



# “Pharmacovigilance And Adverse Drug Reactions: An Ayurvedic Perspective- A Review”

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## Abstract

Pharmacovigilance is a science aimed at ensuring the safety of medicines by detecting, assessing, and preventing adverse drug reactions (ADRs). This article explores the evolution and objectives of pharmacovigilance, emphasizing its importance in modern healthcare. It also highlights parallels with Ayurvedic teachings, which stress the responsible use of medicines and the risks of improper administration. The article offers a comprehensive perspective on the shared goal of both systems, safeguarding public health through vigilance and informed medicine use.

Keywords: Pharmacovigilance, Ayurveda, Adverse Drug Reactions, Drug Safety etc

## Introduction

**Pharmacovigilance** is derived from two words: *Pharmacon*, meaning drug, and *Vigilance*, meaning to be awake or alert. It is a pharmacologically oriented science that focuses on the detection, collection, assessment, understanding, and prevention of adverse effects, particularly the long-term and short-term side effects of medicines[1].

Pharmacovigilance serves as a cornerstone for ensuring the safe and rational use of pharmaceutical products, fostering public trust in drug safety. It plays a pivotal role in improving patient care, minimizing medication-related risks, and enhancing overall public health outcomes.

Although the term "pharmacovigilance" is not explicitly mentioned in Ayurvedic texts, its core principles align closely with the teachings of classical Ayurvedic scriptures, such as the Brihatraye and Laghutraye. These ancient texts emphasize the need for vigilance, precision, and responsibility in the preparation and administration of medicines.

A prevalent misconception is that Ayurvedic medicines are entirely free from adverse effects. However, classical Ayurvedic wisdom clearly highlights that even the most beneficial drugs can become harmful if misused. Charaka Samhita profoundly states that a powerful medicine, if handled carelessly, can act as poison, whereas a potent poison can serve as an excellent remedy when administered appropriately and judiciously[2].

This perspective underscores the timeless relevance of pharmacovigilance principles and the necessity of adopting a cautious, informed approach to both modern and traditional medicines.

### **Evolution of Pharmacovigilance**

The field of pharmacovigilance has evolved significantly since its inception. Key events that shaped its development include:

1956: The launch of thalidomide in the market

1959-1961: Reports of fetal abnormalities due to thalidomide.

1962: US laws revised for drug safety and efficacy.

1964: UK's "Yellow Card" system introduced for ADR reporting.[2].

