World Journal of Biology Pharmacy and Health Sciences
eISSN: 2582-5542
Cross Ref DOI: 10.30574/wjbphs
Journal homepage: https://wjbphs.com/

(REVIEW ARTICLE)

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Rethinking pharmacovigilance: Building inclusive drug safety systems for marginalized populations

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World Journal of Biology Pharmacy and Health Sciences, 2025, 21(01), 214-223

Publication history: Received on 29 November 2024; revised on 08 January 2025; accepted on 10 January 2025

Article DOI: https://doi.org/10.30574/wjbphs.2025.21.1.0027

Abstract

Pharmacovigilance is critical in facilitating efforts targeted at closing the health gap by monitoring, assessing and preventing the occurrence of adverse drug reactions (ADRs) across diverse populations. This review aims to evaluate how pharmacovigilance systems can help mitigate healthcare inequalities specifically in low and middle-income countries (LMICs). The role of pharmacovigilance as part of the modern drug safety system integrated within a healthcare system became indispensable during the COVID-19 pandemic when drug decision-making required strong supervision systems in terms of vaccine safety. However challenges exist, such as lack of resources, training and inadequate infrastructure that is particularly apparent in LMICs. The manuscript considers the social determinants of health; structural inequities and other system factors that account for the differences in the health status and medication safety among different marginalized groups. The use of modern technology such as electronic health records coupled with data mining strategies is an effective way of enhancing pharmacovigilance. Community engagement, educating healthcare providers, and collaborating internationally appear to be strong strategies for enhancing pharmacovigilance systems. Case studies from Bolivia and Nigeria illustrate such a strategy effectively. The review concludes that healthcare professionals and drug monitoring systems must be strengthened, and improved and recommends a unified approach involving healthcare workers, policymakers, and communities to build robust, equitable drug safety monitoring systems.

Keywords: Pharmacovigilance; Drug Safety; Social Determinants of Health; Health disparities; Low and middle-income countries (LMICs); Structural Inequities; Adverse reactions

1. Introduction

The World Health Organization (WHO) defines pharmacovigilance as the science and activities of monitoring, evaluating, and understanding how to prevent adverse effects or any other drug problem[1]. An increasing focus on this area has become more evident in recent years, notably in the context of addressing numerous health inequalities underlying different populations. Health inequalities are termed as the differences in health outcomes and healthcare access which are closely associated with social, economic, or environmental deprivation[2]. Such inequalities could be disease occurrences, treatment options, or care services. The role of pharmacovigilance in addressing these inequalities varies as it includes drug safety surveillance, adverse drug reaction monitoring, and risk management of safe medicines. These examples indicate that the scope of pharmacovigilance should not be limited to drug safety surveillance only as it can change the course of public health. For example, there are often disparities regarding the rates of adverse drug reactions among marginalized groups in society, and these differences can often be attributed to genetic factors or socioeconomic status that inflate health access barriers[3]. Therefore, through a proactive approach of gathering and studying data about specific populations, pharmacovigilance seeks to be at the forefront of such endeavors so that health

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practitioners as well as regulators can understand how to address potential issues with drug usage in these communities[4]. The integration of pharmacovigilance into healthcare systems can enhance the overall quality of care, ensuring that all individuals, regardless of their background, receive safe and effective treatments. Indeed, the COVID-19 pandemic has accentuated in the recent past the need to strengthen pharmacovigilance systems, especially in regard to vaccines. The increase in demand and supply of COVID-19 vaccines saw the need to make available adequate and effective pharmacovigilance systems to monitor the safety and efficacy of these vaccines. According to the literature, there is substantial evidence that indicates that there is improved pharmacovigilance during vaccination campaigns and this greatly decreases the likelihood of any adverse event occurring via pro-active risk management, which in return enhances the public confidence in future vaccinations[5]. This is important, especially for the more vulnerable communities that are likely to be hesitant to receive vaccines due to fears of adverse effects.

