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Review Article

FUNDAMENTALS AND AWARENESS OF PHARMACOVIGILANCE IN UNANI SYSTEM OF MEDICINE

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ABSTRACT

Unani System of Medicine refers to Graeco-Arabic drug, which is established on the training of Greek physician Hippocrates and Roman physician Galen and developed into an elaborate medical system in middle age period by Arabian and Persian physicians, similar as Rhazes (al Razi), Avicenna (Ibn-e-Sina), Al-Zahrawi, and Ibn Nafis. Buqrat (more known as Hippocrates, 460-377 BC) is said to be a progeny of Aesculapius and honored as „ father of Unani drug'. It appeared in Greece nearly 2500 times back and has been using drugs of around 90 herbal, 4-5 animal and 5-6 mineral origin. It is not only the original knowledge of drug but also a rich store house of principles and philosophies of drug which can be of immense value to the drug in particular and knowledge in general. Diseases and complications are considered to derange the normal temperament and homeostasis of the humours in the body. So regimental remedy or (Ilaj bi " l-Tadabeer) pharmacotherapy (Ilaj bi " l-Dawa) have been used since ancient times as per the sole generalization to bring back the homeostasis of the humours and to correct the unusual temperament involved. Once this mode of treatment proved impotent, section (Ilaj bi " l-yad) has been advised as a last resort.

Unani system of medicine, although began in Greece, is one of the recognized systems of medicine in India. They're regarded as the safest medical systems. Still with the scientific morality everything is rejected or accepted in the light of available clinical data only. Hence, to produce pharmacovigilance, program for ASU medicines come essential for giving them credibility. Pharmacovigilance is an important tool to assay the medicine effect particularly its side effects, if any. To raise awareness among health care professionals about the pharmacovigilance of Unani medicines and to explore different ways of making it operationally better among health care professionals and inspire a culture of reporting regularly to the separate addition or advanced centers. In order to achieve functional capability in the enhancement of pharmacovigilance for Unani drugs and for the best practice model for Unani medicines, a methodical analysis of the areas to be concentrated upon and the challenges ahead, starting from proper nomenclature of Unani medicines, civilization, procurement, drying, transportation, processing, labelling and administering was accepted. All the critical areas were related and an understanding for the recognition and management of adverse responses due to Unani medicines was developed. This paper gives brief conception of pharmacovigilance, and reporting of ADR of Unani Medicines.

KEYWORDS: Pharmacovigilance, Unani system of medicine, Therapy, Dietotherapy, Unani treatment Unani drugs.

INTRODUCTION:

Pharmacovigilance is the science of detection, understanding, assessment and prevention of adverse drug reactions and related untoward effects.^[1]

Traditional systems of medicine including Unani, Ayurveda, Sidha, Homeopathy, Naturopathy etc. are gathering adding recognition in recent times. Traditional systems of medicine have always played important part in meeting the global health care requirements. The World Health Organization (WHO) estimates that, 80 percent of the world population use herbal drug for some treatment purposes. This is also in Media that soon AYUSH (Department of supplementary and optional drug) will be the mainstream medical knowledge ahead. Unani System of medicine is one of the oldest traditional system of medicine which has strived through times in the forestallment and treatment of chromatic medical conditions.^[2]

The aim of pharmacovigilance is to identify, assay and understand adverse effects or any other specific medicine- related problems that aren't limited to chemical medicines, but also to herbal, conventional and supplementary drugs, natural drugs, vaccines, blood products and medical devices, and to help them.^[4]

The thorough testing of herbal drug in the demand for their pharmacology and toxicology has not been tested; pharmacovigilance has consummate significance in detecting unwanted responses. Besides that, there's a problem regarding sudden poison of herbal drug due to quality issues including incorrect or differenced herbs,

use of poor-quality herbal material, supply of diluted or contaminated herbs or products, incorrect processing methods. These quality issues should be minimised to some extent by perfecting regulation i.e. GMP ethics for manufacturing. Therefore, regulation of herbal drug/ products from multiple countries with different manufacturing ethics remains a problem for poor quality products^[3]. Thus, ultimate aim of Pharmacovigilance is to achieve rational and safe use of medical medicines, to assess and communicate the hazards, benefits of medicines on the demand and to give education and information to the case and to be safe from misleading announcement.

