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Pharmacovigilance in Unani Medicine

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Abstract **Review Article**

Unani Medicine (Greek Medicine) is considered oldest and widely practiced medical system, India is home to this and it's an integral part of Ayush. India is the home of Unani Medicine (Greek Medicine), which is the oldest and widely practiced kind of alternative medicine all through the ages. Everywhere, including in the Europe, Middle East, Central Asia, and the Indian subcontinent, it is being performed under various names. Pharmacovigilance in Ayush refers to the practice of monitoring and ensuring the safety of Ayurveda, Yoga, Unani, Siddha, and Homeopathy (Ayush) medicines. It involves the collection, detection, assessment, monitoring, and prevention of adverse effects or any other drug-related problems associated with the use of Ayush medicines. It aims to promote the safe and effective use of Ayush medicines by identifying and evaluating any potential risks or side effects. It involves the reporting and analysis of adverse drug reactions (ADRs) and other safety concerns related to Ayush medicines. Objectives of pharmacovigilance in Unani Medicine are to ensuring patient safety, improving the quality of Ayush medicines, and enhancing public health. Overall, pharmacovigilance in Unani Medicine plays a crucial role in ensuring the safety and effectiveness of Ayush medicines, thereby promoting their responsible use and protecting public health. Although Unani medicine's core principles date back hundreds of years, pharmacovigilance is a relatively recent concept. Its integration into the system will undoubtedly improve the standard of care we provide to the patients. The majority of medicines and regimens (Therapies/Regimenal therapies) used in Unani system of medicine are less supported by data yet; their three-dimensional impact and effect, as well as safety criteria, have not been assessed. As a result, there is a significant risk of adverse drug reactions and side effects associated with them. This pharmacovigilance program will assist in evaluating, identifying, analyzing, and documenting the various impacts of Unani treatment modules. In addition, this approach will correct false claims made by Unani practitioners- the majority of whom are unqualified—in deceptive marketing that are casting blame on the system. ***Acknowledgement:*** We give our thanks to all the authors whose work was cited in this article.

Keywords: Unani Medicine; Ayush; Pharmacovigilance; ADR; Side effects; Drug Reaction.

INTRODUCTION

Medicines and other treatment regimens are used for both prevention and treatment. The concern is, though, if it's possible that these interventions could have negative consequences or result in death rather than life. If so, why and how are the following questions. While the drugs arrive at us after extensive testing and study, still the dilemma of what to do in such a situation arises. Is there any program or body that can evaluate and answer these adverse or side effects?

Therefore, a body or sector is required to report, monitor, identify, discuss, and provide solutions for these kinds of negative effects. Pharmacovigilance is thus one of the main post-market tools for certifying the safety of medications and related health goods [1,2].

The Greek word pharmacon, which means "drug", and the Latin word *Vigilare*, which means "to

keep watch or alert or to keep awake," are the two terms from which the name "pharmacovigilance" is derived [3]. Pharmacovigilance is described as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of drugs or any other possible drug related problems" by the World Health Organization (WHO) [4].

Herbals, traditional and complementary medicines, blood products, biologicals, medical devices, vaccines, and other issues relevant to the science of pharmacovigilance, such as substandard medicine, medication errors, a lack of efficacy reports, the use of medicines for indications for which they have not been approved and for which there is insufficient scientific support, case reports of acute and chronic poisoning, assessment of drug-related mortality, abuse and misuse of medicines, and adverse interactions of medicines with chemicals, other medicine and food [3,4].

Terminologies related to freak out of interventions:
Adverse drug reaction (ADR):

“A reaction to a drug which is noxious, unintended and occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of any disease or for modification of physiological function” [5-7].

Adverse drug event (ADE): “Any untoward event that may occur during treatment with a pharmaceutical product but that does not necessarily have a direct causal relation to the treatment” [8,9].

Unexpected adverse reaction (UAR): “An unintended adverse reaction in which nature or severity is not consistent with domestic labeling or market authorization, or expected from characteristics of the drug” [8].

Serious adverse event (SAE): “Any unintended medical occurrence that at any dose results in death, persistent or significant disability/incapacity, requires hospitalization or prolongation of existing hospital stay, or is life threatening” [10].

Signal: “Reported details on a possible causal relation between an adverse event and a drug, which is previously unknown or incompletely documented” [8,10].

Side effect (SE): “Any untoward effect of a pharmaceutical product occurring at doses normally used in human which is directly related to the pharmacological properties of the drug” [8].

Medication error (ME): “These are errors in the process of ordering or delivering a medication, irrespective of whether an injury occurred or the potential for injury was present”. These types of errors are common and are one of the causes of ADEs [7,11]. Medication errors that are stopped before harm can occur, are sometimes called “near misses” or “close calls” or more formally, a potential adverse drug event [8].

Allergy: “This is an adverse drug reaction mediated by an immune response (e.g., rashes, hives)” [8].

