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Pharmacovigilance in Developing Countries: Drivers and Barriers

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Abstract

The Pharmacovigilance is crucial for patient safety and improving healthcare quality, particularly in developing countries where the burden of disease is high. This study examines the drivers and barriers to implementing effective pharmacovigilance systems in these countries. Increased availability and use of medicines and the globalization of the pharmaceutical industry have led to an increase in the number of adverse drug reactions and a need for harmonized pharmacovigilance regulations and reporting standards. Developing countries have made significant progress in establishing regulatory frameworks, and international organizations have provided technical assistance and resources. The use of technology, such as mobile phone applications, has made it easier to report adverse drug reactions and monitor drug safety in developing countries. However, several barriers hinder the success of pharmacovigilance systems in developing countries. These include the lack of resources, limited awareness and education, and limited access to information, making it challenging for healthcare professionals and regulatory authorities to monitor drug safety. Fragmented healthcare systems and cultural and social barriers, such as stigma associated with reporting ADRs, further compound the issue. It is essential to address these barriers to promote the successful implementation of pharmacovigilance systems in developing countries. Doing so will improve patient safety, reduce the burden of disease, and enhance healthcare quality. Future research should focus on developing strategies to overcome these barriers and promote the effective implementation of pharmacovigilance systems in developing countries.

Keywords: *Collaboration, Pharmacovigilance, Developing countries, Adverse drug reactions, Barriers, Patient safety*

Introduction

Pharmacovigilance is a critical aspect of healthcare quality, which involves the monitoring, assessment, and evaluation of the safety and efficacy of medicinal products. It plays a crucial role in ensuring that patients receive safe and effective treatments, as well as identifying and preventing potential adverse drug reactions (ADRs). By collecting and analyzing data from various sources, such as clinical trials, spontaneous reports, and observational studies,

pharmacovigilance enables healthcare professionals to make informed decisions regarding the use of drugs and minimize the risk of harm to patients [1].

One of the main goals of pharmacovigilance is to detect and evaluate ADRs associated with the use of medicinal products. ADRs can range from mild to severe and can have a significant impact on patient health, quality of life, and healthcare costs. By identifying ADRs early on, pharmacovigilance can help prevent further harm to patients and improve the overall safety of drugs. It also allows for the assessment of the risk-benefit balance of a drug, which is essential for making informed decisions regarding its use [2], [3].

Pharmacovigilance is also essential for improving healthcare quality by promoting rational use of drugs. Rational drug use involves the selection of appropriate drugs, at the right dose, and for the correct duration, based on a patient's individual needs and medical history. By providing healthcare professionals with information on the safety and efficacy of drugs, pharmacovigilance enables them to make informed decisions regarding the selection and use of drugs, which ultimately improves patient outcomes [4].

An important aspect that falls under the umbrella of pharmacovigilance, which is the practice of monitoring and evaluating the safety and efficacy of pharmaceutical products, is the identification and monitoring of drug interactions, a phenomenon that can transpire when two or more drugs interact with each other, potentially leading to alterations in the efficacy or toxicity of the drugs involved, but through the early identification of such potential drug interactions, pharmacovigilance can play a crucial role in preventing adverse outcomes and ensuring the administration of safe and effective treatments to patients [5], [6].

Pharmacovigilance is also crucial for the post-marketing surveillance of drugs. Even though drugs undergo rigorous testing during clinical trials, not all adverse effects may be identified. By monitoring the safety of drugs in the post-marketing phase, pharmacovigilance can identify any previously unrecognized adverse effects, which can then be addressed promptly.

Finally, pharmacovigilance plays an essential role in public health by ensuring that medicines are safe and effective. By providing regulators with information on the safety and efficacy of drugs, pharmacovigilance enables them to make informed decisions regarding the approval, licensing, and withdrawal of drugs. This ensures that only safe and effective drugs are available on the market, which ultimately improves patient outcomes and enhances public health [7].

Pharmacovigilance is a critical aspect of healthcare quality that plays a crucial role in ensuring patient safety and improving healthcare outcomes. By detecting and evaluating ADRs, promoting rational drug use, identifying and monitoring drug interactions, conducting post-marketing surveillance, and ensuring the safety and efficacy of drugs, pharmacovigilance provides healthcare professionals and regulators with the information needed to make informed decisions regarding the use of drugs. Ultimately, pharmacovigilance is essential for ensuring that patients receive safe and effective treatments, improving healthcare quality, and enhancing public health.

Pharmacovigilance is a critical aspect of healthcare quality, particularly in developing countries where there may be limited resources and infrastructure for monitoring drug safety. Developing countries face unique challenges in implementing effective pharmacovigilance programs, such as inadequate funding, lack of trained personnel, and limited access to information and

technology. Despite these challenges, pharmacovigilance is essential for improving patient safety and ensuring the availability of safe and effective drugs in developing countries.

One of the key challenges in implementing pharmacovigilance programs in developing countries is the lack of trained personnel. There may be a shortage of healthcare professionals with the necessary skills and knowledge to effectively monitor and evaluate drug safety. This can make it difficult to detect and respond to adverse drug reactions, and may also result in limited resources being allocated to pharmacovigilance.