### **Aims of Pharmacovigilance**

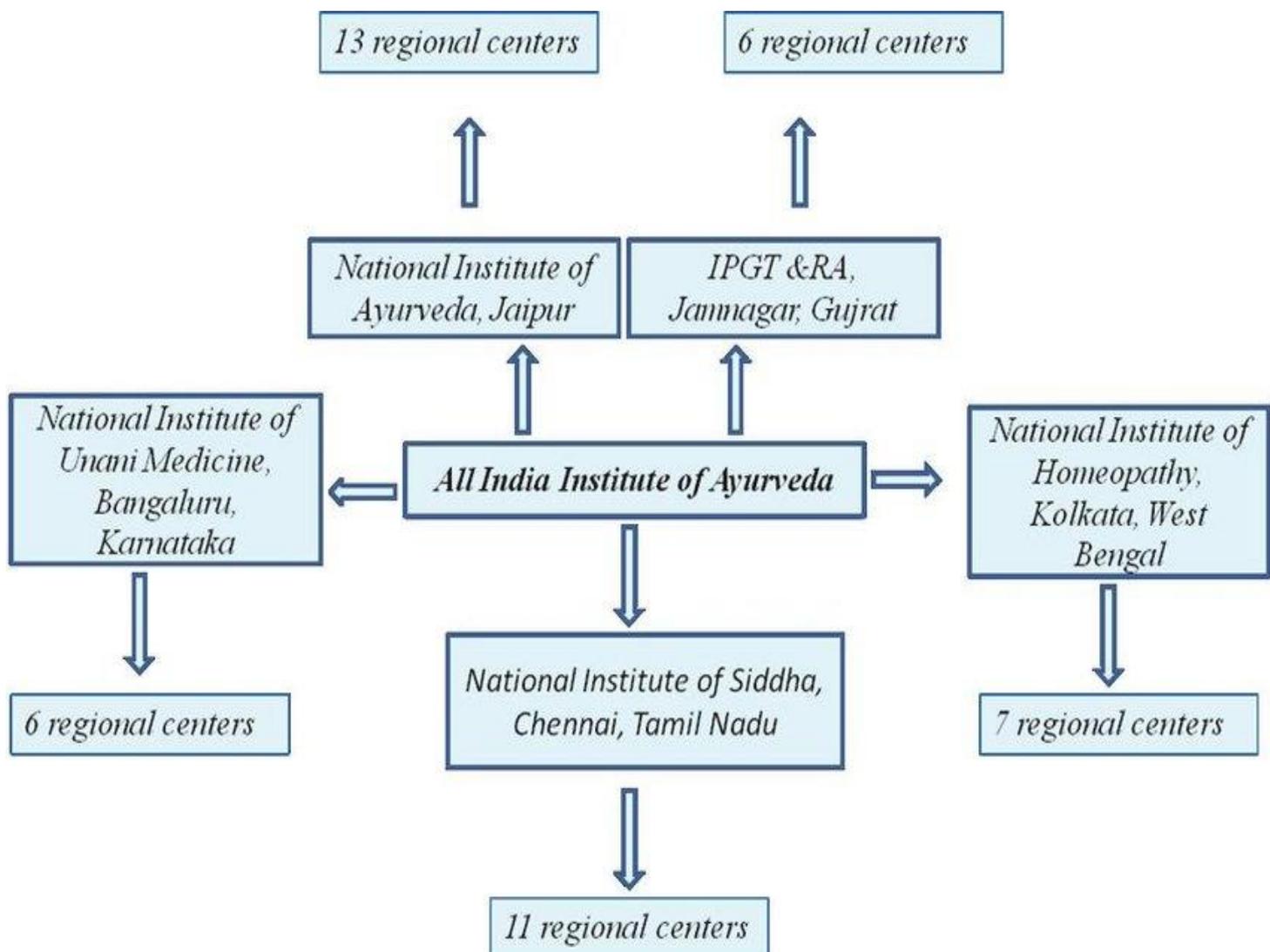
The primary aims of pharmacovigilance are:

- To improve patient care and safety related to the use of medicines.
- To improve public health by identifying risks and minimizing harm from drug usage.

### **Objectives of Pharmacovigilance**

Pharmacovigilance works towards achieving the following objectives:

1. Short-Term Objective: Develop a culture of ADR notification and reporting among healthcare professionals and the public.
2. Medium-Term Objective: Involve professional associations and healthcare providers in drug safety monitoring and information dissemination.
3. Long-Term Objective: Establish operational efficiencies that make pharmacovigilance a global benchmark for drug safety monitoring [1].

**Pharmacovigilance Centers in India:****ADR Classification**

- Type A: (Augmented): predictable on basis of known pharmacology of the Drug
- Type B (Bizarre): Unpredictable / Idiosyncratic reaction Can not be explained on basis of known Pharmacology
- Type C: (chronic use) Develop with long term therapy
- Type D (delayed effect) The effect such as carcinogenicity, teratogenicity, fall under this category
- Type E (End of Use): Such reaction occurs after stopping use of the drug. Eg. Withdrawal syndrome
- Type F (Failure): This relate to unexpected failure of treatment.[4]

## Steps to Monitor and Analyze ADRs in Pharmacovigilance

Effective ADR monitoring involves several steps:

1. Data Collection: Collect ADR reports systematically from healthcare professionals, patients, and pharmacovigilance centers.
2. Signal Detection: Identify signals - information suggesting a new or known ADR that requires further evaluation - using statistical tools like disproportionality analysis and Bayesian methods [5]
3. Causality Assessment: Evaluate the relationship between drug exposure and the reported adverse event using standardized methods(Naranjo's scale).
4. Conduct Risk-Benefit Analysis: Compare the drug's risks (side effects) to its benefits (therapeutic effects) to determine if the drug should remain on the market.
5. Take Regulatory Actions: Based on the analysis, make decisions like updating the drug's label with new warnings, issuing safety alerts, or even withdrawing the drug if it's too risky.
6. Public Awareness: Educate healthcare professionals and the public about ADRs and their prevention [6].

## Pharmacovigilance in Ayurveda

Ayurveda's approach to pharmacovigilance is based on, focusing on the prevention of secondary diseases or ADRs while addressing the primary health concern. The following Charaka Samhita shloka underscores the importance of using treatments that do not cause additional harm:

प्रयोगः शमयेत् व्याधिं योऽन्यमन्यमुदीरयेत्॥

नाऽसौ विशुद्धः शुद्धस्तु शमयेत् यो न कोपयेत्॥

(Charaka Samhita, Nidana Sthana, 8/23)

This means: "A treatment which relieves one disease and gives rise to another disease is Asuddha(not proper treatment) Suddha(proper) treatment is that which relieves one disease and does not give rise to another disease.[7].

न कोपयेत् इति व्याधि अनन्तरं न कुर्यादित्यर्थः। चक्रपाणि

Chakrapani datta called it as Adarsha Chikitsa.

The given treatment for the particular disease will cure the disease and does not producing any other disease.

## Characteristics of Ideal Medicines

The Charaka Samhita describes qualities of an ideal medicine:

अल्पमात्रं महावेगं बहुदोषहरं सुखम्।

लघुपाकं सुखस्वादं प्रीणनं व्याधिनाशनम्॥

अविकारि च व्यापत्तौ नातिग्लानिकरं च यत्।

गन्धवर्णरसोपेतं विद्यात्मात्रावदौषधम्॥

(Charaka Samhita, Siddhi Sthana, 6/15-16)

This means: "अल्पमात्रं - It should work optimally in small dosage

- महावेगं - It must have quick action,
- बहुदोषहरं - It must eliminate large amounts of Dosha,
- सुखम् - It should bring in comfort,
- लघुपाकं - It should be easily digestible, • सुखास्वादं - It must be palatable,
- प्रीणनं व्याधिनाशनम् - It must be vitalizing and disease pacifying • अविकारि च व्यापत्तौ - It should not lead to any other complication
- ईषद्विकारकारि - Causes minimal diseases
- नातिग्लानिकरं - It should not produce tiredness,

गन्धवर्णरसोपेतं - - It should be endowed with good smell, color, taste etc. and should be pleasing in nature [8]

### Drug Abuse

Ayurveda warns that even beneficial substances can become harmful if not used correctly. The following Charaka Samhita shloka emphasizes that improper drug use can turn beneficial substances into harmful ones:

योगादपि विषं तीक्ष्णमुत्तमं भेषजं भवेत्।

भेषजं चापि दुर्युक्तं तीक्ष्णं सम्पद्यते विषम्॥

(Charaka Samhita, Sutra Sthana, 1/126)

This means: "Even a poison, if used correctly, can act as medicine, while a well-intended medicine can become poisonous if misused." [9] This reflects modern pharmacovigilance's emphasis on correct dosages and proper administration to avoid ADRs .

