

**ADVERSE DRUG REACTION MONITORING IN THE AYUSH SYSTEM: A REVIEW OF
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ABSTRACT

AYUSH system of medicine consists of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy is an ancient and well established system of healthcare in India. Its relevance was reiterated during the COVID-19 pandemic, where ASU (Ayurveda, Siddha, Unani) drugs were found beneficial in prevention, management and treatment of postCOVID complications. However, ASU drugs, like all pharmacologically active substances, are not free of adverse effects and their perception as intrinsically safe has often delayed the setting up of safety monitoring systems. Pharmacovigilance (PV) the science of detecting, assessing and preventing adverse effects or adverse reactions to medicines is crucial to safeguarding patients receiving these therapies. India's pharmacovigilance infrastructure is expanding through initiatives like the Pharmacovigilance Program of India (PvPI) and the National Pharmacovigilance Program for ASU&H Drugs, but remains in its early stages compared to established drug monitoring systems. The major challenge is the chronic underreporting of ADRS due to the lack of knowledge of reporting tools among practitioners, underreporting by patients, the absence of a standardized system of causality assessment, and the polyherbal, multi-ingredients nature of many of the ASU preparations making it difficult to attribute a reaction to a causative agent. ADR is known to be a cause of hospitalization and causality assessment is particularly difficult when multiple medicines are used concomitantly. The review discusses the present status of ADR monitoring in AYUSH system, regulatory framework available for it and causality, severity and preventability assessment scales such as WHO-UMC, Naranjo and Hartwig scales used or adaptable for ASU drug safety evaluation. Pharmacovigilance in AYUSH needs to be strengthened for ensuring patient safety and confidence in traditional Indian medicine.

KEYWORDS: AYUSH system, ASUdrugs, pharmacovigilance, adverse drug reactions, ADR assessment scales, Ayush Suraksha.

1 INTRODUCTION

AYUSH is an acronym for Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy, a system of medicine and represents an ancient and culturally embedded medical tradition in India, on which millions of people depend, either as a primary or complementary healthcare. The role of AYUSH-based interventions in immunity-building, symptomatic relief and management of post-COVID sequelae was revisited during public health emergencies such as COVID-19 pandemic. The market for Indian systems of medicine has grown worldwide significantly in recent years and this has been paralleled by a similar increase in scientific scrutiny of drug safety.^[1,2]

Though ASU (Ayurveda, Siddha, Unani) drugs have been in use for a long time and are generally considered safe, they are not risk free. Inappropriate selection of drug, improper dosage, prolonged use, drug-drug interactions, herbo-mineral (Rasashastra) formulations and poor drug quality can lead to adverse drug reactions (ADRs).^[2,3] In many instances, the long-held assumption that “natural” or “traditional” implies “harmless” has obstructed the formal creation of specific safety monitoring frameworks for such systems.^[3,4]

Pharmacovigilance (PV) is defined by the World Health Organization as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. Founded in 1968, the WHO International Drug Monitoring Program established the global collaborating center, the Uppsala Monitoring Center in Sweden. In 2004, WHO published specific guidelines to include traditional and herbal medicines within the scope of national pharmacovigilance systems.^[7]

In India, the Central Drugs Standard Control Organization (CDSCO) launched the National Pharmacovigilance Program for conventional drugs in 2003, which later evolved as the Pharmacovigilance Program of India (PvPI) coordinated by the Indian Pharmacopoeia Commission (IPC) (11). In particular for AYUSH drugs, the Department of AYUSH (now Ministry of AYUSH) had organized the first National Consultative Meeting on Pharmacovigilance for ASU Drugs in August 2008 with WHO support, and the National Pharmacovigilance Program for ASU Drugs was formally launched on 29 September 2008.^[6] Further to the institutional development, on 1st November 2017, the Standing Finance Committee approved a separate Central Sector Scheme for Pharmacovigilance of Ayurveda, Siddha, Unani and Homeopathy (ASU&H) drugs.