TRADITIONAL UNANI SYSTEM OF MEDICINE:

The Unani Medicine System is one of the oldest traditional drug systems that has was to help and treat different medical problems over the periods. Unani is the Arabic word for Ionian, or Greek, for which Unani drug is also generally appertained to as Unani Tibb or Graeco-Arab Medicine, since it was developed and meliorated by Avicenna through methodical experimentation^[7]. According to Unani drug, health is considered as a state of body with humors in equilibrium and body functions normal.

Health is rested on six essential elements:

1. Air
2. Drinks and food
3. Sleep and insomnia
4. Excretion and retention
5. Physical exertion and repose
6. Mental exertion and repose.

The human body is composed of four fundamental elements as per this conventional system earth, air, water and fire with cold, hot, wet and dry grains, independently^[5]. Mortal disposition is composed of the dominant humor i.e. Sanguine (Damawi), affectless (Balghami), Chloretic (Safrawi) and Malancholic (Sawdawi), which can be compared with the disposition of Diet, Medicines, Environmental factorsetc. as the beings of non-human world is being made up of directly by elements which are described in terms of qualitative disposition. The loss of equilibrium of humors cause disease and hence the aim of treatment is by restoring the equilibrium of giving factors and by medicine with diametric disposition. In addition, Unani System of drug believes that Mediatrix naturae (Tabiyat Muddabira Badan) is the supreme power, which controls all the physiological functions of the body, provides resistance against the diseases and helps in healing naturally^[6]. Interestingly the description of health notice by WHO is in close imperfect with the idea of health characterize by Unani System of Medicine.

THE CONCEPT OF PHARMACOVIGILANCE IN UNANI SYSTEM OF MEDICINE:

The Unani System of Medicine refers to Graeco-Arabic drug, predicated on the training of the Greek physician Hippocrates and the Roman physician Galen, and developed by Arab and Persian physicians, similar as Rhazes (al Razi), Avicenna (Ibn-e-Sina), Al-Zahrawi, and IbnNafis, into an elaborate medical system in the middle periods. Buqrat (more known as Hippocrates, 460-377 BC) is known as the " father of Unani drug"and is said to be a beneficiary of Aesculapius. It began nearly 2500 times ago in Greece and used medicines of around 90 herbal, 4-5 animal and 5-6 mineral origin ^[7].

The conception of Pharmacovigilance is vibrant in the Unani system of drug. Ibn-i-Sina has done a progressive work in this regard. An developed general and systemic pharmacology of the also existing medicines includes cardio-active medicines, law of approaches and a precious knowledge on the techniques of medication of further than 2000 simple & compound drugs. Unani medicines of all origins (plants, animals and minerals) are classified by four degrees on the base of their disposition, potential (power) and effectiveness (efficacy) which, in their wholeness, check adverse medicine responses. A medicine used in Unani system has a documented temperament (hot, dry and wettish). The temperament of the medicine is measured on a scale of one to three degrees. The temperament of a medicine may be (Haras Hot and Cold, Hot and Dry, Hot and Moist; Barid as Cold and Hot, Cold and Dry, Cold and Moist; Yabis as Dry and Hot, Dry and Cold, Dry and Moist). This category of herbs seems to be based on the clinical observances of the yesteryear physicians of Unani system ^[10].

Occasionally it becomes necessary to use a cover when the medicines are unapproachable or when they're artificially expensive or when there's a religious prohibition on the use of the medicine. Occasionally it so happens that the needed part of the plant might not be available while its other parts are fluently available. In similar cases physicians make do with whatever is available ^[8].

There are three types of substances that come into contact with the body and respond to it:

- (a) those that are altered by the body but don't cause any change in the body,
- (b) those that are altered by the body and generate changes in it,
- (c) those that aren't altered by the body but even also produce changes in it ^[10].