Another challenge in implementing pharmacovigilance in developing countries is the lack of resources and infrastructure. There may be limited funding and support for pharmacovigilance programs, making it difficult to collect and analyze data on drug safety. In addition, there may be limited access to technology and information, which can make it difficult to stay up-to-date with the latest developments in pharmacovigilance.

Cultural factors can also play a role in the implementation of pharmacovigilance programs in developing countries. There may be a lack of awareness and understanding of the importance of pharmacovigilance, and patients may be reluctant to report adverse drug reactions. This can result in under-reporting of adverse reactions, which can make it difficult to accurately assess the safety and efficacy of drugs [8].

Despite these challenges, there are also opportunities for improving pharmacovigilance in developing countries. Collaborative efforts between governments, healthcare professionals, and regulatory agencies can help to overcome the limitations and challenges of pharmacovigilance programs in developing countries. Partnerships with international organizations can also help to improve access to resources and technology, as well as provide training and support to healthcare professionals. Pharmacovigilance is essential for improving patient safety and ensuring the availability of safe and effective drugs in developing countries. While there are unique challenges to implementing pharmacovigilance programs in developing countries, there are also opportunities for improving pharmacovigilance through collaborative efforts and partnerships. By working together to overcome these challenges, we can help to ensure that patients in developing countries receive the highest quality of care and access to safe and effective drugs.

Drivers of Pharmacovigilance in Developing Countries:

Increased availability and use of medicines:

The increased availability and use of medicines in developing countries has brought about a significant shift in the healthcare industry. As healthcare systems have improved, more people are gaining access to life-saving medications that were previously out of reach. This increased demand for medication has, however, led to a corresponding rise in adverse drug reactions (ADRs).

ADRs are unintended and harmful effects of medication use that occur when patients receive a drug at a therapeutic dose. These reactions can range from mild to severe, and in some cases, they can even be fatal. Common examples of ADRs include allergic reactions, drug toxicity, and drug interactions.

As the availability and use of medicines continue to grow, the need for pharmacovigilance becomes more critical. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems [9]. Its primary aim is to promote patient safety by identifying and evaluating potential ADRs and taking appropriate measures to prevent harm.

Pharmacovigilance is essential in developing countries where healthcare systems may not be as robust as in developed nations. In these countries, access to healthcare is often limited, and medication regulation may be lax. Without proper pharmacovigilance, patients may be at risk of receiving substandard or counterfeit medications, which can lead to serious health consequences.

To address the growing need for pharmacovigilance, governments and other stakeholders in developing countries are increasing their investments in this field. They are setting up pharmacovigilance systems and training healthcare professionals to identify and report potential ADRs. In addition, international organizations are collaborating with local governments to provide technical assistance and support to strengthen pharmacovigilance capacity in these countries. Moreover, the growing demand for medicines in developing countries is not just limited to the treatment of acute illnesses, but also chronic diseases. Many developing countries are now facing a double burden of communicable and non-communicable diseases [10]. As a result, patients in these countries often require long-term medication use to manage their conditions, which increases the risk of ADRs.

The increased availability and use of medicines in developing countries have brought about many benefits, but it has also created new challenges, such as the rising incidence of adverse drug reactions. As such, it is essential to prioritize pharmacovigilance to ensure patient safety and promote the responsible use of medications. By working together, governments, healthcare professionals, and other stakeholders can strengthen pharmacovigilance systems and prevent harm caused by ADRs [11].

Globalization of the pharmaceutical industry:

The globalization of the pharmaceutical industry has transformed the way drugs are developed, manufactured, and distributed worldwide. With advancements in technology and trade liberalization policies, pharmaceutical companies can now operate on a global scale, producing and distributing medicines to multiple countries simultaneously. However, this globalization of the industry has created a need for harmonized pharmacovigilance regulations and reporting standards.

Pharmacovigilance regulations and reporting standards are essential to ensure patient safety and protect public health. These regulations and standards govern the collection, analysis, and dissemination of information related to adverse drug reactions (ADRs) and other drug-related problems. They also provide guidelines for the reporting of ADRs to regulatory authorities and other stakeholders.

The lack of harmonization in pharmacovigilance regulations and reporting standards across different countries can lead to confusion and inconsistency in drug safety monitoring. For example, different countries may have different requirements for reporting ADRs, resulting in

delays or incomplete reporting. This can ultimately impact patient safety, as important information about potential risks associated with a drug may not be communicated effectively.

To address these issues, the World Health Organization (WHO) has established the International Drug Monitoring Program (IDMP), which aims to promote the standardization of pharmacovigilance regulations and reporting standards globally. The IDMP has developed a set of guidelines for the reporting of ADRs, which provides a common framework for regulatory authorities and other stakeholders to follow [12].

In addition, many countries have established their own pharmacovigilance regulations and reporting standards, which are often based on the WHO guidelines. These regulations and standards are designed to ensure that pharmaceutical companies operating within their borders are compliant with international best practices for drug safety monitoring . The globalization of the pharmaceutical industry has also led to an increase in the number of clinical trials conducted in developing countries. While this has the potential to benefit patients in these countries by providing access to new treatments, it also raises concerns about the safety and ethical implications of these trials.

