Traditional Medicine in Asia

Edited by

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Photographs on cover page (clockwise)

- Acupuncture is widely used in hospitals of western medicine (courtesy Prof. Chen Qui-Ting)
- Yoga posture
- A herbalist, preparing fresh herbal medicines
- Crocus sativus - source of saffron

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Preface

All countries in the South-East Asia Region of the World Health Organization (WHO) have a heritage of traditional systems of medicine. There are large numbers of traditional medicine practitioners who provide help and service to the ill and the needy. Some of these practitioners are qualified doctors who have taken a five-year course in the system of medicine they practise; there are others who have learnt their system of medicine and the use of the different plants from their forbears, while there are still others who offer their services after working with practitioners and learning from them.

It is important that this unique knowledge, often found in ancient texts, be utilized by countries to the maximum extent possible without endangering the environment and destroying the very plants which are the source of the medicine. Unfortunately, this too is happening. There are many ways in which the practitioners of these systems and the products and plants they use could be more effectively utilized for the benefit of the countries and their people. Greater use could be made of these medicinal plants at the primary health care level so that all persons could have recourse to herbal medicine–particularly those living in areas without any allopathic health care coverage. Further research directed at a few of the chronic diseases against which more drugs are needed, such as diabetes, bronchial asthma and arthritis, could lead to the discovery of new drugs for these conditions. Regulated and selective export of some of these medicinal plants being eagerly sought after in other parts of the world could considerably enhance the foreign exchange earnings of countries with this biodiversity. Careful planning is needed so that such a programme could be launched without detriment to the environment and without reducing the availability of the medicinal plants in the countries. The very large numbers of trained and semi-trained practitioners of the traditional systems of medicine could become more involved in the national health care systems of the countries. Such involvement can come about only as a result of some regulation of the systems being followed, the products used for health care and the practitioners of such systems.

It is important also to take steps to ensure that unethical and unjustified exploitation of these plants, which have been used for centuries, is prevented—particularly the patenting in western countries of these remedies. At the same time, it is necessary to protect the discoveries being made in the countries of the Region by scientists and research workers who are carrying out research and discovering and documenting the effectiveness of the plants used.

The WHO Regional Office for South-East Asia has published this book in order to present to the governments, policy-makers, clinical investigators, regulatory authorities, doctors, practitioners of traditional systems of medicine and the public, the state of the art in these wide and many-faceted fields. It is felt that the information in this publication, presented by some of the most eminent international authorities, would help not only in our understanding of these systems of medicine but also in making better use of them.

The book is divided into three sections. The first section describes broadly several of the systems of traditional medicine in the countries of the Region. The second discusses policy issues such as harmonization of traditional and modern medicine, the role of traditional systems of medicine in national health care, a framework for cost-benefit analysis of traditional and conventional medicines, and the development of training programmes. The third section discusses technical issues such as legislation and regulation, standardization, pre-clinical toxicology and clinical evaluation, including ethical considerations and protection of traditional systems of medicines and research, drug development and manufacture of herbal drugs. Finally, the last part of the third section contains a brief description of the current status of traditional medicine in each of the 10 countries of the Region.

We are grateful to the contributors for not only accepting readily our invitation to contribute to this book but also for adhering to the time frame. We are also indebted to Dr Palitha Abeykoon of the Regional Office for his help in planning the book, and to Mr S. Khanna, Administrative Assistant at the Delhi Society for the Promotion of Rational Use of Drugs, for his contribution at all stages in the preparation of this book.

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Systems

Ayurveda

P.N.V. Kurup

Ayurveda, which means the Science of Life, is the oldest medical science in the Indian subcontinent and has been practised since the 12th Century BC. Ayurveda is not merely a system of medicine; rather it is a way of life. Its objective is to accomplish physical, mental, social and spiritual well-being by adopting preventive and promotive approaches as well as treating diseases with the holistic approach.[1] The theory of Loka Purusha Samya[2] – macrocosm, microcosm continuum, *Panchamahabhuta*, *Tridosha*, *Dhatus*, *Prakriti* and *Vikriti*, *Agni* and *Ama* – is the unique concept of Ayurveda. Ayurveda is effective not only in common ailments but also in many incurable, chronic and degenerative diseases as well as iatrogenic conditions. It not only takes care of the health of human beings but also of animals and plants, known as *Pashu* Ayurveda and *Vriksha* Ayurveda, respectively. Ayurveda is prevalent not only in India but also in Nepal, Sri Lanka, Mauritius, Bangladesh, Pakistan, Indonesia, Malaysia, Singapore, Maldives, etc. The traditional systems prevalent in Myanmar, Bhutan and Thailand bear a close resemblance to Ayurveda. It is also practised in Japan, Australia, USA, Russia, UK, Germany, etc., as herbal medicine or alternative medicine. Recently Australia, The Netherlands and Hungary have recognized Ayurveda as an alternative medicine. A White House Commission for Alternative Medicine has been constituted in the US to find ways and means of recognizing alternative medicine, which includes Ayurveda also for the purpose of practice.

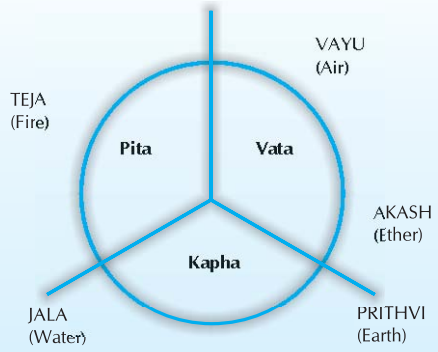
Four types of Ayurvedic practitioners exist in various parts of the world:

- *Traditional Ayurvedic practitioners* (about 300,000) who are not institutionally trained, but have gained knowledge through their family traditions;
- *Tribal healers* who practise in the tribal areas using various local medicinal herbs;
- *Institutionally qualified physicians* (around 300,000 throughout the world);
- *Graduates of modern medicine* who have faith in Ayurvedic practice.

Siddha System of Medicine

The *Siddha* system of medicine, more prevalent in the Southern States of India as well as Sri Lanka, Singapore and Malaysia, traces its origin to Dravidian

Fig. 1: Panchamahabhuta and Tridosha



culture, which owes allegiance to the cult of Shiva and the worship of the Phallus (*linga*). The *Siddha* system of medicine extensively describes the use of herbo-mineral products like mercury, sulfur, iron, copper, gold and arsenic. The principles and doctrines of the *Siddha* system have a close similarity to Ayurveda with specialization in iatrochemistry.

Historical Background

The history of Ayurveda can be traced to different periods, the earliest being the Vedic period when the Aryans compiled the four *Vedas* (1500–800 BC) with maximum references in *Rigveda* and *Atharvaveda*. Ayurveda originated in Heaven from Lord Brahma, who passed on this knowledge to Dakshaprajapati and then to the Ashwinikumaras – the physicians of *Devatas* who transmitted it to Lord Indra.[3] On earth, when diseases were at their peak, Maharshi Bharadwaj approached Indra and got the knowledge of Ayurveda. Later, Maharshi Atreya learnt Ayurveda from Bharadwaj and taught it to Agnivesh and others. Agnivesh authored the Agnivesh Tantra, known as Charak Samhita (5th Century BC). Kashiraj Divodas Dhanvantari obtained knowledge of Ayurveda from Lord Indra and taught it to Sushruta, who authored the Sushrut Samhita[4] (6th – 5th Century BC). Vagbhata (7th Century AD) was highly influenced by the teachings of Lord Buddha. He authored *Ashtanga Sangraha* and *Ashtanga Hridaya* texts. During the Medieval Period, *Sharangadhara Samhita* (14th Century AD) described the examination of the pulse for the first time,[5] as a method of clinical examination and use of metals and minerals like gold, silver, iron, mercury and copper for preparing Ayurvedic medicines. In the 16th Century, *Rasa Tantra* in Northern India and *Siddha* in the South dealt mostly with a large number of metallic preparations as remedies. The most important metal used with success was mercury in many forms.

Fundamental Principles

Ayurveda accepts the metaphysical concept of creation as proclaimed in ancient Indian treatises.[6] The *Prakriti* and *Purush* prelude gross creation. *Mahat* originates from the absolute nature (the un-manifest) with all its qualities leading to *Ahamkara*, which is of three types – *Vaikarika* (*Sattvika*), *Taijasa* (*Rajasa*) and *Bhutadi* (*Tamasa*). The 11 *Indriyas* – five organs of perception (ear, skin, eye, tongue, nose), five effecter organs (speech organ, hands, sex organs, rectum, feet) and the mind – are created out of the *Vaikarika Ahamkara* with the help of *Taijasa Ahamkara*. The *Panchatanmatras* (five basic substances – sound, touch, vision, taste, odour) are created out of *Bhutadi Ahamkara* with the help of *Taijasa Ahamkara*.

The *Panchamahabhuta* (five basic elements) are evolved from these *Panchatanmatras*, i.e., *Akash* (ether), *Vayu* (air), *Agni* (fire), *Jala* (water) and *Prithvi* (earth).

Tridosha – *Vata*, *Pitta* and *Kapha* – are the psychobiological dimensions or biological rhythms regulating the entire functioning of the human body. These *doshas* are formed by the *Panchama-habhutas*. *Vata* is formed by the combination of *Akash+Vayu* and has the properties of cold, light, coarse and dry, *Pitta* by *Teja* having hot and liquid and *Kapha* by *Jala+Prithvi* with cold, heavy, solid, smooth and moist properties. *Vata*, *Pitta* and *Kapha* are of five types having physiological functions and pathological manifestations.[7]

The five types of *Vata* include, i) *Prana Vayu*, which strengthens the vital capacity, improves the intellectual power, respiration, deglutition, and the activities of the sense organs, etc., with pathological manifestations like hiccough, flatulence, breathing troubles, etc.; ii) Udana Vayu, which regulates strength, encouragement, colour, knowledge, intelligence, memory, etc., with pathological manifestations of the eye, ear, nose and throat; iii) *Samana Vayu*, which improves digestion and metabolism, transformation of nutrients, circulation of lymph and expulsion of urine, stool, etc., with pathological manifestations like anorexia, diarrhoea and abdominal tumour; iv) *Vyana Vayu*, which regulates blood circulation, sweating, contraction, taste, ejaculation of sperm, development of all the tissues, etc., with pathological manifestations like fever and convulsion; and v) *Apana Vayu*, which regulates expulsion of urine, stool, sperm, menstruation, etc., with pathological manifestations of urinary and the uterine tract and ano-rectal diseases.

The five types of *Pitta* include, i) *Pachaka Pitta*, which regulates digestion of food, stimulates the digestive enzymes and separates the waste products with pathological manifestations of anorexia, rise of body temperature, burning sensation, indigestion, etc.; ii) *Ranjaka Pitta*, which has a role in blood formation with the pathological manifestation of anaemia; iii) *Sadhaka Pitta*, which is responsible for intelligence and memory with pathological manifestation for lack of concentration, loss of intelligence, loss of sleep, etc.; iv) *Alochaka Pitta*, which is responsible for vision with pathological manifestations pertaining to eye and vision; and v) *Bhrajaka Pitta*, which regulates body complexion, body heat regulation, etc., with pathological manifestations like vitiligo, discolouration and skin diseases.

The five types of *Kapha* include, i) *Avalambaka Kapha*, which is responsible for the lubrication of joints, pericardium with pathological manifestations like stiffness of the joints and chest pain; ii) *Kledaka Kapha*, which disintegrates food, maintains the fluid, lubrication, etc., with pathological manifestations like indigestion and mucoid stool; iii) *Bodhaka Kapha*, which is responsible for feeling the taste of various substances with pathological manifestations like dryness of mouth and palate and loss of sensation of different tastes; iv) *Tarpaka Kapha*, which provides nutrition to the sense organs with pathological manifestations like loss of the activities of the sense organs; and v) *Shlesaka Kapha*, which lubricates all body joints with pathological manifestations of the bony joints.

The body and the mind are the two complementary constituents of a living being, its dynamic normalcy being responsible for health and its imbalance for disease.

The mind exhibits three properties:

- *Sattva* (intelligence), which is signified by goodness, virtue, excellence, wisdom and good sense;

Greater emphasis is given to deformity or pathological involvement of the related channels for the initiation of the disease process which results in susceptibility to the disease due to lowered resistance of the channels

- *Rajas*, signified by passion, emotion and restlessness;
- *Tamas*, signified by mental darkness, illusion, error, and inertia.

At the biological level, *Vata*, *Pitta* and *Kapha* are stated to be predominantly *Rajasika*, *Sattvika* and *Tamasika,* respectively, in their constitution, highlighting the psychosomatic approach of Ayurveda towards disease.

Concept of Pathogenesis

The concept of health is based upon the equilibrium of *Dosha* (humour), Dhatu (seven body tissues – lymph, blood, muscle, adipose tissue, bone, bone marrow, semen) and *Mala* (faeces, urine and other waste products), i.e., soil and seed theory.[8] If this equilibrium of *doshas* is maintained (soil), then the disease process cannot take place even if any causative organism/factor (seed) exists in the body. The disease process takes place whenever the equilibrium of *doshas* is disturbed, causing its vitiation. The *Kayagni* or *Pachakagni* comprehends various factors responsible for digestion and metabolism involving the splitting of complex food substances into their simpler components for absorption. It also contributes moieties of itself to the *Dhatus* as *Dhatwagni* dealing with tissue metabolism.[9] *Ama* means unripe, uncooked and undigested and refers to the events caused by impaired digestion and metabolism due to the hypo-functioning of the Agni.[10] The products arising out of this impaired digestion and metabolism form toxic substances having excessive pastiness, depriving the body of its nutrition and are called *Ama*, which is the root cause of all diseases.

Any external factor, i.e., bacteria, virus or climatic conditions may increase or accumulate the *dosha* leading to disturbance in its equilibrium and causing its vitiation. These vitiated *doshas*, while travelling through the macro- and micro-channels of the body, are stuck due to deformity of the channels.[11] They will lead to blockage causing obstruction of the normal flow of *doshas* and nutrient material and stasis of waste products. Thus, *doshas* retained interact with *dushyas* of the affected region, leading to *dosha dushya sammurchana* resulting in disturbance of the body metabolism and *Ama* formation, which corresponds to the phase of *Sthansamshraya* when prodromal symptoms of the disease are said to manifest.[12] Greater emphasis is given to deformity or pathological involvement of the related channels for the initiation of the disease process which results in susceptibility to the disease due to lowered resistance of the channels. This organ susceptibility is often due to genetic predisposition, but is also dependent on environmental factors. Subsequently, full manifestation of the disease occurs with clear-cut symptomatology.

Eight Clinical Disciplines of Ayurveda

There are eight major clinical disciplines of Ayurveda that help deal with various disease conditions effectively.[13] These are:

- *Rasayana Tantra* (Geriatrics);
- *Vajikarana* (Reproductive health and aphrodisiacs);
- *Kayachikitsa* (Internal medicine);
- *Shalya Tantra* (Surgery);
- *Shalakya Tantra* (Diseases of eye, ear, nose and throat);
- *Bhootavidya* (Psychiatry);
- *Agada Tantra* (Toxicology);
- *Kaumarabhritya* (Paediatrics, obstetrics and gynaecology).

Approach to the Diagnosis and Principles of Treatment

Ayurveda stands for extensive and elaborate clinical examination to understand the nature of the disease process. It identifies the patient and the disease separately. Thus, the Ayurvedic clinical method is broadly divided into two parts:[14] i) Examination of the patient, and ii) Examination of the disease. The patient is not examined as a diseased entity but also as an individual human being with all its usual attributes, including his constitution and lifestyle. The 10-fold examination of the patient evaluates:[15]

- Psychosomatic constitution;
- Disease susceptibility;
- Quality of tissues;
- Body build;
- Anthropometry;
- Adaptability;
- Mental Health;
- Digestive power;
- Exercise endurance;
- Age.

The examination of disease is carried out by general examination, through interrogation and physical examination.[16] The eight-fold examination covers.[17]

- Pulse;
- Urine;
- Stool;
- Tongue;
- Voice and Speech;
- Skin;
- Eyes;
- Overall appearance.

This eight-fold examination provides a comprehensive general survey of the body and its functions.

Dushya (*dhatu* and *mala*), environment, vitality, time, digestion and metabolism, body constitution, age, psyche, acceptability, diet – all these should be minutely analysed and taken into consideration before deciding the actual line of treatment. If the principles are applied to all the disease conditions, perhaps a better management can be evolved. To eliminate and correct the *doshic* disturbances, internal medicine, external medicine and surgical treatment have been mentioned.[18] Under curative treatment, *Dipan* (which also includes appetizer) and *Pachan* (helpful in digestion and metabolism) drugs are indicated for dissolving the vitiated *doshas* by correcting the disturbed metabolism, provided the intensity of the disease is of a mild to moderate nature. If the pathological lesion is of a more severer type than that which stimulates *Agni* to improve hunger or appetite, these alone may not serve the purpose and the internal purification measure or *Panchakarma* therapy should be applied. To deal with psychosomatic problems, divine therapy, objectively planned therapy and psychotherapy have been described.[19]

In *Daivavyapashraya Chikitsa* (Divine Therapy), *Daiv* refers to divinity and/or to the events of one's past life. It is believed that many diseases are caused due to actions or *Karmas* of an individual past life which can be treated by appropriate and auspicious *Karmas* in this life. This approach to therapy is called *Daivavya-*

pashraya Chiktisa. Divine *karmas* like prayer, chanting *mantras*, ablutions, *yagya*, wearing precious stones, etc., are the usual methods of *Daivavyapashraya Chikitsa*.

Special mode of treatment

Rasayana

Rasayana (Rejuvenation Therapy) is a speciality of Ayurveda which mainly deals with the preservation and promotion of health. It promotes longevity and prevents or delays the aging process. *Rasayana* promotes resistance against infections and other causative factors for the disease by maintaining the equilibrium of *Vata*, *Pitta* and *Kapha*.[20] The *Rasayana*, if administered at an early age, also helps the body metabolism in such a way that the genetic predisposition for a particular disease is avoided and the intensity of the symptoms of a particular disease is greatly reduced.

Rejuvenation therapy, in addition to dealing with the preventive and promotive aspects of health rather than merely with the disease condition, acts also by improving micro-circulation in the body leading to better bio-availability of nutrients to tissues. The use of *Rasayana* drugs and other measures produces longevity, improves memory, intelligence and good health, promotes youthfulness, good lusture, complexion and voice, promotes optimum strength of the body and the sense organs, efficiency in talk and humility, and makes the personality attractive. There are many *Rasayana* preparations which are used according to the psychosomatic constitution and disease condition of the patient. The immunomodulatory effect of *Rasayana* drugs like *Withania somnifera*, *Asparagus racemosus* and *Tinospora cordifolia* is well-established through scientific parameters. Therefore, administration of *Rasayana* drugs having an immunoprotective effect is helpful in improving the immunity and general well-being of patients.

Panchakarma

Panchakarma (Purification Therapy) deals mainly with the removal of toxins and waste materials from the body to purify the biological system from gross channels to eradicate the disease completely. It is helpful in the prevention of disease and preservation and promotion of health, as well as the management of psychosomatic, neurological, gastrointestinal, cardiovascular and many other chronic, degenerative diseases and iatrogenic conditions. *Panchakarma* plays a vital role in Ayurvedic therapeutics and occupies an important place in the Ayurvedic system of medicine. This five-fold purification therapy, a classical form of treatment in Ayurveda, includes *Vamana* (emesis), *Virechana* (Purgation), *Asthapana* (Decoction enema), *Anuvasana* (Oily enema) and *Nasya* (Nasal Insufflation).[21] Under pre-operative management, the *doshas* are liquefied by external and internal oleation by *ghee*, oil, massages and fomentation followed by the main purification processes, which also include intra-vaginal and intra-urethral enemas and blood letting, for the elimination of toxins from the body. Under post-operative management, various types of dietetics and disciplined living for a few days after the treatment have been indicated. In Ayurveda many treatment methods are described, i.e., *Abhyanga*, *Tarpana*, 13 types of fomentations, etc. In Kerala, physicians have developed specialized techniques of *Panchakarma*, which is something more than the purification therapy. The Arya Vaidya Sala, Kottakkal, and the Arya Vaidyan Rama Variar Educational Foundation of Ayurveda,

Coimbatore, are the pioneer institutions in the field of *Keraliya Panchakarma*.

Pizhichil

In this therapeutic measure, warm medicated oil is poured all over the body, followed by massage, in seven positions in a systematic manner for the treatment of diseases of the nervous system like paralysis, sciatica, osteoarthritis, musculo-skeletal, neuro-muscular and degenerative diseases. *Pizhichil* is very useful as a health restorative measure for elderly persons when it is regularly used once a year or so. This treatment cleanses the minute channels in the body of morbid substances.

Shirobasti[22]

This is an oil treatment applied to the head in which a leather belt is tied to the clean-shaven scalp. The junction of the scalp and leather belt is sealed with paste prepared from wheat flour or black gram. Medicated oil is then poured into it and kept for the stipulated time. This is recommended for headaches, myopial conditions, insomnia, psychiatric illnesses, epilepsy, hair fall, etc. It improves the functioning of the sensory systems and removes exhaustion.

Shirodhara[23]

This therapeutic measure is carried out by pouring oil or medicated liquids on the forehead for treating headaches, vertigo, insomnia, anxiety, etc. It is also useful in many psychosomatic disorders and hypertension.

Ksharasutra[24]

This Alkaline Thread Therapy is a popular herbal treatment for ano-rectal diseases like fistula-in-Ano and haemorrhoids (piles) under the speciality of *Shalyatantra*. The medicated threads

Shirobasti treatment in Ayurveda

are prepared from plants like *Arka* and *Snuhi* by using their milk or herbal alkaline material and tying it at the site. The advantage of this therapy is that the patients may remain mobile during the treatment. It can also be carried out on patients for whom modern surgery is contra-indicated.

Role of Ayurveda in Primary Health Care

Ayurveda has laid due emphasis on the preventive and promotive aspects of health, in which dietetics and way of life, according to *Prakriti* (psychosomatic constitution), play an important role. The balance of *Vata*, *Pitta* and *Kapha* leads to a healthy state and disturbance in this equilibrium leads to diseases. If one follows the daily routine and seasonal routines as prescribed under personal hygiene and socio-behavioural conduct, then health can be preserved and diseases prevented by developing the capacity to adapt to the cosmic changes which have an impact on the human biological system. The violation of these principles disturbs the equilibrium of *doshas* increasing susceptibility to diseases.

The simple, effective, non-toxic locally available medicinal herbs which cost very little – and are more acceptable to the people – are being used successfully to treat common ailments by the practitioners of Ayurveda, who are playing an important role in providing basic health services in remote areas where institutionally qualified doctors are not available. Traditionally, each village had the traditional physician, who used to be a friend, philosopher and guide to the local people not only by taking care of health-related issues but also in regard to other socio-cultural matters which play an important role in the maintenance of health and precipitation of disease. Ayurveda is used in various national health programmes. The thera-peutic efficacy of medicinal plants is well-established on scientific lines for the promotion of health and the treatment of common as well as chronic diseases. Primary health care includes maternity and child health care, family planning, immuni-zation, control of communicable diseases, nutrition, clean water supply, health education, treatment of common and chronic diseases. In Ayurveda many methods are described to promote the health of the pregnant woman in the antenatal period and later, in the postnatal period, with due emphasis on breast-feeding of the baby for its optimal growth in the early period. Drugs like *Asparagus racemosus* promote lactation in the postnatal period and the drugs *Sida cordifolia* and *Abutilon indicum* promote the

Therapeutic efficacy of medicinal plants

For the Brain

Sankhapushpi	Convolvulus pluricaulis
Mandukaparni	Centella asiatica
Brahmi	Bacopa monnieri
Vacha	Acorus calamus
Jyotishmati	Celastrus paniculatus

For the Heart

Arjuna	Terminalia arjuna
Guggulu	Commiphora wightii
Pushkaramula	Inula racemosa
Kushta	Saussurea lappa

For the Respiratory Tract

Haridra	Curcuma longa
Vasa	Adhatoda vasica
Yashtimadhu	Glycyrrhiza glabra
Shirish	Albizzia lebbeck

For the Stomach

Amalaki	Emblica officinalis
Bhringaraja	Eclipta alba
Satavari	Asparagus racemosus

For the Liver

Bhoomyamalaki	Phyllanthus amarus
Pippali	Piper longum
Kalamegh	Andrographis paniculata
Katukarohini	Picrorhiza kurroa

For the Alimentary Canal

Bilva	Aegle marmelos
Haritaki	Terminalia chebula
Kutaja	Holarrhena antidysenterica

For the Pancreas

Tejpatra	Cinnamomum tamala
Jambu	Syzygium cumini
Vijayasara	Pterocarpus marsupium
Karavella	Momordica charantia
Kiratatikta	Swertia chirata

For the Urinary Tract

Punarnava	Boerhaavia diffusa
Gokshura	Tribulus terrestris
Varuna	Crataeva nurvala

For the Genital System

Men

Kapikacchu	Mucuna pruriens
Aswagandha	Withania somnifera

Women

Satavari	Asparagus racemosus
Ashok	Saraca asoca
Japapushpam	Hibiscus rosa-sinensis

growth of the baby. The nutritional deficiency may cause anaemia, malnutrition and other vitamin deficiencies which can be corrected by available food articles in the rural areas such as carrot, cabbage, milk, leafy vegetables and pulses. With regard to family planning, drugs like *Hibiscus rosa-sinensis* and *Piper longum Linn* have shown promising results after scientific investi-gations. *Withania somnifera*, *Asparagus racemosus*, *Tinospora cordifolia*, etc., are good immunity-promoting drugs which can play an important role in primary health care from the preventive, promotive and curative points of view.

Extensive research has shown that some of the medicinal plants exert specific action on various vital organs. They not only promote the normal functioning of the organ but also take care of the disease-condition as well.

Treatment of Common Diseases

To deal with various common diseases at the primary health care level, many time-tested standard Ayurvedic formulations are highly effective.

Common Diseases	*Treatment*	*Common Diseases*	*Treatment*
Common Cold	*Laxmivilas rasa* and *Godanti Bhasma*	**Bacillary Dysentery**	*Sanjivani and Shankhodar*
Fever	*Tribhuvankirti rasa*, *Godanti Bhasma* and *Sudarshan Ghanvati*	**Piles**	*Arshakuthar rasa*
		Hepatitis	*Arogyavardhani rasa* Liver Diseases
Hyper Acidity and Duodenal Ulcer	*Sutshekhar rasa*, *Shankh Bhasma*	**Dysfunctional Uterine Bleeding**	*Pushyanug*
Cough	*Sitopaladi, Khadiradivati*	**Urinary Tract Infection**	*Chandraprabha vati*
Gastro-intestinal problems	*Shankhvati*	**Arthritic Condition**	*Yograj guggulu* and *Rasnadi kvath*
Diarrhoea	*Jatiphaladi, Karpura rasa*	**Gout**	*Kaishore guggulu*
		Bronchial Asthma	*Shvasa kuthar rasa*
Diarrhoea and Amoebic Dysentery	*Kutajghanavati*	**Various Eye Diseases**	*Saptamrata lauha* and *Mahatriphalaghrita*

These are a few well-established Ayurvedic recipes frequently used by Ayurvedic physicians throughout India for the disease-conditions mentioned above. Many surgical cases, if treated during the early stage, may be managed better by medicinal treatment. Medicinal plants like *Bilva* (*Aegle marmelos*), *Haritaki* (*Terminalia chebula*), *Nimba* (*Azadirachta indica*), *Shirish* (*Albizzia lebbeck*), *Vasa* (*Adhatoda vasica*), *Ghritkumari* (*Aloe vera*) and *Guduchi* (*Tinospora cordifolia*) are very useful in treating common diseases.

Treatment of Chronic Diseases

The peculiarity of Ayurveda is that compound preparations are more powerful and potentiate the therapeutic efficacy of medicinal herbs. Ayurveda not only treats the disease but, more importantly, takes care of the patient as a whole with its holistic approach. Various Ayurvedic herbal and herbo-mineral preparations are used for the treatment of chronic diseases, degenerative diseases and iatrogenic conditions without any side-effect. The use of *Rasayana* and *Panchakarma* therapy is of immense value for treating such conditions. Many people living in rural areas often suffer from common chronic ailments such as diabetes mellitus, hypertension, ischaemic heart disease and bronchial asthma.

For the management of these conditions, a large number of Ayurvedic drugs, based on established scientific investigations, have shown excellent results. The therapeutic effect of *Vijayasara* (*Pterocarpus marsupium*), *Karavella* (*Momordica charantia*), *Tejpatra* (*Cinnamomum tamala*), *Kiratatikta* (*Swertia chirata*) in **diabetes mellitus**, *Sarpagandha* (*Rauwolfia serpentina*) in **Hypertension**, *Arjuna* (*Terminalia arjuna*) and *Pushkaramula* (Inula racemosa) in **ischaemic heart disease**, *Shirish* (*Albizzia lebbeck*), *Haridra* (*Curcuma longa*) in **bronchial asthma**, *Kalamegh* (*Andrographis paniculata*) and *Bhoomyamalaki* (*Phyllanthus amarus*) in **infective hepatitis**, *Kapikacchu* (*Mucuna pruriens*) in **impotency** and *Varuna* (*Crataeva nurvala*), *Gokshura* (*Tribulus terrestris*) and *Punarnava* (*Boerhaavia diffusa*) in **stone and urinary tract infection** is well-established.

Ayurvedic Pharmaceutics

Traditionally physicians used to manufacture Ayurvedic medicine by themselves or guide the local villagers in collecting the medicinal plants for preventive, promotive and curative purposes. The formulations were used as *churna*, *vati*, *gutika*, *bhasma*, *sindoor* extract, decoction, *asava-arishta*, medicated oil and *ghee*. The pharmaceutical industry has played a revolutionary role in popularizing Ayurveda by providing modern technology for standard and quality Ayurvedic drugs in the national and international market. At present 8800 pharmacies in India are producing these drugs worth Rs. 3000 crore (one crore = $ 200,000) for domestic use and exporting drugs worth Rs. 300 crore. The availability of required medicinal herbs is gradually decreasing. It is necessary to involve the local people by forming **cooperatives for medicinal plants**. Such village-level cooperatives will be highly useful in creating an awareness about the development of medicinal plants and the need for their **conservation** to achieve the objectives of producing and marketing Ayurvedic drugs of quality.

The Government of India, under the Ministry of Health and Family Welfare, has established a separate Department of Indian System of Medicine and Homoeopathy to promote this ancient system of medicine. This department has published two volumes of a Pharma-copoeia containing 158 drugs. The Essential Drugs list for dispensaries and hospitals has also been published. Ayurvedic drugs have been introduced in reproductive and child health programmes. Agro- techniques have been developed for 100 medicinal plants. To promote Good Manufacturing Practices, laboratories have been identified for the standardization and quality control of ayurvedic drugs.

The prime foundation of pharmacodynamics of ayurvedic drugs is based upon the theory of *Pancha-mahabhuta*,

which forms the physico-chemical basis of the body as well as diet and drugs. The pharmaco-therapeutics is based on the theory of *tridosha*, which controls and maintains the biological functions and are the cause of health in a state of equilibrium and of disease in cases of disequilibrium. The composition, metabolism and action of the drug are based on its *Rasa* (taste), *Guna* (properties), *Virya* (potency), *Vipaka* (metabolism), *Prabhava* (specific potency) and *Karma* (action).

Education and Research

College level education in Ayurveda started about 100 years ago with royal petronage. Subsequently, modern knowledge was also introduced in these colleges. At present, the number of Ayurvedic institutions in the Indian Subcontinent is 186 (which includes two graduate-level institutes in Sri Lanka and 12 in Nepal). In addition, the National Institute of Traditional Medicines at Nawinna in Sri Lanka conducts training programmes for doctors, Ayurvedic students, farmers and practitioners of Folklore Medicine. Free Ayurvedic treatment facilities are available in about 21,000 Ayurvedic dispensaries and hospitals. Some 50 universities in the Subcontinent have facilities for Ayurvedic graduate (BAMS) and postgraduate (M.D.-Ayu) education. Postgraduate education in Ayurveda is available in 31 colleges, which include three major postgraduate centres: the Institute of Postgraduate Teaching and Research in Ayurveda at Gujarat Ayurved University, Jamnagar; Banaras Hindu University, Varanasi, and the National Institute of Ayurveda at Jaipur. The Faculty of Ayurveda, Banaras Hindu University, has made significant contributions in the field of research in Ayurveda.

The Government of India has established a National Academy of Ayurveda to promote intensive training in different specialities for graduates and postgraduates of Ayurveda under the guidance of eminent scholars according to the *Guru Shishya Parampara*-tradition. In this region, three *Siddha* colleges are functioning with the facility of postgraduate education in one college, 107 hospitals and 306 dispensaries.

The Government of India, by an Act of Parliament, established the Central Council of Indian Medicine (CCIM) in 1972 for regulating education and registration in Ayurveda, Siddha and Unani medicine. Ayurvedic education and registration is regulated in the neighbouring countries as well. The Government of India also established a research council, the Central Council for Research in Indian Medicine, Homoeopathy and Yoga (CCRIMH) in 1971, which was subsequently developed into four independent councils in 1978.

The Central Council for Research in Ayurveda and Siddha (CCRAS) promotes research in Ayurveda. The CCRAS has 10 central research institutes of Ayurveda, 17 regional research institutes and nine regional research centres/research units, fully devoted to research in Ayurveda. The Bandaranayake Memorial Ayurvedic Research Institute at Nawinna, Sri Lanka,

Ayurveda takes care of the patient as a whole with its holistic approach. Various Ayurvedic herbal and herbo-mineral preparations are used for the treatment of chronic and degenerative diseases without any side-effect.

is also making a significant contribution in the field of research in Ayurveda. The Central Research Institute, the Regional Research Institute and the Literary Research and Documentation Department are also devoted to research in the Siddha system of medicine.

The Gujarat Ayurved University is the only statutory university in the world exclusively devoted to Ayurvedic studies and research. It has adequate facilities for extensive training in Ayurveda for foreign students. The University has nine affiliated Ayurvedic colleges in Gujarat. Outside Gujarat, the Ayurvedic institutions at Coimbatore (Tamil Nadu) and Manipal (Karnataka) have also been granted recognition for postgraduate education in Ayurveda. Similarly, Ayurvedic institutions in Japan and South Australia have also been granted recognition.

The details of the courses are as under:

Bachelor of Ayurveda Medicine and Surgery Degree Course (B.A.M.S.)

This five-and-a-half-year degree course covers comprehensive and intensive practical and theoretical training in all the subjects of Ayurveda along with good exposure to modern basic medical subjects like anatomy and physiology, which makes these B.A.M.S. graduates competent enough to practise Ayurveda.

The subjects under this degree course are taught utilizing the latest knowledge of the basic principles of Ayurveda and history of Ayurveda, *Sharir Rachana* – anatomy, *Sharir Kriya* – physiology, *Dravya Guna* – pharmacology, pharmacognosy and *Materia Medica*, *Rasa Shastra* and *Bhaishajya Kalpana* – science of mineral, herbal and aquatic drugs, pharmacy and pharmaceutics, *Agada Tantra* – medical jurisprudence and toxicology, *Swastha Vritta* – hygiene, preventive, promotive and public health, Yoga and nature cure, *Vikriti Vigyana* – diagnostic methods and pathology, *Charaka Samhita* – classical textbook, *Kayachikitsa* – internal medicine, *Rasayana* and *Vajikarana* – promotion of longevity, rejuvenation and reproductive health, *Manas Roga* – psychiatry, *Panchakarma* – internal purification, massage and physiotherapy, *Kaumarabhritya*, *Prasuti Tantra*, *Striroga* – paediatrics, obstetrics and gynaecology, *Shalya* – surgery, *Shalakya* – ophthalmology, and otorhinolaryngology.

Doctor of Medicine in Ayurveda [M.D.(Ayu)]

This postgraduate course of three years' duration is available in 13 specialities of Ayurveda, i.e., Ayurveda *Siddhanta* and *Darshan* – fundamental principles of Ayurveda, *Samhita* – classical Ayurvedic texts, *Dravyaguna* – pharmacognosy and pharmacology, *Rasa Shastra* – science of mineral, herbal and aquatic drugs, *Bhaishajya Kalpana* – pharmacy and pharmaceutics, *ITSA* – internal medicine, *Vikritivigyana* and *Roga Nidan* – diagnostic methods and pathology, *Manas Roga* and *Manovigyana* – psychiatry and psychology, *Panchakarma* – internal purification and massage therapy, *Kaumarabhritya* – paediatrics, *Prasuti Tantra* and *Striroga* – obstetrics and gynaecology, *Shalya* – Surgery, *Shalakya* – ophthalmology and otorhino-laryngology.

Doctor of Philosophy (Ph.D.)

The facility for the award of Ph.D. degree is available in 13 specialities of Ayurveda. The M.D. (Ayu) or its equivalent degree in the concerned subject/speciality is essential for registration in Ph.D. The minimum duration for this course is two years.

Diploma Course in Ayurveda

The objective of this one-year course (divided into three semesters of four months each) is to provide intensive theoretical and practical training in Ayurveda, covering most of the five-year degree course in Ayurveda. This course is designed for the graduates of modern medicine or any other traditional medicine to prepare them to become efficient Ayurvedic practitioners.

The details of the subjects are, basic principles of Ayurveda, including hygiene and public health, detailed study of medicinal plants, their properties and uses (*Dravyaguna*), Ayurvedic mineral, herbal and aquatic drugs (*Rasa Shastra*), herbal pharmaceutical preparations (*Bhaishajya Kalpana*), intensive training in traditional and classical preparation of Ayurvedic medicines; Ayurvedic diagnostic procedures, pathology and pathogenesis (*Roga Nidana*), *Kayachikitsa* – internal medicine, *Rasayana* – rejuvenation therapy in the promotion and preservation of health and the treatment of various chronic illnesses, *Vajikarana* – promotion of reproductive health, *Manas Roga* – psychiatry, *Panchakarma*, its role in the preservation and promotion of health and treatment of chronic degenerative diseases, Yoga and nature cure; *Kaumarabhritya*, *Prasuti* and *Striroga* – paediatrics, obstetrics and gynaecology, *Shalya* – surgery, including *Ksharasutra* preparation and management of ano-rectal diseases, *Shalakya* – ophthalmology and otorhino-laryngology, *Pathyapathya* – Ayurvedic dietetic preparations and management.

Introductory Course in Ayurveda

This three-month course is designed to impart basic knowledge of Ayurveda to scholars having a medical background or graduation in bio-sciences or in fields allied to medicine. The details of the subjects under this course are, basic principles of Ayurveda, including *Swasthavritta* (hygiene and positive health), the fundamentals of herbo-mineral *Materia Medica* and pharmaceutics, the fundamentals of diagnosis and pathogenesis of diseases (*Nidana*), the fundamentals of treatment (*Chikitsa*) including *Panchakarma* (internal purification and massage therapies), *Rasayana* (geriatrics and rejuvenation therapy), fundamentals of surgery (*Shalya*) including *Ksharasootra* (alkaline thread cauterization), *Agnikarma* (cauterization), *Jalaukavacharana* (leech application), etc., management of common clinical conditions through herbal preparation.

Bachelor of Pharmacy in Ayurveda [B.Pharm (Ayu)]

The main aim of this four-year Bachelor Degree Course is to produce high quality technologists capable of producing quality Ayurvedic drugs by employing traditional, modern or upgraded or modified traditional techniques as well as controlling and maintaining their quality. The course has been planned in such a manner that the personnel completing it should be capable of meeting different requirements of both the manufacturing and consumer sectors for Ayurvedic drugs and other traditional systems of medicine.

Master of Pharmacy in Ayurveda [M. Pharm (Ayu)]

This two-year Master's Degree course is designed to provide in-depth knowledge of Ayurvedic drugs, their method of manufacturing and also their standardization and quality control aspects with specialization in two subjects: Pharmaceutics of Ayurvedic Drugs and Quality Control and Standardization of Ayurvedic Drugs.

Diploma in Pharmacy in Ayurveda [D.Pharm (Ayu)]

This course of two years' duration is intended to train personnel, mainly for meeting the requirements of the consumer sector of Ayurvedic drugs and other traditional systems of medicine. They should be acquainted with the manufacture of Ayurvedic drugs and should be qualified and competent to dispense Ayurvedic drugs in hospitals, dispensaries, drug stores and related activities. They should also be trained to maintain the stores of Ayurvedic drugs (both raw materials and finished products) properly.

Master of Science (M.Sc.) in Medicinal Plants

The objective of this two-year course is to adopt a multi-disciplinary approach for comprehensive teaching of all aspects related to medicinal plants, to generate skilled manpower to meet the present and future requirements of human resources in the field of medicinal plant resources development, and to provide distinctive education and training in all aspects of medicinal plants. This course is designed for graduates in botany, pharmacy, agriculture or Ayurveda.

References

1. *Charaka Samhita – Sutrasthana*. 30th Chapter. Sloka 26.
2. *Charaka Samhita – Sharirasthana*. 5th Chapter. Sloka 3.
3. *Charaka Samhita – Sutrasthana*. 1st Chapter. Sloka 4–5.
4. *Sushruta Samhita – Sutrasthana*. 1st Chapter. Sloka 3.
5. *Sharangadhara Samhita* – Purva Khanda. 3rd Chapter. Sloka 1.
6. *Charaka Samhita – Sharirasthana*. 1st Chapter. Sloka 16.
   Sushruta Samhita – Sharirasthana. 1st Chapter. Sloka 4.
7. *Sushruta Samihta – Sutrasthana*. 35th Chapter. Sloka 19.
   Ahstanga Hridaya – Sutrasthana. 12th Chapter. Sloka 4.
8. *Charaka Samhita – Chikitsasthana*. 3rd Chapter. Sloka 68.
9. *Ashtanga Hridaya – Sutrasthana*. 11th Chapter. Sloka 34.
10. *Ashtanga Hridaya – Sutrasthana*. 13th Chapter. Sloka 25.
11. *Sushruta Samhita – Sutrasthana*. 24th Chapter. Sloka 10.
12. *Sushruta Samhita – Sutrasthana*. 21st Chapter. Sloka 33.
13. *Charaka Samhita – Sutrasthana*. 30th Chapter. Sloka 28.
    Sushruta Samhita – Sutrasthana. 1st Chapter. Sloka 7.
14. *Charaka Samhita – Vimanasthana*. 8th Chapter. Sloka 83–84.
    Ashtanga Hridaya – Sutrasthana. 1st Chapter. Sloka 22.
15. *Charaka Samhita – Vimanasthana*. 8th Chapter. Sloka 84.
16. *Sushruta Samhita – Sutrasthana*. 10th Chapter. Sloka 4.
17. *Yoga Ratnakara*. Chowkhamba Samskrit Samsthana. 5th Edition. 1993. Page 5. Sloka 1. Chapter 1.
18. *Charaka Samhita – Sutrasthana*. 11th Chapter. Sloka 55.
19. *Charaka Samhita – Sutrasthana*. 1st Chapter. Sloka 58.
20. *Charaka Samhita – Chikitsasthana*. 1st Chapter. 1st Pada. Sloka 5.
21. *Sharangadhara Samhita – Uttara Khanda*. 8th Chapter. Sloka 1.
22. *Ashtanga Hridaya – Sutrasthana*. 22nd Chapter. Sloka 23.
23. *Ashtanga Hridaya – Sutrasthana*. 22nd Chapter. Sloka 29.
24. *Sushruta Samhita – Chikitsasthana*. 17th Chapter. Sloka 29.

An overview of traditional Chinese medicine

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Introduction

During the past decade, traditional systems of medicine have received growing attention around the world. According to some estimates, a large number of people in many developing countries rely heavily on traditional practices to meet their primary health care needs.[1] In China, although Western medicine is available, the majority of the population still rely on *zhongyi* (Chinese medicine or traditional Chinese medicine, or TCM) to solve their health problems. Western medicine and Chinese medicine are practised side by side at every level of the national health care system.[2]

With a history of over 2000 years, the TCM practice offers natural, safe and effective therapies and cures for many diseases with much less side- effects. TCM takes a unique theoretical and practical approach to health. In treatment, it includes the use of various intervention modalities, such as Chinese medication, acupuncture and moxibustion, *Tuina* (massotherapy), dietary, and *Qigong*.[2, 3] These modalities may be used separately or in combination to effect a treatment. TCM differs in fundamental ways from Western medicine. This paper is thus prompted by a desire to present an overview of the Chinese system of medicine.

Fundamentals of TCM

As an important part of the Chinese culture, TCM has evolved into a unique and complete medical system during the long history of China. The *Huang Di Nei Jing* (*The Yellow Emperor's Classic of Medicine* or *Canon of Medicine*) was the first monumental classic which systematically documented the etiology, physiology, diagnosis, treatment and prevention of disease. This work was probably compiled over several centuries by various authors and consists of two parts: *Su Wen* (Plain Questions) and *Ling Shu* (*Miraculous Pivot*, also known as *Canon of Acupuncture*). It takes the form of a dialogue between the legendary Yellow Emperor and his minister, Qi Bo, on the topic of medicine. Its appearance between 300 BC and 100 BC marked the establishment of TCM.[4] One striking difference between TCM and Western medicine is in the way in which the human body is observed, and hence the difference in the concept of health.

Chinese medicine holds a holistic view of the human body. It stresses the overall,

Every modality of intervention is aimed at regulating and balancing *yin* and *yang*. As stated in *The Yellow Emperor's Classic of Medicine*, *yin* is even and well while *yang* is firm, hence a relative balance is maintained and health is guaranteed

delicate harmony and coordination among different parts of the human body. Therefore, it lays great emphasis on the careful readjustment and maintenance of this natural balance in the body.[5] It uses *zang fu* (visceral organs) and the meridians as its theoretical basis and *yin yang* and "five elements" as its theoretical tools. According to TCM, *qi*, 'blood' and 'body fluid' are the fundamental substances which make up the human body and maintain its normal physiological functioning.[6] Health implies harmonious coordination among the various parts of the body and their adaptation to the physical environment.

The fundamental mechanism of disease is the breakdown of the relative equilibrium within the organism or between the organism and its environment.[7] In TCM terms, this is known as an imbalance between *yin* and *yang*.[8] In the diagnosis and treatment of diseases, the basic characteristic of TCM, which sets itself apart from modern Western medicine, is that of 'syndromes differentiation[(9)] or translated as diagnosis and treatment based on overall analysis of symptoms and signs'. Holism views not only the human body as an organic whole but also the unity of the human body and nature. On the one hand, nature constantly influences the human body and, on the other, the body adapts to the variations in the natural environment.

The concept of *yin* and *yang*

The concept of *yin* and *yang* is fundamental to the understanding of Chinese medicine. The earliest reference of *yin* and *yang* is probably the one in the book "*Yi Jing*" (*Book of Change,* 700 BC). Originally, *yin* and *yang* were two topographic terms used to designate the shady and the sunny sides of a hill, or the north side and south side of a mountain. The sunny side of mountain, in the sunlight, represents warm, bright, and other active characteristics; and the shady side of the mountain represents cold, dark, and other passive properties. By extension, the theory of *yin* and *yang* holds that the universe consists of two opposing but mutually dependent forces that complement and supplement each other, resonate harmoniously, and maintain a constant balance. As man is considered as a microcosm in the universe, to achieve a healthy state a balance between the forces of *yin* and *yang* in the human body should be maintained.

With respect to medicine, it could be said that the whole of the Chinese system of medicine, its physiology, pathology, diagnosis, and treatment, can all be reduced to the basic and fundamental theory of *yin* and *yang*. Every physiological process and every pathological change can be analysed in the light of the *yin yang* theory. Ultimately, every modality of intervention is aimed at regulating *yin* and *yang*, to balance *yin* and *yang*. As stated in *The Yellow Emperor's Classic of Medicine*, *yin* is even and well while *yang* is firm, hence a relative balance between *yin* and *yang* is maintained and health is guaranteed.

The theory of Five Elements

Together with the theory of *yin yang*, the theory of Five Elements constitutes the basis of Chinese medicine. Originally, the Five Elements referred to the five kinds of materials, which are wood, fire, earth, metal and water with their characteristic properties—an ancient philosophical concept to explain the composition and phenomena of the physical universe. The primitive concept of Five Elements was further developed into a more complex theory and was used to summarize the properties of things in nature into five categories. Each matter in the universe has a dominant character which bears resemblance to the properties of one of five elements. The theory of Five Elements is thus used to group the things through their different properties and to interpret the relationships among these different things through a generating sequence and a counteracting sequence among the Five Elements. The generating sequence is in the following sequence: wood, fire, earth, metal and water, in which each Element is conceived to promote or produce the subsequent one, namely, wood produces fire, fire produces earth, etc. The counteracting sequence is in the following sequence: water, fire, metal, wood and earth, in which each Element is considered checking the subsequent one, namely, water checks fire, fire checks metal, etc. It should be stressed that this is a symbolic recognition, an analogy. According to the *Yellow Emperor's Classic of Medicine,* "metal, wood, water, fire and earth encompass all natural phenomena. This symbolism also applies to man". In other words, all parts of the human body have affinities in nature with particular elements.

The Five Elements view is important from the perspective of demonstrating the way in which Chinese medicine has built on the view of balance, holism, and harmony in the human body. This theory initially likened the organs in the human body to the Five Elements. The organ:element analogies are lung:metal; liver:wood; kidney:water; heart:fire; and spleen:earth (Tables 1a & 1b). This analogy broadens out to encompass all components of the body, since each and every part of the anatomy is controlled by a particular vital organ. For example, in TCM, liver stores blood, ensures the smooth flow of *qi*, controls the sinews; lung governs *qi* and respiration, regulates water passages and controls skin; spleen transports and transforms water and food essence, keeping the blood flowing within the vessels, controls muscles and the four limbs, etc.

