

A COMPREHENSIVE STUDY ON THE CONCEPT OF PHARMACOVIGILANCE IN
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ABSTRACT**Background and Objectives**

According to WHO Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug- related problem. The concept of pharmacovigilance is vibrantly described and corrective measures have been defined under the context of Muḍirr & Muṣliḥ in Unani medical literature, accordingly Unani physicians laid down clear principles on different dosage form, dose and potency of the drugs used. To thoroughly study and to compile the concept of Pharmacovigilance in Unani medicine, and also to assess the Knowledge, Attitude and Practice of Pharmacovigilance among the Unani stake holders, this study is hypothesized. **Methods:** This literary study will be started with the collection of information from selected authors books, manuscripts and many other forms of authentic material, followed by thorough review of literature on the concept and practices of Pharmacovigilance (includes drugs, regimens, manipulative techniques, and nutraceuticals). Then after understanding, it will be further explored on the opinions and difference of opinions of different authoritative works by scholars of Unani. After thorough review and categorization of literary material, a questionnaire will be developed based on the available information / data on pharmacovigilance in Unani medical texts of reputed authors and their practices on pharmacological associated events. This questionnaire will be consisting of 50-60 multiple choice questions on Knowledge, Attitude, and Practices of pharmacovigilance on Unani medicine, provided in Google document form will be circulated through digital media (WhatsApp, emails) and data will be analyzed.

KEYWORDS: Pharmacovigilance, Unani Medicine, Muḍirr, Muṣliḥ.**INTRODUCTION**

Background/rationale: According to WHO Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug- related problems.^[1] The etymology of Pharmacovigilance is derived from the Greek term 'pharmakon' means 'drug' and a Latin term vigilare means-to keep watch or alert or to keep awake.^[2] Unani medicine is one of the oldest medicines, and it is being recognized by the WHO as TM (traditional medicine) to cater the health care needs of human population. As per the report of WHO, 117 member countries are using herbal medicine.^[3] Unani medicine alone was reported using by 82 Member States.^[4] Unani medicine is vibrant and vigorous nowadays, as it is being taught, practiced and researched in and around 20 countries, and now become part of the mainstream system of medicine in some countries.^[5,6]

The growing popularity of traditional medicine, with 80% global usage (WHO) and widespread use in India

(NSSO survey), highlights the need for rigorous quality control. The exponential growth of the Ayush market and exports reaching \$2.16 billion to over 150 countries reflect the increasing acceptance and quality of Ayush products.^[7] There are about 625 licensed pharmacies manufacturing Unani drugs in different parts of the country. Out of this, 383 license pharmacies have obtained GMP certification.^[8] Moreover, the AYUSH pharmaceutical industry has risen unprecedentedly which clears the picture about consumption of herbal drugs, and it is also fact that over 40% of pharmaceutical formulations are based on natural products and many drugs are originated from traditional medicine.^[9,10]

According to Unani every individual is having a unique temperament^[11] & Unani drugs are categorized based on the temperament, and sub categorized on the degrees of temperament, as Dawa-e-moatadil, first-degree, second-degree, third-degree, and fourth-degree. First-degree drugs do not interfere with physiological function on the

prescribed dose, likewise, second-degree drugs exhibit effects of their temperament clearly, but do not alter physiological function, whereas, the third-degree drugs change the body's daily activity (physiological processes) but do not prove fatal. The concern is with the fourth-degree drugs which produces toxic effects, and also alters body functions, leading to be fatal, and this 4th degree drugs cannot be given without detoxification.^[12] Ibne Rushd stated that Ratab (moist) drug of the third degree is as fatal as poison.^[13]

The concept of pharmacovigilance is vibrantly described and corrective measures have been defined under the context of Muḍirr, Muṣliḥ^[14] in Unani medical literature, accordingly Unani physicians laid down clear principles on different dosage form, dose and potency of the drugs used. The classification of drugs according to temperament and expression of degree is main stay of pharmacovigilance in Unani medicine. But to thoroughly study, and to compile the concept of Pharmacovigilance in Unani medicine, and also to assess the Knowledge, Attitude and Practice of Pharmacovigilance^[15] among the Unani stake holders, this study is hypothesized

Objectives

- A. To explore the concept of Pharmacovigilance in Unani Medicine with reference to Moalajat
- B. To assess the Knowledge, Attitude, and Practice of Pharmacovigilance among stakeholders of Unani medicine.