Under the scheme, the All India Institute of Ayurveda (AIIA), New Delhi was designated as the National Pharmacovigilance Coordination Center (NPvCC) supported by a three tier network of Intermediary Pharmacovigilance Centers (IpcCs) and Peripheral Pharmacovigilance Centers (PPvCCs).^[2] More recently,

the Ministry of AYUSH has launched the “Ayush Suraksha” portal, a digital platform developed with technical assistance of the Central Council for Research in Siddha (CCRS) for capture, analysis and reporting of ADRs and for surveillance of misleading advertisements (MLAs) associated with AYUSH products.^[4,5,9]

Underreporting continues to be the major challenge for India’s ADR monitoring ecosystem when both conventional and traditional medicine. This is exacerbated in AYUSH by a number of other factors: inadequate training of the practitioners on the principles of pharmacovigilance; lack of user-friendly mechanisms for reporting of ADRs in many clinical settings; sociocultural trust that works against recognizing “natural” remedies as harmful; poor scientific mapping between specific traditional-medicine products and their adverse effects; and the multiingredient nature of many ASU formulations, which makes it methodologically difficult to assign a specific reaction to a single causative agent especially when patients are on concurrent allopathic medication.^[10] The Ministry of AYUSH has received 809 complaints regarding misleading advertisements from 2015 to 2018 and two deaths have been attributed to herbal medicines.

This shows that the consequences of lack of proper safety monitoring are not theoretical.^[14] ADRs are a known and largely preventable cause of hospitalization, and causality assessment requires structured, validated assessment tools in polypharmacy settings.^[8,13] This review aims to describe the present status of ADR monitoring in the AYUSH system, institutional and regulatory support to ADR monitoring, causality, severity and preventability assessment scales for ADR assessment for ASU drugs.

2 MATERIALS AND METHODS

❖ Study Design This is a narrative review that collates and synthesizes information from peer-reviewed literature, government and institutional publications and official regulatory resources relevant to pharmacovigilance in the AYUSH system.

❖ Sources of Information The information was obtained from the following types of sources:

- Articles and case reports on pharmacovigilance and ADR reporting in Ayurveda, Siddha, Unani and Homeopathy published in peer-reviewed journals identified by PubMed/PMC and other academic databases.
- Official publications and websites of Ministry of AYUSH, Ayush Pharmacovigilance Program of India (Ayush Suraksha portal) and All India Institute of Ayurveda (AIIA), New Delhi.
- WHO guidelines on safety monitoring of herbal / traditional medicines.
 - Published descriptions and validation studies on standardized scales for assessment of causality, severity and preventability of ADRs, including their application in Indian pharmacovigilance settings.

❖ SelectionCriteria

Sources published in the last two decades, with priority given to those directly addressing AYUSH/ASU&H pharmacovigilance, Indian regulatory systems, or standardized ADR assessment methodology, were included. Sources without verifiable institutional or peer-reviewed source were eliminated.

❖ The findings from the data synthesis were organized thematically into three sections:

- (i) Institutional and regulatory framework of AYUSH pharmacovigilance in India;
- (ii) Reported patterns and challenges of ADR reporting and underreporting.
- (iii) The standardized scales, used or adaptable, for the evaluation of causality, severity and preventability of ADRs from ASU&H drugs. This is a narrative review, not a systematic review, so there was no meta-analysis or statistical pooling of primary data.

3 RESULTS

❖ Institutional and Regulatory Framework

The pharmacovigilance framework for AYUSH medicines in India has been phased out. The National Pharmacovigilance Program for ASU drugs was launched on 29 September 2008 after a consultative process supported by WHO.^[6] This was significantly bolstered by the approval of a Central Sector Scheme on 1 November 2017 by the Standing Finance Committee of Ministry of AYUSH for establishment of a formal three tier network of National Pharmacovigilance Coordination Center (NPVCC) at All India Institute of Ayurveda (AIIA), New Delhi supported by five Intermediary Pharmacovigilance Centers (IPVCCs) and 99 Peripheral Pharmacovigilance Centers (PPVCCs) as

per recent reporting.^[2] This program is now popularly known as the Ayush Pharmacovigilance Program of India (APvPI) and runs parallel to the Pharmacovigilance Program of India (PvPI) for allopathic drugs operated by the CDSCO.^[11] A significant recent development is the launch of the “Ayush Suraksha” digital portal by the Ministry of AYUSH developed with technical support from the Central Council for Research in Siddha (CCRS). The portal is designed to enable consumers, healthcare professionals and regulatory bodies to report suspected ADRs and misleading advertisements directly. The stated aim of the portal is to allow real time data capture, faster stakeholder communication and evidence based safety action.^[4,5,9]