The Five Elements theory is extensively applied in almost every aspect of Chinese medicine. It is used in physiology to explain the functions of different organs, tissues and their connections. In pathology, it is applied to demonstrate the mutual pathological influence and transmission among the viscera organs. It is used in diagnosis to synthetize the data obtained through the four methods of diagnosis (given in detail in the following chapter) and deduce the evolution of disease. In treatment, the theory of Five Elements is applied mainly under two headings: to prevent the transmission of disease and to guide the therapeutic method.

When considering a certain disharmony organ, one should keep in mind the various relationships between this organ and the others (the generating sequence and counteracting sequence). This disharmony may be affected by another organ, and meanwhile it may be affecting another organ.

To prevent the transmission of disease: This was demonstrated by the "Classic on

Table 1a Some of the main characteristics of the five elements

Elements	Human Body				
	Five Zang	Five Fu	Five Sense Organs	Five Tissues	Five Emotions
Wood	Liver	Gall Bladder	Eyes	Tendon	Anger
Fire	Heart	Small Intestine	Tongue	Vessel	Joy
Earth	Spleen	Stomach	Mouth	Muscle	Anxiety
Metal	Lung	Large Intestine	Nose	Skin	Sorrow
Water	Kidney	Bladder	Ears	Bone	Terror

Table 1b Some of the main characteristics of the five elements

Elements	Nature				
	Five Directions	Five Seasons	Five Climates	Five Tastes	Five Stages of Development
Wood	East	Spring	Wind	Sours	Birth
Fire	South	Summer	Heat	Bitter	Growth
Earth	Centre	Late Summer	Dampness	Sweet	Transformation
Metal	West	Autumn	Dryness	Pungent	Harvest
Water	North	Winter	Cold	Salty	Storage

Medical Problems" in chapter 77: "If Liver is diseased, it can invade the Spleen, the Spleen must therefore be tonified before it is affected"

To guide the therapeutic method: The "Classic on Medical Problems" in chapter 69[8] presents a classic interpretation: "If deficiency is found in the son organ, one would tonify the mother organ; if excess is found in the mother organ, one would sedate the son organ".

The human body

In Chinese medicine, much stress is laid on the observation of the outward physiological and pathological manifes-tations of the human body. It is believed that all internal organs and their activities will have their corresponding external manifestations. For this reason, TCM* does not emphasize the anatomy of the human body. Although TCM uses similar names for organs as those used in Western medicine, and many of these organs perform similar functions as recognized in Western medicine, they in fact do not reflect completely the same concepts. For example, in Chinese medicine, each visceral organ is a comprehensive system and performs a set of physiological functions which often cover an area related to but much larger than those in its anatomical sense.

The visceral organs are divided into three categories according to their morphological features and physiological functions.

* Some terms in TCM are the same as those in Western medicine, but they may mean quite different things. In order to avoid confusing them with the notions of Western medicine, these terms are italicised to remind readers. Some terms applied directly from TCM are also italicised to remind readers.

The five *zang* organs: these are substantial in morphology, and function to store the "essence of life". They include "liver, heart, spleen, lung, kidney".

The six *fu* organs: these are hollow in morphology, and their function is to transport and transform foodstuff. They consist of the "small intestine, large intestine, gall bladder, stomach, bladder and *sanjiao* (triple energizer: a collective term for the three portions of the body cavity)"

"Extraordinary organs": these are hollow in morphology, and their function is to store the "essence of life". They are the "brain, marrow, bone, vessels, gall bladder and uterus".

Each of the *zang* organs is linked to a *fu* organ. The function of one organ in TCM may include the functional activities of several anatomically defined organs in Western medicine. For example, the "kidney" in Chinese medicine is not just the organ that excretes urine; it stores the "essence of life", controls reproduction, growth and development and is closely related to the "brain, marrow and bones". Thus, in TCM the concept of "kidney" includes most of the functions of the urinary system, some functions of the endocrine system, and something similar to those of the pituitary-adenocortical-gonadal axis.[10]

Material basis of the vital activities of the human body

***Qi*:** The major premise of TCM is that all living things, including human beings, have a life force within them. This essential vital biological energy, which is invisible, is known in Chinese philosophy as *qi* (pronounced: chee; often also written as 'chi'). *Qi* circulates regularly along the meridians in the body. Disruption in this flow is believed to be responsible for diseases. When *qi* gathers, the physical body is formed; when *qi* dissipates, the body "dies".[11] *Qi* has variously been translated as "energy", "vital energy", or "life force"; however, it is almost impossible to capture the exact concept fully in one English word or phrase; therefore we have decided to use its original Chinese word: *Qi*.

The sources of *qi* can be divided into the inborn and the acquired. The inborn *qi* is the innate vital essence stored in the "kidney" which was inherited from the parents at the moment of conception, and augmented postnatally which is a combination of the essence absorbed by the "spleen" from food and fresh air which is inhaled by the "lung". The two sources of *qi* are gathered in the chest and form *zhengqi* (genuine *qi*), which circulates through the body's organs and tissues. Since *qi* is invisible, it can only be perceived through its actions. For instance, the deficiency of the "kidney *qi*" means the deficiency of energy required for the functioning of the "kidney" (namely, the hypofunction of the "kidney"). Generally speaking, *qi* has five functions: it i) Serves as the energy source of body activities, ii) Warms and nourishes the body, iii) Defends the body surface against invasion by any pathogenic factor, iv)Is the vehicle of transportation inside the body, and v) Maintains the normal positions of body organs.[12, 13] **Blood:** The concept of blood in TCM is not the same as it is in Western medicine. In TCM, the blood is a vital nutrient substance in the body. It is formed from the combination of essence of food, which is derived via digestion and absorption by the spleen and the stomach, and fluids containing nutrients. The kidney also contributes to the formation of blood as it is the kidney-stored essence that produces bone marrow. After being formed, blood circulates in the vessels

Map of lung meridian

throughout the body, promoted by the heart with the help of the lung, controlled by the spleen which keeps blood flowing within the vessels, and regulated by the liver as a reserve.

Jing : *Jing*, which is defined as the vital essence of the body, consists of two parts: congenital essence and acquired essence. Congenital essence, which is inherited from the parents at conception, is responsible for reproduction, thus also known as "reproductive essence". It is stored in the kidney and serves as the origin of life. Acquired essence is derived from the essential substance of food and is distributed to various organs and tissues. It serves as the material basis for life activities. The congenital and the acquired essence rely on, and promote each other. Congenital essence can be transformed into acquired essence and acquired essence replenishes congenital essence. Sexual over-indulgence is taken as an important cause of disease because it consumes the reproductive essence stored in the kidney, thus impairing the other organs.

Jing Ye (Body fluids): *Jing Ye* is a general term for all normal liquids in the body. It is derived from the essence of food and drink, which is digested and absorbed by the spleen and the stomach. The difference in nature, form and location, and body fluid can be divided into two categories: *Jing* and *Ye*. Clear and thin fluids are referred to as *jing*, while thick and heavy fluids are known as *ye*. Body fluid moistens and nourishes various parts of the body. The formation, distribution and excretion of body fluid is a complicated process resulting from the coodinated activity of many *Zang Fu* organs, especially the lung, spleen and kidney.

Meridians–Pathways of the human body

Both Western and Chinese medicine agree that the organs are physically connected. TCM believes that there exists in the human body a network of pathways called meridian (or channel) system, through which *qi* and "blood" circulate, and by which internal organs are connected to and coordinated with superficial organs and tissues, thus creating an integral whole. The meridian system consists of 12 pairs of regular meridians (six pairs of *yin* and six pairs of *yang* meridians), eight extra meridians, 12 collateral, and their connective parts. The 12 regular meridians consist of the main parts of the meridian systems and are symmetrically distributed on both sides of the body, and run respectively through the medial or lateral side of each limb. Each regular meridian

pertains to a corresponding visceral organ and is named accordingly. To facilitate the learning and use of these meridians, the names of the meridians have been translated into English. WHO has further given standardized alphabetic codes to them.[14]

Acupuncture points are found along the meridians under the skin. Each acupuncture point is anatomically located and has its own specific therapeutic effects. Three hundred and sixty-one acupuncture points have been identified along the 14 meridians. WHO has also recommended the standardized nomenclature of these points.[15] The meridian system is used in TCM to explain the physiological functions and pathological changes in the human body as well as to guide the diagnosis and treatment of diseases. Acupuncture and Moxibustion, *Tuina*, and Q*igong* are therapeutic techniques based mainly on the meridian theory.

Causes of disease

According to TCM, health implies that the body system is in a state of dynamic equilibrium, not only between the various parts of the body but also between the body and environmental conditions. Disease results when the equilibrium is destroyed (i.e., there is imbalance of *yin* and *yang*) by certain factors. The factors which cause disturbance in the harmony and balance of the body are called pathogenic factors. In TCM, these are generally classified as exogenous and endogenous pathogenic factors. Exogenous pathogenic factors encompass atmospheric changes ("wind", "cold", "summer heat", "dampness", "dryness" and "fire" known as Six Excessive Atmospheric Influences). These are the six excessive climatic conditions to which the individual concerned has lost his ability to adapt.

Endogenous pathogenic factors include emotional factors (joy, anger, worry, anxiety, sorrow, terror and fright, known as the Seven Emotions).

There are also several other factors which do not belong to either of these two categories, such as pestilential pathogens, trauma, improper diet, exhaustion and over-indulgence in sex.

In essence, whether disease will occur depends on the outcome of the struggle between the vital energy and pathogenic factors. As stated in *Su Wen* (*The Yellow Emperor's Classic of Medicine*): "Pathogens cannot invade the body when vital energy is sufficient"; and, "only when the vital energy is in deficiency, can pathogens invade the body".[16]

TCM pays utmost attention to the maintenance of the vital energy. Therefore, TCM gives a prominent place to prevention. It can be said that the traditional Chinese medicine is essentially a prevention-oriented medicine. This preventive philosophy of TCM is expressed at two levels: prevention against the occurrence of disease, and prevention against its further development if disease has already occurred.

Principle of diagnosis

Diagnosis is an important component of the theoretical system of TCM. It includes two parts: diagnosis of disease and

TCM is essentially a prevention-oriented medicine. This preventive philosophy is expressed as prevention against the occurrence of disease, and prevention against its further development if disease has already occurred.

differentiation of syndromes. Differentiation of syndromes is often more important.

TCM regards the human body as an organic entity. The component parts of the body are physically interconnected, so a local pathological change may influence the whole body. Similarly, disorders of internal organs may be reflected on the surface of the body. There are four major diagnostic methods used in TCM: inspection, auscultation and olfaction, interrogation and palpation.

Inspection is a method used to examine the mental state, complexion, physical condition, behaviour, secretion and excretion, as well as observation of the tongue.

Auscultation and olfaction detects the clinical status of a patient by listening to his voice, his breathing, and his coughing, and by smelling his body odours.

Interrogation is a way to interview the patient, find out his or her family history to determine the patient's health state, major complaints, and progress of illness. Apart from this, other specific conditions must be inquired into while interrogating. This was called "Ten Questions" recommended by Dr Zhang Jie-bin (1563–1640) and includes: chills and fever; perspiration; headache and general pains; urination and defecation; appetite; feeling in the chest and abdomen; hearing; thirst; pulse taking and observation; auscultation and smelling; characteristic of menstruation for women patients.

Palpation is the most important diagnostic method unique to TCM. It include two parts: pulse feeling and body palpation. Pulse feeling emphasizes the quality of the pulse at the radial arteries of both wrists. It is recognized that there are 28 different pulse qualities which can be felt and each with its own subtle nuance of interpretation. It is used to examine the strength or weakness of *qi* and "blood" and predict the progress of the illness. Body palpation refers to systematic feeling of the surface of the body, the meridians, body temperature, and body moisture. Body palpation is applied especially when pain is concerned. The final diagnosis is based on the information gathered from all the above-mentioned diagnostic methods. These methods are not used in isolation, but as parts of a system.

Differentiation of syndromes is a process in which the characteristics of disease and syndrome are decided through interpretation and summing-up of the phenomena collected from the four basic diagnostic methods. "Syndromes" in TCM is not a simple summation of symptoms and sign; it reflects rather the pathogenesis and pathophysiology of a given case, and provides a basis for the prevention and treatment of disease.

There are a number of methods in TCM for syndromes diagnosis (differentiation of syndromes). It includes the differentiation of pathological conditions in accordance with the eight principal differentiation syndromes according to pathological changes of *zang fu* organs, differentiation syndromes according to the condition of body *qi*, blood and fluid, differentiation syndromes in accordance with the theory of meridians, differentiation of epidemic febrile disease in accordance with the theory of *wei*, *qi*, *ying* and *xiue,* and the differentiation syndromes in accordance with the theory of triple energizer. Of the several ways of syndrome differentiation, differentiation of pathological conditions in accordance with the eight principal differentiation syndromes according to pathological changes of *zang fu* organs are the most useful.

The eight principal syndromes serve as a guideline, namely, *yin* and *yang*, exterior

and interior, cold and heat, deficiency and excessiveness. Differentiation of pathological conditions in accordance with the eight principal syndromes is the foundation for all the other methods of syndrome differentiation. It signifies the location and nature of disease, the confrontation between the pathogenic factor and body resistance, as well as establishes the principle of treatment.

Differentiation syndromes according to the pathological changes of *zang fu* organs are based on the symptoms and signs obtained by four diagnostic methods when *qi* and the blood of the internal organs are out of balance. This method of syndrome differentiation is applied to identify the particular disharmony of a specific internal organ.

Intervention in TCM

Chinese medication

Chinese medication is the primary component of TCM and is used commonly in China. Chinese medication involves the use of herbal medicine, animal parts and minerals. The term "herb" used in Chinese medicine often goes beyond the traditional concept of "plant", since the 6000– 8000 substances used include, in addition to numerous plants, substance from animals and minerals.

According to Chinese history, Chinese medicine arose from mythical medicine to become a system of herbal medicine. *Shen Nong Ben Cao Jing* (*Divine Husbandman's Classic of Materia Medica*; or *Shen Nong's Herbal*) is the first work (25–220 AD) which prescribed the therapeutic effect of herbs and other materials. It contains 365 entries. These are botanical (252 entries), zoological (67 entries), and mineral (46 entries) substances. Beginning with *Shen Nong Ben Cao Jing*, the literature of Chinese *materia medica* developed continuously by the addition of new herbs, together with a re-evaluation and addition of new uses for existing herbs. Among these, two pieces of work need to be noted: *Xin Xiu Ben Cao* (Newly Revised *Materia Medica*, 659 AD) was considered to be the first official pharmacopoeia in China, compiled and issued by the Government. *Ben Cao Gang Mu* (*Compendium of Materia Medica*, 1596) is considered as a world-renowned classic, written by Li Shi-zhen (1518–1593 AD).

The concept of Chinese medicine differs from that of the synthesized drugs in the ways their properties are determined. Chinese medicines are determined mainly by the outcomes of their clinically observed interaction within the human body.

The terminology used in describing the pharmacology of Chinese medicine includes: property; taste or flavour; action of ascending, descending, floating and sinking; attributive of meridians, and toxicity.

Properties or four properties of herbs: Based on their therapeutic effects, there are four ways of describing property: cold, hot, warm, cool. For example, herbs effective for the treatment of heat syndromes are endowed with cold or cool properties, while those effective for cold syndromes are herbs with warm or hot properties.

Taste: Sour, bitter, sweet, pungent, and salty taste of herbs. They are the expression of the feature of the herb's actions; thus the taste does not necessarily mean the real taste of the herb.

Action of ascending, descending, floating and sinking: Direction of a herb's action. The ascending and floating herbs have an upward and outward effect, while descending and sinking herbs have a downward and inward effect. The action of a herb can be changed by processing or by combined use with other herbs.

Attributive of meridians: Classification of herbs according to the meridians on which their therapeutic action is manifested. In addition, attributive of meridians also refers to some herbs capable of guiding or leading other herbs included in the prescription to the targeted meridians or organs. For example, *Radix bupleuri* (*Chai Hu*) can relieve the pain in the hypochondriac region, which is believed in Chinese medicine to be the result of stagnation of live *qi*. As the liver meridian crosses through the hypochondriac region, it can be deduced that this herb acts on the liver meridian. A herb can act on more than one meridian.

Toxicity: Refers to the harmful effects produced by herbs on the human body. Toxic herbs are usually marked by "highly toxic", "moderatly toxic" or "slightly toxic" to indicate the different degrees of toxicity.

The prescription in Chinese medicine must follow strict rules.[11] A typical prescription is composed of principal herbs, associate herbs, adjuvant herbs and messenger herbs. The principal ingredient is a substance which provides the main therapeutic thrust; associate herb is a substance which enhances or assists the therapeutic action of the first; the adjuvant one treats the accompanying symptoms, and moderately diminishes the harshness or toxicity of the primary ones; the messenger herbs guide the medicine to the proper organs, or exert a harmonizing effect. These herbs are often described in Chinese pharmacology as emperors, ministers, assistants and envoys, respectively.

The most common methods of applying herbal therapy are decoction (the herb is boiled with water) and honey-bound pills. Decoction is generally regarded as fast and strong in action, and is used for acute cases; honey-bound pills are slower and milder in action but have sustained effects, and are therefore used for chronic cases. However, more convenient formulations in such forms as tablets and capsules are also available.

Acupuncture

Acupuncture is defined as "puncturing with a sharp instrument",[12] but the original term in Chinese includes both "needling" and "moxibustion" (burning herbs, usually mugwort, to stimulate acupuncture points). It is an important component of TCM for the prevention and treatment of diseases. The theoretical basis of acupuncture is the premise that there are patterns of *qi* that flow through the pathways-meridians of the body, and any potential disruptions of this *qi* flow are believed to be responsible for diseases. Acupuncture treatment can correct imbalances in the flow of *qi* by inserting a needle at identified acupuncture points. Other stimulating methods can also be applied at the acupuncture points to regulate the body's *qi*, and help restore balance and harmony. The *deqi* (getting the *qi* or needling sensation) is a crucial factor in achieving acupuncture effects. It involves the feeling of "soreness, numbness, expansion, heaviness" by the patient; at the same time, the operator should feel heaviness and tightness around the needle. As stated in *The Yellow Emperor's Classic of Medicine*: "the acupuncture effects can be achieved only when the *deqi* is achieved".[(4)] There exist many types of stimulating techniques which often produce different results. However, this crucial issue has often been ignored in clinical research on acupuncture.[13] Moxibustion is used to treat and prevent diseases by applying ignited moxa at acupuncture points or certain parts of the human body. The material used in moxibustion is mainly *Artemisia Vulgaris*

(mugwort), a kind of herb in Chinese called *Ai* (moxa). Generally speaking, moxibustion is applied in cold syndrome, deficient conditions and chronic diseases. Moxibustion may be used in combination with acupuncture or separately to effect a treatment.

Qigong

The term *qigong* is composed of two Chinese characters, *qi* and *gong*, where *qi* can be translated roughly into English as "vital energy", and *gong* as "method" or "performance". *Qigong* is a system of exercise performed by taking a proper posture, adjusting breathing and concentrating the mind and uniting vital essence and energy and mentality as a whole for physical training, health preservation, prevention and treatment of diseases.[14] Since *qi* plays an important role in the vital processes of the human body, it is natural that regulation of the flow of *qi* can be used as a method to preserve health and prevent diseases. *Qigong* is different from physical exercises. The latter is aimed at building up health or at restoring the body's physical functioning by enhancing strength, whereas the former is focused on the mobilization of functional potentialities through regulating the mind and breathing. In other words, physical exercise is purely somatic, whereas *qigong* therapy is generally psychosomatic. Another difference between physical exercise and *qigong* is that physical exercise expands energy by tensing up the muscle and accelerating the heart beat and respiration, while *qigong* works to relax, calm and regulate breathing so as to accumulate vital energy in the body.

Tuina

The term *Tuina* is composed of two Chinese characters, *Tui* and *Na*. *Tui* can be translated as pressing and dragging, and *Na* as grasping. It belongs to external therapy and has evolved over thousands of years. As a component of TCM intervention, *tuina* is based on a solid theoretical background, and includes basic theories, diagnostic methods and syndrome differentiation of TCM, particularly the theory of meridians. In addition, *tuina* is also involved in a series of different kinds of specific manipulation techniques.

Tuina has its own specific benefits and advantages in a wide range of applications. *Tuina* is used in both prevention and treatment of diseases. It may be used in the treatment of internal and external conditions, traumatic injury, and musculoskeletal, gynaecological, obstetric and paediatric diseases.

Stringent and comprehensive practitioner training is important. When performing *tuina*, the physician must first concentrate his mind, regulate his breathing, and actuate the *qi* and power of his entire body towards his hands, elbow or other part of body with the requirement of treatment, then apply manipulation on certain points or areas of the patient's body to stimulate the flow of *qi* and blood in order to normalize the function of *zang fu* and balance *yin* and *yang*.

Proper use of TCM

In TCM, the conception of the organism as a whole and diagnosis and treatment based on overall analysis of symptoms and signs are two key elements. Diagnosis, prevention and treatment of illness in TCM rely on a holistic approach towards the sick individual, and disturbances are treated at the physical, emotional, mental, spiritual and environmental levels simultaneously.

Safety issues are of paramount concern. Since Chinese medicine is

"natural" and has stood the test of history, it is often automatically perceived as being harmless. It is true that Chinese medications in general are less toxic and safer as compared to synthetic drugs or other forms of therapy, but they are by no means free from adverse effects.

The question of the toxic potentials of herbs has long been recognized in Chinese pharmacopoeia, and relevant theories have been developed to avoid harmful uses or combinations of potentially toxic herbs, such as the theories of "Eighteen Incompatibilities", "Nineteen Antagonism" and "Contraindication during pregnancy", "*Pao Zhi*" (herbal process). These theories continue to guide the Chinese pharmacopoeia to this day.

Quality assurance procedures must be strictly enforced in order to standardize herbal medicine. Chemical tests and assay procedures must be used to supplement the traditional standards of the Chinese pharmacopoeia.

Concerns have also been expressed regarding the safety of acupuncture. The risks associated with acupuncture have been shown to be very small compared to orthodox interventions.[15] In November 1997, an Acupuncture Consensus Statement made by the National Institute of Health in the United States mentioned: "One of the advantages of acupuncture is that the incidence of adverse effects is substantially lower than that of many drugs or other accepted procedures for the same conditions.[16]" In general, side- effects from acupuncture procedure itself have been minimal in the hands of a well-trained practitioner.[16] Reports show that one of the more common problems of acupuncture is forgotten needles.[17] Life-threatening adverse reactions are possible with acupuncture treatment;[18, 19, 20] however, these are usually caused by practitioners who have not received any or adequate training. Qualification in medical practice is important. There should be no exception in the case of Chinese medicine.

Prospects for TCM

TCM is, by definition, traditional, but this in no way prevents it from evolving. Great progress has been made since the past decade in efforts to understand the mechanisms of TCM, especially the physiological effects of acupuncture. In the meantime, efforts to combine TCM with biomedicine in China have also accumulated a great amount of experience and data. More concerted efforts are needed relating to theoretical studies which may elucidate the fundamentals of TCM through acquired knowledge in Western medicine. Another challenge lies in how to clinically combine TCM and Western medicine more effectively which may eventually contribute to the organic integration of these two schools of medicine.

One frequent criticism regarding researches in TCM is the quality of such research. Improving the methodology and devising an approach for the specific use of researches on TCM may be a worthwhile task.

References

1. WHO monographs on selected medicinal plants (Volume 1). 1–4, 1999. (1) World Health Organization. Geneva.
2. Hesketh T., Zhu WX. *Health in China*. Traditional Chinese medicine: one country, two systems. *BMJ* 1997;315:115–17.
3. Diehl D.L. Acupuncture for gastrointestinal and hepatobiliary disorders. J.Altern. *Complement Med.* 1999;5:27–45.
4. Maoshing Ni. *The Yellow emperor's classic of medicine*. A new translation of Neijing Suwen with Commentary. 1995. Boston Massachusetts, Shambhala.
5. CHEN G.T. et al. Unbelievable cures and medicine from China. 1997; Beijing. China. New World Press.
6. Xie Z.F. Introduction to basic medical theories In: *Best of traditional Chinese medicine*. 16. 1995; Beijing. China, New World Press.
7. Lu Y.B. and Liu C.C. Concepts and theories of traditional Chinese medicine In: *Advanced TCM Series 101*. 1997; Beijing. China, Science Press.
8. Qin Y.R. Classic on Medical Problems. 1978; Beijing. China, People's Health Publication House.
9. Williams T. The idea behind Chinese medicine In: *The Complete Illustrated Guide to Chinese Medicine*. 31–34. 1996. Great Britain, Element Books.
10. World Health Organization. Standard acupuncture nomenclature (second edition). 1993; World Health Organization.
11. Yuan R., Lin Y. Traditional Chinese medicine: an approach to scientific proof and clinical validation. *Pharmacol.Ther*. 2000;86:191–98.
12. NG LKY, Liao S.J. Acupuncture: Ancient Chinese and Modern Western. A Comparative Inquiry. J Altern. *Complement Med*. 1997;11–23.
13. Morey S.S. NIH issues consensus statement on acupuncture. *Am.Fam.Physician.* 1998;57:2545–46.
14. Xie Z.F. Qigong and Health Preservation In: *Classified Dictionary of Traditional Chinese Medicine*. 533–555. 1994. Beijing. China. New World Press. Beijing 100037. China.
15. MacPherson H. Fatal and adverse events from acupuncture: allegation, evidence, and the implications [see comments]. J Altern. *Complement Med*.1999;5:47–56.
16. Moyad M.A., Hathaway S., Ni H.S. Traditional Chinese medicine, acupuncture, and other alternative medicines for prostate cancer: an introduction and the need for more research. *Semin.Urol.Oncol*. 1999;17:103–10.
17. Yamashita H., Tsukayama H., Tanno Y., Nishijo K. Adverse events in acupuncture and moxibustion treatment: a six-year survey at a national clinic in Japan [see comments]. J Altern. *Complement Med.* 1999;5:229–36.
18. Ernst E., White A. Life-threatening adverse reactions after acupuncture? A systematic review [see comments]. *Pain.* 1997;71:123–26.
19. Norheim A.J., Fonnebo V. Adverse effects of acupuncture [letter] [see comments]. *Lancet.* 1995;345:1576.
20. Yamashita H., Tsukayama H., Tanno Y., Nishijo K. Adverse events related to acupuncture [letter]. *JAMA* 1998;280:1563–64.

Unani medicine

Syed Khaleefathullah

Origin and development

The Horizon of Unani Tibb: Unani medicine originated from Greece under the patronage of Bukrat Hippocrates (460 BC–377 BC) and from the fusion of diverse thoughts and experiences of nations with ancient cultural heritages, and advanced with the wealth of scientific thought of that age. Among the distinguished scholars and translators of that period, Ibn-E-Masawayh, Hunain Bin Ishaque and Qusha Bin Luqah deserve mention. When this rich material was made available, it paved the way for further researchers, physicians and surgeons like Rabban Tabari, Zakaria Razi, Ali Bin Abbas, Abu Sehl Masihi, Abu Ali Ibnsina and Abul Hassan Tabari.

Al Razi (850–923AD) is regarded as a distinguished physician in the history of Unani Tibb. He devoted his life to literary and clinical research. After his death, his disciples edited the material collected by him. His book, *Al-Hawi,* was translated into Latin in 1486 and published in Venice in 1547AD. He was the first to describe smallpox and measles in his valuable treatise, *Al-Hasaba-Wa-Al-Judri*, which is considered as the best heritage of Unani Tibb.

Ali Ibn-E-Sina (980–1037AD) is the chief luminary of Unani Tibb. His brilliance is shown in classifying and arranging all the medical knowledge of his time, and in presenting it in a logical form. His famous book of medicine is *Al-Qanon-Fit-Tibb* (Canon of Medicine). This book was written in five volumes.

Avicenna refers to the uniqueness of the human personality as a union of the body with an immaterial soul. From the scientific point of view, the strength and weakness of the *Al-Qanon* lie in its passion for observation, classification and generalization. There is repeated counselling to medical practitioners against indulgence in speculation.

Avicenna's theory of interaction between the four causes reveals that every illness is a product of (i) heredity (ii) environment (iii) constitutional strength and the quality of temperament, and (iv) nature's own effort for the life and integrity of functions.

The concepts of Avicenna which require to be accepted as truth are the elements – symbols of mass and energy; temperament – the energy pattern of the body as a whole; humours – the building material for the body and the source of energy for work; the faculties – the power

or drive for organs and functions; and finally vital force – the metabolic energy for the organization and differentiation of life. These are hypotheses imported from the physics and biology of Avicenna's time and thus deserve not ridicule but serious consideration as helpful generalizations.

Avicenna's mode of presentation gives the impression of concepts being true for all times. It is this impression which led his successors to regard the pursuit of other medical literature as superfluous and thus acted as a deterrent to progress for several centuries. It was, however, not the fault of Avicenna that he presented it as such to general practitioners and there is no reason for us to avoid the dispassionate examination of *Al-Qanon* for useful ideas.

The most frequently quoted surgeon during the middle ages was Abul Qasim Al-Zahrawi. His book, *Al-Tasrif,* was used as a textbook until the beginning of the 17th century. Hippocrates systemized the tibb and gave it the status of ''Science''. Galen established its foundation on which the Arab physicians constructed an imposing edifice.

The greatest name in botany is Ibn-Al-Baytar (1248 AD). His book, *Al-Jami-Li Mufaradat Al-Adviya Wa Al-Aghziyah,* contains all Greek and Arabic literature on botany and *Materia Medica*.

The Unani physicians were also advanced in midwifery and performed the operation of "Cranio Clasty" for the delivery of the dead foetus. Zahrawi's book, *Al-Tasreef*, is full of such examples. He was the first to describe the Walcher's position in obstetrics.

The modern "Germ Therapy" is in fact a reflection of the views of the Unani physicians who realized the connection between foul bodies and putrefaction. In this connection, Avicenna has discussed in detail that unless a bodily secretion is contaminated with these foul earthly bodies, no infection can occur. The Spanish Arab physician, Ibn-E-Khatima knew that man is surrounded by minute bodies, which enter the human body and produce disease. Dr Grunner, the translator of *Al-Qanon* of Avicenna, remarks in his preface that the above two views considered together give us glimpses of modern germ therapy.

Unani Tibb was introduced in India by Arab and Persian settlers. The Unani physicians paid special attention to the medicinal herbs found in India and wrote books on the therapeutic qualities of these herbs.

India has produced eminent Unani physicians. A few among them are Hakim Ajmal Khan and Hakim Abdul Hameed in northern India, and Hakim Zahoorul Huq, Hakim Mohammed Muqeem, Shifa Ul Mulk and Hakim Syed Maqdoom Ashraf in southern India.

General Principles

Concepts

Unani Tibb is based on the humoral theory. This theory supposes the presence of four humours in the body – blood, phlegm, yellow bile and black bile. The temperament of a person is accordingly expressed by the words sanguine, phlegmatic, choloric and melancholic, according to the prepon-derance in him/her, respectively, of the above humours. The humours are assigned temperaments. Blood is hot and moist, phlegm is cold and moist, yellow bile is hot and dry, and black bile is cold and dry. Drugs are also assigned tempera-ments. Every person is supposed to have a unique humoral constitution, which represents his healthy state. Any change in this brings about a change in the state of health. A power of self-preservation or adjustment,

"medicarix naturae", is formulated, which strives to restore any disturbance within the limits prescribed by the constitution of an individual. This corresponds to the defence mechanism, which is called to action in case of insult to the body. The aim of the physician is to help and develop rather than supersede or impede the action of this power. The consequence of this is that not only is the system enabled to overcome the present disturbance by dint of its intrinsic power, but it also emerges, after recovery, with greater power of resistance to further disturbances.

In Unani Tibb, drugs of plant, mineral and animal origin are extensively used. The Unani physicians encouraged poly-pharmacy and devised a large number of poly-pharmaceutical recipes, which are still in use in Unani Tibb.

Gruner in a treatise on the *Canon of Medicine* of Avicenna published in 1930, states:

"Modern medicine is based on the conception of the universe as a conglomeration of dead matter out of which, by some unexplained process, life may become evolved in forms. To Avicenna the whole of the universe is the manifestation of a universal principle of life, acting through the instrumentality of forms. In modern medicine, the forms are the source of life but to Avicenna, they are the product of life."

Principles

The human body is considered to be made up of the following seven components (*Umore Tabaiya*) each having a close relation to and direct bearing on the state of health of an individual and it is therefore necessary for a Unani physician to take all these factors of the human entity into consideration for arriving at a correct diagnosis and deciding the line of treatment.

Arkan (Elements)

The human body consists of four elements, viz., air, fire, water and earth. These elements actually symbolize the four states of matter. They have their own temperaments. Air: hot and moist; water: cold and moist; earth: cold and dry; and fire: hot and dry.

Mizaj (Temperament)

The interaction of the elements produces various states, which in their turn determine the temperament of an individual, and it is of paramount importance to keep the temperament of an individual in mind while prescribing a course of treatment. A temperament may be (i) real equitable – the temperaments of the four elements are in equal quantities – which do not exist, (ii) equitable – just and required amount having compatible temperaments, and (iii) inequitable – an absence of a just distribution according to their requirements.

Aklat (Humours)

These are the fluids which the human body obtains from food, and include various hormones and enzymes. These fluids are (i) primary fluids – four humours, and (ii) secondary fluids – these are also four in number and are called *Rotubat E Arba* (four fluids). These are responsible for maintaining the moisture of the different organs of the body and also provide nutrition to the body. There are four types of moisture: moisture of the small vessels; moisture in the small spaces of the body; moisture of the different parts of the organ; and the moisture that holds the body together.

There are four stages of digestion (i) *hazm e medi* – gastric digestion followed by and including *hazm e mevi* – intestinal digestion when food is turned into chyme and chyle and carried to the liver by mesentric veins, (ii) *hazm e kabid* – hepatic digestion. In the course of this process chyle is converted into four humours in varying quantities, that of blood being the largest, (iii) *hazm e urooqui* – vessel digestion, and (iv) *hazm e uzuvi* – tissue digestion.

While the humours are flowing in the blood vessels, every tissue absorbs its nutrition by its *quvat e jaziba*, (attractive power), and retains it by its *quvat e masika* (retentive power). Then the *quvat e hazima* (digestive power), in conjunction with *quvat e mushbah* (assimilative power), converts it into tissues. The waste material at this stage is excreted by *quvat e dafia* (expulsive power).

Aaza (Organs)

These are the various organs of the human body. The health or disease of each individual organ affects the state of health of the whole body.

There are four organs of primary importance in Unani medicine. These are the brain, the heart, the liver, and the testicles or the ovaries. Other organs are servers to the main organs. This shows that the brain is served by the nerves, the heart by the arteries, the liver by the veins, the testicles by spermatic vessels and the ovaries by fallopian tubes. The heart is the source or starting point of the vital power or innate heat of the body. The brain is the seat of the mental faculties, sensation and movement. The liver is the seat of the nutritive or the vegetative faculties. The generative organs (testes, ovaries) give the masculine and feminine form and temperament, and form the generative elements for propagation of the race.

Arwah (Spirits)

These are considered to be the life force and are therefore given importance in the diagnosis and treatment of diseases. They are defined as carriers of different powers.

Quwa (Faculties)

The faculties are of three kinds,

(a) ***Quvat e tabaiya*:** Natural power, the power of metabolism and reproduction. The seat of this power is the liver but the process is carried on in every tissue of the body. The process of metabolism is completed by two factors, namely,

- Nutritive power, which is served by four powers. These are (i) Attractive power, (ii) Retentive power, (iii) Digestive power, and (iv) Expulsive power.
- Growing power is responsible for the construction and growth of the human organism and is served by three powers. These are (i) Receptive power, (ii) Power to retain nutrition, and (iii) Assimilative power.

  As far as reproduction is concerned, the function is accompanied by two powers which are (i) Generative power, and (ii) Forming power.

(b) Psychic power: Nervous and psychic power. Its seat is the brain and it is constituted by two powers,

- Perceptive power, which conveys impression or sensations;
- Motive power, which brings about movement as a response to sensation.

Perceptive power works in two directions: External perceptive, when it recognizes objects outside, and is served by the five senses and internal perceptive,

when perceptions are not from outside but are inferences drawn from external impressions and recognition. This consists of five powers: (i) Composite senses: Its function is to collect in one place all the external recognitions, (ii) Imagination: It retains all material collected by composite senses, (iii) Conception: It co-relates all the external recognitions and draws conclusions from them, (iv) Memory: It retains conclusion, and (v) Modifying faculty: This power is possessed only by human beings which gives us the capacity to explain one thing in different ways and which interprets all internal and external recognitions.

Motive power is of two types, (i) Power that is the cause of motions, and (ii) Power that causes motions.

(c) Vital power: Power that maintains life and enables all the organs to accept the effect of psychic power. The seat of this power is (i) Heart – the centre of vital life, (ii) Brain – the centre of sensation and movement, and (iii) Liver – the centre of nutrition.

Functions

This includes the movement and functions of the various organs of the body. Every organ has a primary innate faculty (force or drive) for nutrition by which it absorbs, retains, assimilates and integrates the food material into tissues and excretes the wastes. Some organs are also capable of influencing the activity of other organs while certain other organs have no such faculty. It is on account of such differences that the various organs of the body are described as (i) receptors as well as effectors, (ii) receptors, (iii) effectors, and (iv) neither receptors nor effectors.

States of the body: According to Unani Tibb the states of the body are grouped under three heads. They are,

- Health – The bodily functions are carried on normally;
- Disease – The opposite of health, in which one or more functions or forms of the organs are at fault;
- Neither health nor disease – There is neither complete health nor disease. As in the case of old people or those who are convalescing.

Disease can be classified into two types:

(1) Simple disease that completes its course without complications. It involves simple organs, compound organs, or both and is differentiated as,

(a) **Diseases of temperament:** These affect only simple organs. When compound organs are involved it is through the affection of their composing simple organs. Diseases of temperament are thus always referred to as affecting simple organs and not compound organs;

(b) **Diseases of structure:** These involve compound organs which are composed of simple organs and are in reality the instruments of body functions;

(c) **Diseases of continuity and dislocations:** These affect both simple as well as compound organs. In the latter case, loss of continuity involves compound organs directly and independently, and not through the involvement of simple organs which compose them. Dislocation is a loss of continuity in a joint but without damage to any of its individual components.

(2) Complex disease does not mean the simultaneous occurrence of several diseases in one person, but the presence of a number of abnormal conditions in the form of a single disease.

Principles of Diagnosis

In Unani Tibb, great reliance is placed on investigating the cause of the disease thoroughly for proper diagnosis. The pulse, urine and stool are employed as the general indications to diagnose the various states of the body.

Pulse

Pulse is a movement of expansion and contraction in the receptacles of the vital force (heart and arteries). The purpose of this movement is to condition the vital force with light air (oxygen from lungs). The pulse can be discussed from the point of view of:

- The general principles governing the pulse;
- The type of pulse in each disease.

Each pulse-beat consists of two periods of movement and two periods of rest. Since each beat has one period of expansion and one of contraction, it is also important that between the two opposite types of movement, there should be a period of rest because it is impossible for any movement to reach the end of its course and change into any type of movement without intermission. This has been made clear in physics. It is, therefore, obvious that each pulse-beat before the next has two periods of movement and two of rest, which are:

- Expansion (systolic);
- Rest between expansion and contraction;
- Contraction (diastolic);
- Rest after the contraction (diastolic) of preceding beat and before the expansion of the next beat.

According to most physicians, the phase of contraction in pulse is not perceptible. According to some it can be perceived occasionally in a strong pulse on account of additional strength; in a large pulse on account of greater height; in a hard pulse on account of greater resistance, and in a slow pulse on account of increased length of the beat.

Method of feeling the pulse

The pulse is felt by palpating the radial artery at the wrist for three distinct reasons. First it is more accessible, second, it is in direct continuity with the heart and third, because it is quite close to it.

The forearm should be kept in mid-prone position, as in thin and weak persons pronation increases the height and width of the pulse but decreases the length, while supination increases the height and length but decreases the width.

Features of the pulse

Unani physicians have laid down 10 features for examining the pulse. In this way the pulse varies in respect of its size, i.e., in the degree of expansion as estimated by its height, length, and breath; strength of the pulse-beat as felt by the fingers; velocity of the pulse-beat depending on the duration of the movement; quality of the vessel wall; fullness or emptiness of the artery; quality of the pulse regarding its hot or cold condition; frequency of pulse-beats based on the length of the rest period (between two beats); constancy and inconstancy regarding the various features; regularity or irregularity of the beats or rhythm of the pulse.

Size

This is noted in the three spatial relations of the pulse during expansion, i.e., height, length, breadth. The pulse thus has nine simple and a large number of compound varieties which are the long, short and

medium; the broad, narrow and medium and the high, low and medium. A pulse which is large in length, breath and height is called a pulse of large volume and the one which is small in these dimensions is called the pulse of small volume. The average pulse between these two is known as the pulse of medium volume. Similarly, a pulse which is large in breadth and height is known as a bounding pulse and that which is small in this respect is called a thin pulse. A pulse which is average between these two extremes is a medium pulse.

Strength

The pulse as felt by the fingers may be strong, feeble or medium. A strong pulse is the one which during expansion strikes forcibly against the physician's palpating fingers. A feeble pulse is the opposite of a strong pulse and a medium pulse in this respect is midway between the two.

Speed (Velocity)

The velocity of pulse-beats may be quick, sluggish or medium in speed. A quick pulse is one in which the duration of individual beats is shorter. A sluggish pulse is the opposite of a quick pulse and a medium pulse, in this regard, is of the average speed between the quick and the sluggish pulse.

Consistency (Elasticity)

The vessel wall may be soft, hard or medium. A soft pulse is one which is easily compressed (with the fingers) while a hard pulse is the opposite of a soft pulse. A medium pulse in this respect is the average between the two.

Fullness (Volume)

The pulse may be full, empty or medium. A full pulse is one which feels as if the artery is full of blood. An empty pulse feels the opposite of the full pulse and a medium pulse in this respect is the pulse of average fullness between the two extremes.

Temperature

The pulse may be hot, cold or moderate in temperature.

Rate (Frequency)

The pulse is rapid when the period between the two beats is less than the normal. It is slow when this period is long. A medium pulse in this respect is of the average rate between the two extremes.

Constancy

A pulse may remain constant or vary in respect of the features mentioned above. The variation may extend over several beats or involve a single beat, or part of a beat, e.g., the pulse may be rapid in one beat because of increased (metabolic) requirement of the body and weak in another beat due to reduced vitality. The five features of the pulse, which vary in a beat, are, size – as large or small; strength – as strong or weak; velocity – as quick or sluggish; frequency – as rapid or slow, and consistency – as hard or soft. The pulse may thus be constant or varied. A constant pulse remains absolutely unaltered, i.e., it is smooth and even in respect of all the above-mentioned features. If the pulse remains constant in any of the five features, it is known as being constant in that particular feature, i.e., constant in strength or rate. Similarly, a pulse which is variable may vary in only one or two features of the pulse.

Regularity

An irregular pulse may be regularly irregular or irregularly irregular. A regular irregularity is the one which is repeated in a systematic manner. The irregularity is simple when it pertains to a single feature

of the pulse. It is complex when more than one feature is involved, e.g., the pulse shows two different types of irregularities but each one is so repeated that both irregularities form a single cycle of a regular complex irregularity. An irregularly irregular pulse is the converse of the above.

Rhythm

The rhythm of the pulse is the time relation between the two periods of movement and the two periods of rest. When these relations are not perceived, the rhythm is taken to be the relation between the period of rise and the period of rest in two consecutive pulse beats. In short, the period of movement should be compared with the period of rest. The pulse may thus be eurhythmic or dysrhythmic.

Dysrhythmic pulse is of three varieties:

- Pararhythmic, in which the rhythm of a child's pulse is like that of the pulse of a young man;
- Hetrorhythmic, in which the rhythm of a child's pulse corresponds to that of an old man's pulse;
- Etrhythmic, in which the rhythm is so utterly abnormal that it does not correspond to the rhythm of any age. Marked deviations of rhythm indicate gross derangement in the body.

The factors which govern the pulse are of two types:

- **Intrinsic factors:** These are of a general type and are fundamentally responsible for the formation of pulse and are thus known as the constitutional factors;
- **Extrinsic factors:** Although these are not directly concerned with the formation of the pulse, they do produce changes in it and are thus, (i) Absolute as those which are necessary concomitants of a healthy life, and (ii) Subsidiary, which are not so necessary.

Effects on the pulse of factors inimical to the body are:

- **Temperament:** The effects of various abnormal temperaments have already been described.
- **Compression of the vessel:** This changes the form of the pulse by suppressing the strength and thus making it inconstant. When the pressure is overwhelming the pulse becomes irregular and arrhythmic. The compression may or may not be from an inflammatory mass.
- **Strength:** Dispersal of strength makes the pulse weak, as in severe pain, and psychological factors also cause severe dispersal.

Urine

The following conditions have to be observed so that the information derived out of it is reliable. The specimen should be of overnight urine. Urine should be collected in a clear and colourless bottle in the morning on empty stomach and not retained for too long after collection.

The individual should not have used diuretics or any sustenances which colour the urine. Undue mental and physical exertions should be avoided as these too colour the urine, e.g., fasting, lack of sleep, fatigue, hunger and outbursts of anger make the urine red or yellow. Coitus gives a marked oily appearance to the urine. Vomiting, diarrhoea and polyuria also change its colour and density. In infants and children, urine does not give any reliable indication because milk feeding hides the proper colour and consistency of urine. Also, their phlegmatic nature tends to hold back the pigments and

excretes them in a smaller quantity. Since children are relatively weaker and more delicate and sleep longer than adults, their urinary findings are apt to be misleading.

It is only when the examination is carried out with due observance of the above-mentioned rules that it provides helpful indications. Let it be known that urine gives direct information only about the functional condition of the liver, urinary organs and the vascular system, and it is through these findings that the functional state of other organs is also learnt. Urine examination is a particularly reliable test of the functional efficiency of the liver, especially of its convex part.

The points to be noted about urine are colour, density, turbidity or transparency, sediment, quantity, odour and froth.

Colour: The various shades of colour observed by the unaided eye, i.e., white, black and the intermediate shade.

Density: The thickness and thinness of urine. Density is different from the turbidity and transparency of urine. Thick urine may be clear like the white of an egg, fish glue or olive oil. Sometimes it is thin and yet looks like turbid water. Urine becomes turbid from the suspension of dark-coloured particles.

Transparency: This is the opposite of turbidity. Turbidity differs from sediment. In turbidity the particles are intimately mixed with urine while the sediment is quite distinct and separate from the liquid part of urine. Colour is the result of dissolved particles while turbidity is due to suspended particles.

Sediment: Refers to the deposit and also to the suspension of material denser than usual, i.e., it refers to the deposited as well as the suspended matter.

Froth: This is due to the admixture of reeh in the liquid urine during micturition. The points to be noted about froth are (i) Colour – dark or orange-coloured froth indicates jaundice, (ii) Quality – bubbles being large, coarse, fine or small. Coarse foam indicates that the eliminated matter is viscid, (iii) Quantity – excess of foam points to excess of reeh, (iv) Persistence of froth shows that the eliminated matter is viscid. Increased viscosity of urine is a bad sign in kidney disease since it shows abnormal phlegm or sauda is present in the system, or this organ has become unduly cold in temperament.

Odour

Urine of sick persons never has the same odour as that of healthy persons. If the urine is odourless, it points to either a cold temperament or excessive immaturity of humours.

Quantity

Scanty urine means impairment of vitality. If urine is scanty in spite of taking adequate fluids it is likely to be due to excessive perspiration or diarrhoea. The passage of a large quantity of urine is a sign of early recovery, especially if the urine is pale and is being passed freely.

Mature urine (normal for health)

Mature urine is of moderate density and pale yellow in colour. If there is sediment, it is of laudable type as described above, namely, white, smooth, light and moderate smell, i.e., free from malodour but not totally without smell.

Urine at different age periods

During infancy urine tends to be white because of milk feeding and moisture in the temperament. In childhood urine is thick, viscid and inclined to be excessively frothy. At maturity it is yellowish and of moderate density. In middle age it is pale and watery but may, at times, become thick from the elimination of waste matter. In old

age urine is pale, watery and of low density. If it becomes dense it points to stone formation.

Stools

Quantity

This is judged by taking into consideration the amount of food consumed. Large stools indicate abundance of humours while scanty stools their deficiency. Stools are retained through obstruction in the caccum, colon or small intestine as a prelude to colic. Sometimes the stools may be scanty due to weakness of the expulsive faculty.

Consistency

Liquid stools point to indigestion or obstruction. Weakness and obstruction of the messentric vessels produce liquid stools by interfering with the absorption of fluid into the portal vein. Sometimes catarrh produces liquid stools. Laxatives also have a similar effect. Viscid stools are a sign of wasting but the stools then are foul smelling. When stools are not foul smelling they indicate excessive quantity of some abnormal and viscid humour. Sometimes viscid stools result from the presence of some mucilaginous matter in the food which, because of excessive heat, has not been digested properly. Frothy stools result from excessive heat or the excess of reeh. Stools become dry from exhausting illness or strenuous work causing dispersion. Dry stools are also passed during polyuria and in cases of excessive heat in the body. Dry food and constipation also make the stools dry.

Hard and dry stools with mucus indicate delay in the passage of stools or lack of irritable bile. When there is no evidence of delay in bowels and no sign of excessive mucus, the cause is likely to be the presence of some thin purulent material or irritating humour expelled by the liver into the neighbouring organs being hurried out with the stools.