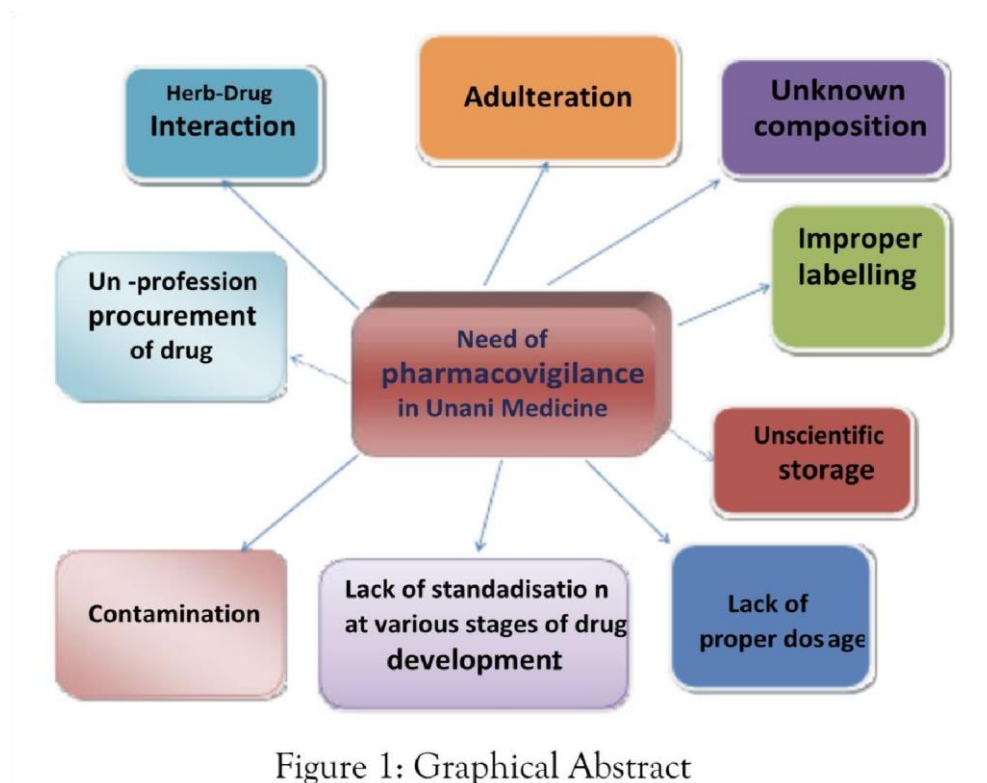
NEED OF PHARMACOVIGILANCE IN UNANI MEDICINE:^[9]

Figure 1: Graphical Abstract

CHALLENGES IN THE PHARMACOVIGILANCE OF UNANI MEDICINE:^[9,12]

- Ignorance among physicians regarding ADR's.
- Genuinely low reporting of ADR's.
- Too multiple products and multiple component formulations are tough to cover.
- False belief about the universal safety of Unani medicines.
- Herbal and allopathic medicines are generally specified together.
- False belief that Unani medicines have no expiry date, though this factor has been taken care of by introducing a rule regarding shelf life of all forms of medicines in Medicines and Cosmetics Act, 1945.
- Bulk allocating. This is one of the most important causes of ADR as some medicines like Kushta are specified in much advanced dosages than actual dosage.
- Concept related to adverse responses not covered in class.
- Lack of quality control to produce standard drug.
- Informal drug store sector- dealing spurious, misbranded and sub-standard medicines.
- A lot of Unani medicines which are available in the market don't have the actual elements as are described in Unani literature. This may be due to non-identification/ false identification or non-availability of that medicine. As similar formulation with similar names may have different elements

thereby and Pharmacovigilance observation of one may not be applicable to other till their content and quality of elements are same.

- Also, assessment of adverse responses is difficult because of multi component composition of most medicines.
- Practice of Pseudo-allopathy which refers to co-administration of Allopathy medicines along with Unani drugs.
- Poor case compliance and ignorance, apart from self-medication and home remedies that are practiced by multiple people.
- Techniques to study medicine safety problems haven't evolved adequately in Unani Medicine. Non-availability of compendium of ADRs for Unani medicine.

PRINCIPLE OF DIETOTHERAPY (ILAJ BI'L-GHIZA) IN UNANI MEDICINE:

Diet (Ghiza) in Unani medicine is considered a two brand, helps in maintaining health and excess or bad quality is a seed to disease ^[11]. Dietotherapy (Ilaj bi 'l-Ghiza) involves advise a specific diet, which is the simplest and maximum natural course of treatment by a hakim. For fever, for case, Unani drug stresses a nutrient-rich, low- roughage diet that might include dalia (porridge) and kheer (a milk broth). Both the quantity and quality of food are taken into consideration. Relatively occasional in ultramodern Unani remedy is ilaj-bi-misla, or organotherapy, a mode of treatment that involves healing a diseased organ with the use of tissue extracts from the same organ of a healthy animal ^[13]. Hearts, kidneys and brains of animals are recommended in the separate organ 's treatment of an existent ^[11,14,15]. Before medicinal treatment, Unani physicians have advised restriction or change in day-to-day diet and that should be acclimated according to disease and may hold on for many days because some diseases can be cured even by diet. So specific diets are advised according to disease. Originally, treatment of chromatic diseases has been tried however changing healthful pattern or quality or amount of food. Pharmacotherpay is generally given once it appears ineffective or used along with dietotherapy. According to Unani scholars similar as Avicenna, Hippocrates and Razes, physician shouldn't interfere with tabiyat in the original stages of the disease. Only amping healthful measure may be taken ^[17].

