



Review Article	Volume 15 Issue 08	August 2026
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BUILDING A SAFER PEDIATRIC AYURVEDA SYSTEM: PHARMACOVIGILANCE GAPS AND THE CHILD-SAFE MONITORING FRAMEWORK

An Integrative Review & Framework Proposal

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DOI: <https://doi.org/10.5281/zenodo.22296859>

Highlights

- Children require age- and development-specific monitoring of Ayurvedic medicines.
- Conventional adverse drug reaction forms often inadequately capture product identity, dose, formulation, co-exposures and developmental outcomes.
- Ayurvedic pharmacovigilance must integrate clinical events with medication errors, herb-drug interactions and product-quality defects.
- This article proposes the CHILD-SAFE Ayurveda framework for pediatric safety monitoring.
- Active surveillance, product traceability and coordinated clinical-laboratory investigation are essential for reliable signal detection.

Abstract

Background

Ayurvedic medicines are commonly used in children for preventive and therapeutic purposes. However, pediatric safety cannot be inferred from traditional use alone. Children differ from adults in drug absorption, metabolism, organ maturity, dose requirements and ability to communicate adverse effects. Product quality, caregiver administration, concurrent medicines and duration of exposure also influence safety.

Objective

To identify current gaps in pediatric pharmacovigilance of Ayurvedic medicines and propose a practical monitoring framework.

Methods

A focused integrative review was conducted using World Health Organisation guidance, pediatric pharmacovigilance recommendations, Indian AYUSH pharmacovigilance resources and relevant literature on herbal medicine safety.

Findings

Major gaps include underreporting, poor product and batch identification, incomplete dose documentation, inadequate recording of herb–drug interactions, limited developmental follow-up and weak linkage between clinical reporting and product-quality laboratories. Existing systems rarely analyse pediatric reports by developmental age or capture caregiver administration errors.

Conclusion

Pediatric Ayurvedic pharmacovigilance requires a dedicated approach that integrates child characteristics, precise product identification, exposure assessment, longitudinal follow-up, causality evaluation, and analytical investigation. The proposed **CHILD-SAFE Ayurveda framework** may support standardised reporting, signal detection and regulatory action.

Keywords: Ayurveda, adverse drug reaction, children, herbal medicine, medication safety, pharmacovigilance, pediatric pharmacology, traditional medicine.

1. Introduction

Pharmacovigilance involves the detection, assessment, understanding and prevention of adverse effects and other medicine-related problems. Its scope extends beyond adverse drug reactions to include medication errors, interactions, overdose, misuse, therapeutic failure and product-quality defects.^[1]

Children are not small adults. Hepatic metabolism, renal clearance, body composition and pharmacodynamic responses change considerably from the neonatal period through adolescence. Young children may also be unable to describe symptoms such as dizziness, nausea, palpitations or visual disturbances. Adverse effects may therefore manifest as poor feeding, excessive crying, irritability, altered sleep, reduced activity or behavioural change.^[2–4]

These concerns are particularly relevant to Ayurvedic medicines, which include single-herb preparations, polyherbal formulations, medicated oils, medicated ghee, fermented products, proprietary medicines and herbo-mineral formulations. Their safety may be influenced by the dose, duration, processing method, manufacturing quality, concomitant medicines, excipients and method of administration.

The World Health Organization Global Traditional Medicine Strategy 2025–2034 emphasises evidence generation, patient safety, appropriate regulation and responsible integration of traditional medicine into healthcare systems.^[5] India operates a three-tier pharmacovigilance network for Ayurveda, Siddha, Unani and Homoeopathy medicines. This network includes a National Pharmacovigilance Coordination Centre, Intermediary Pharmacovigilance Centres and Peripheral Pharmacovigilance Centres, supported by the Ayush Suraksha portal for reporting suspected adverse reactions and misleading advertisements.^[6]

This infrastructure provides an important foundation. However, publicly available programme materials largely describe a general safety-monitoring system rather than a dedicated pediatric pathway. A report containing only the child's age, medicine name and adverse event is insufficient to determine whether the event resulted from the formulation, dose, developmental vulnerability, herb–drug interaction, product defect or administration error.

