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Bridging the Gap in Herbal Pharmacovigilance: Global Insights, Challenges, and Future Directions

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ABSTRACT: Herbal medicines are widely used across the globe due to their perceived safety, affordability, and cultural acceptance. However, increasing reports of adverse drug reactions (ADRs), herb–drug interactions, and quality issues highlight the need for robust pharmacovigilance systems. Herbal pharmacovigilance (herbovigilance) focuses on monitoring the safety of plant-based medicines. Despite global efforts, significant gaps persist due to lack of standardization, underreporting, and regulatory limitations. This review explores global perspectives, identifies major challenges, and proposes future strategies to strengthen herbal pharmacovigilance systems.

KEYWORDS: Herbal medicines, Pharmacovigilance, Herbovigilance, ADR, Safety monitoring, Traditional medicine

1.INTRODUCTION:-

Pharmacovigilance of herbal medicines refers to the science and activities involved in detecting, assessing, understanding, and preventing adverse effects or any other problems related to the use of herbal products. With the growing global use of herbal medicines—often perceived as natural and safe—there is an increasing need to monitor their safety and efficacy. Herbal preparations can cause adverse reactions due to factors such as poor quality control, contamination, adulteration with synthetic drugs or heavy metals, misidentification of plants, and herb–drug interactions. Unlike conventional drugs, many herbal products lack standardization, clinical evidence, and proper labelling. leading to unpredictable therapeutic outcomes. The World Health Organization (WHO) has recognized the importance of integrating herbal pharmacovigilance into national drug monitoring systems to ensure patient safety. In India, the Ministry of AYUSH has established the Pharmacovigilance Programme for Ayurveda, Siddha, Unani, and Homeopathy (ASU&H) to monitor and document adverse drug reactions associated with traditional medicines. The main objectives of herbal pharmacovigilance include ensuring safe use, identifying risks, maintaining product quality, and promoting rational therapy. However, challenges such as underreporting, lack of awareness among healthcare professionals, and limited scientific data still exist. Therefore, strengthening herbal pharmacovigilance systems is essential to enhance the credibility, safety, and effectiveness of herbal medicines in global healthcare.

Pharmacovigilance (PV) is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. While traditionally focused on synthetic drugs, the principles of PV are increasingly being applied to herbal medicines, traditional remedies, and dietary supplements. This has become crucial due to the global increase in the use of herbal products, driven by factors such as a perception of them being "natural" and therefore safe, and a growing interest in alternative therapies. However, this perception is often flawed, as herbal medicines are not without risks and can cause significant adverse reactions (ADRs) and drug-herb interactions.

Safety is a fundamental principle in the provision of herbal medicines and herbal products for health care, and a critical component of quality control. These guidelines provide practical technical guidance for monitoring the safety of herbal medicines within the pharmacovigilance systems. The safety monitoring of herbal medicines is compared and contrasted with that of other medicines currently undertaken in the context of the WHO International Drug Monitoring Program. Although there are regulatory and cultural differences in the preparation and use of different types of medicines, they are all equally important from a pharmacovigilance perspective. Despite the growing interest in the safety of herbal medicines, national surveillance systems to monitor and evaluate adverse reactions associated with herbal medicines are rare, even among the more than 70 Member States participating in the WHO International Drug Monitoring Program. Moreover, there is a lack of effective communication on this subject at all levels, from international to local. A recent WHO survey showed that around 90 countries, less than half of WHO's Member States, currently regulate herbal medicines, and an even smaller proportion has systems in place for the regulation/qualification of providers of herbal medicines. Moreover, there are disparities in regulation between different countries, and this has serious implications for international access to and distribution of such products. The WHO has taken the lead in tackling the need for drug safety monitoring since 1970 (resolution WHA23.13 on international monitoring of adverse reactions to drugs, 1970). The WHO International Drug Monitoring Program, together with the WHO Collaborating Centre in Sweden, the Uppsala Monitoring Centre (UMC), has instituted a coherent program of action for pharmacovigilance, which includes the establishment of a program for exchange of safety information, maintenance of the global WHO database of adverse drug reaction (ADR) reports (hereafter referred to as the global WHO database), and the provision of numerous guidelines on monitoring drug safety. It also seeks to bridge the gap between the industry and the regulatory authorities. As an immediate response to the need for pharmacovigilance for herbal medicines, the WHO has increased its efforts to promote their safety monitoring within the context of the WHO International Drug Monitoring Program.