In case of chronic diseases, Unani scholar have advised administration of nutritional proteinacious diet in good amount has been advised to serve wear and tear (badane ma tehlul) caused by disease and maintaining the tabiat (exemption) to fight diseases over a long period.

IMPORTANCE OF PHARMACOVIGILANCE IN UNANI SYSTEM OF MEDICINE:

Rationality in the Use of Unani Drugs for the Prevention of ADRs:-

According to WHO, "Pharmacovigilance activities are done to watch discovery, assessment, understanding and forestallment of any offensive adverse responses to medicines at healing concentration that's used or is intended to be used to modify or explore physiological system or pathological countries for the benefit of beneficiary." These medicines may be any substance or product including herbs, minerals, etc. for animals and mortal beings and can even be that specified by interpreters of Unani or ayurvedic system of drug.

In Unani drug, proper logic in the technique of medication of medicines, including a rationality underpinning combination of chromatic medicinal plants, minerals, animals productsetc.; technique of administration; chromatic preservatives; suggestions and contraindications in different situations; restriction, avoidance and abstinence of certain diet (Parhez); adverse medicine effect; complete medicine profile; adverse medicine or food- medicine relation; guidelines for specifying in maxima of age or in the presence of altered organ function or in the presence of pregnancy or lactation, etc., are given in chromatic Unani Formularies. Also, correctives (Muslehat) to medicines are used since a long time to minimize some undesirable effects, which the elemental and the adjuvant ingredients may produce in a typically specified combination of with both single and composite medicines. Medicines that are poisonous in crude form are reprocessed and purified in numerous ways before use (Tadbir). In malignancy of the fact that every medicine used in traditional systems of drug may have some side- effects (Muzarrât), the aim of the below preventives, taken by well- informed and endured physician, was obviously to avoid any adverse medicine responses.

The physicians after noticing any unknown side- effect in cases either used to write those adverse responses in their Bayaz (Notebooks) or communicate their adventures to their pupils (in ultramodern language tradition auditing and monitoring). There was also no association of physicians worldwide as prevalent currently under different names and different governmental patronage, in order to interact or change experiences. The Indian physicians used to exercise in their own region or community. In other words, there was no aimless/ automatic or medicine- orientated ADR monitoring ^[16].

Modern Trends of Indigenous Drugs Monitoring including Unani Medicine: -

Modern drug rests largely only on the conception of disease and suffering to be treated by administering commodity, a medicine or potion, to the existent. Still, substantiation is accumulating that a wide range of evidently unconnected affections can be due to abnormal responses to ingested materials (like food) and that a cure can be affected by simply withholding those materials. A difficulty also arises because symptoms are frequently vague rather than specific, and inveterate rather than acute. Complaints of irritability, depression, fatigue, headache, joint and muscle pain or gastro-intestinal disturbances may well be dismissed as being of

cerebral or emotional origin. Diagnosis is frequently delicate and time consuming, and may well demand experience, which can be handed only by one who has taken a special interest. Although indigenous medicines, which are generally known as herbal remedies in the United States and Europe, continue to be extensively used in the community and there's a perception among consumers that these medications are "natural", and thus have no ill-effects and are safe. Adverse responses are a cost of ultramodern remedy.

Reasons for adverse medicine responses in herbal drug may be varied, like pitfalls associated with parenteral use are lesser because all medicines are prepared for internal purpose or for external operation.

Contamination of herbals with pharmaceutical medicines is a problem in numerous countries. In the present script, when ADR Monitoring is being done on wide scale and in a well-maintained way, there's still a veritably low reporting of adverse medicine responses of saucers. The legal status and blessing medium of herbal drug also varies from country to country and pitfalls associated with its illogical use are also lesser.

