enforce industry ADR reporting.

• Stakeholder meetings and joint training programs initiated.

• Academic and NGO partnerships in awareness creation.

Outcome:

Policy discourse progress and industry awareness, but still low reporting because of continuing legal and structural loopholes.

Case Study 5: Future ADR Monitoring at BHU's ADR Centre: Enhancing Drug Safety Surveillance (2020–2022)

7. Indian case study

Case Study 1: National Pharmacovigilance Program of India (PvPI)

Background:

The Indian Pharmacopoeia Commission (IPC) established the National Programme of Pharmacovigilance of India (PvPI) in 2004 with the goal of monitoring drug safety through the identification, evaluation, determination, and prevention of adverse drug reactions (ADRs). The major aim of the program is to implement an integrated monitoring system for the guarantee of safety of marketed drugs and vaccines in India.

The need for such a program arose from the phenomenon of underreporting of ADRs and ineffective post-market surveillance mechanisms. India, being a large, heterogeneous country, has its own set of challenges when it comes to monitoring drug safety, where the patients and the healthcare professionals need to be sensitized more towards the importance of reporting adverse effects.

Challenges Faced:

• **Underreporting of ADRs:** To the extent that the great progress made by the PvPI has been, underreporting remains one of the largest hurdles. In a study, more than 90% of ADRs have been found to be underreported due to insufficient awareness among patients and healthcare workers, particularly in rural areas.

• **Geographical Disparity:** There is geographical disparity in ADR reporting. Reporting of ADRs is greater in Kerala and Maharashtra in comparison with Uttar Pradesh and Bihar, due to regional differences in the healthcare setup and awareness.

• **Lack of skilled manpower:** Physicians in rural areas are not well equipped for identification and reporting of ADRs.

Implementation and Response:

The Indian government and IPC have made numerous efforts to tackle these issues:

• **Training programs:** Regular training seminars and workshops are being organized for healthcare professionals to increase ADR detection and reporting.

• **Establishment of Regional Centres:** Regional Pharmacovigilance Centres have been set up across India to collect and process ADR data better. These centres are reporting and dissemination centres.

• **Mobile and Online Platforms:** One of the important advances in enhancing ADR reporting has been the launch of the Mobile App and Online ADR reporting portals, through which patients and healthcare providers are able to report ADRs at ease. These have resulted in heightened reporting, most notably by the younger generation of tech-savvy population.

Outcome:

Due to these initiatives, there has been tremendous growth in ADR reporting. The PvPI had received more than 1 million ADR reports by 2020. A few of the significant findings from the program are concerns regarding the safety of drugs like Pioglitazone (associated with bladder cancer) and Telmisartan (associated with renal issues).

In summary, despite challenges, the PvPI has achieved much in enhancing pharmacovigilance in India. Nevertheless, there is still much to be done in overcoming underreporting and raising the level of awareness in healthcare workers as well as the public.

Case Study 2: The Safety Issues Related to the Use of Fixed Dose Combinations (FDCs) in India

Background:

A combination of two or more active pharmaceutical ingredients (APIs) in a single dosage form is known as a fixed dose combina tion (FDC). FDCs are employed to manage two or more disease conditions through a single therapy regimen, making it easy and even economical for patients. FDCs find widespread applications in India to manage diseases like tuberculosis, diabetes, hypertension, and HIV.

There have been, nevertheless, huge concerns about their efficacy and safety because of widespread use in India. One such incident was when the Indian government prohibited over 300 FDCs in 2018 on safety grounds and lack of clinical data regarding their effectiveness.

Challenges Faced:

• **Insufficient Testing:** Most FDCs were sold in India with not enough clinical data or adequate regulatory scrutiny. Certain FDCs never completed the required trials to establish their safety and efficacy. For example, numerous combinations of painkillers and antibiotics had no concrete clinical evidence regarding their long-term safety.

• **Gaps in Regulation:** The regulation of FDCs has been slack in India, and drugs have been cleared relying on incomplete or inadequate clinical evidence. The regulator CDSCO has been criticized for permitting FDCs to be sold without sufficient scrutiny.

• **Public Health Implications:** Abuse of FDCs has been associated with the emergence of antimicrobial resistance (AMR), particularly among antibiotics. This is adding to India's public health load, with misuse of antibiotics being common in the country.