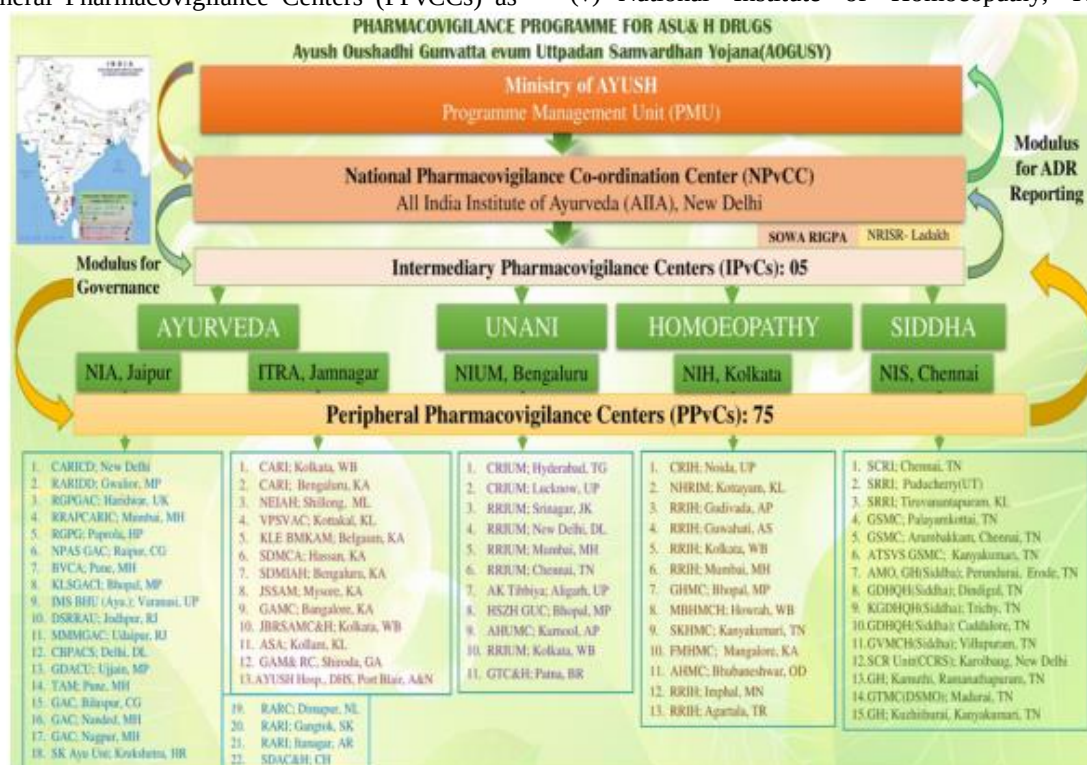
PHARMACOVIGILANCE CENTRES

A three tier structure is-

- (i) National Pharmacovigilance Co-ordination Centre (NPVCC)
- (ii) Intermediary Pharmacovigilance Centres (IPVCCs)
- (iii) Peripheral Pharmacovigilance Centres (PPVCCs)

The National Pharmacovigilance Co-ordination Center (NPVCC) for implementation of pharmacovigilance program for ASU & H Drugs is All India Institute of Ayurveda, New Delhi. The NPVCC will take in inputs from the Intermediary Pharmacovigilance Centers (IPVCCs) regarding suspected ADRs, which will start with:

- (i) National Institute of Ayurveda, Jaipur.
- (ii) Institute for Post-Graduate Teaching & Research in Ayurveda, Jamnagar.
- (iii) National Institute of Unani Medicine, Bengaluru.
- (iv) National Institute of Siddha, Chennai.
- (v) National Institute of Homoeopathy, Kolkata.^[3]



❖ Reported Patterns and Under reporting

In this institutional framework, underreporting has been consistently identified in the literature as the main operational weakness of AYUSH pharmacovigilance. Contributing elements, identified across sources include limited practitioner awareness of what constitutes a reportable ADR and how to use reporting channels; weak integration of ADR documentation into routine clinical workflows; a widespread perception among both patients and practitioners that herbal and traditional remedies are inherently safe; failure of patients to disclose concurrent use of AYUSH products to allopathic physicians (and viceversa), since such products are often not viewed as "medicines"; and the practice of many patients discontinuing traditional medicines once symptoms improve or worsen, without reporting the reaction.^[10,14]

The case-level data describe the nature of ADRs being captured through the current system. A published case report described a 28-year-old woman who developed extensive erythematous rash after taking Ayurvedic formulations, namely, Vyoshadi Vati and Drakshasava. The reaction was graded as moderate, non-serious, was resolved within 24 hours of drug discontinuation and antihistamine administration, and was reported to a Peripheral Pharmacovigilance Center through Ayush Suraksha portal.^[9] Institutional data also indicate that the Ministry of AYUSH received 809 complaints of misleading advertisements and 2 deaths related to herbal medicine between 2015 and 2018, figures that, although limited, indicate that the reporting system is beginning to capture safety signals of genuine clinical significance.^[14]

A cross-sectional knowledge-attitude-practice (KAP) study among AYUSH-associated participants found generally favorable knowledge of pharmacovigilance concepts and a positive attitude to ADR and misleading-advertisement reporting, though the correlation between knowledge, attitude and actual reporting practice was only weakly positive suggesting that awareness alone does not reliably translate into reporting behavior.^[1]

Causes of Adverse Drug Reactions

The review identified several causes of adverse effects in *Ayurveda*

- Incompatible drug combinations.
- Errors by the physician (iatrogenic factors).
- Excessive dosage.
- Use of unsuitable substances.
- Improper drug use according to disease stage.
- Complications from therapeutic procedures.
- Incorrect preparation of mineral-based medicines.

These causes show strong similarity to modern explanations of ADRs.

Preventive Approaches

Ayurveda outlines several preventive strategies to minimize adverse effects

- Careful selection and preparation of medicines.

- Individualized treatment based on patient characteristics.
- Following dietary and lifestyle recommendations.
- Proper timing and method of drug administration.
- Ensuring quality standards similar to modern manufacturing practices.

These measures demonstrate a preventive approach to drug safety.

❖ Assessment Scales Applicable to ADR Evaluation

In the drug safety assessment of ASU&H, various standardized scales, originally developed for conventional pharmacovigilance, have been utilized with varying degrees of adaptation

• WHO-Uppsala Monitoring Center (WHO-UMC)

Causality Assessment Scale - Suspected ADRs are classified as certain, probable/likely, possible, unlikely, conditional/unclassified or Unassessable based on the temporal relationship to drug exposure, existing knowledge of the reaction profile, and response to de-challenge or rechallenge.^[12,13]

• Naranjo Adverse Drug Reaction Probability Scale - a 10-item weighted questionnaire that produces a cumulative score to classify causality as definite, probable, possible, or doubtful; one of the most widely used causality tools, but assumes a single suspected drug, limiting its direct applicability for polyherbal ASU formulations.^[12]

• Modified Hartwig and Siegel Severity Assessment Scale - grades the severity of the ADR on a spectrum of mild (Level 1) to severe/fatal (Level 7-9) according to clinical consequence and the level of medical intervention required.^[12,13]

• Modified Schumock and Thornton Preventability Assessment Scale - classifies an ADR as definitely preventable, probably preventable or not preventable, giving a view on prescribing, dispensing and monitoring practice rather than the drug itself.^[12,13]