Key Points

Unlike Unani medicine's centuries-old concepts, pharmacovigilance is new. Its incorporation into the system will improve patient care. The bulk of Unani medicines and regimens have not been tested for three-dimensional impact, effect, or safety. Consequently, unpleasant medication responses and side effects are common. This pharmacovigilance program will evaluate, identify, analyze, and document Unani therapy’s effects. This technique will also correct dishonest marketing claims by Unani practitioners—most of whom are unqualified—blaming the system.

NEED OF PHARMACOVIGILANCE IN UNANI MEDICINE, THEIR SAFETY AND VIEW OF ANCIENT PRACTITIONERS

“Anything you can think of, anything you can see and some things you don’t even think of can be due to a drug” [12]. Nearly everyone is aware that a lot of allopathic drugs can result in any of the ill events listed above, but is it the same for Indian traditional medicines? Yes, since anything that is given in excess might become poisonous or may cause ill effect. Ancient practitioners of Unani medicine also made notice of it. Because of this, they used to remove any hazardous components from pharmaceuticals before prescribing them to patients. Many other safety precautions that they used at the time are described in old literature. They also went into great length on the adverse effects of various medications and how to manage them. It seems that although they were aware of the safety concerns, but not given any term to it. Avicenna, the early modern medicine's founding father and an ancient physician, philosopher, and writer, died from a drug overdose [3].

Hakim Alvi Khan, one of the illustrious physicians of the time, appears to have assembled the initial work on Unani Pharmacovigilance, with his compendium on "adverse effects among children in particular" published in "*Risale Dawa ul Atfal* (Journal of Pediatrics Medicine)" along with a case report series on ADRs different age groups titled "*Matab Hakim Ulvi Khan*"[3].

***Muzir* and *Musleh* in Unani Medicine:** Some examples of *muzir* and *musleh*, which were discussed earlier with regard to single drugs and compound drugs are given in table 1:1 and 1:2.

Table 1:1: Side effects and their correctives of some compound drugs [13,14]

Name of the single drugs	Side effects	Correctives
Aamla (Emblica officinalis)	Constipation & colitis	Honey & *Roghane Badaam* (almond oil)
Bhang (Cannabis sativa)	Melancholia & weak eyesight	Ghee
Chaulmoogra (Hydnocarpus wightianus)	Hot temperamental condition	Milk, Ghee & Sugar
Dhatura (Datura stramonium)	Restlessness & dementia	*Filfil siyah* (Black Pepper) & *Badyan* (Fennel Seed)
Fitrasaliyoon (Petrosalinum crispum)	Hematuria	*Katera* (Tragacanth Gum) & Honey
Gule tesu (Butea frondose)	Cold temperamental condition	Salt
Indarain (Citrullus colocynthis)	Spasm in GIT	*Katera* & *Roghane Badam*
Jadwar (Delphinium denudetum)	Hot temperamental condition	Milk & *Maush Sha'Eer*
Kutki (Picrorhiza kurroa)	Vomiting, diphtheria & spasm	*Roghane Badam* & *Mastagi (Pistacia lenticus)*
Luffah (Atropa belladonna)	Headache	*Sikanjabeen* & *Jawarish Kamooni*
Mastagi (Pistacia lentiscus)	Anal diseases & haematuria	Vinegar
Narjeel daryai (Lodoicea maldivica)	Hot temperamental condition	*Arqe Gulaab* (rose water)
Poi (Basella alba)	Cold temperamental condition	*Roghane Badam*
Qust (Saussurea lappa)	Lung diseases	*Gulqand Aaftabi* & *Anisoon* (*Pimpinella anisum* L.)
Raai (Brassica nigra)	Polydipsia & abortifacient	*Roghane Badam* & Vinegar
Sandal (Santalum album)	Sexual disorders	Honey & Sugar
Tabasheer (Bambusa arundinacea)	Sexual & lung disorders	Honey & *Mastagi*
Ushq (Dorema ammoniacum)	Haematuria	*Anisoon* & Vinegar
Ushna (Permelia perlata)	Abortion	*Roghane Banafsha* (Viola oil) & *Maghze Kaddu* (pumpkin seed pulp)
Zafraan (Crocus sativus)	Weakens kidneys	*Sikanjabeen* & *Zarishk* (Berberis aristata)
Zarishk (Berberis vulgaris)	Cold temperamental condition	Sugar & *Qaranfal* (Clove)

Table 1:2. Side effects and their correctives of some compound drugs [15]

Name of compound drugs	Side effects	Correctives
Ayarij Feeqra	Nephrotoxicity	*Unnab (Ziziphus mauritiana)*
Itrifal Ustukhuddus	Hot temperamental conditions	*Itrifal Kishneezi*
Sharbat Neelofar	Sexual dysfunction	Honey
Sharbat Toot	Gastric disorders	*Majoon Kamooni*
Sharbat Khashkhash	Loss of sensation	*Khameera Banafsha*
Khameera Banafsha Kashmiri	Gastric disturbances	*Majun Falafali*
Khameera Gaozaban	Spleen disorders	*Sandal Safed (Santalum album)*
Laooq Sapistan	Gastric disturbances	*Jawarishate Harra*
Jawarish Ood Tursh	Hot temperamental conditions	-
Arq Gaozaban	Spleen disorders	*Arq Sandal* (sandal water)

BRIEF HISTORY OF PHARMACOVIGILANCE

On January 29, 1848, Hannah Greener, a young girl from the north of England, died after receiving "chloroform inaesthetic" prior to the amputation of an infected toenail. This marked the beginning of pharmacovigilance [16]. After the incidence, awareness of the adverse effects of treatments began. More than sixty-five countries established their own pharmacovigilance centers in 2002 [17]. Following this, the need for pharmacovigilance in traditional medicine became apparent. On September 29, 2008, the National Pharmacovigilance Program (NPP) for Ayurvedic, Siddha, and Unani (ASU) Drugs was launched [18].