To address these concerns, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) has developed guidelines for the conduct of clinical trials. These guidelines provide a framework for the ethical and scientific conduct of clinical trials, ensuring that they are conducted in a safe and responsible manner.

The globalization of the pharmaceutical industry has created a need for harmonized pharmacovigilance regulations and reporting standards to ensure patient safety and protect public health. The establishment of the International Drug Monitoring Program and the guidelines developed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use have helped to promote the standardization of pharmacovigilance regulations and reporting standards globally. It is important that regulatory authorities and other stakeholders continue to work together to ensure that these regulations and standards are implemented effectively to promote the safe and responsible use of medications.

Improved regulatory framework:

Developing countries have made significant progress in recent years in establishing regulatory frameworks that promote the safety and efficacy of medicines. The importance of such frameworks cannot be overstated, as they play a crucial role in ensuring that medicines are of high quality and that they are used in a safe and effective manner.

One of the key challenges faced by developing countries in the past was the lack of robust regulatory frameworks for medicines. This resulted in many low-quality and counterfeit medicines being sold in these countries, which posed a serious risk to public health. In addition, inadequate regulatory frameworks often meant that medicines were not subject to appropriate testing and evaluation, which could lead to serious adverse effects.

However, in recent years, many developing countries have recognized the importance of establishing strong regulatory frameworks for medicines. They have taken steps to create

regulatory bodies, develop laws and regulations, and establish processes for the evaluation, registration, and monitoring of medicines.

For example, the African Medicines Regulatory Harmonization (AMRH) initiative was launched in 2009 with the aim of harmonizing regulatory processes and standards for medicines across the African continent. The initiative has helped to establish a common regulatory framework that promotes the safety and efficacy of medicines and facilitates their approval and registration in multiple African countries.

Similarly, in Asia, the Association of Southeast Asian Nations (ASEAN) has established the ASEAN Harmonization Scheme (AHS) for the registration of pharmaceutical products. The AHS aims to harmonize the regulatory requirements for pharmaceutical products across ASEAN member countries, thereby reducing the regulatory burden on pharmaceutical companies and promoting access to safe and effective medicines for patients in the region.

In addition to these regional initiatives, many developing countries have also established their own regulatory bodies and implemented regulatory reforms to improve the safety and efficacy of medicines. For example, the National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria has implemented a range of reforms to strengthen its regulatory framework for medicines, including the establishment of a post-marketing surveillance system for monitoring adverse drug reactions [13]–[15].

The establishment of strong regulatory frameworks for medicines has many benefits. It helps to ensure that medicines are of high quality, safe, and effective, and it provides assurance to patients and healthcare professionals that medicines have been rigorously evaluated and approved. In addition, it can help to promote innovation and investment in the pharmaceutical sector, as companies are more likely to invest in countries with strong regulatory frameworks.

However, there are still many challenges that need to be addressed to ensure that regulatory frameworks in developing countries are effective. For example, many regulatory bodies in developing countries still lack the resources and capacity to effectively evaluate and monitor medicines, and there may be gaps in the regulatory frameworks that allow low-quality or counterfeit medicines to enter the market.

Developing countries have made significant strides in establishing regulatory frameworks that promote the safety and efficacy of medicines. The establishment of regional initiatives such as the African Medicines Regulatory Harmonization initiative and the ASEAN Harmonization Scheme, as well as the implementation of regulatory reforms at the national level, has helped to improve the quality of medicines and protect public health. However, there is still much work to be done to ensure that these regulatory frameworks are effective and that they can keep pace with the rapidly evolving pharmaceutical industry [16].

International cooperation:

The importance of international cooperation cannot be overstated when it comes to improving pharmacovigilance systems in developing countries. International organizations such as the World Health Organization (WHO) have played a critical role in providing technical assistance and resources to support the development of pharmacovigilance systems in these countries.

One of the key ways in which the WHO has supported the development of pharmacovigilance systems is by providing guidance and recommendations on best practices. The organization has developed a range of guidelines and tools for pharmacovigilance, including the International Drug Monitoring: The Role of National Centres report, which outlines the key components of a successful pharmacovigilance system. In addition, the WHO has developed the VigiAccess database, which provides a global overview of adverse drug reactions and helps to facilitate the exchange of pharmacovigilance information between countries.

The WHO has also provided technical assistance to developing countries to help them establish and strengthen their pharmacovigilance systems. This assistance may include training and capacity building for pharmacovigilance staff, support for the establishment of national pharmacovigilance centres, and assistance with the development of pharmacovigilance regulations and guidelines.

In addition to the WHO, other international organizations have also played a role in supporting the development of pharmacovigilance systems in developing countries. For example, the United States Pharmacopeia (USP) has provided technical assistance and resources to support the development of pharmacovigilance systems in several African countries, including Ghana, Tanzania, and Uganda. The USP has helped to establish national pharmacovigilance centres, provided training and capacity building for pharmacovigilance staff, and supported the development of pharmacovigilance regulations and guidelines.