Need for pharmacovigilance of herbal-

The need for robust PV systems for herbal medicines stems from several key factors:

1. **Safety Concerns**: Herbal products can cause serious adverse effects, including hepatotoxicity (liver damage), nephrotoxicity (kidney damage), and allergic reactions. Case studies have documented instances of liver injury from ingredients like Tinospora cordifolia and severe skin reactions from metal-based Siddha medicines. (3)
2. **Herb-Drug Interactions**: Herbal medicines are frequently used alongside conventional drugs, leading to potential interactions. These interactions can alter the efficacy or increase the toxicity of either the herb or the drug. For example, St. John's Wort is known to interact with various conventional drugs, including antidepressants and oral contraceptives.
3. **Adulteration and Contamination**: The lack of standardized manufacturing and quality control can lead to herbal products being adulterated with undeclared potent substances (e.g., steroids, heavy metals) or contaminated with pesticides, microbial toxins, or other hazardous materials.
4. **Misidentification of Plants**: Improper identification of plant species used in preparations can lead to unintended toxic effects.
5. **Dosage and Formulation Issues**: Unlike conventional medicines, the active ingredients, dosage, and standardization of herbal products can vary significantly. Traditional herbal preparations often contain multiple ingredients, making it difficult to pinpoint the causative agent of an ADR.

Challenges in Herbal Pharmacovigilance-

Applying the conventional PV model to herbal medicines presents unique and significant challenges:

1. **Underreporting**: This is a major issue. Both healthcare professionals and the public often fail to report ADRs associated with herbal products, believing them to be safe. Patients may not even disclose their use of herbal remedies to their doctors. (5)
2. **Lack of Standardization and Quality Control**: The quality of herbal products can be highly variable. Factors such as the plant's origin, the season of collection, processing methods, and the presence of adulterants can all influence the safety and efficacy of the final product. (6)
3. **Complex Chemical Composition**: Herbal products are typically a mixture of many chemical compounds, not a single active molecule. This makes it difficult to establish a clear dose-response relationship or identify the specific component responsible for an adverse effect. (7)
4. **Misinformation and Lack of Awareness**: The public's belief in the inherent safety of "natural" products, coupled with a lack of awareness among healthcare professionals about potential risks, contributes to the problem. Many practitioners are not formally trained in traditional medicine, making it difficult to assess and interpret causality reports.
5. **Difficulty in Causality Assessment**: Establishing a causal link between an herbal product and an ADR can be challenging. It requires a detailed understanding of the herb's pharmacology, potential interactions, and a thorough patient history, including the use of all concomitant medications. (8)
6. **Regulatory Hurdles**: In many countries, herbal products are classified as dietary supplements or foods, not medicines. This classification often means they are not subject to the same stringent regulations for safety and efficacy as conventional drugs.

Global Perspective on Herbal Pharmacovigilance

Published reviews indicate that nearly 70–80% of the global population relies on herbal medicines for primary healthcare, particularly in Asia and Africa. Countries such as India and China have well-established traditional medicine systems, including Ayurveda and Traditional Chinese Medicine.

The World Health Organization has emphasized integrating herbal medicines into national pharmacovigilance systems. However:

- Reporting of herbal ADRs remains significantly lower than synthetic drugs
- Many countries lack structured herbal safety monitoring systems
- Existing pharmacovigilance frameworks often do not adequately capture herbal-related data

Developed countries have begun incorporating herbal medicines into their regulatory frameworks, whereas developing nations face infrastructural and awareness-related barriers.

Advantages Of A Robust Pharmacovigilance System for Herbal Medicine

A well-functioning pharmacovigilance (PV) system for herbal medicine offers numerous benefits, not just for patient safety but also for the broader healthcare landscape.

1. **Enhanced Patient Safety**: This is the primary advantage. A PV system enables the early detection of safety signals and previously unknown adverse reactions (ADRs). This leads to timely warnings, regulatory actions (e.g., product recalls, labeling changes), and ultimately, a reduction in harm to patients from contaminated, adulterated, or inherently toxic herbal products. For instance, the system can quickly identify and address issues like liver damage caused by a specific herbal supplement.
2. **Increased Public and Healthcare Professional Confidence**: By demonstrating a commitment to safety, a robust PV system builds trust in both herbal medicine products and the regulatory bodies that oversee them. This encourages more open conversations between patients and healthcare professionals (HCPs) about herbal medicine use, which is crucial for preventing drug-herb interactions and managing potential side effects. When patients feel confident that safety is a priority, they are more likely to disclose their use of herbal remedies.

3. **Improved Quality and Manufacturing Standards**: The requirement for manufacturers to report adverse events and adhere to Good Manufacturing Practices (GMP) incentivizes them to improve quality control. This includes ensuring proper plant identification, preventing contamination with heavy metals or pesticides, and using standardized extraction processes. PV data can also highlight problems in the supply chain or manufacturing process that need to be addressed.

Disadvantages and Challenges of Pharmacovigilance for Herbal Medicine

Despite the clear advantages, implementing and maintaining a robust PV system for herbal medicine is fraught with significant challenges and disadvantages.