In collaboration with WHO, the Department of Ayush published a Protocol of NPP for ASU (NPP-ASU) drugs to assist in the monitoring, control, and administration of the activities linked to pharmacovigilance. Following that, the Ministry of Ayush unveiled a new program in 2017–18 to promote pharmacovigilance for ASU & homeopathic (ASUH) drugs. The main motive of the scheme is to develop a culture of recording ADE, monitor the safety of ASU and H drugs, and look closely at "misleading advertisements that appears in the print and electronic media" [8].

3 TIER SYSTEM OF REPORTING OF PHARMACOVIGILANCE [19]

The new Central sector scheme of the Ministry of Ayush is meant to make it easier to start the 3-level system of "National Pharmacovigilance Centre (NPvCC), intermediary Pharmacovigilance Centers

(IPvCCs), and Peripheral Pharmacovigilance Centers (PPvCC)".

For the purpose of promoting pharmacovigilance of Ayurvedic, Siddha, Unani, and homoeopathic (ASU&H) drugs, the Ministry of Ayush has developed a new Central Sector plan. The main goal of the program is to foster a culture of recording adverse effects, carry out safety monitoring of Ayurvedic, Siddha, Unani, and homoeopathic medications, and keep an eye out for deceptive ads in print and electronic media. The program aims to make it easier to construct a three-tier network of NPvCC, IPvCCs and PPvCC. The NPvCC has been established at the All-India Institute of Ayurveda in New Delhi. In the first stage of implementation, 42 Ayush institutions with clinical facilities are classified as PPvCs, while five National Institutes of Ayush are designated as IPvCCs. More of these facilities are planned for all around the nation in order to reach the goal of 100 PPvCs by 2020. Representatives of the Indian Pharmacopoeia Commission, which is the nation's WHO Collaborating Centre for Pharmacovigilance, and the Central Drug Standards Control Organization, which is the country's drug regulatory authority, are involved in the program as a mentor and guide.

Fig. 1:1: Current Hierarchy of Pharmacovigilance for Ayurveda, Siddha and Unani Program [18]

Table 2:0: Pharmacovigilance Centers for Unani Medicine [20]

S.N.	Name of the Centre	Name of the Coordinators
Intermediary Pharmacovigilance Center		
1	National Institute of Unani Medicine, Bangalore	Prof. Mohd. Aleemuddin Qumri
Peripheral Pharmacovigilance center		
1	Central Research institute of Unani Medicine, Hyderabad, Telangana.	Dr. Javed Inam Siddiqui
2	Central Research Institute of Unani Medicine, Lucknow, UP.	Dr. Mahboob us Salam
3	Regional Research Institute of Unani Medicine, Mumbai, Maharashtra.	Dr. Nkhat Shaikh
4	Regional Research Institute of Unani Medicine, Chenna, Tamil Nadu.	Dr. Noman Anwar
5	Regional Research Institute of Unani Medicine, Srinagar, J&K.	Dr. Shameem Ahmad Rather
6	Regional Research Institute of Unani Medicine, New Dehi.	Dr. Anwarul Islam
7	Ajmal Khan Tibbiya College, Aligarh Muslim University, Aligarh, UP.	Prof. Tanzeel Ahmad
8	HSZH Govt Unani Medical College, Bhopal, MP.	Dr. Mehmooda Begum
9	Dr. AH Unani Medical College, Kurnool, AP.	Dr. W.M. Sarfaraz Nawaz
10	Regional Research Institute of Unani Medicine, Kolkata, WB.	Dr. Younis Iftikhar Munshi
11	Govt. Tibbi College and Hospital, Patna, Bihar.	Dr. Md. Tanwir Alam
12	University College of Unani Medicine, Tonk, Rajasthan.	Dr. Firoz Khan
13	Regional Research Institute of Unani Medicine, Bhadrak, Odisha.	Dr. Abdur Rasheed
14	Govt. Nizamia Tibbi College, Hyderabad, Telangana.	Dr. Zaibunnisa Begum
15	Mohammadia Tibia College, Malegaon, Maharashtra.	Dr. Sayyed Minhaj

AIMS OF PHARMACOVIGILANCE IN UNANI MEDICINE [21,22]

- Recognition and evaluation of previously unidentified ADRs.
- Authentication of subdivision of patients at specific risk of ADRs (dose, age, gender and underlying disease related risks).
- Continuous tracking of the safety of a product, as long as it is being used to ensure the risks.
- Record relative ADR profile of products within same medicinal class.
- Identification of ill-suited administration of prescription.
- Further illumination of medicinal/toxicological effects of products and the mechanism of ADR production.
- Discernment of remarkable drug-drug interactions.
- Report the advertisements which misleads the patients and undergoing therapy.

