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PHARMACOVIGILANCE: SCOPE, NEED, CLINICAL ASPECTS AND CHALLENGES IN HOMOEOPATHY

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ABSTRACT: -

Pharmacovigilance (PV) is a multidisciplinary field that intersects with various other disciplines to ensure comprehensive drug safety monitoring and risk management. The related fields of pharmacovigilance include pharmacoepidemiology, clinical pharmacology, regulatory affairs, pharmacogenomics, and health informatics. This review will highlighten the contributions to pharmacovigilance and their collaborative roles in enhancing drug safety.

This abstract provides an overview of PV's development, its regulatory framework, and the various methods employed to monitor and improve drug safety. Emphasis is placed on the importance of spontaneous reporting systems, the role of regulatory agencies.

Pharmacovigilance, like in conventional medicine, is an essential part of homoeopathy. The practitioners are ignorant and lack sufficient knowledge. Raising awareness and motivating homoeopathic practitioners about medication safety surveillance, adverse event reporting, and documentation is essential.

KEY WORDS: Pharmacovigilance, Scope, Clinical aspect, need, Challenges, Homoeopathy.

INTRODUCTION OF PHARMACOVIGILANCE:

Pharmacovigilance (PV), as defined by the World Health Organization (WHO), encompasses "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem." It is essential for ensuring that patients and medical professionals have enough knowledge to choose treatments with the right medications[1].
PV significantly impacts drug safety, achieving intended therapeutic outcomes, reducing morbidity and mortality, shortening hospital stays, lowering medical expenses, and enhancing patient quality of life[2].

SCOPE

Pharmacovigilance covers various critical areas, including:

- **Adverse Drug Reaction (ADR) Monitoring:** Identifying and assessing adverse reactions to medications[3].
- **Safety Surveillance:** Continuous monitoring of drug safety profiles[4].
- **Risk Assessment:** Evaluating the potential risks associated with drug use[5].
- **Regulatory Compliance:** Ensuring adherence to drug safety regulations[6].
- **Education and Communication:** Disseminating safety information to healthcare professionals and the public[7].
- **Data Management and Research:** Handling and analyzing safety data[8].
- **Global Cooperation:** Collaborating internationally to enhance drug safety[9].
- **Policy Development:** Formulating policies to promote drug safety[10].

NEED

The AYUSH systems prioritize safety, emphasizing proper medication administration to avoid side effects. Literature consistently advocates for using the right medication in the correct dosage for positive outcomes. Traditional systems warn against overuse and recommend disease-specific medications in small doses with suitable adjuvants like ghee, milk, and honey to avoid adverse consequences[11].

Pharmacovigilance aims to minimize patient injury from drugs. In 2003, India's Central Drug Standards Control Organization (CDSCO) launched the National Pharmacovigilance Program, and the WHO released guidelines in 2004 to include herbal medicines in safety monitoring. The Ministry of AYUSH funds a program to create and maintain an Adverse Drug Reactions (ADR) database, develop system-specific ADR databases, and provide evidence-based safety recommendations for ASU and H drugs, while also monitoring deceptive advertisements[12].

Using the Suspected Adverse Reactions Reporting Form for ASU & H Drugs also monitors offensive or deceptive adverts[12].

The longstanding practices of Ayurveda, Siddha, Unani, and Homoeopathy in India face new safety concerns in the global era, such as drug interactions and contamination. Many ASU and H products are produced globally and used outside their traditional contexts, leading to adverse effects from improper use or poor quality. Despite having their own pharmacopoeia, ASU and H medicines are sometimes used as over-the-counter drugs without prescriptions, emphasizing the need for their inclusion in pharmacovigilance systems to ensure safety[12].

CLINICAL ASPECTS OF PHARMACOVIGILANCE [13]

Pharmacovigilance (PV) operations collaborate with clinical research teams to collect data on serious adverse events (SAEs) and adverse drug reactions (ADRs) during clinical studies. SAEs are major events that can be fatal, cause disability, or result in birth abnormalities, whereas ADRs are less severe reactions such as fatigue, nausea, and headaches.

PV operations also manage standard operating procedures (SOPs), case study reports, literature screening, and regulatory expedited reporting of suspected unexpected serious adverse reactions (SUSARs) once drugs are on the market. Those interested in this field may benefit from the ICH-GCP course for deeper insights into SOPs and case studies.