1. **Underreporting:** This is arguably the most significant drawback. The perception that "natural" means "safe" leads to a low reporting rate of ADRs by both patients and HCPs. Patients may not even associate a symptom with an herbal product, and HCPs may not consider herbal use in their differential diagnosis. This makes it very difficult to get a true picture of the safety issues.
2. **Lack of Standardization and Quality Control**: Unlike conventional pharmaceuticals, which have a single, well-defined active ingredient, herbal products can be highly variable. The chemical composition can differ based on the plant species, growing conditions, harvest time, and processing methods. This makes it extremely challenging to link an adverse event to a specific product or batch, as the same product from two different manufacturers may have a completely different chemical profile.
3. **Complex Causality Assessment**: Establishing a causal link between an herbal product and an ADR is difficult.
   Multi-component products: Most herbal products contain a mixture of compounds, making it hard to identify the single culprit.
   Confounding factors: Patients using herbal medicine often use conventional drugs as well, making it difficult to differentiate between a drug-herb interaction and a side effect of the herb itself.
   Delayed effects: Some adverse effects (e.g., liver damage) may not appear for weeks or months after use, making it hard for patients or doctors to connect the symptom to the herbal product.
4. **Regulatory Gaps and Misclassification**: In many countries, herbal products are not classified as medicines but as dietary supplements, food, or traditional remedies. This means they are often not subject to the same stringent regulations for pre-market approval or post-market surveillance. This regulatory gray area hinders the ability of PV systems to effectively monitor these products.
5. **Lack of Scientific Data**: Many herbal products have not been subjected to rigorous clinical trials. This means there is often a lack of pre-existing data on their pharmacology, toxicology, and potential side effects, making it difficult for PV systems to predict and interpret emerging safety signals. The absence of a clear dose-response relationship also complicates risk assessment.

Risk Factors and Adverse Drug Reactions

Associated with Herbal Medicines Drug-Related Risk Factors Adverse reactions associated with herbal medicines arise from multiple categories of causative factors that can be broadly classified as drug-related, patient-related, and system-related contributors.Understanding these distinct etiological pathways is essential for implementing targeted risk mitigation strategies. Drug-related factors encompassing intrinsic toxicity represent a primary category of concern. Certain herbs contain constituents with inherent toxic potential, such as alkaloids in Aconitum species, aristolochic acid in Aristo lochia species, and various other naturally occurring toxins.[3] The toxicity of these substances varies considerably based on dose, duration of exposure, and individual patient susceptibility factors. For example, comparative research on Radix Bupleuri Chinensis demonstrated that the toxic dose (192g per 60kg body weight) substantially exceeds the clinically employed dose (9g per 60kg), indicating a reasona ble therapeutic window when medications are appropriately dosed. External toxicity factors represent a second critical category of drug-related risk. These include contamination of herbal products with toxic metals (lead, mercury, arsenic), bacterial and fungal contamination, pesticide residues, and incorporation of undeclared potent pharmaceutical substances.[13] Multiple documented cases have illustrated the severity of these risks, including instances where herbal formulations were discovered to contain undeclared corticosteroids causing iatrogenic Cushing's syndrome, and cases where misidentification of plant species resulted in aristolochic acid exposure causing severe nephrotoxicity.

Regulatory Challenges

Regulatory systems for herbal medicines are not as strict as those for conventional drugs in many countries. Herbal products are often classified as dietary supplements, which require less rigorous testing. This lack of strict regulation can lead to unsa fe products entering the market.

Future Directions

Future improvements should focus on strengthening regulatory frameworks, improving quality control, and increasing awareness. Training healthcare professionals, encouraging ADR reporting, and integrating herbal medicine into mainstream healthcare systems are key steps. Development of standardized guidelines and better research will further strengthen pharmacovigilance.

Integration with Modern Technology: Mobile apps and web-based platforms are being developed to make it easier for patients and healthcare providers to report adverse events. These tools can also provide a structured way to collect the detailed information needed for causality assessment. (15

Herbal Drug Interactions (HDIs): Research on HDIs is an area of growing importance. Studies are using "omics" technologies (e.g., genomics, proteomics, metabolomics) to understand the mechanisms by which herbal components interact with drug-metabolizing enzymes (e.g., cytochrome P450 enzymes). This can help predict and prevent dangerous interactions. (16)

Real-World Evidence (RWE): The use of large-scale electronic health records (EHRs) and insurance claims data is becoming a new source of information for PV. By analyzing RWE, researchers can identify potential safety issues with herbal products in real-world clinical practice.

Conclusion

Herbal pharmacovigilance is essential to ensure the safe use of herbal medicines. Despite global progress, several challenges such as underreporting, lack of regulation, and poor awareness still exist. By addressing these issues through better policies, research, and education, a strong and effective pharmacovigilance system can be developed to protect public health.

Herbal medicines are widely used in health care in both developed and developing countries. However, in recent years, there have been several high-profile herbal safety concerns that have had an impact on the public health, and there is increasing recognition of the need to develop pharmacovigilance (safety monitoring) systems for herbal medicines. Pharmacovigilance for herbal medicines is, in many respects, in its infancy and monitoring the safety of herbal medicines presents unique challenges.

This meeting aims to provide a comprehensive and critical overview of the current state of pharmacovigilance activities for herbal medicines at the national and global levels. It will explore in depth the challenges that pharmacovigilance of herbal medicines presents, consider relevant emerging issues and what steps could and should be taken to improve safety monitoring for herbal medicines in the future.

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