An exclusive medicine response examiner centre for herbal medicines should be set-up by WHO or other Organization. Still, the design of WHO Uniting Centre for International Drug Monitoring on safety monitoring of herbal drugs is under way. Herbal ATC bracket for medicinal purposes into a logical hierarchical structure compatible with the WHO Drug Dictionary is one step ahead in this direction.

CONCLUSION:

Unani system of medicine addresses homeostasis of the body that depends on balance of the four humours and grains which are balanced by six essential factor similar as atmospheric air, diet, sleep and insomnia, elimination and retention, mobility, cerebral condition will come a cause of the disease. Disturbance in any of these factors will alter the quality of grain and amount of humours which disturb homeostasis and lead to product of morbid humours. Morbid humours are main malefactor of pathological changes. To except the morbid humours chromatic administrations and medicines are employed but modulation of real cause of disturbance in homeostasis i.e. six important factors are the root to treat. Hence, Unani system of drug treats deeply and especially concentrating the actual root of pathology else condition may stabilize for a duration but can develop again. Hence, understanding these doctrines appropriately to find the cause is the key of treatment. Hence, the practical knowledge is based on the elemental principles rooted in the oldest classical manuals of Unani medicine.

The need of the hour is to educate the physicians and encourage them to assay and report any adverse belongings that do in a case, no matter how petty or extraneous they may act. Quality medicines are one of the main pillars of effective antidote. The onus of furnishing quality medicines lies with the pharmaceutical houses. This essay recommends for further sensitizing programs, announcement about ADR reporting at grass root health care system. This step won't only promote ADR reporting, but also will be helpful in reducing overall profitable burden of health care cost, morbidity & mortality.

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REFERENCES:

- [1] Samal J. Pharmacovigilance in Ayurveda –Concept and Regulations. *Current Pharmacogenomics and Personalized Medicine (Formerly Current Pharmacogenomics)* 2018;16(1):4 -8.
- [2] AYUSH.Background. 2016. Available from: <http://ayush.gov.in/>
- [3] Shaw D, Graeme L, Pierre D, Elizabeth W, Kelvin C. Pharmacovigilance of herbal medicine. *Journal of ethnopharmacology* 2012;140(3):513 -8.
- [4] Wal A, Wal P, Gupta S, Sharma G, Rai AK. Pharmacovigilance of herbal products in India. *Journal of Young Pharmacists* 2011;3(3):256 -8.
- [5] Ahmad S. Unani medicine: Introduction and present status in India. *The Internet Journal of Alternative Medicine* 2007;6(1):1 -4.
- [6] Ur -Rahman R. Unani system of medicine: The science of health and healing 2013.
- [7] Ansari S, Khan QA, Anjum R, Siddiqui A, Sultana K. Fundamentals of Unani system of medicine -a review. *European Journal of Biomedical and Pharmaceutical Science* 2017;4:219 -23.
- [8] Azmi HWA. *Kulliyat - e -Advia*. New Delhi: Ejaz Publishing House 1997.
- [9] Pervaiz AD, Nahida R, Shameem AR, Farooq AD, Shabir AP, Hussain IM. Proactive Pharmacovigilance of Unani drugs. Prospects and Challenges. *J Pharamacovigil* 2020;8:285.
- [10] Rahman SZ, Khan RA, Latif A. Importance of pharmacovigilance in Unani system of medicine. *Indian Journal of pharmacology* 2008;40(S1):S17.
- [11] Hamadani KH. *Usoole-Tibb*. New Delhi: Komi council baraye farg urdu zaban, 2001; 400-80.
- [12] Vijay Malik . *Laws relating to Drugs and Cosmetics*, 22nd edition, Eastern Book Company, Lucknow 2012.
- [13] Unani medicine. Britannica. Available from: <https://www.britannica.com/topic/Unani-medicine,2016>.
- [14] Karshi MH. *Jamiul Hikmat*. Volume 2. New Delhi: Aijaz Publishing, 2011; 797-800.
- [15] Unani medicine. NHP portal. 2015. <http://www.nhp.gov.in/ilaj-bil-ghiza-dietotherapy-ml>.
- [16] Rahman HSZ. Historical perspective of traditional medicine with special reference to ADRs. National Symposium on Relevance of Pharmacovigilance for Indian System of Medicine. 2006 Nov 4th;:53–61. Department of AYUSH, Ministry of Health and Family Welfare, Government of India and Society of Pharmacovigilance, India.
- [17] Azmi AA. Basic concepts of unani medicine. New Delhi: Jamia hamdard, 1995; 135-136.