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Review Paper

Herbovigilance: Monitoring the Safety of Herbal Medicines

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ABSTRACT

Herbovigilance is defined as the monitoring of the safety of herbal medicinal products (HMPs). Herbal medicinal products, while considered to be 'natural and safe,' have been shown to have a high level of risks associated with their use, which are generally underestimated. The world over, nearly 80% of the population in developing countries rely on traditional medicine, while in developed countries, the use of herbal medicines is increasing steadily as a complement to conventional medicine in the realm of alternative therapy.This article aims to discuss the increasing public health concerns associated with the use of herbal medicines, which include the intrinsic toxicity of plants, contaminants, adulteration of herbal products with synthetic drugs, and herb-drug interactions that may jeopardize life-saving drugs. The increased risks to pregnant women, elderly patients, and patients with chronic diseases, owing to a lack of data on the safety of herbal medicines, have been a major public health concern in the current scenario, while the under-reporting of adverse drug reactions, unstandardized herbal products, and surveillance issues make it difficult to ascertain the risks associated with their use.

INTRODUCTION

The practice of herbovigilance, which can be described as the science of identifying, evaluating, interpreting, and preventing any possible harm associated with HMPs, constitutes a critical but largely neglected component of the worldwide pharmacovigilance system [1], [2]. The need for it arises from an obvious contradiction: the extensive worldwide dependence on natural remedies and the widespread belief that such medicines are absolutely safe [3], [4]. The WHO observes that about 80 percent of the population in developing countries relies on traditional medicine for their health care needs, whereas in developed countries, its consumption as an alternative and complementary treatment is rising [5], [6]. The

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consumption is common in an area of regulation that is highly fragmented, whereby most of the HMPs escape the stringent pre-market safety assessments required for all artificial drugs [7], [8].

This is because the extent of consumption results in a large-scale exposure to the substance whose risks are poorly understood. For instance, the cost incurred annually on herbal supplements in both the US and the European Union alone exceeds several billion dollars despite being sold under dietary supplement laws that emphasize post-market monitoring rather than pre-market safety assessment [8]. The 'sales first, testing later' strategy cannot possibly be considered effective with regard to compounds that have complicated pharmacology. What is more, the globalized nature of supply lines has made things even more complicated since the material can come from one continent, be processed in another, and finally be consumed in yet another continent [9], [10]

The rapid increase in the activities of Electronic Business and direct marketing towards consumers has just made things more difficult for all of us. Today, in the current context, herbal medicines can be found in an exponential amount through the internet in different types of websites and social networking sites; needless to mention the new "transactions on the internet," which sometimes do not follow any conventional retail norms [11], [12]. Consumers who are purchasing their goods from any of the aforementioned sources hardly ever encounter any standard information about the possible contraindications and side effects of the product. The development of technology within this particular industry has not done anything but establish a second "chain" where adulterated and poor-quality herbal products can easily be bought because they always seem to find a way to “escape regulations” [13].

The adverse impact of substandard herbovigilance on both public health and the economy is considerable. From immediate and severe liver-kidney toxicity to the gradual development of undiagnosed kidney disease and the failure of antiretrovirals, the adverse clinical outcomes are wide-ranging [14]. The most vulnerable patients include pregnant women, the elderly population, and individuals with several comorbid conditions, but the research on the safe use of such medicines in such patients is limited. Economic burden is associated with longer hospital stays, management of failure of treatments, diagnosis of the underlying causes of the adverse effects from medications or toxins, and taking care of chronic injuries due to drug abuse [14].

Awareness of this deficit has led organizations such as WHO to recommend incorporating herbovigilance into national healthcare infrastructures [1], [15]. Existing approaches involve developing better risk evaluation methodologies, employing sophisticated methods for identifying adulteration, and collaborating internationally for signal detection [8], [9]. Nevertheless, more needs to be done in light of the enormity of the problem.

Rationale

The growing use of HMPs on the global front can be attributed to the fact that they have become an integral belief system, as traditional cultures use them, along with the general consensus that natural remedies provide better protection against side effects, coupled with the rising rate of self-medication and the pursuit of holistic health. However, it can be stated that the use of HMPs has posed a bigger threat to public health, as the rate at which they have become integral in the healthcare system is greater than the rate at which the dangers associated with them have been minimized.