Colour

Stools are normally of faint yellow colour. When they are a darker shade of yellow then there is excess of bile. Stools which are pale indicate defective digestion and lack of maturation. White stools denote obstruction in the bile duct and jaundice. If stools contain offensive white pus, it is likely to be from rupture of an abscess. Stools resembling pus are often passed by healthy persons of sedentary habits and those who have given up exercise. These stools are not bad as they indicate purification and elimination of the body rendered sluggish from lack of exercise, as mentioned in the section on urine. Deep yellow stools passed at the height of an illness are a sign of good maturation. However, these stools may be a warning of the illness having got worse. Black stools are generally due to excessive combustion or maturation. Sometimes the black colour is due to the intake of coloured substances or wine having helped in eliminating sauda. The worst type of black stool is the one which has been excessively burnt. This type of stool is, however, not only black but has acidity and putrefaction as revealed by the appearance of froth on its contact with the ground. Such acidity is bad, whether in stools or vomit. These stools are also shiny. However, black stools which arise from destruction from moisture and excessive dispersion instead of ending in death have good prognosis. Green and bluish stools indicate failure of innate heat. Stools of unusual colours are unhealthy.

Froth

Stools which, instead of being firm and compact, are puffed up like cow dung are a sign of reeh.

Time

If stools are passed on quickly, there is likely to be some disturbance such as excess of bile or weakness of the retentive faculty. When there is a delay in the passage of stools there is either weak digestion, cold temperament of the intestines or excess of moisture.

The Unani system considers that food and drinks taken as nutrients constitute the building material of the body, including the humours.

Flatus

Stools are passed noisily with the elimination of wind.

Other means of diagnoses

In addition to the above, other conventional methods of diagnosis such as inspection, palpation, percussion and auscultation have also been used by Unani physicians. Regular case history of the patient is recorded and maintained as is evident from the books of Rhazes and Avicenna.

Preservation of Health

Definition of health

Health is a state in which the temperament and structure of the human body are such that all its functions are carried out in a correct and whole manner.

The Unani Tibb recognizes the influence of surroundings and ecological conditions on the state of health. It has laid down six essentials for the prevention of disease. These essentials are:

Air

Avicenna, the famous Unani physician, says that the change of environment relieves the patient of many diseases. He has also emphasized the need for open, airy houses with proper ventilation, playgrounds and gardens. Air is deemed fresh when it is free from pollution with smoke and vapour. It should be free and open and not enclosed by walls or under cover. If outside air is polluted, indoors should be preferred. The best type of air is that which is pure, clean, and free of vapours from ponds, ditches, bamboo fields, water-logged areas and vegetable fields, especially of cabbage and herb-rockets. It should not be polluted with vapour arising from the dense overgrowth of trees, such as yew-trees, walnuts and figs. It is also essential that air should be free from pollution with foul gases. Good air should be open to fresh breeze and it should come from the plains and mountains. It should not be confined to pits and depressions where it warms up quickly by the rising sun and cools down immediately after sunset. Air which is surrounded by recently painted or plastered walls is not fresh. Air is not healthy if it produces choking or discomfort.

Food and Drink

Avicenna was the first to observe that dirt and polluted water were carriers of disease and emphasized the need for keeping water free from all impurities. Food and drink after being taken by mouth affect the body by their (i) Quality, (ii) Elementary constitution, and (iii) Essence. The Unani system considers that food and drinks taken as nutrients constitute the building material of the body, including the humours. Therefore, the selection of foods for general nutrition and in correcting imbalances forms the core of the Unani system of healing.

Bodily Movement and Repose

To maintain perfect health and a trim body, exercise and rest are essential. All forms of activity – whether vigorous, prolonged, mild or slow – produce heat in varying degrees but moderately vigorous activity differs from prolonged mild and slow activity in that it produces more heat and less dispersion. On the other hand, prolonged activity, even though mild, produces greater dispersion rather than heat. Prolonged activity of any kind leads to dispersion of the innate heat and thus produces cold and dryness in the system. The presence of some additional factors may hinder or enhance the effect of the activity. Rest is always cooling and moistening. It is cooling because there is no excitation of heat and there is an inward collection and aggregation of matter which suppresses the heat. It is moistening because it hinders the proper disposal of wastes.

Psychic Movement and Repose

Unani physicians maintain that certain diseases like hysteria and mental disorders are caused, in most cases, by emotional strain and maladjustment and therefore, while dealing with such cases, these factors are taken into account. The curative effect of music, pleasant company and beautiful scenery is also recognized by Unani physicians.

Sleep and Wakefulness

Normal slumber and wakefulness are essential for health. Sleep resembles rest while wakefulness is akin to activity. Sleep directs the innate heat inwards and strengthens the physical faculty. It weakens the nervous faculty by relaxing and moistening the passage of impulses and by making the vital force dense by stopping dispersion produced by wake-fulness. Sleep removes all types of fatigue and stops the excessive flow of excretions promoted by activity. Sleep takes up the digestion and maturation of food and converts it into blood. Wakefulness has the opposite effect of sleep. When it is excessive it disturbs the brain by producing dryness and weakness and thus causes confusion and also dulls the nervous and mental faculties and makes the head heavy. Wakefulness increases the desire for food and stimulates appetite by dispersing the waste. It, however, impairs digestion by dissipating the strength of faculties. Sleep which is restless and disturbed is harmful.

Evacuation and Retention

Natural means of excretion are diuresis, diaphoresis, vomiting, faeces, excretion through uterus in the form of menstruation, etc. Proper and normal functioning of the excretory process must be ensured in order to maintain perfect health.

Curative Treatment

Definition of Disease

Disease is an abnormal state of the human body which, primarily and independently but not secondarily, disturbs normal functions. Disease may thus be a disorder of temperament or of structure.

Stages of Diseases

A disease generally has four stages, viz., onset, increment, acme and decline. Stages of onset and acme are not just the beginning and the end of disease, but definite periods of onset and acme, during which special rules of management have to be observed.

Onset

The stage when the disease has just appeared, remains stationary and does not advance to any appreciable extent.

Increment

The stage during which the disease goes on increasing until it becomes quite severe.

Acme

The stage during which the disease reaches its height and remains stationary in all respects.

Decline

The stage during which the disease begins to subside and with the passage of time starts decreasing in intensity.

Transmission of Disease

Disease can be transmitted from one person to another in the following manner:

Contagion occurs in leprosy, smallpox, epidemic fever and scabies. Contagion occurs more frequently in persons living in congested areas or in the direction of the wind from infected places.

Heredity is found in baldness, gout, leucoderma, consumption and leprosy.

Racial transmission occurs particularly in certain groups of persons.

Regional transmission is endemic to certain regions.

Prognosis of Diseases

A disease is curable when there is nothing to hinder efficient treatment. A disease is easier to cure if the age, temperament and season are favourable. If these factors are adverse, the case would be different because, under certain conditions the cause of disease must be extraordinarily strong and thus more difficult to eradicate. It must be remembered that some diseases may change into new ones or disappear completely. This is a good sign. Certain diseases cure some other disease, e.g., quartan fever frequently cures epilepsy, arthritis, scabies and various spasmodic conditions. Bleeding from piles benefits diseases caused by sauda and painful disease of the kidneys and uterus.

Unani medicine has the following modes of treating an ailment, depending upon the nature of the ailment and its cause:

Regimental Therapy

The Unani physician attempts to use simple physical means to cure a disease, but for certain specific and complicated diseases he applies special techniques, some of which are as follows:

(a) **Venesection**
- To bring down hypertension.
- Stimulation of metabolism.
- Correction of hot material in temperament.

(b) **Cupping:** Cupping purifies the skin and underlying tissues better than venesection. Since cupping removes only thin blood, it is of little use in robust persons whose blood is generally thicker and more difficult to draw. There are two types of cupping – dry cupping and wet cupping.

(c) **Sweating:** Hot fomentation (dry and wet) bath with warm water, massage and keeping the patient in a room and blowing hot air are some of the methods of diaphoresis.

(d) **Diuresis:** This method is used in cases of diseases of the heart, lungs and liver.

(e) **Turkish Bath:** Hot bath is generally applied for curing diseases like paralysis and muscular wasting, after massage.

(f) **Massage:** Soft massage is a sedative and a relaxant. Dry and hard massage is a deodorant. Massage with oil relaxes the muscles and softens the skin.

(g) **Counter Irritant:** For providing relief in pain, burning sensation and irritation.

(h) **Cauterization:** By this, the pathogenic matters which are attached to some structures are removed or resolved. It is applied (i) To prevent the spread of destructive lesions, (ii) To strengthen organs which have become cold in temperament, (iii) To remove putre-factive matters which are firmly adherent to the tissues, and (iv) to arrest haemorrhage.

(i) **Purgatives:** Purgatives and laxatives are widely used by Unani physicians. This method has a resolving, anti-spasmodic and detoxicating effect.

(j) **Vomiting:** Emetics are used in certain cases for relief.

(k) **Exercise:** Physical exercise has great importance in the treatment of certain diseases as well as in the maintenance of the healthy condition of an individual. Unani physicians have laid down rules regarding hard, moderate and light exercises and have also indicated the timings and conditions for various physical exercises.

(l) **Leeching:** This is a unique method. Application of leeches is better than cupping in drawing the blood from deeper tissues. Certain conditions have been laid down for applying this method. Leeches should be collected, preferably a day earlier. They should be held upside down to empty the stomach and sponged clean of the dirty viscid slime. Leeches with large heads and black, grey or green colour should be avoided. The application of leeches is most useful in the treatment of skin diseases such as favus, ringworm, freckles and mole.

Dietotherapy

Unani medicine lays great stress on treating certain ailments by the administration of specific diets or by regulating the quality and quantity of food. Many books are available on this subject in Unani Tibb.

Pharmacotherapy

Natural drugs like plants, minerals and of animal origin are widely used when compared to synthetic ones used in modern pharmacy.

(a) State of drugs: Drugs having states opposite to those present in the disease are used.

(b) Drugs Temperament: It is supposed that drugs have their own tempera-ment due to their special constituents. Some drugs are composed of ingre-dients having the opposite qualities, one quality acting in a way contrary to the other, and these qualities are accommodated in two different parts of the drugs. Ingredients possessing special actions are called active principles of the drugs. This theory of temperaments of the drugs is based on analogy and careful experiments.

(c) Potency of drugs: Drugs are graded into four degrees according to their potency.

(d) Mode of Action: The mechanism or mode of action of a drug can be explained only partially. Unani physicians have tried to explain this as follows:

- The direct action of a drug is the result of its physical or acquired characters;
- Drugs mainly act by heat, coldness, moisture or dryness;
- Some of the drugs have peculiar characteristics, which influence the body when these drugs are administered.

(e) Division of drugs according to quality:

- *First group* – This group contains drugs with a hot temperament such as heat-producing drugs.

- *Second group* – This group contains cold drugs like refrigerants, repellants and anaesthetics.
- *Third group* – Comprises moist drugs, lubricants, etc.
- *Fourth group* – These are drugs like drying agents, astringents and obstruents, etc.

(f) Use of Coctive and Purgative: Coctives are used to prepare the matter for excretion through purging or other means of excretion. This is used particularly for treating chronic or obstinate diseases. This method has no parallel in any other system.

(g) Dosage and Timings: While determining the dosage of a drug, factors like temperament and potency of drugs, temperament and age of the patient, nature of disease, severity of disease and route of drug are kept in mind. High-potency drugs or strong purgatives and emetics are avoided in summer and severe winter. Different types of treatment are prescribed for different stages of the same disease. Some drugs are used when the stomach is empty and some are used after meals.

(h) Route of drug use: In addition to oral drugs, Unani physicians also administer drugs through *huqna, abzan, farzaja, shiaf*, *zimad* and *tila*.

(i) Forms and shapes of drugs: Powders, tablets, decoctions, infusions distillates, *jawarish, majoon, sharbat, khameerajat, lavooq* and perfumes, etc., are used to achieve the desired effect.

(j) **Compounding and correction of harmful-effect drugs:** The harmful effects are either corrected by simple methods or by compounding with other drugs, e.g., frying in oil decreases the irritant effect of the drugs. Drugs are compounded for the following purposes:

- To potentiate the drug's effect (synergism);
- To decrease the harmful or excessive effect (Antagonism);
- For sharp diffusion of the drug;
- For slow diffusion of the drug;
- For slow preservation of active principles;
- To increase the quantity of a drug.

(k) Substitute of Drugs: Rhazes (920 AD) has compiled a treatise titled, *Miquala Fil-Abdal- Il Adviyah-Fit-Tibb- Wal- Ilaj,* on the subject of medicinal substitute wherein he has described the laws of selection of substitutes of a drug and has mentioned substitutes of 122 single drugs.

Unani physicians were pioneers in surgery and had developed their own instruments and techniques. Abul Qasim Zahravi wrote a book entitled '*Al-Tasrif*' on this subject.

The general principles of *Al-Qanon* could equip medicine with the basic principles of science in the historical perspective, offer education to masses in the preservation of health and the cure of diseases, serve as an introductory course in the bedside techniques of diagnosis and treatment, and act as a key to the study of Unani Tibb for research.

The various systems, whether Eastern or Western, merely represent different approaches to medical science as practised in different ages and in different parts of the world. The aim of all systems is the maintenance of health and prevention of disease. Anything of value in them should be utilized for the benefit of humanity as a whole without any reservation.

References

1. Ghulam Jilani, *Mukhzanul Jawaher* (Urdu). 1923. Tibbi Kutubkhana. Lahore.
2. Ghulam Hussain Kantoori – Avicenna. *Al Qanoon*, Vol. I–V (Urdu). 1930. Neval Kishore Press. Lucknow.
3. Gruner O.C., *Treatise on the Canon of Medicine of Avicenna*. 1930. Luzac and Company. London.
4. Kabiruddin Mohammed. Kulliyath I Qanoon (Urdu translation). *Canon of Medicine* Vol. I. 1930. Karol Bagh. Delhi.
5. Shah, M.H. Avicenna Kuliyath e Qanoon (English), *The General Principles of Avicenna's Canon of Medicine*. 1966. Naveed Clinic. Karachi.

Traditional system of medicine in Indonesia

Lestari Handayani, Haryadi Suparto and Agus Suprapto

Introduction

Before 1987, traditional medicine had no place in any formal health system in Indonesia. However, in 1988, in order to achieve greater equity in health development, traditional medicine was declared as an area for launching a potential development programme. Traditional herbal medicine and health care practitioners, who have developed in line with community needs, are to provide the alternative health services. Indigenous knowledge and healing techniques, herbal medicines and traditional practitioners are all very popular and familiar in the community, because they are easily usable and valuable, and have been proved safe empirically. In 1995, a rule which regulates traditional medicine and healers who contribute to health care, was laid down by the Ministry of Health (MOH).[1] Acupuncture, adopted from China's traditional medicine system, was integrated into the national health system in November 1996. This rule has streng-thened the role of traditional medicine and practitioners within the country's health system.

Indonesian traditional medicine uses many terms and categories, ranging from very simple to sophisticated ones. Most of these are related to the local culture, which makes it a little difficult for the outsider to understand them. A plant, animal, mineral or an intangible like metaphysics, may be used for healing. The tool/instrument used may be very sophisticated like laser, or simple, like a wooden rod. Alternatively, there may be no tool at all, and the healer may simply use mental concentration. The process could involve chemistry, mechanics, electricity and psychology/metaphysics. The route of administration could be the mouth, nostril, skin, vagina, rectum, etc. Usually, a traditional practitioner/healer uses different combinations of categories, e.g., to treat a bone fracture, a bone healer uses a mechanical bandage, oil mixed with flower and inner power (concentration). There are no strict, standard procedures of treatment because of the many factors to be considered in the holistic approach.

Subjectivity plays a major role in the selection of the method of healing. The methodology of testing traditional medicines should be adjusted to the philosophy on which they are based, such as the holistic approach, the concept of equilibrium or deep feeling. In such cases,

Traditional medicines are continuously being developed and used by the community. Government and private enterprises have made several efforts to develop *jamu* as modern therapy (physiotherapy).

scientific methods like statistical probability and multivariate analysis, the use of sensitive instruments like Kirlian photography, the aura camera and other electronic devices, are recommended. A methodology to evaluate traditional medicines is yet to be developed. However, the profitability or otherwise of traditional medicine can be judged by its impact on the community.

This paper will take up specific case studies because the methods of different local healers cannot be generalized. Information was obtained through several means: observation, interviews, and secondary data from literature. This article will concentrate on traditional medicine based on herbs, not because the other systems are not important, but because they have already been included in the formal health programme and therefore more information is available on them. The regulations regarding traditional herbal medicine, especially for industries, are well established—those dealing with standards of production and the procedure for acquiring a licence. These regulations were laid down by the MOH via the Directorate General of Food and Drug Control. The regulation pertaining to traditional healers (alternative healing), however, concerns only the license for practice, which is given by a district or a provincial attorney.[1] To promote safe and effective traditional health care, the Government will provide resources for research on traditional medicine.

Traditional Practices Using *Jamu*

In general, traditional medicine is called *jamu* (originating from the Javanese language) throughout Indonesia. *Jamu*, as indigenous Indonesian traditional medicine, was practised in the country centuries ago and has been passed down from generation to generation for purposes of health promotion, maintenance and treatment.[2] *Jamu* received a blow under colonial rule, so that today the middle and upper classes are no longer interested in using traditional medicines. These people have greater faith in and use only modern medicine; *jamu* is considered appropriate only for poor people. This is evidenced by the fact that till recently, the national health system was exclusively using modern medicines.

However, though formally not acceptable, traditional medicines are continuously being developed and used by the community. Recently, with the call of "back to nature", both Government and private enterprises have made several efforts to develop *jamu* so that it can be used as modern therapy (physiotherapy). Implicit in this is the assumption that phytopharmacology can be used in formal health systems. The development of phytopharmacology would focus on certain herbal medicines. Such traditional medicines are effective for specific diseases that are prevalent among the population, and are the only alternative medicines for certain diseases. They are also predicted to have a therapeutic effect in certain diseases. For the purposes of phyto-

pharmacology, priority is being given to herbal medicines which can cure diseases; *jamu* focuses more on health maintenance, promotion and rehabilitation.[2,3]

Traditional medicine can thus be categorized into two groups, i.e., *jamu* and phytopharmacology. The next section deals exclusively with *jamu*, which is part of indigenous Indonesian medicine. Phytopharmacy is not discussed here as it belongs to the realm of modern medicine.

Jamu and Indonesian Culture

The use of *jamu* is a part and parcel of Indonesian culture. It is said that *jamu* is akin to a daily need for a section of people, both in urban and rural areas, where *jamus* are easily available. To understand the role of *jamu* in the community's daily life, we present an example of a custom of the Maduranese[a] women in producing and using *jamu*.[4,5]

Case 1

It is culturally accepted that in daily living, women consume more *jamus* than men. Women are especially particular about using *jamu*, such behaviour being culturally institutionalized within the community. Maduranese women are fanatical about consuming *jamu* as reflected in the motto: "Better to not have a meal than not consume *jamu*". Madura's tradition of using *jamu* is intrinsically linked with the human life-cycle. Thus, the consumption of *jamu* is adjusted according to the phases of life of a woman.

Mothers encourage their daughters to use *jamus* for their health. Girls are started on *jamu* at the time of menarche. During the menarche, a girl gets special treatment; she bathes with aroma and *lulur*[b] and then consumes special *jamu*. Also, a teenage girl is not allowed to step on animal droppings, as this is believed to give the genitals a bad odour. The *jamu* that is consumed every day is provided by the mother. This consists of water-extracted *kunci* (*Kaempferia pandurata*), turmeric (*Curcuma domestica*), and *sirih* (*Piper betle*). *Jamu* made in home industries is bought for teenage girls, to be taken twice a week as a beauty aid (i.e., for a slim body and good health, good skin, and to fight body odour).

The day of marriage is a special day for the bride. A month before the marriage ceremony, the bride is given a comprehensive body care treatment consisting of *lulur* and cool powder made from rice and jasmine flowers. The treatment is meant to make the skin smooth and shiny. A bride is not allowed to drink too much and is advised to have water-extracted *jamu* as a substitute so that her body smells fresh and excessive perspiration is reduced. In addition, she must consume *jamu rapat* (vagina-constricting *jamu*), which is intended to constrict the vagina and reduce excessive vaginal discharge, so that she can satisfy her husband on their first night. A bridegroom should prepare himself by consuming *jamu* that serves as a sexual stimulant, but his preparation is not as elaborate as that required for a bride.

Married women, too, follow the tradition of consuming *jamu* to keep their bodies fit to serve their husbands. This is done voluntarily as proof of their submission to their beloved husbands. For body care, they routinely use *jamu*, either made at home or bought from a kiosk near the house. Every day, they prepare

[a] Madura is an island located north-east of Java.

[b] *Lulur* is a compound paste, used for lubrication.

water-extracted *jamu* made from *kemangi* (*Ocimum basilicum*), *kunci* and *sirih* to keep the body smelling fresh and to prevent leucorrhoea (excessive vaginal discharge). To prepare for sex, they take *jamu sari rapat,* which is available at kiosks. It can contain from 10–40 *jamu* materials. Mondays and Thursdays are special days for couples: there is a belief that having sexual intercourse in these days is *ibadah,*[c] and that the reward awaiting them is as glorious as that merited by a killer of 40 disbelievers and a thousand demons. To effectively constrict the vaginal opening and lubricate the vagina, *jamu* is applied externally or a *jamu* stick is inserted into the vagina just before intercourse to absorb the cervical mucus. In order to enhance sexual potency and relieve fatigue, the husband takes *jamu selokarang*, supplemented with eggs and honey. To indicate that she is ready, the wife adorns the bed with jasmines and lights some fragrant incense.

Special care is taken during pregnancy, which can be categorized into early and advanced. In the early stages of pregnancy, the woman uses *jamu anton muda*. After six months, *jamu cabe puyang* is used to relieve fatigue and pain. To hasten delivery, the woman should take coconut oil supplemented with raw egg yolk. Some also drink the water of green coconuts. Finally, they take *jamu* that serves as a stimulant for lactation in order to prepare for breastfeeding.

Postnatally, the mother uses certain postnatal *jamus*, packages of which can be ordered before delivery. Such *jamu* is taken from the first day after delivery upto day 35 or 40. The package consists of many kinds of *jamu*s, which should be consumed sequentially, in accordance with the post-pregnancy convalescence process. For the first 20 days, *jamu* is taken to remove blood residue and mucus from the uterus. Subsequently, *jamu* is used for restoring the uterus and abdomen to their former size, and for relieving fatigue. The mother takes various kinds of food to enhance the production of breast milk. These include vegetables*, katu* (*Sauropus androgynus*) leaves and different varieties of beans. Spicy foods, ice and foods with a high water content are avoided.

The child of a lactating mother using *jamu* may suffer from constipation, and his stool may be dark and have a bad odour. This is believed to indicate good health, the assumption being that the baby is thus getting rid of harmful abdominal wastes. This continues for around a month, till the time the mother stops taking *jamu*.

Jamu is also used for the spacing of births. Most mothers in Sumenep take *jamu* pills made at home. These contain a small amount of lime encased in tamarind (*Tamarindus indica*) flesh. About five to seven such pills are taken as a single dose after each menstruation. According to a herbalist, this method is quite effective. Though they do not use modern contraceptive methods, each couple in Sumenep has only one or two children. In order to treat primary or secondary amenorrhoea, while avoiding pregnancy at the same time, women consume "hot *jamu*" containing clove, pepper, cabe *jamu* (*Piper retrofractum*), ginger, tamarind flesh and other substances. To overcome infertility, women use "cool *jamu*", which contains *beluntas* (*Pluchea indica*), *sirih* (*Piper betle*), *trawas* (*Litsea odorifera*) leaves and 10–20 other substances.

[c] *Ibadah* signifies good deeds in the eyes of Allah

Provision of *Jamu*

The Maduranese customs, thus, consist of the use of two types of *jamu*: (i) That which is home-made, bought from the *jamu* peddler (*jamu gendong*), or from industries, and (ii) That provided by herbalists. As most of the Indonesian population resides in the island of Java, the *jamu*s discussed here are mostly those used by the people in Java.

Home-made *Jamu*

According to Javanese custom, it is traditionally the mother who is responsible for looking after the health of the family members, especially the children. This practice is well-entrenched, especially among traditional folk, as is evident in the rural areas. A mother is expected to know how to make simple *jamu* for the maintenance of the health of the family members and for purposes of first aid. These skills are generally acquired without any special training. Women learn and practise making *jamu* by observing others who make it, as well as by gathering information from neighbours. In addition, they may hone their knowledge and skills through a programme called *TOGA* (family herb garden). Due to the attention of the Government in this matter, *TOGA* programmes have spread over large areas of the country. The programme recommends that families cultivate herbs in their gardens or yards to have a source of fresh herbs which are ready for use.[(6)]

Within a family, the tradition of using *jamu* is introduced at a young age. Families commonly use a health drink (*roborantia*) to promote good health and familiarize the members with *jamu*. An example is *sinom*, which is made from young leaves of the tamarind, supplemented with turmeric and red sugar (traditional sugar) as well as *temulawak* (*Curcuma xanthorrhiza*).

Apart from restoring health, *jamu* is also used for certain illnesses and health problems, which are bound to afflict a family member at some time or the other. A mother is expected to provide at least first aid in such situations. The disorders that can be handled by mothers are mild ailments. A common cold with symptoms of a running nose, mild cough and fever can be treated with *jamu* made of materials taken from the kitchen. Fever resulting from infection is commonly treated with *jamu* made from turmeric juice, or water extracted from papaya leaves. Crushed onion mixed with *kajuputi* (*Leucodedron leacodendra*) oil or coconut oil is commonly applied to children with fever. Febrile convulsion is prevented by a compound containing *sangket* (*Moschosma poly-stachyum*) leaves. Children with a poor appetite are forcibly given *temu ireng* (*Curcuma aeruginosa*), which is very bitter. A paste of heated castor leaves is applied on the abdomen to relieve abdominal disorders (colic and dyspepsia), while chewing young guava leaves is effective in treating diarrhoea.[6, 7]

A *jamu* drink like *beras kencur*, which is made from finely pounded rice and *kencur (Kaempferia galanga*), tamarind flesh and red sugar, together with the lubricating *bobok beras kencur,*[d] helps in reducing the oedema and pain caused by a sprain.[7] Rheumatic pain can be treated by rubbing the painful area with finely pounded ginger. Rubbing castor sap or papaya leaves, *kamboja* (*Plumeria acuminata*) or *patah tulang* (*Pedilanthus pringlai Robins*) sap on a fresh cut/wound can provide immediate relief.[6]

[d] *Bobok beras kencur* is a paste made from rice and *kencur*.

A herbalist, preparing fresh herbal medicines in a traditional market

The materials that mothers use to make *jamu* for the family members are not of many types. They can be obtained from the kitchen, and consist of spices used in traditional Indonesian cooking. These include turmeric, ginger, *kencur*, *kunci* and garlic. Some fruits, like *nipis* lemon (*Citrus aurantifolia*) and onion are also used. Plants growing in the yard, garden, or rice fields—whether planted or growing wild—may also be used. Fresh materials are extracted from certain parts of plants (leaves, roots, flowers, fruits, trunk, seeds), or from the entire plant. A number of plants are deliberately cultivated in the garden for their fruits, leaves or seeds. These include papaya, guava, *pares* (*Momordica charantia*), *nipis* lemon, *daun ungu* (*Pseuderthemum andersoniil*), and *pecut kuda* (*Stachytarpheta jamaicensis*). Among the wild plants that are commonly used are *sambiloto* (*Andrographis paniculata*), *tapak liman* (*Elephantopus scaber*), *patikan kebo* (*Euphorbia hirta*), *tapak dara (Vinca rosea*), *ciplukan* (*Physalis minima*), *kudu (Morinda citrifolia*), *gempur batu* (*Ruellia naifera*), and *sembung* (*Blumea balsamifera*).[3, 6]

To make *jamu* drinks or external medicines these herbs or spices are simply processed. The process of making *jamu* requires boiling, and kitchen utensils such as ceramic pots may be used. A traditional tool called *lumpang* or *pipisan,* made of stone, can be used for pounding.

Jamu drinks can be made in the form of percolates (water-extracted) or concentrates of *jamu* materials. To obtain the essence of the raw materials, they are often cleaned and chewed. Home-made *jamu* is usually made when the need arises, so it is always fresh. The unused *jamu* is disposed of.

Jamu gendong

Jamu gendong is liquid *jamu*, which is stored in bottles. It is usually sold by women, who carry the bottles in bamboo baskets slung on their backs. *Jamu gendong* is cultivated extensively, and may be seen growing in Java, Sumatra and Kalimantan island, in the cities, towns, or remote areas. Most *jamu gendong* sellers come from the Central Java province (especially Wonogiri) and make their living wandering about the country. They come from a low socio-economic stratum, and have a low level of education, usually elementary school. Their consumers could be urban or rural people, who, too, are mostly from a similar background.[7]

The following example from Surabaya city, East Java, illustrates how a *jamu gendong* seller lives.[7, 8]

Case 2

Surti (a pseudonym) is a *jamu gendong* seller from Central Java. Twelve years ago, she and her husband, together with their two daughters, moved to Surabaya to earn

a living by selling *jamu gendong*. Surti, who is 40 years old, lives in a 3 m x 4 m rented room. She shares the room with her husband, who works as a *dawet*[e] seller, a 15-year-old daughter, and another daughter who is married with a three-year-old child. The small room has a single bed, a simple wardrobe, a wooden rack attached to the wall, a basket containing bottles, and a number of pockets and plastic bags hanging on nails. In the corner is a small wooden table which is heaped with various things, including a small radio. The room, which has a small fan, is small and rather dark even in the daytime, as it is lit only by a 25-watt bulb. A bicycle with a wooden frame to carry bottles poised on its back is also in the room.

The entire family wakes up with *Shubuh*[f] at about 4:30 a.m., after which they begin working. Surti immediately starts preparing her cooking utensils, stove and pan to boil water. Next, she adds a quantity of red sugar and some white sugar to the water. She then lays a mat on one side of the room, where she prepares a number of plastic jars, a funnel, liquid filter, dipper and steel mortar with its pestle.

She takes *jamu* materials out of plastic bags and jars, and places them on the floor. After the water has boiled, she prepares certain materials for the *jamu* to be compounded. Sitting on a wooden barstool, she processes *jamu* with great skill. She adds *jamu* materials (there can be three to five kinds of materials), and then pounds them into a fine mixture. Next, she takes plastic jars and fills them with the sugar liquid and the pounded *jamu* mixture. The liquid is then stirred and tasted. The processed *jamu* is poured into several clean bottles. She uses the same process to make other kinds of *jamu.* To make *jamu pahitan,*[g] in particular, the *jamu* materials are boiled in a special container but no sugar is added. In about an hour, eight kinds of *jamu* have been processed and stored in 22 bottles.

At around 6:00 a.m., Surti starts selling her *jamu,* covering her daily route on her bicycle. She places 14 bottles on a wooden rack at the rear of her bicycle, and another eight bottles in the bamboo basket, to be sold by her daughter. Her daughter, wearing a kabaya,[h] walks in another direction, carrying the basket on her back.

It seems that Surti already has certain customers. Riding slowly into a lower socio-economic dwelling complex, which she visits routinely, she rings the bells as a signal to her customers. A few mothers and young household attendants come out to buy *jamu.* When she is sure that there are no more buyers, she proceeds to a complex where a group of men are busy with construction work. A number of workers come forward to buy *jamu* and she greets them with a pleasant smile. The workers relish the *jamu.* By 10:00 a.m., most of her bottles have been sold and she goes home. Her daughter is already there, having sold all her *jamu* bottles as well.

Every day, Surti manages to sell 14 bottles of various kinds of *jamu*s. *Jamu kudu laos* is believed to be good for hypertension and for improving blood circulation; *Jamu pahitan* relieves the itching caused by allergies, parasitic infections and diabetes mellitus*; Jamu cabe puyang* is good for muscle stiffness

[e] *Dawet* is a kind of drink made of syrup containing small portions of boiled rice.

[f] *Shubuh* is a Muslim morning prayer

[g] *Pahitan* is a very bitter *jamu.*

[h] *Kabaya* is a special traditional Javanese dress.

Jamu industries are concentrated among those communities which have acquired the skill of producing *jamu* from their ancestors and use it as a means of earning their livelihood.

and fatigue; while *jamu sinom* refreshes and cools the body; *Jamu beras kencur* improves the appetite and relieves fatigue; *Jamu kunci suruh* is helpful in cases of leucorrhoea or excessive vaginal discharge, and *jamu uyup-uyup* stimulates lactation.

On the way home, Surti stops by a *jamu* kiosk in the market to buy *jamu* materials for the following day and for some foodstuff. Back at home, she rests for about one hour. After preparing the family lunch, she makes another *jamu,* to be sold at 3:00 p.m.

Industry-made *Jamu*

Both small and large-scale *jamu* industries are thriving in Indonesia. Many regulations pertaining to the *jamu* industry have been formulated by the Government (MOH). These cover several aspects, such as the licence for establishing a *jamu* industry, recommended practices for the processing of *jamu,* and compulsory registration of *jamu*. The industry can be categorized into big or small, depending on the amount of capital invested. There are just a few large *jamu* industries, mostly in Java, while small industries are scattered all over the country.[1,4]

Jamu industries must fulfil a number of prerequisites so as to be able to sell their products in the market. A person seeking to start an industry must obtain a licence from the provincial health office. *Jamus* may be sold in the market provided that the seller has a registration licence from the Directorate General of Food and Drug Control, MOH. One regulation states that *jamu* products must not be mixed with pharmaceutical chemical substances. The sale of *jamus* in the form of vaginal or anal suppositories is not allowed; and only a specified concentration of preservatives may be used in producing *jamu.* [1] These MOH regulations represent an effort to promote and control the *jamu* industry in the hope of improving the quality of *jamus.*

Big industries are capable of producing many forms of *jamu* to meet the people's requirements (e.g., extracts in the form of capsules, effervescent or sugar-coated tablets and syrups). Their capital allows them to purchase modern machines for superior processing. With such resources, they can provide *jamu* in the same form as modern medicines. There is a lot of competition among the *jamu* industries, and *jamu* products are advertised in the electronic (television, radio) and print media (newspapers, magazines), and through the distribution of leaflets. Given the large-scale production of these industries, their market could extend to various places in the country.

Small *jamu* industries are spread over extensive areas of Indonesia. They are concentrated among those communities which have acquired the skill of producing *jamu* from their ancestors and use it as a means of earning their livelihood. As a home industry, it contributes on the economic front. Among the areas that produce *jamu* are Madura, Wonogiri (Central Java) and Cilacap (Central Java). These industries use only simple production tools, and some have no special tools at all. For the milling of raw materials, the producer has to hire the services of someone in the market with a milling

machine. Some producers cannot even compound *jamu*, so they purchase the compound powder, divide it into several small packets and sell them. Often, they also use kitchen utensils to process *jamu.*[5]

Home industries produce *jamu* forms that can be readily served. The producers compound *jamu* materials and then grind them to a fine powder. This is packed in plastic or paper packets and then re-packed in bigger paper packets that are labelled. Some are packaged very well, while others are simply packed. An advanced method of *jamu* processing comprises the production of pills, either dried or moistened with honey. Some producers pack *jamu* powder in capsules for consumers who do not like the taste of *jamu*. Though very rare, some produce *jamu* in the form of tablets. Pills, capsules and tablets are packed in labelled plastic pots. Besides producing *jamu* to be taken orally, producers also manufacture *jamu* for external use like *bobok*[i] (lubricants), *pilis*[j] and *parem.*[k] These three are sold in the form of big pills or powders, which can be easily mixed with water. *Godogan*[l], which is compound *jamu* in the form of raw material, has to be boiled for extracting its essence and is then taken orally. Compound *jamu godogan* is packed in labelled or unlabelled transparent plastic bags.[5]

The market for industrial *jamu* is very large, as the culture of consuming *jamu* is already institutionalized in most of the country. These days, industrial *jamu* seems to be more popular than traditionally made *jamu* since it is more convenient to consume and store. The market for industrial *jamu* is varied, depending on the producer's capacity to promote his products. Some big industries have even opened special outlets in supermarkets and luxury malls, which cater to the middle- and higher-income groups. But, as most *jamu* consumers belong to the lower economic stratum, promoting techniques which are friendly for lay people would be more popular. The same applies to the marketing system. Most industrial *jamu* sellers have limited capital and vend their products in small kiosks. Such businesses are beginning to thrive in dwelling complexes and markets. The *jamu* is sold at an affordable price and the products are sometimes varied. The most popular variation is dissolved *jamu* mixed with egg yolk and honey. Then there are the peripatetic *jamu* sellers like Surti, who visit residential complexes on carriages or bicycles, complete with musical instruments. Their products are suited to the consumer's needs, and have different brand names. *Jamu* sellers serve the drink *sinom*, after the customer has had the *jamu* to overcome its bitter taste. A simple way of consuming *jamu* is by buying it at a kiosk, and then having it there. *Jamu gendong* sellers also provide industrial *jamu* to complement their product.

Jamu provided by herbalists

Herbalists include those who use local herbs grown in various areas of Indonesia, and those who use materials from outside the country. The latter are mostly from China, Saudi Arabia or Pakistan. They use materials from their own countries, though some also add local materials.

[i] *Bobok* is a lubricant used on the arms and legs.

[j] *Pilis* is a lubricant used on the face.

[k] *Parem* is a lubricant used on the abdomen.

[l] *Godogan* is *jamu* in the form of raw materials, the essence of which has to be extracted by boiling.

Javanese herbalists

The Javanese community can easily buy *jamu* from one of many traditional markets almost anywhere on the island. The provinces of Yogyakarta and Central Java, which are well-known cultural centres, have many traditional markets where *jamu* peddlers sell the *jamu racikan* (blended *jamu*) made by them in accordance with the consumer's needs. Basically, there are two types of Javanese herbalists: (i) Those who compound, prepare and sell fresh *jamu* materials, and (ii) Those who compound and sell dried *jamu* materials. As the community has long been aware of these herbalists' skills in compounding *jamu,* it uses their blended *jamu* for specific illnesses. Yogyakarta's case will provide an insight into their roles.

Case 3

A 60-year-old mother runs a small kiosk at the roadside in front of Yogyakarta's market. Usually she sits calmly on a dilapidated wooden chair and sometimes she stands in her kiosk talking to prospective customers in her warm and friendly voice. Various dried herbs lie in small containers inside partitioned wooden boxes in the kiosk. The materials include *temulawak, mesoyi (Crytocarya massoy Kosterm), kayu legi (Glycyrrhiza glabra), adas (Foeniculum vulgare)* seeds, turmeric and *temu ireng*. Some are stored in neatly arranged jars of various sizes on a rack attached to the wall. On the floor may be seen several brown paper bags containing stocks of *jamu* materials. A woman accompanied by her 15-year-old daughter comes along and a friendly conversation ensues. The woman wants to buy *jamu* to treat her daughter for dysmenorrhoea (severe pain during menstruation). Holding the girl's hand and stroking her hair, the *jamu* seller asks her a few questions regarding her complaints, which the girl answers shyly. After skilfully getting her answers, the herbalist takes a pinch of *jamu* powder from the wooden boxes and jars. After completing the compound *jamu*, the herbalist hands it to the mother with some instructions on how to administer it. The mother pays her some money.

Soon after, a young woman comes to the kiosk. The two hug each other, and have a long, friendly chat occasionally punctuated with laughter. They seem to be aunt and niece. The niece also sells *jamu* (*jamu gendong*) in other cities. She wants a stock of materials, including *jamu pahitan*, for the next three months. She notes these down on a piece of paper, and arranges to collect them the following day.

Not far from this kiosk, in a corner of the traditional market, many mothers in typical Javanese attire guard their merchandise, some of which is lying in *tampahs*[m] and some in bamboo baskets. They sell fresh *jamu* materials and their staple stock comprises various leaves, radishes, varieties of lemon, something wrapped in banana leaves, and various rhizomes. Some of the sellers are busy serving their customers. A middle-aged woman asks one of them for *jamu* for the postnatal care of her daughter. The *jamu* seller asks when the delivery took place, quickly fills a small plastic bag with certain leaves, rhizomes and radishes. She also picks up some lime and three lemons. She then explains how to clean and boil these materials, and tells her that their concentrate should be given orally for postnatal care. She advises the woman not to throw away the residues as they can be percolated again the following day. Lime and *nipis* lemon are

[m] *Tampah* is a circular and flat bamboo container.

used as *bobak perut* [n] for postnatal care. After the *bobok* has been applied, the abdomen should be twisted with a *bengkung.*[o] The mother pays and leaves. Shortly afterwards, a young mother in modern dress comes to buy *jamu* for body odour. The *jamu* seller takes out *beluntas* leaves, turmeric, tamarind leaves and some red sugar and asks the lady to boil these at home. Many other buyers who purchase *jamu* materials without asking for compounding can also be seen.

Chinese herbalist (*sin she*)

A *sin she* is a Chinese herbalist skilled in compounding *jamu,* as well as performing acupuncture and acupressure. Usually he compounds his *jamu* on his own, or asks the patient to make the *jamu* according to his recipes. A *sin she* does not always provide the *jamu* himself; instead, he often jots down some in Chinese on a piece of paper, like a medical prescription. The customer has to buy the material from a Chinese drug store. The following is a detailed account of how a *sin she* practises.

A *sin she's* practice is relatively more formal. His name and hours are written on a board outside his clinic. *Sin she's* practise mostly in big cities. The room in which a *sin she* practises is like a physician's clinic, complete with a waiting room and an examination room. An attendant admits patients and is in charge of the administrative procedures. Examination is conducted according to traditional Chinese medicine methods, i.e., by anamnesis (asking about the patient's complaints and symptoms), and checking the pulse at both wrists while continuing with the anamnesis. Many patients are treated with acupuncture or acupressure. For this, the patient has to lie down on a bed in a manner that facilitates the process of puncturing the abdomen, back, legs and hands.

For the sale of compound *jamu,* a *sin she* charges a fee based on the price of the ingredients. This charge is higher than that of other traditional healers, as some materials are imported from China.

Jamu based on Raw Material

Indonesia is a tropical country with forests containing thousands of small and large plants, and several species of animals. The country's natural resources, as well as its cultural and ethnic variety, have had an influence on the way traditional medicines are prepared. Plants (herbal medicine), animals and minerals are all used in the preparation of traditional medicines.

Jamu from plants (herbal medicine)

Nearly all kinds of *jamu* produced by big *jamu* industries, small-scale home industries and herbalists are made from medicinal plants (herbs). There are about 940 plant species that have therapeutic effects, but the *jamu* industry uses only about 200 species. In general, the plant species used as *jamu* in different parts of Indonesia are the same. However, some areas have their own specifications in this regard, e.g., *kayu pasak bumi* (earth wooden pike) is used only in Kalimantan.

The *jamu* made by both industries and herbalists usually utilizes a number of plant species; rarely is just a single plant used. The number of plant species used for a particular kind of *jamu* usually ranges from 5–10. Certain *jamus* contain 30–40 species. Home-made *jamu* contains just two to three plant species.[3, 4, 6]

[n] *Bobok perut* consist of abdominal lubricants.

[o] *Bengkung* is a long cloth, about five metres long and 15 cm wide.

Jamu from animal materials

Jamu made from animal materials is not as popular as herbal *jamu*. These remedies use substances from the cobra, lizard, house lizard, molluscs, earthworm, *gabus* fish and other creatures.[9] The animal can be captured from its natural surroundings, or procured from the markets. The trade in animal remedies is not flourishing as well as that in herbal medicines. Animal medicines may be more easily obtained from Chinese drug stores than the regular markets.

Lizard and house lizard

The house lizard can be easily found in dwellings or trees while other lizards may be found in the bushes or grass near the house, in a garden, or in a paddy field. Both are used as remedies for *Tinea versicolor*, fungal skin infections, eczema and other skin problems. The medicine may be taken orally or applied externally. For external use the animal's flesh is crushed and applied to the affected area for 10–15 minutes, after which the skin is cleaned. For oral use, the lizard is baked until it is charred black, ground to a powder, mixed with some coffee and diluted with water.

Cobra

The cobra is a poisonous snake whose bite can be fatal. Cobras are found near swamps, in paddy fields, or in the underbrush. Cobra remedies are well-known in the big cities of Indonesia. All parts of the snake's body are used for medicines. Cobra blood is believed to enhance the sexual potency of men. The uncooked bile and spinal cord, mixed with special herbs, are considered beneficial for diabetes, high levels of cholesterol or uric acid, cancer, asthma, malaria, skin problems and general physical fitness. The cobra's flesh is cooked and served by food vendors or in restaurants. It is also sold in a dried form.

Cobra remedies are sold in kiosks along the streets of Surabaya. The vendors, who know how to prepare medicines out of the cobra blood, bile and spinal cord, get live cobras from East Java. The preparation involves the use of *arak* (alcohol), other herbs and honey. There are many cobra consumers, as can be seen from the fact that, on an average, a cobra seller can sell up to 20 cobras a day.

Molluscs

Molluscs are considered a plant pest by farmers as they consume the leaves of plants rapidly. However, they can be used for the treatment of certain illnesses. For example, they can be of use in clearing the respiratory tract of mucus (mucolytic), treating oedema, pharyngitis and haemorrhoids and as a diuretic. The transparent liquid of a mollusc, obtained by cutting the small pole of its shell, can be used as first aid for fresh wounds.

Earthworms

Earthworms loosen the soil and are found in the earth in pots, yards or gardens. They are used to treat several ailments. For example, the rural population drinks the blended, dried and fried oil of the worms to treat fever due to typhoid. Chinese drug stores sell dried and processed worms which they claim have a beneficial effect on patients with breast tumours, nose polyps, headaches and hypertension. Earthworms are also used as diuretics.

Jamu from minerals

Minerals are not often used as *jamu*. *Tawas* (hydrated alumni kali sulfas) help relieve body odour, while sulphur powder is commonly used for treating skin diseases. In certain areas, women consume *ampo*,

i.e., soil that is water-blended, then dried and cut into slices, as it contains iron. Lime is used as *bobok,* i.e., to lubricate and warm the abdomen of postnatal women.[6]

Other Traditional Practices

People opt for traditional healing techniques for a variety of reasons. The major reasons are that they are accessible and acceptable in social, cultural and economic terms. The other benefits are that traditional healers make home visits, without charging any fixed fee. Another reason is the inadequacy of modern medicine in treating certain cases, such as cancers at an advanced stage, or irrational ailments like *santet* or *tenung.*[p] The community learns of the existence of traditional healers by word of mouth, though these days magazines and newspapers also carry advertisements and information on the subject.

Traditional practitioners in Indonesia have acquired their knowledge and skills not through formal education, but from their parents. Some learn while assisting established practitioners, some of whom teach their skills to just one or two trusted persons. A few healers claim to be graced by *wangsit,*[q] which comes to them either through dreams or after performing "special deeds", such as fasting, abiding by certain taboos, or living in seclusion.

Many traditional healing skills, however, are mass taught through an informal process. These include acupressure, *urut* massage,[r] acupuncture and the skill of compounding *jamu* either for males or females. The age of the pupils ranges from 20 to over 60 years. While some have acquired higher levels of education, most are in elementary school or junior high school, and some have received no formal education at all.

According to traditional perspectives, diseases may be categorized as rational and irrational. The former are believed to be caused by the disturbance of homeostasis, such as an imbalance in nutrition. Irrational diseases are said to be caused by mystics. Supernatural/magic healers, who believe in the existence of such ailments, often cure the latter, as well as certain strange problems, such as the removal of nails, stones, iron and other objects embedded in the abdomen.

Traditional healers usually do not have a special room in which to examine their patients. In fact, they do not have a name board, fixed hours or fees. Most of them practise on a part-time basis, though some who are well-known do work full-time as traditional healers. The latter have many patients, which can be seen from the long queues of patients awaiting consultation. Some have in-patient facilities to complement outpatient services. A traditional healer often combines a number of traditional techniques, like massage and *jamu*, magic treatment and *jamu*, and so on.

The following section focuses on traditional healing practices that are commonly used by the community, such as traditional methods of bone healing, attending to deliveries, *kerikan* and circumcision.

Traditional Bone Setting

Almost all ethnic groups in Indonesia have traditional bonesetters (TBSs), who thrive both in urban and rural areas. These

[p] *Santet* or *tenung* is believed to be an ailment caused by black magic.

[q] *Wangsit* is God's revelation.

[r] *Urut* massage is a type of traditional massage to relax the muscles.

healers honour certain ethnic concepts in their practice. In Java, the TBS is commonly referred to as *sangkal putung.* These healers can help cure any kind of complaint related to bone fracture (e.g., complete, incomplete or multiple fracture), joint dislocation, as well as muscle sprains. The reason why people choose TBSs is because they are easily accessible, both in terms of expense and distance, as well as to avoid invasive surgical procedures.[10]

Of the traditional bone-setting techniques, some are purely traditional while others attempt to incorporate certain modern techniques.[3, 10, 11] The procedure is as follows. A specific *mantra*[s] is chanted to a patient or he is given a drink which is treated by chanting *mantras*. Some healers use charms, like a stone or a *keris.*[t] The patient is asked to drink water into which the charm has been dipped. It is believed that through the medium of drinking water, the prayer or charm would help relieve the ailment. A TBS does not ask many questions. By simply observing the fracture and touching it physically, he identifies the exact problem. Many healers say that their feelings guide them in determining the specific problem and the method of handling it.[11] This faculty of feeling is said to be acquired through special deeds.

To convince the patient and her/his family about his diagnosis, the healer often employs a symbol. For instance, to demonstrate whether or not the bone is fractured, the healer feels a banana and if the flesh is found to be broken, it means that the bone is fractured.[11] Some, however, utilize modern techniques such as X-rays.

Some healers, especially those living in cities, treat a fracture with modern techniques, medicines and materials, like betadine, rivanol, alcohol, sterile gauze and cotton. Patients with open fractures are referred to the local health care centre. Some healers even have informal partnerships with nurses practising in the local institution.