In Ayurveda, the effects of substances depend on their context of use, such as dose, preparation, and timing. The following Sushruta Samhita shloka articulates this idea:

"न किञ्चित् द्रव्यं एकान्तेन हितमहितं वाऽस्ति"

(Sushruta Samhita, Sutra Sthana, 20/3)

This means: "Ekanta-Hita- Absolutely suitable means those which do not harm the body in spite of them being always used. Like water, ghee etc

Ekanta Ahita - absolutely unsuitable means those which harm the body quickly and so cannot be used even for short periods. Like fire, poison

Hitahita - suitable-unsuitable, are those which do not harm in certain conditions (proper quantity, time, season, processing etc) but cause harm in certain other conditions (improper quantity, time, season, processing etc). The substance which are suitable to vata and unsuitable to pitta. Etc[10] .

## Discussion

Ayurveda, has always prioritized patient safety and effective healing by addressing roga, rogi, pariksha and personalized healing through aushadha . It emphasizes prakriti , vikruti , dosha-dhatu-mala , and factors like vaha, ritu, and vihara to craft precise treatments, ensuring minimal adverse effects

The safety of Ayurvedic formulations is upheld through processes like shodhana (purification) and samskara (processing) of dravya (substances), transforming potentially harmful elements into therapeutic remedies. As highlighted in the Charaka Samhita:

"यथाविषं यथाशस्त्रं यथाऽग्निरशनिर्यथा। तथौषधमविज्ञातं विज्ञातममृतं यथा॥"

(Charaka Sutra Sthana, 1/124),

any dravya can be amrita (life-saving) or visha (poison) depending on its knowledge and application.

## Why ADRs Occur in Ayurveda Despite Personalization

### 1. Incorrect Preparation or Processing:

- **Example:** Bhallataka (Semecarpus anacardium), if improperly purified, can cause skin irritation. Additionally, its use is contraindicated in Pitta Prakriti persons due to its Ushna and Tikshna Guna, which aggravate Pitta.
- **Relevance:** Adhering to purification processes and considering Prakriti minimizes ADRs.

### 2. Overdose or Misuse:

- **Example:** Excessive use of Haritaki (Terminalia chebula) can cause dehydration due to its strong Virechana (purgative) action. It is also contraindicated during pregnancy (Garbhini) as it may stimulate uterine contractions, posing risks to fetal health., and exceeding recommended doses can lead to adverse effects.
- **Relevance:** Educates on the importance of patient-specific dosages to avoid ADRs.

### 3. Contamination or Poor Storage:

- **Example:** Shatavari (Asparagus racemosus) may develop fungal contamination if stored improperly, leading to ADRs. Ayurveda emphasizes proper storage to maintain efficacy.
- **Relevance:** Points out the role of good practices in preventing unintended harm. Etc

### 4. Improper Anupana (Vehicle):

- **Example:** Consuming Pippali (Piper longum) with hot water in individuals with Pitta dominance can aggravate acidity and Pitta-related disorders.
- **Relevance:** Stresses the importance of selecting an appropriate Anupana based on the patient's prakriti and dosha condition.

### 5. Incompatible Combinations (Viruddha Ahara):

- **Example:** Consuming milk with sour fruits (e.g., amra) may lead to indigestion, skin disorders, or toxin accumulation in the body. Ayurveda identifies such combinations as Viruddha Ahara
- **Relevance:** Emphasizes avoiding incompatible combinations to prevent ADRs.

## 6.Improper Dosage Calculations:

- **Example:** Sariva is used in skin diseases if use it in excess cause vomiting.
- **Relevance:** Accurate dosage based on age, Prakruti, and Agni is needed.

## Conclusion

Pharmacovigilance plays a critical role in promoting the safe use of medicines by preventing adverse drug reactions and ensuring public trust in healthcare. Although the term pharmacovigilance is modern, its essence aligns closely with Ayurvedic principles, which emphasize precise medicine use and caution against misuse. Classical Ayurvedic texts highlight the importance of understanding the effects of medicines, proper dosage, and preparation to

avoid harmful outcomes. This article bridges modern pharmacovigilance with the time-tested wisdom of Ayurveda, offering insights into creating a safer and more effective healthcare system through vigilance and responsible practices.

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