The present review identifies the major gaps in pediatric pharmacovigilance of Ayurvedic medicines and proposes an implementable child-specific monitoring framework.

2. Methodology

2.1 Review design

This article was developed as a policy-oriented integrative review rather than a systematic review or meta-analysis. The purpose was to synthesise pediatric pharmacology, herbal-medicine safety, Ayurvedic pharmacovigilance and regulatory principles into a practical monitoring model.

2.2 Sources of information

Targeted literature searches were conducted up to August 2026 using PubMed and official sources from:

- the World Health Organisation
- the International Council for Harmonisation
- the European Medicines Agency
- the Ministry of Ayush
- Ayush Suraksha
- the Indian Pharmacopoeia Commission
- relevant pediatric, herbal-medicine and Ayurveda journals

2.3 Areas reviewed

The review focused on:

- Pediatric pharmacovigilance
- Safety monitoring of herbal and traditional medicines
- Adverse reactions associated with Ayurvedic medicines
- Product quality, contamination and adulteration
- Herb–drug interactions
- Medication and caregiver-administration errors
- Causality and preventability assessment
- Active surveillance
- Digital reporting systems
- Long-term developmental safety monitoring

2.4 Development of the proposed framework

The proposed framework was developed by combining general Pediatric pharmacovigilance principles with safety variables specific to Ayurvedic products and their patterns of use.

The framework is conceptual and requires prospective validation before routine national implementation.

3. Discussion and Framework Proposal

3.1 Interpretation of the identified gaps

The findings indicate that pediatric Ayurvedic pharmacovigilance requires a broader approach than conventional spontaneous adverse-reaction reporting.

An adverse event associated with an Ayurvedic medicine may arise from:

- the intrinsic action of a declared ingredient
- excessive or inappropriate dosing
- prolonged administration
- interaction with another medicine
- unsuitable formulation
- contamination or adulteration
- botanical substitution
- manufacturing variation
- caregiver-administration error

Clinical causality assessment alone may therefore be insufficient. Product identity, manufacturing quality, actual exposure and administration practices must be investigated simultaneously.

3.2 Causality assessment

The occurrence of an event after administration of a medicine does not establish causation. Assessment should consider:

- Temporal relationship
- Dose-response association
- Known pharmacological effects
- Alternative disease-related causes
- Infection and environmental exposure
- Concurrent medicines
- Response to withdrawal
- Recurrence after inadvertent re-exposure
- Product-quality concerns
- Biological plausibility

The WHO–Uppsala Monitoring Centre system may be used for general causality assessment. Pediatric-specific methods such as the Liverpool adverse drug reaction causality assessment tool may provide additional structure. Organ-specific methods, such as the updated Roussel Uclaf Causality Assessment Method, may be used for suspected herb-induced liver injury.^[7-9] Deliberate rechallenge should generally be avoided following serious Pediatric adverse reactions.

3.3 Need for active surveillance

Spontaneous reporting is essential for detecting rare and unexpected reactions but cannot estimate frequency without a denominator. It should be supplemented by:

- cohort event monitoring
- sentinel Pediatric centres
- product-specific registries
- electronic health-record surveillance
- longitudinal follow-up studies

A prospective cohort of children receiving a defined formulation provides information on the number exposed and permits estimation of event frequency.

3.4 Role of caregivers

Parents and caregivers are often the first to observe changes in feeding, sleep, activity, behaviour and school functioning. They also prepare, measure and administer most pediatric medicines. Caregiver reports should therefore be accepted even when causality is uncertain. Clinical verification can occur after submission. Consumer reporting may identify symptoms and medication errors that are not apparent during clinical consultations.^[10]

3.5 Age-stratified signal detection

All persons below 18 years should not be analysed as a single homogeneous group. Safety signals should be evaluated separately among:

- neonates
- infants
- preschool children
- school-age children
- adolescents

A signal concentrated in neonates or infants may be obscured when combined with a much larger adolescent population.

3.6 Proposed CHILD-SAFE Ayurveda Framework

The **CHILD-SAFE Ayurveda framework** is proposed for use at the bedside, in institutional pharmacovigilance units and within national safety programmes.

It provides a minimum structure for identifying, documenting, assessing and preventing safety problems related to Ayurvedic medicines in children.