The pattern of treatment used by different healers is similar. The difference lies only in the way they express their supernatural or magical powers, e.g., in the kind of *jimat* (charm), special oil or special water used. The processes of treatment and diagnosis are simultaneous. For example, by uttering special prayers (*mantra*), the healer diagnoses as well as fixes the fractured bone. Joint dislocation is managed by pressing, pulling and massaging the affected area. The manner of handling the problem depends on individual cases.

To heal a fracture, the areas around the site of fracture are first massaged in order to relax the muscles. The bone is then repositioned and aligned correctly. This is followed by continuously massaging the area with a special oil. During the process of treatment, the patient is asked to move the injured part, which is then pressed again. The materials used to secure the area are hardboard paper, the stem of banana leaves, bamboo or wood, though modern TBSs use elastic bandages. Whatever the material used, the dressing is opened every three to four days to assess the alignment. The patient then receives another massage. In-patients are given a daily massage.[11]

The effectiveness of the traditional healing process is judged more by the extent to which it meets the expectations of the patient and his/her family. Psychological support is also considered

[s] A *mantra* is a special prayer based on traditional beliefs.

[t] *Keris* is a traditional Javanese weapon.

important. A patient is considered to have recovered if he is able to move the injured part or walk, even if movement is painful or unsteady. However, some healers define recovery as the ability to perform in a normal way. The extent of recovery may be assessed by asking the patient to lift weights; if no pain is experienced, it signifies recovery.

Traditional Birth Attendants

Many deliveries in Indonesia are still assisted by traditional birth attendants (TBAs), who may be either trained or untrained. TBAs practise under the supervision of health centre personnel, namely midwives. A programme to staff villages all over the country with midwives was launched with the aim of providing mothers access to professional help for deliveries.[12] TBAs are expected to assist these midwives. Though the Government is trying to prevent the proliferation of TBAs, this is not possible as the community still seems to need them.

Some communities prefer TBAs to midwives. One reason for this is that the TBA is one of the local people, and thus understands the local culture and is already familiar with members of the community.

TBAs not only assist with deliveries, but also render certain other services. For example, they take care of women all through pregnancy and advise them about the norms to be followed during this period. TBAs provide *jamu* as well as massages to relieve fatigue. A special massage is done to fix the foetal presentation, if necessary.[(13)]

As deliveries are natural events, the techniques used by most TBAs are similar. They simply wait through the process of delivery, until the baby is born naturally. Some untrained TBAs still use traditional tools, like bamboo knives (*welat*) to cut the umbilical cord. Crushed pepper leaves or *kunyit* together with salt is applied to the pole of the umbilicus.[13] Some of the more daring TBAs go a step further to facilitate problematic deliveries. For instance, they may push the abdomen downward in difficult cases, or grope inside the uterus to disentangle the placenta. TBAs perform special ceremonies or chant prayers (*mantra*) during the process of delivery.

TBAs make daily visits to the mother's house to take care of her and the baby, for 35–40 days after delivery. They bathe the baby, massage both the baby and the mother, and also help prepare for birth ceremonies. The placenta is bathed and several *uborampe*[u] are made to it. It is then buried in front of the house, and the spot is lit by a lamp at night. A ceremony is performed when the dried up umbilicus is severed from the baby's stomach. Such ceremonies are performed at every step in the baby's growth. Apart from taking care of the baby and the mother, TBAs also help in household work, like washing the baby's clothes, preparing *jamu* for the mother, and so on.[13]

Traditional Circumcision (*Khitan*)

Since most Indonesians are Muslims, circumcision is obligatory for male children. Traditional circumcision is practised widely in Indonesia, the demand for it arising from the belief that the prayer performed during the ceremony has a healing power. It is also believed to have certain other advantages, e.g., the child is said to experience less pain and fear, and the healing process is faster.

The skill of performing traditional circumcision is learnt from parents or family members who know how to do it. To be a *khitan* practitioner, one needs to

[u] *Uborampe* are offerings.

perform special deeds, in accordance with certain Muslim norms. These deeds include fasting for 40 days, and going without a meal for 24 hours on the last day. The person can only drink water at the time of *Maghrib.*[v] For a traditional circumcision, either the practitioner goes to his patient's house, or the patient comes to him.

The techniques used for *khitan* do not vary much—basically, the practitioner cuts the prepuce of the penis. In the purely traditional technique, the prepuce is held in place by a clamp of wood, bamboo or tusk, and then cut with a sharp knife. No local anaesthetic or medicine is used. The patient is merely given water before the procedure. However, nowadays most practitioners use modern medicines and tools, like scissors and modern knives.

Antiseptics like rivanol, betadine and alcohol, and materials like cotton and gauze are used. A few practitioners prescribe antibiotics to prevent infection and analgesics to relieve pain. The following is an account of a traditional circumcision:

The boy who is to go through *khitan* is given a new sarong, white shirt and cap by his parents. After the son is ready and all the preparations have been made, the practitioner begins the process. After chanting a special prayer, he clamps the prepuce of the penis and cuts it quickly with a sharp knife. The wound is dressed with gauze. The boy then wears the sarong, shirt and cap. To prevent the wound from touching the sarong, a supporting wooden frame is used, in the ventral surface of the lower abdomen. Purely traditional practitioners used only prayers or *mantras* for pain relief and recovery.

One ethnic group in East Java, which believes in traditional circumcision, has a different custom. The *khitan* practitioner is asked to cut off a small part of the prepuce before the doctor or the nurse is asked to complete the procedure. This is perhaps explained by the belief that it is only a *khitan* practitioner who can perform the prayers properly, so he should initiate the process.

The Practice of *Kerikan*

The practice of *kerikan* is well-entrenched in Indonesian society, especially among the people of Java. The word *kerikan,* which has its roots in the Javanese language, means to peel off or remove a surface layer that is unwanted. Thus, *kerikan* is a healing technique which consists of scraping the affected area of the body. It could be the chest, back, abdomen, neck, arms or legs. Usually, coins and spoon-holders are used for scraping, complemented by the use of herbs like onions and *kajuputi* oil.[14] *Kerikan* is commonly used as a first-aid method during illnesses. Generally, it is quite effective in providing relief from the symptoms of non-infectious diseases. Traditionally, it is believed to be very effective for *masuk angin.*[w] *Kerikan* may be used to treat almost all people, from a one-year-old child to an elderly person. *Kerikan* can cure children of abdominal distension, cough and laboured breathing, nausea and vomiting, diarrhoea, and fever. Adults use *kerikan* to obtain relief from toothache, intercostal ache, chest pain, backache, acute oedema, insomnia, fatigue, headache, fever and other complaints.

A family member of the patient performs the procedure. The scraping is

[v] *Magrib* is Muslim evening prayer (done at sunset).

[w] *Masuk angin* is an illness characterized by fatigue, nausea and vomiting, headache and muscle pain. It is sometimes accompanied with fever.

done over the affected part of the body. Frequent and continuous scraping makes the skin turn a specific colour and produces erythematous stripes. It is believed that the degree of redness reflects the severity of the illness. The redder the skin, the more severe the ailment. Inexplicably, the patient feels more comfortable. During the process of *kerikan*, the patient does *uwat.*[x] This movement would stretch the muscles, which in turn would improve blood circulation and help the body reach homeostasis. All these are ways of effecting a recovery.[14]

The patient could undergo *kerikan* in a sitting or supine position. To enhance the effect of the procedure, a number of oils like coconut or *kajuputi* oil, or analgesic balm are commonly used. *Kerikan* should be done as follows. The coin should be used with a strong but smooth pressure. On an average, one stripe of *kerikan* is produced after 20–30 strokes of scraping. A good tool for scraping is one that is blunt but is able to produce deep pressure, so that it can reach the deeper muscles. *Kerikan* should be done thoroughly and sequentially in a proper order, over the skin surface. The sequential procedure is known as *tapis*. The direction of scraping should follow the bundle of the muscle, called *turut* (meaning to follow) so that the target points can be located. Warm oil is commonly used after *kerikan.*

The Practice of *KOP*

The method of *kop* is similar to *kerikan*, but the tools used are different. In *kop*, the skin of the affected part of the body is sucked upwards to produce an erythematous effect. This method is employed in some areas, like Lombok, Madura and East Java. The tools used are varied and include a buffalo/bull horn, coconut shell and rubber *kop*.

To begin with, the inside of a coconut shell or a buffalo horn is heated, for example, by a candle. The concave surface of the shell is then applied to the skin of the affected area. Due to the negative pressure, the shell sucks in the skin. The shell is removed once the negative pressure ceases. The process results in a circular erythematous protuberance. A more modern technique consists of using a kind of pump that can suck in the skin without the use of heat.

The Practice of Traditional Massage

Massage therapy is practised everywhere in urban and rural areas. The therapist could be a male or a female, usually above the age of 40 years. Massages can be of two types, *urut* massage and reflexive massage. A masseuse learns the skill either from other masseuses, by attending a course, through trial and error, or from books.

Urut massage is beneficial for fatigue, myalgia, cough and muscle stiffness.[14] The whole body is massaged, with the focus on the affected areas. Women and children are given massages by females and men by males. *Urut* massage includes the massage given by TBAs to postnatal women and babies. Fussy babies are frequently taken to TBAs for this purpose,[4] as it is believed that fever and fussing are caused by muscular problems. A mother can ask the TBA for *walik dadah.*[y]

Reflexive massage focuses on particular points in the palm of the hand

[x] *Uwat* means writhing, which occurs because of pain, ticklishness or the sensation of heat.

[y] *Walik dadah* is a massage to change the position of the uterus into one of retroflexion with the aim of preventing pregnancy.

and the sole of the foot. This type of massage, believed to have originated in Egypt and China, is very popular in Indonesia. The technique used is similar to that of acupuncture. While some reflexive masseuses use their hands to give the massage, others use a special tool, like a wooden or a metal stick.

Reflexive massages can be given to people of all age groups. A person can learn the methods on his own, then attempt to try them out and practise them. Malfunctioning organs can be identified by examining certain points in the palm or sole, the assumption being that specific points are associated with different body parts, like the intestines, spleen, pancreas, heart, and so on. It is believed that reflexive massage can help treat all diseases, including infectious diseases, because it improves the immunity status of the patient. According to the doctors who practise reflexive massage, this kind of massage enhances general fitness, relieves depression and is of benefit in other emotional ailments.[3, 4]

The Practice of *Timung*

The technique of *timung* used for therapy or body care, employs steam enriched with various herbs. Traditional *timung*, which originated in Kalimantan, focuses especially on body care, including skin care and preparing the bride for marriage. *Timung* can be practised for the same purposes by family members at home. The herbs required are available in the market. Many fitness centres in the cities offer *timung*. It is claimed that besides improving fitness, the technique also relieves a number of ailments, like common cold, rheumatic complaints, fatigue, and so on.

A person who wants traditional *timung* care is first undressed and seated on a chair, covered with mats made of *pandan* leaves. Under the chair is a pan on a lighted stove. The pan contains several herbs and boiling water. The steam, which contains the essence of the herbs, warms the body. The steaming process lasts for about half an hour. The technique is often combined with massage.

Therapy of *Gurah*

Gurah is a therapeutic technique that uses special extracts of herbs to clear the nasal cavity and pharynx of mucus. It is claimed that *gurah* benefits asthma, rhinitis, common cold, haemoptysis and pertussis.[15] The technique is believed to have originated from *pesantren.*[z] Its original aim was to improve the quality of the voice of those who read out the Koran. However, these days people of all kinds use the technique in many areas of Java. According to a *gurah* practitioner in Central Java, anybody can learn the technique.

The *gurah* method is very simple. The healer instils a special liquid into the patient's nostrils. The liquid is prepared by the healer and contains certain herbs, of which the common ones are *Srigunggu (Clerodendron javanicum)* or *Awar-awar (Ficus septica*) leaves and turmeric. Honey is also used. The extracts of the herbs are diluted to a weak concentration. The patient lies supine with the neck bent backwards. The liquid is then instilled into the nostrils for about three to five minutes through a funnel made of banana leaves. The composition of ingredients is adjusted according to the patient's condition. The process heats up the nasal cavity and the mucus flows out automatically. When the mucus is being discharged, the patient has

[z] *Pesantren* is a place where people learn how to read the Koran, the Muslim holy book.

to either sit up or lie on his stomach. He remains in that position until the mucus stops dripping. This therapy is often combined with *jamu* remedies, and sometimes with massage.[15]

Therapy based on a Religious Approach

As a majority of Indonesians are Muslims, therapy based on the religion of Islam is fairly common. This approach is commonly mistaken to be similar to a supernatural one, as the methods are similar. In the religious approach, based on Islamic teachings, the healer advises patients to perform special prayers or deeds.

The clients need not fulfil any special prerequisites to avail themselves of such therapy. The prayer and *ibadah* (deeds to come closer to God) vary depending on individual needs, particularly the kind of ailment. Commonly, the patient is asked to drink water that has been sanctified by the chanting of special prayers. Some healers write Arabic letters on a plate, then fill it with water and ask the patient to drink it. Other healers give the patient a piece of paper or cloth with Arabic letters printed on it, which the patient must keep in a certain part of his/her house to guard the family.

A religious healer is usually the leader (chief person) of *pesantren*, or men who are learned in Muslim teachings (*Kyai*). Usually, he requires no training to give therapy and his capacity to heal is seen as God's blessing. Such healers often help people deal with family issues arising from health problems. In fact, some *pesantren* help drug abusers and treat psychological ailments.

Supernatural or Magic Therapy

As mentioned earlier, irrational diseases are believed to be caused by some source of magic. Many magic healers have opined that certain diseases are caused by something that is rationally unacceptable. An ailment can result from the curse of a rival who has hired a black magic practitioner (*dukun santet*) to harm the subject. It is quite common for magic healers to remove strange objects like nails, stone and iron which may be embedded in the patient's abdomen or some other part of the body.

A magic healer sometimes uses certain tools as a source of magic power. A number of charms are believed to possess magic power that can help in the process of healing. These include the eye of finger rings, a special bark called *pring temu rose* (meetingros of bamboo), *keris*, a piece of cloth with Arabic letters printed on it, and soil wrapped in white cloth. Only magic healers possess such articles, though some give the patient a portion of it to guard him.

Therapy for removal of tumours

Cancer is one of the most dreaded diseases. People seek cures from magic/ supernatural healers because treatment involves invasive procedures and they are suspicious of modern medicine or find modern treatment unaffordable. The following techniques are used by healers to remove tumours.

Case 4

A traditional practitioner called "Gus" (the nickname for a son of *Kyai*, or a man whom people respect) is believed to heal patients with his supernatural powers. Not only can he remove tumours, he can also cure many diseases, like paralysis and psychosis. In fact, he even helps in solving problems that are not related to health. His technique for removing tumours is totally different from those used in modern medicine. Gus first uses a knife to cut open the tumour but,

later, he uses only his fingernails. The excised tumour is handed over to the patient. The wound is dressed with gauze or cotton. No antiseptic is used.

Gus does not charge a fee, but patients may contribute voluntarily, for which the healer provides a box. He has many pupils who learn the Koran from him and, at certain times, they chant prayers together (*isthighosah*). However, Gus does not impart his therapeutic technique to his pupils, though they help him in curing his patients.

Another kind of supernatural healer is one who is able to remove tumours without touching the patient. After registration, the patient writes out his/her complaints on a piece of paper, which is handed over to the healer. The healer sends the paper back to the patient after writing (in Javanese) about the disease, the procedure to be followed and the fee. If a patient agrees to these recommendations, he lies down in a supine position while the healer goes up to the second floor of his house. The healer later comes down and gives the patient a brief glimpse of a lump of bloody flesh, said to be the removed tumour. If the patient desires, he can ask a doctor for an ultrasonographic (USG) examination. Besides removing tumours, the healer prescribes *jamu* remedies or recipes which are available in drug stores.

Women healers in the rural areas of East Java use a different technique. They remove the tumour by sucking the area with the mouth. If the tumour has been successfully removed, the healer brings out some bloody flesh (supposed to be the removed tumour) from her mouth. Such healers also provide complementary *jamu* remedies.

Another technique consists of displacing the tumour from the patient's body into another creature (animal). A traditional healer in Tuban, East Java, claims to have the ability to displace the tumour into a goat. Either the patient or a member of his family visits the healer and tells him about the problem. After understanding the disease, the healer asks the family to buy a goat and bring it to him. He performs certain ceremonies and utters a *mantra,* after which the goat is slaughtered. The goat's organs are checked to ascertain whether the patient's disease has been transferred to the goat. For example, in a case of hepatoma, the liver of the slaughtered goat would show signs of hepatoma, such as a lump or a change in colour. The diseased portion of the organ should be thrown away, while the healthy portion may be cooked and eaten. If the cancer is in too advanced a stage, the healer usually admits his inability to cure it.

Therapy of *susuk*

Susuk is one or many small rod/s, commonly made of copper or gold, though some healers use diamond. The *susuk* is implanted in a certain part of the body to keep it healthy. Before a *susuk* is implanted, the patient is advised to fast for two nights and days. But some traditional implanters feel that they themselves can take over this deed. Some others do not lay down any conditions. If the person implanting the *susuk* is not an expert, or if certain prerequisites are not fulfilled, the procedure is believed to have unexpected consequences, such as death. Some believe that the untoward consequences can be prevented by rubbing *kelor* (*Cucumis sativus*) leaves on the body of the user.

It is said that the skill of implanting *susuk* is acquired by performing certain deeds, like performing *ngebleng.*[zz] The kind of *susuk* to be implanted depends on

[zz] In *Ngebleng* fasting, a person must go without food or drink, for a number of days.

the client's demand. The fee varies, depending on the kind of metal used. The more expensive the metal/material, the more potent the effect of the procedure.

The technique of implantation seems fairly easy. The implanter inserts the *susuk* into a specific part of the body after wiping the skin and then rubbing it with pepper leaves. The *susuk* may become less potent or lose its potency altogether if the client breaks certain taboos. The presence of the *susuk* in the body can be ascertained by an X-ray.

Therapy using inner power

Therapy with inner power is a technique which utilizes energy emitted by the human body. Such energy is acquired by regulating respiration or doing respiratory exercises. With regular exercise and by abiding by a number of basic principles, one can accumulate inner power and use it to treat others. Inner power is said to heal several diseases like diabetes, hypertension and cancer. It is also used for non-therapeutic purposes, like protecting the body from real or magic assault.[16]

This type of therapy can be of the active or passive kind. In active healing, the healer uses his own inner power to treat patients, while in passive healing the patient obtains inner power from the healer. A healer treats a patient without touching him. The energy emitted from the healer's hands enters the area to be treated. An expert healer is said to be capable of curing patients who are far away, with or without a medium. The medium could be a photograph, or any possession of the patient. For example, a healer in Indonesia can cure a patient in the US. The technique is also used for curing magic ailments, like removing nails from the stomach. The nails would be expelled from the body automatically by vomiting.

In Indonesia, there are many groups of inner power practitioners, such as the Satria Nusantara group. In fact, some have branches overseas. The major focus of the members of these groups is on maintaining and improving their health; only a few utilize their expertise to treat patients. The respiratory exercises can also produce supernatural powers, which lighten the body and make one capable of accomplishing various feats. For example, an expert becomes so light that four persons can lift him if he stands on a newspaper. One can even see or read with his eyes closed.

Conclusion

These traditional practices of medicine are just a few of the many currently in use in Indonesia. Several methods or techniques, with their variations, have not been discussed in this paper. These traditional practices stand testimony to Indonesia's rich cultural heritage.

The safety and efficacy of the techniques used in the traditional system of medicine are questionable. Most of the traditional practices have not yet been studied systematically by modern science. However, it is beyond doubt that they serve a large portion of the Indonesian population. Any effort to do away with such practices would be unsuccessful, as these forms of health services have their own markets. The Indonesian Government's effort to promote and develop traditional medicine into a safe and effective option is a good policy, which could contribute towards achieving greater equity in health services.

References

1. Ministry of Health, Republic of Indonesia. *The rule codification of traditional medicine. Part I*. Jakarta: Directorate General of Food and Drug Control. 1994.
2. Suparto H. *Jamu*, an inherent traditional medicine. *TOGA.* 2000. 2:27.
3. Salan R. et al. *A study on traditional medicine practices (workshop).* Jakarta: National Institute of Health Research and Development. MOH. Republic of Indonesia. 1989.
4. Handayani L., et al. Madura herbal medicine inventory of women's reproductive remedies. *Bulletin of Health System Research.* 1998. 2(1):40–45.
5. Handayani L., Suharti S. Traditional medicine small-scale industry in Madura. *Medika No.5.*1999. XX:290–295.
6. Suharmiati. et al. *Guidance for health cadres. Introducing and the usage of medicinal plants for family health care*. Surabaya: Health Services and Technology Research and Development Center. 1996.
7. Suharmiati, Handayani L. *Study on quality of handling jamu gendong* (research report). Surabaya: Health Services and Technology Research and Development Center. 1998.
8. Handayani L. Suharmiati. The microbiology test of *jamu gendong*. *Medika No.7.* 2000. XXVI:424–428.
9. Maryani H. Raw material from animals. *TOGA.* 2000. 4:30.
10. Notosiswoyo M. *Research on traditional bone healing in Cimande*. Jakarta: Center of Noninfectious Research and Development, National Institute of Health Research and Development, MOH, Republic of Indonesia. 1992.
11. Suprapto A., et al. *Study on traditional bone healing* (research report). Surabaya: Health Services and Technology Research and Development Center. 1996.
12. Ministry of Health. Republic of Indonesia. *Guidance of midwives in rural area, Parts I and II.* Jakarta: Ministry of Health. 1989.
13. Handayani L. et al. *Leading to comprehensive delivery services*. Yogyakarta: Gajahmada University. Report series 70. 1997.
14. Krido Wiyoto S.S.K. *Traditional medicine practices using massage, kerikan/kerokan and jamu*. Pekalongan: Bahagia. 1982.
15. Masruri. *The secret of gurah therapy*. Solo: CV Aneka Solo. 2000.
16. Safriyanur. *Treatment of Satria Nusantara inner power guidance*. Surabaya: Health Services and Technology Research and Development Center. 2000.

Koryo system of medicine in DPR Korea

Choe Thae Sop

Although the *Koryo* system of medicine has some similarities with the traditional system of Chinese medicine, it is quite different from the Ayurveda, Siddha and Unani systems prevalent in India.

The theoretical basis of *Koryo* medicine (KM) is recorded in detail in the ancient medical classics of Korea.[1]

Materia medica

The *materia medica*, the main part of the medical classics published in a wooden edition in the 15th century in Korea, described medicines as being divided into three types – those derived from vegetable, animal and mineral sources.

The classification according to the mode of action and use is similar to that of modern medicine, and includes antipyretics, antidotes, antitussives, digestives, astringents, diuretics, and so on. However, it has some additional traditional categories, peculiar to KM, such as interior-warming drugs, drugs for eliminating dampness and drugs for regulating *Ki*.

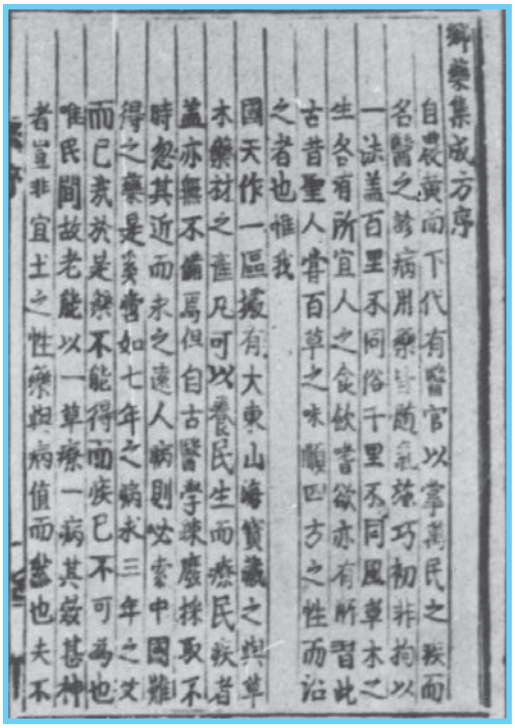
The description of each drug includes the forms of the various medicinal plants, cultivation and picking period, the parts that are used, processing methods, properties and flavours, efficacy, scale of use, toxicity, compatibility, dosages and administration. The action and efficacy of the drugs are explained on the basis of the peculiar theories of KM, while the scale of use (indication) is determined by considering the symptoms or syndromes as the main target of treatment.[1]

Hyangyakjipsongbang (85 volumes), a classic *materia medica* published in DPR Korea in 1443 AD,[2] contains a description of 694 kinds of plants growing in the country, as well as 10,706 prescriptions for the treatment of 955 symptoms.[3]

In the preface to the book, the author says: "Thanks to the limpid water and beautiful mountains, my country has unlimited resources of medicinal plants. But there are those who disregard their own resources out of admiration for others' and strive to get drugs from far-away, alien lands, even though they are available in any quantity in their own country." Saddened at this lamentable situation, the author stresses that for treating diseases, one should use medicinal plants growing in one's own country.[1, 2]

Acupuncture

According to the existing source materials, needles made of sharpened stone were



鄕藥集成方序
自殷黃而下代有醫官以掌萬民之疾而
名醫之診病用藥皆隨氣運巧拙非拘以
一法蓋百里不同俗千里不同風草木之
生各有所宜人之食飲者欲亦有所習此
古昔聖人嘗百草之味驗四方之性而治
之者也惟我
國天作一區擁有大東山海寶藏之與草
木藥材之產凡可以養民生而療民疾者
蓋亦無不備焉但自古醫學疎廢採取不
時恐其近而求之遠人病則必索中國難
得之藥是奚啻如七年之病求三年之艾
而已哉於是無不能得而疾已不可為也
惟民間故老能以一草療一病其效甚神
者豈非宜土之性藥與病值而然也夫不

A part of the preface of *Hyangyakjipsongbang*, which was written with a writing brush in block letters in 1443 AD.

used for the treatment of diseases for several centuries.[4] From the specialized book on acupuncture or the sections on acupuncture in various classics, it is evident that acupuncture had already been established as a scientific system of medicine.[1]

The general introduction to the acupuncture section of *Tonguibogam,*[(5)] a typical medical classic, describes the methods of making needles, seasonal acupuncture, the selection of acu-points, application of moxibustion, acu-moxa combination and the stimulation intensity of acupuncture and moxibustion, etc. This section contains a systematic description of the circulation course of the 14 meridians, the 365 acu-points on each meridian, selection of acu-points, indications, contraindications, application of acupuncture and moxibustion, as well as the theory of meridians.[1,5]

Clinical aspects of Koryo medicine

The medical classics published in DPR Korea before the 17th century include manuals addressing the clinical aspects, as well as systematic and specialized books on internal medicine, surgery, gynaecology, etc.[1]

Uyebanryuchwi,[6] a comprehensive medical classic published in the country in 1445, has the value of a great encyclopaedia. The book, consisting of as many as 365 volumes, contains a compilation of the material from 153 medical classics published before the 16th century at home and abroad, and a systematic presentation of the contents, which are divided into different categories.[1, 6]

Tonguibogam is a well-known classic in the form of a manual which was published in 25 volumes in 1610. One section of it describes the function (physiology) and shape (anatomy) of the five viscera and six entrails, manifestations of the illness connected with them, and the pathological mechanisms involved.

The clinical section contains a detailed description of the causes of various symptoms and syndromes, methods of differentiating these, prognosis, medication (use of a single medicinal plant and herbal prescriptions), the therapeutic methods of acupuncture and moxibustion, their contraindications, etc. The section on diarrhoea alone mentions 20 syndromes, classified according to the shape of the stool, the different factors that induce diarrhoea, the correlationship between diarrhoea and the internal organs and the severity and duration of the illness. It

explains the causes and describes the symptoms and methods of treatment in detail.[5]

Thus, the medical classics that we have inherited from our ancestors include almost all the clinical disciplines, such as internal medicine, surgery, paediatrics, neurology, gynaecology and ENT. These classics are easy to consult because they contain systematic classifications[1,4].

Teaching of Koryo medicine

Koryo medicine is taught at the KM faculties of the medical universities, which are found in each province. The duration of the course is seven years. Koryo medicine is practised mainly in the General Hospital of *Koryo* Medicine (GHKM).

The KM faculties in the country train a number of Koryo doctors annually who are also conversant with modern medicine. The textbook in use teaches the basic theories of KM, acupuncture, *materia medica*, Koryo internal medicine, surgery, gynaecology, paediatrics, ophthalmology, ENT, etc. Each KM faculty has separate departments for each subject and specific lessons are given by the respective department teachers.

In the training of KM doctors, the ratio of KM to modern medicine during the total course is 70 per cent to 30 per cent. Therefore, a graduate from the Faculty is able to diagnose and treat with modern methods and medicines as well.[1,4]

Implementation of the Koryo system

The Ministry of Public Health (MOPH) has an administrative department for KM. This department is in charge of implementing the state policy to develop KM at all levels of the KM health institutions.

Diarrhoea caused by chronica colitis suffered for over 10 years was cured by moxibustion

In the provinces and counties, this task is performed by the health administrative departments of the respective local governments.

Under the aegis of MOPH, GHKM provides the scientific and technical guidance for various KM health networks.[1,4]

Koryo medicine network

The capital and all cities have specialized KM hospitals, and all large as well as small hospitals and clinics have KM departments. The population can receive free KM treatment through various KM medical networks which are evenly distributed all over the country. These networks are national institutions under the MOPH and the local health administration. Their working expenses are provided for in the national budget.

Not a single unit of the private KM health sector is driven by the motive of making money.[1,4]

The combination of *Koryo* and modern medicine is one of the mainstays of the health policy, whereby the State helps in developing KM.

It is also a manifestation of the state's concern for providing the inhabitants with health care of high quality.[1]

Combination of Koryo and modern medicine in the university's regular education system

Medical education in KM faculties is of a seven-year duration where KM takes up 70 per cent of the time allotted and modern medicine systems the remaining 30 per cent. This enables the graduates to attain a certain level of knowledge of modern medicine required for modern methods of diagnosis and treatment.

In the KM faculty, the lectures delivered on the theoretical aspects of KM are just as detailed as the expositions in the medical classics.

The students are taught the clinical aspects of KM, including internal medicine, surgery, paediatrics and gynaecology, as well as the auxiliary ones, such as the *Materia Medica*, herbal prescriptions and acupuncture. As for modern medicine, KM faculties teach basic aspects like anatomy, physiology and pathology, as well as clinical ones like internal medicine, surgery, paediatrics and gynaecology.

Unlike the KM faculty, the seven-year course of the medical faculty gives a weightage of 70 per cent to modern medicine and 30 per cent to KM. This system aims to enable doctors to combine their treatment methods with KM methods. Though KM theories are taught with extreme brevity, more detailed lessons are imparted on the methods of KM treatment, including acupuncture and herbal medication.[1,4]

Combination of Koryo and modern medicine in the re-education system

A six-month re-education course is conducted in the re-education colleges of the capital city and each province. Those attending are the KM doctors, as well as other doctors who graduate from the KM or medical faculty and have been working for more than five years.

These re-education courses are free of charge, and the doctors continue to receive their usual monthly salary throughout the six months. This course enables them to consolidate their knowledge, learn about new developments, as well as advanced methods of KM treatment. The course covers the latest therapeutic techniques developed both at home and abroad. Greater importance is attached to modern medicine for KM doctors and to KM for other doctors.[1,4]

Combination of Koryo and modern medicine at each level of medical care

At all levels in the hospitals, treatment by modern medicine and KM is combined in a ratio of 7:3. The larger the hospital, the higher the share of the former; the smaller the hospital, the higher the share of the latter. In specialized KM hospitals and each of the KM departments in other hospitals, 70 per cent of the treatment is according to KM methods and 30 per cent according to modern medicine. Generally, the utility rate of chemical drugs is higher in the larger hospitals, where conditions favour their use, rather than in the smaller hospitals, especially in clinics in the rural areas.

For purposes of diagnosis, KM doctors adopt modern methods. No KM doctor uses the conventional method of diagnosing diseases (i.e., by simply feeling the pulse).

Almost all KM hospitals are equipped with clinical laboratories and various diagnostic equipment, enabling KM doctors to use modern methods of diagnosis.[1]

Collaboration between Koryo and modern medicine in research activities

Persons in charge of research projects for the modernization and rationalization of KM are obliged to first study the KM classics on the subject of research. In summing up the project, the researcher first gives an overview of the description in the classic, and then states the findings of his research.

Such research activities are undertaken to either scientifically prove or invalidate the descriptions in the classics. The lectures delivered by Professor Ranjit Roy Chaudhury on the clinico-pharmacological methodologies during his visit to DPR Korea still serve as a programmatic guide for our research activities.[1]

National policy for development of Koryo medicine

The aims of the national policy are:

- To preserve, utilize and develop the national medical heritage – a major objective to which the State attaches great importance;
- To actively encourage medical workers to use KM, a target facilitated by the fact that the country has no regulation that can obstruct its development;
- To do away with the unscientific and superstitious elements contained in the national medical heritage, and assimilate and utilize only the superior ones in public health services;
- To diagnose diseases through modern methods, considering that the conventional method of merely feeling the pulse lacks a scientific basis;
- To decisively enhance the quality of health care in the country by combining Koryo and modern medicine;
- To scientifically explain the real nature of the meridians and the therapeutic mechanism of acupuncture;
- To study the components and pharmacological action of various medicinal plants;
- To use medicinal plants with knowledge of their components and their influence on the internal organs;
- To use the best possible methods of treatment.

The State has allocated sufficient funds for the translation of all ancient medical classics, including three well-known classics which were published in modern Korean from the seventh to the nineteenth centuries. Today, the translated versions are used extensively as reference books in educational, research and medical activities.

In order to discover the best possible methods of treatment, the State actively encourages health workers to gather information on folk cures popular among the country's inhabitants, and to carry out research activities to scientifically establish the efficacy of selected cures.[1,4]

Clinical and basic studies for the development of drugs

Studies for the development of drugs are carried out mainly by the GHKM, the Korean Academy of Medical Science, Institute of Materia Medica and the pharmacological sections of medical universities.

The funds required for these research projects are provided for in the State budget.

A project is proposed at the Science Council of the institution concerned,

endorsed by MOPH, and then carried out. In the GHKM alone, 30– 40 projects are implemented each year. A clinical study is conducted under approved conditions, with a placebo group to adjudge the relative efficacy of the drugs to be developed by clinico-pharmacological observation.

For basic studies, the GHKM puts in considerable effort to identify the components and the pharmacological action of medicinal plants. Studies to clarify the therapeutic mechanism of acupuncture and the real nature of the meridians are also being carried out.

The results of the study are reviewed by the Science Council of the institution concerned.

In the case of a drug, the approval of the MOPH has to be obtained so that it can be used as a standardized formulation. Newly developed drugs which have been standardized are manufactured in the pharmaceutical factories of hospitals as per the requirement of the hospital. If a drug shows really marked benefits, it is included in the State production plan, and is manufactured in the central and local pharmaceutical factories in large quantities.

Newly developed drugs replace existing drugs with similar or inferior action. The latter are then weeded out, and their production and utilization is discontinued.[1,4]

Utility of Koryo Medicine

As a national medical heritage, KM enjoys State protection and its utilization is actively encouraged.[(3,4)] In no other country is the State developing KM with such a high degree of commitment, nor is any other country providing all its inhabitants high-quality KM health care, free of charge.

In spite of the fact that KM is being promoted, it is not well-known all over the world.

In Juche 78 (1989), WHO nominated the GHKM as its collaborating centre for traditional medicine. Since then, it has annually been publishing technical information in English and has distributed it widely to many countries. Especially in recent years, the uniqueness of KM in DPR Korea has become known in many countries through these publication activities, with the financial support of WHO, SEARO.

References

1. Choe Thae Sop (1999). Development history of traditional medicine in DPRK, *Korea Today*, **7**:35–36, Juche 88 (1999).
2. Ro Jung Rye, *Hyangyakjipsongbang*, an ancient classic (85 Vols).
3. Choe Thae Sop (1995). Primary health care and herbal self-medication, *Technical Information*, WHO C.C. for TM, **7**:5–11.
4. Choe Chang Sik (1995). Traditional medicine in DPRK, *Technical Information*, WHO C.C. for TM, **7**:1–5.
5. Ho Jun (1610). *Tonguibogam* (25 Vols).
6. Ro Jung Rye, Yu Hyo Tong et al. (1445). *Ulbanryuchwi* (365 Vols).

Chinese acupuncture-moxibustion

Deng Liangyue

The science of acupuncture–moxibustion is an important component of traditional Chinese medicine (TCM). It is the study of the meridians and collaterals, acupoints, acupuncture techniques, and the laws of prevention and treatment of diseases by acupuncture–moxibustion. Thousands of years ago, ancient Chinese medicine used *bian* stone (needle stone) as an instrument for the treatment of diseases, and then discovered the points and invented special acupuncture instruments. Gradually, the "theory of meridians and collaterals", a system of treatment rich both in practice and in theory, was founded, and has been applied worldwide. For thousands of years, acupuncture–moxibustion has contributed immensely to the growth and health of the Chinese population. Today, even with the rapid development of medical science, it is regarded as an important part of the Chinese cultural heritage.

Since the foundation of new China, the science of acupuncture–moxibustion has developed rapidly due to the attention and support provided by the Government. Numerous studies have been carried out, particularly in the functional mechanism of acupuncture–moxibustion, which has given it a leading role in modernizing TCM. Research on the mechanism of acupuncture analgesia has revealed some sectors of the functional mechanism of acupuncture. These achievements have been internationally recognized in academic circles, and China thereby enjoys a pre-eminent position in this field. In the 1950s, scientific research on acupuncture–moxibustion concentrated on publishing and popularizing the basic knowledge of this science and generally summarizing the clinical practice of acupuncture–moxibustion. In the 1960s, clinical research on acupuncture–moxibustion and acupuncture anaesthesia was carried out. In the 1970s, numerous organized studies were undertaken on the clinical applications and principles of acupuncture anaesthesia and on the mechanism of acupuncture analgesia. In the 1980s, research on the clinical applications and principles of acupuncture–moxibustion and acupuncture anaesthesia as well as research on meridians and collaterals, was brought together in an organized and planned manner. In November 1987, the World Foundation of Acupuncture–Moxibustion Societies (WFAS) was established in China, with its head office in Beijing. Professor Hu Ximin of China was elected president of the First Conference of WFAS. In the 1990s, the science of

acupuncture–moxibustion moved out of China into the outside world and combined with the modern sciences, thus becoming an inseparable component of world medical science. Since the 1980s, the basic theory of acupuncture and moxibustion has included "Research on Meridians and Collaterals " in the special plan of all the major basic research projects of the State (State Climbing Plan). As a result of research during the past half century, the science of acupuncture–moxibustion has taken the lead in modernizing TCM.

Clinical application and research on acupuncture–moxibustion

Clinical application and experimental research has shown that acupuncture–moxibustion could adjust the functions of all systems and organs of the human body and so could effectively prevent and treat diseases. Chinese medical workers have carried out extensive research programmes in the areas of clinical application of acupuncture–moxibustion, acupuncture anaesthesia and acupuncture analgesia, and have accumulated rich experience and documented significant advances.

Expanding the scope of clinical application

According to an estimate, there were approximately 200 diseases that could be treated by acupuncture–moxibustion in the 1950s. The number increased to 300 by the 1970s, of which effective treatment was available for about 100 diseases. In the meantime, acupuncture anaesthesia was also being widely used.[1] In 1979, on the basis of research, the World Health Organization (WHO) began to disseminate safety indications for the use of acupuncture–moxibustion. WHO also publicized the first group of 43 acupuncture–moxibustion-treated diseases, which involved the respiratory system, digestive system and neuromuscular–skeletal system, as well as areas such as stomatology and the five sense organs. Clinical practice shows that the indications for acupuncture–moxibustion encompass all clinical areas, and satisfactory clinical results have been obtained, particularly in the treatment of painful diseases such as neuromuscular system diseases, sequelae of cardiocerebral and visceral functional disorders, dysfunctional diseases of the endocrine system, diseases due to depressed immunity, and some allergic conditions. In addition, acupuncture–moxibustion has certain clinical benefits in the treatment of some difficult diseases such as tumour and organic diseases in which the toxicity and sequelae are reduced. Combined with modern medicine, acupuncture–moxibustion can treat some life-threatening diseases, such as chronic renal insufficiency, myocardial infarction, haemorrhagic fever, and acute perforating ulcers. Infectious and infective diseases such as viral hepatitis, pulmonary tuberculosis, epidemic parotitis, bacillary dysentery and acute mastitis can also be treated. Acupuncture–moxibustion also has an effect on the union of fractures, ovulation, and helps in easing labour pains and in correcting abnormal foetal position.

In 1996, a special issue—*The Frontiers of Medicine*—was published in the United States of America. This issue focused mainly on the Chinese acupuncture therapy, which was included as a special topic. In November 1997, the National Institutes of Health (NIH), USA, held a special meeting with more than 1000 participants. The meeting discussed the effect of acupuncture

therapy on nausea, vomiting, various painful diseases (including postoperative pain, dysmenorrhoea, tennis elbow, and myositis fibrosa, etc.), or pain induced by chemotherapy or operation. Other areas where acupuncture could be used were discussed. These included the after-effects of stopping of smoking, management of drug dependence, osteoarthritis, sequelae of wind stroke, and headache and asthma, and it was agreed that acupuncture therapy in these cases was appropriate. A statement was made after the meeting about the efficacy of acupuncture which further influenced the worldwide application of acupuncture–moxibustion.

Meridian diagnosis

Research on the pathological reaction of meridian points, for example, paraesthesiae, tissue abnormality, change in the volume of electric conduction and change in thermal sensitivity, has boosted the application of the diagnosis of differentiation according to the tenderness of meridians and points. Many scholars have tried to diagnose meridians and collaterals with the aid of devices developed by the modern technologies of physiology, biochemistry, acoustics, optics, electricity, thermal, magnetics and computers. These instruments not only increase the accuracy of diagnosis, but also have a good therapeutic effect.

Acupuncture anaesthesia

Acupuncture anaesthesia is a new method of administering anaesthesia that is based on clinical acupuncture analgesia. This is used in the treatment of complications following surgical operation. It has been developed according to the theory of meridians and the principle of acupuncture functions. It functions mainly by needling the points along with supplementation by medicines, and is used during operations while the patient remains conscious. Acupuncture anaesthesia resulted from the combination of modern anaesthesiology, surgery and the neurosciences. Acupuncture analgesia in China has a history of more than 2000 years. It was introduced as early as the Yellow Emperor's *Internal Classics*. Acupuncture anaesthesia started in the late 1950s. On 30 August, 1958, with the cooperation of the Departments of Otorhinolaryngology and Acupuncture, the First Shanghai Municipal People's Hospital replaced allopathic anaesthesia by acupuncture analgesia, and successfully performed a tonsillectomy. A new chapter was thus started in the history of acupuncture. During the past 40 years, practitioners of acupuncture anaesthesia have, on the one hand, been conducting demonstration operations with acupuncture anaesthesia, evaluating the treatment effects and documenting experiences while, on the other hand, there have been efforts to solve the problems of "incomplete analgesia and insufficient relaxation of the abdominal muscles". The "theory of acupuncture–medicine composite anaesthesia" was launched in the 1980s, under which the anaesthetic effect is achieved by acupuncture along with a small dose of medicine which not only preserves the advantages of the operations by acupuncture anaesthesia, but also increases the effect of analgesia. Nowadays, some medical organizations in China and abroad are continuing further research on the method of acupuncture–medicine composite anaesthesia for those special situations where medical anaesthesia is unsuitable.[2,3]

Up till the late 1970s, more than 200 acupuncture anaesthesia operations had been carried out. Acupuncture anaesthesia is now applicable for more than a

Acupuncture–moxibustion has an adjusting effect with the heart rate, rhythm of the heartbeat, blood pressure. It can be used for the treatment of the blood vessels of the brain and rheumatic heart diseases.

hundred types of diseases. Further research on points prescription, the degree of acupuncture stimulation, supplementary medication and surgical performance has improved the effect of acupuncture anaesthesia, which proved to be effective for about 30 kinds of operations. Of these, the anterior basocranial, cervical vertebrae, thyroid gland, tooth extraction, caesarean section, pneumonectomy and abdominal ligation of oviduct have received approbation at the Chinese ministerial level. Acupuncture anaesthesia is regarded as a common practice with a success rate of 80 per cent. Some of the difficult operations such as throat restoration, renal transplantation, and operation in the functional area of the brain, have been successfully carried out with acupuncture anaesthesia. After years of exploration, the points for acupuncture anaesthesia operation have been streamlined, and the practice of acupuncture has become simpler and more effective.

Indications of acupuncture treatment

Visceral diseases

Acupuncture–moxibustion has an adjusting function with all the organ systems.

(1) Respiratory system: Acupuncture–moxibustion has an adjusting function with the frequency and amplitude of respiratory movement, the motor function of bronchial smooth muscle, ventilation, vital capacity, airway resistance, respiratory muscle strength, and the movement of the diaphragm. Hence, it can be used for the treatment of acute and chronic bronchitis,[4] bronchial asthma,[5] and haemoptysis of pulmonary origin.[6] Central and peripheral respiratory failure can also be treated by electric acupuncture at the points of Su Liao (GV25), Nei Guan (PC6), and Tai Chong (LV3), etc.

(2) Cardio-cerebral system:[7] Acupuncture–moxibustion has an adjusting effect with the heart rate, rhythm of the heartbeat, blood pressure, function of the peripheral blood vessels, functional state of the left heart, coronary function and cerebrovascular function. It can be used for the treatment of the blood vessels of the brain,[8] rheumatic heart diseases and acute myocardial infarction.[9] It was discovered that the treatment of wind stroke and the absorption of blood following cerebral haemorrhage can be promoted by acupuncture at Nei Guan (PC6). Following intensive research, Professor Shi Xuemin found an effective acupuncture method for the treatment of wind stroke.

(3) Circulatory system: Acupuncture–moxibustion adjusts the red-cell count in the peripheral blood, haemoglobin content, surface charge density of the red blood cells, and the content of oxygen and carbon dioxide. Therefore, there are occasional reports of acupuncture treatment for primary thrombocytopenic purpura[10] or haemorrhage, thrombocytosis after splenectomy due to schistosomiasis, and hypoimmunity induced by radiotherapy and chemotherapy.[11]

(4) Alimentary system: Acupuncture–moxibustion can effectively adjust the movement of the digestive canal, secretion

of the digestive glands, flow of bile, and the peristaltic function of the gall bladder and bile duct.

(5) Urinary system: Acupuncture–moxibustion can affect the urinary function of the kidneys, the movement of the ureter, the movement of the bladder, and the function of the sphincter muscle of the urethra, and can therefore be used for the treatment of stones in the urinary system.[12] The rate of efficacy of treatment of postpartum and postoperative retention of urine by acupuncture and moxibustion is as high as 97.5 per cent.

(6) Endocrine system: Owing to its dual-directional adjusting function to the sympathetic–adrenomedullary system, acupuncture–moxibustion can also be applied for the treatment of thyroid diseases and diabetes, etc.

(7) Genital system: Acupuncture and moxibustion have an obvious adjusting effect on the uterotonic function, so artificial abortion or oxytocia can be successfully carried out by electric needling at the points of He Gu (LI 4), San Yin Jiao (SP 6), and Zu San Li (ST 36), or supplemented by auricular acupuncture. By giving moxibustion at Zhi Yin (BL 67), abnormal foetal position can also be successfully corrected.[13]

Clinical research has also proved that acupuncture and moxibustion have an adjusting function on the immune system; for example, the success rate for the treatment of allergic asthma is as high as 96.8 per cent. Treatment for other allergic diseases is also satisfactory, as is the treatment of common inflammatory diseases such as parotitis, tonsillitis, pharyngitis, laryngitis, mastitis, otitis media, gastroenteritis, cholecystitis and bronchitis. The rate of successful acupuncture treatment for icterohepatitis has been reported to be 98.5 per cent. Besides, acupuncture–moxibustion has a good therapeutic effect in cases of malaria.

Meridian, collateral and tendon diseases

Meridian, collateral and tendon diseases refer to diseases of the tendon–muscle–joint system (motor system) and the neurological system. These include, for example, various types of headache, trigeminal neuralgia, sciatica, lumbago, costalgia, cervical spondylopathy, scapulo-humeral periarthritis, fasciitis, sprain, stiff neck, carpal tunnel syndrome, tenosynovitis arthritis, rheumatoid arthritis, as well as ankylosing spondylitis, hyperosteogeny, hemiparalysis and numbness after wind stroke. Acupuncture–moxibustion has a special effect on the treatment of these diseases. The commonly used methods in clinical practice are the various needling methods (including elongated needling, opposing needling, short-thrust needling, nape needling, tapping and penetrating needling), point injection, moxibustion, scraping, cupping, electric needling, fire needling, collateral pricking and blood-letting, laser therapy, magnetic tape, and conductor of meridians and collaterals.

As regards the field of neurology, acupuncture–moxibustion has more advantages than allopathic medicine in the treatment of some diseases. One example is a common ailment, facial paralysis, which is normally caused by acute nonsuppurative inflammation of the facial nerve in the foramen of the styloid process, and is characterized by peripheral facial paralysis. Since the pathogenesis of this disease is not clear, Western medicine has no effective treatment other than antipyretics, analgesics and corticosteroids. According to TCM, the cause of this disease is stagnation of *qi* and blood and blockage of the meridians and hence it

should be diagnosed and treated on the basis of the overall analysis of symptoms and signs, the cause, nature, location of the illness and the patient's physical condition. Acupuncture–moxibustion, *tuina* and massage usually have a beneficial effect. In clinical practice, the penetrating method is mainly applied at the nearby facial points, such as Jia Che (ST6) penetrating to Di Cang (ST4), Yang Bai (GB14) penetrating to Yu Yao (EX.), and Si Bai (ST2) penetrating to Ying Xiang (LI20). The treatment of facial paralysis[14] with acupuncture is brief and satisfactory. Basically, there are no sequelae. In China, most patients who suffer from this disease prefer acupuncture treatment, the superiority of which is widely recognized.