As a result of timely information about vaccine safety, there is an increase in the rate of vaccination in these communities, which means that pharmacovigilance has a fundamental functional capacity to improve health in these communities. Also, the support and education on pharmacovigilance is important for health equity. It has been found that healthcare workers who are familiar with the basic principles of pharmacovigilance are more willing to report adverse drug reactions and practice safer prescribing[6]. This brings to the forefront the importance of regular refresher courses in major areas related to drug therapy including the reporting mechanism for adverse events[7]. In a number of LMIC's (low- and middle-income countries) there are a number of trained staff and a lack of resources that create bottlenecks for effective pharmacovigilance systems and further aggravate health inequities[8]. So, there is a need to dedicate resources to systems training and enhancement as this would help strengthen the pharmacovigilance systems in such a way that all societies are able to integrate medication security. Over and above, the importance of members of the community and the way they know about the functions of pharmacovigilance is equally important. It is believed that public relations campaigns to make patients aware of the importance of pharmacovigilance can empower them to participate actively in their healthcare[9]. For instance, programs that promote medication use among patients provide essential information for pharmacovigilance systems, which in turn, lead to better drug safety and subsequent health outcomes. The advancement of Information Technology in the practice of pharmacovigilance will also help in achieving effectiveness and efficiency in the monitoring of drugs. Electronic health records (EHRs) together with data mining strategies will ease the work of detecting ADRs and will improve the pharmacovigilance practice as a whole[10]. In parallel, social media sites have provided current real-time drug safety information which enables early response to the safety issue that is emerging[11]. Such technologies could therefore make pharmacovigilance systems more effective in addressing health inequities and other health issues.

2. Understanding Health Disparities

2.1. Role of Social Determinants of Health

Health inequalities are intricacies resulting from various causes that tend to be located in the social determinants of health. The social determinants include the diverse circumstances in which people are born, grow, live, and work as well as the older age in which people live and all of these contribute to the health status of certain populations in different ways[12]. Certain factors such as the individual's social class, level of education, and neighborhood have a direct bearing on whether one can seek health services or not, the type of services one receives, and the type of services. Previous studies have highlighted that health inequities remain an issue and that people in marginalized groups such as racial and ethnic groups and low-income people who live in rural areas are more likely to experience such challenges[13]. The interplay of access to healthy food options, safe housing, and adequate medical care explains the higher rates of chronic illnesses such as diabetes, hypertension, and cardiovascular diseases in these populations more thoroughly[14]

2.2. Structural Inequities

Health disparities do not only arise from individual actions or individual functioning, but rather such disparities are reinforced by structural inequities in the society. For example, people residing in economically disadvantaged neighborhoods may not have easy access to healthcare centers, which may result in postponing seeking healthcare services, thus yielding poor health consequences[4]. Nor is this access aided by cross-cultural and linguistic issues where people from different cultures have problems with navigating the healthcare system or even stating their health or medical needs. Such systemic problems are alarming since they indicate that there is a need for the inclusion of health inequalities in the agenda for public health action through an explicit focus on the underlying social determinants[15].

2.3. Integrating Pharmacovigilance into Public Health Initiatives

The focus of pharmacovigilance is indeed an important area to start in seeking to redress such inequalities since it focuses on evaluating ADRs in a more population-adverse way. Pharmacovigilance systems are able to identify the presence of specific discrepancies among marginalized populations because they are able to discern and assess data on Adverse Drug Reactions (ADRs). For example, specific groups may possess a higher risk for the adverse effects of certain medications due to genetics, environmental, and other social determinants of health[16]. These factors have significant implications for clinicians and policy advocates when seeking targeted interventions for individuals who are facing heightened risks for medication-related adverse effects and will be able to explain why a nuanced approach is desired. They want to augment the safety of medication and its effectiveness for all people, especially those at greater risk. Moreover, pharmacovigilance can strengthen existing national public health strategies and counteract the effects of safety events on people already receiving healthcare interventions. Together with local organizations, communities, and other relevant stakeholders, those in charge of monitoring adverse drug events can better pinpoint the specific needs of a diverse population[17]. Such clinical care integration helps to build confidence within the target population and makes them more willing to be responsible for their treatment choices[18]. As an example, it can be argued that if patients are taught to recognize the importance of ADRs, then patients are most likely to show more activity and report specific occurrences, thus assisting medical professionals and ultimately contributing to improved health outcomes.

3. Importance of Pharmacovigilance systems

Pharmacovigilance maintains a critical role in healthcare systems as it is designed to track the safety and effectiveness of products after they have been commercialized. These systems protect the population by actively organizing and evaluating information on adverse drug reactions (ADRs) and other drug-related problems during the post-marketing stage of a drug life cycle[19] . The role of pharmacovigilance goes further than simply reporting data; it provides an opportunity to get a better grasp on the myriad of issues related to drug safety, as well as the risks brought on by drug treatments among different groups.

