

Pharmacovigilance in Ayurveda: Current Challenges and Strategies for Strengthening Adverse Drug Reaction Reporting

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Abstract—Background: The increasing use of Ayurvedic medicines in India and internationally makes systematic medicine-safety surveillance essential. Although a national pharmacovigilance programme for Ayurveda, Siddha, Unani and Homoeopathy medicines is in place, recognition and reporting of suspected adverse drug reactions (ADRs) remain limited. **Materials and methods:** This narrative review synthesizes published studies on Ayurvedic pharmacovigilance and ADR reporting, together with World Health Organization and Ministry of Ayush resources. Findings were organized into three themes: the existing reporting system, determinants of under-reporting, and strategies for strengthening pharmacovigilance. **Results:** Available evidence shows that ADRs can be detected in Ayurvedic settings, but actual reporting is much lower than awareness or favourable attitudes toward pharmacovigilance. Important contributors include the perception that Ayurvedic medicines are inherently safe, incomplete clinical documentation, multi-ingredient formulations, concomitant use of conventional medicines, product-quality variation, self-medication, and limited confidence in causality assessment. Education, simplified digital reporting, routine documentation and interdisciplinary collaboration are actionable responses. **Conclusion:** Pharmacovigilance should be integrated into routine Ayurvedic care rather than treated as a separate administrative activity. Consistent documentation and reporting of suspected ADRs can generate useful post-marketing safety evidence, strengthen patient protection and support responsible, evidence-informed use of Ayurvedic medicines.

Keywords— Ayurveda; pharmacovigilance; adverse drug reaction; patient safety; ADR reporting; Ayush Suraksha.

I. INTRODUCTION

Pharmacovigilance is concerned with the detection, assessment, understanding and prevention of adverse effects and other medicine-related problems.[1] Its purpose is not to label a medicine as unsafe on the basis of a single report; rather, it provides a systematic means of recognising possible risks, evaluating patterns and reducing avoidable harm. Because medicines are used in a wide range of conditions, formulations, and care settings, this function is particularly relevant to Ayurvedic practice.

Traditional medicine is used across many countries, and Ayurveda is among the systems used in India and abroad.[2] In India, the National Sample Survey on Ayush reported substantial use of Ayush systems for prevention or treatment, with Ayurveda being the most commonly used system for treatment.[3] At the same time, Ayurvedic medicines are no longer confined to individualized preparation and dispensing. Nowadays, traditional and proprietary products are being manufactured and distributed on a large scale. This expansion creates a greater need for consistent product-quality oversight and real-world safety monitoring.

Ayurvedic clinical reasoning already places emphasis on individual variation. Factors such as prakriti, age, disease stage, suitability, digestive capacity and coexisting illness are relevant to the selection and administration of therapy. A contemporary pharmacovigilance approach can complement these principles by documenting unexpected or harmful

responses in a form that enables learning across patients and settings.

Objectives of the Review

To critically review the current status of pharmacovigilance in Ayurveda: To understand the existing system for monitoring and reporting suspected adverse drug reactions related to Ayurvedic medicines.

To identify factors affecting ADR reporting: To examine the major challenges influencing recognition, documentation and reporting of suspected adverse drug reactions in Ayurvedic practice.

To explore strategies for strengthening medicine-safety surveillance: To identify practical ways to improve ADR documentation, reporting, and pharmacovigilance awareness in Ayurvedic clinical practice.

II. MATERIALS AND METHODS

Using official pharmacovigilance resources, published research articles, and review literature relevant to Ayurveda and ASU&H medicines, a narrative review was carried out. Research on knowledge, attitude and practice, clinical ADR monitoring, pharmacovigilance programme organization, and digital reporting guidance were all included in the review.

Pharmacovigilance and Adverse Drug Reactions in Ayurveda

An ADR is a harmful and unintended response for which a relationship with a medicine is suspected. In Ayurveda, the possibility of harm may arise from the medicine itself, its

processing and quality, the dose and route of administration, interactions, or patient-specific susceptibility. A suspected report therefore deserves documentation even when causality is not immediately certain. Spontaneous reports are designed to capture suspicion; confirmation can follow through structured assessment.

Recognition of a reaction can be delayed due to the widespread belief that a natural or traditional product is always safe. This belief is inconsistent with classical Ayurvedic caution regarding appropriate selection, dose, preparation, and administration, as well as clinical experience. Patient safety requires a balanced approach: neither assuming causality without evidence nor dismissing a possible reaction because the product is Ayurvedic.

Current Pharmacovigilance System for ASU and H Medicines

India has established a three-tier pharmacovigilance network for ASU&H medicines. The National Pharmacovigilance Coordination Centre is located at the All India Institute of Ayurveda, New Delhi, and is supported by intermediary and peripheral pharmacovigilance centres.[4,5] Suspected ADRs may be entered through the Ayush Suraksha digital platform, launched as an IT-enabled portal in May 2025. The system is intended to enable centralized documentation, safety-signal generation and better communication of medicine-safety information.

The value of this network depends on reports from the point of care. Physicians, pharmacists, nursing and paramedical staff, postgraduate scholars and patients may all contribute to early recognition. A report should capture the patient profile, indication, formulation and batch details where available, dose, timing, co-medications, relevant investigations, dechallenge or rechallenge information if known, management and outcome. Complete clinical details improve the later assessment of a report.

Factors Contributing to Suspected ADRs

Product and formulation factors

Substitution of raw materials, adulteration, contamination, inadequate storage and inconsistent manufacturing can complicate both patient safety and causality assessment. Product quality may be a confounder when a patient experiences a suspected reaction. Potent substances and herbo-mineral preparations require appropriate purification, processing, quality assurance and medical supervision. Without reliable product information, it is difficult to distinguish an effect of the intended formulation from a quality-related problem.