Management of weight-loss and prevention of effects of stopping drugs, AIDS and tumour

Clinical observation shows that needling at Tian Mei (EX.) is effective in stopping smoking, yet owing to psychological factors, there are differing views on the effect of the treatment. Some Chinese medical doctors have also tried acupuncture for drug de-addiction or for treating physical and psychological disorders caused by drug addiction,[15] such as irregular menstruation and menopause. This research is still in progress. The practice of acupuncture for weight loss continues, with some treatment effects. However, a stricter comparative analysis is required because weight loss is affected by various factors.

Treatment of AIDS[16] with acupuncture–moxibustion is a subject which is worth serious research. Research on malignant tumour[17] shows that acupuncture–moxibustion, as a supplementary treatment method, could improve clinical symptoms of patients, minimize side-effects of radiotherapy and chemotherapy, and prolong life. However, this function of acupuncture and moxibustion cannot be separated from its capability of improving the efficiency of the immune system.

Development of treating methods

Traditional acupuncture–moxibustion therapy warrants a good foundation for its development. Based on the Nine-needles, Nine-needling methods and Twelve-needling methods in the *Internal Classic,* various needling instruments were developed, such as cutaneous needle, intradermal needle, three-edged needle, point catgut embedding therapy, elongated needle, fire needle, and knife needling. Different methods have been applied in clinical treatment with effective results, for example, superficial puncture, tapping method, penetrating method, multiple oblique needling, the three easing methods, and many more.

Non-invasive treatment methods in combination with modern physical techniques include point electric conduction therapy, drug ion-introduction therapy, point electrothermal moxibustion therapy, point microwave radiation, laser radiation therapy, point ultrasonic input, point low-frequency input, infrared radiation, ultraviolet radiation, cryotherapy, drug application on point, etc.

Traditional acupuncture therapy, in combination with modern physical therapy, developed into electric acupuncture therapy, electrothermal acupuncture therapy and magnetic acupuncture therapy. In combination with drug injection technique, point injection with small dosage and point block therapy have been developed. The knife needling method has been developed in combination with

dissection in the Departments of Orthopaedics and Traumatology.

(1) Specific-area acupuncture therapy (also called micro-acupuncture therapy), which incorporates the *Zangfu*, meridian-collateral, and point theories of TCM with modern anatomy, is different from traditional acupuncture therapy, but reflects the characteristic of Chinese acupuncture–moxibustion, and possesses the dual functions of both diagnosis and treatment. It covers auricular acupuncture, as well as acupuncture of the scalp, face, eye, nose, tongue, abdomen, hand, foot, and wrist- ankle, and the theory of holography. It is worth mentioning a little about auricular acupuncture and scalp acupuncture.

(a) *Auricular acupuncture therapy:* In recent years, interest in research by doctors on auricular acupuncture and on treating methods is growing. These include traditional needling methods, embedding and massage methods, drug application on auricular points, herbal seeds pressing method, magnetic ball pressing method, liquid nitrogen refrigeration treating method, as well as instrumental detection and treatment on auricular points. Therefore, the indications for auricular acupuncture have been extended from a dozen to more than a hundred—common cold, epidemic encephalitis, tracheitis, pneumonia, bronchitis, coronary heart disease, myocarditis, pulseless disease, shock, gastritis, ulcer, gastrointestinal neurosis, phrenospasm, facial paralysis, intercostal neuralgia, epilepsy, Parkinson's disease, cerebral thrombosis, cerebral embolism, infantile chorea, Meniere's disease, enuresis, cervical spondylopathy, scapulohumeral periarthritis, acute lumbar sprain, ascariasis of the biliary duct, cholelithiasis, stiff neck, irregular menstruation, dysmenorrhoea, functional endometrorrhagia, and acne.

(b) *Scalp acupuncture therapy:* After nearly 30 years of clinical research, the methodology of locating the meridian according to the area and then locating the point on the meridian has been determined. Penetrating, twisting, lifting and thrusting, electric stimulating methods as well as reinforcing and reducing by puncturing along and against the direction of the meridian, respectively, have been applied for the treatment of more than a hundred diseases. These include hemiplegia, facial paralysis, headache, trigeminal neuralgia, paralysis agitans, dizziness, tinnitus, sensory aphasia, apraxia, enuresis, prolapse of the uterus, functional endometro-rrhagia, pelvic inflammation, hypertension, coronary heart disease, asthma, cataract, myopia and cortical visual disturbance.

(2) Conducting research and observing the factors influencing the therapeutic effects of acupuncture and moxi-bustion, and analysing and comparing these factors are the focus of present and future clinical studies. The therapeutic effects of acupuncture are now being observed by objective testing methods, as modern technology is being introduced in clinics. Some

scholars have observed that varying stimulation and parameters produces different clinical therapeutic effects. Han Jisheng observed that when electric stimulation is applied in acupuncture treatment twice weekly, the therapeutic effect may gradually accumulate. Using relatively weak stimulation (2 mA is better than 1 mA) and a relatively longer duration between two treatments (treatment applied once weekly) may achieve better relief for chronic pain. Thirty cases of cerebral haemorrhage treated by acupuncture with CT scan guidance denote that the acupuncture technique for promoting brain functions and resuscitation obviously accelerates the absorption of cerebral bleeding. In the application of suppurative moxibustion for asthma, the relationship between the season and the pain present or absent during the treatment has been analysed.

(3) The clinical combination of acupuncture and moxibustion with medicaments to raise the therapeutic effect has been common practice and diseases are managed using this combination in various clinical departments. The medicaments applied are in the form of oral administration, acupoint injection, muscular injection, venous injection and subcutaneous absorption. Medicaments may enhance the therapeutic effect of acupuncture,[18] depending on the type and dosage of the drug used. The therapeutic effect produced by the combination of acupuncture and medicaments is not merely the addition of the original effect of the two, but is more than that. A probable mechanism is that: acupuncture, by inducing the release of some active substances in the body, changes the number of receptors and their reactions, alters the cell membrane and the blood–cerebral barrier permeability, and influences the enzyme-inducing activity of the drug. Therefore, on the one hand, endogenous drug-like substances in the body are activated to perform a therapeutic effect while, on the other hand, the therapeutic effect of the exogenous drug is enhanced.

(4) Development and application of the apparatus of acupuncture and moxibustion, development in the areas of optics, electrothermal, magnetic and computer technologies has led to the development of a variety of acupuncture and moxibustion apparatus. These have been designed and manufactured in keeping with optimal stimulating parameters according to the findings of acupuncture pain suppression research. The electro-acupoint stimulator, electrothermal needle instrument, laser needle apparatus, low-frequency electric therapeutic apparatus, electrothermal moxibustioner, permanent magnetic needle, etc., are examples of such apparatus and have been frequently used in acupuncture clinics and for experimental research. Sterilized disposable needles and needles with applicators (tubes) are examples of the modernization of acupuncture equipment. With regard to moxibustion, the moxibustioner and non-smoke moxa stick promote the development of moxibustion. Application of these new technologies and new approaches enables traditional Chinese acupuncture and moxibustion practices based on experience, to be developed in modern scientific ways.

Theoretical study of acupuncture and moxibustion

Study on the mechanism of acupuncture and moxibustion

The various afferent nerve fibres to be stimulated must be selected based on the intensity of hand manipulation and the current of electric stimulation. Generally speaking, moderate hand manipulation and low electro-current activate afferent fibres with a relatively large diameter, whereas strong hand manipulation and electric stimulation of relatively strong intensity activate afferent fibres of various diameters, particularly the fine fibres.[19] The effect of acupuncture takes place via its action on the afferent fibre. Once the peripheral nerve is cut, most of the pain disappears. At some points near the arteries, the afferent fibres of the sympathetic nerve distributed in the vessels also form a part of the acupuncture afferent system, for even after the destruction of the somatic nerves, when these points are punctured, some effect of needling still remains. However, when the autonomous nerve supplying the vessel wall is damaged, acupuncture has no effect.

The effect of acupuncture on the human body is manifold. Its functions include regulating the endocrine and immune systems. The activities of the various organs are under the control of the nervous system and the nerve–endocrine–immune system. The effect of acupuncture is also related to the participation of these organ regulation systems.

The effect of acupuncture on the immune system includes the regulation of specific immunocytes, non-specific immunocytes and the humoral immune system. Acupuncture and moxibustion increase T lymphocytes in the peripheral blood and enhance intracellular esterase activities, thereby raising the lymphocyte transformation rate and rosette formation rate, activating the natural killer cells, and also increasing the amount of lymphocytes. Acupuncture and moxibustion also increase the phagocytic power of the non-specific immunocytes and the content of granulocytes. In humoral immunity, acupuncture and moxibustion may elevate the amount of beta- and alpha-globulin, as well as immunoglobulins IgG, IgA and IgM. The proliferative reaction of splenic lymphocytes and the splenic lymphocyte transformation rate are also increased.

Acupuncture regulation of the immunological function is related to the intact functioning of the vegetative nervous system. Only under intact conditions of the nerves and the adrenalin system can acupuncture evoke immunoreaction. Endogenous opioid peptides (such as encephalin) have a close relationship with cellular and humoral immunity; enhancement of the immune system due to acupuncture may be achieved via its action on the endorphin. The benign regulation of the endocrine and immune systems by acupuncture explains its therapeutic effect in many diseases.[20]

Research on meridians and collaterals

Research on meridians and collaterals is an important area of scientific research in China. In 1956, it was listed among the projects for the first national natural science developing plan. In 1986, it was again listed as one of the “Seventh Five-Year Plan” projects to be undertaken by the State Committee of Science. In 1989, the subject of research on meridians and collaterals was considered one of the “planned projects to be scaled”.

In order to keep abreast of the latest on internationalization of acupuncture, in 1990 the State Technology Supervision Bureau of the People's Republic of China issued the People's Republic of China State Standardization of Acupoints' Locations.

Researchers working hard for many years have yielded initial achievements.

In China, a general study has been conducted on 200,000 people concerning the phenomenon of "sensation transmission along the meridians". The existence of the running course of the meridians put forward by the ancients has been approved and the fundamental characteristics of sensation transmission along the meridians have been understood. Literature and information from the ancient to the present time have proved that sensation transmission along the meridians is a kind of objective physiological phenomenon that exists. Recent tests show that when the skeletal muscles are in a state of excitement, sensation transmission along the meridians is in relation to the nerve connected with the long axis and induced by the summational current. The transneural segments and transjoint transmission mechanism are caused by secondary excitement of the skeletal muscles. Yet, there is not enough evidence to prove the physiological significance of this phenomenon neurobiologically. The spinal cord is marked by the distribution of motor neurons according to the meridians. A mutual dendrodendritic synapse relationship exists among the motor neurons. Local stimulation on the meridians and points may cause excitement of the skeletal muscle of the same meridian on another part through synaptic reflection and synaptic transmission among the motor neuron. Since such progressive excitement of the skeletal muscle fibre needs repeated time–space summation, there is a phenomenon of slow sensory movement and release of myoelectricity. This phenomenon observed in animals has been proved in humans who are sensitive to sensation transmission along the meridians.

Systematic study of the relationship between the meridians and *zang fu* organs and their ways of connection:

Neuroscientific research by integrated methods suggests that there is a relative connection of specificity between the superficial meridians and the internal organs. On the one hand, such specific connection is related to the anastomotic level of the nerve segments and density dominated by the nerve segments. On the other hand, acupuncture stimulation on the meridians may cause changes in the release of some neuropeptides of the relevant target organs specifically, and affect the reactivity of the target organs to the corresponding neuropeptide.

Existence of active energy metabolism along the running course of the meridians

The system of meridians and collaterals is a functional system. Previous tests suggest that energy metabolism is relatively active on the running course of the meridians. For instance, the index of skin temperature and the amount of carbon dioxide exhalation on the running course of the meridians is obviously higher than that on the other lines. This phenomenon shows that the energy metabolism along the running course of the meridians is active.

Research on the morphology of acupoints

During 1960–1970, researchers in many laboratories in China and elsewhere worked on the morphological characteristics of tissue at the meridian points. As a result, besides the muscle spindle, Meissner corpuscle, Pacinian corpuscle, Kraus end-bulb and free nerve ending, a "special" receptor was found. A histochemical study shows that there is a network formed by the adrenergic nerve of the postganglionic fibres of the sympathetic nerve and the cholinergic nerve, which is distributed over the small vascular wall of some points of both human beings and animals. Research on stereo-structures of points based on lamina, cross-section and study of CT scan anatomy has proved that the points are stereo-space structures made up of various kinds of known tissues. The difference between points and non-points depends on the different distribution of known normal tissues.

Research on the specificity of acupoints

Extensive research has shown that significant differences exist in puncturing acupoints and non-acupoints. For instance, when points such as *guanyuan* (CV4), *qihai* (CV6), *zusanli* (ST36) with replenishing functions are punctured and compared to *weizhong* (BL40), which has functions of reducing heat and cooling blood, there is a remarkable difference in raising the transformation rate of lymphocytes. No obvious changes in the immunological functions of the body have been found when non-acupoints are punctured. In pneumonectomy under acupuncture anaesthesia, *sanyangluo* (TE8) has the best analgesic effect.

Standardization of location of points

In order to keep abreast of the latest on internationalization of acupuncture, in 1990 the State Technology Supervision Bureau of the People's Republic of China issued the People's Republic of China State Standardization of Acupoints' Locations. This was put forward by the State Administration of TCM and was implemented on 1 January, 1991. The standardization determined the methods of locating points and the locations of 361 meridian points and 48 extra points, suiting the needs of acupuncture teaching, scientific research treatment, publications, and academic exchange in China and abroad. In addition, based on the suggestion and demand by the Western Pacific Region of WHO, China also formulated the Plan of Standardization of Acupoints' Names, A Draft Plan of International Standardization of Auricular Points, and the Plan of Standardization of Scalp Points' Names, all of which were extensively used in clinical work.

With the development of acupuncture, especially the expansion of its experimental studies, animal experiments with acupuncture are increasing day by day. On the basis of massive achievements of contemporary traditional acupuncture, veterinary acupuncture and experimental acupuncture, the Academy of TCM of Jiangsu Province and some other units studied the nomenclature, location, anatomical structures and indications of acupoints from the viewpoint of comparative anatomy, comparative physiology and comparative acupuncture, with commonly used experimental animals. Based on these findings, an atlas of animal acupoints was made, defining 71 points of dog, 71 points of cat, 51 points of

rabbit, 51 points of guineapig, 42 points of rat, and 20 points of mouse.

Study on acupuncture literature

Sifting through the literature on acupuncture of past generations, the proof and annotation of some important ancient acupuncture books such as *Miraculous Pivot*, *Systematic Classic of Acupuncture and Moxibustion*, the revision of *Huangdi's Mingtang Classic*, and the publication of the *Four Mirrors of Chinese Acupuncture* and *Collective Works of Chinese Acupuncture*, laid a strong foundation for scientific research and clinical practice. On the other hand, publication of the index of acupuncture papers, establishment of the consulting and analysing system of acupuncture literature, and exchange of literature amongst China and foreign countries facilitated the analysis of acupuncture information and literature consulting and promoted academic exchange on acupuncture throughout the world.

Acupuncture education

Education in China

There are various forms of acupuncture education in China: high-level professional education, medium-level professional education, postgraduate education, correspondence college, night college, doctors training as apprentices, self-study examination, and social strength running schools. These have opened up avenues for training acupuncture personnel.

Medium-level education

At present, there are 51 medium-level schools of Chinese medicine, which have 51,260 students. Most of these schools offer acupuncture courses. Through teaching reforms and standardization, the teaching of medium-level schools has been improved. Among these schools, the School of Chinese Medicine of Shandong Province was chosen as an important one at the State level, and 19 of these schools were named as standard ones by the State Administration of TCM.

High-level professional education

In 1956, TCM colleges of the first batch were established in Beijing, Shanghai, Nanjing and Chengdu. Till the end of 1997, there were a total of 30 colleges of TCM and national medical colleges in China, and all of them offered acupuncture, or acupuncture and massage courses. The school system included undergraduate, postgraduate and doctorate, seven years' undergraduate, and doctors of Western medicine learning Chinese medicine, and so on. Up till 1998, a total of 88,665 TCM students and 5000 doctors of Western medicine had been trained in acupuncture. There are 2056 personnel above the level of associate medical professors in universities and 690 professors. The reforms in higher education stress on teaching content and courses are continuing in full swing.

Adult education

Adult education is of two kinds–informal and formal. In addition to education through correspondence, night college, social college, self-study examination and full-day courses, there are also continuing education, postgraduate training, doctors' training apprentices, and inheritance of famous TCM experts' experiences, which form the system of adult education in TCM. Some lectures and symposia are also part of the activities of continuing education; the participants get credit for attending.

International training

WHO set up seven collaborating centres for traditional medicine in China. The Collaborating Centres in the Beijing China Academy of Traditional Chinese Medicine, Nanjing and Shanghai are mainly engaged in the study of acupuncture. In 1975, international TCM training centres were established at Beijing, Guangzhou, Xiamen, etc., to train foreign doctors in acupuncture and Chinese medicine, thus promoting the spread of acupuncture in the world. At the Beijing centre itself, more than 5600 doctors from 104 countries and regions have been trained in acupuncture in the last 25 years. Some high-level TCM universities recruit foreign students as well. Some of the students have received postgraduate degrees or doctorates. These skilled acupuncture doctors will quicken the process of internationalization of TCM.

Current problems in acupuncture

- *Differences in the functions of acupuncture and moxibustion.* Is there any specific difference between the functions of acupuncture and moxibustion? For example, ancient acupuncture literature clearly recorded that, the point *Shenting* (GV 24), "if treated by acupuncture, it is indicated in manic mental disorders, and if by moxibustion, indicated in depressive mental disorders". Some points are suitable for puncture and some for moxibustion, and some can be treated by both, but there are differences in their functions. What is worth noting is that these experiences were mostly recorded in the famous acupuncture doctor Zhenquan's book during the Tang dynasty. However, further study is needed to ascertain these differences.
- *Lack of objective and standardization in prescribing points.* Research work on acupuncture standardization has completed the standardization of names and locations of the points. Yet the most important and complicated task—the standardization of indications of acupoints—has not yet started. Different textbooks list different indications and there are no standards in prescribing points when treating patients. This situation influences the therapeutic effect of acupuncture.
- *Lack of a quantity index in acupuncture manipulation.* Objective indices approved by academicians remain to be formed on many counts. There are no strict and systematic clinical observations and experimental studies on defining terms such as reinforcing and reducing acupuncture, the intensity and quantity of stimulation, and the duration of retention of needles.
- *There is a lack of objective criteria in the evaluation of the therapeutic effects of acupuncture and moxibustion.*

Developing trends in acupuncture medicine

Elaborating the principles and scientific bases of the indications of acupoints

To a great extent, the therapeutic effectiveness of acupuncture is determined by the scientific basis of the acupoints prescription. However, the scientific basis of the acupoints prescription relies on the scientific understanding of people regarding the indications of the acupoints. In order to establish the scientific basis of the indications of the acupoints, studies should be conducted on two aspects: (i) By probing and analysing the acupuncture literature of all generations; those indications of the acupoints summarized

directly from practical experience should be sorted out to ensure that the indications of traditional acupuncture points have a solid practical basis, (ii) These indications should be applied again in clinical practice, and verified under strict scientific experimental design so that the indications can be re-sorted. The clinical experience of modern acupuncturists should be summarized systematically and generally so that acupuncture can be furbished with modern features. These experiences should then be used in clinical practice for strict verification. Only by undergoing the process of "panning the gold in the sand" can the real value of modern and traditional Chinese medicine and acupuncture be guaranteed, and the serious situation of poor integration of acupuncture theory and practice be changed. Only then can acupuncture medicine take a great leap from the level of "empirical medicine" to the level of "evidence-based medicine". Keeping this in view, the foundation has been laid for researching and working out "International Standard Acupuncture Points' Indications".

Quantifying the principles of acupuncture treatment

Ancient people practising acupuncture observed that there are different principles in terms of various acupuncture points, different needling techniques, single acupuncture stimulation, total acupuncture stimulation and various treatment intervals. Also, depending on various disease conditions, during the same treatment course, the amount of stimulation increases gradually from low to high, or decreases from high to low, or increases in the beginning and decreases later. In order to improve the therapeutic effectiveness and to minimize ad hocism in treatment, the principle of cumulative effectiveness of acupuncture treatment must be worked out. In other words, what needs to be explored should include the time when the acupuncture effectiveness reaches its maximum; how long the effectiveness would last upon reaching the maximum; whether there is a non-responding period before the new stimulation starts having an effect; and how long the non-responding period lasts, if there is one. Only after these basic questions are clearly settled can the best acupuncture treatment plan be worked out. This would include the amount of each stimulation, the amount of total stimulation, the interval between stimulations and the treatment courses required by various diseases.

Peak value of therapeutic effectiveness of acupuncture and the best time to perform treatment

Since the therapeutic actions of acupuncture rely on the intrinsic functions of self-regulation and self-recovery of the human body, the intensity of its functions is limited. If clinical therapeutic effectiveness needs to be advanced to its maximum, and if clinical indications of acupuncture are to be widened, future clinical research on acupuncture should be carried out in two directions. One is to further develop the potentiality: by conducting strictly controlled research, by sorting out diseases, by establishing the best time and opportunity to perform acupuncture treatment, as well as by determining the acupuncture stimulation parameters of different diseases, so that the effectiveness of acupuncture can be utilized to its optimum extent. The other is to blaze new trails, by integrating other supplementary methods scientifically to enhance the

effectiveness of acupuncture treatment and broaden its scope. Promising supplementary methods include the integration of acupuncture with Chinese herbal medicine or the integration of moxibustion with Chinese herbal medicine. This method has been tried to increase the strength of acupuncture functions and to reduce or eliminate the side-effects of medication. However, to enable this therapy to demonstrate its advantages we still have a long way to go, because the human body's physiological and biochemical functions are very complicated. Any functional activity is not a single biological change but rather a series of biological processes mutually linked and influenced. For example, while the afferent nerve conducts the physiological and biochemical regulations to the organs around it, apart from the nerve impulse, there are such processes as the synthesis, storage and release of the neural transmitter, the combination of the transmitter and the receptor, and the inactivation of the transmitter. The regulative function of acupuncture is probably realized through the induced release of some active substances, through alternating the numbers and the reactivity of the receptor, changing the permeability of the cell membrane and the blood–cerebral barrier, and influencing the activity of the enzyme. Once medication is involved, in which way does acupuncture affect the actions of the medication? Among the links that are important, are there any differences in various diseases and for different medications? If it is said that acupuncture and medication coordinate in terms of function, would their functions be merely combined or increased? To answer these questions, Chinese scholars have already performed preliminary clinical observations and experimental research and the basic principles will be mastered only in due course of time.

Expounding the functional mechanism of acupuncture

According to deepened recognition of pain physiology, acupuncture mechanisms to stop pain will be gradually proved at the level of molecular biology, especially the primary centre of afferent pain sensation. Various methods of neuroscience research will be applied to verify how the posterior horn of the spinal cord has a restraining effect on afferent harmful signals, and how the higher centre influences the process of stopping pain. These will provide theoretical proof and a wide choice of clinical applications to eliminate pain.

Manufacture of safe and effective acupuncture apparatus

The clinical meaning of traditional acupuncture skills should be judged by strict experiments. For one kind of acupuncture skill, out of 10 experiments just one may be of practical importance, while the rest may even trigger off reactions. The questions faced are: how to distinguish meaningful composition, sum up regulation, simplify and standardize manipulation, reduce blindness of acupuncture manipulation, diminish unnecessary (no clinical meaning) harmful stimulation, increase its scientific nature,

In the last 10 years, the relationship of stimulation parameter of acupuncture with the ability to stop pain has been systematically observed by research on acupuncture to stop pain.

effectively apply it in clinics, and gradually increase curative effect. In the last 10 years, the relationship of stimulation parameter of acupuncture with the ability to stop pain has been systematically observed by research on acupuncture to stop pain. On the basis of this research, the public should be told of the interaction regulation of acupuncture skill and of clinical curative effect. New models of acupuncture apparatus to further enhance acupuncture skills should be made available. With the development of biological sensing technologies, a sensor with needle style can be produced. Combined with the development of biomembrane technology, biological material with activity can probably be added to the acupuncture apparatus. These techniques may urge acupuncture medicine to develop into needle medicine compound acupuncture medicine. Besides, with progress in techniques, no-wound acupuncture tools combined with traditional acupuncture skills will be presented in the 21st century; trained persons have begun to try it.

Standardization of acupuncture

Research work on acupuncture standardization has been completed in certain areas. These include "location of meridian points", "name and location of auricular points", which have been promulgated by the People's Republic of China, and "acupuncture points name with international standard", "acupuncture clinical research standard" promulgated by WHO. Following this, primary indications of points most related to acupuncture clinics will make great progress.

Traditional Chinese Medicine belongs to the category of natural medicine and people today want to return to nature. They appreciate that TCM is a type of natural medicine. WHO appreciates the traditional medicines of countries all over the world, especially TCM. It has founded seven Collaborating Centres of Traditional Medicine, and is supporting nine governments through the Federation of World Acupuncture Association. With the guidance of WHO, China will gradually standardize research and clinical treatment of TCM.

The Constitution of China explicitly states "to develop modern medicine and Traditional Chinese Medicine", paying equal attention to modern medicine, and TCM is the primary law of medical and public health undertakings. It offers a very good opportunity for undertaking TCM, and boosts its substantial healthy development. In the 21st century, Chinese medicine and acupuncture would occupy a significant position in the world of medicine.

References

1. Wang Xuetai. *The present situation and the future development of acupuncture and moxibustion*. Collection of Academic Articles for the 10th Anniversary of the Founding of the World Federation and Acupuncture Societies. 1997.
2. Zhang Ren. *The history of the development of acupuncture anaesthesia in China* (1st edition). Shanghai Science and Technology Literature Publishing House. March 1989.
3. Qian Xinzhong (chief editor). *Acupuncture anaesthesia in China*, *Vol. 1* (1st edition). Shanxi Science and Education Publishing House. December 1987.
4. Liu Xinlian, Wu Yixin, Jiang Shuying. Treatment of 97 cases of chronic bronchitis with seed-plaster auricular therapy. *Shanghai Acupuncture and Moxibustion Journal.* 1988. 7(1): 8–9.

5. Sun Guixia, Chen Jingtao, Chuan Jianjun. Clinical observation on 141 cases of bronchial asthma treated with acupuncture and moxibustion. *Journal of Acupuncture and Moxibustion Clinic.* 1994. 10(2):13–15.
6. Yang Shufang. 224 cases of hemoptysis of TB treated by atropine and acupuncture at Yintang. *Integration of Traditional Chinese Medicine and western medicine on Practical Clinical First Aid*. 1995. 2(2):67.
7. Zhou Jiren, Fang Depei, You Haiqing. Impact of acupuncture on the left cardiac function and humoral endocrine of ectatic myocardosis patients with heart failure. *Shanghai Acupuncture and Moxibustion Journal.* 1992. 11(3):3–4.
8. Lu Hongxia, Zhang Zhenhui, Zhang Yunxiu. Observation of the therapeutic effect of the treatment for 200 cases of hemiplegia of wind stroke by acupuncture combined with immune functional regulation instrument. *Chinese Acupuncture.* 1996. 16(3):27–28.
9. Sun Jiqing, Wang Shaokai, Chen Jinglan. Observation on the therapeutic effect of 37 cases of acute myocardial infarction treated with integration of Traditional Chinese Medicine and western medicine. *Journal of Chinese Medicine and Pharmacology.* 1992. 1:34–36.
10. Cai Ligao. Observation on the short-term therapeutic effect of acupuncture treatment for 37 cases of chronic primary thrombocytopenic purpura. *Acupuncture Research.* 1988. 13(3):255–259.
11. Ouyang Qun, Jiang Yi, Ma Defeng. Impact of salt-insulted indirect moxibustion at Shenque (CV8) on the immune function of the organism–animal experiment and clinical evidence. *New Chinese Medicine*. 1992. 24(2):30–32.
12. Zhang Yongchen, Jia Hongling, Liu Yutan. Situation of the acupuncture treatment in the last 14 years for urinary stone. *Chinese Acupuncture and Moxibustion*. 1994. 14(5):273–276.
13. China Acupuncture and Moxibustion Society. *Acupuncture and moxibustion in the new century.* Chinese Science and Technology Publishing House. 1998:826.
14. Chen Daoqing, Wang Bingkun, Zhou Liya. Treatment of 102 cases of facial nerve inflammation by combination of acupuncture and herbal therapy. *Chinese Folk Therapies*. 1996. 3:23.
15. Qian Zhiyun. Some experience on the acupuncture treatment for drug addiction. *Chinese Acupuncture and Moxibustion.* 1997. 17(12):735–736.
16. Zhou Janwei. Progress of the research on prevention and treatment of AIDS by acupuncture and moxibustion both in China and the World. *Chinese Acupuncture and Moxibustion.* 1996. 16(9):54–56.
17. Bao Fei. Application of acupuncture and moxibustion to the treatment of malignant tumor. *News Report of Medical Research.* 1997. 26(3):36–38.
18. Xu Shaofen, Cao Xiaoding, Xu Zhenbang. Research on the enhancement of pain suppression effect of acupuncture by medicaments. *Acupuncture Research.* 1991. 61(3–4):240–242.
19. Tang Jingshi, et al. Research on the pain suppression of the afferent nerve by acupuncture. *Acupuncture Research.* 1989. 59(1–2):135.
20. Zhu Bing. *Scientific foundation of Acupuncture and Moxibustion*. Qingdao Publishing House. 1998:87–109.

Fundamentals of Yoga

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What is *Yoga*?

The word *Yoga* comes from the Sanskrit *yuj*, which means 'yoke' indicating a joining together, a unity, a harmony, balance between internal and external consciou-sness and manifestation. Thus, *yoga* means self-knowledge, understan-ding, awareness, and union with the highest consciousness as the ultimate develop-ment. *Yoga* is a system of lifestyle, philosophy and practices, which evolve the person's potentials, including the physical, vital, mental, emotional, psychic and spiritual qualities.

Early Beginnings

The roots of *Yoga* lie many thousands of years ago, but it is so relevant to our present age that it is deservedly popular worldwide. Through the ages, it developed from the experiences, meditations and realizations of wise people, and it gradually built into the extensive body of knowledge it is today.

As *yoga* is the result of personal inquiry and experience, one might say that it began when humans first became aware and started asking questions on self-discovery. Knowledge of the body and its functions was the beginning of self-understanding, knowledge of the mind and its processes was the beginning of self-awareness, and knowledge of the transcendental force/ spirit was the beginning of self-realization. These required a healthy and vital body, so they developed the *yoga* postures, cleansing practices and breathing practices. They needed clarity of mind, so they developed systems of concentration and clarity, which became the meditation practices. As people started to live in more concentrated communities, they evolved philosophies and behaviour that led to harmony between them.

Vedic Era

The written history of *yoga* goes back thousands of years. The earliest writings are known as the *Vedas*. The word *veda* means 'knowledge'; there are four *Vedas*, the *Rig-Veda* being the oldest book of humanity. They discuss the spiritual and scriptural laws of nature, thoughts on the meaning of life, inner and outer know-ledge, and recommend various rituals and meditations for human development. It is said that they contain eternal truths that have been discovered, not created (just as Newton discovered the law of gravity, which was there before him). At the end of the *Vedic* period, ritual went into the back-

ground, and the path of wisdom came to the fore. This was the age of the *Upanishads*.

Upanishadic Age

The greatest thinkers and sages are from that time. The culture was well-structured and secure. It was an agrarian economy, stable and fertile, giving opportunity for leisure and for delving into the depths of human consciousness.

People went through the four recognized stages of life:

- *Brahmacharya*: The students, who learnt the spiritual teachings, and the ways of controlling the mind, as well as the vocational education to prepare them for their work to support their family in the next stage.
- *Grihastha*: The householder stage, when they married, had children and fulfilled their social responsibilities.
- *Vanaprastha*: After fulfilling the householder responsibilities, they were able to go into the solitude of the forest for contemplation and meditation, which led to the next stage.
- *Sannyasa*: Renunciation, and concentration on spiritual realization.

The results of the contemplation of the wise people came out in more than 10,000 *Upanishads*. Over time these have been whittled down to approximately 108, of which 10 are considered major *Upanishads*. Two of these are especially important for *yoga*:

The *Taittiriya Upanishad* classifies the entire human entity into five dimensions of existence, the *koshas* (sheaths) which interpenetrate each other, each being more subtle than the last:

Annamaya kosha – Matter, the physical body. This is the part of us dealt with in anatomy, physiology and physical medicine.

Pranamaya Kosha – The energy body (*prana*). Western science largely ignores this, yet it represents an area for real improvement in therapy. The wise people conceived that all creation is suffused with *pranic* energy and called it *mahaprana*. The localized collection, associated with the body, is the *pranamaya kosha.*

Manomaya kosha – This consists of the mind and the functions of rationality, interaction, expression of emotion, belief, the conscious, subconscious and unconscious mind. This is the part dealt with in psychology and psychiatry.

Vigyanamaya kosha – This is the dimension of our psychic abilities, wisdom and understanding, which are higher than the *manomaya* qualities.

Anandamaya kosha – This is the sheath of bliss, when the ego is merged with super-consciousness.

This concept was fully incorporated into *yoga* and is the foundation of its great benefit as it attends to the whole person. Thus, *yoga* is ultimately a spiritual journey, but can easily be a science of health and therapy, and can be used when things go wrong in any or all five dimensions of the person.

The *Mandukya Upanishad* indicates the process to alter the states of consciousness. These are the wakeful state (*jagriti),* where consciousness operates through the senses, the dream state (*swapna*), where the senses are withdrawn and we experience the subconscious mind, and deep sleep (*nidra*), where awareness of the individual self is lost. Above these is the state of *turiya,* which is transcendental consciousness that can observe all three lower states. The first three have certainly been recognized by Western psychology, though only in the

last century, but *turiya* is not acknowledged at all.

Puranic Age

After the *Upanishadic* Age came the *Puranic* Age. This period was the time of the writing of the two great epics, the *Ramayana* and the *Mahabharata*. The *Ramayana* describes the life of Sri Ram and his wife Sita. It includes the *Yoga Vashistha*, which is in the form of instructions given to Ram about life, wisdom and knowledge by his Guru, Vashistha.

The *Mahabharata*, another epic, contains the *Bhagavad Gita*, which is a dialogue between a spiritual master, Krishna, and his disciple, Arjuna. Krishna clearly explains, among many other principles, the synthesis of action and meditation in life, a branch of *yoga* known as *Karma Yoga* with which we will deal later.

Raja Yoga is best illustrated by the *Yoga Sutras* of the great Sage Patanjali. It is a psychological approach to human development, a science of mind control centring on meditation. This is also called *Ashtanga Yoga*, the yoga of eight limbs, and we will deal with it in detail later.

Hatha Yoga is described in Swatmarama's *Hatha Yoga Pradipika* and the *Gheranda Samhita* by Sage Gherand. These texts contain a set of purification techniques known as the *shatkarmas,* which work on the vitality aspect, balancing the energy with the mental force. These are important in *yoga* therapy and indeed in the prevention of illness, and will be dealt with at length later.

The Main *Yoga*s and their Contribution to Health

We have defined *yoga* as a system of lifestyle, philosophy and practices. In this section we will deal with different types of *yoga*. When people discuss the subject of health, they usually categorize their work in terms of the different forms of illness. In our opinion, this is not dealing with 'health', it is dealing with sickness and abnormality. The subject of 'health' surely deals with ways in which we can stay healthy in all dimensions of our being, and *yoga* is pre-eminent in this area. It cares for our physical well-being, general vitality, mental balance and tranquillity, emotional balance and direction, our higher mental, psychic and intuitive abilities, and the awareness of our spiritual reality. *Yoga* is a holistic and extensive system of attaining and maintaining health in its widest sense.

As well as the many useful practices *yoga* teaches, the lifestyle improvements that it recommends help us to live in a much more harmonious and useful way and improve the quality of our relationships with other people. It has been said that the best way to have good friends is to be a good friend. The person who absorbs the teachings of *yoga* certainly becomes a good friend, because of their better personal discipline and more considerate attitude to other people and their needs. In this way our life becomes less stressful and this flows on to better health all round.

Yoga philosophy teaches us to understand the real meaning of our lives. In this age, in so many communities people have lost the sense of meaning in their lives. This is leading to a serious vacuum in their self-esteem, their attitudes to their fellow human beings and their world in general. A 'meaningless' life is perceived as one that is worthless, and so suicide, murder, cruelty and war atrocities are rife at this time.

The practices of *yoga* bestow many benefits. From the health point of view, prevention of physical, mental and emotional illness is most important. However, *yoga* can be used as a therapy

also, and there is a large body of research which has demonstrated the effectiveness of the many *yoga* practices in curing or relieving illness. We will consider some of these in this article.

The forms of *yoga* we will discuss are:

- *Hatha Yoga* – The *yoga* of purification;
- *Raja Yoga* – The *yoga* of the mind, of introspection;
- *Karma Yoga* – The *yoga* of action with meditative awareness;
- *Jnana Yoga* – The *yoga* of knowledge and wisdom;
- *Mantra Yoga* – Ehich deals with the vibratory aspects of our nature.

Hatha Yoga

Originally, *Hatha Yoga* was designed to balance the mental and vital functions of the person, prior to meditation, in order to attain higher states of consciousness.

For thousands of years, the *yogis* have said that vital energy – *prana* – pervades the whole universe, both manifest and un-manifest, whether animate or not. Modern physicists now agree with this, and they call it 'background energy'. They tell us that it also forms the substrate of matter. They say that matter is just organized energy, and can be converted back to it, albeit with the release of vast amounts of energy – the atom bomb is an example.

When energy or *prana* is un-manifest, it is known as *mahaprana*; when it is in human existence, it is divided into *chitta shakti* and *prana shakti*, the mental and the vital forces. *Hatha Yoga* aims at creating a balance between mind and energy. The different amounts of air flowing through the nostrils correspond to these forces and should alternate for fixed periods of time during the day. If they are not balanced, neither are we. The *Hatha Yoga Pradipika* and the *Gheranda Samhita* tell us that in order to achieve balance we need to first purify the gross body. For this purpose, *hatha yoga* recommends the following cleansing techniques, known as *shatkarmas* (**please note** that all practices in this paper are mentioned only for description and not for instruction. They should only be learnt under the guidance of a qualified *yoga* instructor).

Shatkarmas

(1) *Neti* – The practice has been simplified by Swami Satyananda Saraswati, and the technique can be found, with all the other practices in this section, in his book *Asana, Pranayama, Mudra, Bandha.*[1] *Neti* aims to clean out the nostrils and paranasal sinuses of the head, of stale and purulent mucous, and to balance the flows of the breath by decongesting the mucous membranes of the nose. It is usually practised by pouring warm salt water through the individual nostrils, but if the nasal passages are very much blocked, it can be done with a catheter. *Neti* is effective for treating chronic sinusitis and asthma.

(2) *Dhauti* – The word means 'cleansing' – there are six forms of *dhauti*:
   - *Danda dhauti* – Cleaning teeth, ears and tongue;
   - *Vatasara dhauti* – Swallowing air and burping it up again, which is said to ventilate the inside of the stomach, cleaning it with air;
   - *Vaman dhauti* – (same as *kunjal kriya*) – Quickly swallowing four glasses of warm salty water and vomiting it back. Good for acidity and clearing the lungs, it can be used to treat asthma. If used early in an asthma attack it can actually stop the attack. It dilates the bronchial tubes and causes the

secretion of thin mucous, which cleans out the respiratory tract. It probably does this by either stimulating the sympathetic nervous system or retarding the action of the parasympathetic nervous system;

- *Varisara dhauti* – Also called *shankhaprakshalana*, this technique cleans out the whole intestinal tract. The practitioner quickly swallows two glasses of warm salty water, then does a series of five postures (*asanas*), which open the valves of the stomach and intestines, eight times each. This technique of swallowing the water and practising the asanas is repeated until clear fluid comes out of the bowels. It is excellent for constipation, but it also forms the mainstay of the *yoga* treatment for diabetes. There is a shortened version, *laghoo shankhaprakshalana*, in which only three rounds are done. People with high blood pressure, hernia, peptic ulcer or cardiac illness should not do it, but it is generally quite safe and easy;
- *Vastra dhauti* – Swallowing a long piece of cloth, and gently pulling it back up. This is also good for asthma, and probably works the same way as *vaman dhauti*. It sounds difficult, and may be so for some people at first, but most people can generally master it;
- *Vahnisara dhauti* is also called *agnisar kriya*; the muscles of the front of the abdomen are rapidly contracted and relaxed, with the breath held out. It strengthens and massages abdominal muscles and organs, and stimulates the digestive fire.

(3) *Basti* – Yogic enema, cleans out the lower intestine. It is not needed if one is doing *shankhaprakshalana*.

(4) *Nauli* – Advanced practice that needs excellent control of abdominal muscles.

(5) *Kapalbhati* – (transl. 'frontal lobes' + 'to shine'). In this practice, there is forced exhalation and passive inhalation. It is said to stimulate the frontal lobes of the brain, and so clear the mind of disturbance, and allow it to become one pointed and concentrated. It also increases the vitality.

(6) *Tratak* – Visual concentration on one point, develops mental concentration, mind control, clarity and calmness. It stimulates melatonin hormone secretion.

Done in this sequence, the *shatkarmas* are designed to clean and purify the gross body (*neti, dhauti and basti*), then stimulate the *pranic* energy (*nauli*), then stop mental dissipation (*kapalbhati*), and then concentrate the mind (*tratak*). After this preparation, the practices of meditation can progress smoothly.

Nowadays, it is usual to include in *hatha yoga*, the group of techniques called *asanas, pranayamas, mudras* and *bandhas.*

Asanas

Asanas are the postures usually associated with the name '*yoga*'. They vary in complexity from simple stretching practices to difficult advanced postures. It should be noted, however, that even the simplest *asanas* can have a profoundly beneficial effect.

Asanas affect all dimensions of the person, especially the body-mind connection. Swami Satyananda states in *Asana, Pranayama, Mudra, Bandha.*[1]

***Bhastrika Pranayama* is known as the bellows breath, *bhastrika* means 'bellows' in Sanskrit. *Bhastrika* rapidly increases the vitality and warms the body, just as the bellows increases the heat of the fire.**

"The mind and body are not separate entities, although there is a tendency to think and act as if they are. The gross form of the mind is the body and the subtle form of the body is the mind. The practice of asana integrates and harmonizes the two.

"Both the body and the mind harbour knots. Every mental knot has a corresponding physical muscular knot and vice versa. The aim of asana is to release these knots. Asanas release mental tensions by dealing with them on the physical level, acting somato-psychically through the body to the mind. For example, emotional tensions and suppression can tighten up and block the smooth functioning of the lungs, diaphragm and breathing process, contributing to a very debilitating form of illness in the form of asthma.

"Muscular knots can occur anywhere in the body: tightness of the neck leading to cervical spondylosis, or of the face as neuralgia, etc. A well chosen set of asanas, combined with pranayama, shatkarmas, meditation and Yoga nidra, is most effective in eliminating these knots, tackling them from both the physical and mental levels. The result is the release of dormant energy; the body becomes full of vitality and strength, the mind becomes light, creative, joyful and balanced.

"Regular practice of asana maintains the physical body in an optimum condition and promotes health, even in an unhealthy body. Through asana practice the dormant potential energy is released and experienced as increased confidence in all areas of life."

Pranayama

Pranayama is generally defined as 'breath control'. Although this interpretation may seem correct in view of the practices involved, it does not convey the full meaning of the term. *Pranayama* should not be considered as mere breathing practices to introduce more oxygen into the lungs. It is the utilization of breathing to influence the vitality of the body, and the balance and calmness of the mind and emotions. Four *pranayamas* are worthy of mention in this respect.

Nadi Shodhana Pranayama is the technique of blocking each nostril in turn as the breathing goes on. The breath flows in through the left nostril and out through the right, then in through the right nostril and out through the left, the eyes remaining closed throughout. This practice balances the emotions, and induces tranquillity of the mind, clarity of thought, and improved concentration. How does it create such balance? The most likely explanation is this: it has been clearly demonstrated that breathing only through the right nostril stimulates the left cerebral hemisphere and breathing only through the left nostril stimulates the right cerebral hemisphere. Balancing the flows through both nostrils, as in *nadi shodhana*, balances the two sides of the brain, and with it, the thinking and emotions. *Nadi shodhana* can become quite powerful with advanced additions such as breath holding and muscle locks. Simple *nadi shodhana* can be done for 5–10 minutes.

Bhramari Pranayama consists of blocking the ears with the fingers, and, with the eyes closed, making a humming sound

like a bee, as we breath out (*bhramari* means 'bumble bee'). A strong vibration can be felt inside the head. Physically it is excellent for tension headache, and to loosen thick mucus in the sinuses. Mentally it alleviates stress, tension, anger, and anxiety and produces peace of mind. It is usually done for a few minutes, but in cases of extreme anxiety or panic, can be practised for half an hour, a few times a day.

Ujjayi Pranayama is done with the eyes closed. We remain aware of the natural breathing, while slightly contracting the glottis to make a soft snoring sound. The breath should be slow and deep – first into the abdomen, then into the lower chest, then into the upper chest; then out in the reverse order. The practitioner notices increasing tranquillity of mind and relaxation of the body during the practice. *Ujjayi* can be used in combination with other yogic techniques for an even stronger effect.

Bhastrika Pranayama is known as the bellows breath, *bhastrika* means 'bellows' in Sanskrit. In this practice, with the eyes closed, we breathe in and out forcefully through the nostrils, making sure the breathing is abdominal, i.e., from the diaphragm. *Bhastrika* rapidly increases the vitality and warms the body, just as the bellows increases the heat of the fire. It is used for fatigue, tiredness, sluggish bowels, asthma and the birth process. As it induces tranquillity and one-pointedness of mind, it is often used before meditation.

Mudras

Mudras are a group of gestures or attitudes which alter mood, attitude and perception, and which deepen awareness and concentration. They are introduced after some proficiency has been attained in asana, *pranayama* and *bandha*.

Bandhas

Bandhas are a group of muscle locks, which aim to lock the *pranic* energy in particular areas and redirect their flow for the purpose of spiritual awakening. There are four *bandhas*: *jalandhara, uddiyana, moola* and *maha.* The last one is a combination of the first three. The three basic *bandhas* have therapeutic effects.

Jalandhara bandha is done in the sitting position with the hands on the knees. With the breath in, the head is bent forward, and the chin is pressed into the upper chest as high as is comfortable – if possible into the sternal notch. Physically, this practice helps to balance the secretions of the thyroid gland, and so regulate the metabolism. Psychologically, it produces mental relaxation, and relieves stress, anxiety and anger.

Uddiyana bandha is done either standing, bending over with the arms straight and the hands on the knees, or sitting with the arms the same way. The stomach and bowels should be empty. With the breath fully out, we make a false inhalation with the glottis closed, as though breathing in but not actually taking in any air. The anterior abdominal wall is automatically drawn up towards the spine and diaphragm to form *uddiyana bandha*. After a comfortable time it is released. *Uddiyana bandha* is useful for constipation, indigestion and early diabetes. The digestion is stimulated, and the abdominal organs are all massaged and toned. It is said that the adrenal glands are balanced, which removes lethargy and soothes anxiety and tension.

Moola bandha is the contraction of the muscles deep to the centre of the perineum. It is held for the duration of a breath, then relaxed, and repeated 10 times. In a more advanced version it is combined with *jalandhara bandha*. *Moola bandha*

stimulates the pelvic nerves and tones the urinary and genital systems. As a result, it raises low libido and helps erectile dysfunction in men, and vaginal dryness in women. It relieves the symptoms of depression and can also immediately neutralize other emotions. For example, if a person wants to control crying, laughing, or even coughing, applying *moola bandha* will stop it.

The practices of *hatha yoga* combined with the techniques of meditation form the foundation of *Yoga* Therapy. The blockages – mental, emotional, physical, psychic and spiritual – that stop us from realizing our fullest potential, are the same ones that cause most illnesses. The *yoga* practices were developed for spiritual evolution, but they can be just as easily applied to relieving illness. There are a number of advantages of *yoga* used in this way:

- After we have learnt the practices, they are free of charge. So if we benefit from them, we do not have to continue paying for medicines. This can be reflected at a national level where vast amounts of money, which would have been spent on pharmaceutical drugs, can be saved by governments.
- The practitioner gains mastery over whole areas of his/her life, becomes independent of outside sources of treatment, and is able to apply the practices at any time they are needed. For instance, a person with asthma who masters *vaman dhauti* has a means to stop an early attack any time. The person with anxiety that leads to panic attacks, can settle the anxiety with many practices such as *bhramari pranayama*, *ujjayi pranayama*, and *yoga nidra* and avoid the panic. Then by a virtuous circle effect, because they know they have the practices, their anxiety about the possibility of panic also reduces.
- A person who has mastered *yoga* can teach the practices to other people when the need arises. In some cases it can be used as a form of *yogic* first aid. Many a time a *yoga* teacher has taught *vaman dhauti* to a person in the early stages of an asthma attack and stopped it.

Raja Yoga

Until we can calm the disturbances of the mind, we will always have problems with our mental and emotional states, difficulties in our behaviour and relationships, and be unable to attain our true potential. *Raja yoga*, the *yoga* of meditation, shows us how to calm the mind and realize who we really are.

