Consumers Claim on Safety and Efficacy of Herbal Medicine: A Prospective Analysis

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**Prospective and Retrospective Review of the Topic**

Unani, Ayurvedic and Homeopathic medicine have been used from primitive age to till now. All forms of medicine usually obtained from six major sources (Plants, Animals, Mineral/Earth, Synthetic & Semi-synthetic, Microbiological and Recombinant DNA technology) [1]. The quality of herbs (leaves, flowers, fruit, seeds, stems, wood, bark, roots, rhizomes or other plant parts or entire plants, fragmented or powdered), herbal materials (herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs), herbal preparations (finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils, expressed juices and processed exudates of herbal materials) and herbal medicinal products have a direct impact on their safety and efficacy [2]. Scientific technology from macro to nano and retrospective to prospective research suggested that source of drug, collection of drug, preservation of drug, sort out of drug, storage of drug, formulation development, titration of dosages, safety and efficacy studies, side-effects, pharmaco-dynamic and pharmacokinetic drug interaction, drug reaction, drug resistance, assessment of the safety of potentially hazardous substances in herbal medicines, with particular reference to biological, chemical, and radioactive contaminants and pesticide residues and post marketing surveillance etc are basic indicators for assessment of qualitative, quantitative properties. Declaration of any effective drug is totally depended on aforementioned properties. So, I would like to describe the topic on the basis of these properties.

**Source, selection, cultivation, collection, correct identification and preservation of Drugs**

Medicinal plants used in Traditional Medicine are often collected in the wrong season; at wrong time of the day and the wrong stage of their growth due to ignorance on the parts of the collectors [3]. Correct identification, proper cultivation and the preservation of drug are also very important for drug development.

**Sort out of drug, cleaning, drying, extracts preparation, purification and storage of drug**

Sort out and storage of drug is also important for assurance of quality process and products. Standard Operating Procedure (SOPs) by following Current Good Manufacturing Practices (CGMP) for store or stock of raw or finished materials or products is basic demand for qualitative and effective herbal medicines.

**Formulation development**

To follow the earlier assumption based pharmacopeia also a great drawback of herbal medicine in the developing countries. Appropriate quantity of recipients and revalidation of the formulation are very important factors for preparation of effective herbal medicine. Example, Formulation of Syrup Faulad by following Unani
pharmacopiea could not be possible to develop effective syrup for Anemia. I worked for more than 2 years for stability of the drug for formulation development. Nowadays, herbal formulation development by following earlier pharmacopeia is very difficult task and revalidation with scientific techniques and technology are painstaking issues.

**Titration of dosages**

Dose titration is also prime factor for effectiveness of drug. Proper dosage for proper disease is very important for declaration of effective drug. Clinical Trials especially from second phase to fourth phase in multicenter, multinationals, multicultural environment are very time-seeking approach for generalization of herbal medicine.

**Safety, Efficacy and Side-Effects Studies**

All most herbal medicines are traditional based. Experimental animal study is very poor level for toxicity, efficacy and safety, identification of possible side-effects and minimization of side effects of herbal medicine. So, clinical trials are utmost important for drug development. Detection of biological activity of the crude extract and establishment of a bioassay system to permit identification of the active fractions is needed.

**Pharmacodynamic and Pharmacokinetic Properties of Drug**

Evaluation of Pharmacokinetics (absorption, distribution, chemical changes of the substance in the body, the effects & routes of excretion of the metabolites of the drug) and pharmacodynamics (biochemical & physiological effects of drugs on the body or on microorganisms or parasites within or on the body and the mechanisms of drug action and the relationship between drug concentration and effect) activities are very important for drug development.

**Drug Interaction and Drug Reaction**

A drug interaction is a condition where two or more drugs administered simultaneously and perform as an antagonistic to produces unwanted side-effects. Typically, interactions observed in drug-drug interaction, drug-food interactions and drug-plant interactions. These interactions may occur due to accidental misuse or lack of knowledge about the active ingredients involved in the relevant substances [4]. ADRs (pharmacovigilance) may occur following a single dose or at normal dosage and/or due to overdose or prolonged administration of a drug or result from the combination of two or more drugs.

**Drug Resistance (DR)**

DR refers to reduce the effectiveness of a drug for curing a disease or condition due to failure of dosages or intolerance. Resistance may be intrinsic or acquired. Drug resistance develops naturally, but careless practices in drug supply and use are hastening it unnecessarily.” Resistance to first-line drugs in most of the pathogens causing these diseases ranges from zero to almost 100% [5]. The four main mechanisms for DR are drug inactivation or modification, alteration of target site, alteration of metabolic pathway, reduced drug accumulation. Socioeconomic factors such as race and poverty affect the accessibility of and adherence to drug therapy [6].

<table>
<thead>
<tr>
<th>Host resistance- defenses possessed by the host to prevent infection.</th>
<th>Natural Resistance-- susceptibility to infection by a particular organism.</th>
<th>Individual resistance-- due to single or multiple factors.</th>
<th>Acquired / Innate Immunity</th>
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<tbody>
<tr>
<td>1. Specific resistance-- directed against particular microbe</td>
<td>Metabolism, physiological, and anatomical differences between species</td>
<td>Age--adolescence development--acquired adult immunity Nutrition</td>
<td>Immune system promotes homeostasis and conducts surveillance</td>
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<tr>
<td>2. Nonspecific (natural) resistance</td>
<td>affect the ability of a pathogen to cause infection</td>
<td>Occupation--societal interactions Miscellaneous--gender, hygiene, etc.</td>
<td>Types of immune responses, first front of defense--natural nonspecific Sec- ond front of defense--acquired specific Dual response.</td>
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The entire production process, starting from cultivation and ending with the sale of the products should be standard. Compliance with GMP is crucial for the production of good quality and the pesticide free herbal medicines.

Some prospective approaches can be adopted for developments of herbal medicine in Bangladesh are as follows:
1. Selection & correct identification of the medicinal plants and extraction of the identified plant with suitable solvent.

2. Detection of biological activity of the crude extract and establishment of a bioassay system to permit identification of the active fractions and rapid discarding of the inactive ones.

3. Fractionation of the crude extracts by using physical-chemical procedures and monitored by biological tests. Identification and separation of the active fractions.

4. Isolation of the active constituents by chromatographic or other suitable techniques and purification of the isolated compounds by repeated chromatography and crystallization.

5. Establishment of the chemical structures of the pure compounds by various physical-chemical techniques and determine of their biological activity by various pharmacological and toxicological tests.

6. To develop quality control methods for medicinal plant materials.

7. To follow good agricultural and collection practices (GACP) for medicinal plants.

8. To follow International Pharmacopoeia (if needed).

9. To follow good manufacturing practices, guidelines for methodologies on research, assessment, and evaluation for pharmaceutical products and storage practices.

10. To follow good trade and distribution practices (GTDP) for pharmaceutical materials.

So, reduction of any drug efficiency depends on the aforementioned process, output and outcome indicators or measures. Management should be given emphasis to consumer claim and take necessary action to achieve the desire goals.

References

1. Sources of Drugs.

2. WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues.