3.1. Identifying and Characterizing ADRs

One of the primary functions of pharmacovigilance systems is to identify and characterize ADRs that may not have been evident during clinical trials. The results of clinical trials, though important in determining the first level of drug safety and efficacy, are normally conducted on a selected and limited population group, which may not fully represent the broader patient demographics that will ultimately use the medication[20]. As a result, some of the adverse drug reactions may only be detected when the drug is given to a more varied and broader group of people, comorbid populations, polypharmacy, and different ethnicity groups[21]. Such reactions monitored in the post-marketing stage are relevant since they make it possible to evaluate the drug safety in real-world conditions and recommend other possible uses in patient management. These systems may also assist healthcare professionals and policymakers in identifying medication safety issues or concerns, which in turn may aid the development or strengthen existing risk management frameworks. As an example, whenever there is a significant number of reports of ADRs for a particular medication, regulators tend to initiate to reassess the safety of the drug[4]. This type of action can result in quick actions such as revising the drug label information; giving warnings to the public regarding safety issues, or even suspending the drug from commercialization. Prevention and mitigation measures of this type are crucial for safeguarding the health status of the population and for the effective management of the treatment of patients.

3.2. Safeguarding Vulnerable Populations and Integrating Technology

Effective pharmacovigilance is particularly essential when dealing with ADRs in vulnerable populations. Genetic, environmental, and even socioeconomic factors play a role in how individuals respond to medication[10]. For example, drug metabolism may be impaired in certain ethnic subpopulations to the extent that they are at risk for ADR. Additionally, individuals from lower socioeconomic backgrounds may face barriers to utilization of the health services that may result in delayed reporting of ADRs or seeking care[22]. By focusing on these at-risk populations, pharmacovigilance systems can help identify specific safety concerns and tailor interventions to mitigate risks effectively. Moreover, technology nowadays can be embraced in pharmacovigilance activities thus increasing the monitoring effectiveness of drug safety. The introduction of EHRs and data mining techniques facilitates the quick analysis of large quantities of data, and this increased access to information helps in the identification of ADRs that are difficult to see with the use of traditional reporting techniques[10]. Social networks have also become important sources for capturing drug safety events, allowing pharmacovigilance systems to address safety issues that arise in a timely fashion. Utilization of these technological trends can bring about more responsive and flexible pharmacovigilance and thus improve patient safety and ultimately leading to better patient safety outcomes[23].

4. Pharmacovigilance in Low- and Middle-Income Countries (LMICs):

4.1. Inadequate pharmacovigilance in LMICs

There are many issues associated with the pharmacovigilance system in low- middle-income countries which in turn does not allow drug safety monitoring system to be effective. The issues basically arise out of resource constraints, lack of appropriate staff training and inadequate primary health care system[24]. Because of these deficiencies there are dire consequences due to magnification of health inequalities. The majority of people in low and middle income countries lack proper access to medication safety supervision which put them at a more dangerous risk than those in high income countries[8]. For example, a survey conducted in Nepal revealed that medical care providers have poor understanding and practice of pharmacovigilance which makes them ineffective in reporting and monitoring adverse drug reactions (ADRs). This barrier to reporting adverse drug reactions can be insufficient education and training in these areas which can be critical in safeguarding the use of drugs in such regions[25].

4.2. Financial and human resource constraints

The financial limitations encountered by the LMICs worsen the already existing costs associated with establishing and even keeping functioning pharmacovigilance systems. Numerous countries in this group have problems with budgetary allocations which do not enable them to undertake active pharmacovigilance activities. As an example, comparison of national pharmacovigilance systems in Eastern Africa highlighted that even when some budgets are provided, those relatively do not meet the potential allocation needed for effective understanding of the pharmacovigilance regulation and guidelines[26]. This financial deficiency can give rise to under resourcing of drug safety monitoring including the lack of reporting ADRs databases and the safety data analysis systems[27]. Besides budgetary issues, the human resource part of the pharmacovigilance in LMIC is also insufficient. There is a lack of qualified personnel capable of performing pharmacovigilance functions such as collection and analysis of ADR reports. Most of the time, with the excessive workload they have, the medical staff have no chance to perform the activities for drug safety. Also, the absence of such specialized training programs renders a more or less unprepared drug safety workforce who are not able to detect and report ADRs properly[26,27]. Furthermore, this fact is aggravated by the fact that many healthcare workers are not likely to view pharmacovigilance activities as highly important and are therefore less likely to report abuse, which creates an environment resistant to good pharmacovigilance practices[28].