These tools together lay down the methodological backbone for objective ADR evaluation in Indian pharmacovigilance centers including those affiliated to the ASU&H network. However, none of these instruments have been originally developed specifically for polyherbal or multi-constituent formulations, posing a practical challenge in identifying a single causative ingredient especially for Rasashastra (herbo-mineral) preparations consisting of multiple botanical and mineral constituents.^[3,10]

4 DISCUSSION

In this review, we see a pharmacovigilance system in active transition. The establishment of the Ayush Pharmacovigilance Program of India, the three-tier NPvCC-IPvCC-PPvCC network and the digital Ayush Suraksha portal represent true and quantifiable steps toward the formal surveillance of ADRs for medicine systems historically excluded from structured safety monitoring.^[2,4,5] However, the AYUSH pharmacovigilance ecosystem remains relatively young

in comparison to the more mature PvPI network for conventional drugs, having only received a dedicated funded scheme in 2017, nearly a decade after conventional PV had achieved a national scale.^[2,11] A recurring theme in the reviewed literature is the persistent gap between the extent of AYUSH drug consumption in India and the volume of ADR reports generated.

This gap appears to be less a matter of a lack of infrastructure and more a matter of attitudinal and behavioral factors: a deeply ingrained perception shared by patients and, at times, practitioners that traditional or “natural” remedies are inherently safe and therefore not routinely scrutinized for adverse effects the way conventional pharmaceuticals are.¹⁾ The weak association between practitioner knowledge/attitude and actual reporting practice in at least one KAP study (1) adds weight to the idea that awareness campaigns alone are insufficient, and that integrating ADR documentation directly into routine clinical workflow and making reporting easier with tools such as the Ayush Suraksha portal might be more effective levers than education alone. The application of causality and severity assessment scales developed for single-drug allopathic contexts, most notably the Naranjo scale, to polyherbal ASU formulations is methodologically imperfect, as these tools implicitly assume one suspected drug per assessment.^[12]

In the attribution of causality, a special problem is posed by rasashastra (herbo-mineral) preparations that may combine a multiplicity of botanical and mineral constituents. A key area for future methodological work in this field is the development or adaptation of AYUSH-specific causality assessment tools that can manage multi-ingredient formulations and known herb–herb and herb–drug interactions. Another area that needs attention is the integration between AYUSH and mainstream (PvPI) pharmacovigilance networks especially in the light of increasing number of patients using AYUSH and allopathic medicines simultaneously. Without organized sharing of cross-system data, ADRs from herb–drug interactions may be missed or attributed to only one of the systems. If interoperability with PvPI’s reporting infrastructure is pursued, digital platforms like Ayush Suraksha provide an opportunity to bridge this gap.^[4,5,9]

There are limitations to this review. It is a narrative, not a systematic review, so it does not use a pre-registered search protocol or a formal quality-appraisal instrument, and it draws heavily on institutional and secondary sources rather than on primary quantitative ADR datasets. Therefore, firm epidemiological conclusions about ADR incidence rates specific to AYUSH populations cannot be drawn from this synthesis alone; such conclusions would require dedicated prospective pharmacovigilance studies across the PPvCC network.

5 CONCLUSION

Pharmacovigilance in AYUSH system is an important and emerging field which is important to ensure the safety of patients using ASU&H drugs which has seen a remarkable growth in post covid era. Institutional progress in India has seen the establishment of the Ayush Pharmacovigilance Program, its three-tier monitoring network and the digital Ayush Suraksha portal. The main challenge however, is still underreporting of ADRs, mainly due to practitioner and patient perception of safety, poor integration of reporting into clinical practice and difficulty in establishing causality in polyherbal and herbo-mineral formulations using tools designed for single drug allopathic formulations. In the future, enhancing AYUSH pharmacovigilance will require continuous education of practitioners and patients integrated into clinical workflows, broader and simplified use of digital reporting tools, the creation of causality and severity assessment tools tailored to multi-ingredient traditional formulations, and increased interoperability with the larger Indian pharmacovigilance ecosystem. Such measures are necessary not only to ensure the safety of individual patients but also to maintain the global confidence in the safety profile of India’s traditional systems of medicine.

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