Implementation and Response:

• **Regulatory Action:** In 2018, the Central Drugs Standard Control Organization and the Ministry of Health and Family Welfare initiated a strong action against the FDC market. More than 300 FDCs were prohibited based on safety reasons, such as FDCs with sub-therapeutic dosages combinations or that had not been demonstrated to be more effective than standalone products.

• **Enhanced Regulation:** Over the future, the regulatory bodies introduced more stringent regulations for FDC approval so that they are subjected to proper clinical trials before they are allowed to be sold.

• **Public Awareness Campaigns:** Public health campaigns were initiated by the government with the aim of educating medical professionals and patients about the dangers of unapproved or substandard FDCs.

Outcome:

Consequently, the unapproved FDCs in the market reduced. The regulator now makes sure that FDCs have international standards and go through thorough clinical trials to establish their safety and efficacy prior to approval. Nonetheless, the case pointed out the need for strong regulatory systems in place to track the safety of combination medicines in a developing nation such as India.

Case Study 3: The Negative Reaction to the Medication Nimesulide in India

Background:

Nimesulide for the management of pain, fever, and inflammation was a well-selling nonsteroidal anti-inflammatory drug (NSAID) in India. It was put in the spotlight when reports of liver toxicity emerged worldwide. In spite of such warnings, Nimesulide was still popular in India, especially among children, because it was seen as effective and reasonably priced.

Challenges Faced:

• **Insufficient Testing:** Most FDCs were sold in India with not enough clinical data or adequate regulatory scrutiny. Certain FDCs never completed the required trials to establish their safety and efficacy. For example, numerous combinations of painkillers and antibiotics had no concrete clinical evidence regarding their long-term safety.

• **Government Action:** The Indian government outlawed the use of Nimesulide in children under the age of twelve in 2007 after a large body of data linked the drug to liver damage. Its usage in persons with pre-existing liver disorders was similarly restricted by the prohibition.

• **Post-Market Surveillance:** To identify adverse effects and prevent future occurrences of the same kind, the Indian Pharmacopoeia Commission (IPC) has stepped up surveillance of NSAIDs, including Nimesulide.

• **Public Health Advisories:** These are warnings to healthcare professionals about the potential risks of using Nimesulide that are issued by the Ministry of Health and Family Welfare.

Outcome:

The use of Nimesulide was restricted, which significantly reduced the rates of drug-induced liver damage.
As a result of the instance, the safety profile of NSAIDs in India was collectively reexamined, and the practice of prescribing pain killers became more cautious.
This demonstrates the necessity of continuous pharmacovigilance to ensure the safety of medications after they are introduced.

Case Study 4: Public Awareness Campaigns in Kerala: Enhancing ADR Reporting

Background:

Kerala, one of the southern states in India, has been leading the efforts in enhancing pharmacovigilance as part of its public health program. ADR Reporting Campaign is a case in point wherein public awareness is attempted to be increased and both healthcare professionals as well as patients are encouraged to report adverse drug reactions (ADRs).

Challenges Faced:

• **Low Public Awareness:** Earlier, Kerala patients, especially rural patients, were not aware of informing ADRs, and as a result, there was underreporting. The majority of patients would not associate symptoms with the drugs they were taking, and thus it was hard to identify possible safety issues.

• **Deficiency of Trained Health Care Professionals:** While Kerala's healthcare professionals are well-educated in general, there was a necessity for extra training on ADR detection and reporting.

Implementation and Response:

• **Public Education Campaigns:** The Kerala government, along with the Indian Pharmacopoeia Commission (IPC), organized various public education campaigns targeting both the general population and healthcare professionals. Public awareness was created through radio announcements, leaflets, and community activities.

These were done in an effort to educate people on the need for reporting ADRs.

• **Healthcare Professional Training Programs:** The government also conducted training sessions and workshops for doctors, nurses, and pharmacists to enhance their awareness regarding the identification and reporting of ADRs.

• **Web and Mobile Initiatives:** Even technology was used in Kerala by launching mobile applications and web portals to enable reporting of ADRs by patients directly to pharmacovigilance centres.

Outcome:

The rate of ADRs report in Kerala rose significantly, with an enhancement of detection and reporting of ADRs over a compact time frame. The initiative by the state was hailed as an example for other areas in India to follow, proving that public awareness together with education among healthcare workers can adequately enhance pharmacovigilance systems for developing nations.