4.3. Opportunities for Improvement: Technology and Collaboration

One of the ways to address some of these issues is to consider the application of technology in pharmacovigilance practices. For example, mobile health apps and electronic reporting systems can make the process of reporting even adverse drug reaction in cases where the resources are scarce quite easy[8]. In a study that was conducted in Namibia, healthcare practitioners expressed a desire to employ mobile health apps in reporting ADRs which indicates that pharmacovigilance could be advanced by technology in the case of LMIC[29]. However, the successful implementation of such technologies requires adequate infrastructure and training, which are often lacking in these regions. The effective use of available data and sharing of information between countries may enhance the pharmacovigilance system in developing countries. That is, the creation of regional pharmacovigilance networks can facilitate the sharing of best practices, existing resources and data on ADRs[30]. Such collaborative endeavors help countries to be more vigilant and therefore safer in terms of drug use and can also provide timely answers to safety matters that arise[31]. In addition, the local population's involvement in pharmacovigilance may raise the knowledge level concerning reporting adverse drug effects and in the end improve patients' safety and lead to better outcomes.

5. Overcoming disparities in Pharmacovigilance awareness

5.1. Education and Training in Pharmacovigilance:

Education and training of healthcare professionals are prerequisites for the success of pharmacovigilance programs. The studies indicated that healthcare staff with a sound understanding of pharmacovigilance are predisposed to reporting ADRs[32]. Pharmacovigilance education programs are capable of improving the knowledge and understanding of these responsibilities among healthcare providers thereby enhancing the rate of reporting and bettering patient safety. For example, the addition of pharmacovigilance training into courses such as medical and pharmacy education can prepare future healthcare workers to identify and report on ADRs[32,33].

5.2. Community Engagement and Public Awareness

It is important to involve the community and create public awareness on pharmacovigilance so as to improve the ADRs reporting levels. Many of the patients who receive these medications do not understand the need for reporting of ADRs, which leads to low reporting and loss of data on drug safety. Campaigns on health issues aimed at patients by educating them about pharmacovigilance can ensure that they take part in their health care actively. For instance, campaigns aimed at patients to report their experience with use of medications can be beneficial to pharmacovigilance systems [34].

6. Challenges in Pharmacovigilance Implementation and Future Directions

6.1. Challenges in implementation

There are a number of barriers preventing the establishment of systems of pharmacovigilance despite having the potential to be beneficial especially in LMICs. These barriers include the lack of funds, regulatory enforcement, absence of stakeholder cooperation, and a general lack of willingness to incorporate pharmacovigilance in the larger healthcare system[35]. Such exceptions do not take into consideration the existing regulatory frameworks within the LMIC, where adaptability plays a key role in seamless drug monitoring. For example, healthcare workers may be reluctant to report ADRs due to the need for excessive documentation and bureaucratic procedures can deter healthcare professionals from reporting ADRs, leading to significant underreporting. For instance, during outbreaks of infectious diseases, resources may be diverted away from pharmacovigilance efforts, further weakening the system's capacity to monitor drug safety[8].

Effective pharmacovigilance requires coordination between health professionals, the government, the community, and pharmaceutical companies. Yet in many LMICs, these stakeholders are known to operate in silos, leading to fragmented efforts to improve drug safety. For instance, poor communication among healthcare professionals and regulators can lead to persistent safety issues and concerns, potentially putting patients at risk. The absence of a unified approach to pharmacovigilance does not allow for standardization of practices such as the reporting of adverse drug reactions and data collection activities, which is pivotal in examining patterns and determining safety signals that may be present[36].

6.2. Disparities in Pharmacovigilance Awareness

The challenge of incorporating pharmacovigilance into the broader context of the health system is another issue. In several countries, pharmacovigilance is regarded as an independent system rather than an essential component of patient safety and quality of care. This separation could facilitate a lack of knowledge among healthcare workers with respect to the significance of ADR reporting and the role of pharmacovigilance in patient care[16]. Moreover, this lack of coordination is compounded by the absence of standardized training programs for healthcare practitioners regarding pharmacovigilance, creates a general knowledge gap, and hinders effective reporting of adverse drug reactions (ADRs) for reporting and monitoring[32]. Studies have demonstrated that, healthcare professionals do not understand the existing pharmacovigilance systems as well as reporting processes, this could cause further incidences of underreporting[31].

6.3. Future Directions

Solutions to the challenge of under-reporting should be multi-strategic in nature. First, the regulatory frameworks of the pharmacovigilance systems have to be revised to simplify the reporting of ADRs and facilitate participation of the healthcare professionals in surveillance activities. This may involve streamlining documentation requirements and providing clear guidelines on how to report ADRs appropriately. Furthermore, increasing the allocation of resources to pharmacovigilance systems requires also an increase in funding in existing systems. International organizations and governments should consider pharmacovigilance and these budgetary responsibilities in their health expenditure strategies and search for strong resources to supplement them.

