

A REVIEW OF MEDICOLEGAL CHALLENGES IN AYURVEDA**Bagwan Parvez Feroz^{1*} and Deo Sunila Hemant²**

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ABSTRACT

Application of law to medical practice is an integral part of the healthcare system, so as to avoid inadequacies, lacunae and malpractices. This include a range of practices like consent, prevention of adulteration, marketing, advertising, practices, etc. While these facets are thoroughly implemented in medical practice, the implementation in Ayurveda practice is still lagging in many aspects. It is a challenge that needs to be taken up considering the many lacunae in today's time. Some of these problems include lack of consents for various procedures like panchakarma, agnikarma, ksharkarma etc; misleading advertisement of Ayurveda treatment; false claims regarding durability and use of Ayurveda drugs, marketing of herbal

preparation as "Ayurveda drugs" Lack of such medico legal vigilance adds to the already deteriorating condition of the image of Ayurveda in front of society therefore it is necessary as a fraternity to take up the cause of medicolegal application to Ayurveda practice.

KEYWORDS:- Medico-legal, consent, malpractice, adulteration, misleading, marketing.

INTRODUCTION

In medical practice application of law to various aspects forms an important part for the achievement of ethical conduct by practitioner around the globe law ensures that inadequacies, lacunae and malpractices do not harm medical care provided to patient's medical vigilance is thus achieved throughout the world.

Unfortunately in Ayurvedic practice, this medico-legal vigilance is a rare phenomenon in

terms of various aspects many clinical procedures like panchakarma, raktamokshan, ksharsutra, etc. are carried out without proper informed consent or without explaining the hazards and necessary precautions {as there is no uniform proforma/SOP available}. This consent is an otherwise common and essential practice globally. Similarly, there is mass misinformation being spread through various media of advertisement many of this advertisement are illegal misleading and purely made of tall claims. Additionally, such acts go unseen by authorities or even if noticed, stringent action is not taken.

There is also a gross problem regarding usage of Ayurvedic drug in terms of improper dosaging, toxicity and adulteration of drugs. The standardization and safety of these drugs is a major concern and still taken lightly due to multiple misunderstanding regarding Ayurveda drugs (for example the concept that Ayurveda drugs have no expiry or that they have no harmful effects).

Lastly, it needs to be highlighted that in Ayurveda practice, biomedical waste management has become relevant only recently when the Biomedical Waste Management Act was amended to include AYUSH hospitals in 2016. The implementation is still a concern with respect to awareness.

Many such factors contribute to marring the reputation of Ayurveda. As a fraternity it becomes the duty of every practitioner to contribute to changing scenario. This study tries to bring forth the problems and aims at triggering further studies to finding solutions for the same.

Aims

To explore the medico-legal challenges in field of Ayurveda.

Objectives

1. To review the medico-legal aspect pertaining to Ayurveda
2. To provide collective data for further study and constructive work in the field of Ayurvedic medico-legal vigilance

MATERIALS AND METHODS

Materials

Classical and modern text books, research Articles and internet source reviewed for the research content

Methods

The literature was reviewed and data was classified broadly into following categories:

1. Consent
2. Drug related problems
3. Advertising practice
4. Bio medical waste

RESULT

1) Consent

The term consent implies voluntary agreement, compliance or permission (section 13 of Indian contract act) it is legally mandatory to give reasonable information and leave decision upon the patient/relatives. However, unlike modern medical practice, it is not common or mandatory for taking informed consent for procedures like agnikarma, vaman, virechan, basti, raktamokshana etc. in case any of these procedure result in any complication, there is no proof of valid informed consent as a standard proforma/uniform protocol is not available.

2) Drug related problems

Ayurvedic medicine is often misconstrued. Medicines are not considered like other drugs, inspite of having a separate pharmacopoeia and formulary.

The attitude towards this is influenced by misconceptions like “Ayurvedic drugs have no expiry/side effects”. However, there are specific definitions provided for ASU (Ayurveda, siddha and unani) drugs which categorically imply that ASU (Ayurveda, siddha and unani) drugs are to be treated as any other drugs.

The problems can be broadly categorised as

- a) Adulteration.
- b) Improper dosage and toxicity.
- c) Lack of proper standardization.

a) Adulteration

Section 33EE deals with the adulteration of Drugs. To summarise, the drugs which contain any putrid/filthy substances or have been prepared in unsanitary conditions or that have been mixed with any other substance like colouring etc. (toxic or non-toxic), will be treated as an adulterated drug.