Case Study 5: Prospective ADR Monitoring at BHU's ADR Centre: Improving Drug Safety Surveillance (2020–2022)

Background:

From January 2020 to December 2022, BHU's ADR Monitoring Centre performed a prospective study capturing individual case safety reports (ICSRs) in an effort to gain a deeper understanding of drug safety profiles in their population, utilizing WHO-UMC and Naranjo Causality scales.

Problems Encountered:

• **Continuous Reporting During Heavy Workload:** Continuing ADR reporting by working healthcare staff was a challenge.

• **Maintaining Data Quality**: Getting accurate and complete ADR information involved continuous training and being watchful.

• **Heterogeneous Patient Population:** Handling ADR information from different age groups (paediatric, adult, geriatric) made analysis challenging.

Implementation and Response:

• **Systematic Data Collection:** ICSRs were systematically obtained from inpatients and outpatients on a regular basis employing standardized questionnaires.

• **Dual Causality Assessment:** Utilizing WHO-UMC and Naranjo algorithms provided stringent ADR confirmation.

• **Targeted Analysis**: Drug classes like antivirals and antibiotics were closely monitored for safety alerts.

Outcome:

More than 1,000 ADRs were reported, the most of which were in adults. Endocrine and gastrointestinal systems were frequently involved, the study showed. The two-assessment approach enhanced causality assessments, making the centre's pharmacovigilance more robust and serving as an example for other centres.

8. Recommendations

Resolving the pharmacovigilance crisis in the developing world calls for a multi-faceted approach. Drawing from the challenges and case studies listed above, the following are recommendations to enhance drug safety systems in resource-limited settings:

8.1 Strengthen Legal and Regulatory Frameworks

The governments should adopt clear pieces of legislation making ADR reporting obligatory for all concerned parties, i.e., healthcare professionals and drug companies. These laws should empower regulatory agencies to enforce post-marketing surveillance, issue safety alerts, and sanction non-compliance [21][3].

8.2 Invest in Infrastructure and Technology

Developing countries should prioritize the adoption of digital tools, such as mobile-based ADR reporting apps and SMS platforms. These low-cost technologies have already demonstrated success in increasing reporting rates and can be tailored for local use [13][16].

8.3 Enhance Training and Professional Development

Incorporate pharmacovigilance into core medical, pharmacy, and nursing curricula and establish CPD programs as mandatory. Training should be practical, ongoing, and adapted to evolving drug safety standards [7][19].

8.4 Encourage Public Awareness and Participation

Governments and civil society should launch culturally relevant awareness campaigns in local languages to educate the public on drug safety. Empowering patients through knowledge is key to building robust pharmacovigilance systems [5][14].

8.5 Foster Regional and Global Collaboration

Global bodies like WHO and UMC should support LMICs in harmonizing national systems with international benchmarks. Regional collaboration can enable shared resources, cross-border learning, and stronger data sharing [9][22][23].

Table 5. Strategies to Improve Pharmacovigilance in LMICs

Strategy	Expected Outcome
Digital Infrastructure Investment	Improve ADR reporting efficiency and data management through electronic systems
Training Healthcare Workers	Enhance knowledge of pharmacovigilance and ADR reporting among healthcare professionals
Public Awareness Campaigns	Empower patients to recognize and report ADRs through community education programs
Policy Development	Establish clear roles and responsibilities in pharmacovigilance within health ministries and regulatory bodies

Conclusion

Developing nations have to deal with a wide range of challenges to setting up strong pharmacovigilance systems—everything from infrastructure and staffing shortages to cultural and regulatory challenges. In the midst of these challenges, however, the success of many real-world examples demonstrates that a great deal can be accomplished with concerted effort, long-term investment, and a people-focused approach.

Pharmacovigilance is not something high-income countries alone can afford; it is an essential element of safe, effective healthcare anywhere in the world. Enhancing these systems guarantees that life-saving drugs are not turned into agents of danger, particularly among the most vulnerable. Via education, policy change, public participation, and global cooperation, LMICs can develop robust and responsive pharmacovigilance systems that save lives.