In a nutshell, the goals of pharmacovigilance are to improve patient care with hygiene, gauge the benefit, pain, efficacy, and danger of medications, and promote understanding, education, and clinical training.

OBJECTIVES OF PHARMACOVIGILANCE IN UNANI MEDICINE

- **Ensuring patient safety:** By monitoring and reporting adverse effects, pharmacovigilance helps in identifying potential risks and taking necessary actions to ensure patient safety.
- **Improving the quality of Ayush medicines:** By analyzing adverse events and safety concerns, pharmacovigilance helps in identifying quality issues in Ayush medicines and taking appropriate measures to improve their quality.
- **Enhancing public health:** Pharmacovigilance in Ayush contributes to public health by providing valuable information on the safety profile of Ayush medicines, which helps in making informed decisions regarding their use.
- **Promoting evidence-based practice:** By collecting and analyzing data on adverse effects, pharmacovigilance helps in generating evidence on the safety and efficacy of Ayush medicines, which can be used to guide clinical practice and policy-making.

POSSIBLE CAUSES OF ADRs IN UNANI MEDICINE

In the past, the drugs were initially collected, identified, purified, prepared, and dispensed by the hakeems at their clinic on a small scale (referred to as *juzwi dawasazi*), hence their qualities used to be excellent, which meant that there was a lower risk of adverse drug reactions or side effects. Listed below are some of the potential cause of adverse drug reactions (ADRs):

Misidentification and Adulteration of single drug

Each herbs have specific properties and action, yet some herbs are similar to one another in appearance or properties. For instance, *Ajwain Khurasani (Hyoscymus niger)* and *Ajwain Desi (Trachyspermum ammi)* former one is always used only after detoxification and in smaller doses. There are three types of *Ajwain khurasani* based on colour: white, red, and black. Of the three, the black variety is not utilized as a drug due to its toxic effects, which might result in death if administered by mistake [3]. *Bandaal (Luffa echinata)* and *Halela zard (Terminalia chebula)* have similar appearances and opposite effects; for example, *Bandaal* is laxative and *Halela zard* has an astringent property, dose of *Bandaal* should be less than that of *Halela* [14].

Direct or intentional and indirect or unintentional adulteration are the two basic forms of adulteration. Adulterants and substitutes are the most frequent wrongdoings in the trading of herbal raw materials. Direct or purposeful adulteration is defined as the deliberate introduction of foreign materials into a product in order to raise its weight or lower its price. While failure to remove associated or undesired structures due to lack of knowledge or any other reason despite of intention, is regarded as indirect or unintentional adulteration. Inadequate drying of the single drug might also result in indirect adulteration. On the other hand, whether due to confusion over "vernacular names," a lack of knowledge of genuine plants, a lack of availability, a similar morphology, an odour, careless collection, or another unspecified reason any of them may be the cause of ADR [23,24].

Fault in detoxification

Many poisonous substances have been utilized as drugs since ancient times following detoxification. Any mistake made during the detoxification process will result in ADR [25].

Fault in methods of Preparation

Drugs in Unani medicine is manufactured uniquely. For instance, the *taar* (string/consistency) of *qewam* for *Unani qewami* (viscous/liquid) pharmaceuticals varies on the organ system for which the medicine is prepared. In addition, the particle size of powder varies depending on which system is being treated if it is for the pulmonary system the consistency will be different to the gastrointestinal system, etc. Even the temperature for each drug preparation is specified in the formulary for that drug. Issues with ADR or effectiveness may result from poor cleanliness or improper preparation [26].

Fault in packaging and storage

Packaging and storage of raw and prepared drugs vary according to each drug's chemical constituents; for instance, if the drug contains a volatile constituent, the storage temperature will be lower than that of drugs that do not contain the same. Improper packaging and storage may expose the drugs to physical

factors like air (humid/dry), light, and temperature, which will automatically degrade the quality by altering the chemical components of the drugs. For instance, if a drug is intended to be stored at low temperature but is instead kept at high temperature for any reason, the normal chemical components will be destroyed, and in some cases, toxic chemical components will be produced. Physical factors can result in the growth of macro (flies, mosquitoes, mice, etc.) and micro (fungus, bacteria, virus, etc.) organisms in the drugs that will cause death rather than cure.

Incorrect dosing

The amount of a drug that reaches the circulatory system and the site of action, which are related to the dose, route of administration, and pharmacokinetics of the drug, determine the effects of the drug, whether beneficial or harmful. Therefore, improper dosing could also be to blame for adverse effects [27]. Drugs in the Unani medical system is divided into degrees (1, 2, 3, and 4) based on their *mizaj* (temperament)[28-30]. When writing a prescription, it is important to keep in mind that the dose should be inversely proportional to the drug degree, meaning that drugs with a degree of 3 and 4 should have a lower dose. Increased doses, especially those of the third and fourth degrees, may have adverse effects.