It is such a disparity between widely used application and lack of effective monitoring that is the main cause of concern prompting the need to consider herbovigilance as a distinct field.

This article is needed due to various factors that have transformed HerboVigilance from a secondary issue into a primary public health concern.

The major reasons for this may include the vast number of users who are increasingly utilizing herbal medicinal products. This basically involves millions of users worldwide, both from the developing and the developed world, who consume herbal medicine at the same time with prescribed medication, though this vast population does not fall under the review scheme post-marketing .

Another reason may involve the distinctive risks that are normally related to HMPs. Unlike standard medications, these medicinal facilities are not pre tested to identify their undesirable effects; they normally go through different mechanisms not requiring such extensive investigations .

Review of Literature

1. Global Utilization and Regulatory Landscape:

Herbal medicines have been reported in literature to be widely used on a global scale and this is deeply rooted within the culture and also becoming increasingly popular within CAM approaches [5], [6]. Surveys from nations such as Australia, Germany, and the US show that over a third of the population regularly engages in the use of some type of HMP without even informing their family doctor [11], [12]. Such extensive use occurs within a complex and contradictory regulatory framework. In the EU, the Traditional Herbal Medicinal Products Directive offers a system of registration on the basis of extensive traditional use rather than conducting any new clinical trials, despite the acknowledgment of traditional use not being equivalent to ensuring safety in every regard [8]. Contrastingly, in the case of United States of America, HMPs sold as "dietary supplements" according to the Dietary Supplement Health and Education Act (DSHEA) passed in 1994 do not need to establish the safety or effectiveness of their products to the FDA prior to their being put on sale [8]. There is an obvious disparity of information and power here. In its repeated call for enhanced national policies for assuring quality, safety, and efficacy, the World Health Organization has stressed that traditional medicine should be incorporated within the national health care system, but the process has not been adequately implemented [1], [15].

2. Nature and Scope of Associated Risks:

The literature reveals a complex and multi layered risk profile associated with HMPs that extends far beyond simple side effects. Key risk categories, supported by a growing body of case reports, toxicological studies, and systematic reviews, include.

Intrinsic Plant Toxicity:- Bioactivities of plant extracts have two sides of the same coin. There have been many studies done which correlate certain plants with direct organ toxicity. One such toxicity that has well been documented is that of hepatotoxicity and some of the plants involved include Kava, comfrey, and chaparral [14], [16]. Nephrotoxicity, especially related to aristolochic acid that is present in plants like Aristolochia that are used as ingredients in traditional Chinese and Ayurvedic medicines, may cause renal fibrosis and urothelial tumors, which has been collectively referred to as Chinese Herb Nephropathy/Balkan Endemic Nephropathy [17]. Cardiotoxicity (e.g., from Aconitum species) and neurotoxicity are also documented.

Quality Compromise and Adulteration:- This is arguably the most insidious and pervasive threat, particularly in products sourced through unregulated or globalized supply chains. Research demonstrates that quality issues exist on a spectrum. Misidentification and substitution of plant material are common, where a toxic or less expensive species is used in place of the intended one. Deliberate adulteration with undeclared

synthetic drugs is a major public health concern. Analytical studies using techniques like HPLC and mass spectrometry have repeatedly identified pharmaceuticals such as corticosteroids in "natural" anti-arthritis formulas, NSAIDs in pain remedies, oral hypoglycemics like glibenclamide in "herbal" diabetes products, and sildenafil analogs in sexual enhancement supplements [9], [10]. This practice poses severe risks of overdose, unexpected side effects, and dangerous interactions with other medications the patient may be taking. Contamination with heavy metals (lead, mercury, arsenic), pesticides, and microbial pathogens due to poor agricultural and manufacturing practices further compounds the risk [17].

Herb-Drug Interactions (HDIs):- Scholars have taken notice of this domain, and have discovered that there is a serious danger for pharmacotherapy. There are many systematic reviews, including one by Izzo and Ernst, which have thoroughly documented interactions with clinical importance [7], [18]. Mechanisms are primarily pharmacokinetic, involving the modulation of cytochrome P450 enzymes and drug transporters. The classic example is St. John's Wort (Hypericum perforatum), a potent inducer of CYP3A4 and P-glycoprotein, which can drastically reduce plasma concentrations of cyclosporine (risking transplant rejection), oral contraceptives (risking pregnancy), warfarin (risking thrombosis), and many antiretroviral and anticancer drugs [18]. Other important interactions include Ginkgo biloba (potential bleeding risk with anticoagulants like warfarin), Ginseng (interference with warfarin), and Garlic (increased bleeding risk). Pharmacodynamic interactions, where herbs and drugs have additive or opposing effects, are also concerning (e.g., sedative herbs with benzodiazepines, hypoglycemic herbs with insulin).