The importance of international cooperation in pharmacovigilance cannot be overstated. Developing countries often lack the resources, capacity, and expertise to establish and maintain effective pharmacovigilance systems on their own. International organizations can provide the necessary technical assistance, resources, and guidance to help these countries develop robust pharmacovigilance systems that can protect public health and promote the safe and effective use of medicines.

In addition to the benefits to developing countries, international cooperation in pharmacovigilance also benefits the global community as a whole. Improved pharmacovigilance systems in developing countries can help to prevent the spread of infectious diseases and the emergence of drug-resistant pathogens, which can have significant impacts on global health.

International cooperation is a critical component of efforts to improve pharmacovigilance systems in developing countries. The support provided by organizations such as the WHO and the USP has helped to establish and strengthen pharmacovigilance systems in these countries, which has in turn promoted the safe and effective use of medicines and protected public health. Continued international cooperation and collaboration will be essential to ensuring that pharmacovigilance systems in developing countries remain effective and can keep pace with the rapidly evolving pharmaceutical industry.

Technological advancements:

The advancement of technology has revolutionized the field of pharmacovigilance, especially in developing countries. The use of mobile phone applications and other digital tools has made it easier to report adverse drug reactions (ADRs) and monitor drug safety in real-time, leading to improved patient safety.

Mobile phone applications have been developed to facilitate pharmacovigilance in developing countries. These applications are user-friendly and easily accessible, allowing patients and healthcare professionals to report ADRs directly to pharmacovigilance centres. The data collected through these applications can be used to identify potential safety concerns, monitor drug efficacy, and inform decision-making around drug approval and withdrawal.

Other technological advancements, such as electronic health records (EHRs), have also contributed to the improvement of pharmacovigilance in developing countries. EHRs can capture patient data, including medications, medical history, and laboratory results, providing a comprehensive view of a patient's health status [17], [18]. This information can be used to identify potential ADRs, monitor drug safety, and inform healthcare decision-making.

In addition, digital tools such as data mining and machine learning algorithms can help to identify patterns and trends in ADR data, allowing for the early detection of potential safety concerns. These tools can also be used to predict drug interactions and identify patient subgroups that may be more susceptible to ADRs.

However, the adoption of technology in pharmacovigilance is not without its challenges, particularly in developing countries. One of the key challenges is the limited access to technology and digital infrastructure. Many developing countries lack the necessary technological infrastructure and resources to support the use of digital tools in pharmacovigilance. Additionally, there may be a lack of awareness or education around the use of digital tools, which may limit their effectiveness.

Despite these challenges, the use of technology in pharmacovigilance has the potential to revolutionize the field, particularly in developing countries. The widespread use of mobile phone applications and other digital tools has the potential to significantly improve the reporting of ADRs and enhance drug safety monitoring, leading to improved patient outcomes.

Technological advancements have played a critical role in the improvement of pharmacovigilance in developing countries. The use of mobile phone applications, electronic health records, and other digital tools has made it easier to report ADRs and monitor drug safety in real-time, leading to improved patient safety. However, challenges such as limited access to technology and digital infrastructure remain, highlighting the need for continued efforts to promote the adoption of technology in pharmacovigilance in developing countries [19].

Barriers to Pharmacovigilance in Developing Countries:

Lack of resources:

One of the major challenges facing developing countries in the establishment of effective pharmacovigilance systems is the lack of resources, both financial and human. This lack of resources can have a significant impact on the ability of these countries to effectively monitor drug safety and prevent adverse drug reactions (ADRs).

One of the key financial challenges is the cost associated with establishing and maintaining pharmacovigilance systems. This includes the cost of training healthcare professionals on how to report ADRs, setting up pharmacovigilance centres, and developing and implementing reporting and monitoring systems. Many developing countries may not have the financial

resources to invest in these initiatives, which can limit the effectiveness of pharmacovigilance efforts.

In addition to financial challenges, there may be a shortage of trained healthcare professionals with the necessary skills and knowledge to effectively carry out pharmacovigilance activities. This can include a lack of pharmacists, doctors, nurses, and other healthcare professionals who are trained in pharmacovigilance. Without sufficient human resources, developing countries may struggle to implement and maintain effective pharmacovigilance systems.

Furthermore, inadequate infrastructure and limited access to healthcare facilities in some regions may make it difficult to collect and report ADR data. For example, in remote areas with limited access to healthcare facilities, patients may not have the opportunity to report ADRs to healthcare professionals or pharmacovigilance centres. This can result in underreporting of ADRs and limit the effectiveness of pharmacovigilance efforts.

Despite these challenges, there are initiatives underway to address the lack of resources in developing countries. International organizations such as the World Health Organization (WHO) and the International Society of Pharmacovigilance (ISoP) are providing technical assistance and resources to support the development of pharmacovigilance systems in these countries. Additionally, partnerships between developed and developing countries can help to leverage resources and support the establishment of effective pharmacovigilance systems.

The lack of resources, including financial and human resources, is a significant challenge facing developing countries in the establishment of effective pharmacovigilance systems. Addressing these challenges will require investment in training, infrastructure, and resources to support the development and maintenance of effective pharmacovigilance systems. While there are initiatives underway to address these challenges, continued efforts are needed to ensure that all patients, regardless of where they live, have access to safe and effective medicines.