The PV systems team ensures safety data is well-organized and accessible to research partners, continuously managing and improving data due to changing laws and expectations. The surveillance team analyzes this safety data to produce Development Safety Update Reports (DSURs), determining if a medication can proceed to the next clinical investigation stage. If deemed safe by the third phase, PV applies for FDA approval. Professionals aiming to oversee these critical tasks might consider the Advanced Clinical Research Project Manager Certification.

AUTHORITIES OF PHARMACOVIGILENCE CENTER FOF ASU&H DRUGS[12]

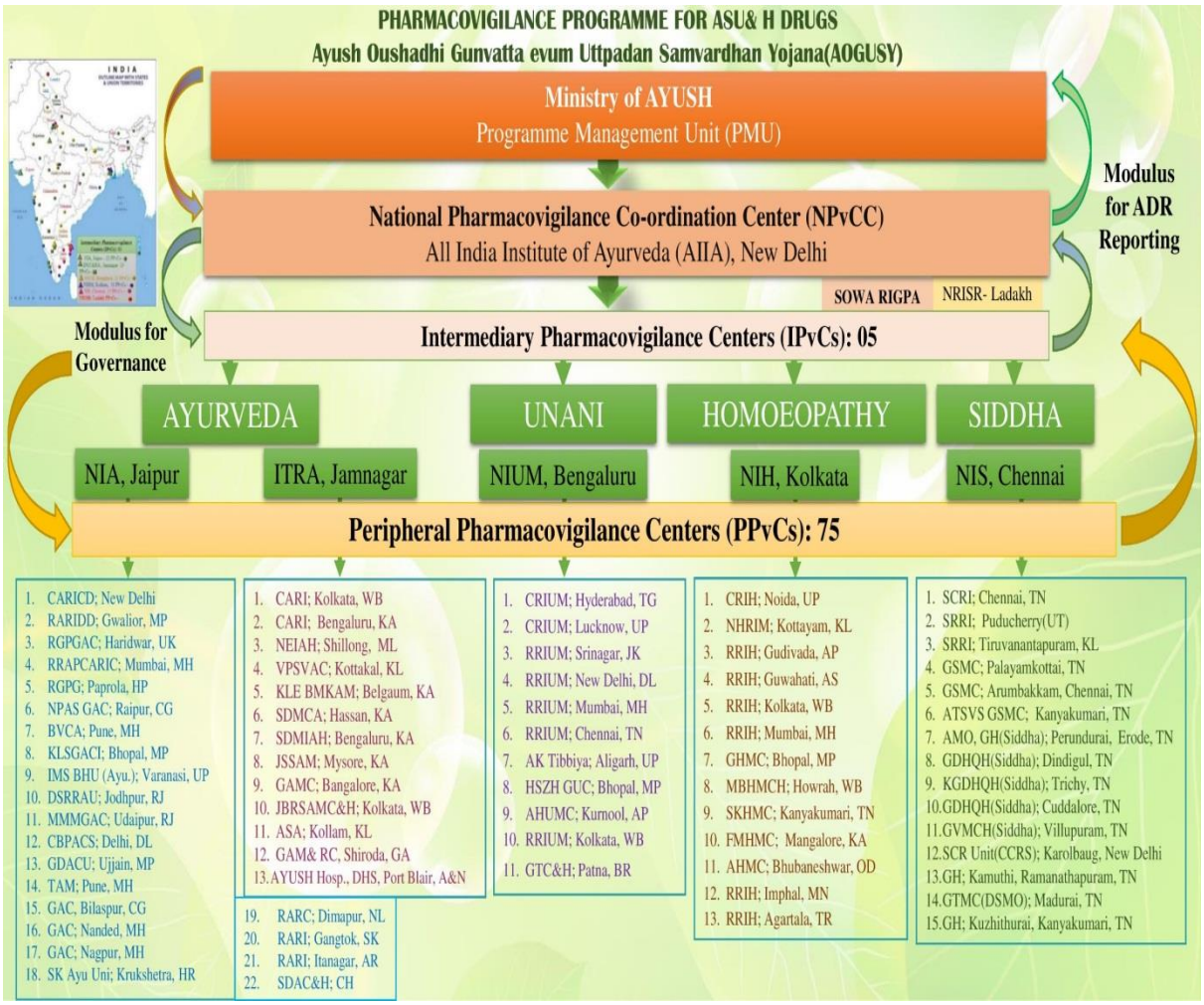

FIG NO 1: AUTHORISES PHARMACOVIGILENCE CENTER FOF ASU&H DRUGS[12]

The scheme aims at

- Inculcating the reporting culture among the consumers as well as ASU & H practitioners to facilitate documentation of Adverse Drug Reactions (ADRs)
- Developing a system-wise database of Adverse Drug Reactions of ASU & H drugs and evolving evidence based recommendations regarding clinical safety
- Reporting instances of misleading advertisements of ASU & H drugs for regulatory actions.