Use in Vulnerable Populations:- There is also a constant reminder that there is an alarming lack of safety data regarding HMP utilization among pregnant and breastfeeding mothers. Some plants can be emmenagogic or even have hormone-like effects that could endanger the developing fetus. Likewise, the safety and correct dosage of HMPs in children and elderly patients who differ metabolically and physiologically from adults remain undocumented, leading practitioners to resort to adult data and tradition that might not apply to the modern day.

3. Challenges in Surveillance and Reporting:

One common theme that is highlighted time and again in the literature is that of the inherent limitations of current pharmacovigilance systems when dealing with HMPs. The spontaneous reporting system, which serves as the basis for drug safety surveillance, has a number of disadvantages for the following reasons:

Profound Under-Reporting:- This is the most significant bottleneck. Patients often do not consider HMPs as "drugs" and thus do not report adverse reactions. Healthcare providers frequently lack the training to suspect an HMP as the causative agent, may not know how to report such an event, or may dismiss patient-reported symptoms linked to "natural" products [11], [12]. Less than 1% of major adverse events linked to dietary supplements are reported to the FDA, according to studies.

Complex Causality Assessment:- Establishing a definitive link between an HMP and an adverse event is fraught with difficulty. Challenges include the presence of polypharmacy (which herb or drug caused the problem?), variability in product composition (different brands or batches may have different ingredients/potency), and the fact that the adverse event (e.g., hepatitis, renal failure) often has multiple potential etiologies [2], [19]. Standardized algorithms like the Naranjo Scale or

WHO-UMC criteria are difficult to apply confidently in this context.

Failure to Standardize Products and Identify Them:-The inconsistency of plant genetics, cultivation techniques, harvesting period, extraction methods, and final product manufacturing means that varying amounts of pharmacologically active components will be produced. In cases where a consumer has an adverse reaction to the product, it becomes very difficult to identify what product was involved, who manufactured it, and which batch number it had [8].

4. Approaches Towards Enhancing Herbovigilance:

In view of the above difficulties, emerging research suggests that a holistic strategy should be adopted for increasing capacity.

Legal Reforms and Harmonization:- There have been strong arguments made towards the need for updating legal frameworks. These involve embracing good practices for pharmacovigilance but for herbs, enforcing stringent good manufacturing practices and improving regulations on post marketing surveillance. A mandatory adverse drug reaction reporting requirement can be applied for manufacturers and distributors just like is done in the pharmaceutical industry [8].

Technology and Methods Innovations:- The use of innovative methods is essential. This will involve the application of data-mining methodologies on electronic medical records and insurance databases for discovering HDI indicators, the use of sophisticated molecular and chemical profiling techniques like DNA bar coding and NMR spectroscopy for identification and adulteration verification, and the creation of convenient mobile apps for consumer/health practitioner reporting [9].

Education and Training:- This is referred to as being fundamental. Specialists stress the critical importance of incorporating the education of pharmacovigilance of herbal medicine into the basic curriculum of medical, pharmacy, nursing, and naturopathic institutions. The training should be geared towards enhancing history-taking skills (taking history of herbal medication usage), identifying possible toxidromes, and knowing common herb-drug interactions and reporting procedures [11], [13].

International Collaboration and Data Sharing:- Given the global nature of the market, isolating efforts is inefficient. Strengthening networks like the WHO Programme for International Drug Monitoring (PIDM) to better handle HMP data, harmonizing terminologies (using ISO standards), and creating shared alert systems for adulterated products are seen as essential steps for a coordinated global defense [1], [19].