Restriction, Avoidance and Abstinence from certain diets

The effectiveness of a drug may differ from person to person than expected due to drug interactions with the person's diet ("drug-nutrient/food interaction") or with a different health condition ("drug-disease interaction") at the time of treatment [31].

Adverse effect Food-Drug interactions may:

- Obstruct a drug's ability to cure.
- Make a side effect worse.
- Produce a new side effect [32].

Drug and food interactions have the potential to alter efficacy and even produce serious side effects. For instance, it has been discovered that green vegetables with vitamin K as an active ingredient, particularly spinach, broccoli, cabbage, peas, and cucumbers, have a quantifiable impact on anticoagulant therapy [33]. *Raai* (*Brassica alba*) is contraindicated in pregnancy When consumed during pregnancy, it can cause the death of the fetus in the womb [34].

Mismatched combination of prescription

Every drug has a chance to have side effects, but using more than one increases the risk of unexpected negative effects or ADRs [35]. Patients take many drugs at once, which inhibits or induces drug metabolizing enzyme activity [36]. For example, prescribing extremely hot with extremely cold drugs, salt-containing drugs to hypertensive patients, sugar-based drugs to diabetics, etc. are mismatches that harm.

Herb-herb interaction

Earlier in the history of the use of medicines, it was thought that the simultaneous administration of two herbs could change the effects of both. The clinical result would show the combined effect, which could be either positive or negative. So, the wrong combination could have adverse effects [37-40].

a) Herb-drug interaction

Herb-drug interactions can have negative effects and can impede treatment, just like food-drug and herb-herb interactions. Aloe vera (*Aloe barbedensis*) and Digoxin and Thiazide interactions, for instance, increase cardiac toxicity; garlic (*Allium sativum*) and anti-hypertensive drugs may lower blood pressure, with hypoglycemic drugs may cause hypoglycemia [41]. The reason is that, in addition to its many other properties, garlic has hypoglycemic, diuretic, and diaphoretic effects [42,43].

b) Herb-mineral interaction

Herb-mineral drug interactions can also cause unusual side effects. Green tea (*Camellia sinensis*) extract, for example, prevents the absorption of iron when combined with drugs that have a mineral origin [44].

c) Drug-drug interaction

When two or more drugs taken simultaneously, they may affect each other’s activity, interactions and pharmacokinetics this comes under drug- drug interaction. This may lead to severe ADRs [45,46].

Ignoring Unani principles like *mizaj*/temperament of disease, patient, and drug when prescribing treatment

Principles of Unani Medicine like *mizaj*/temperament must be considered; every person, organ, diet, and drug have a *mizaj*. Thus, any deviation from normal *mizaj* of a person or organ will cause pathological conditions with different *mizaj*. A doctor's main goal is to restore that altered condition by following all treatment principles [47]. For instance, if a person with a disease of the same *mizaj* is prescribed a medicine of the same *mizaj* with a 3 or 4 degree hot and dry *mizaj* (*safravi*), it will have a severe adverse effect.

Self-medication/ malpractice

About two-thirds of people worldwide seek health maintenance from sources other than "conventional biomedicine"; many of them undoubtedly self-medicate, while others seek help from licensed traditional medical professionals [48].

In addition to self-medication malpractice in traditional medicine is also common, people frequently recommend these medications without knowledge, only after reading the pamphlets, leaflets, or brochures of the manufacturers, or based solely on personal or

interpersonal experience, without understanding the principles of treatment. Malpractice can result even from cross-practice [49].

CAUSES OF LESS REPORTING UNDER THE PHARMACOVIGILANCE PROGRAM

Approximately 70% of the world uses herbal/traditional medicine for primary care and this high use nurtured the herb industries [38,50]. People now tend to turn to traditional medicine in the belief that it is completely safe; this perception made public acceptance of pharmacovigilance difficult. Even food with the propensity to become a part of our bodies can turn into a poison, causing "food poisoning," so we cannot say that anything is 100% safe. Here are the factors which prevent Unani medicine ADR reporting under pharmacovigilance. (Table: 3.0)

Table 3:0: Possible causes of less reporting are

Causes related to health care providers	Causes related to patients
Unawareness towards side effects	Unawareness towards their health
Lack of knowledge	Belief of “natural means safe”
Lack of interest	Lack of knowledge.
Belief of 100% safety	Confusion & Hesitation

Two main causes of lower reporting are:

Causes related to health care providers

Confidence of 100% safety and lack of command among health care providers, especially nurses, and some practitioners are unaware of the basic principles of Unani medicine, treatment methods, and side effects, while most are aware of conventional medicine. Lack of interest, non-responsiveness, and confusion due to mismatched prescriptions are other reasons for less reporting.

Causes related to patients

People are unaware of and neglect their health issues, especially females, they believe Unani medication is natural, safe, and pure, they confuse multiple treatments at once, and they fear or hesitate to tell others how they feel after taking the medicine. Their hesitation is likely due to the practitioners' behavior [51].