C — Child characterisation

Record:

- exact chronological age
- gestational and postnatal age in neonates
- sex
- weight and height
- nutritional status
- developmental history
- renal and hepatic dysfunction
- allergies
- comorbidities
- previous adverse reactions

Neonates, infants, children and adolescents should be analysed separately.

H — Herbal and product identification

Document:

- full product name
- classical or proprietary category
- manufacturer
- manufacturing licence
- batch number and expiry date
- complete ingredients
- botanical names and plant parts
- mineral or animal-derived ingredients
- dosage form
- source of purchase
- label photographs
- retained sample, where available

I — Indication and exposure assessment

Record:

- therapeutic indication
- prescriber or source of recommendation
- prescribed dose
- actual administered dose
- frequency and duration

- route
- Anupana or vehicle
- relation to food
- adherence
- measuring device
- missed or repeated doses
- all concomitant medicines and supplements

Assessment should be based on actual exposure rather than the written prescription alone.

L — Longitudinal monitoring

Follow-up should reflect the age of the child, duration of treatment and risk profile of the product.

Enhanced monitoring is appropriate for:

- neonates and infants
- prolonged therapy
- multiple medicines
- herbo-mineral preparations
- chronic systemic illness
- concurrent conventional medicines
- previous drug reactions
- products with inadequate pediatric safety information

Monitoring may include:

- growth
- blood pressure
- feeding and nutritional status
- behaviour and sleep
- developmental milestones
- school functioning
- relevant laboratory tests

D — Differential diagnosis and causality

Assessment should include:

- temporal relationship
- alternative disease-related causes
- dose–response relationship
- concomitant medicine

- dechallenge response
- recurrence after accidental re-exposure
- known pharmacology
- medication error
- product-quality concerns

Causality, seriousness and preventability should be assessed separately.

S — Signal detection and stratification

Reports should be grouped by:

- ingredient
- formulation
- manufacturer
- batch
- developmental age group
- dose
- organ system
- seriousness
- duration
- interaction
- type of medication error

Priority should be given to:

- deaths and life-threatening reactions
- hospitalisation
- reactions in neonates and infants
- congenital or developmental outcomes
- hepatic, renal, cardiac or neurological injury
- repeated batch-related reports
- suspected adulteration
- interactions with essential conventional medicines

A single well-documented serious case may justify immediate investigation.

A — Analytical verification and action

When product quality is suspected, the response may include:

- retrieval and quarantine of the implicated batch
- pharmacognostic authentication
- chemical fingerprinting

- testing for declared ingredients
- elemental and heavy-metal analysis
- microbial and pesticide testing
- screening for undeclared pharmaceutical substances
- manufacturing-site review
- label revision
- safety communication
- restriction of use
- batch recall

Clinical and analytical investigations should proceed in parallel.

F — Family communication and feedback

Caregivers should receive clear instructions regarding:

- correct dose measurement
- method of administration
- storage
- expected effects
- warning symptoms
- accidental ingestion
- disclosure of other medicines
- emergency contact
- available reporting pathways

Reporters should receive acknowledgement and, where possible, feedback regarding assessment and safety action.

E — Evaluation, education and equity

Institutions should monitor:

- completeness of reports
- reporting timeliness
- serious-case follow-up
- batch identification
- medication-error detection
- safety actions
- age-group coverage
- regional coverage
- accessibility in local languages

Pharmacovigilance training should be included in Ayurveda, paediatrics, pharmacology, nursing and pharmacy education.

3.7 Minimum Pediatric Ayurvedic Safety Dataset

Table 1. Essential data elements

Domain	Information required
Child	Exact age, sex, weight, height, developmental stage and relevant comorbidities
Product	Name, manufacturer, category, batch, expiry, composition, dosage form and label image
Exposure	Indication, dose, frequency, route, dates, duration, Anupana, food relation and actual administration
Co-exposure	Conventional medicines, other Ayurvedic products, supplements and relevant foods
Event	Description, onset, seriousness, severity, clinical findings and investigations
Management	Product withdrawal, treatment, hospitalisation and outcome
Causality	Alternative causes, dechallenge, inadvertent rechallenge and assessment method
Quality	Retained sample, suspected defect, analytical testing and batch investigation
Follow-up	Recovery, residual effects, growth, development and recurrence
Reporter	Parent, practitioner, paediatrician, pharmacist, nurse, manufacturer or other source

A report should be accepted even when some fields are unavailable. However, serious cases should trigger active follow-up to obtain missing information.