Research Gaps

1. Epidemiological Data and Burden of Disease: - There is a significant lack of strong epidemiologic data at the population level regarding the actual incidence and prevalence of adverse reactions that are directly related to herbal medicinal products (HMPs). Most of the current data comes from individual case reports, analysis of liver transplant registries, or poisoning center information, all of which suffer from potential bias problems [14]. These data cannot be used to determine the denominator information needed for calculating risk ratios and Population Attributable Fractions. While there may be enough information available on the causation of hepatotoxicity from kava use, there is still no information on the absolute risk among a population of normal users within a defined period of time. In addition, the economic impact of herbs worldwide is another area which remains largely undiscovered territory. The cost involved is not limited to the direct cost of treating the condition but also includes other significant costs in the form of loss of productivity and

chronic disability due to permanent organ damage. Other indirect costs associated with the failure of treatment as a result of Herbs-Drug Interactions (HDIs) include managing complications such as stroke resulting from inadequate anticoagulant therapy or managing rejection of an organ transplant [18].

2. Advanced Diagnostics and Causality Assessment Tools:- The existing clinical and forensic techniques used to identify the causality between the HMP and any given adverse reaction are not adequate enough and fall short of being sophisticated when compared with traditional drugs. This inadequacy is exhibited by a number of factors. Firstly, there is an urgent need to establish definitive biomarkers. In DILI, one may find certain patterns which would help to identify the causative agent; however, the same cannot be established for herb-induced hepatotoxicity/nephrotoxicity in comparison with viral or autoimmune or other drug-induced causes [16], [17]. Second, the analytical toolkit for regulatory and forensic laboratories is playing catch up with adulterers. While testing for known adulterants like sildenafil or dexamethasone is routine, clandestine laboratories constantly develop novel synthetic analogs ("designer adulterants") to evade standard detection methods. Research is needed to develop agile, non-targeted screening approaches using techniques like high resolution mass spectrometry and nuclear magnetic resonance (NMR) spectroscopy to create comprehensive spectral libraries capable of identifying unknown compounds in complex herbal matrices [9], [10].

3. Pharmacokinetic and Interaction Profiling:- The pharmacokinetic profiles of the vast majority of HMPs their absorption, distribution, metabolism, and excretion (ADME) in humans are complete unknowns. This foundational data gap has a cascade of consequences. While we have identified major interactions for a few herbs like St. John's Wort, we lack a systematic mapping of the effects of common herbs on the full spectrum of human drug metabolizing enzymes (e.g., CYPs, UGTs) and transporters (e.g., P-gp, OATPs) [7], [18]. Interactions data are most commonly based on in vitro research, which lacks clinical applicability without additional in vivo research. Crucially, there is a major gap in the absence of clinical investigations into the risks of HDIs in realistic, polypharmacy settings. Many elderly individuals suffering from several health problems will be taking 5-10 drugs in combination with various HMPs, generating a tangled array of possible interactions which have never been comprehensively investigated. We need to progress beyond examining individual herb-drug pairs toward modeling pharmacokinetics networks [18].

4. Safety in Vulnerable and Special Populations:- There is an insufficient body of evidence regarding the safety profile of HMP use in people with changed physiological parameters. In pregnant and nursing women, there is no substantial evidence other than case reports or empirical studies from the time when herbal medicines were used traditionally, without considering the current social sensitivity. Some of the herbs can cause uterine stimulation or act as hormones; however, there is no evidence on the risk-benefit ratio in such cases. Similarly, children and elderly people exhibit different pharmacokinetics of herbs compared with adult patients, and the dosages of herbs are calculated based on data related to adult patients. The most concerning fact is that there is no evidence of HMP use in patients with existing liver or kidney dysfunction, as these organs are highly susceptible to toxic effects.

5. Behavioral and Socio-Cultural Determinants:- The choice regarding whether to use or report problems associated with HMPs is far more behavioral, cultural, and trust-based rather than simply clinical in nature. There is a severe need for

research to understand the motivations of the behaviors of both patients and practitioners involved. Do patients withhold information on the use of herbs out of fear, belief that it is irrelevant, or because nobody asks? How do patients get information from retailers and social media about what is safe and effective? Such an understanding is crucial in order to design effective public health messaging, improve the clinical interview process, and develop reporting frameworks that people will trust and use [11], [12], [13].