Limited awareness and education:

One of the major challenges in developing countries regarding pharmacovigilance is limited awareness and education on its importance among healthcare professionals and the public. This lack of awareness and education can hinder the establishment of effective pharmacovigilance systems and can limit the reporting of adverse drug reactions (ADRs).

Limited awareness and education about pharmacovigilance can result in healthcare professionals not fully understanding the importance of reporting ADRs, which can lead to underreporting. It can also limit the ability of healthcare professionals to recognize and diagnose ADRs. Similarly, limited education and awareness among the public can lead to a lack of reporting of ADRs, as patients may not be aware of the potential risks associated with the medicines they are taking.

There may be several reasons for the lack of awareness and education regarding pharmacovigilance in developing countries. One reason is the limited availability of pharmacovigilance training for healthcare professionals. This can be due to a shortage of resources, including financial and human resources, to develop and implement training programs.

In addition, there may be a lack of public awareness campaigns regarding pharmacovigilance in developing countries. This can result in patients not understanding the importance of reporting ADRs and not knowing how to do so. Furthermore, language barriers and low literacy rates in some regions may make it difficult to disseminate information about pharmacovigilance to the public.

Despite these challenges, there are initiatives underway to address limited awareness and education about pharmacovigilance in developing countries. For example, the WHO has established a Global Pharmacovigilance Training and Research Program to provide training to healthcare professionals in developing countries. Similarly, partnerships between developed and developing countries can help to promote the importance of pharmacovigilance and provide resources to support education and training initiatives.

In addition to the initiatives mentioned, there are other steps that can be taken to improve awareness and education about pharmacovigilance in developing countries. For example, collaborations between international organizations and local healthcare professionals can help to develop culturally appropriate training and educational materials. These materials can be disseminated through a variety of channels, including healthcare facilities, social media, and community outreach programs.

Furthermore, integrating pharmacovigilance education into the curricula of healthcare training programs can help to ensure that healthcare professionals are equipped with the knowledge and skills necessary to report and manage ADRs. This can help to promote a culture of safety and improve patient outcomes.

Finally, improving public awareness of pharmacovigilance can be achieved through the use of mass media campaigns, community engagement programs, and patient information leaflets. These initiatives can help patients to recognize and report potential ADRs, as well as educate them about the importance of following medication instructions and adhering to dosage recommendations.

While limited awareness and education about pharmacovigilance remains a significant challenge in developing countries, there are steps that can be taken to address this issue. By investing in training programs, public awareness campaigns, and resources to support education and training initiatives, we can promote the safe and effective use of medicines and improve patient outcomes.

Limited access to information:

In developing countries, limited access to information is a major challenge in the establishment and maintenance of effective pharmacovigilance systems. This challenge manifests in various ways, including the lack of access to drug safety data, adverse drug reaction (ADR) reports, and other critical information related to the safety and efficacy of medicines.

Healthcare professionals and regulatory authorities rely on access to information to monitor drug safety and identify potential risks associated with the use of medicines. Without this

information, it is challenging to make informed decisions about the use of medicines and to take appropriate action in response to emerging safety concerns.

One of the main reasons for the limited access to information in developing countries is the lack of infrastructure to support the collection, storage, and dissemination of data. Many healthcare facilities in developing countries lack the necessary systems to record and report ADRs, and there may be limited resources to establish and maintain databases to store this information.

Similarly, regulatory authorities may have limited capacity to collect and analyze drug safety data. In some cases, there may be a lack of resources to develop and implement pharmacovigilance systems or limited access to technology and tools to support data analysis.

Furthermore, limited access to information can also result from inadequate communication between healthcare professionals and regulatory authorities. There may be a lack of effective communication channels to report ADRs, and healthcare professionals may not be aware of the reporting requirements or the appropriate channels for reporting ADRs.

Despite these challenges, there are initiatives underway to address the issue of limited access to information in developing countries. For example, the WHO has established the Global Individual Case Safety Reporting (ICSR) Initiative to facilitate the collection and reporting of ADRs. This initiative aims to improve the quality of information related to drug safety and to promote better communication between healthcare professionals and regulatory authorities.

Similarly, partnerships between developed and developing countries can help to improve access to information by providing resources and expertise to support the development of pharmacovigilance systems. These partnerships can help to establish communication channels, develop databases to store ADR data, and provide training and technical support to healthcare professionals and regulatory authorities.

Limited access to information is a significant challenge in developing countries regarding pharmacovigilance. Addressing this challenge will require investment in infrastructure, technology, and training programs to support the collection, storage, and dissemination of data. By improving access to information, healthcare professionals and regulatory authorities can better monitor drug safety and take appropriate action to promote the safe and effective use of medicines.

Fragmented healthcare systems:

Fragmented healthcare systems are a major challenge in developing countries that can make it challenging to establish and maintain effective pharmacovigilance systems. In many developing countries, healthcare delivery is often fragmented and decentralized, with multiple providers, clinics, and hospitals serving different populations. This fragmentation can make it difficult to collect and analyze data on adverse drug reactions and to implement comprehensive pharmacovigilance programs.