3.8 Proposed Operational Pathway

A practical institutional process may include the following steps:

- **Detect:** Ask specifically about Ayurvedic medicines, household remedies and supplements during every pediatric medicine history.
- **Stabilise:** Treat the child before completing pharmacovigilance documentation.
- **Document:** Record the CHILD-SAFE dataset, photograph the product and retain a sample where possible.
- **Assess:** Evaluate seriousness, causality, preventability and differential diagnoses.
- **Report:** Submit the case through institutional and national Ayush pharmacovigilance channels.
- **Investigate:** Initiate batch and laboratory evaluation when a quality defect is suspected.
- **Follow up:** Monitor the child until recovery or clinical stabilisation.
- **Learn:** Convert confirmed or plausible signals into alerts, training, label changes or regulatory action.

3.9 From Passive Reporting to Active Surveillance

3.9.1. Cohort event monitoring

A defined cohort of children receiving a specified formulation should be followed prospectively. All clinical events should be recorded, whether or not they are initially considered medicine-related. This provides an exposure denominator and reduces selective reporting.

3.9.2. Sentinel Pediatric centres

Selected Ayurveda teaching hospitals and integrative Pediatric departments may conduct enhanced surveillance for high-priority formulations, serious reactions and vulnerable age groups.

3.9.3. Product registries

Registries may be developed for:

- Long-term Rasayana use
- Neurodevelopmental indications
- Recurrent respiratory disorders
- Epilepsy and behavioural disorders
- Herbo-mineral preparations
- Concurrent use of Ayurvedic and conventional medicines

3.9.4. Electronic health-record surveillance

Electronic health records may identify temporal associations between medicine exposure and laboratory abnormalities, emergency visits, hospitalisation or diagnostic codes. Routinely collected healthcare data can support paediatric signal detection when definitions and validation procedures are standardised.^[11]

3.9.5. Dual clinical coding

Ayurvedic terminology should be integrated with internationally recognised disease and adverse-event terminology to improve interoperability and comparison across safety databases.

3.10 Integration with the Existing Indian System

The proposed framework does not require creation of a separate national pharmacovigilance programme. It can be incorporated as a pediatric module within the existing Ayush pharmacovigilance network.

Institutional level

Each Ayurveda teaching hospital should identify:

- A Pediatric pharmacovigilance focal person
- An Ayurveda pharmacologist
- A Paediatrician
- A Pharmacist
- A Nursing Representative

- Access to an analytical laboratory

Network level

Peripheral and Intermediary Pharmacovigilance Centres should:

- Flag Pediatric reports
- Obtain missing age, weight, dose and batch information
- Conduct multidisciplinary causality reviews
- Aggregate signals by developmental age
- Communicate urgent reports to the national centre

National level

The National Pharmacovigilance Coordination Centre may consider:

- A Pediatric safety dashboard
- Age-stratified signal detection
- A Pediatric reporting form or digital module
- Integration with the Pharmacovigilance Programme of India
- Linkage with poison-information centres and pediatric hospitals
- Product-sample tracking
- Periodic Pediatric safety bulletins
- Public reporting facilities in regional languages

The WHO smart pharmacovigilance approach supports risk-based prioritisation, integration and the use of systems adapted to available national resources.^[12]

3.11 Indicators for Evaluation

Table 2. Suggested performance indicators

Type	Indicator
Structure	Proportion of centres with a designated pediatric focal person
Completeness	Reports containing age, weight, dose and batch number
Timeliness	Median interval from event recognition to submission
Follow-up	Serious reports with completed clinical follow-up
Product investigation	Suspected quality cases undergoing analytical testing
Causality	Reports assessed using a defined causality method
Preventability	Reports evaluated for dose, administration or labelling errors
Signal detection	Pediatric signals reviewed within a defined period
Clinical impact	Reduction in recurrence of preventable events
Equity	Reporting coverage across age groups, regions and healthcare settings

These indicators should be piloted before national performance thresholds are established.