The principles of *raja yoga* are set out in the *Yoga Sutras* written by Sage Patanjali about 2,500 years ago. As it is laid out in eight consecutive steps, it is also known as *ashtanga Yoga* (eight-fold path), which has sequential steps through:

(1) Yamas
(2) Niyamas
(3) Asanas
(4) Pranayamas
(5) Pratyahara
(6) Dharana
(7) Dhyana
(8) Samadhi.

The *yamas* and *niyamas* are recommended moral codes, which the practitioner is to integrate into life more and more as time goes on:

Yamas

The purpose of the *yamas* is to harmonize the external environment and our responses to it:

Ahimsa – Feeling of non-violence towards all things, from thoughts, words

and deeds. As one develops *ahimsa*, one detects one's violence to be more and more subtle, but also that there is less violence around one.

Satya – Truthfulness – this also involves our thoughts, words and deeds. We must be truthful at all these levels, sincere and true to ourselves as well. But truth should not be used to intentionally hurt another.

Asteya – Honesty – This means not stealing other peoples' possessions, but it also means internal honesty, simplicity and sincerity.

Aparigraha – Non-possessiveness – This is really the result of developing detachment. We care for our possessions or the people in our lives, but we are not addicted to them.

Brahmacharya – Being established in the higher reality (nature of Brahman). Often equated with celibacy, but that is just a small part; in that state, carnality has no place.

Niyamas

Special codes of self-restraint aimed at internal discipline:

Saucha – Cleanliness of the body, external and internal, neatness and order in our environment, and purification of the mind. The *hatha yoga shatkarmas* are designed to help with this.

Santosha – Contentment, being satisfied with what we have. This develops as we do; our demands become fewer, our life becomes simpler and so we are more contented.

Tapas – Austerity – As we live simply we become better able to cope with hardships.

Swadhyaya – Self-study – Analysis and knowledge of our own personality, becoming aware of our strengths, weaknesses, ambitions and needs.

Ishwara pranidhana – Belief in higher reality.

Why moral codes in a work on meditation? Paramahamsa Satyananda says in *Four Chapters on Freedom.*[(2)]

"The yamas are designed to harmonise one's social interactions, and the niyamas are intended to harmonise one's inner feelings. All the rules, yamas and niyamas, are designed to reduce friction between one's outer actions and inner attitudes. There is a two-way relationship: the mind stimulates external actions and external actions stimulate the mind. If the external actions are not harmonious, then the mind will be disturbed. Conversely, a disturbed mind will tend to produce disharmonious acts."

He goes on to state: "The rules are not easy to apply, but even limited application will lead to greater peace of mind. Perfect application can only arise with self-realisation", but we can continue to improve as our life goes on.

Asanas

These are the *yoga* postures. The *Yoga Sutras* define *asana* as "that posture which is still and comfortable"; this refers to meditative postures.

Swami Niranjanananda in *Yoga Darshan*[3] says the human body is capable of five movements and the *yoga* postures (dealt with in the *hatha yoga* section) reproduce these:

- Natural, like walking (stretching postures such as *pawanmuktasana*);
- Dynamic, like running (dynamic postures such as salute to the sun);
- Adaptable, like comfort in the folded positions (e.g., forward and backward bends);
- Balance, like standing still (balancing *asanas*);

Stillness (meditative *asanas*)

Asanas teach us to know our body through these types of movements. They change body chemistry, free energy flows and bring balance to the mind and emotions. Therefore, they affect us on three levels, the physical, energy and mental levels.

Pranayama

Patanjali states that "pranayama is the cessation of the movement of the breath". It sounds dangerous, but it really means that if we can gradually widen the time between each inhalation and exhalation, the mind becomes calmer and calmer. This is the meaning of *pranayama* according to *raja yoga*, but in other *yogas*, as we have mentioned, there are many practices of *pranayama* which have different effects such as calming the mind and emotions, increasing the vitality and balancing the activities of the cerebral hemispheres. They are very helpful in many different illnesses such as anxiety, depression, emotional instability and so forth.

Pratyahara

Pratyahara means withdrawal of the mind from the objects of sensory experience. The mind then introverts and experiences its deeper nature. The aroused mind recognizes the parameters of name, form, object and time. *Pratyahara* cuts off awareness of the objects. As it is the sensory input that mainly keeps us fully conscious when we practise *pratyahara*, the rhythms of the brain slow down and we 'descend' from beta rhythms to alpha rhythms, down to the borderline of theta (sometimes known as the alpha-theta state) – the threshold between waking and sleeping. At this level, we are mentally relaxed and unaware of our external environment or sensations from the physical body.

The state of pratyahara is deeply relaxing, but it is also the threshold of the subconscious and unconscious levels of the mind. These are then available for analysis and inserting positive affirmations. This state of mind is useful for many health practices, and personal development techniques.

Some pratyahara techniques are:

Yoga Nidra™ – In this practice we use rotation of consciousness through all parts of the body, and we easily reach a sensitive state of mind to bring up and deal with deep mental impressions.

Ajapa Japa – Internalized awareness of breath with the *mantra* of the sound of the breath 'so hum'. It quickly calms the mind and stops mental dissipation.

Tratak – Concentrating on an external form, often the flame of a candle – Develops one-pointed concentration and calms the mind. It has been found to increase the secretion of melatonin, the body's natural tranquillizer, from the brain.

Antar Mouna – Works on observing, changing and stopping thoughts, and also tracing them to their source.

When the state of *pratyahara* has been attained, we focus the mind and come to:

Dharana

The important thing here is to keep the mind fixed on one point only. Any point of concentration can be used, such as a *mantra*, symbol, thought or idea. At the time of meditation, if there is oscillation of the mind then concentration will not be experienced. In the beginning it is difficult to concentrate the mind for a long time, but when the mind wanders we just gently bring it back to the object of concentration. It is easier if we have done the preliminary practices first.

Dhyana

Dhyana is the state of meditation. Note that this is a state, not a practice. It is the result of perfecting *dharana*, when there are no breaks in concentration. One also remains aware that one is practising *dhyana*. Thus, *dhyana* includes two things: one, an unbroken continuous flow of consciousness of a single object, and two, the awareness of *dhyana*; that is the awareness that one is practising unbroken concentration. These two kinds of awareness go hand in hand.

Samadhi

Dhyana leads to this final stage. In meditation there are three active parameters: the meditator, the process of meditation and the object being meditated upon. In *samadhi*, only the object remains.

Benefits of Raja Yoga

As discussed above, the lifestyle benefits of *yamas* and *niyamas* are many, and the advantages of *asanas* and *pranayamas* have been mentioned. It is the inner practices, *pratyahara*, *dharana*, *dhyana* and *samadhi*, that can bestow inner peace and reverse many health problems. There are at least four ways in which this can happen.

Deep mental and physical relaxation – Stress is rampant in our world, and most of it comes from our own minds. Our expectations, which far exceed our needs, cause us frustration, disappointment and anxiety. Our sympathetic nervous systems are on full alert much of the time and our bodies and minds get little rest, even when we sleep. This state of arousal leads to many illnesses such as hypertension, asthma, headaches, heart disease, arthritis, bowel complaints and general deterioration of all tissues by free radical damage, etc. The exhaustion phase that succeeds it leads to many more, such as diabetes, and the results of exhaustion of the immune system such as chronic infections and cancer. It is little wonder, then, that the inner practices are used to prevent and treat these conditions.

In the 1970s, Ainslie Meares, an Australian psychiatrist, published in the *Medical Journal of Australia*, excellent results of his cancer patients using deep meditation. They only used the meditation practices and many cancers regressed. Carl Simonton, a radiotherapist from Fort Worth, Texas, used meditation practices with visualizations, and his patients also experienced good results.

Positive influences on the unconscious mind – The evidence on using positive affirmations and visualizations in the state of *pratyahara* and deeper, has been well-known and reported in innumerable books and articles over the years. It almost seems that people use medications rather than meditations for many illnesses, only because they do not know about the latter, or they prefer the pills because they are easier and quicker.

Eliminating negative content in the unconscious mind – The many yogic internal visualizations allow the negative impressions in the deeper layers of the mind to come into consciousness, where they can be dealt with. When they are still repressed, they cause trouble on all levels of the person, the physical, the energy, the mental, emotional and behavioural, and at more subtle levels. They affect the person's attitudes, perceptions and expectations of themselves, others and their world, so they are crucial in all areas of our lives. When we eliminate the effects of these deep mental impressions, we benefit our lives immeasurably.

Karma Yoga

Karma Yoga is the 'yoga of action'. We are always in action even when we are apparently doing nothing. At least our minds are in action, and at some level we still affect the objects or people about whom we are thinking. Even when asleep we dream, and even in deep sleep we are interacting at some level. The *yogis* say that if we are always in action we had better do it the right way. The right way is *karma yoga*, in which we are functioning in the world but our inner attitude to that action is of a special kind. It is the *yoga* of dynamic action – interaction with the world and normal daily situations, but with meditative awareness and continuous flow of energy. It aims to increase the level of our awareness of our internal reactions such as our expectations.

The word *karma* means 'action', but in some respects also the results of our actions – we reap what we sow. The actions can be physical ones, but they can occur in all dimensions of our being, or at any level of consciousness. However, the important thing is to develop the ability to act with the inner attitude which has the following qualities:

Efficiency – This needs full concentration and awareness of the Self, of the mind. It is necessary to be one pointed and not distracted. You must be able to observe the whole event to become efficient, to have the 'big picture'.

Equanimity – The mind should remain balanced in success and in failure. In order to maintain mental balance, it is easiest if one practises the other *yogas* as well, and abandons the desire of attachment, the desire of result and the desire of achievement.

Absence of Expectation – The *Bhagavad Gita* says, "It is not possible for embodied beings to renounce action, but it is possible to renounce the results of the action". People often answer this by saying, "but surely I can expect to be paid for my work". *Karma yoga* says, "yes, but make your contracts for payment, then get on with doing the job for its own sake and with all your attention". Many people who embark on the road of *karma yoga* find that they start to receive abundant payment because the people they work for appreciate their efforts. This is part of the natural law of *karma*; we do indeed reap what we sow.

Lack of Ego – The *Gita* also says, "He who is free from the feeling of ego and who is not swayed by the feeling of good and bad, walks the path of righteousness and righteous action". Egolessness also implies that one has to be simple (uncomplicated), sincere and desireless. Our actions become unselfish with no ego motive, done for others or the world. This lets us live in harmony with nature, to give and keep on giving.

Renunciation of limiting desires – Most desires limit us, such as the desire to accumulate more and more possessions, to soothe the insecurities caused by our spiritual vacuum. These nagging desires cause a vicious circle and take us even further away from our spiritual goal. Other desires, such as the desire to help others without expectation, take us towards it. The more we are able to limit our desires, the less disappointed we will be and the more calm and balanced our mind. We also need to have the ability to discriminate between our needs and our desires.

No identification with the work – Have the attitude of only being the instrument, not the doer, that you are not indispensable. When this is working properly, it is a wonderful feeling as the work flows along as if 'guided by a higher force'. Everything

we need for the job comes our way, and everyone we need to help us comes along at exactly the right time. It all happens so regularly that we realize these could not possibly be coincidences. Then a higher realization starts to dawn within us. When we are non-attached, it is possible to exhaust our *karmas*, which is another aim of *karma yoga*.

Conversion of negative into positive – Some people habitually see the positive side of a thing (optimists), others the negative side (pessimists). *Karma yoga* is a process of converting our negative attitudes into positive ones.

Duty or dharma – In *Yoga Darshan* by Swami Niranjanananda Saraswati,[3] this point and *karma yoga* in general is described thus:

"The last attribute of karma Yoga is consideration of every action as a duty. Do your duty, because action is superior to inaction. Action when performed with the idea of duty produces a very deep experience of bhakti (devotion), surrender, belief, trust and faith in a higher nature, a higher reality guiding us. This duty is to be understood in relation to one's individual dharma, social dharma, global dharma and universal dharma.

"When one develops the awareness of dharma, as an inherent commitment of duty or obligation to other beings, then one develops a giving or helping nature. Many times people talk about, and believe in giving, a helping hand to others. Our actions, which outwardly may seem like helping, do not necessarily convey the same feeling to others. Often, even the desire to help others carries with it some kind of ulterior motive, whether for gain or profit. We should not be restricted to the idea of some kind of personal gain.

"Initially the practice of karma yoga is difficult, because to combine so many attitudes such as efficiency, renunciation, equanimity, egolessness and duty in one action is difficult. The thrust of karma yoga is to have these concepts combined in one thought, one action, in one moment. Once these different ideas are combined, then we can proudly say we are practising *karma yoga*."

However, until then we can do the best we can to have that attitude. In the workplace, at home with the family, when we are with other people, and indeed even when we are alone, relating to ourselves, we can remember to apply the above principles. Then over time, it will become second nature in all our actions, bringing a peace of mind that most people never attain. *Karma yoga* clears the mind of phobias, insecurities and complexes, and makes it steadier for further practices and for life. The ultimate state is total serenity in the midst of intense action.

Jnana Yoga

Literally *jnana* means 'wisdom' or 'knowledge'. So *jnana yoga* means the *yoga* of real knowledge. This knowledge is not intellectual, acquired from books and different sources of communication. It is an advanced *yogic sadhana* (spiritual practice), a process of self-inquiry with a concentrated mind. *Jnana yoga* is linked with the *Vedanta* of Indian philosophy, which is a path of inquiry into *Brahman*, the Absolute.

In order to understand the *Brahman* or the Absolute, the process of *jnana yoga* begins with self-analysis. The form of self-analysis is not high, abstract or abstruse; it is very definite. In fact, the practices of *pratyahara* and *dharana* may be classified as part of *jnana yoga* also, because through these practices we analyse ourselves. What is happening at the level

The highest order of need structure has been named by Maslow as self-actualization need. These needs include pursuit of knowledge in a field of specialization that results in realizations of one's unique potential.

of our thoughts? How are the thoughts, emotions and feelings swaying us? Do we have the ability to stop them or to recall them at will? This kind of self-analysis, in terms of the physical, mental, emotional and intellectual aspects, can be considered a part of *jnana yoga*. This kind of self-knowledge helps a person mentally and emotionally.

Swami Niranjanananda has proposed a technique of self-analysis known as SWAN technique. The four letters of SWAN stand for Strengths, Weaknesses, Ambitions and Needs. Anyone can analyse himself or herself by perceiving the extent of these four dimensions in their personality. 'Strength' refers to such qualities and characteristics that contribute towards advancement of spiritual evolution, resulting in mental quietness and inner happiness. Self-confidence, loving nature, concern for others, compassion for the needy, contentment with one's possessions, etc., may be cited as examples of one's strengths. On the other hand, negative thoughts, emotional instability, anxiety, stress, hatred, egoism, etc., may be taken as one's 'Weaknesses'. 'Ambitions' refer to one's aspirations for material achievement, social prestige, positions, etc., 'Needs' include basic requirements for survival and maintenance like need for food, education, love and belongingness. A self-assessment on these dimensions provides the person a picture of their personality as perceived by them. This provides a basis for improving the quality of life by adopting *yogic* practices and *sadhanas*. The practice of *jnana yoga* results in expanding one's awareness to cover wider and wider areas of consciousness. This is called meditative awareness and it ultimately results in the power of discrimination and right understanding, and the ability to distinguish between the real and the unreal.

In contemporary psychology, the humanistic approach is very close to *jnana yoga*. The famous humanistic psychologist, Abraham Maslow (1908–1970,) proposed a hierarchical structure of human needs. According to him, all human needs can be arranged into seven categories, of which five are distinctive and often cited. These categories of needs may be placed in a sequential order of hierarchy. Most basic are the physiological needs that must be satisfied for physical survival, for example, need for food, water, oxygen, etc. Then come safety needs that are related to protection and security from potential dangers. The physiological and safety needs are obviously 'biological needs' related to physical survival and protection. The third group of needs are called needs for belongingness and love, i.e., the need to love or to be loved and the need of affiliations and associations with a group or groups.

The fourth level in the hierarchy of needs is the category of esteem needs, i.e., the need to gain power, prestige and recognition in society. Apparently, the second and third order needs in Maslow's model consist of 'psychological needs'. The highest order of need structure has been named by Maslow as self-actualization

need. These needs include pursuit of knowledge in a field of specialization that results in realizations of one's unique potential. Although few people reach this level, everyone has a self-actualizing need. In order to become self-actualized, the persons must be well-adjusted and self-fulfilled. Maslow has given 15 characteristics of a self-actualized individual which include efficient perceptions of reality, acceptance of self and others, spontaneity, simplicity, task-oriented attitude, self-discipline and self-reliance, sense of appreciation, mystic experiences, compassion and sympathy for humanity, creativeness, harmony with culture, need for privacy and a life of detachment. Taken together, these characteristics seem to refer to the spiritual awakenings and are very similar to a self-realized *yogi* as described in *jnana yoga*.

The different sequential needs as propounded by Maslow refer to the three interactive aspects of evolution of the human personality as conceived in *yogic* literature. They are from body awareness (*annamaya kosha*) to spiritual enlightenment and experience of inner bliss (*anandamaya kosha*) through the psychological awakening (*manomaya kosha*).

We find that Maslow's need structure highly resembles the *yogic* theory of self-realization. However, *yogic* literature is very rich in terms of techniques or practices, called *sadhana*, to achieve the highest level of self.

Jnana yoga practices develop two distinctive qualities in the practitioner. They are *viveka* and *vairagya*.

Viveka is the power of discrimination between the real and the unreal, the eternal and the decaying. *Viveka* provides understanding and knowledge of reality and illusion. The person with *viveka* perceives the world as a changing play and does not confuse it with the permanence of the ultimate.

Vairagya means 'detachment'; it is freedom from *raga* (attraction) and *dwesha* (repulsion), it is dispassion and non-attachment to the fruits and benefits of one's activities.

Both *viveka* and *vairagya* continue to grow and manifest in different behaviour and modes of adjustment, and with expanding areas of consciousness through *jnana yoga sadhana*. *Jnana yoga* is a higher order *sadhana* and not meant for every one. It has to be combined with other practices of *yoga* as per the tendencies and nature of the practitioner. Some who are dynamically inclined can practise *jnana yoga* if they combine it with *karma yoga*. People whose emotions are charged can practice *jnana yoga* by combining it with *bhakti yoga* (the path of devotion, expression of the heart, of emotions). Those who have potential psychic abilities can practise *jnana yoga* combined with *raja yoga*. Only those with indomitable will can practise *jnana yoga* by itself. So *jnana yoga* is generally considered a supplement to meditation, *dhyana*. In *dhyana* there is total identification and merger of the mind, and in *jnana* there is full experiential knowledge of that merger. So *jnana* and *dhyana* combined give the experience of *samadhi*.

Mantra Yoga

The word *mantra* is generally translated as 'sound vibration', but the literal translation is 'the force which liberates the mind from bondage'. However, *mantras* have effects in all aspects of the person, not just the mind. The *mantras* used in *yoga* are formed from combinations of the sounds of the 50 Sanskrit alphabet characters, which correspond to different energy

centres in the psychic body. *Mantras* which are composed of those sounds create vibrations in specific areas of the psychic body. Their vibrations have effects on our physical bodies and our mental functioning.

Physical effects – Since the *mantras*, when sounded audibly, vibrate the appropriate parts of the physical body, any problems in those parts that respond to vibration, improve when the appropriate *mantras* are repeated. For instance, the last letter of the often-used *mantra,* OM, produces a humming sound, which vibrates the head area. It is an excellent practice for relieving tension, headache and chronic sinusitis. Similarly, other *mantras* especially vibrate the chest area, and are good for relieving tension there. In this way, if one knows the area of action of *mantras*, one can virtually prescribe an appropriate *mantra* for that area.

Mental effects – If *mantra* is the force that liberates the mind from bondage, what is this bondage? It has two aspects, impurities (*mala*) and oscillation (*vikshepa*). The impurities are the sum total of all the negative impressions deep in the mind. They are the result of past problems in all areas of our mental being, and relate to such areas of our life as love, joy, security, power and self-esteem. *Mantras* activate these parts of our mental apparatus and allow memories to surface where they can be dealt with and eliminated. The other aspect of the mind, *vikshepa*, is the oscillation and distraction of the mind; the internal monologue goes on all day, the desires, the fears, the plans, the disappointments, the mind is never at peace. By repeating the *mantras* with one-pointed awareness, the oscillations can be quietened and the mind becomes tranquil and peaceful.

Psychic effects – Mantras can also be used to awaken our psychic potentials, but this subject is better left to be imparted by one's own yoga instructor who is experienced in the science of mantra.

Some research data on Yoga

As we have seen, *yoga* covers a broad range of techniques applicable to all aspects of life. This needs to be taken into account when examining *yoga* research, since there are many articles that discuss relaxation, hypometabolism, etc., which are directly or indirectly related to *yoga*, although this relationship may not be explicitly stated.

Yoga and Cardiovascular Disease

Considerable research data have been collected on *yoga's* capacity to influence the cardiovascular system and improve function. Research has focused on hypertension and coronary artery disease in particular. Yoga is seen to be a good alternative to exercise, because of its additional relaxation effect, and the fact that it can be finely adjusted to the physical needs of the individual person.

The research on hypertension is now conclusive as a result of more than 30 years of data.[4,5,6,7] In 1969, Datey successfully treated 53 per cent of 47 patients suffering from hypertension using the meditation technique of *shavasana*. There have been several studies, which have compared various meditative practices and their effects on blood pressure. Bagga and Gandhi compared *shavasana* with Transcendental Meditation© and found that both techniques lowered heart rate and blood pressure, and increased skin resistance; however, a *mantra*-based meditation practice was relatively more significant.[8]

There have been a number of studies on the heart itself and it has been shown that yoga improves cardiovascular

efficiency.[9,10] Carson, et al., investigated the effect of a relaxation technique on coronary risk factors and found that relaxation had a significantly beneficial effect on plasma lipids, weight, blood pressure and blood glucose.[10] Carson found that the use of a relaxation technique might be considered beneficial in reducing the risk factors.

Tulpule used *yoga* in the treatment of myocardial infarction.[11] He found that simple *yoga* postures and *pranayama* (*sukhasana, shavasana, bhujangasana, matsyasana*, etc.) were beneficial, when taught to 102 male patients with myocardial infarction who practised for one year. The results indicated that *yoga* is easy to learn; it needs no medical supervision, and it can be practised at home as part of a rehabilitation programme. *Yoga* significantly reduced long-term mortality in the *yoga* group compared to controls and had a high rate of rehabilitation. Only three out of the 102 subjects practising *yoga* died during one year, while 13 of the 103 controls died. Significantly, no patient in the *yoga* group developed any evidence of cardiac decompensation or dysrhythmia during the one year while doing the *yoga* practice.

Generally speaking, *yoga* is taught in conjunction with other techniques in order to produce a synergistic effect. There have been several studies showing that multi-factorial approaches have many benefits and that one approach alone may not give as good a result.[12,13,14]

Jurek, et al., showed that the addition of a behavioural intervention (biofeedback-assisted relaxation) produced a decrease in blood pressure beyond that associated with the diuretic alone.[12] Ornish has produced reversal in coronary artery occlusion using a combination of *yoga* meditation and intensive lifestyle changes (10 per cent fat in the diet, whole foods vegetarian diet, aerobic exercise, smoking cessation, and group psychosocial support).[15] Ornish showed that a group who maintained lifestyle changes for one year had a 4.5 per cent relative improvement in the decrease of their baseline stenosis, and 7.9 per cent after five years. These figures may seem small, but they translate into a significant improvement in the person's functioning.

L.Bernardi, et al., have shown that after one month of training in *yoga pranayama*, patients with chronic heart failure had a significant improvement in oxygen saturation and exercise perfor-mance.[16] In chronic heart failure, impaired pulmonary function can itself contribute to oxygen de-saturation and reduced physical activity. Bernardi found that by slowing the breathing rate to 3–6 breaths per minute using the 'complete *yogic* breath' the patients were able to reduce ventilation by 40 per cent, but increase oxygen saturation, with a substantial improvement in ventilation to perfusion ratio. The method by which this is thought to work is that deeper and slower breathing makes more efficient use of the diaphragm with no increase in respiratory workload.

Apart from its capacity to improve physiology, *yoga* can be seen as an ideal form of exercise for heart disease and blood pressure when it is practised with a relaxed mind, and appropriate to the situation of the individual patient. All patients need to engage in exercise programmes to rehabilitate their hearts and blood pressure. However, exercise programmes are recommended for a select group of patients, and there are definite contrain-dications to exercise testing in-patients. This may be due to the fact that many people strain, because they have a fixed idea of how aerobic exercise should be.

Tulpule, for example, said that yoga is, "completely free of complications, whereas at every centre exercise has produced either death, arrhythmia, severe angina or precipitated myocardial infarction".[11,17]

Fitness

Gharote, Ganguly, Bhole and Karambekar have shown that *yoga* increases fitness and vital capacity. This is an essential part of rehabilitation.[18,19,20]

Asana

K. N. Udupa and R. H. Singh from Benares Hindu University have done much research on the effect of *yoga asana* on stress.[21,22,23] Udupa has studied biochemical parameters such as catecholamines, cholinesterase, mono-amine oxidase, diamine oxidase, plasma cortisol, serum PBI, serum proteins, and blood sugar. He measured students practising *yoga* versus normal exercise and found that *yoga* induces more vital effects than exercise, which works mainly on muscle. Different types of *yogic* practices produce different effects.

Gopal, et al., studied the effects of *asana* and *pranayama* on pulse rate, blood pressure and respiratory functions.[6] He showed that *yoga* practitioners when compared with controls had greater vital capacity and tidal volume, and a relaxed respiratory rate. Also, diastolic blood pressure was less in the *yoga* group indicating decreased sympathetic tone.

M. S. Garfinkel, et al., showed that *asanas* improve grip strength and pain reduction in patients with carpal tunnel syndrome.[24]

Pranayama

Morse, et al., studied the effect of *yoga* and breath on the autonomic nervous system.[25] Such were measured for heart rate, blood pressure and skin resistance. They showed that there is a strong link between breath and autonomic control.

Pratap, et al., showed that there is no major change in blood gases after *pranayama* in normal subjects.[26] However, L. Bernardi, et al., in 1998 showed that after one month of training in *yoga pranayama* there was a significant improvement in oxygen saturation and exercise performance in patients with chronic heart failure. Prakasamma and A. Bhaduri also showed that patients with pleural effusion, who practised *prana-yama*, demonstrated a quicker re-expansion of the lungs in most of the measures of lung function.[27]

Chronic Illness in General

Goyeche has reviewed research highlighting the ability of *yoga* to be of great use in chronic illness as a method of rehabilitation.[28] He cites studies on the use of *yoga* and meditation in cancer, headache, migraine, asthma, emphysema, sinusitis, ulcers, diabetes, gastro-intestinal disorders, spondylosis, arthritis, and mental disorders, including anxiety and depersonalization.

Herbert Benson and Goodale have shown that meditation and the relaxation response is an effective treatment for physical and emotional pre-menstrual symptoms and is most effective in women with severe symptoms.[29]

Uma, et al., showed that *yoga* demonstrated a highly significant improvement in IQ and social adaptation parameters in a *yogic* group as compared to controls.[30]

Preventive and Promotive Measures

Dr W. Selvamurthy reported the findings of a study conducted by the Defence Institute of Physiological and Allied Sciences of

India. Over a period of six months, the *yoga* group sustained a low pulse rate (about 50–60 per minute), decreased rate of breathing and quicker adjustment to conditions of extreme cold on the Himalayan border, perhaps due to better heat conservation in the body. *Yoga* practices were found helpful to tone up non-shivering thermo genesis.[31]

Singh and Madhu conducted a study on 20 male adults who underwent *yoga* training for six months. The results revealed significant improvement in short-term memory and steadiness.[32] Barnes and Nagarkar studied 40 students of Standard VIII (between the ages of 12–14 years) who were provided four months' *yoga* training. Results indicated an improvement in scholastic aptitude.[33] Sridevi, Sitamma and Rao found *yoga* promoted cognitive abilities.[34]

A study conducted by Prof. L. I. Bhushan on 102 resident students of Bihar Yoga Bharati, Munger, indicated a decrease in levels of anxiety, depression, somatization, sensitivity, obsessive compulsive reaction, paranoid ideas, hostility, and psychotism.[35]

Unpublished Studies

In 1996, a study was carried out on 1150 prisoners during a *yoga* training programme in 24 Bihar (India) prisons. Results included reductions in anxiety, depression, hostility and feelings of revenge, together with relief of various physical symptoms such as insomnia, arthritis and digestive problems. As a result of the programme, the State Government of Bihar took a policy decision to introduce regular *yoga* training in all 82 state prisons.

References

1. Satyananda Saraswati Swami. *Asana Pranayama Mudra Bandha.* Bihar School of Yoga. Munger. Bihar. India. 1999.
2. Satyananda Saraswati Swami. *Four chapters on Freedom.* Bihar School of Yoga. Munger. Bihar. India. 1989.
3. Niranjanananda Saraswati Swami. *Yoga Darshan.* Sri Panchdashnam Paramahamsa Alakh Bara. Deoghar. Bihar. India. 1993.
4. Datey K.K., et al. Shavasana: a yogic exercise in the management of hypentension. *Angiology.* 1969; 20 : 333.
5. Benson H. and Wallace R.K. Decreased blood pressure in hypertensive subjects who practised meditation. *Circulation.* 1972; 46 & 45 (Suppl.II): 516.
6. Gopal K.S., et al. Effects of Yogasanas and pranayamas on blood pressure, pulse rate and some respiratory functions. *Indian J. of physiology and pharmacology.* 1973; 17(3): 276.
7. Patel C. and North W.R.S. Randomised controlled trial of Yoga and blood pressure in management of hypertension. *Lancet.* 1975; 2 (7925): 95.
8. Bagga O.P. and Gandhi A. A comparative study of the effect of Transcendental Meditation and Shavasana practice on the cardiovascular system. *Indian Heart J.* 1983; 35 (1): 39.
9. Tulpule T.H., et al. Yogic exercises in management of ischaemic heart disease. *Indian Heart J. 1971; 23: 259.*
10. Carson M.A., et al. The effect of a relaxation technique on coronary risk factors. *Behavioral Medicine.* 1988; Summer: 71.
11. Tulpule T.H. and Tulpule A.T. Yoga – a method of relaxation for rehabilitation and myocardial infarction. *Indian Heart. 1980; 22 (1):* 1.

12. Jurek H.E., et al. Interaction of biofeedback-assisted relaxation and diuretic in treatment of essential hypertension. *Biofeedback and diuretic treatment of essential hypertension. 1992;* 17 (2): 125.
13. Ornish D.M., et al. Effects of a vegetarian diet and selected Yoga techniques in the treatment of coronary heart disease (abstract). *Clinical Research.1979; 27*: 720A.
14. Ornish D.M., et al. Can lifestyle changes reverse coronary atherosclerosis? The Lifestyle Heart Trial. *Lancet.* 1990; 336: 129.
15. Ornish D., et al. Intensive lifestyle changes for reversal of coronary artery disease. *JAMA. 1998;* 280: 23.
16. Bernardi L., et al. Effect of breathing rate on oxygen saturation and exercise performance in chronic heart failure. *Lancet. 1*998; 351: 1308.
17. Haskell W.L. Cardiovascular complications during exercise training of cardiac patients. *Circulation.* 1975; 57: 920.
18. Gharote M.L. Physical fitness in relation to the practice of selected yogic exercises. *Yoga Mimamsa.* 14 April 1976; *DVIII*
19. Bhole M. Effect of Yoga practices on vital capacity. *Indian J. of Chest Disease.* Jan–April 1970; XII (1 and 2).
20. Ganguly S. and Gharote M. Cardiovascular efficiency before and after Yoga training. *Yoga Mimamsa*. 1974; 17: 89.
21. Udupa K.N., et al. Studies on physiological, endocrine and metabolic response to the practice of Yoga in young normal volunteers. *J. Research Indian J. Medicine.* 1971; 6: 345.
22. Udupa K.N., et al. Certain studies on psychological and biochemical response of hatha Yoga in young normal volunteers. *Indian J. Med Res.* 1977*;* 61: 237.
23. Udupa K.N. and Singh R.H. Scientific Basis of Yoga. *JAMA.* 1972; 220: 1365.
24. Garfinkel, et al. Yoga-based intervention for carpal tunnel syndrome. *JAMA* 1998; 280:18.
25. Morse D.R., et al. A physiological evaluation of the Yoga concept of respiratory control of the autonomic nervous system activity. *Int. J. Psychosomatics*, 1984; 31 (1): 3.
26. Pratap V., et al. Arterial blood gases in pranayama practice. *Perceptual and Motor Skills.* 1978*;* 46: 171.
27. Prakasamma M. and Bhaduri M. A study of Yoga as a nursing intervention in the care of patients with pleural effusion. *J. of Advanced Nursing.* 1984; 9: 127.
28. Goyeche J.R.M. Yoga as therapy in psychosomatic medicine. Proc. 4th Cong. Int. College Psychosomatic Med. Kyoto, 1977. *Psychoth. Psychosom.* 1979; 31: 373.
29. Goodale I., et al. Alleviation of premenstrual symptoms with the relaxation response. *Obs & Gyn.* 1990*; 75 (4): 649.*
30. Uma K., et al. The integrated approach of Yoga; a therapeutic tool for mentally retarded children: a one-year controlled study. *J. Mental Deficiency Res*: 1989; 33: 415.
31. Selvamurthy W. Yoga in the Army, *Yoga.* May 1998; Issue 3. (Journal published by Sivananda Math, Munger, India).
32. Singh V.A. and Madhu. A study of the effect of yogic practices on certain psychological parameters. *Indian J. Clinical Psychology.* 1987*;* 14*:* 80.
33. Barnes and Nagarkar S. Yoga education and scholastic achievement. *Indian J. Clinical Psychology.* 1989; 16: 96.
34. Sridevi K., Sitamma M. and Rao K.P.V. Perceptual organization and Yoga training. *J. Indian Psychology.*1995; 13: 21.
35. Bhushan L.I. Yogic lifestyle and psychological wellbeing. *Yoga.* May 1998; Issue 3. (Journal published by Sivananda Math, Munger, India).

Policy issues

Harmonization of traditional and modern medicine

Zhu-fan Xie

The age-old wisdom of the people of every country has been crystallized into different systems of traditional medicine, each nation having its own system/s. Some of these traditional systems are well-established, supported by theories and rich experience and recorded in writing, such as the Indian system of Ayurveda, the Muslim system of Unani, traditional Chinese medicine, ancient Greek medicine and the systems that evolved from it, and the humoral theory and therapy of Latin America. But traditional medicine in some other parts of the world has merely been practised and handed down verbally from generation to generation, without any written record. Whether sophisticated or not, the systems of traditional medicine served as the only means of health care for ages, till modern biomedicine came into being.

In contrast to modern biomedicine, which was founded on the basis of modern natural sciences, most traditional systems of medicine originated in and developed according to the principles of ancient schools of philosophy. A description of their characteristic features follows.

Common features of traditional medicine systems

Basic theories of various traditional systems

There are similarities in the basic theories of various systems of traditional medicine. Ayurveda considers human beings in their totality, in their subtle relationship with the universe, and postulates the theory that a human being is a microcosm of the universe. Therefore, there is a close relationship between the two. Ayurveda believes that the human body and all matter in the universe are made up of the five great elements: earth, water, fire, air and ether. All the physiological processes in the human body and the pathogenesis of various diseases can be explained by the three *doshas:* motion (*vata*), energy (*pitta*) and inertia (*kapha*).[1] In ancient Greece, the authors of the Hippocratic Corpus all presumed that bodily processes, health and disease could be explained in the same way as other natural phenomena. According to the Hippocratic humoral system, all things are composed of the four elements – fire, air, earth and water – and are formed by the union of matter, as well as the four qualities of hot, cold, dry and moist. The

elements in the human body are represented by yellow bile (fire), black bile (earth) and phlegm (water), while air is directly supplied by respiration.[2] The Unani system postulates the presence in the human body of four humours; blood, phlegm, yellow bile and black bile. *Arkan* (elements) forms the universe as well as the human body.[3] Traditional Chinese medicine regards *qi* as the basic constituent element of the universe. *Qi* produces everything, including human beings. Together with the five elements, wood, fire, earth, metal and water, with their characteristic properties and inter-relationships, *qi* explains the composition and phenomena of the universe, as well as the physiological and pathological processes of human beings. It is thus clear that the various systems of traditional medicine view the human body and the universe as an integral whole.

Basic concepts of health and disease

In Ayurveda, the body remains healthy so long as a balance is maintained between the three invisible forces of *vata, pitta* and *kapha,* and disease results when they go out of balance.[1] In ancient Greece, Hippocrates believed that good health resulted from an equilibrium between the four humours in the body, as well as from harmony between the body and the environment. He regarded illness as some form of imbalance.[2] In the Unani system, disease is regarded as an expression of an imbalance of the humours or a disturbance in their harmony.[3] According to traditional Chinese medicine, good health results from the maintenance of a normal dynamic balance between *yin* and *yang* within the human body, and between the human being and circumstances. A *yin–yang* imbalance gives rise to disease. *Yin* and *yang* refer to the two fundamental principles, ever opposing and complementing each other. Their ceaseless motion gives rise to all changes in the world, including in the spheres of physiology, pathology, diagnosis and treatment. The doctrine of the five elements further explains the inter-relationship of *yin* and *yang*. Therefore, the different systems of traditional medicine are based on a common dialectic way of thinking, and various parts or constituents of the body are viewed as an organic whole, with an emphasis on a balanced relationship between them.

Correlation between the mind and body

Ayurveda considers the body, mind and soul as complementary to each other. All imbalance and disease in the body begin with an imbalance or stress in the awareness, or consciousness, of the individual. Therefore, mental techniques such as meditation are considered essential to the promotion of healing and prevention.[4] According to Hippocrates, the mind and body profoundly affect each other, and cannot be considered as independent entities. Health consists of a healthy mind in a healthy body, and it is always necessary to consider the "whole" person while treating a patient. The basic philosophy of Unani medicine is that the body, composed of matter and spirit, should be taken as a whole because harmonious life is possible only when there is a proper balance between the physical and spiritual functions.[3] In traditional Chinese medicine, mental activities and emotions are taken as functions of the corresponding visceral organs: spirit is attributed to the heart, while excessive joy injures the heart; soul is attributed to the liver, while anger injures the liver, and so

on. Thus, mind and body, emotions and viscera, are parts of an integral whole.

No matter how diversified the various systems of traditional medicine in the spheres of diagnosis, treatment and management of diseases and patients, they have a common viewpoint which may be summed up by the term holistic medical model or holism.

Basic concepts of modern biomedicine

In the Middle Ages in the West, the domination of religion and feudalistic monarchy greatly hampered the development of the natural sciences, and obstructed the progress of medicine. Thus, medieval medicine was shrouded in the mists of theology.

Modern western medicine was first established in the 18th century, during the "enlightenment" in Europe. The new natural sciences created by Galileo, Descartes, Newton, Boyle and others no longer conceived of the world in terms of qualities and elements, but as consisting of particles of measurable sizes, shapes and motion. Descartes saw the body as he saw the world, in mechanical terms. This new and influential philosophy was one that reduced biological processes to mechanical events.[5]

Closely related to mechanism is reductionism, which explains the properties of the whole entirely by the properties of the parts that compose it. In medicine, reductionism offers explanations in terms of physical, chemical and mechanical principles. The biomedicine which thus evolved "considers biological entities more or less as equal to the sum of their anatomical parts and endeavours to elucidate molecular, physiological and pathological mechanisms believed to form the basis of biological processes".[6]

The achievements of the natural sciences and the reductionistic approaches, and the use of analytical methodologies, brought about a medical revolution in the West – medieval medicine was transformed into scientific biomedicine. The revolution started with anatomy, which explored the precise structure of the human body. The microscope not only became an essential aid for anatomists, but also furthered pathological study from the organic and histological levels to the cellular level. Progress in the physical sciences inspired experimental investigations in physiology. Breakthroughs in chemistry, such as the study of energy conversion in the human body, also held great promise for medicine. In the latter half of the 19th century, the "bacteriological revolution" clarified the true pathogens of many communicable diseases. Along with the advance of anatomy, physiology, pathology and bacteriology, clinical medicine also progressed, particularly in respect of diagnostics and surgical operations. A new system of medicine – modern biomedicine – was thus formed and developed in the West. This system is different from the traditional systems, not only in terms of concrete knowledge and practice, but also with respect to the underlying philosophical views.

Conflicts between traditional medicine and modern biomedicine

Owing to the fact that traditional medicine and modern medicine evolved on the basis of different philosophical assumptions and with different methodological approaches, conflicts are bound to arise when the two systems are used simultaneously in the same country or area. Different countries

have found different ways of solving this problem, but since the People's Republic of China seems to be one of the countries that has harmonized well the functioning of the two systems of medicine, the developments which took place in China are described as an example.

Modern biomedicine was introduced in China in the late 19th and early 20th centuries. At this juncture, China felt the urgent need to firmly establish and assert its national identity, and to gain competence in various spheres. In addition to the need for new political and technological initiatives, the issue of health and medicine also came to the forefront. Particularly after the Revolution of 1911, many intellectuals who were frustrated by China's failure to forge ahead began to re-evaluate the country's traditional culture in the light of what they perceived to be the key to the success of the West – modern science. A Descartian faith in the potential of science to solve mankind's problems led them to embrace Western biomedicine. At the same time, they denounced traditional practices as defunct remnants of the old order. These, they felt, were impeding China's modernization. They blasted traditional physicians for being ignorant and irrational, and condemned their system of medicine as an amalgam of superstitions incompatible with scientific progress.[7] In 1929, the Central Government passed a Bill "to ban traditional medicine in order to clear the way for developing medical work".

However, in spite of the persecution it suffered, traditional Chinese medicine has never been eliminated, nor replaced by modern biomedicine. First, most Chinese people continued to believe in traditional medicine, not so much because of their cultural background, but more because of the benefits that they, their family members and acquaintances had experienced by using traditional methods of treatment. Second, traditional remedies were simple, convenient and affordable, and had fewer side-effects. Modern biomedicine, on the other hand, often necessitated surgical procedures, which could cause pain and result in complications. Third, the unique philosophy underlying traditional medicine was well-received by the common people, and had no satisfactory parallel in modern biomedicine. Traditional medicine had a unique theoretical system which was well-received by the common people and could not be replaced by modern biomedicine. Some of the traditional medical expressions and terminologies had already been absorbed into the language of the common people. Last but not the least, medical professionals well-trained in modern Western biomedicine were to be found only in some big cities. With the ban on traditional medicine, the vast majority of the Chinese population had no access to health care of any kind. This scenario gave rise to a bitter conflict between the traditional practitioner and the modern doctor, as well as between the common people and the Government.

It was only after the founding of the People's Republic of China in 1949 that attempts began to be made to revive traditional Chinese medicine, and to harmonize it with modern medicine.

Policies to harmonize traditional and modern medicine

To begin with, the Chinese Government formulated official policies to protect and develop traditional medicine. In 1950, it stipulated "uniting the traditional Chinese and modern western medical professionals" as one of the guiding principles

of health work. A major reason for this was that traditional medicine had been of great benefit to the Chinese population, especially the common people, who loved and endorsed the system. Also, according to the statistics of 1949, the total population of mainland China was 5.4 hundred million, while the number of doctors formally trained in modern Western medicine was only 38,875, i.e., the ratio between these doctors and the population was approximately 1:14,000.[8] The situation in rural areas was much worse, with most of the trained modern doctors concentrated in the big cities. Of all the practitioners of either system, the majority (about 80 per cent) were trained in traditional medicine.

The Constitution promulgated in 1982 and the present Constitution declared that the State should "develop both modern medicine and traditional medicine". Thus, the Chinese Government has clearly put both systems of medicine at par, and "realizing modernization and globalization of traditional Chinese medicine" is seen as a task of primary importance. The Constitution advocates that "traditional Chinese medicine and Western medicine should unite and learn from each other, mutually complement each other and improve together, in order to promote the integration of traditional Chinese and western medicine".[9]

Besides the official policies, the remarks made by the leaders of China have had a great impact on the development of traditional medicine and its harmonization with modern medicine. In 1958, Mao Zedong declared that "traditional Chinese medicine is a great treasure-house, and efforts should be made to explore and raise it to a higher level". He called upon Western-trained doctors to learn traditional Chinese medicine and hoped that some brilliant theorists would emerge through the integration of both systems. In 1978, Deng Xiaoping requested governments at all levels to "provide good and favourable conditions for the development and improvement of Chinese medicine". The present leader, Jiang Zemin, has emphasized that practitioners of traditional and Western medicine should strive for greater unity still, and learn from and complement each other so as to promote integration of the two systems.[9]

The Government has adopted a series of measures for the implementation of its policies. These include the establishment of administrative bodies at the central and local levels for the execution of policy, exploitation of human resources, development of related academic organizations and publications, gathering and summarizing of the knowledge of experienced traditional medical doctors, and setting up of institutions for clinical practice, education and research (both for traditional and integrated medicine). One of the most powerful organizations for the implementation of these policies is the relatively independent State Administration of Traditional Chinese Medicine, which provides protection to traditional medicine.[10]

Incorporation of traditional medicine in modern hospitals

The first step adopted by the Government in the 1950s for the purpose of "uniting the traditional Chinese and modern Western medical professionals" was the incorporation of traditional medical doctors into the staff of hospitals of modern medicine, as well as the establishment of hospitals of traditional Chinese medicine (TCM). Doctors in ancient China used to see outpatients only in clinics or in the

patients' homes. There were no institutions for in-patients. Hospitals began to be set up in the early 20th century, once modern Western medicine was imported into China, but working in these hospitals was the privilege of Western-trained medical professionals. By 1950, the word "hospital" had been defined in China as an institution providing modern Western medical and surgical treatment, and nursing care. To remedy this situation, TCM departments were established in most hospitals. This made matters easier for patients referred to traditional medicine practitioners. In some hospitals or specialized departments, TCM doctors were appointed directly as staff members in the departments of Western medicine, thus creating improved opportunities for the exchange of ideas and cooperation between doctors of both systems.

This step seemed to facilitate collaboration between doctors of the two systems. Practitioners of modern medicine became particularly interested in traditional methods of treatment when the latter succeeded where modern methods had failed. On the other hand, the TCM doctors also required a modicum of knowledge of Western medicine, in order to function effectively in a set-up run on modern lines. Many hospitals of Western medicine still have a department of traditional medicine, even though several hospitals devoted exclusively to TCM have been set up.

Establishment of TCM hospitals

Advantages aside, the inclusion of practitioners of traditional medicine in hospitals had certain limitations. These doctors were always in a minority, and the patients referred to them were often those whom modern methods of treatment had failed to help. Thus, their role became largely limited to such cases and they were not in the mainstream of hospital services. In order to allow them greater initiative, and also to provide training bases for students of traditional medicine, TCM hospitals were established. The number of TCM hospitals and beds has been growing rapidly (Table 1). In 1997, there were 10,789 general hospitals of Western medicine with 1,485,625 beds, and 2424 TCM hospitals with 223,696 beds. The ratios between the number of the two types of hospitals and the number of beds allotted to each were roughly 1:4.5 and 1:6.5, respectively.[11] (It should be noted that at present, general hospitals of Western medicine in China are simply called general hospitals because none of them is exclusively devoted to Western medicine.)

Table 1. Increase in number of TCM hospitals, beds and research institutions in China since the 1950s[11]

	1952	1957	1963	1975	1980	1985	1990	1995
Number of TCM hospitals	19	257	124	160	647	1414	2037	2371
Number of beds in TCM hospitals	224	5684	9254	13 675	49 151	101 418	160 899	206 812
Number of TCM research institutions	–	16	33	29	47	54	55	65

The difference between the two types of hospitals lies chiefly in the methods of treatment. Generally speaking, TCM hospitals are equipped with facilities for modern laboratory diagnosis and emergency treatment. Therefore, the staff of these hospitals also includes a few professionals trained in modern Western medicine. Some Western-trained doctors prefer to shift to TCM hospitals.

The establishment of TCM hospitals has played an important role in the harmonization of traditional and modern medicine. The earlier conflict between the two systems had found expression not only in the contempt in which the practitioners of modern medicine held the "unscientific" practices of traditional medicine, but also in the traditional medical practitioners' exaggeration of the helplessness of modern Western medicine in the treatment of chronic diseases. While the TCM doctors were not as virulent as their rivals, they, too, needed to compromise. In TCM hospitals, modern Western medical professionals proved the value of their work either by carrying out laboratory tests for diagnosis or by the emergency treatment of a chronic case. Harmonization between the two medical systems is possible only if they begin to respect each other.

Confirmation of the efficacy of traditional medicine

Traditional Chinese medicine has a brilliant history, but whether it is still of practical value depends upon its advantages over modern biomedicine, particularly as far as its efficacy is concerned. Traditional literature contains numerous case reports of successful treatment of various diseases, but the diseases were not diagnosed, observed or recorded in a modern, scientific way. Moreover, in most cases the methods of treatment were highly individualized and varied from person to person. Therefore, it is difficult to convince modern-trained medical doctors to believe in the effectiveness of traditional medicines. After the inclusion of traditional medical practitioners in hospitals of modern medicine and the establishment of TCM hospitals, it became possible to carry out comparative clinical trials. At first, the diseases studied were those that were difficult to cure with modern Western medicine, such as chronic nephritis, chronic hepatitis and chronic gastritis. Traditional treatment for these diseases often achieved better results than contemporary Western treatment. The most convincing evidence came from an epidemic of encephalitis B which broke out in the early 1950s in northern China. In those days, modern medicine could do little to help encephalitis patients, and could barely provide even symptomatic relief from the high fever. Traditional treatment, however, cured a large number of serious patients and reduced the fatality considerably. In the mid-1950s, traditional treatment of haemorrhoids made a strong impression on modern-trained surgeons. Traditional necrotizing therapy for haemorrhoids and ligation therapy for anal fistulae succeeded in curing more than 90 per cent of patients. Moreover, recovery was quicker and there was less suffering than with modern surgery. The treatments were well-received by the patients. By the end of the 1950s, the analgesic effect of acupuncture was acknowledged by all and acupuncture analgesia was successfully used for tooth extraction and tonsillectomy. In the 1960s, modern medical circles came to acknowledge the benefits of herbal treatment for diphtheria

Chiropractic treatment is commonly used for curing infantile malnutrition (Courtesy Prof. Chen Gui-ting)

and conservative treatment for ectopic pregnancy with herbal medication to remove stagnant blood. In addition, a herbal homeostatic formula that had been developed, as well as couching in cataract operation were seen to achieve very good results.[12] Most of these clinical studies were carried out on large samples, at first jointly by traditional and modern medical practitioners and, later, by traditional and integrated medical practitioners. Therefore, modern medical circles were convinced by the results. There are many more diseases in which traditional treatment has been proved to be effective. In daily clinical practice, traditional medicine has been shown to be effective in the treatment of many common diseases, as assessed by modern criteria of diagnosis and efficacy evaluation.