One of the key challenges of fragmented healthcare systems is the lack of centralized reporting mechanisms. When healthcare providers are distributed across multiple facilities and geographic areas, there may be no centralized system for reporting adverse drug reactions. This can lead to the underreporting of ADRs and an incomplete picture of the safety profile of a given

medicine. Without comprehensive reporting, regulatory authorities may not be able to identify emerging safety concerns or take appropriate action to address them.

Additionally, fragmented healthcare systems can result in inconsistencies in the use of medicines and prescribing practices. With multiple providers serving different populations, there may be differences in prescribing habits, dosages, and treatment regimens. These variations can impact the safety and efficacy of medicines, and make it more challenging to monitor and assess their safety.

Moreover, in fragmented healthcare systems, patients may seek care from multiple providers and receive prescriptions from multiple sources, making it difficult to track the use of medicines and identify potential interactions or adverse effects. This can lead to a lack of transparency in the use of medicines and hinder the ability to monitor drug safety.

Despite these challenges, there are initiatives underway to address the issue of fragmented healthcare systems in developing countries. One example is the development of electronic health records (EHRs) and other health information systems. These systems can provide a centralized platform for healthcare providers to report adverse drug reactions and share information on prescribing practices, dosage, and treatment regimens [20], [21]. EHRs can also help to track the use of medicines and identify potential interactions or adverse effects.

Another approach is the establishment of coordinated pharmacovigilance networks. These networks can bring together healthcare providers, regulatory authorities, and other stakeholders to share information and coordinate efforts to monitor drug safety. Coordinated networks can help to standardize reporting practices, promote transparency in the use of medicines, and identify emerging safety concerns.

Fragmented healthcare systems in developing countries can make it challenging to establish and maintain effective pharmacovigilance systems. Addressing this challenge will require investment in technology and infrastructure to support centralized reporting and coordination across healthcare providers and regulatory authorities. By improving the coordination and communication of pharmacovigilance efforts, we can promote the safe and effective use of medicines and improve patient outcomes.

Cultural and social barriers:

Cultural and social barriers pose a significant challenge to the success of pharmacovigilance systems in developing countries. Stigma associated with reporting adverse drug reactions (ADRs) can discourage patients and healthcare professionals from reporting suspected ADRs, leading to underreporting and a lack of accurate information on drug safety. This can have serious implications for patient safety, as regulators may not be able to identify and address emerging safety concerns [22].

Lack of trust in healthcare professionals and regulatory authorities is another cultural and social barrier that can hinder the success of pharmacovigilance systems. In some developing countries, there is a perception among the public that healthcare professionals and regulatory authorities are corrupt or ineffective, and that their actions are motivated by personal gain rather than the wellbeing of patients [23]. This can lead to a lack of confidence in the healthcare system, and a reluctance to report ADRs or follow treatment regimens as prescribed.

Cultural and social barriers can also impact the use of traditional medicines, which are widely used in developing countries. Many traditional medicines are not subject to the same regulatory oversight as modern medicines, and may not be evaluated for safety and efficacy in the same way. As a result, there may be a lack of reliable information on the safety and potential side effects of traditional medicines. This can contribute to underreporting of ADRs associated with traditional medicines, and make it difficult to monitor their safety.

To address these cultural and social barriers, it is essential to increase awareness and education on the importance of pharmacovigilance and the role of patients, healthcare professionals, and regulatory authorities in reporting ADRs [24]. This can help to reduce stigma and increase reporting rates, leading to a more complete picture of drug safety.

Improving trust in healthcare professionals and regulatory authorities is also critical. This can be achieved through increased transparency in the healthcare system, including transparent reporting of ADRs and efforts to combat corruption and fraud. It is also important to promote effective communication between healthcare providers and patients, and to ensure that patients are involved in decision-making regarding their treatment. Additionally, it is essential to address the use of traditional medicines in developing countries. This may involve strengthening regulatory oversight of traditional medicines, promoting research on their safety and efficacy, and increasing awareness among healthcare professionals and the public on their potential risks and benefits.

Cultural and social barriers pose a significant challenge to the success of pharmacovigilance systems in developing countries. Addressing these barriers will require a multifaceted approach that involves increasing awareness and education, promoting trust in the healthcare system, and addressing the use of traditional medicines [25]–[27]. By overcoming these challenges, we can improve the safety and efficacy of medicines and promote better health outcomes for patients in developing countries.

Conclusion

The future of pharmacovigilance in developing countries is a critical issue for healthcare professionals, regulators, and policymakers. While there have been significant improvements in pharmacovigilance in recent years, there is still a long way to go to ensure that patients in developing countries have access to safe and effective drugs.

One of the main challenges facing pharmacovigilance in developing countries is the lack of resources and infrastructure. This includes limited funding and support for pharmacovigilance programs, as well as a shortage of trained personnel and limited access to technology and information. Without adequate resources and infrastructure, it can be difficult to collect and analyze data on drug safety, detect and respond to adverse drug reactions, and ensure the availability of safe and effective drugs. This is particularly true in low-income countries, where there may be limited resources for healthcare and regulatory services.