3.12 Research Priorities

Priority areas for future research include:

- Validation of the CHILD-SAFE Ayurveda dataset and workflow
- Development of pediatric-specific causality and preventability methods for multi-ingredient products
- Prospective cohort-event monitoring of commonly used pediatric formulations
- Pharmaco-epidemiological estimation of exposure and adverse-event incidence
- Developmental pharmacokinetic studies
- Evaluation of pediatric excipients and dosage forms
- Systematic investigation of herb–drug interactions
- Long-term growth and neurodevelopmental follow-up
- Chemical authentication of products implicated in serious events
- Linkage of clinical, laboratory and regulatory databases
- Inclusion of caregiver-reported outcomes
- Evaluation of risk communication in regional language

3.13 Strengths and Limitations

The principal strength of this review is its integration of pediatric pharmacology, Ayurvedic product characteristics, clinical causality assessment, product-quality investigation and regulatory action within a single framework.

The CHILD-SAFE Ayurveda framework is not yet a validated instrument. It is based on established pharmacovigilance principles and synthesis of identified practice gaps. Prospective testing is required to assess:

- feasibility
- completeness
- inter-rater reliability
- cost
- acceptability
- effect on clinical and regulatory outcome

This review is policy-oriented rather than systematic. It does not estimate the incidence of adverse reactions to Ayurvedic medicines in children because reliable exposure-denominator data are currently unavailable.

4. Results

4.1 Need for a distinct Pediatric approach

The review identified several child-specific variables that should be considered when evaluating the safety of Ayurvedic medicines:

- exact age and developmental stage

- body weight, height and nutritional status
- hepatic and renal maturity
- age-appropriate formulation
- actual rather than prescribed dose
- caregiver preparation and administration
- concurrent conventional medicines and supplements
- possible effects on growth, behaviour, cognition and development

Weight-based dose reduction alone may not adequately account for developmental pharmacology. A dose tolerated in an adolescent may produce greater systemic exposure or toxicity in an infant because of differences in absorption, metabolism and elimination. Caregivers may crush tablets, dilute syrups, mix medicines with milk or food, repeat doses after vomiting or measure medicines using household spoons. Such practices alter actual exposure and should be documented during safety assessment.

4.2 Safety problems requiring monitoring

Pediatric Ayurvedic pharmacovigilance should extend beyond suspected adverse drug reactions. It should include:

- accidental ingestion and overdose
- repeated, missed or incorrectly timed doses
- administration of the wrong medicine or medicine to the wrong child
- dispensing and labelling errors
- use in an unsuitable age group
- herb–drug and herb–food interactions
- adverse effects of excipients
- therapeutic failure with clinical deterioration
- contamination, substitution and adulteration
- substandard or falsified products
- batch-related event clusters
- misleading therapeutic claims
- delayed growth, endocrine, behavioural or neurodevelopmental effects

A reaction caused by incorrect dose measurement or caregiver administration should be distinguished from an adverse effect caused by the medicine itself. WHO guidance similarly recognises that pharmacovigilance covers herbal medicines and a broad range of medicine-related problems, not only previously recognised pharmacological reactions.^[13,14]

4.3 Current gaps

4.3.1. Underreporting

Safety reporting remains predominantly passive. Mild, delayed or apparently common reactions may not be reported. Ayurvedic or natural medicines may also be assumed to be inherently safe, reducing reporting by practitioners and families.

Published pediatric herb-related case reports frequently omit the administered dose, duration, complete product composition, manufacturer, batch details and concomitant therapies.^[15]

4.3.2. Product quality and contamination

Herbal medicinal products may be affected by:

- microbial contamination
- pesticides
- mycotoxins
- residual solvents
- environmental metals
- undeclared pharmaceutical substances
- incorrect botanical species
- substitution of plant parts

Systematic evidence from low- and middle-income countries indicates that contamination remains an important concern in herbal medicinal products.^[16]

Intentional inclusion of appropriately processed mineral ingredients should be distinguished from unintended contamination. Interpretation requires information on the formulation, manufacturing process, chemical form, concentration and administered dose.

