v. Knowledge of pharmaco-vigilance in Āyurveda

v. Knowledge of pharmaco-vigilance in Āyurveda and conventional system of medicine

Pharmacovigilance (PV)—*"the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem"* (WHO)—is crucial for **patient safety** in both **conventional** and **traditional** (Āyurvedic) healthcare systems. This overview combines **historical contexts**, **present frameworks**, **challenges**, **case examples**, and **future directions** to illustrate how **pharmacovigilance** ensures the safe, effective, and evidence-based use of medicines.

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Definition and Core Objectives of Pharmacovigilance

- **Definition**: Per WHO, pharmacovigilance oversees the **safety** of medicines post-marketing, rapidly identifying and mitigating drug-related risks.
- **Objectives**:
  1. **Ensure patient safety** by monitoring adverse drug reactions (ADRs).
  2. **Promote evidence-based prescribing** and optimize therapeutic outcomes.
  3. **Communicate** findings to healthcare professionals and the public, facilitating informed risk-benefit decisions.

Historical Background

Thalidomide Tragedy (1960s)

1. **Incident**
   - Thalidomide, launched as a sedative/anti-nausea drug for pregnant women, caused severe congenital malformations (*phocomelia*) in >20,000 infants worldwide.
2. **Global Impact**
   - **USA (1962)**: Amended the Federal Food, Drug, and Cosmetic Act to mandate comprehensive safety and efficacy data pre-approval.
   - **UK (1964)**: Launched the **Yellow Card Scheme** for ADR reporting.
   - **WHO (1968)**: Established the **Programme for International Drug Monitoring**, anchoring a global PV network.

Broader Pharmacovigilance Systems

- **ICH (International Council for Harmonisation)**: Issues guidelines for PV in conventional medicine.
- **WHO Guidelines (2004)**: Called for the inclusion of **traditional medicines** in national PV systems, acknowledging their widespread usage and potential risks if unmonitored.

Pharmacovigilance in India

Conventional Medicine (Allopathic)

1. **Establishment**
   - **2003**: **Pharmacovigilance Programme of India (PvPI)** under the Central Drugs Standard Control Organization (CDSCO).
   - Collaborates with WHO–Uppsala Monitoring Centre (UMC) for global signal detection.
2. **Key Features**
   - **ADR Reporting**: Vigiflow software centralizes data.
   - **Regulatory Oversight**: Monitors post-marketing drug safety, issues alerts on potential hazards.

Ayurveda, Siddha, and Unani (ASU) Medicine

1. **Traditional Perception of Safety**
   - ASU drugs historically deemed “safe” due to natural origin. Yet, sporadic ADRs (heavy metal contamination, incorrect usage) raised concern for formal PV.
2. **Milestones**
   - **2007**: IPGT & RA, Jamnagar workshop: “Pharmacovigilance for Ayurvedic Drugs.”
   - **2008**: Launch of the **National Pharmacovigilance Programme for ASU Drugs (NPP-ASU)**, sponsored by WHO.
   - **Objective**: Collect, analyze, and disseminate ADR data for safe use of classical and proprietary Ayurvedic formulations.
3. **NPP-ASU Implementation**
   - **Reporting Form**: Specially designed for suspected ADRs with herbal details, classical references if any.
   - Encourages multi-level engagement: practitioners (reporting), manufacturers (quality compliance), regulators (signal detection).

Scope of Pharmacovigilance in Āyurveda

Challenges

1. **Complex Formulations**
   - Many ASU drugs are multi-ingredient (polyherbal or herbo-mineral), complicating pinpointing the culprit ingredient in ADRs.
2. **Lack of Awareness**
   - Underreporting from practitioners or patients due to cultural assumptions of no side effects.
3. **Standardization Issues**
   - Inconsistent raw materials or varied manufacturing protocols hamper uniform safety profiles.

Key Areas of Focus

1. **Heavy Metal Toxicity**
   - Bhasma or Rasa preparations containing mercury, lead, or arsenic must comply with permissible limits (e.g., lead ≤10 ppm, arsenic ≤3 ppm as per national guidelines).
2. **Herb–Drug Interactions**
   - E.g., *Ashwagandha* potentially interacts with sedatives; *Guduchi* might potentiate certain immunosuppressants.
3. **Adulteration Detection**
   - Checking for steroid contamination or substitution with cheaper herbs, essential for consumer safety.

Implementation Strategies for Pharmacovigilance in Āyurveda

NPP-ASU Framework

1. **Data Collection**
   - ADR forms from AYUSH hospitals, clinics, pharmacies.
   - Real-time reporting of minor or major suspected reactions.
2. **Analysis**
   - Trend detection, signal generation (if multiple reports converge on a specific drug).
   - Safety alerts or recall advisories if severe risk emerges.
3. **Communication**
   - Disseminate safety information to practitioners, public, and government agencies.
   - Revisions in labeling or dosage if needed.

Role of Stakeholders

1. **Practitioners**

    - Document ADRs meticulously, counsel patients on rational use and potential side effects.
2. **Manufacturers**
    - Comply with GMP (Schedule T) and QC protocols (heavy metals, microbial load).
3. **Regulators**
    - Enforce PV guidelines, update safety bulletins, refine schedule E(I) or API standards if a pattern emerges.

Case Studies

Heavy Metal Toxicity in Bhasma

- **Issue**: Reports of lead/mercury poisoning from improperly calcined bhasma (e.g., *Nāga bhasma*).
- **Resolution**: Stricter **Schedule T** enforcement, ensuring multi-stage śodhana and final product testing for permissible heavy metal limits (≤10 ppm lead, etc.).

Herb–Drug Interactions

- **Example**: *Ashwagandha* (Withania somnifera) co-administered with sedatives → possible additive sedation.
- **Solution**: Label disclaimers, counseling on concurrent usage with psychotropics or anxiolytics.

Future Directions

1. **Integration with Modern Systems**
    - Linking **NPP-ASU** and **PvPI** for a **comprehensive** national PV database.
    - Encourages consistent training in BAMS curricula on ADR reporting and coding.
2. **Technological Advancements**
    - AI-based signal detection for large volumes of AYUSH data.
    - Blockchain to ensure authenticity of supply chains, addressing adulteration.
3. **Global Collaboration**
    - Share data with WHO’s T&CM pharmacovigilance network for mutual knowledge exchange.
    - Align labeling/warnings to match EU or USFDA norms, facilitating export acceptance.

Conclusion

Pharmacovigilance is pivotal in **protecting patients** from adverse reactions, whether from allopathic or **Āyurvedic** medicines. Historically spurred by the **thalidomide** tragedy, PV has expanded to **traditional systems**—including **Āyurveda, Siddha, and Unani (ASU)**—due to rising global usage of herbal remedies. In India, while the **Pharmacovigilance Programme of India** addresses allopathic drugs, a parallel **National Pharmacovigilance Programme for ASU** (NPP-ASU) ensures that **classical** and **proprietary** Ayurvedic medicines also undergo systematic ADR monitoring.

By highlighting challenges such as **heavy metal toxicity**, **herb–drug interactions**, and **adulteration**, PV in **Āyurveda** fosters **safe prescribing** and heightened consumer confidence. Ongoing initiatives—**technical training**, **research** on synergy vs. toxicity, **regulatory** synergy with global bodies—signal a future where AYUSH medicines are both **traditionally authentic** and **scientifically validated**, ensuring that integrative healthcare truly benefits patients worldwide.