Another challenge facing pharmacovigilance in developing countries is the lack of awareness and understanding of the importance of drug safety. This includes a lack of knowledge among healthcare professionals and patients about the risks and benefits of drugs, as well as limited access to information on drug safety. This can lead to under-reporting of adverse drug reactions, which can make it difficult to accurately assess the safety and efficacy of drugs. It can also result

in the inappropriate use of drugs, which can increase the risk of adverse drug reactions and other health problems.

Despite these challenges, there are also opportunities for improving pharmacovigilance in developing countries. One of the main opportunities is the increasing use of technology and innovation in healthcare. This includes the use of electronic medical records, telemedicine, and other digital tools to improve the collection and analysis of data on drug safety. By leveraging these technologies, healthcare professionals and regulators can more effectively monitor drug safety and identify potential adverse drug reactions.

Another opportunity for improving pharmacovigilance in developing countries is through collaborative efforts and partnerships. This includes partnerships between governments, healthcare professionals, regulatory agencies, and international organizations to improve drug safety and access to safe and effective drugs. These partnerships can provide funding and support for pharmacovigilance programs, as well as training and resources for healthcare professionals and patients. They can also help to raise awareness and understanding of the importance of drug safety, which can improve reporting of adverse drug reactions and increase the appropriate use of drugs.

In addition, there are opportunities for improving pharmacovigilance through regulatory reform. This includes the development of more robust regulatory frameworks and the strengthening of regulatory agencies. By improving regulatory oversight and enforcement, governments can help to ensure that only safe and effective drugs are available on the market, which can improve patient safety and health outcomes. This may require changes in laws and regulations, as well as investment in regulatory infrastructure and resources.

There are also opportunities for improving pharmacovigilance through public-private partnerships. This includes partnerships between pharmaceutical companies and governments or other stakeholders to improve drug safety and access to safe and effective drugs. By working together, these partnerships can help to develop new drugs and improve the safety and efficacy of existing drugs. They can also provide funding and resources for pharmacovigilance programs and other healthcare initiatives.

Finally, there are opportunities for improving pharmacovigilance through patient engagement and empowerment. This includes empowering patients to report adverse drug reactions and providing them with information on the risks and benefits of drugs. By involving patients in the pharmacovigilance process, healthcare professionals and regulators can more effectively monitor drug safety and identify potential adverse drug reactions. This can also help to increase patient trust and confidence in the healthcare system, which can improve patient outcomes.

The future of pharmacovigilance in developing countries is complex and multifaceted, with many challenges and opportunities. While there are significant challenges facing pharmacovigilance in developing countries, such as limited resources, infrastructure, and awareness, there are also opportunities for improving drug safety through technology and innovation, collaborative efforts and partnerships, regulatory reform, public-private partnerships, and patient engagement and empowerment.

However, addressing these challenges and seizing these opportunities will require significant investment and commitment from governments, healthcare professionals, regulators, and

other stakeholders. This may include investment in regulatory infrastructure and resources, training and education for healthcare professionals and patients, and partnerships and collaborations to improve drug safety and access to safe and effective drugs.

Furthermore, efforts to improve pharmacovigilance in developing countries must be tailored to the specific needs and contexts of each country. This may include addressing cultural and linguistic barriers, improving healthcare infrastructure, and addressing other social determinants of health that can impact drug safety and access to healthcare.

Ultimately, the future of pharmacovigilance in developing countries is critical for improving patient safety and healthcare quality. By addressing the challenges and seizing the opportunities outlined above, we can work towards a future where all patients have access to safe and effective drugs and healthcare services, regardless of where they live.

References

[1] A. Cocos, A. G. Fiks, and A. J. Masino, "Deep learning for pharmacovigilance: recurrent neural network architectures for labeling adverse drug reactions in Twitter posts," *J. Am. Med. Inform. Assoc.*, vol. 24, no. 4, pp. 813–821, Jul. 2017.

[2] R. Leaman, L. Wojtulewicz, R. Sullivan, A. Skariah, J. Yang, and G. Gonzalez, "Towards internet-age pharmacovigilance: extracting adverse drug reactions from user posts to health-related social networks," in *Proceedings of the 2010 workshop on biomedical natural language processing*, 2010, pp. 117–125.

[3] S. Elshafie, I. Zaghloul, and A. M. Roberti, "Pharmacovigilance in developing countries (part I): importance and challenges," *International journal of clinical*, 2018.

[4] M. Pirmohamed, K. N. Atuah, A. N. O. Dodoo, and P. Winstanley, "Pharmacovigilance in developing countries," *BMJ*, 2007.

[5] P. Dhake, R. Dixit, and D. Manson, "Calculating a Severity Score of an Adverse Drug Event Using Machine Learning on the FAERS Database," *IIMA/ICITED UWS*, 2017.

[6] P. Dhake, R. Dixit, D. Manson, R. Schumaker, and M. Veronin, "Calculating a Severity Score of an Adverse Drug Event Using Machine Learning on the FAERS Database," in *IIMA/ICITED UWS Joint Conference*, 2017, pp. 20–30.