4.3.3. Incomplete product identification

A brand name alone is insufficient for pharmacovigilance. Safety reports commonly omit:

- manufacturer
- manufacturing licence
- batch number
- expiry date
- complete composition
- dosage form
- source of purchase
- photograph of the label and container

Without adequate product traceability, batch-related defects, substitution, adulteration and manufacturing variation cannot be investigated.

4.3.4. Uncertain dose and exposure

Instructions such as “one spoon,” “a pinch” or “half the adult dose” prevent accurate exposure assessment. The actual administered dose should be documented in measurable units and, where appropriate, expressed as milligrams or millilitres per kilogram per day.

The following should also be recorded:

- concentration of the dosage form
- frequency
- duration
- missed or repeated doses
- relation to meals
- Anupana or vehicle
- device used for dose measurement

4.3.5. Inadequate documentation of co-medication and interactions

Children with epilepsy, asthma, diabetes, malignancy, autoimmune disease or chronic renal, hepatic or cardiac disorders may receive Ayurvedic and conventional medicines concurrently.

Potential interactions may involve:

- gastrointestinal absorption
- hepatic enzymes
- drug transporters
- renal elimination
- electrolyte balance
- haemostasis
- additive pharmacodynamic effects

Failure to record all concurrent medicines, supplements and dietary products may conceal clinically important interactions. WHO guidance recommends systematic documentation and evaluation of concurrent herbal and conventional medicine use.^[17]

4.3.6. Inadequate developmental follow-up

Many reports are closed once the acute reaction resolves. However, suspected effects on growth, cognition, puberty, endocrine function or organ development may require longer follow-up.

The duration of follow-up should be determined by:

- seriousness of the event
- affected organ system
- biological plausibility
- duration of exposure
- developmental stage of the child

4.3.7. Weak clinical–laboratory linkage

Suspected product-quality events are often assessed clinically without testing the implicated batch. When contamination, adulteration, substitution or manufacturing variation is suspected, clinical investigation and analytical product testing should occur together.

Table 3: Major gaps and their consequences

Gap	Consequence for pediatric safety
Reliance on spontaneous reporting	Common, mild, delayed and non-serious reactions remain undetected
Absence of exposure denominators	Incidence and comparative risk cannot be estimated
Incomplete child data	Dose–exposure relationships and developmental susceptibility cannot be assessed
Poor product identification	The implicated formulation, ingredient or batch cannot be verified
Failure to document conventional medicines	Herb–drug interactions may be missed
Limited longitudinal follow-up	Growth, neurodevelopmental and endocrine effects remain unrecognised
Weak linkage with laboratories	Clinical signals cannot be correlated with product composition
Absence of Pediatric signal stratification	Signals in neonates or infants may be diluted within all-age data
Inadequate feedback to reporters	Reporting motivation and clinical learning decline
Limited family engagement	Early symptoms and administration errors may not be reported

5. Conclusion

Pediatric pharmacovigilance of Ayurvedic medicines requires more than passive reporting of isolated adverse reactions. Reliable safety assessment depends on the child's developmental characteristics, the actual dose administered, the specific product and batch, concurrent medications, caregiver practices, and product quality.

India's existing Ayush pharmacovigilance network and digital reporting system provide a strong institutional foundation. The next step is to incorporate a pediatric-specific pathway that can produce clinically interpretable and regulatory-actionable evidence.

The proposed CHILD-SAFE Ayurveda framework links bedside recognition with product identification, causality assessment, analytical investigation, signal detection, family engagement and regulatory learning. Its purpose is neither to presume that Ayurvedic medicines are inherently unsafe nor to accept traditional use alone as proof of safety.

Prospective multicentre validation is required to determine whether the framework improves report quality, identifies preventable harm and supports safer use of Ayurvedic medicines in children.

6. Declarations

Ethical approval: Not applicable

Consent for publication: Not applicable.

Funding: Self-funding

Conflict of interest: Nil

Author contributions: Introduction, Methodology: SAA; Results: STS; Discussion & Conclusion: SAA, STS.

Data availability: All analysed data are extracted from the published studies cited in the reference list

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How to cite this article:

Arora SA, Saini ST. Building a Safer Pediatric Ayurveda System: Pharmacovigilance Gaps and the CHILD-SAFE Monitoring Framework. International Journal of AYUSH. 2026;15(08):216-234.