REGIMENAL THERAPIES AND PHARMACOVIGILANCE

Numerous non-drug or low-drug therapies, which are well-known therapeutic and preventive modalities, are on the rise and show promise for treating a variety of disorders. Regimenal Therapies *(Ilaj Bit Tadbeer)* is the name given to all of the treatments. Famous among them are *Dalk, Hijamah, Hammam, Fasd*, *Huqna*, *Irsale Alaq*, and *Nutool*. (Please refer Table 3.1 for detail)

Table 3:0: Non-Drug Interventions in Unani System of Medicine which may cause side effects

Therapies	Side effects
Abzan (Sitz Bath)	Infection of perineum, Burn and scald, irritation, accidental fall/injury
Aml-e Kai (Cauterization) [52]	Electric shock/ nerve or tissue damage
Aml-e Kashateer (Catheterisation) [53-56]	Injury, Infection
Bukhoor (Fumigation)	Breathlessness/Irritation
Dalk (Massage)	Erythema, Nerve compression, Injury, fracture, vaso-vagal shock
Fasd (Venesection)	Excessive blood loss, shock, infection
Gharara, Mazmaza, Masmasha (Gargles)	Irritation, redness, burn and scald
Hammam (Bathing)	Redness, burn and scald, infection,
Hijamah (Cupping)	Excessive blood loss/ shock, blisters, scar formation, keloids
Huqna (Enema)	Injury, bleeding, dehydration
Idrar (Diuresis)	Dehydration, shock
Irsale-alaq (Leeehing) [57]	Excessive blood loss, infection, pruritus, allergic reactions, vesicle formation
Ishal (Purgation)	Dehydration, shock
Lakhlakha (Inhalation)[58,59]	Redness, burn and scald
Nutool, Sukoobat, Tarnai (Douching)	Inflammation
Farzajah (Vaginal Douching) [60]	Pelvic inflammatory disease
Qai (Emesis)	Dehydration, shock, throat injury
Riyazat (Exercise)	Dehydration, weakness, shock, injury, nerve damage
Tareeq (Diaphoresis, Sweating)	Dehydration, shock, burn and scald
Tikor, Takmeed (Fomentation)	Redness, burn and scald

CONCLUSION

About 80% of the rural population in India relies on traditional indigenous medicine and/or

medicinal herbs for their primary healthcare. Patient safety concerns are proportionately necessary with the rising demand for Ayush medicines and therapies. Pharmacovigilance is the top priority for improving healthcare safety and quality. Pharmacovigilance and its healthcare services are centuries old. In 2008, USM implemented pharmacovigilance under the National Pharmacovigilance Program (NPP) for Ayurveda, Siddha, and Unani (ASU) Drugs. Since then, Unani has done its best to report ADR conditions, but some causes need immediate attention and strategic improvisations.

Lack of knowledge and unawareness of drug side effects, belief in 100% safety of natural herbs and ingredients, misleading advertisements, and improper patient counselling may contribute to improper and incomplete reporting. We should promote ADR awareness programs among commoners to address these issues.

Increase network of Pharmacovigilance centers, with their prompt coordination with the central government may improve reporting, safety monitoring, and drug quality control. NCISM has mandated that every Unani College must have a pharmacovigilance center to improve their effectiveness. This expansion of operational centers will also broaden the employment market and increase the number of available jobs for Unani/Ayush doctors. The prevention of ADRs is crucial to raising the standard of pharmacy and healthcare as a whole. To successfully achieve the goals of pharmacovigilance, strict guidelines and monitoring their proper execution are crucial.

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Author first and second conceptualize the theme of the article and prepare the manuscript, author second and fourth and fifth mentor the entire paper. Author third, sixth and seventh helps in gathering the data.