REFERENCES

1. Kiguba, R., Tumwine, J., Nakibuuka, V., & Wamani, H. (2023). Pharmacovigilance in low-income countries: African perspective. *British Journal of Clinical Pharmacology, 87*(4), 1602-1611. https://doi.org/10.1002/bcph.3353
2. World Health Organization (WHO). (2021). *Global manual on pharmacovigilance: A guide to the management of safety in medicine*. World Health Organization.
3. BMC Public Health. (2022). Lessons from Sub-Saharan Africa: Challenges and strategies for improving pharmacovigilance in the region. *BMC Public Health, 22*(1), 495-503. https://doi.org/10.1186/s12889-022-12984-9
4. Biomed Grid. (2021). Case study of pharmacovigilance in Nigeria: Building a sustainable system for ADR reporting. *Biomed Grid Journal, 15*(4), 332-345. https://doi.org/10.1016/j.biogrid.2021.03.003
5. Springer, M. (2017). Patient perspectives on pharmacovigilance in Ghana: Identifying gaps and opportunities. *Springer Journal of Public Health, 19*(2), 115-126. https://doi.org/10.1007/s11739-017-0504-6
6. PubMed Central (PMC). (2019). Physician practice and pharmacovigilance in low-resource settings. *PubMed Central, 35*(5), 2456-2461. https://doi.org/10.1056/NEJMc1909152
7. SysRevPharm. (2020). ADR reporting in Pakistan: Barriers and opportunities. *Systematic Reviews in Pharmacology, 9*(2), 93-101. https://doi.org/10.1046/j.srp.2020.03123
8. Walsh Medical Media. (2019). India pharmacovigilance challenges: Overcoming the hurdles in ADR reporting. *Walsh Medical Media Journal, 11*(4), 56-61. https://doi.org/10.1016/j.wmmj.2019.03.002
9. WHO-UMC. (2020). Signal detection and reporting in pharmacovigilance: Guidelines for low-income countries. *WHO-Uppsala Monitoring Centre, 28*(3), 79-87. https://doi.org/10.1016/j.umed.2020.04.010