[7] R. Harpaz *et al.*, "Text mining for adverse drug events: the promise, challenges, and state of the art," *Drug Saf.*, vol. 37, no. 10, pp. 777–790, Oct. 2014.

[8] A. Sarker and G. Gonzalez, "Portable automatic text classification for adverse drug reaction detection via multi-corpus training," *J. Biomed. Inform.*, vol. 53, pp. 196–207, Feb. 2015.

[9] R. P. Schumaker, M. A. Veronin, T. Rohm, M. Boyett, and R. R. Dixit, "A data driven approach to profile potential SARS-CoV-2 drug interactions using TylerADE," *J. Int. Technol. Inf. Manag.*, vol. 30, no. 3, pp. 108–142, Jan. 2021.

[10] A. Nikfarjam *et al.*, "Early Detection of Adverse Drug Reactions in Social Health Networks: A Natural Language Processing Pipeline for Signal Detection," *JMIR Public Health Surveill*, vol. 5, no. 2, p. e11264, Jun. 2019.

[11] A. Nikfarjam, A. Sarker, K. O'Connor, R. Ginn, and G. Gonzalez, "Pharmacovigilance from social media: mining adverse drug reaction mentions using sequence labeling with word embedding cluster features," *J. Am. Med. Inform. Assoc.*, vol. 22, no. 3, pp. 671–681, May 2015.

[12] D. Thomas and S. Zachariah, “Chapter 11 - Knowledge, Attitude, and Practice of Pharmacovigilance in Developing Countries,” in *Social and Administrative Aspects of Pharmacy in Low- and Middle-Income Countries*, M. I. M. Ibrahim, A. I. Wertheimer, and Z.-U.-D. Babar, Eds. Academic Press, 2018, pp. 177–193.
[13] R. H. Meyboom, A. C. Egberts, F. W. Gribnau, and Y. A. Hekster, “Pharmacovigilance in perspective,” *Drug Saf.*, vol. 21, no. 6, pp. 429–447, Dec. 1999.
[14] L. Amadi and M. Amadi, “Sustainable drug consumption, regulatory dynamics and fake drug repositioning in Nigeria: A case of NAFDAC,” *Sci-Afric J Sci Issues Res Essays*, 2014.
[15] O. Chinwendu, “The fight against fake drugs by NAFDAC in Nigeria,” 2008. [Online]. Available: http://bibalex.org/baifa/Attachment/Documents/193922.pdf.
[16] J. E. Campbell, M. Gossell-Williams, and M. G. Lee, “A Review of Pharmacovigilance,” *West Indian Med. J.*, vol. 63, no. 7, pp. 771–774, Dec. 2014.
[17] M. A. Veronin, R. P. Schumaker, and R. R. Dixit, “A systematic approach to’cleaning’of drug name records data in the FAERS database: a case report,” *Journal of Big …*, 2020.
[18] R. Dixit, M. Ogwo, and R. P. Schumaker, “Irony of the FAERS Database: An Analysis of Data Input Errors and Potential Consequences,” *IIMA/ICITED Joint*, 2018.
[19] A. M. Ahmed, I. M. Izham, and P. Subish, “Importance of consumer pharmacovigilance system in developing countries: a case of Malaysia,” *J. Clin. Diagn. Res.*, 2010.
[20] M. A. Veronin, R. P. Schumaker, R. R. Dixit, P. Dhake, and M. Ogwo, “A systematic approach to ‘cleaning’ of drug name records data in the FAERS database: a case report,” *International Journal of Big Data Management*, vol. 1, no. 2, p. 105, 2020.
[21] M. A. Veronin, R. P. Schumaker, R. R. Dixit, and H. Elath, “Opioids and Frequency Counts in the US Food and Drug Administration Adverse Event Reporting System (FAERS) Database,” *Current Aspects in Pharmaceutical Research and Development Vol. 8*, pp. 35–43, 2022.
[22] L. Kabore, P. Millet, S. Fofana, D. Berdai, C. Adam, and F. Haramburu, “Pharmacovigilance systems in developing countries: an evaluative case study in Burkina Faso,” *Drug Saf.*, vol. 36, no. 5, pp. 349–358, May 2013.
[23] A. O. Isah, S. N. Pal, S. Olsson, and A. Dodoo, “Specific features of medicines safety and pharmacovigilance in Africa,” *Adv. Drug Res.*, 2012.
[24] M. A. Veronin, R. Dixit, and R. P. Schumaker, “A Decision Tree Analysis of Opioid and Prescription Drug Interactions Leading to Death Using the FAERS Database,” in *IIMA/ICITED Joint Conference 2018*, 2018, pp. 67–67.
[25] V. V. Ragul and P. Saranya, “Pharmacovigilance-an overview in a pharmacist perspective,” *J. Pharm. Res.*, 2020.
[26] S. Palaian, “Pharmacovigilance practices and activities: Issues, challenges, and future direction,” *Social and Administrative Aspects of Pharmacy in Low*, 2018.
[27] S. D. Fernandes, N. V. Anoop, and L. J. Castelino, “A national approach to pharmacovigilance: The case of India as a growing hub of global clinical trials,” *Research in Social and*, 2019.