What to Report

The Suspected Adverse Drug Reaction Reporting Form for ASU & H Drugs is an application that will be used to facilitate the reporting of any suspected drug-related adverse events, including those that may have resulted from food incompatibilities or medication interactions. Reporting of common or seemingly insignificant adverse reactions would be crucial since they could point to a widespread issue with prescription practices.

Who can Report

Using the Suspected Adverse Reactions Reporting Form for ASU & H Drugs, any healthcare professional can report suspected adverse drug incidents to the relevant PPvCs / IPvCs.

Where to Report

The reporting on prescribed format can be submitted to the nearby / concerned PPvCs / IPvCs.

What happens to the submitted Reports

The information in the form shall be handled in confidentiality. Peripheral Pharmacovigilance Centres shall forward the form to the respective Intermediary Pharmacovigilance Centres who will carry out the causality analysis. This information shall be forwarded to the National Pharmacovigilance Centre. The data will be analysed and forwarded to the Ministry of AYUSH, Govt. of India.

CHALLENGES IN PHARMACOVIGILANCE AND DRUG [14]

1. *Administration*: Administrative bodies often do not incentivize pharmacovigilance practices, leading to insufficient reporting of adverse drug reactions (ADRs) by doctors, resulting in many ADRs going undetected at the clinical level.
2. *Health Professionals*: Lack of Continuing Medical Education (CME) in pharmacovigilance for healthcare professionals contributes to underreporting of ADRs. Reasons include uncertainty about identifying ADRs, confusion on reporting procedures, and time constraints due to busy schedules.
3. *Self-Medication*: Patients frequently use over-the-counter (OTC) medications based on pharmacist recommendations influenced by misleading drug advertisements, potentially leading to undisclosed negative effects.
4. *Web-Based Medication*: Misinformation on web-based platforms promotes the unrestricted sale of medications with questionable quality, safety, and efficacy, increasing the likelihood of missed adverse effects.
5. *Privacy of Health Data*: Concerns over patient privacy sometimes lead doctors to avoid recording ADRs, compromising the disclosure of sensitive personal health information.
6. *Counterfeit Drugs*: Global drug counterfeiting complicates ADR reporting, as distinguishing between reactions caused by genuine medications versus counterfeit substances can be challenging.
7. **Confounding illness**: - Treating complex diseases like cancer often involves multiple medications, increasing the risk of drug interactions and complicating the identification of specific ADR-causing agents.
8. **Clinical trial Monitoring**: - In India's burgeoning clinical trial sector, ADRs from test medications frequently go unnoticed due to personal biases or legal concerns, leading to underreporting to regulatory bodies.

CONCLUSION :

Pharmacovigilance (PV) is crucial in ensuring drug safety and efficacy by monitoring, assessing, and preventing adverse drug reactions (ADRs) and other drug-related issues. This multidisciplinary field encompasses various activities, including ADR monitoring, safety surveillance, risk assessment, regulatory compliance, education, communication, data management, research, global cooperation, and policy development.

PV's integration with related disciplines such as pharmacoepidemiology, clinical pharmacology, regulatory affairs, pharmacogenomics, and health informatics underscores its comprehensive approach to drug safety. Collaborative efforts in PV contribute significantly to achieving therapeutic outcomes, reducing morbidity and mortality, shortening hospital stays, lowering medical expenses, and enhancing patient quality of life.

Challenges in PV, such as insufficient ADR reporting, lack of continuing medical education for healthcare professionals, self-medication practices, misinformation on web-based platforms, privacy concerns, counterfeit drugs, confounding illnesses, and underreporting in clinical trials, highlight the need for improved systems and practices. Addressing these challenges through enhanced reporting culture, better education, stricter regulations, and international collaboration is essential for the continued advancement of pharmacovigilance and drug safety.

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