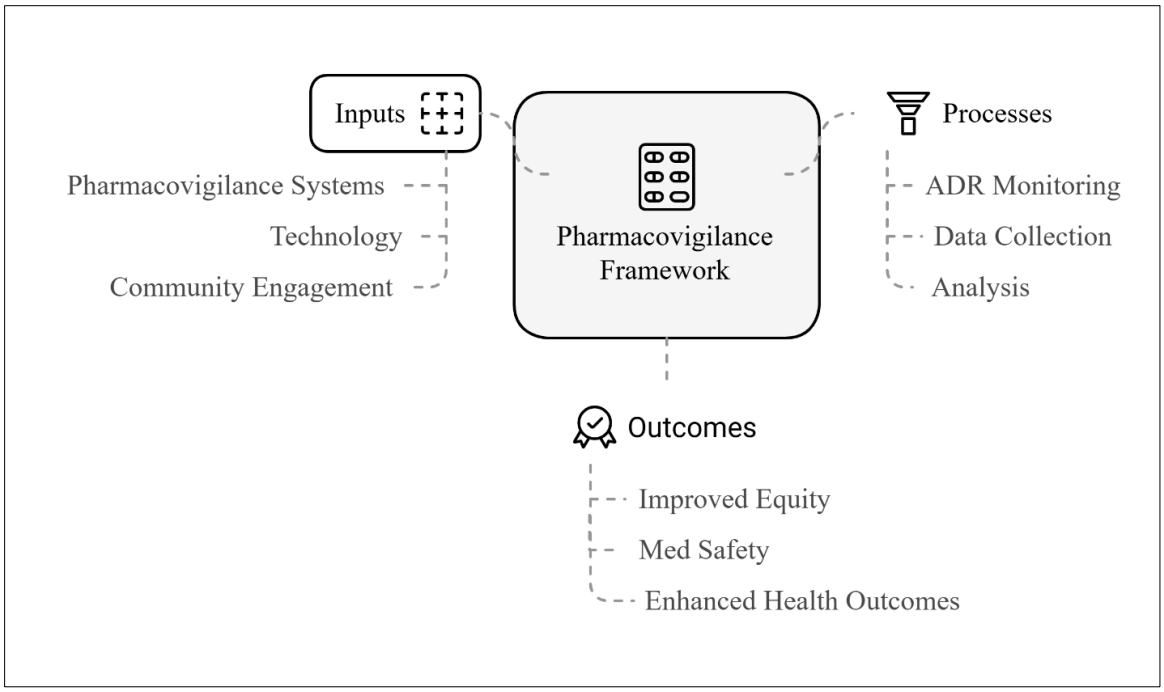

Figure 1 Pharmacovigilance framework for inclusiveness

7. Case Studies

There are many case studies that demonstrate the role of pharmacovigilance in reducing health disparities, particularly in LMICs that have vulnerable populations that are at increased risk when it comes to the use of medications.

- One such case is Bolivia, where sustained efforts towards improvement of the pharmacovigilance system have helped in addressing the problem of low monitoring of adverse drug reactions (ADRs) relating to Chagas disease and tuberculosis medicines. These diseases have a strong incidence in low-income populations and thus effective pharmacovigilance is crucial to ensure patient safety and treatment effectiveness[37]. In Bolivia, international health organizations teamed up with the government to design an elaborate educational package on the recognition and reporting of ADRs to health practitioners. This project not only improved the competence of the health providers but also nurtured the safety culture in the health system. Consequently, there was a huge increase in the reporting of ADRs which made it possible to administer timely changes in allowing for timely interventions and adjustments to treatment protocols hereby promoting the safety and health of the populations in the targeted regions[37]
- In Nigeria, Community health workers have been crucial in preventing health disparities in regard to malaria through the use of pharmacovigilance. In malaria control initiatives, community health workers were recruited to collect data on adverse events associated with the drugs used—this converged with the idea of grassroots pharmacovigilance to encourage local involvement in these efforts as community health workers serve as vital links between healthcare systems and the populations they serve[38]. This initiative empowered these workers with the ability to capture ADRs and helped the Nigerian health authorities complement their drug safety surveillance efforts. Namely, this information was useful not just to showcase to the healthcare providers the risks associated with various treatment options, but also to realize certain risk groups, which would be inherently at more risk of being affected so that resources could be efficiently utilized to reduce the risk[38]

These case studies collectively demonstrate that it is possible to address specific public health issues affecting marginalized groups through targeted pharmacovigilance policies. By strengthening local participation, improving education and training of practitioners as well as embedding pharmacovigilance in other public health activities, countries will be able to strengthen drug safety practices and ultimately improve health outcomes for the whole population, with a particular focus on those populations most likely to suffer from adverse drug events.