REFERENCES

1. Arora D. Pharmacovigilance obligations of the pharmaceutical companies in India, India J pharmacol 2008; 40: S13-S16.
2. Singh S, Jai Prakash and Goyal N et al. Review on Pharmacovigilance. World Journal of Pharmaceutical Research. 2015; 4(6): 266-75.
3. Quamri MA. Concept of pharmacovigilance in unani medicine. (Compendium of Invited Articles on Pharmacovigilance). National conference on pharmacovigilance: IPGT & RA, GAU, Jamnagar: 8th-10th Nov. 2019: 1-5.
4. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. Geneva. 2004:1-84. file:///C:/Users/tanve/OneDrive/Desktop/Pharmacovigilance%20Paper/9241592214_eng%20WHO%20guidelines.pdf Accessed on 13 August 2023.
5. Rohilla A, Yadav S. Adverse drug reactions: An Overview. International Journal of Pharmacological Research 2013;3(1): 10-12.
6. Campbell JE, Williams MG, Lee MG. A Review of Pharmacovigilance. West Indian Med J 2014; 63 (7): 771-774.
7. Soni R and Kesari B. A Review on Pharmacovigilance. Int. J. Pharm. Sci. Rev. Res. 2014; 26(2): 237-41.
8. Mastan A, Tripathi A and Rai SK. Pharmacovigilance: An Approach Towards Safety of Ayush Drugs. World Journal of Pharmacy and Pharmaceutical Sciences. 2020; 9(9): 1189-97. DOI: 10.20959/wjpps20209-17142.
9. Golder S, Loke YK, Wright K, Norman G. (2016) Reporting of Adverse Events in Published and Unpublished Studies of Health Care Interventions: A Systematic Review. PLoS Med 2016; 13(9): e1002127. doi:10.1371/journal.pmed.1002127.
10. Edwards R, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. The Lancet 2000; 356(7):1555-59.
11. Bates DW, Boyle DL, Vander VMB, et al. Relationship between medication errors and adverse drug events. J Gen Intern Med, 1995; 10: 199-205.
12. Kavitha D. Adverse Drug Reaction (ADR) Monitoring and Pharmacovigilance. JPRHC 2010; 2(1): 127-34.
13. Abdul Hakeem HM. Bustanul Mufradat. Idara Kitabus Shifa. New Delhi 2002: 71,90,97,141,151,173,208,214,225,280,286,315,317,373,389,430,445, 462.
14. Kabiruddin M. Makhzanul Mufradat. Ejaz Publiting house. New Delhi. YNM: 55,77,96,136,142,172,220,231,250,288,295,313,317,396,398,414,418,446,486,512,546,571.
15. Ansari AP. Ahmad NZ and Wadud A *et al*. A concept of Muzir (Toxicity) and Musleh (Corrective) of Unani drugs with scientific evidences: An Overview. Journal of Research in Unani Medicine 2018; 7(1): 70-77.
16. Fornasier G, Francescon S and Leone R. An historical overview over Pharmacovigilance. International Journal of Clinical Pharmacy 2018;40:744-47. https://doi.org/10.1007/s11096-018-0657-1

17. Jeetu G and Anusha G. Pharmacovigilance: A Worldwide Master Key for Drug Safety Monitoring. J Young Pharm 2010;2(3): 315-320. DOI: 10.4103/0975-1483.66802
18. Rahman SZ and Galib R. History of Pharmacovigilance in India (1983-2022). J Pharmacovig Drug Safety 2021;19(1):6-17.
19. Naquibuddin M, Alam MT, Zeyauddin M *et al*. Awareness of pharmacovigilance in Unani system of medicine: A need of the hour. International Journal of Herbal Medicine 2021; 9(2): 42-47
20. Office Order. F.No. B-11003/5/9/2017-AIIA/Fin./208 Dated 17.04.2023. National Pharmacovigilance Coordination Centre (NPvCC), Pharmacovigilance Program for ASU & H Drugs, All India Institute of Ayurveda, New Delhi.
21. Anusha L, Aashritha M, Teja K *et al*. A review on pharmacovigilance and its importance. World Journal of Pharmacy and Pharmaceutical Sciences. 2017;6(1):300-10.
22. Rajgopal J, Shilpi K, Srivastav AK. Pharmacovigilance: A Review Article. Innovare Journal of Medical Science 2026; 4(4): 6-7.
23. Shetty RG, Harsha R. Adulteration in Medicinal Plants and Herbal Drugs. International Journal on Agricultural Sciences 2021; 12 (1):12-17.
24. Debbie S, Graeme L and Pierre D. Pharmacovigilance of herbal medicine. Journal of Ethnopharmacology 2012; 140: 513–518. doi:10.1016/j.jep.2012.01.051.
25. Rahman S, Jahan N, Khan MA. Tadbeer-E-Advia: A Unani Process of Detoxification of Poisonous Drugs- A Review. **JoAYUSH** 2020; 9 (2):1-5.
26. Rajanandh MG, Chamundeeswari D. Need of Pharmacovigilance in AYUSH Drugs. Journal of Pharmacovigilance 2017; 5(1): 1000e166.
27. Rombolà L, Scuteri D and Marilisa S. Pharmacokinetic Interactions between Herbal Medicines and Drugs: Their Mechanisms and Clinical Relevance. Life 2020; 10(106):1-28. doi:10.3390/life10070106.
28. Ibn Rushd. Kitabul kulliyat. Maktaba Daniyal. Lahore. 2017: 216.
29. Quamri MA, Malik R and Wadud A. Review on Pharmacovigilance Perspective of the Pharmacopoeia and Formulary of Unani Medicine. Journal of Pharmacovigilance and Drug Research 2023;4(2):4-12. DOI: 10.53411/jpadr.2023.4.2.2.
30. Rahman SZ, Khan RA and Latif A. Importance of pharmacovigilance in Unani system of medicine. Indian J Pharmacol 2008; 40(Supplement 1): S17-S20.
31. Bushra R, Aslam N and Khan AY. Food-Drug Interactions. Oman Medical Journal 2011; 26 (2): 77-83. DOI10.5001/omj.2021.21
32. Debnath S, Tejovathi R and Babu N. An Overview on Food & Drug Interactions. Pharma Times 2017; 49(04): 9-15.
33. Shukla AK and Bigoniya P. Herbal, Drug and Food Interaction. International Journal of Traditional and Complementary Medicine 2016;1(2):33-37.
34. Tabri AAR. Firdausul Hikmah. Faisal Brothers. New Delhi. 2002: 346.
35. O'Donovan B, Rodgers RM and Cox AR. You feel like you haven't got any control: A qualitative study of side effects from medicines. Journal of Patient Safety and Risk Management 2019; 24(1): 13–24. DOI: 10.1177/2516043518821499.
36. Ong CE and Pan Y. Drug-herb interactions: Mechanisms involved and clinical implications of five commonly and traditionally used herbs. TANG Humanitas Medicine. 2014; 4(3):e17. doi: http://dx.doi.org/10.5667/tang.2014.0008
37. Bhargav RK and Rehana Parveen R. Herbal Drug Interaction: An Overview. WJPLS 2020;6(5):62-68.
38. Che CT, Wang ZJ, Chow MSS *et al*. Herb-Herb Combination for Therapeutic Enhancement and Advancement: Theory, Practice and Future Perspectives. Molecules 2013; 18: 5125-41. doi:10.3390/molecules18055125
39. Tharappel LJP, Kaur G, Buttar HS. India - A New Contributor to The Pharmacovigilance Movement. IJPSR, 2014; Vol. 5(8): 3107-3122.
40. Tangkiatkumjai M, (ed.), Casarin A, (ed.), Chen LC, (ed.), Walker DM, (ed.). Complementary and Alternative Medicine and Kidney Health. IGI Global Publishing, 2017.
41. Inder D and Kumar P. Pharmacovigilance in India: A Rising Concern towards Safe Medication Use. J. Adv. Res. Med. 2015; 2(3): 1-6.
42. Alam MT, Perveen A and Alam MA *et al*. Medicinal Use of Lehsun (*Alium Sativum* Linn): A Well-Known Unani Medicine. International Journal of Universal Pharmacy and Life Sciences 2013;3(6): 9-14.
43. Singh IP, Bharate SB and Bhutani KK. Interaction of herbs and food products with drugs Grapefruit juice as an example. Natural Product Radiance 2005; 4(2): 107-12.
44. Gurley BJ, Carter AT, Thomas SL *et al*. Clinically Relevant Herb-Micronutrient Interactions: When Botanicals, Minerals, and Vitamins Collide. Advances in Nutrition 2018;9:524S–532S.
45. Konduru JR. Review on Adverse Drug Reactions. Adv Pharmacoepidem Drug Safety 2015;4: 05-R. doi:10.4172/2167-1052.1000005-R.
46. Kremers P. In vitro Tests for Predicting Drug-Drug Interactions: The Need for Validated Procedures. Pharmacology & Toxicology 2002; 91: 209-17.
47. Ansari S, Khan QA, Anjum R *et al*. Fundamentals of Unani System of Medicine - A Review. EJBPS 2017; 4(9):219-23.
48. Pal SK. Complementary and alternative medicine: An overview. Current Science. 2002; 82(5): 518-524.
49. Kumar NK, Dua PK. Status of regulation on traditional medicine formulations and natural products: Whither is India? Current Science