Reform of educational system of traditional medicine

Historical review of TCM education

Training of TCM professionals is of utmost importance in the development of this system of medicine. In ancient China, most practitioners learned through apprenticeship. In most cases, knowledge was handed down from one generation to the next within the family. Although TCM could boast of the earliest teaching institutions, these institutions imparted training mainly to the court physicians of the imperial family and to high-ranking physicians in the service of feudal nobles and officials.

As early as the fifth century, the Tang Dynasty set up a central institution called the "Imperial Medical Bureau", which served both as a medical school and as a clinic. It had four departments: medicine, acupuncture, massage (including traumatology) and incantation. The department of medicine consisted of the specialities of internal medicine, paediatrics, sores and ulcers, diseases of the ears, eyes, mouth and teeth, and cupping. The duration of training varied according to the speciality. For example, the training period for general medicine was seven years, paediatrics five years and cupping three years. Other than the Imperial Medical Bureau some prefectures had their own medical educational institutions.

The succeeding dynasties developed medical education further. For example, during the reign of the Song Dynasty (960–1279), the Imperial Medical Bureau became a purely educational institution, consisting of nine departments: internal medicine, stroke, paediatrics, sores and ulcers (including bone fractures), obstetrics, eye diseases, diseases of the mouth, teeth and throat, acupuncture, and incised wounds. A professor was appointed for each department and the teachers were given the title of "doctor of medicine". The institution admitted 300 students annually through an entrance examination. Besides the Imperial Medical Bureau, which was the premier institution, medical schools were set up by the local governments.[13]

After the early 20th century, once the rule of the feudal dynasties came to an end, this education system stopped operating. This had little impact on the health services available to the common people, as most of the practitioners they consulted were trained in the master–apprentice style, or had learnt from their family members or elders. The latter type of practitioner was held in high esteem by the people. There were other practitioners who studied medicine on their own. These included *literati* who had failed the imperial examination for officialdom, or shifted their interest from the management of state affairs to the management of diseases. The large volume of medical literature was of great use to those who wanted to teach themselves. According to the catalogue compiled jointly by the China Academy of Traditional Chinese Medicine and the Peking National Library, the number of medical works collected before 1959 was 7661.[14] Most of them were written in the classical literary style, which ordinary people could not follow easily, but the *literati* could. Since the Chinese *literati* were Confucian scholars, those who practised medicine were also called Confucian physicians.

In the 19th century, modern Western medicine was introduced into China, posing a serious challenge to TCM, including the TCM educational systems. Private medical schools of TCM, run by famous physicians, began to appear by the end of the 19th century. The schools of Western medicine – initially the missionary medical schools, and later public and private medical schools – soon surpassed the TCM schools, both in number and in scale. In the late 1940s, TCM schools were on the verge of extinction.

Establishment of colleges and universities of traditional medicine

After the founding of new China in 1949, in order to implement the new policy of developing traditional medicine, it was urgently felt that the educational system for TCM should be promoted to a higher level. In 1956, four TCM colleges were established in Beijing, Shanghai, Guangzhou and Chendu, four big cities situated in the northern, southern, eastern and western regions of China. Since then, a regular higher educational system has been developed for the training of traditional medical personnel. The single-minded devotion of the Government resulted in the rapid expansion of the number of TCM colleges, which increased from five in 1957 to 30 in 1995. The number of students enrolled increased from 1021 in 1957 to 39,786 in 1995 (Table 2). Furthermore, since the late 1990s, some TCM colleges have been promoted to university level. The duration of training has been extended to seven years for the specialty of general medicine, and five years each for acupuncture and traditional health protection and rehabilitation. It should be noted that China's traditional medicine is not limited to the traditional medicine of the Han nationality; it also includes the traditional systems of medicine of minority nationalities, such as Tibetan medicine. Among the traditional medical colleges, one is a college of minority medicine. Parallel to the growth of colleges and universities, secondary schools of TCM were also established, and there has been a steady increase both in the number of schools and of students enrolled. Other than the regular schools, correspondence schools have also been started for paramedical professionals to give them the opportunity of receiving practical training.

Table 2. Increase in number of TCM colleges and universities and number of TCM students enrolled since the 1950s[11]

Year	Total number of medical colleges and universities	Number of TCM colleges and universities	Percentage	Total number of students enrolled	Number of TCM students enrolled	Percentage
1957	37	5	13.5	49 107	1021*	2.1
1965	92	21	22.8	82 861	10 155*	12.3
1975	88	17	19.3	86 336	13 538*	15.7
1980	109	22	20.2	139 569	25 282*	18.1
1985	116	24	20.7	157 388	28 450*	18.1
1990	122	31	25.4	201 789	34 048*	16.9
1995	126	30	23.8	256 003	39 786*	15.5

* The number of TCM students enrolled includes those enrolled in TCM colleges and universities, and those enrolled in a TCM department or specialty in Western medical colleges and universities.

In 1978, a programme of postgraduate study was introduced in the traditional medical colleges and universities. A Master's degree is granted to those who have studied for three years after graduation and passed the examinations and completed the required academic paper. A doctorate (Ph.D.) is issued to those who have studied for another two years after obtaining the Master's degree and completed a high-level academic paper. This postgraduate educational system is exactly the same as that being implemented for modern medicine.

Modern apprenticeship

In the past, apprenticeship was a unique way of teaching Chinese medicine. It has certain advantages even now, as Chinese medicine is not simply a branch of science, but includes a large component of art and skill which are better learnt as an apprentice practising under the direct guidance of, or together with, the master. Therefore, the system of apprenticeship was encouraged for a few years after 1949. Apprenticeship with experienced traditional practitioners allowed one to practise after passing the requisite examinations. In the 1990s, a special form of apprenticeship was adopted for training and grooming successors to famous physicians and pharmacists. Licensed practitioners and pharmacists with formal college or university qualifications were selected to serve with famous traditional physicians and pharmacists for an effective period of three years. This form of training has proved to be particularly suitable for learning certain special skills and techniques that could hardly be described in words.

Compilation of standard textbooks

Traditional Chinese medicine is distinguished by the vast amount of literature on it. Many books were used as textbooks in different historical periods, but most of them could be used only as references. As they were no longer suitable for teaching in the 20th century and in order to improve the quality of training, the Ministry of Health had a set of standard textbooks compiled for TCM colleges. These were published in 1958 and have

been revised five times since then. The last (sixth) edition, which consisted of 32 textbooks for various specialties of traditional medicine (general medicine, herbology, pharmaceutics, acupuncture and moxibustion, and orthopaedics and traumatology), was completed in 1994–1995. Besides the 32 TCM textbooks, the standard textbooks for TCM colleges include another six textbooks on modern Western medicine, one each for anatomy, physiology, pathology, biochemistry, the fundamentals of diagnosis, and internal medicine. These courses are offered not only to train the TCM graduates for their future practice, but also to facilitate the exchange of ideas between them and medical professionals trained in modern Western medicine, thus facilitating the harmonization of the two systems of medicine.

A large number of traditional medical practitioners have now been trained. According to official statistics, the number of qualified medical doctors in mainland China in 1998 was 2,724,670, 9.38 per cent (255,641) of whom were traditional medical doctors and 0.41 per cent (11,077) integrated medical doctors. The number of practitioners with secondary medical education was 1,235,212, of whom 5.67 per cent (70,085) were traditional practitioners.[15] Thus, an appropriate and adequate number of traditional medical professionals have been trained to meet the people's health care needs.

Establishment of the legal status of traditional medicine

In implementing the policy of placing both traditional and western medicine on an equal footing, various issues need to be considered, particularly those of legitimacy and economics. The former deals chiefly with the legal status of traditional medical practice and the licensing system for traditional medical professionals. In China, traditional medical practice is officially recognized as being equivalent to modern Western medicine. Since in traditional practice the diagnosis is often made in a different way from that in modern Western medicine, a national standard entitled "Classification and Coding of Diseases and Syndromes in TCM", as well as criteria for diagnosis and efficacy evaluation were promulgated in the 1990s. This has further strengthened the legal basis of traditional medical practice.

In order to guarantee the competence of traditional medical professionals, a licensing and accreditation system similar to the one that applies to Western medical professionals has been adopted. The system of promotion for medical professionals of both schools is the same. There are four ranks of medical doctors: resident, physician/surgeon-in-charge, vice-chief physician/surgeon and chief physician/surgeon. The salary of each rank is the same in the case of both schools. Other remuneration paid according to the quality and quantity of medical practice may vary from individual to individual, but these differences have nothing to do with the particular system of medicine being practised. A hard-working, experienced physician of traditional medicine is usually paid just as much, if not more, than his Western medicine counterpart.

Getting Western-trained doctors to study traditional medicine

All the measures mentioned so far have been of great help in harmonizing traditional and modern medicine, but real harmonization involves two important

issues. These are the modernization of traditional medicine, and the integration of traditional and modern medicine. There is a large overlap between the two, but they are different theoretically. Modernization of traditional medicine refers to the application of modern scientific theories, knowledge and methodologies in the study of TCM, as well as the adoption of modern science and technology to develop TCM. In this way, it would not only contain distinctive Chinese features, but also be relevant in modern scientific terms. Integration of Chinese and Western medicine involves discovering the common points between the theories of the two systems, a process of mutual learning so that each can benefit the other, and combining the best elements of the two systems so as to establish a new system of medicine.

Both for modernization of traditional medicine and integration of the two systems, it is essential for traditional medical practitioners to learn modern medicine, and for Western-trained doctors to learn traditional medicine. Measures to facilitate both were taken in the 1950s, but it was the latter that seemed to work more efficiently. While summarizing this experience, the former Chairman of the Chinese Government, Mao Zedong, lauded the efforts in this direction and called on more Western-trained doctors to devote themselves to the integration of the two systems. Since then, many types of courses have been started to help Western-trained doctors learn traditional medicine. Moreover, research institutes for integrating the two systems, as well as integrated hospitals and clinics, have been set up for Western-trained doctors who wish to carry out research and practices in integrated medicine on completing the courses. At present, there are about 12,000 high-ranking "integrated" medical doctors. They have not only contributed to the progress in many areas of medicine, but have also been playing a particularly important role in encouraging cooperation and harmonization between practitioners of the two systems. Broadly speaking, their achievements have been in the following areas.

Proposal of modern scientific explanation for traditional medical theories

It is mainly the unique theories underlying TCM that make it so difficult to understand. Some of these are actually ancient Chinese philosophical ideas, which, though rather quaint, are not disconsonant with modern perspectives. Some other theories, however, such as the concept of visceral organs, are misleading. While the anatomical description and names of these organs correspond to those in modern Western medicine, the physiological and patho-physiological expositions on them are so different from modern concepts that they cast doubts on the correctness of TCM. Extensive studies carried out by the "integrated" doctors have revealed that each visceral organ in TCM is actually viewed as a comprehensive functional system rather than an individual internal organ. Also, greater emphasis is laid on the inter-relationships among the functional systems than on the consideration of individual organs. For example, the word *kidney* in TCM signifies far more than an organ of the urinary system; besides urine secretion, the kidneys are believed to be in charge of the endocrine function (particularly the function of the hypothalamic–pituitary–adrenocortical, hypothalamic–pituitary–gonad and hypothalamic–pituitary–thyroid axes), myeloid haemopoiesis, bone metabolism, and a few brain activities. That is why kidney tonics are considered to be effective

in the treatment of many disorders besides renal diseases, such as in aplastic anaemia, osteoporosis, the menopausal syndrome, anovulatory menstrual disorders, sexual disturbances and certain geriatric diseases.

Why these seemingly unrelated functional activities are lumped together in one group is difficult to explain in terms of modern physiology and pathology. However, research using sophisticated techniques and knowledge of molecular biology and genetics has found a rational basis for these traditional Chinese concepts. Similarities have been found in the abnormal changes occurring in the various diseases clubbed into one category, and the changes have been successfully remedied with the administration of herbal formulae according to this theory.

Discovering advantages of traditional medicine through comparison with modern Western medicine

While modern Western medicine has made rapid strides, particularly in the 20th century, TCM evolved many centuries ago. Whether the latter still has advantages over modern Western medicine is a question that is widely debated. It is the doctors proficient in both traditional and modern medicine who are best qualified to answer this. Comparative clinical and experimental studies have revealed the advantages of traditional treatment in many diseases or conditions. In many instances, traditional treatment is more effective and has fewer side-effects. It is also more affordable than modern Western treatment. Acupuncture analgesia is a good example. The analgesic effect of acupuncture is comparable with that of morphine or meperidine and, at the same time, the process has minimal side-effects and no addiction-inducing properties. It is hence recommended for the treatment of various painful conditions, as long as it does not interfere with the treatment of the primary lesions.

Modern Western medicine still finds it difficult to treat viral diseases, and interferon is of limited clinical use in China due to its high cost and side-effects. However, controlled clinical studies have shown many medicinal herbs and herbal formulae to be effective in the treatment of viral diseases such as influenza, viral hepatitis, viral myocarditis and epidemic haemorrhagic fever. Some herbal ingredients used for treatment have also been demonstrated to have antiviral effects in laboratory experiments.

Combined treatment with superior results

Both modern and traditional medicine have their own strong points. It is but natural to speculate that a combination of their strong points may lead to better results. Comparing the traditional and modern treatment of bone fracture, Chinese orthopaedic surgeons found that while the use of modern technology and methodology had many advantages, traditional treatment, too, had its own advantages: it often achieved more rapid union. Further studies revealed that the traditional approach advised only relative fixation, with appropriate compression and stress on the site of fracture, following manipulative reduction and timely functional exercise. They, therefore, designed a new method of treatment based on the principle of combining mobilization with immobilization, instead of extensive immobilization and complete rest. This method has resulted in a marked reduction in the period for clinical union and has minimized the complications of fracture treatment.

The treatment of cancer poses a major problem to modern medicine and the

possibility of recurrence is often not eliminated even after resection of the tumour. As for traditional treatment, a number of medicinal herbs have been found to be cytotoxic, but clinical trials have shown them to be either less potent than modern chemotherapeutic agents or to cause similar side-effects. However, the tonics used by traditional medical practitioners have the effect of improving the patient's general condition. Recent research has shown that most of these tonics enhance the host's immunity. They cannot inhibit the growth of the cancer once the tumour has already become large and the antigens from the cancer cells have crippled the host's immune response. However, they help prevent recurrence after removal of the tumour, and are also useful in preventing the formation of tumours in the precancerous stage. In addition, both acupuncture and herbal medication can give considerable relief from the toxic effects and side-effects of modern chemotherapy. Therefore, a combined programme of traditional and modern treatment is often adopted. Herbal medication is used to aid convalescence after surgery. This is followed by acupuncture and/or herbal treatment to provide relief from the toxic effects and side-effects of chemotherapy, and the administration of tonics and other measures to improve general health and promote immunity so as to prevent relapse.

Education of TCM students in modern sciences

The harmonization of traditional and modern medicine requires efforts on the part of both medical systems. In the 1950s, however, the focus was on the need to promote traditional medicine by establishing formal educational institutions that would provide regular training in TCM and produce qualified traditional medical doctors. Although the curriculum included some courses in modern Western medicine, these merely served the purpose of facilitating communication with Western-trained doctors, or for proper transfer of patients for receiving modern Western treatment. Even with an increase in teaching hours devoted to the modern sciences, the graduates still faced difficulties in practising integrated medicine or in truly modernizing traditional medicine. After all, both modernization of traditional medicine and integration of the two systems required, and still require, scientific research. Since the setting up of the postgraduate educational system in 1978, a conside-rable number of research fellows have been trained. Many of them have been engaged in the modernization of traditional medicine, which concerns mainly the following issues:

(1) Technical innovation in the diagnostic methods of the system, especially the formulation of objective criteria and quantitative measurement of symptoms and signs, for example, objective recording and quantitative analysis of pulse conditions (as assessed in the traditional system), and colorimetric assessment of the tongue and its coating.

(2) Investigation of the pathophysiological changes in the disease patterns identified by traditional medicine, and the systematization of traditional diagnosis and treatment by means of modern scientific methods, for example, immunological studies in different types of deficiency and their treatment with the appropriate tonics.

(3) Improvement of traditional therapeutic measures and techniques, particularly the emergency treatment of serious cases, to enhance their efficacy, for example, the traditional treatment of

toxic shock in severe infections, and resuscitation of patients in coma.

(4) Development of new preparations of traditional drugs to make their administration more convenient, acceptable and efficient, for example, the manufacture of some herbal formulae in the form of aerosols and injections.

(5) Creating a database from the experience of experts in traditional diagnosis and treatment of certain diseases, for example, pattern identification and herbal medication in patients with viral hepatitis.

Development of research

Traditional medicine, an age-old heritage culled from years of experience, is bound to contain some valuable elements but inevitably it also contains some aspects which are no longer useful. It is therefore necessary to carry out scientific research in order to separate the grain from the chaff, and to develop and improve the useful elements.

In the late 1950s, the Chinese Government began establishing research institutes with a view to facilitating the exploration of the real value of traditional medicine and developing it further. Over the years, there has been an increase not only in the number of personnel trained in traditional medicine, but also in that of research institutions (Table 1). In the 1950s, most of the results regarding the efficacy of traditional medicine were obtained from hospitals, both of Western medicine (with the cooperation of traditional medical doctors) and TCM. Later, however, research began to be conducted mainly at research institutions. Moreover, to facilitate the exchange of information among researchers, two national organizations, the China Association of Traditional Chinese Medicine and Pharmacy, and the Chinese Association of the Integration of Traditional and Western Medicine, were set up in the late 1970s and early 1980s. The former sponsors the *Journal of Traditional Chinese Medicine,* and the latter the *Chinese Journal of Modern Developments in Traditional Medicine* (later renamed *Chinese Journal of Integrated Traditional and Western Medicine*). Both journals are published in Chinese as well as English. Besides these two leading journals, there are dozens of other journals in the fields of traditional as well as integrated medicine.

The work of researchers in these research institutions is no longer confined to determining the efficacy of traditional medicine. They also study the following aspects: (i) The elucidation of the basic theories of traditional medicine, such as the theory of *yin–yang* and *qi*, the unique doctrine regarding the physiology and pathophysiology of the internal organs (called "visceral manifestations" in TCM), and the theory of the meridian system, (ii) the rationale behind the differentiation of disease patterns and the identification of syndromes, which are based on a unique, holistic approach, and (iii) the mechanisms of traditional therapies, and pharmaco-logical studies of individual medicinal herbs and compound formulae. In brief, the research addresses not only the issue of whether traditional treatment works but also of how and why it works.

Since the late 1970s such research has progressed through the collaboration of traditional, Western and "integrated" doctors, who may be working in hospitals, medical colleges, universities or research institutions of either traditional or modern medicine.[16] The following examples illustrate this.

A concept unique to traditional medicine is that of "blood stasis". This not

New dosage forms have been produced, for intravenous administration in the treatment of ischaemic cardiovascular and cerebrovascular diseases, and compound *danshen* pills for oral or sublingual administration to relieve angina pectoris.

only refers to venous congestion but also includes all kinds of pathological conditions related to stagnant blood in the body. It may occur locally or generally, and within or outside the vessels. Clinically, a series of diseases can be diagnosed as "blood stasis" and successfully treated with "blood-activating stasis-removing" therapy. From the Western medical perspective, the diseases related to this concept would include coronary heart disease, ischaemic cerebrovascular disease, thromboangiitis obliterans, chronic obstructive lung disease, chronic hepatitis, liver cirrhosis, scleroderma, ectopic pregnancy, and other diseases and traumatic conditions characterized by impeded blood circulation. Clinical observations demonstrated that most patients with these diseases had manifestations of "blood stasis" as described by traditional medicine, and that herbal formulae could be successfully used to activate the circulation of blood and remove stasis. Further studies revealed that patients with these diseases did have common pathological features: haemodynamic and microcirculatory disturbances, haematological abnormalities, immunological changes, and disorders of connective tissue metabolism. Experimental research, including pharmacological studies, has been able to explain the mechanism of the therapeutic effects. Animal models of diseases related to blood stasis showed microcirculatory and/or haemodynamic disturbances and haematological abnormalities, which were ameliorated together. These animals were treated with blood-activating and stasis-removing herbs, which resulted in distinct improvements in their condition. Most of the herbs used for activating the circulation of blood and removing stasis have the effect of improving the micro-circulation, dilating the blood vessels and rectifying the rheological characters of the blood. In other animal experiments, a number of these herbs have been shown to be immunosuppressive and/or effective in normalizing connective tissue metabolism. These data not only explain the curative mechanisms of blood-activating and stasis-removing therapy but also expand the clinical indications of this therapy. Besides the diseases already mentioned, various autoimmune diseases (such as systemic lupus erythematosus, rheumatoid arthritis, chronic glomerulonephritis), cicatricial diseases (such as keloids, postoperative adhesion of the small intestine), and gynaecological conditions (such as endometriosis, inflammatory pelvic mass) are presently often treated with herbs meant to activate the circulation and remove stasis. This therapy has also been reported to be useful in the treatment of disseminated intravascular coagulation in serious infections. Moreover, extensive studies have been conducted to identify the active components of some of the most frequently used herbs of this category. New dosage forms have been produced, e.g., ligustrazine injection (derived from the rhizome of *Ligustecum chuanxiong*) for intravenous administration in the treatment of ischaemic cardiovascular and cerebrovascular diseases, and compound *danshen* pills (derived mainly from the root

and rhizome of *Salvia miltiorrhiza*) for oral or sublingual administration to relieve angina pectoris. These can be easily used by Western-trained medical professionals, and have become a part of the routine treatment prescribed by them. As for the traditional practitioners, they were unfamiliar with most of the diseases listed above, at least in terms of the Western views on the pathogenesis and diagnostic criteria. Research has inspired them to keep abreast of the relevant information uncovered by modern Western medicine.

It is difficult to classify the intravenous drip of ligustrazine for ischaemic cerebro-vascular disease and the sublingual administration of compound danshen pills for angina pectoris as either traditional Chinese therapies or modern Western therapies. However, doctors of both systems are now using these as routine treatment. They are often called "integrated therapies" since they have originated from traditional medicine and been modified by the modern approach.

The successful application of acupuncture for anaesthetic purposes in surgery shook not only China but the entire world. Needless to say, it aroused the keen interest of researchers everywhere. Research was carried out on two main aspects: (i) The clinical aspect, including evaluation of the efficacy of the technique, its improvement, and determination of the indications, and (ii) The laboratory aspect, including the mechanisms by which acupuncture provides relief from pain. The latter stimulated the study of pain and pain-relief, particularly among the modern medical community of China, as well as in some other countries. These studies resulted in the discovery of endorphins and related substances, the release of which during the process of acupuncture relieves pain. However, the studies have not been able to answer the basic question as to why these pain-killing substances are produced in the body.

Acupuncture is effective in the treatment of a number of disorders other than pain, particularly functional disorders marked either by hyperfunction or hypofunction. For example, it helps in lowering the blood pressure in hypertension and elevates it in hypotension. It is useful in relieving retention and helps in incontinence of urine. Acupuncture is also beneficial for patients with muscle spasm and nerve paralysis. Clinical observations and experimental studies have revealed the regulatory mechanism of acupuncture treatment. In fact, its analgesic effect can be attributed to its regulatory mechanism. Yet another category of disease that can be treated by acupuncture is infections. Although acupuncture is seldom used for this purpose now, the results it can achieve are of great academic significance. Clinical and experimental studies have confirmed the therapeutic effect of acupuncture in the treatment of bacillary dysentery and malaria. Controlled clinical trials have repeatedly shown that the effect of acupuncture in bacillary dysentery is comparable to that of furazolidine, and that the mechanism involved is the enhance-ment of the patients' immune function.

Another example is the research on "tonification". One of the characteristic features of traditional diagnosis is to determine the confrontation between the antipathogenic capability of the human body and pathogenic factors. The former includes all kinds of functional activities and the substances required for fighting these pathogenic factors, as well as for maintaining good health. Whenever the antipathogenic capability is insufficient to overcome the pathogenic factor, illness ensues. Therefore, all illnesses can be

classified into two main categories: (i) Those caused by lowered antipathogenic capability, called "deficiency" conditions, and (ii) Those caused by excessive pathogenic factors, called "excess" conditions. The former are treated by the principle of "tonification", i.e., the administration of various tonics to strengthen the vital functions and/or replenish the required substances.

The purpose of treatment in traditional and modern medicine is often the same, but the approach is different. According to the approach of modern Western medicine, deficiency is made up mostly by supplying the substance concerned, i.e., replacement therapy. For example, thyroxin is administered for hypothyroidism, adrenocorticosteroid for adrenocortical deficiency, and gamma-globulins or specific antibodies for immunodeficiencies. Indeed, replacement therapy is often of vital importance, such as for patients who need blood transfusion for massive loss of blood. Its promptness in correcting the deficiency is incomparable.

Replacement therapy, however, also has its disadvantages, especially if used over a long period. These include the need to carefully determine the dosage and frequently adjust it. Overdosage causes severe side-effects or complications, while underdosage does not relieve the symptoms. Another important disadvantage is that of drug dependence in chronic cases. Replacement therapy cannot stimulate the recovery of the diseased tissues or organs; on the contrary, it may cause atrophy of the tissues or further reduction of function due to disuse. That is why, for example, sudden discontinuation of prednisone therapy may cause an adrenal crisis, and a rapid and overwhelming intensification of chronic adrenal insufficiency.

Tonification, on the other hand, attempts to stimulate the patient's own capability. Even when used to replenish the required substances, in most cases the aim of the treatment is to stimulate the body to produce these substances instead of directly substituting them. Ginseng, the most famous traditional tonic, is a good example. It increases the anti-stress function, but contains no corticosteroid; by stimulating the hypothalamic–pituitary–adrenocortical axis, it induces the body to synthesize and release corticosteroid. Also, though it contains no estrogen or testosterone, by stimulating the hypothalamic–pituitary–gonadotrophic axis, it acts like a sex hormone in both males and females. It enhances thyroid function, but contains no thyroxin. It promotes the release of insulin, but does not cause hypoglycaemia; on the contrary, it can be used for treating hypoglycaemia induced by insulin. Thus, the advantages of traditional tonification are that it seldom causes side-effects, and there is usually no "withdrawal syndrome" when the treatment is discontinued. The major disadvantage is that its therapeutic effect is usually not as prompt as that of modern replacement therapy. Also, it is of limited benefit once the related tissue has been totally destroyed.

Both acupuncture and tonification therapy are guided by the principle of stimulating the body's natural healing power or functional potentiality. On the other hand, modern biomedicine has made rapid progress on the basis of the replacement principle of treatment. Organ transplantation, too, is based on the principle of replacement, and has been invaluable to many patients, with plenty of promise for the future. There is great scope for traditional medicine, with its rich experience in the mobilization and utilization of the body's potentialities, and

modern biomedicine to complement each other.

Future prospects of harmonization

This brief review of the development of traditional medicine in the People's Republic of China clearly indicates the possibility and benefits of the harmonization of traditional and modern medicine. Harmonization has progressed in China mainly because of the Government's efforts to formulate and implement appropriate policies, as well as the efforts made by the Chinese medical community. In the quest for harmonization, one must keep in mind that the breach between the two systems is increasingly narrowing, with the rapid advance of modern medicine in recent decades. Earlier, there were irreconcilable conflicts between the mechanistic and reductionistic approach of modern medicine and the dialectic and holistic approach of traditional medicine; and between modern medicine's analytical approach to arriving at conclusions and traditional medicine's method of comprehensive observation. However, the prospects of harmonization seem brighter now that biomedicine has proceeded from the cellular to the molecular level. The combined analytico–synthetic methodology is replacing the purely analytical methodology in the medical sciences, and the biomedical model is being transformed into a bio–psycho–socio–medical model, developments which are bound to facilitate harmonization.[17] Research into traditional medicine at the molecular and genetic levels is likely to throw greater light on the mechanisms of traditional therapies and their integration with modern medicine.

References

1. Svoboda R.E. (1993) *Ayurveda : Life, Health and Longevity*. Penguin Books.
2. Conrad L.I., Neve M. Nutton V., Porter R., Wear A. (1995). *The Western Medical Tradition: 800 BC to AD 1800*. Cambridge University Press.
3. Said H.M. (1983). The Unani system of health and medicare. In: *Traditional Medicine and Health Care Coverage*. World Health Organization, Geneva, Ed: Robert H. Bannerman, John Burton and Ch'en Wen Chieh. pp 61–67.
4. *Alternative Medicine: Expanding Medical Horizons (1992*). A Report to the National Institute of Health on Alternative Medical Systems and Practices in the United States, prepared under the auspices of the Workshop on Alternative Medicine. Chantilly. VA, p. 79.
5. Farquhar J (1994). *Knowing Practice: The Clinical Encounter of Chinese Medicine.* Westview Press. Boulder/San Francisco/Oxford.
6. Eskinaze D.P. (1998). Factors that shape alternative medicine. *Journal of the American Medical Association*. 1998, 280: 1621–1623.
7. Yip Ka-che (1995). *Health and National Reconstruction in Nationalist China*. Association for Asian Studies Inc. p. 27.
8. Huang Yongchang (1994). *National Conditions of Health in China* (in Chinese). Shanghai Medical University Press; pp 151–154.
9. Zhu Qingsheng (2000). Adhering to stress on both Chinese and Western medicine and promoting their integration, strive for the construction of Chinese socialistic health services (in Chinese*) Zhongguo Zhongxiyi Jiehe Zazhi (Chinese Journal of Integrated Traditional and Western medicine)*. 2000; 6(2): 82–87.

10. Zhu Qingsheng. Strive for the Adaptation of Traditional Medicine to the Demands of Health-Care. *Chinese Journal of Integrated Traditional and Western Medicine*. 6(2): 82–87.
11. Zhang Wenkang (Editor-in-Chief) *Zhongguo Weisheng Nianjian* (Year Book of Health of the People's Republic of China) People's Health Publishing House. 1999. p. 392 and 428.
12. Huang Shuze and Lin Shixiao. *Dangdai Zhongguo de Weisheng Shiye* (Health Services in Contemporary China) Vol. II. China Social Science Press. 1986, pp. 68–92. (in Chinese).
13. Zhen Zhiya and Fu Weikang, Zhongguo Yixueshi *(Chinese Medical History.* People's Health Publishing House. 1991. p. 201–210 (in Chinese).
14. Ma Jixing (1990). *Lore of Traditional Chinese Medical Literature* (in Chinese). Shanghai Press Science and Technology. p.16.
15. Zhang Wenkang (Editor-in-chief). *Zhongguo Zhongyiyao Nianjian* (Year Book of Traditional Chinese Medicine of the People's Republic of China). China Traditional Medicine Press. 1999. p. 492. (in Chinese).
16. Chen Ke-ji. Forty years of integrated medicine in China. *Chinese Journal of Integrated Traditional and Western Medicine.* 1997, 3(3): 162–166.
17. Deng Pingxiu. *Zhongyi Xiandaihua he Zhongxiyi Jiehe Yanjiu Fangfa* (Research Methodology on Modernization of Traditional Chinese Medicine and Integration of Chinese and Western Medicine). A chapter of the book Yixue Bianzhengfa (Medical Dialectics) edited by Peng Ruicong. People's Health Publishing House. 1992; pp. 152–160. (in Chinese).

Role of traditional systems of medicine in national health care systems

Shailaja Chandra

Introduction

The world-wide interest in the use of natural products and plant-based remedies has led to different situations developing in different countries. In countries with a strong foundation of traditional medicine such as India and China, nationally recognized parallel traditional systems have run for long periods, along with Western medicine with varying degrees of acceptance, integration and assimilation. In other countries like those in Africa, there is now a move to give legitimacy to the traditional healer whose medical practice has been the mainstay of the local people, even after Western medicine made its appearance and took firm roots. In Europe and USA, a new and growing consumer interest in the use of natural medicine and herbal products has opened burgeoning markets for health promotion products aimed at the improvement of physical well-being. This is a comparatively new constituency of herbal medicine users for the prevention of disease rather than cures for illnesses. Their emphasis has been on the use of single herbs and therapies promoted by consumer interest and demand and not yet fully understood or recognized by governments, including drug authorities. Meanwhile, a strong consumer demand for herbal products, plant-based remedies and a growing interest in Ayurveda, Acupuncture, Chinese Medicine, and their concepts, applications and strengths, which are millennia old, is taking place. Often this is happening without the knowledge of the allopathic personal physician who is seen to be ignorant or incapable of understanding why patients find relief in the use of alternative medicine. Added to that, the attainment of sensory control through self-restraint and self-realization through meditation has become the aspiration for a large number of people, propelled to some extent by the belief that the human body and the human mind have the ability to prevent and cure disease and achieve a state of well-being given the right tools. That this approach has merit is significant to some extent, by the fact that *Yoga* is a nationally recognized system of medicine in India.

Countries today, the world over, are flooded with thousands of plant-based remedies which have entered the markets as food supplements. Such products, which are primarily plant based and may or may

not contain synthetic ingredients, are being freely manufactured and exported. Many of the remedies have their roots in the use of plants for their medicinal value. With the growth of consumer demand on the one hand and the current socio-political ideologies on the other, governments have been trying to grapple with the task of approaching the traditional medicine practitioners and products in a way that can be simple and meaningful enough to make a significant improvement to people's daily lives while ensuring safety. In this pursuit, the government has naturally to confer legitimacy only on such systems, practices, therapies and drugs which have been investigated and found to be efficacious and where a process of standardization can be assured. This exercise, however, calls for the integration of several facets which go into the making and practice of traditional medicine, which requires an understanding of the sector, its strengths and weaknesses and what will work.

Traditional medicine in every country wherever it has a strong base, has emerged out of an individual physician's approach to the problems of an individual patient spreading to the family, and later the community. Rooted in traditional medicine is the belief that every person belongs to a broad stereotype and problems can be treated by understanding the individual's personal traits and specific factors which have brought about disequilibrium. Whereas Western allopathic medicine has a reductionistic approach and looks upon the removal of the symptoms of disease as the main objective, Traditional Medicine does not see only a single remedy or a single approach as being suitable for all people. Symptoms are seen only as an indication of a deeper malaise which is not necessarily considered to be caused by physiological factors alone.

In terms of priorities, the epidemiological situation compels governments to confront basic public health problems, leaving little time, space or funds for including traditional medicine approaches which are necessarily individualistic, slow and difficult to monitor and evaluate. On yet another plane lies the clinical approach, extended through allopathic dispensaries and hospitals designed to treat individual and specialized problems with modern diagnostics and drugs.

With such a wide difference in concepts and approaches, is it at all possible to bring about any kind of integration which would be of significant benefit to the people? Are comparisons between the loss of productivity on the one hand (which invariably calls for strong medication) and the elimination of side-effects on the other (albeit with gentler but slower traditional drugs) at all possible? Can one weigh the short-term benefits of getting back to work over the long-term benefits of avoiding dependence on strong drugs and resistance patterns? Is there at all a case for identifying which part of the traditional systems can be integrated into a health system? Where does traditional medicine fall between the public health approach on the one hand and the specialist-driven hospital-based approach on the other? Where will the inclusion of traditional medicine work to the greatest advantage, and can there be a policy on its integration into the health system?

These are some of the issues which policy-makers administering the health sector have to grapple with, and at the back of every decision-making process lies the question of whether the alternative offered by traditional medicine will lead to a significant improvement over the current situation, sufficient to call for a change of policy. Would governments like to introduce

strategies which may suit the individual but which may lead to delay in the diagnosis of a really serious illness? How can the expertise of the practitioner and the quality and safety of the drugs be assured? Would governments be in a position to introduce regulations and enforcement mechanisms that protect the patient against malpractice and spurious drugs, without curbing the individuality of the practitioner? Equally, should the consumer be denied access to simpler, gentler forms of treatment only because there is no one to inform him about such alternatives? If at all traditional medicine is to be used as a strategy to bolster the normal health care approach, where will its inclusion make the greatest impact and how can such assimilation take place?

These are some of the questions that need to be answered. This paper is an attempt to respond to them based primarily on the Indian experience, but also documented elsewhere.

Giving Legitimacy to Traditional Medicine

Traditional medicine can play a far more meaningful role in the health system of a country if it receives legitimacy from governments. For this, several requirements need to be fulfilled.

National Recognition for Traditional Medicine

Governments need to recognize a system or practice, therapies and drugs which have been studied by professional evaluators for safety and efficacy to give legitimacy to what is considered appropriate for public use. Thousands of formulations in Ayurveda and, for that matter, tribal and folk remedies the world over speak of the use of various herbs,

Pupils practising surgical procedures on vegetables in ancient India

singly or in combination mixed with other natural substances of mineral, animal or marine origin having properties to improve physical well-being, remove disease and disability and prevent the onset of seasonal problems. If the remedy has been documented and has been in use in a community for hundreds of years or, for that matter, even two or three decades, does it call for safety and toxicity studies to be conducted if there is a way of testing the absence of high microbial content and the absence of non-permissible substances?[2]

Many traditional medicines are no different from food items like home-made wines, jams, jellies, squashes and syrups. They contain only natural ingredients and, just as there are standards for food, formularies and pharmacopoeias have been evolved to set standards for the preparation of many such traditional medicines. For assimilation into a health system, if the pharmacopoeial standards are adhered to, if a licensing mechanism is in place and if there are ways of testing the product for the presence of the main ingredients and the absence of non-permissible substances, the system is in place.

In India there are thousands of Ayurvedic and Unani formulations licensed as medicines and sold over the counter and included in the formularies of health departments, both by the national and state governments. These formulations can be prescribed by practitioners of the respective traditional stream who suggest the use of classical (generic) or proprietary drugs exactly as done in allopathy. All such items are sold as Ayurvedic, Unani or Siddha medicines and carry a licence number, together with the list of ingredients on the label.

Role of Traditional Home Remedies in the Health System

Home remedies and licensed drugs fall into two distinct categories. On the one hand there are what could be determined as common remedies for common problems, and almost every country in South-East Asia, China and Korea have their own tried and tested traditional remedies for problems falling in the category of gastric problems, diseases of the respiratory system, skin and muscular problems, treatment of diseases of the reproductive and urinary systems, digestive disorders, treatment for wound healing, and common paediatric problems. This list is not exhaustive, but countries like India, Thailand, China, Sri Lanka, Bhutan, Nepal, South Africa and Korea, to name but a few, all have their own lists of herbs which are commonly used singly or in combination, made into a fresh paste, decoctions, or dried and powdered, having no side-effects and which have been in use in the community for generations as the first remedy when symptoms manifest.

Urbanization and the advent of the nuclear family leading to the virtual disappearance of the grandmother, the mother-in-law, and the village elders, have led to a situation where common remedies which had been administered without any doctors for years have now become questionable for a new generation of Western-educated urban public exposed only to the allopathic system and allopathic drugs. The age-old practices of maintaining kitchen gardens and visits to the village grocer who stocked all the dried herbs have gone into disuse in the cities. Knowledge about which part of the plant is to be used, namely, the root, stem, bark or leaves, has been effaced. Yet, for centuries this had been the mainstay of entire populations, long before allopathy came on the scene, and continues to be so for tribal and village people in many developing countries even today.

Every government is in a position to identify such drugs, whether they are in use in the country of origin or in another country having a similar socio-cultural environment, to be used for self-care, primary health care and as preventive medicine.[1] Such remedies are used very frequently in countries like India, Sri Lanka, Thailand, Nepal and Bhutan, and the same or similar plants are used with little indigenous difference. Thailand is reported to have identified about 150 selected herbs, screened them and brought the list down to 61 items accepted as a cure for illnesses signified by 17 symptoms. The herbs selected were mostly items used regularly in foods grown in domestic gardens like ginger, garlic, banana and aloe vera. The idea is to provide an alternative to promote good health, by attempting to solve health problems through self-reliance at the personal, family and community level. These remedies can take care of common maladies such as constipation, diarrhoea, nausea, joint pains, burns, cough and cold and sore throat.

In India, the Department of Indian Systems of Medicine and Homoeopathy of the Ministry of Health has published Home Remedies for Ayurvedic[2] and Unani[3] medicines and circulated them for use by community leaders, extension workers, nurse midwives and school teachers at the village level.

The Use of Traditional Drugs where Therapeutic Claims are made

For the wider sale of processed drugs where therapeutic claims are made, licensing is a prerequisite. Legislation to enforce licensing and registration is available in countries like India, Indonesia and Sri Lanka assisted by pharmacopoeias and texts which are recognized under the drugs enforcement legislation of the country. India and Indonesia have also introduced Good Manufacturing Practices (GMP) for traditional drugs which cover the requirements relating to the qualification of employees, the responsibility of the quality control managers, essential requirement of space, equipment, documentation of processing and packaging methods and need for self-regulation, coupled with enforcement by the licencing authorities. India, China, Bhutan, Indonesia and Thailand have national drug lists for use in primary health care and in hospitals. These examples can be emulated with advantage as such lists bring about confidence in the user and the utilization patterns can be studied for modifications in stocking policy.

Use of Traditional Medicine in More Complicated illnesses

In the case of complicated illnesses, simply stating that these drugs are recognized by the Government and that they can be safely used for self-care and primary health care for all kinds of diseases will not automatically lead to their use. The calibre of the practitioner and his skills decide whether patients place reliance on the system. In India, there is a vast infrastructure comprising more than 2854 traditional medicine hospitals with 49,353 beds, 400,000 institutionally trained practitioners of Ayurveda, Unani, Siddha and Homoeopathy, more than 387 colleges of indigenous medicine, and more than 22,000 dispensaries mostly situated in the rural areas of the country.[4] The practitioners have attended a five-and-a-half-year degree course after completing the final year of school. They have been registered by a statutorily elected professional Council called the Central Council of Indian Medicine. People come of their own volition to access traditional care, particularly for certain chronic ailments. In some states of India like Maharashtra and Tamil Nadu, the traditional medicine practitioner is very much a part of the primary health care system and provides diagnosis and treatment in the same health facility along with allopaths. In times of national disasters like cyclones, floods and earthquakes, under Government orders traditional medicine practitioners provide their own emergency medical relief, more specifically to prevent diarrhoea, dysentery and skin ailments and to help people overcome shock and disorientation. They have been used extensively during outbreaks of Japanese encephalitis where homoeopathy was found to have particular efficacy.

When the practitioner is part of the health system, his registration after completion of a recognized educational course is absolutely necessary. The public have a right to receive standardized treatment and drugs and to hold practitioners responsible for the medication they administer.

Role of Research in Traditional Medicine

Today, research is done mainly to establish evidence of the efficacy of the drug or therapy that is being used. In the area of traditional medicine, unfortunately most people feel that it is mainly anecdotal evidence or at best confined to case studies or observational studies. A few uncontrolled trials or small randomized clinical trials do not inspire much confidence.

The Government of India set up four research councils almost 30 years ago to look at the efficacy of Ayurveda, Unani, Siddha, *Yoga* and Naturopathy and subsequently that of Homoeopathy. Research conducted over the last 20 years has shown specific areas of strength where traditional medicine is particularly useful, often where western medicine has little to offer. Areas where it can be used as a stand-alone therapy or as an adjunct therapy have also been identified. Some of the major outcomes of the clinical research undertaken in the field of Indian Systems of Medicine include:

Ayurveda

- An Ayurvedic Antimalarial *Ayush*-64 for P-vivax;[5–7]
- An Ayurvedic Antiepileptic drug *Ayush*-56;[8]
- An Ayurvedic drug *Vijayasara* for Diabetes Mellitus (ICMR Communications);
- An Ayurvedic drug *Guggulu* and its extracts for hyperlipidaemia and atherosclerosis;[9]
- An Ayurvedic formulation *Pushkara Guggulu* for Coronary insufficiency for stable angina;[10]
- An Ayurvedic drug *Varuna* for UTI, Urolithiasis and benign prostate hypertrophy;[11]
- *Bhoomyamalaki* for Hepatitis B;
- *Brahmi* and *Mandukaparni* to promote Mental Health;[12,13]
- Ayurvedic drugs *Aswagandha* and *Guduchi* as rejuvenators and immunomodulators;
- *Panchakarma* therapies for paralytic disorders;[14]
- *Ksharasootra* ligation for anal fistulae and haemorrhoids.[15,16]
- Bio-enhancers like *pippali* and *maricha* to increase the bio-availability of drugs;
- *Brahmyadi Yoga* for Schizophrenia;[17]
- Oral contraceptives like *pippaliyadi yoga* (CCRAS communication);
- Spermicidal – *Nimba Taila*.[18]

Siddha

- A Siddha preparation 777 Oil for Psoriasis.[19]

Unani

The Council for Research in Unani Medicine prepared Unani formulations for the following areas:

- Bronchial Asthma, Filariasis,[20] Infective Hepatitis[21] and Vitiligo [22]

Homoeopathy

- **Behavioural Disorders**
  Belladonna, Hyoscyamus, Ignatia amara, Stramonium;
- **Diabetes Mellitus**
  Cephalandra or Coccinia indica (Bimbi);
- **Filaria**
  Apis mellifica, Bryonia alba, Rhus tox;
- **Gall stone**
  Fel tauri 2X or 3X;
- **Malposition of human foetus**
  Pulsatilla nigra 200;
- **HIV/AIDS**
  Tuberculinum, Phosphorus, Arsenicum album, Azadirachta indica, nux vomica, syphilinum, sepin, mercurius solubitis.[23,24]

Presently, in India, operational research studies are about to start in the area of healthy aging, using Ayurvedic drugs for specific problems like benign prostrate hypertrophy, reduction in menopausal symptoms, preventive cardiology, arthritis and the use of "*Rasayana*" for rejuvenation. Likewise, operational research studies have been designed and will commence shortly to cover nine specific areas affecting women and children's health which include menstrual disorders, reproductive tract infections, antenatal care, postnatal care, complications of pregnancy (vomiting, oedema) galactogogue, health promotion of neonates and infants, and the management of common colds, etc.

Some of the important extra-mural research projects which have been approved by the Department of Indian Systems of Medicine and Homoeopathy of the Government of India, and which are in progress, include examining the benefits of the integrated Approach of *Yoga* Therapy on Schizophrenia, Clinical, Haematological, Biochemical and Immu-nological Studies on Patients of Chronic Arsenic Toxicity and its Homoeopathic Management, Role of Ayurvedic Drugs in the prevention and Treatment of Occupational Health Problems (Pnemo-conicosis) in Industrial Workers, an objective Evaluation of the Efficacy of *Panchavalkal*, an Ayurvedic preparation, in treating Leucorhoea, a primary Study of Cancer treated through the Ayurvedic approach, a study on the treatment of Keloids in Homoeopathy and Allopathy, Efficacy of Ayurvedic Treatment as an Adjuvant Therapy for Fracture Treatment and Delayed Bone Healing, and a Comparative Trial of Ayurvedic and Allopathic Therapy for Spasticity and Paralysis-A randomized Controlled Study.

It will, thus, be seen that there are areas of interest to the health systems of any country, particularly in the growing fields of non-communicable diseases and geriatric and mental care. In handling difficult and intractable conditions, clinical trials are necessary. The challenge for health administrators lies in designing studies and motivating allopathic hospitals to undertake trials to establish the extent of benefits likely to be received by using the traditional approach, whether as a direct measure or as an adjunct therapy. However, research methodologies have to be designed keeping in mind the individualistic nature of the traditional diagnosis and the holistic side of traditional drugs. WHO has recently finalized guidelines on research methodologies for traditional medicine. The publication of the guidelines will create new and achievable parameters for research in this area, designed to foster greater enquiry, shorn of a restricted approach not tenable for medical research in the traditional area.

Why Raw Material and Standardization are of Paramount Importance in Traditional Medicine

Traditional medicine relies almost 90 per cent on the use of medicinal plants supplemented by minerals and metals and animal and marine products like corals and shells. Health systems and health administrators have perforce to get involved with the raw material aspect if traditional medicine is to be taken seriously. Without this the quality of medicine can suffer, affecting the credibility of traditional remedies.

Medicinal plants comprising thousands of species of plants constitute a vast, undocumented and over-exploited resource. The growth and cultivation of such plants, their collection, storage, distribution, processing and marketing are now gaining

importance as they all have an impact on quality. For traditional medicine to get a foothold on a sustained basis, the quality of the medicine has to be assured. There is a world of difference between the efficacy of a medicine made from plants cultivated and harvested using good agricultural practices and that derived from plants uprooted from the wild.[25]

In most countries, even in those where the use of traditional medicine is strong, the cultivation of medicinal plants is at present limited to a few items, most natural products being collected by villagers and tribal people from wastelands and forests. For want of training, they may destroy the whole plant instead of collecting just the part to be used. Re-plantation and propagation is left to nature. Collection not done during the proper season often detracts from the efficacy of the end product. The networking of collection is under the control of traders and the material collected is sold in the nearby township from where it reaches regional centres for domestic use or export. Enlightened industries do, however, cultivate plants so as to be assured of standard quality and the presence of active ingredients. They have invested in recruiting botanists and standardization experts in order to access quality raw material. Some of these industries have their own R&D facilities where documentation is maintained and quality assured through finger printing, HPLC and TLC tests. However, small manufacturing industries rely on market sources which have many attendant problems which affect quality.