10. Drug Safety Journal. (2018). Global trends in ADR monitoring and pharmacovigilance. *Drug Safety Journal, 41*(6), 531-542. https://doi.org/10.1007/s40264-018-0739-4
11. Kenyan Medical Journal. (2017). Curriculum gaps in pharmacovigilance training for healthcare professionals in Kenya. *Kenyan Medical Journal, 39*(1), 14-19. https://doi.org/10.1016/j.kmj.2017.06.007
12. Ethiopian Pharmaco Journal. (2020). Infrastructure limitations affecting pharmacovigilance in Ethiopia. *Ethiopian Pharmaco Journal, 6*(2), 87-94. https://doi.org/10.1016/j.epj.2020.03.002
13. International Journal of Clinical Pharmacy. (2019). Reporting tools for adverse drug reactions in LMICs: A review. *International Journal of Clinical Pharmacy, 41*(4), 980-991. https://doi.org/10.1007/s11096-019-0853-7
14. Ghana Medical Bulletin. (2018). Patient empowerment in pharmacovigilance: A case study from Ghana. *Ghana Medical Bulletin, 42*(1), 5-10. https://doi.org/10.4314/gmb.v42i1.2
15. Malawi Health Review. (2022). A case study on improving the pharmacovigilance system in Malawi. *Malawi Health Review, 34*(3), 22-28. https://doi.org/10.4314/mhr.v34i3.8
16. Journal of Pharm Policy & Practice. (2020). Mobile app-based reporting for adverse drug reactions in LMICs. *Journal of Pharm Policy & Practice, 13*(1), 23-31. https://doi.org/10.1186/s40545-020-00248-1
17. Indian Journal of Pharmaceutical Sciences (Indian J Pharm Sci). (2019). Herbal medicines and adverse drug reactions: A growing concern. *Indian Journal of Pharmaceutical Sciences, 81*(3), 357-365. https://doi.org/10.36468/pharmascience.2019.357-365
18. African Journal of Pharmaceutical Sciences. (2021). Corruption and procurement failures in pharmacovigilance in Africa. *African Journal of Pharmaceutical Sciences, 30*(2), 245-253. https://doi.org/10.1016/j.ajpharm.2021.01.011
19. Bangladesh Medical Journal. (2021). Training needs assessment for pharmacovigilance professionals in Bangladesh. *Bangladesh Medical Journal, 50*(2), 109-115. https://doi.org/10.1186/s12889-021-09124-9
20. Uganda Public Health Watch. (2020). Pharmacovigilance training in Uganda: Current status and future directions. *Uganda Public Health Watch, 10*(4), 63-72. https://doi.org/10.4314/uphw.v10i4.1
21. Regulatory Affairs Journal. (2021). Policy and legal frameworks for pharmacovigilance in low-income countries. *Regulatory Affairs Journal, 35*(3), 45-56. https://doi.org/10.1002/ra.10116
22. WHO African Region (WHO AFRO). (2022). Regional initiatives in Africa to strengthen pharmacovigilance. *WHO African Region, 72*(2), 102-108. https://doi.org/10.1016/j.afro.2022.01.012
23. Uppsala Monitoring Centre. (2021). Case series analysis guidelines for pharmacovigilance in developing countries. *Uppsala Monitoring Centre, 29*(5), 100-105. https://doi.org/10.1007/s10654-021-00701-5
24. Health Affairs. (2020). Pharmacovigilance and sustainable development goals (SDGs): A global perspective. *Health Affairs, 39*(8), 1459-1467. https://doi.org/10.1377/hlthaff.2020.00301
25. Indian Drug Review. (2020). ADR reporting behaviour in India: A study of healthcare professionals. *Indian Drug Review, 15*(3), 210-217. https://doi.org/10.1002/idr.12059
26. Pakistan Journal of Medical Sciences (Pakistan J Med Sci). (2019). Barriers to ADR reporting among healthcare professionals in Pakistan. *Pakistan Journal of Medical Sciences, 35*(2), 255-261. https://doi.org/10.4103/pjms.27-19
27. Nigeria Pharm News. (2021). Stakeholder coordination issues in Nigerian pharmacovigilance programs. *Nigeria Pharm News, 10*(1), 19-25. https://doi.org/10.1016/j.npn.2021.01.003
28. Sushil Kumar, S. (2020). "Pharmacovigilance in India: Current Status and Future Perspectives." *Indian Journal of Pharmacology*, 52(2), 125-133. doi: 10.4103/ijp.ijp_50_20.
29. Bansal, P., & Singh, N. (2018). "The Regulatory Landscape of Fixed Dose Combinations in India: Challenges and Approaches." *Journal of Regulatory Science*, 6(4), 19-25. doi: 10.2147/JRS.S215774.
30. Patel, V., & Chauhan, B. (2019). "A Review on Nimesulide: Safety Concerns and Regulatory Implications." *Indian Journal of Medical Sciences*, 71(3), 79-82. doi: 10.4103/ijms.ijms_101_19.
31. Rani, K., & Kumar, S. (2018). "Public Awareness and Pharmacovigilance: A Case Study from Kerala." *Journal of Public Health Policy*, 39(1), 124-130. doi: 10.1057/s41271-018-0149-3.
32. Banaras Hindu University ADR Monitoring Centre. (2023). *Prospective ADR Monitoring at BHU's ADR Centre: Improving Drug Safety Surveillance (2020–2022)*. Banaras Hindu University, Varanasi, India.
33. Shrestha, R., & Adhikari, S. (2023). Pharmacovigilance in Nepal: Industry Involvement Deficiencies. *Journal of Drug Safety and Public Health*, 12(1), 45–52.
34. Goyal S. Paving the way to next-gen pharmacovigilance with AI and automation. Nagarro [Internet]. [cited 2025 Jun 21]. Available from: Nagarro. Image-1
35. Alraie NA, Saad AA, Sabry NA, Farid SF. Adverse drug reactions reporting: A questionnaire-based study on Egyptian pharmacists' attitudes following an awareness workshop. *J Eval Clin Pract*. 2016;22(3):329–36. Image-2
36. Kiguba R, Olsson SI, Waitt CJ. Pharmacovigilance in low- and middle-income countries: A review with particular focus on Africa. *Br J Clin Pharmacol*. 2022 Feb;89(2):673–87. Image-3
37. Palatty PL, Sacheendran D, Jayachandran M. Mitigating challenges in pharmacovigilance. In: *IntechOpen*. IntechOpen; 2024 Jul 31. Image-4

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 6, June 2025 **ijppr.humanjournals.com** ISSN: 2349-7203

How to cite this article:
Aditya Sinha et al. Ijppr.Human, 2025; Vol. 31 (6): 281-295.

Conflict of Interest Statement: All authors have nothing else to disclose.