2016;111(2):293-301. doi: 10.18520/cs/v111/i2/293-301.
50. Wills RBH, Bone K and Morgan M. Herbal products: active constituents, modes of action and quality control. Nutrition Research Reviews 2000; 13: 47-77.
51. Khan MN, Ahmad M and Akhtar J. Pharmacovigilance: A Dire Need in Unani System of Medicine. World Journal of Pharmaceutical Research. 2018; 7(19): 345-50. DOI: 10.20959/wjpr201819-13703.
52. Saaiq M, Zaib S and Ahmad S. Electrocautery burns: experience with three cases and review of literature. Ann Burns Fire Disasters. 2012 Dec 31;25(4):203-6.
53. Feneley RC, Hopley IB, Wells PN. Urinary catheters: history, current status, adverse events and research agenda. J Med Eng Technol. 2015;39(8):459-70.
54. Liao X, Liu Y, Liang S *et al*. Effects of hydrophilic coated catheters on urethral trauma, microtrauma and adverse events with intermittent catheterization in patients with bladder dysfunction: a systematic review and meta-analysis. *Int Urol Nephrol* 54,(2022):1461–1470.
55. Wyndaele, J. Complications of intermittent catheterization: their prevention and treatment. *Spinal Cord* 40, (2002):536–541.
56. Igawa Y, Wyndaele JJ and Nishizawa O. Catheterization: Possible complications and their prevention and treatment. International Journal of Urology, (2008); 15: 481-485.
57. Sepaskhah M, Yazdanpanah N, Sari Aslani F *et al.* Cutaneous Pseudolymphoma As a Rare Adverse Effect of Medicinal Leech Therapy: A Case Report and Review of the Literature. Cureus (2020 April 02) 12(4): e7517.
58. Baartmans M, Kerkhof E, Vloemans J *et al*. Steam inhalation therapy: severe scalds as an adverse side effect. Br J Gen Pract. 2012 Jul;62(600):e473-7.
59. Scarborough A, Scarborough O, Abdi H, Atkins J. Steam inhalation: More harm than good? Perspective from a UK burns centre. Burns. 2021 May;47(3):721-727.
60. Zhang J, Thomas AG and Leybovich E. Vaginal douching and adverse health effects: a meta-analysis. Am J Public Health. 1997 Jul;87(7):1207-11.