6. Evaluation of Herbovigilance System Interventions:- Despite the abundant suggestions in literature on how to enhance medication error reporting, including using simple mobile applications, adding reminders within electronic medical record systems, and designing focused educational programs for pharmacists, there is an obvious lack of thorough outcome analysis. Very few research works use control groups to test whether such methods are effective in increasing reporting, reducing signal identification delays, improving report quality, or, even more important, resulting in patient safety improvements [2]. Without this evaluative research, resources may be wasted on well intentioned but ineffective programs, and best practices cannot be identified or scaled.

Addressing the Research Gaps

To build a robust and effective herbovigilance ecosystem, a strategic and multi disciplinary research agenda is required. The following actions are critical to address the identified gaps.

1. Conducting Large-Scale Pharmacoepidemiological Studies:

There is a compelling requirement to break away from sporadic case studies. Cohort and case-control studies on a wide scale using a prospective approach are required to estimate the actual risk of harm due to the HMP concerned. There should be active surveillance approaches employed in such studies, because much information that would otherwise go unnoticed through a passive system could then be collected. On the parallel track, health economics studies should also be undertaken to understand the cost implications of HMP-related morbidity issues [18].

2. Developing Advanced Diagnostic and Forensic Capabilities:

Investment in translational research is key. This includes:

Biomarker Discovery:- Utilizing proteomic and metabolomic approaches to identify specific signatures for herb induced organ damage, enabling earlier and more accurate diagnosis [16], [17].

Strengthening Forensic Analysis:- Expanding and standardizing screening libraries using techniques like High Resolution Mass Spectrometry (HRMS) to reliably detect novel synthetic adulterants and contaminants in herbal products, supporting regulatory enforcement [9], [10].

3. Deepening Pharmacological and Interaction Research:

There is a need for a comprehensive, publicly financed system for describing the basic pharmacokinetic properties of commonly used herbs. Attention must first be paid to.

Studies in vitro and in vivo that will assess their potential to interact with various types of enzymes and transporters.

Carrying out controlled clinical pharmacokinetic studies for high-risk herb/drug interactions, particularly with medications having narrow therapeutic indexes (such as anticoagulants, immuno-suppressants, anti-convulsants)[18].

4. Prioritizing Research in Vulnerable Populations:

It is essential to design ethical, longitudinal studies based on observations that provide data concerning the safety of HMPs for pregnant women, children, and older adults. Until such data

becomes available, the precautionary approach needs to be advocated.

5. Integrating Social and Behavioral Science:

Qualitative and mixed methods research play an essential role in studying consumer decision-making behaviors as well as decision-making behaviors of health care professionals. Research needs to identify barriers to disclosure, health information sources, and the effect of cultural beliefs on risk perception [11], [12], [13].

6. Implementing and Evaluating System-Level Interventions:

Possible solutions, including simplified reporting through mobile applications, pharmacy-integrated screening methods, and education for professionals, need to be pilot-tested and their effects evaluated based on indicators, such as increased reporting rates, improved signal detection time, and modified prescribing practices [2].

CONCLUSION

Herbovigilance is neither a marginal issue nor a non-negotiable aspect of comprehensive public health safety in the 21st century. The widespread use of herbal medicinal products across the globe, against the backdrop of inconsistent regulation and the perpetuation of the myth of "natural = safe," has resulted in a substantial and increasing risk environment. As has been discussed in this analysis, the risks are diverse and include direct toxicity from plants and product contamination, as well as the silent but deadly world of herb-drug interactions. The costs of failure are measured in terms of preventable patient injury, treatment failure, and a hidden economic toll on healthcare systems.

The road ahead is clear but it needs dedication and collaboration. Improving herbovigilance will necessitate a two-pronged approach. The first step will be establishing robust infrastructure from harmonization of regulations demanding high quality standards as well as post-marketing surveillance for all herbal medicines products (HMPs), while the second will involve promoting a good safety culture among all stakeholders. This will entail educating healthcare professionals who can then be able to communicate and report any herb-related issues. It will also mean engaging and educating the general public who will play an active role in their healthcare since the products are very bioactive.

However, the goal should be that of harmonization and not prohibition. An effective herbovigilance program seeks to incorporate the advantages of traditional/herbal medicines into the modern health care system by controlling for their risks. In doing so, however, one must address the gaps in the sciences of epidemiology, diagnostics, and interactions, as well as in surveillance programs. This will convert what is currently a reactive approach into a proactive one, and the health of millions depends on it.

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