8. Conclusion

In addressing health disparities, pharmacovigilance is essential as it makes certain that medications used by diverse populations are safe and effective. This has become even more apparent looking at how the world healthcare system is struggling with issues surrounding the safety of drugs as robust pharmacovigilance frameworks are becoming necessary and not optional. These systems not only monitor ADRs but also serve as important mechanism for reducing the adverse drug reactions that could be suffered by a population with high health burden. However, to maximize the impact of pharmacovigilance, there is need for education of the stakeholders such as healthcare providers on how to use these systems by providing them with relevant information, this change could foster a culture of safety within healthcare systems. This is especially the case in LIMC where the providers lack awareness on how and why reporting adverse drug reactions is necessary. Additionally, engaging in the community in pharmacovigilance tends to empower patients or a caregiver to ensure safety and participate in drug safety monitoring thus leading to collecting data that would be useful in determining the risks involved with the medication. Integration of technology is another way that greatly contributes to the improvement of the overall safety monitoring of drugs.

The integration of advanced data analytics, machine learning, and artificial intelligence can enhance the performance of signal detection and risk assessment, facilitating timely and effective responses to new and evolving safety issues. Automated reporting systems will provide help to healthcare providers and patients for the easier submission of ADRs. Moreover, social network tools and online health forums provide insights into how patients feel about the safe use of medications. For a pharmacovigilance system to be effective, the challenges of implementation must be well met. The absence of appropriate regulatory frameworks, inadequate funding and poor engagement can hinder the development of robust pharmacovigilance frameworks. Such systems require the integration of government agencies, medical practitioners and the non-governmental sectors is necessary to create a supportive environment for pharmacovigilance activities. In turn, this collaboration can enable the integration and sharing of resources, skills and experiences to strengthen drug safety monitoring and enhance the overall health status of the population. With the advancement of science and understanding of the role of pharmacovigilance in public health, these systems have to be incorporated in larger health policies encompassing the wider spectrum of social well-being. This will not only increase the efficiency of pharmacovigilance but also foster the achievement of the overarching aim of health equality.

By prioritizing the safety of medications and addressing the unique needs of vulnerable populations, we can strive for the development of a healthcare system that is appropriate for the diverse needs of the patient population. To conclude, it can be stated that strengthening the existing pharmacovigilance systems is an integral part of the strategy for assuring the safety of public health and ensuring that all groups can receive safe and effective medications. By fostering a culture of safety, the use of new technologies, and eliminating of some systemic challenges, it will be possible to improve pharmacovigilance measures and ultimately health outcomes for the entire population, especially the vulnerable ones. A unified approach is needed from all healthcare workers to ensure that pharmacovigilance support systems are acceptable from the onset and are built into patient care and public health initiatives.

Compliance with ethical standards

Disclosure of conflict of interest

The authors have no conflicts of interest that are directly relevant to the content of this article. The views expressed in this article are the personal views of the authors and may not be understood or quoted as being made on behalf of or reflecting the position of their institutions.

Funding

The authors did not receive financial support from any organization for the submitted work

Code availability

Not applicable, as no custom code or software application was developed or used in this study.

Authors' Contribution

Ashish Jain and Zahabia Adenwala contributed to the conception and design of the manuscript. Ashish Jain drafted the manuscript. Zahabia Adenwala provided critical reviews and key inputs to the manuscript. All authors read, reviewed, and approved the final manuscript.

Highlights

- The paper highlights how pharmacovigilance systems are crucial for monitoring drug safety but face significant challenges in low and middle-income countries due to resource constraints and inadequate infrastructure.
- Technology integration through electronic health records and mobile apps offers promising solutions for improving adverse drug reaction reporting and monitoring.
- Success cases from Bolivia and Nigeria demonstrate how community engagement and healthcare worker training can strengthen pharmacovigilance systems in resource-limited settings.
- The COVID-19 pandemic emphasized the critical need for robust pharmacovigilance systems, particularly for vaccine safety monitoring, while showcasing the importance of addressing health disparities through inclusive drug safety monitoring approaches.

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