Hypothesis

Identification and implementation of key pharmacovigilance concepts and practices within Unani Medicine, focusing on Moalajat, significantly improve safety monitoring and risk assessment of Unani drugs and their formulations.

Research Questions

- What are the key components and practices (concepts) of pharmacovigilance in Unani Medicine, especially related to Moalajat, and how do they contribute to the safety monitoring and risk assessment of Unani drugs and their formulations?

METHODS

Study Design

Literary research with Prospective Cross sectional / Longitudinal Cohort study

- Literary Review (narrative, historical, conceptual)
- Prospective Cross-sectional/longitudinal observational survey (KAP-based)

Setting

The study will be conducted at National Institute of Unani medicine, Bengaluru, Karnataka, India. The study will be started by literary review of classical Unani literature followed by KAP survey through Questionnaire that will be circulated through Google forms via email or WhatsApp.

Participants

KAP survey will be done among Unani stake holders as follows

- a) Unani Colleges in India, includes students, faculty, para medical staffs,
- b) Research centers- from Research associates, research officers and supporting staffs
- c) Paramedical staffs from all over India working in Unani clinics, dispensaries
- d) Pharmacy staffs (Procurement, processing, packaging, distribution)

Variables

Knowledge, Attitude, Practice

Data sources/ measurement

I) For Study of literature of Unani Medicine

- a) Literary review of the works of ancient authors from Dioscorides (1st century AD) to modern authors including Hakim Ajmal Khan (early 20th century) such as:
 1. Kitabul Hashayis by Dioscorides
 2. Kitab Man la Yahzuruhu Al-Tabib by Hakim Rofas
 3. Authentic available literature of Galen (Jalinoos)
 4. Firdausul Hikmat by Abul Hasan Ali ibn Sahl Rabban al-Tabri
 5. Kitabul Mansuri and Kitabul Hawi by Abu Bakr Muhammad ibn Zakariyya Razi (Razes)
 6. Al-Mualajat ul buqratiya by Abul Hasan Ahmad bin Muhammad Tabari
 7. Ghina Muna by Abu Mansur Al Hasan ibn Nuh Al Qamri
 8. Kamilus Sana by Ali ibn Abbas Al Majusi
 9. Kitabul Miah by Abu Sahl Isa Ibn Yahya Al Maseehi
 10. Al-Qanoon by Ibn Sina Abu Ali Al Hussain ibn Abdullah
 11. Zakhira Khawarizmshahi by Sharfuddin Ismail ibn Hussain Al Jurjani
 12. Kitabul kulliyat by Abul Walid Muhammad Ibn e Rushd
 13. Kitabul Mukhtarat Fit Tibb by Ibn Hubal Abul Hasan Ali Ibn Ahmad Baghdadi
 14. Al-Jame li Mufradatil Advia wal Aghzia by Abu Muhammad Abdullah Ibn e Baitar
 15. Al-Asbab wal Alaamat by Samarqandi Najibuddin
 16. Tazkiratu Ulil Albab by Dauad Antaki
 17. Qarabadin e Qadri by Muhammad Akbar Arzani
 18. Ilaj ul Amraz by Hakim Sharif Khan
 19. Muheet e Azam by Azam Khan
 20. Haziq by hakim Ajmal Khan

b) Published literature online and offline

c) Manuscripts

II) Longitudinal study on the Knowledge, Attitude and Practice of Pharmacovigilance among Unani stake holders through Questionnaire comprising about 50-60 questions (closed-ended questions)

Bias

- Selection bias for KAP survey - Stratified purposive sampling will be used across colleges, clinics, and regions to ensure diversity.
- Non-response Bias - Some individuals may ignore the survey - broad recruitment channels like WhatsApp, email will be included.

Study size

A sample size of 3000 was selected to ensure sufficient representation of Unani stakeholders from various regions and roles, to provide statistical power for subgroup analysis, and to permit a small margin of error in estimating KAP proportions, all while being practical for a national-level survey conducted through online tools.

Quantitative variables

NA

Statistical methods

- Information gathered from the KAP questionnaire will be obtained through Google Forms and subsequently exported to statistical analysis software, including SPSS, Microsoft Excel, or R, for the purposes of cleaning, coding, and analysis.
- A blend of descriptive and inferential statistical techniques will be utilized. To account for confounding variables, multivariable regression models will be employed, taking into consideration participant attributes such as professional role, experience, and type of institution. The threshold for statistical significance will be established at $p < 0.05$.

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