Today, there are many examples where herbal drugs or herbo-mineral drugs are adulterated with artificial colouring, dust, etc. Cheap drugs are powdered and sold under the name of expensive and rare Ayurvedic raw drugs. There are also examples where some Ayurvedic proprietary medicines are laced with drugs like steroids in order to get faster results (also an offense under section 33EEC-misbranded drugs).

b) Improper dosage and toxicity

Any drug is supposed to be administered in a specific dose and duration. Generally, these are determined through clinical studies for modern drugs. As per Drugs cosmetics act, ASU(Ayurveda, siddha and unani) drugs do not require any such safety studies or trials as the classics are considered as a solid proof for the same. Most drugs are described along with their Matra, Anupan and Kaal. Also Arha-anarha (indications and contra-indications) are described in the classics. Even then, many Ayurvedic drugs are sold over the counter without any physician's advice. Some of these drugs contain substances under Schedule E(I) i.e. poisonous/toxic substances.

These drugs are then consumed for long periods in improper dosage, thus resulting in ADR (adverse drug reactions) e.g Sanjeevani Vati which contains Bhallataka or even Tribhuvan Kirti Ras can cause severe reactions in Pita prakruti patients. Or in some cases, acute/sub-acute toxicity may occur. For e.g. use of parada/Kajjali Kalpas can cause nephrotoxicity/ chronic use of Taamra containing drugs e.g. Arogyavardhini without proper indications can cause hepatotoxicity. Chronic use of Garbhupal Rasa may lead to Neurotoxicity.

c) Lack of proper standardization

According to Section 33EEB and 33EEC, ASU drugs are to be manufactured only under proper license issued by the Licensing Authority. Even proprietary medicines can be manufactured once they have been authorised by the Competent Authorities. Any practitioner is allowed to compound and dispense medicine to their own patients. However, to manufacture, package and distribute these drugs in the market, proper license is required.

Even though these laws have been explicitly mentioned, many small scale pharmacies still exist and drugs are still being dispensed without standardisation and proper license. Many of these drugs do not contain proper labels. This leads to subpar drugs being administered to patients and thus creating even more unnecessary problems.

3) Advertising practices

- a) Generalizing term “Ayurvedic”
- b) Misleading hoardings
- c) Unauthorized TV commercial/newspaper advertisement

There are various laws laid down regarding the advertisement of ASU (Ayurveda, siddha and Unani) drugs. Section 33EEC of Drug and cosmetic act particularly deals with misbranded drugs where it is specifically mentioned that making false claims about activity of drugs is also include under misbranding.

- a. Generalizing term “Ayurvedic”- An Ayurvedic drug is one that has a reference in Ayurveda classics. Any other preparation can be termed as herbal/proprietary/patent. {As per Drug and cosmetic rules, 1945 chapter XIX}. There are a total of 56 Ayurveda Classics scheduled under the Drug and cosmetic act.

However this protocol is not followed and “Ayurvedic” has become a term generically applied to any preparation having even minimal herbal ingredients. This leads to maligning image of Ayurveda as most of these products have no scientific connection/references from any scheduled classics.

- b. Misleading hoardings/pamphlets- it is often seen that large hoardings or fancy pamphlets are put up with tall claims regarding “100% results” or fall recovery from otherwise incurable or disorders. This practised either by practitioner or even by common man with no qualification whatsoever. Soliciting patients with the fake claims of permanent cures is highly unethical and derogatory
- c. Misleading TV commercials/newspapers advertisement- As per various sections of drug and magic remedies (objectionable advertisement) Act, 1955, it is an offense to wrongly advertise drugs and remedies on the basis of false claims and no scientific evidence.

However, many products which are either proprietary herbal medicine products such herbal extracts are advertised as “Ayurvedic” treatments for cure of diseases, improving sexual powers, avoiding surgery for tonic purposes. Influential personalities and sometimes false patients/stories are used to advertise and misguide the judgement of the layman audience. Punsavan Vidhi , which is actually a procedure described with the purpose of ensuring birth of a healthy, ideally developed infant (MALE OR FEMALE), is now used as a tool to

defame Ayurveda for promoting sex selection and female foeticide. Some remedies like gemstones, amulets etc. are also linked to Ayurveda unnecessarily. This is also one of the major concerns as the reach of such media is very high and is early believed by impressionable audience.

IV) Bio medical waste

The biomedical Waste management law 1998 was amended in 2016 to include AYUSH Hospitals. Any waste produced in Ayurvedic practice can be easily classified into the categories described in Schedule I of the BMW management law. There is still need for proper segregation and implementation of the guidelines as it may prove as an environmental bio-hazard.

Summary

As discussed, the lack of standard uniform protocols for documentation, inadequate law and action taken against misleading advertisement and no stringent action being taken against non-compliance to Drug and cosmetics act and rules regulations are the medico-legal challenges being faced by Ayurveda fraternity.

DISCUSSION

As reviewed in this study, the challenges that Ayurveda fraternity faces with respect to the medico-legal aspects of medical practice are grave and of utmost importance at this time. There is need for proper understanding of these problems in order to find appropriate solutions. Further scrutiny of present laws for necessary amendments, along with legislating new laws having stringent punishment against non-compliance to existing acts, will facilitate in changing the current picture. It will also ensure the proper execution of medico-legal vigilance as well as be an adjuvant to medical jurisprudence.

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