Prescription and administration factors

Inappropriate selection, incorrect dose, prolonged unsupervised use, unsuitable anupana, and failure to account for disease stage can increase risk. Medicines such as Vatsanabha and Bhallataka require particular caution because safety depends on correct processing and use. Documentation of the exact formulation, dose, duration and method of administration is therefore essential whenever a suspected ADR is evaluated.

Patient and interaction factors

Age, pregnancy, allergy history, liver or kidney dysfunction, comorbidities, digestive capacity and individual constitution may influence susceptibility. Concomitant use of Ayurvedic, over-the-counter, herbal and conventional medicines can obscure the temporal relationship and introduce interactions. Self-medication adds further uncertainty because the diagnosis, exposure history and dose may be incomplete. Clinicians should specifically ask about all medicines and supplements rather than relying on voluntary disclosure.

Barriers to Recognition and Reporting

The principal barrier is under-reporting. The reason why a clinician might not disclose an event is due to the unfamiliar reporting process, the uncertain relationship, or the minority of the event. However, reports of non-serious, unusual or poorly characterised events can become useful when combined with similar reports. A suspected ADR should be reported without waiting for proof of causality.

Ayurvedic formulations are often multi-ingredient, which makes attribution to a single component difficult. Simultaneous conventional treatment, incomplete labels, lack of pharmacokinetic information for some formulations and variable product quality add further complexity. Information on precautions and adverse effects may also be dispersed across classical texts, contemporary publications and product labels, limiting timely access during clinical care.

Evidence from Indian studies reflects the gap between attitude and reporting practice. In a prospective study at an Ayurvedic teaching hospital, 84 adverse events were observed, of which 52 were confirmed as ADRs; the reported overall incidence was 1.14%.[6] In a knowledge, attitude and practice survey among Ayurveda physicians and teachers in Gujarat, only 6.57% had ever reported an ADR despite a generally favourable attitude toward pharmacovigilance.[7] An educational intervention among postgraduate students also found that only 7.3% had reported an ADR, while structured training improved knowledge and awareness.[8]

Evidence from Published Studies

Study	Design or population	Key contribution
Ajanal et al., 2015[6]	Prospective monitoring in an Ayurvedic teaching hospital	Reported 84 adverse events; 52 were confirmed ADRs, showing that structured observation can identify medicine-related harm.
Acharya et al., 2022[7]	KAP study among Ayurveda physicians and teachers in Gujarat (n=487)	Found a favourable attitude toward pharmacovigilance but low lifetime ADR reporting (6.57%).
Atray et al., 2024[8]	Educational intervention among Ayurvedic postgraduate students	Reported improvement in pharmacovigilance knowledge and awareness after structured training; only 7.3% had previously reported an ADR.

Strategies to Strengthen Pharmacovigilance

Make safety documentation routine

A brief safety review should be built into each follow-up visit: new symptoms, adherence, dose changes, other medicines, pregnancy status where relevant, and recent laboratory abnormalities. In the event of suspected events, it is crucial for the clinician to promptly document it in the case record. Integrating a short ADR checklist into outpatient and

inpatient records can reduce reliance on memory and make later reporting easier.

Improve practical reporting competence

Undergraduate and postgraduate teaching should include practical reporting exercises, not only theoretical definitions. Regular workshops using de-identified cases can teach the minimum information needed, the difference between suspicion and certainty, and the use of digital reporting pathways. Pharmacists and paramedical personnel should be included because they often see adverse effects, adherence issues and product-related concerns before the prescriber does.

Use digital reporting to reduce friction

Ayush Suraksha provides an opportunity to reduce reporting barriers through accessible digital documentation. Institutions can designate a pharmacovigilance focal person, display reporting guidance in clinical areas and periodically review the number and completeness of reports. A digital system is most useful when it is linked with training, feedback to reporters and clear local responsibility.

Strengthen quality and collaboration

Pharmacovigilance should be connected with quality assurance. Where a product-quality issue is suspected, batch number, manufacturer, expiry date, storage details and retained samples should be recorded whenever possible. Collaboration among Ayurveda clinicians, pharmacologists, laboratory personnel, manufacturers and conventional medicine specialists can improve assessment of complex cases, particularly when patients use multiple systems of medicine.

III. DISCUSSION

The central challenge in Ayurvedic pharmacovigilance is not the absence of a national reporting pathway but the conversion of awareness into routine clinical practice. Although there are numerous studies that indicate that training enhances knowledge, it is still uncommon to receive reports. This indicates that education must be accompanied by simple workflows, institutional reinforcement and feedback that shows clinicians why a report matters.

Causality assessment in Ayurveda is understandably complex. Multi-ingredient formulations, mixed-system prescribing and uncertain product quality make simple attribution unreliable. This is a reason for better documentation, not a reason to avoid reporting. A well-documented suspected ADR can be examined by pharmacovigilance centres and can contribute to signal

detection alongside other reports. Reports that ultimately prove unrelated remain part of a transparent safety system.

A strengthened model should retain the individualized logic of Ayurveda while applying contemporary principles of medicine safety. Recording patient factors such as prakriti, agni, disease stage and co-morbidities alongside standard clinical details may help generate richer safety data over time. Such information may eventually clarify whether particular formulations or administration practices are associated with different patterns of risk in defined patient groups.

IV. CONCLUSION

Pharmacovigilance is an essential part of safe and rational Ayurvedic practice India's digital reporting platform and organized ASU&H pharmacovigilance network are important for their impact, but they also depend on timely, complete reports from clinical settings. Under-reporting can be addressed through practical training, routine safety documentation, easy access to reporting, product-quality information and interdisciplinary assessment. Reporting a suspected ADR is a patient-safety action and a contribution to the evidence base for Ayurvedic medicines.

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