In India, at the federal level the Departments in charge of traditional medicine (Indian Systems of Medicine and Homoeopathy under the Ministry of Health and Family Welfare), the Department of Environment and Forests, Agriculture, Biotechnology, Science & Technology and Commerce have come together to evolve a coordinated approach to the development of the medicinal plant sector. A Medicinal Plant Board has been established to coordinate all the activities under the Department of Indian Systems of Medicine and Homoeopathy which also has the responsibility to lay down standards for traditional medicine drugs. Despite this policy-level support, the role of traditional medicine in the health system will be decided by only one factor, i.e., the curing and health-giving ability of the practitioners and the remedies on a sustained basis.

Standardization, a Pre-requisite for Quality Control of Traditional Medicine Drugs

Standardization of plant-based drugs is extremely difficult because presently very few quality control tests are available in most countries using traditional medicine. In their absence, there are no methods to evaluate the contents and the quantities as claimed on the label. Quality control is required at three stages, namely, when the raw material is used, for confirming the process undergone by the drug during manufacture, and at the finishing stage. The shelf-life or date of expiry needs to be indicated and the possibility of mixing modern drugs has to be strictly eliminated and strong deterrents imposed to discourage such practices. Measures to test the absence of pesticide residues, heavy metals and aflatoxin have to be taken through proper regulation and testing.[26, 27] At least a few important markers have to be identified through TLC (finger printing) and the process of making random checks has to be institutionalized and penalties imposed if non-permissible substances are found or the medicine does not conform to safety standards. For patent proprietary drugs, manufacturers must be

asked to provide the recipes. Consumers must be kept informed about how they can access quality products and where tests can be undertaken if doubts about quality are experienced.

In India, pharmacopoeial standards for 158 drugs are available and 634 formulations have been published in the Ayurvedic Formulary of India. Likewise, for Unani medicine pharmacopoeial standards are available for 45 drugs and a Unani Formulary for 603 formulations is available. In respect of Homoeopathy, pharmacopoeial standards are available for 916 drugs.[28-35]

In Ayurvedic and Unani formulations, sometimes a single medication has over 50 ingredients and certainly even the simplest medicines have 6–10 ingredients involving the use of different parts of several plants. Standardization is not a simple task and it has to be undertaken and institutionalized if the traditional medicine sector is to secure a niche for itself in the health system.

Scientists have given numerous suggestions about the standardization and quality control of herbal drugs. In India, the problems have been addressed through a variety of measures, some of which have already been implemented and some are still in the process of being introduced. In order to give an impetus to Quality Control and Standardization, the Department of Indian Systems of Medicine and Homoeopathy has initiated schemes to help strengthen the State Pharmacies and State Drug Testing Laboratories to become models for the proper formulation of quality medicine for use in the public sector and Government-run hospitals and dispensaries. Side by side, recognition of private laboratories which possess the equipment and the scientific and technical manpower as stipulated, and act as Government-approved laboratories authorized to conduct quality control tests and issue certification is also contemplated.

Traditional medicine can play a role in the health system of a country if the system and its medicaments have been prepared in a manner that inspires confidence in the quality and the Government supports the use of such systems with the needed controls.[36,37] Without this input, traditional medicine can grow only in a haphazard way and public confidence may get eroded over time. Issues of quality have to be confronted squarely and national and provincial governments have to be made aware of what is acceptable across the world. Only then will traditional medicine be able to achieve its due position in the health system.

Issues of Integration

Indian Government's Policy on Traditional Medicine

The Central Council for Health and Family Welfare, set up under Article 226 of the Constitution of India, is the highest policy-making body which lays down policy for all sectors covered under the health portfolio. It meets once a year and consists of the federal health ministers, state health ministers, eminent health experts, NGOs with an interest in health, and officials of the central and state governments.

The Council in its last meeting held in 1999, *inter alia*, recommended that at

Traditional medicine can play a role in the health system of a country if the system and its medicaments have been prepared in a manner that inspires confidence in the quality.

least one physician from the Indian Systems of Medicine and Homoeopathy (ISM&H) should be available in every primary health centre in every state and that vacancies caused by non-availability of allopathic personnel should be filled by ISM&H physicians. The Council also resolved that specialist treatment centres for ISM&H should be introduced in rural hospitals and a wing should be created in the existing state and district-level Government hospitals so that the benefits of these systems are made available to the general public, according to their choice. It has also been resolved that expenses on treatment received in traditional medicine hospitals should be recognized for reimbursement as is already permitted in the case of Central Government employees. All these measures have been recommended to all state governments and the action taken thereon is regularly monitored at the central level.

Mainstreaming Indian Systems of Medicine and Homoeopathy for Population Stabilization

The Government of India has adopted a 'National Population Policy 2000' and, for the first time, a Chapter has been introduced on mainstreaming the Indian Systems of Medicine and Homoeopathy (ISM&H). The Policy seeks to use the institutionally qualified practitioners of ISM&H (who have completed a five-and-a-half-year degree) and utilize their services to fill the gaps in manpower at appropriate levels in the health infrastructure. The Policy also seeks to increase utilization of ISM institutions, dispensaries and hospitals for health and population-related programmes. What is particularly noteworthy is that the Policy advocates the use of tried and tested ISM medicines at the village and household level.

The Government of India has set up a Population Commission to address the whole issue of population stabilization. The Commission has further set up a High Powered Advisory Group on Mainstreaming of Indian Systems of Medicine and Homoeopathy (ISM&H) into the health system. The terms of reference seek to:

- Review the status of Reproductive and Child Health (RCH) services extended by ISM&H practitioners, their infrastructure and personnel;
- Identify areas where ISM&H practitioners can be used more effectively by upgrading their knowledge and skills;
- Select effective ISM&H practices which can augment the existing RCH approach;
- Specify significant legislative, administrative and schematic changes which need to be introduced to achieve the objective of utilizing ISM&H and their practitioners to the best advantage.

This is the first time that a separate high-powered group has been set up for using the strategies of ISM in population stabilization, a major area of focus for the Indian Government.

Integration of Traditional Medicine into the Reproductive and Child Health Programme

For the first time, drugs of the Ayurvedic and Unani systems have been incorporated into the kits of nurses and midwives in the sub-centres of seven states and four cities, to be extended to the whole country later. The same drugs are also to be made available in the kits of female extension workers in over 5,00,000 centres providing supplementary nutrition to pregnant and lactating women and children below six years. The traditional drugs have been selected to take care of common problems and are being centrally procured and tested before being added

to the kits. This will further help the health systems to take care of a large number of women and children as a first line of care through traditional medicine.

Meanwhile, but again for the first time, the Ayurvedic concepts of the Healthy Mother and Child are to be studied through an operational research project under the joint aegis of the Indian Council of Medical Research and the Central Council for Research in Ayurveda and Siddha (CCRAS). Five states and 10 blocks have been identified for this study. The areas cover the overall approach to reproductive and child health, including menstruation, antenatal care, preparation for delivery, vomiting in pregnancy, loss of appetite, constipation, gaseous distention, acidity and diarrhoea, treatment of oedema, loss of sleep, piles and anaemia, delivery and its management, contraception and the management of the newborn. In regard to neonatal and child health, the areas include care of the newborn, precautions during the first week after birth, supplementary food for the infant, general growth and development of the child, management of diarrhoea, constipation in children and eradication of worm infestation. The entire approach is traditional and the applications are simple enough to be administered by Ayurvedic practitioners, nurse midwives, traditional birth attendants or even at the household level. This again is the first time that a joint operational research study combining research talent from allopathy and traditional medicine will be undertaken to determine the benefits of the Ayurvedic approach in this area. The objective is to identify areas of greater relevance and significance, which could be introduced in the Reproductive and Child Health Programme.

The Defence Institute of Physiology and Allied Sciences (DIPAS) has successfully developed a vaginal contraceptive (spermicidal agent) from Neem Oil (*Azadirachta indica*) in the form of pessary, which has been approved for clinical trials. This product of DIPAS has overcome the inconveniences of using the oil as such, being done by the CCRAS.

The work on *Pipplyadi Yoga*, a herbal contraceptive, is already undergoing clinical trials in five allopathic centres with allopathic clinical investigators. Both these initiatives will be a boon to rural women if highly effective cheap contraceptives are developed.

These examples show how the benefits of Indian medicine are being brought into the mainstream of health care where they are poised to play an increasingly important role.

Does Traditional Medicine Have a Role in an Allopathic Set-up?

Different countries have made different kinds of efforts to assimilate traditional medicine into the normal health system. This has met with varying degrees of success. Some examples of how India has given a role to traditional medicine in the health sector are described below.

In a 900-bed general allopathic hospital in New Delhi (the R.M.L. Hospital), services for Homoeopathy and Unani treatment are available under the same roof. In another 1500-bed allopathic hospital (Safdarjung Hospital), Ayurvedic and Homoeopathic treatment is available. Medicines are either given by the practitioners or through the Central Government Health Scheme (CGHS) to government employees.

The attendance pattern in the traditional medicine clinics was analysed over a six-month period. The main findings were that in Ayurveda, among the chronic diseases, arthritis (*sandhi vata*) accounted for 10.8

per cent of the attendance, abdominal diseases (*udara vikara*) for 10.1 per cent and nervous diseases (*vata vyadhi*) for 9.2 per cent. In the case of acute diseases, the largest turnover was in respect of bronchitis (*Kasa*), weakness (*dhatuksaya*), disease of mouth (*mukha roga*), etc. (Table 1).

In respect of Homoeopathy, it was found that most people accessed the system for gout, arthritis and bronchial asthma among chronic diseases. In the case of acute diseases it was the upper respiratory tract infections that had the largest attendance (Table 2).

Table 1. Utilization of Ayurvedic Treatment over a six-month period in Safdarjung Hospital, New Delhi (A 1500-Bed Allopathic General Hospital)

Chronic disease	Attendance %	Ordinary disease	Attendance %
Sandhi vata (Arthritis)	10.8	Kasa (Bronchitis)	12.8
Udara vikara (Abdominal disease)	10.1	Pratisyaya (Coryza)	8.4
Vata vyadhi (Nervous diseases)	9.2	Dhatuksaya (Weakness)	7.4
Amlapitta (Hyperacidity)	7.8	Mukha roga (Disease of mouth)	7.2
Sotha (Dropsy)	5.6	Mutra roga (U.T.I.)	6.1
Yakrta vikara (Liver disease)	5.2	Pandu (Anaemia)	5.6
Tvak-roga (Diseases of skin)	5.0	Pradara (Leucorrhoea)	5.6
Amvata (Rheumatism)	5.0	Rakta vikara (Blood impurities)	5.5
Svasa (Asthma)	4.7	Ajirna (Indigestion)	5.0
Grahanidosa (Sprue)	4.6	Kosthabaddhata (Constipation)	4.5
Other Diseases	32.0	Other Diseases	32.0
Total	**100 (5593)**		**100 (3989)**

Table 2. Utilization of Homoeopathic Treatment over a six-month period in Dr. R.M.L. Hospital, New Delhi (A 900-Bed Allopathic General Hospital)

Chronic disease	Attendance %	Acute disease	Attendance %
RA/Gout/Arthritis	9.9	U.R.I. (Upper Respiratory Tract Infections)	27.0
Dyspepsia	5.9	P.U.O. (Pyrexia/Fever of unknown origin)	17.4
Sinusitis	4.8	Allergic Rhinitis/Rhinorrhoea	14.3
Dermatitis	4.4	Urticaria	5.9
Tonsillitis	3.5	Stomatitis	5.6
Bronchial Asthma	3.1	Abscess	3.9
Alopecia areata	2.8	Jaundice	3.4
NBA (Naso Bronchial Allergies)	2.7	Dysentery	3.3
Verruca	2.5	Gastro-enteritis	3.2
Headache	2.4	Dentition period/troubles	3.0
Other Diseases	58.0	Other Diseases	12.9
Total	**100 (10006)**		**100 (2613)**

Table 3. Utilization of Unani Treatment over a six-month period in Dr. R.M.L. Hospital, New Delhi (A 900-Bed Allopathic General Hospital)

Chronic disease	Attendance %	General disease	Attendance %
Waja-ul-Mafasil (Rheumatoid Arthritis)	23.1	Su-e-Hazm (Dyspepsia)	10.5
Bars (Vitiligo)	7.9	Nazla-wa-Zukam (Common cold)	10.5
Sailan-ur-Rahem (Leucorrhoea)	6.1	Qabz (Constipation)	10.1
Saman-e-Mufrit (Obesity)	5.6	Faqruddam (Anaemia)	6.1
Zeequn Nafas (Bronchial Asthma)	5.4	Waja-ul-Batn (Abdominal pain)	6.1
Ziabetus Sukkari (Diabetes Mellitus)	5.2	Humma (Fever)	5.9
Humuzat-e-Meda (Hyperacidity)	4.0	Zaheer (Dysentery)	5.7
Warm-e-Qasbat-ur-Riya (Bronchitis)	3.3	Ishal (Diarrhoea)	4.7
Bawaseer (Piles)	3.2	Qula (Stomatitis)	4.1
Zof-e-Kabid (Liver dysfunction)	2.7	Suda (Headache)	3.9
Other Diseases	33.5	Other Diseases	32.4
Total	**100 (18095)**		**100 (10492)**

The Tables are indicative of the areas where patients visiting an allopathic hospital still prefer to use traditional medicine exclusively or as an adjunct therapy.

The Unani system appears to attract the largest number of people for rheumatoid arthritis (*waja-ul-mafasil*) and vitiligo among chronic diseases, common cold (*nazla-wa-zukam*) and dyspepsia (*su-e-hazm*) (Table 3).

Institute of Medical Sciences, Banaras Hindu University, Varanasi – An example of integration

Banaras Hindu University (BHU) is probably the first institution which conceived the idea of integrating the ancient and modern systems of medicine both at the level of education and professional practice, 73 years ago, when the first ever integrated Ayurvedic College was established. Subsequently, this model became controversial and was opposed by the mainstream of Ayurvedic organizations, and the Ayurvedic College of BHU was closed in 1960 but an integrated education was started at the postgraduate level for teaching and research and this approach is continuing even today. The M.D. Ayurveda Programme of the Faculty of Ayurveda is also open to MBBS graduates. For such candidates, the first-year M.D. Course is a special preparatory course and there is a separate examination for the two streams. But the Final M.D. Ayurveda examination and teaching is common for both the streams. They undergo the same training in the 2nd and 3rd year, clear the same examination and get the same degree.

The University has also passed an Ordinance through which a candidate holding an M.D. degree in Ayurveda may be registered for a Ph.D. degree in the respective speciality of modern medicine and vice versa.

Medical Research in BHU

The M.D. Ayurveda and Ph.D. Ayurveda scholars adopt modern parameters of

study but they also adopt parallel Ayurvedic parameters such as determination of *Prakriti*, Ayurvedic Diagnosis, Status of *Agni* and *Ama*. In all cases the main guide for the thesis-level research is a teacher from the Faculty of Ayurveda but there are one or two co-guides from modern medicine or the basic medical sciences.

There are no formal rules or policy formed for this collaboration. The pattern has evolved spontaneously and mutually over the years.

Cross-referrals in BHU

The treatment and patient care in BHU Hospital too is on an integrated pattern.

The main morbidity areas in which the patients are referred for Ayurvedic treatment at BHU involve:

Fistula in ano, chronic rheumatic diseases, residual psychosis and anxiety disorders, chronic colitis and IBS, diseases of the liver and jaundice, degenerative brain disease and neuropathy and terminally sick patients of all kinds declared incurable and/or financially unable to afford modern treatment. Most cases are referred to the Department of *Kayachikitsa* or Internal Medicine.

Practical areas where Traditional Medicine can be used effectively in the Health System

Traditional medicine falls into several different segments, from the highly researched and documented to that which has been practised through oral tradition, from manual therapy and manipulation to faith healing. There are also important systems like Homoeopathy which are routinely accessed over the counter in some countries but restrictions continue on the use of the medicine (except on the prescription of a practitioner) at other places. Whether traditional medicine can at all be used effectively both in the public health area and in clinical practice as an adjunct or an adjuvant has no uniform answer. At the same time, there are a large number of approaches which may be used to advantage with a little effort, but that requires a policy backup and regulatory systems to make such strategies work. Since it is difficult to generalize, a few examples are given about how the public can be benefited.

Manual Therapy like Yoga

Yoga is known to be effective in the management of various disorders and indexed research papers have shown improvement in cases of anxiety neurosis, depression, arthritis, bronchial asthma, constipation, hypertension, respiratory diseases, back pain, insomnia and postural defects. The most important way that *Yoga* can contribute in improving the state of well-being of a large number of individuals is if governments were to introduce the practice of *yogic asanas* in schools and also if classes were to be held for the benefit of the general public. In New Delhi, such classes are run in the mornings and evenings at a Central Institute for *Yoga* (MDNIY), separately for men and women and these can be accessed free of cost. The general public can participate at will. During summer, when schools are closed, the institute establishes 101 camps in different residential localities of Delhi for the benefit of residents by paying for the services of a *Yoga* teacher after prior screening for their capability, communication skills and knowledge of *yogic* postures. The *yogic asanas* with meditation have helped countless people to maintain physical and mental equilibrium.

The Defence Institute of Physiology

and Allied Sciences (DIPAS) has done extensive work on looking at the effect of *Yoga* on soldiers working in extreme climatic conditions as well as the effect of vegeta-rianism, *yoga* and meditation on persons having over 50 per cent blockage of at least one artery with the results being followed up after six months. Cardiologists from top allopathic institutions tested the results through angiography and the outcome has shown extremely promising results. In this way, patients have been enabled to overcome apparently intractable problems through simple and cheap strategies within their control and devoid of side-effects.

Several specialized institutions in the allopathic sector as well as those committed exclusively to *Yoga* are conducting extensive research on the tremendous healing properties of *Yoga* and its strengths. This is one of the cheapest ways of involving the community in health promotion and in making it a community effort. The health system only needs to screen the *Yoga* teacher, extend occasional supervision and to see that nominal payments are made for the classes. The community can be left to decide the teacher's acceptability. In order to make this a part of the health system, it is necessary to involve the local Government machinery in the rural and urban areas, community leaders, schools teachers and doctors in-charge of PHCs. Through this approach, a number of problems can be taken care of without medication.

Homoeopathy

Homoeopathy is recognized as a system of medicine in many countries and a large number of drugs are available over the counter in the United States, as well as in several European and other countries. It is extremely important that the drugs are licensed and sold with proper labelling and product information. In some countries like the United Kingdom, allopathic practitioners undergo a one-year course in Homoeopathy and can practise the system. In India, students have to enrol after the school level and undergo a five-and-a-half-year degree course to be allowed to practise. Homoeopathy is particularly remarkable in being able to treat routine problems, skin and other allergies, gastric problems and children's ailments. It is possible to list at least 40 simple remedies which could be sold through chemists over the counter without prescription, in 5 ml. vials, so that there is no misuse. These 40 medicines are intended for common ailments to relieve symptoms to aid early restoration of normalcy. It is necessary to improve access to these simple medicines and to sensitize people, who should be encouraged to use such remedies. Several simple booklets are available which describe the condition as well as the mode of administration of the drugs and the dosage. Since Homoeopathy is a gentle and effective medicinal science, its use should be integrated into the health system more effectively.

Traditional Therapies which can be integrated to advantage

Research studies have also shown the beneficial effects of *Ksharasootra* and *Panchakarma*, two Ayurvedic therapies. *Ksharasootra* comprises the use of Ayurvedic medicated thread in the management of fistula-in-ano, and multicentric trials have been conducted at the collaborating centres of the Indian Council of Medical Research on 265 patients where the approach was compared with conventional surgery. The finding showed that the long-term outcome of *Ksharasootra* is better than surgery,

although the initial healing time is longer. It is an effective, ambulatory and safe alternative treatment for patients with fistula-in-ano, the main advantage being that general anaesthesia is avoided and the chance of recurrence of the problem is nil.

Another highly acclaimed procedure in Ayurveda refers to *Panchakarma*, which constitutes a part of the therapeutic approach in the treatment of diseases as well as for the prevention and promotion of health care. *Panchakarma* therapy comprises five purificatory and therapeutic procedures consisting of oilation and fomentation of the body followed by medicated emesis, purgation, medicated enemata, nasal insufflation and blood letting. Five modified procedures of oilation and fomentation of the body have come to be known as *Keraliya Panchakarma*. These include *Sirodhara* (dribbling of oil on forehead), *Sarvangaseka* (dribbling of oil on the whole body while massage is done) *Pinda sweda* (fomentation with hot medicated balls of cooked rice, etc.). *Annalepa* (besmearing of cooked and medicated rice on the whole body) and *Sirolepa* (application of thick medicated paste on the crown of the head). These are followed by specific dietary measures each time. *Panchakarma* has been used in treating many critical diseases like diabetes, cardio-vascular diseases, hypertension, arthritis, rheumatoid arthritis, osteoporosis, and degenerative disorders.

Both these procedures have been advocated by the Department of Indian Systems of Medicine and Homoeopathy for being extended to allopathic hospitals where large numbers of patients congregate. *Panchakarma* has been found to give significant relief well beyond what drugs and physiotherapy can achieve, particularly for symptoms and ailments caused by neurological and neuromuscular and certain orthopaedic disorders.

Ksharasootra has provided an alternative for those patients who either do not want surgery or who have encountered recurrence of the problem after conventional surgery. In fact, it has been seen at the KEM Hospital, a large allopathic hospital in Mumbai, that cases of fistula-in-ano undertaking surgery have declined considerably ever since *Kshar-Sutra* has been offered as an alternative. The cost of these measures is nominal given the outstanding relief they have given patients.

There are applications similar to *Panchakarma* available throughout the traditional system of medicine in most countries of South-East Asia which would be worth incorporating in general hospital wards and other in-patient facilities.

Folk Medicine and Tribal Remedies

Every country has its own list of traditional remedies and countries need to document these after observing local people and their practices. This is important because this information is often the foundation of larger discoveries and inventions, and since this information is passed down by word of mouth, it is likely to be lost forever. It is important to engage botanists, foresters and NGOs working in this area to prepare lists of such tribal, folk and village remedies.

In India, the Central Council for Research in Ayurveda and Siddha (CCRAS),[38] and the Central Council for Research in Unani Medicine (CCRUM) have observed and documented over 10,000 such remedies, although not all of them can be used and not all the plants are readily available. Yet, these remedies represent the knowledge of the people and the intellectual property of the country. Unless these are documented, it will be difficult to give benefit to the country and

the community. Health departments must appoint the right blend of survey staff to document this knowledge, which will otherwise disappear forever along with the disappearance of forests, tribal communities and village doctors. Having documented it, the next step is to identify areas of current importance where the remedy appears to offer a net advantage over available medicaments and to conduct observational or animal studies (in the case of unknown plants) to test their efficacy.

Need for establishing an infrastructure for Traditional Medicine with supporting Legislation

Infrastructure for Indian Systems of Medicine & Homoeopathy

Six systems of traditional medicine are nationally recognized by the Government of India and the state governments – Ayurveda, Siddha, Unani, Yoga Naturopathy and Homoeopathy. There is a full-fledged, independent Department under the Ministry of Health of the Union Government with a Secretary, who reports to the Union Ministers for Health. Public health is a State subject under the Indian Constitution and 18 state governments in the country have set up Directorates of Indian Systems of Medicine & Homoeopathy. Some states have independent ministers in-charge of the non-allopathic recognized systems. India has the following capacity in the traditional medicine sector (Table 4).

Drug Licensing for Traditional Medicine

The drug-based systems, viz., Ayurveda, Unani, Siddha and Homoeopathy, are covered by the Drugs and Cosmetics Act of the country and the rules made thereunder. The licencing authorities for traditional medicine drugs are appointed by the state government, which implements the rules. However, the powers to modify the Act and rules rest with the Union Government, which is guided by the Drugs Technical Advisory Board for Ayurveda, Siddha and Unani drugs and a Drugs

Table 4. Infrastructure for Indian systems of medicine and homoeopathy (1999)

System	Colleges		Registered Traditional Practitioners	Licensed Pharmacies of Traditional Medicine
	Under-graduate	Post-graduate		
Ayurveda	196	49	3,66,812	8,405
Unani	40	03	40,748	549
Siddha	02	01	12,911	417
Homoeopathy	149	15	1,88,527	903
Naturopathy	–	–	402	–
Admission Capacity	14,255	700		
Hospitals of ISM&H (in Govt. Sector)	2,854			
Beds in hospitals of ISM&H	49,353			
Dispensaries of ISM&H (in Govt. Sector)	22,735			

Consultative Committee, both of which are statutory committees where the views of experts and state governments are discussed. All the rules have statutory nationwide application.

Medical Education and the registration of the Traditional Medicine practitioner

Countries like India and China have their own registration processes for traditional medicine practitioners. In India, a student must pursue a five-and-a-half-year degree course after the school level to be able to qualify as a registered practitioner of Ayurveda, Unani, Homoeopathy or Siddha Medicine. The Indian Parliament enacted an Act for the Central Council for Indian Medicine (CCIM) in 1970 and for the Central Council of Homoeopathy (CCH) in 1973. These have been set up on the lines of the Medical Council of India (MCI), patterned on the General Medical Council of UK. The educational standards for colleges including the curriculum, are laid down by the Councils which grant recognition to educational institutes, which also have the powers to regulate the admission capacity, on an appraisal of the infrastructure. Affiliation is granted by the universities.

Gujarat Ayurved University

The Gujarat Ayurved University at Jamnagar is the only statutory university exclusively devoted to Ayurvedic studies and research. It has facilities for teaching Ayurveda up to graduation level as well as for the M.D. and Ph.D. courses in Ayurvedic Medicine. It has Departments of Basic Principles, *Dravyaguna* (Pharmacology), *Rasashastra* (Alchemy) and *Bhaishajya Kalpana* (Pharmaceutics), *Kayachikitsa* (Internal Medicine), Shalya (Surgery), *Shalkya* (eye and ENT), *Kaumarabhritya* (Maternity and Child Health), etc., and laboratories for biochemistry, pathology, pharmacology, modern pharmaceutical chemistry, pharmacognosy and experimental laboratories. These laboratories provide support for research projects by utilizing the ancient knowledge of Ayurveda.

Responding to the growing interest in Ayurveda, the University has broad based its training programmes and also facilities for special diploma and certificate courses in Ayurveda for foreign professionals and students. An International Centre for Ayurvedic Studies has also been established. The courses run by the University are indicative of the different approaches available for educating and training students to equip them with varying degrees of competence to learn about and practise Ayurveda.

Presently, 18 students from 12 countries have completed different courses at the University. Requests for affiliation have already been agreed to in the case of three foreign institutions and six more requests are under consideration. This is indicative of the role that traditional medicine is destined to play as more serious interest devolves on understanding the philosophy and practice of Ayurveda.

Issues of Registration and Practice

For traditional medicine to be accepted on a wider scale, it is necessary for the practitioners to be exposed to an educational system and to possess registration to practise medicine. While there can always be a case for the continuance of traditional healers and their oral family tradition passed on from generation to generation in order to play an effective role in the health system, practitioners need to go through a course of educational training

and skills acquisition if they are to treat patients at a level beyond that of home remedies for common ailments.

Traditional medicine practitioners who have undergone a degree course are fully qualified to perform tasks like supervision of TB drug intake, dispensation of malaria drugs and screening of STI and RTI cases. They can facilitate referrals, undertake counselling and advocacy for the prevention of HIV/AIDS and help identify cases of cataract blindness. Since most health system managers are doctors from the public health stream, they do not readily accept this paradigm, which is why governments need to declare and implement a policy on the utilization of these practitioners. The challenge is to encourage traditional practitioners to primarily use their own systems and to build awareness among the public that relying on traditional remedies for common problems could be safer in the long run. The practitioners can nevertheless be assigned specific duties after being screened for their knowledge and skills, and trained in fulfilling public health responsibilities besides practising their own systems. In order to see that this does not lead to such practitioners practising allopathic medicine, governments need to specify what can be done by such practitioners and should supervise and monitor their work.

Issues of access to Traditional Medicine

For any traditional medical system to work successfully, medicines of standard quality must be available at reasonable prices. In India, the problem has been addressed by specifying an Essential Drug List to be used at the dispensary and hospital levels for the kind of ailments for which people generally seek the services of traditional medicine practitioners and where drugs are easily available. The list comprises some 315 medicines falling under 19 categories of diseases and problem areas. It has been calculated that health departments would need to set aside about $950 per facility per year if classical (generic) medicines are used for an OPD clinic visited by 50 patients a day. Such lists are available in other countries too. Several of them are manufactured in Government-owned pharmacies or are purchased from manufacturers.

There are over 9000 licensed pharmacies manufacturing a vast array of drugs catering to a wide range of human as well as veterinary problems. Their preparations conform to original classical texts or with some deviations, which put them in the category of patent proprietary medicines. These medicines are available with allopathic chemists who stock Indian medicines or with special grocers. The public in India are well-acquainted with these remedies, which are aggressively advertised and marketed throughout the country.

Ayurvedic medicines generally comprise several items.[31–34] These include:

- Arka – *Arkas* are liquid preparations obtained by condensation of vapours by the process of distillation.
- Pak – Avaleha – *Avaleha* or *Leha* is a semi-solid preparation of drugs, prepared with the addition of sugar or candy and boiled with the prescribed drug juice or decoction, useful for chronic ailments. These preparations are usually tonics.
- Chyawanprash – is an example of *Avaleha* and is useful as a health tonic in any season. It is especially indicated for chronic respiratory problems and general debility. Apart from being particularly useful in warding off chronic coughs and respiratory

problems, it revitalizes the metabolic functions.

- Asavas and Arishtas – These are medicinal preparations made by soaking the drugs, either in powder form or in the form of decoction, in a solution of sugar or jaggery for a specified period of time, during which the mixture undergoes a process of fermentation generating alcohol, thus facilitating the extraction of the active principles contained in the drugs. There are several kinds of *Arishtas* and *Asavas* but more than 30 such products are available commonly.
- Vati-Gutikas – These are in the form of tablets or pills made of one or more drugs of plant or mineral origin and these too comprise several items. Their uses range from the treatment of jaundice, hyperacidity, intestinal colic, distention of the abdomen and loose motions to chronic fevers.
- Churna – *Churnas* comprise fine powders of single or multiple-plant drugs and are usually taken as appetizers or digestives and still others as purgatives. *Shatvaryadi Churnas* are widely used for abdominal colic, griping, constipation, worm infestation and acidity. *Trifala Churna* is used for chronic constipation and dropsical conditions and is also used for improving eyesight.
- Guggulu – *Guggulu* is an exudate, obtained from the plant Commiphora mukul. It has excellent properties for treating pain, nervine problems and skin diseases. Combination of Guggulu and herbal powders has been given names like Triphla guggulu and Yogsay guggulu.
- Ghritas – *Ghritas* are preparations in which *ghee*/butter is boiled with the prescribed decoction according to the Ayurvedic formula. These are useful in the treatment of mild fever and in making the body healthy and strong. They are useful in epilepsy and mental disorders, genito-urinary disorders, conjunctivitis and night blindness.
- Ayurveda also has a large number of medicated oils (*Tailas*) which are useful for different kinds of pain in different parts of the body. Medicated oils are also available for hair problems, skin diseases and anorectic problems.
- All these items are prepared according to Ayurvedic principles and the entire recipe, its composition, the formula, the English and botanical names of the items, the parts in which the preparation is made, the indications and the doses, are all available in Pharmacopoeias and with the companies which manufacture the products. Since all these items have been in common use for centuries and the recipe has remained exactly the same as in the case of classical medicines, the Indian public has confidence in their use.

Conclusion

The entire spectrum of the role of traditional medicine in the health system is much too long and varied between and across countries and cannot, with due justice to the subject, be encapsulated in a single chapter. Every country has its own health systems and, within the health system, resources have to be found to pay for the salaries of the providers, equipment, drugs and consumables. All governments are concerned about bringing down costs, improving access to health and health outcomes and, most important of all, preventing ill-health. Many countries have experienced acute problems in trying to do all that medical science and a public health

conscience require one to do. Debates about investment in tertiary health versus primary health, health insurance versus voluntary safety nets for the poor, public health versus preventive care, standard setting versus voluntary accreditation and self-regulation, and over-diagnostics versus the family physician approach, abound in every country. Through all this runs an important thread which essentially determines whether health systems really work, and that refers to the public demand, consumer satisfaction and cost-effectiveness.

Consumer demand for improved health outcomes, more choices, less side-effects, less resistance patterns, less intake of chemicals and synthetic drugs, greater reliance on natural and environmentally friendly products, all have pointed to the burgeoning interest in natural plant-based products and a desire to go back to nature and investigate and re-package old strategies, prescriptions and antidotes to meet the emerging problems of today. Traditional medicine has much to offer and the sheer volume of empirical knowledge and the areas of application are so voluminous that it would be difficult to ever conclude which system, which drug and which application is superior to another.

Traditional systems which are highly documented and which are backed by statute and by regulatory and enforcement mechanisms, are bound to be taken more seriously than those which depend only on the faith of the consumer or the confidence generated by word of mouth, howsoever convincing it may be. Since the medication of an individual can lead to all kinds of effects years from now, governments have a responsibility to ensure not only the efficacy of the medicine but, more important, its safety. This can only be done by making available quality medicine and registering the practitioners who can be held accountable. The experience of India clearly shows that it is possible to have traditional systems which can be used strongly and effectively to reinforce the health system. However, what is essential is strong policy support to give the system national stature, resources to conduct evidence-based research and to include practical strategies for different traditional medical practices to provide an alternative or to complement the work of the normal health system.

In this paper, an effort has been made to place a few examples of what is possible, what can still be done and what is already being done before a public that wants to understand how it can be done and where it would be most relevant. Not all prescriptions given in this paper can be applied universally or emulated entirely. They require investment in time and resources to understand where traditional medicine can contribute most meaningfully, resulting in better health outcome. But, most important of all, they require an open mind to the development of health systems which rise above the ordinary, an end to the hubris that surrounds traditional medicine today and the strength to determine what can be offered to a hungry and curious public with a sense of legitimacy that the situation demands. Now is the time to make better use of the traditional system to augment access to health care, based on empirical evidence, public demand and cost-effectiveness studies.

References

1. Essential Ayurvedic Drugs for Dispensaries & Hospitals. Department of Indian Systems of Medicine & Homoeopathy. Ministry of Health & Family Welfare. Government of India. New Delhi. 2000.
2. A Handbook of Domestic Medicine & Common Ayurvedic Remedies, Central Council for Research in Ayurveda & Siddha. Janakpuri. New Delhi. 1978.
3. A Handbook of Common Remedies in Unani System of Medicine. Central Council for Research in Unani Medicine. Janakpuri. New Delhi. 1977.
4. Indian Systems of Medicine & Homoeopathy in India. Ministry of Health. Government of India. New Delhi. 1998.
5. Ayush-64 A New Anti-Malarial Herbal Compound. Central Council for Research in Ayurveda & Siddha. Janakpuri. New Delhi. 1987.
6. Chari, M.V. et. al. Double-blind Clinical Trial with Ayush-64 an Ayurvedic drug in P.Vivax Malaria, Jour. Res. Ay. Sid. Vol. VI. 1985.
7. Valecha, Neena. et. al. Comparative Efficacy of Ayush-64 Vs. Chloroquine in P. Vivax Malaria. Malaria Research Centre. Delhi. (under publication)
8. Ayush-56 An Ayurvedic Anti-Epileptic Drug. Central Council for Research in Ayurveda & Siddha, Janakpuri. New Delhi. 1997.
9. Clinical and Experimental Trial of Guggulu (Medo-Roga) Central Council for Research in Ayurveda & Siddha. Janakpuri. New Delhi. 1989.
10. Singh, Ramji et. al. Puskara-Guggulu, an Anti-anginal and Hypolipidemic Agent in Coronary Heart Diseases (CHD). *Jour. Res. Ay. & Siddha.* Vol. XII. 1991.
11. Effects of Varuna (Craetavia nurvala). In: *Enlarged Prostate-associated Urinary Disorders* Central Council for Research in Ayurveda & Siddha. Janakpuri. New Delhi. 1987.
12. Clinical and Experimental Studies on Rasayana Drugs and Panchakarma Therapy. Central Council for Research in Ayurveda & Siddha. Janakpuri. New Delhi. 1993.
13. Kuppurajan K. et.al. Anti-anxiety Effect of an Ayurvedic Compound Drug - A Crossover Trial. *Jour. Res. Ay. & Siddha.* Vol. XIII. 1992.
14. Management of Khanja and Pangu. Central Council for Research in Ayurveda & Siddha. Janakpuri. New Delhi. 1999.
15. Management of Bhagandara (Fistula in-Ano) with Ksharasootra. Central Council for Research in Ayurveda & Siddha. Janakpuri. New Delhi. 1989.
16. Shukla N.K., Narang R., Nair K., Radhakrishana S. and Satyavati G.V. Multicentric randomised controlled clinical trials of Ksharasootra (Ayurvedic medicated thread) in the management of fistula in Aro. *Ind. Jour. Med. Res.*(B) 94 June, 1991, p. 177–185.
17. Ayurvedic management of Unmada (Schizophrenia). Central Council for Research in Ayurveda & Siddha. Janakpuri. New Delhi. 1999.
18. Sehrawat, D. et.al. The Clinical Studies on Contraceptive Effect of Nimba Taila. *Jour. Res. Ay. & Siddha* Vol. XIX. 1999.
19. Clinical and Experimental Studies on the Efficacy of '777' Oil, a Siddha Preparation in the Treatment of Kalanjagapadai (Psoriasis). Central Council for Research in Ayurveda & Siddha. Janakpuri. New Delhi. 1987.
20. Clinical Studies on Daul Feel (Filariasis). Central Council for Research in Unani Medicine. Janakpuri. New Delhi. 1992.
21. Report on Clinical Study of Iltechab-E-Kabid Had (Infective Hepatitis). Central Council for Research in Unani Medicine. Janakpuri. New Delhi. 1992.
22. Clinical Studies on Bars (Vitiligo). Central Council for Research in Unani Medicine. Janakpuri. New Delhi. 1986.
23. Rastogi, D.P. et.al. Homoeopathy in HIV Infections: a trial report of double blind placebo control study. *British Homoeopathic Journal*. Vol. 88. 1999.

24. Rastogi, D.P. et.al. Evaluation of Homoeopathic Therapy in 129 asymptomatic HIV carriers. *British Homoeopathic Journal*. Vol. 82. 1993.
25. Report of the Task Force on Conservation & Sustainable Use of Medicinal Plants. Planning Commission. Government of India. New Delhi. 2000.
26. Handa, S.S. Indian Herbal Pharmacopoeia, Vol. I. Regional Research Laboratory. Jammu Tawi and Indian Drug Manufacturers Association. Mumbai. 1998.
27. Handa, S.S. Indian Herbal Pharmacopoeia. Vol. II. Regional Research Laboratory. Jammnu Tawi and Indian Drug Manufacturers Association. Mumbai. 1999.
28. Ayurvedic Formulary of India (Part–I). Ministry of Health. Government of India. New Delhi. 1978.
29. Ayurvedic Formulary of India (Part–II). Ministry of Health. Government of India. New Delhi. 1990.
30. Ayurvedic Pharmacopoeia of India (Part–I). Ministry of Health. Government of India. New Delhi. 1986.
31. Ayurvedic Pharmacopoeia of India (Part–II). Ministry of Health. Government of India. New Delhi. 2000.
32. National Formulary of Unani Medicine (Part-I). Ministry of Health. Government of India. New Delhi. 1981.
33. National Formulary of Unani Medicine (Part-II) Ministry of Health. Government of India. New Delhi. 1998.
34. Unani Pharmacopoeia of India (Part-I). Ministry of Health. Government of India. New Delhi. 1998.
35. Siddha Formulary of India (Part-I). Ministry of Health. Government of India. New Delhi. 1992.
36. Chaudhury, R.R., Herbal Medicine for Human Health. WHO. New Delhi. 1993.
37. General Guidelines on Methodologies on research and evaluation of Traditional Medicine. (In publication). WHO. Geneva.
38. An Appraisal of Tribal-Folk Medicines. Central Council for Research in Ayurveda & Siddha. Janakpuri. New Delhi. 1999.

A framework for cost-benefit analysis of traditional medicine and conventional medicine

Gerard Bodeker

Introduction

Much of the discussion on research into traditional medicine (TRM) has focused around issues of safety, efficacy, standar-dization and quality control. In the absence of serious investment in the sector over the past two decades that this discussion has been running, the issues and arguments have been reiterated time and again without any substantial impact on policy or programmes.

Recent policy interest in this field has added a new dimension to the discussion. This is an economic dimension and the emergence of economics into the TRM policy discussion signals a new seriousness on the part of policy-makers.

In the United States, Canada, Europe, Australia and New Zealand, health policy-makers and medical insurers have accepted that half or more of the public is using some form of complementary medicine (CM) on a regular basis and largely paying for this 'out-of-pocket'. In the US, an estimated $27 billion was spent in 1997.[1] In Australia in 1996, the estimate was $AU621 million – more than the amount spent on pharmaceutical drugs.[2] And in the UK, it has been estimated that £1.6 billion is spent 'out-of-pocket' on CM annually – in addition to the £40 billion spent by the National Health Service.[3]

As a result, the focus of policy has shifted beyond the necessary requirements that products and services be at least safe and, ideally, effective. A new consideration in assessing CM is whether CM services are economically competitive with conventional health services. As governments and insurers increasingly focus on service development in traditional and complementary medicine, the challenge to address basic economic questions is becoming one of central importance.

Potential Areas of Cost Saving in Traditional Medicine

White and Ernst (2000) have outlined five broad areas in which there may be potential for cost savings from the use of CM[3].

- Cost of drugs;
- Visits to a doctor;
- Secondary referral;
- Adverse events arising from conventional therapies;
- Prevention of future disease.

At present, the public in both developing and industrialized societies appear to be using conventional medicine as well as TRM or CM in an integrated way, wherever this is possible.[4,5] The question of cost savings presumes a different question: that of substitution. In other words, while the public is *combining* health services in a pluralistic manner, integrating conventional and CM/TRM into their overall care programme, the choice that is posed within an economic framework is: 'Can traditional therapies *substitute* for conventional treatments?' If not, the combination of traditional and modern medicine can be seen, from an economic perspective, as simply adding to the cost of care.

Underlying the dichotomy between the tendency of consumers to combine health care approaches from conventional and TRM, and the practice of medical insurers and health care providers to seek the single least expensive care option, rests the deeper policy issue of whose perspective and priorities should determine the nature of care that is offered – the consumer, the purchaser, or society in general. In applying or interpreting economic analyses of traditional health care services, it is first necessary to specify the perspective from which the analysis is being conducted. Thus, issues of economics can be weighed against questions of ethics, consumer choice, quality of life and the wider societal impact of a particular intervention. With this perspective as our starting point, it will be useful to consider the various methodologies used in assessing the economic merits of health care approaches.

Methods of economic analysis

A range of methodologies exist for examining the economic issues associated with the provision of health care.[6] These can be as readily applied to the utilization of traditional and complementary health services as to mainstream medical services. The starting point for the choice of methodology is the research question being posed. This may be positioned from the public sector perspective: namely, determining those health care interventions that maximize health gains in a society and to determine allocative efficiency, viz., the basis for deciding how best to choose on allocating resources to one form of treatment over another. Other research questions may reflect the perspective of an insurer, where the issues are different.

Cost descriptions

This would entail collecting and collating all costs involved in providing a particular traditional health care service. This approach provides baseline data for further studies, but does permit other providers to know what the costs of a particular treatment programme may be. This type of research does not provide data on therapeutic outcomes.

Cost-comparison research

This entails a comparison of the costs of two or more treatments which are designed to achieve a common outcome. White and Ernst (2000) have noted that a limitation of this approach is that treatments, including drugs, rarely have directly comparable outcomes.[3] Thus the cost-comparison is at risk of being a comparison of the proverbial 'apples vs. oranges' type.

Cost-effectiveness analysis

These studies are designed to measure the costs of producing a change in a particular health outcome, e.g., life years, blood pressure. In their analysis of different economic methodologies for assessing health care strategies, White and Ernst

point out that this approach overlooks other benefits that a therapy may generate as well as such negative effects as unpleasantness of the treatment or side-effects.

Cost-utility analysis

This is primarily oriented to assessing patient satisfaction with a treatment. Instruments used may be a quality-of-life instrument, such as the WHO Quality of Life Assessment Scale. While comparing different treatments and their outcomes in terms of patient satisfaction, this methodology does not address the question of whether the treatment is worth the financial outlay on it.

Cost-benefit analysis

At the centre of this approach is a methodology designed to assess patients' willingness to pay (WTP) for the benefits that the treatment provides. This is then compared with the actual cost of the treatment to determine if it provides value for money. A challenge of this approach is to define outcomes in monetary terms. This challenge has meant that very few sound studies have been done to determine the cost-benefit issues associated with traditional therapeutic modalities. A further limitation is that WTP does not necessarily indicate ability to pay (ATP).

Households may persist in paying for care, but to mobilize resources they may sacrifice other basic needs such as food and education, with serious consequences for the household and individuals within it. The opportunity costs of payment make the payment "unaffordable" because other basic needs are sacrificed.[7]

Backdrop to the Economic Analysis of Traditional Medicine

There are at least two major forces at work that drive the growing demand for some sort of framework for the analysis of TRM in light of conventional medical options. The first of these is a powerful social trend, namely, the growing public demand for TRM and CM worldwide. The second is the move by governments towards integrating traditional health services into national health care and the need for TRM programmes and departments to justify the value of their sector in both therapeutic and economic terms.

In the following sections, we will review the issues involved in each of these broad forces or emerging societal trends. Then we will move to a consideration of the cost issues entailed in traditional health care services. Finally, there will be a consideration of the policy implications of these trends and the beginnings of a framework for the economic analysis and comparison of traditional and conventional health care services.

Utilization

The widespread demand for TRM services has been recognized as an enduring phenomenon and early calls for TRM to be replaced by modern medical services have now given way to recognition that some degree of formalization of these health services might offer the public increased standards of quality and safety.

In both industrialized and developing societies, use of CM and TRM is on the rise.

In 1993 research at Harvard University found that 30 per cent of Americans were using some form of CM on a regular basis. In 1998, the same research team reported that this number had increased to 40 per cent of the population.[1] Research published in *The Lancet* in 1996 reported that 40 per cent of Australians were using some form of CM.[2] In April 1999,

legislation to establish an Australian Office of Complementary Medicines was announced in *Australian Hansard* as being warranted since 60 per cent of Australians regularly use some form of CM. Demand is spiralling at rates that outstrip the capacity of national health policy to keep abreast.

In the US, higher educational level, higher income, and poor health have been found to be predictors of CM use.[4] Americans and Australians typically pay out of pocket for CM services. Americans spend more out of pocket on CM than on all US hospitalizations. Australians spend more on CM than on all prescription drugs. Women have been found to be the majority of CM users in the US, the UK and Australia.

Use of traditional medicine in developing countries

Traditional health care (THC) remains the source of everyday health care for the majority of the population of most non-industrialized countries. The World Health Organization has consistently estimated that between 60–80 per cent of the population of these countries rely on THC for their basic health care needs – sometimes on its own and sometimes in conjunction with modern medical care. Studies show that demand is on the increase in many countries.

> "In many countries, 80 per cent or more of the population living in rural areas are cared for by traditional practitioners and birth attendants."
>
> (Bannerman, R.H.: Burton, J. & Ch'en, W-C. *In* Bannerman, R.H. *Traditional Medicine and Health Care Coverage*. WHO. Geneva. 1993).

The much-quoted figure that of 80 per cent of the population of many countries utilize TRM for their everyday health needs is overdue to be questioned.

A survey of the literature reveals a diverse range of findings on utilization of TRM services. The much-cited figure of 80 per cent becomes far less clear and it is evident that the needs of special populations – women, the elderly, children, rural communities, immigrant groups, etc. – must all be taken into account when assessing who uses TRM care services, why and in what relationship with the use of modern medical services. The value of considering these findings includes the following:

- For planning purposes, research into health service utilization is a necessary prerequisite for establishing the need for, the nature of and the size of THC services;
- Such studies illustrate the diversity of models used for studying patterns of utilization of THC services – including ethnographic research, survey research and, in the US, telephone surveys;
- The data highlight the great diversity in patterns of use according to region, age, education, gender, income, availability of medical insurance, perception of TRM, and distance to modern medical facilities.

In many countries, life begins with the support of TRM. An estimated 60–70 per cent of births in developing countries still take place with the sole help of traditional birth attendants.[8]

Africa

There have been many general guesstimates of the extent of use in Africa. Bannerman (1993) estimated that TRM

caters for the health needs of 80 per cent of the African population.[9] This figure echoes an earlier estimate of 80 per cent made by Koumare (1983).[10]

However, some estimates of use are strikingly low. Shiferaw (1993), for example, reports on an interview-survey of perceived morbidity in a rural community in South-western Ethiopia, where 55.4 per cent of those reporting illness took no action at all; 30.3 per cent applied to health institutions, 9.2 per cent reported self-care, and only 5.2 per cent visited a traditional healer.[(11)] By contrast, research done at Mogopane Hospital in North-eastern Transvaal, South Africa, showed that nine out of 10 patients who come to the out-patients department first consult traditional healers.[12]

Clearly, studies of community groups and of hospital populations address the needs and choices of different populations with different health profiles. In planning services such differences need to be accounted for.

Age and gender are factors in the utilization of THC services. A study of visitors to traditional healers in central Sudan indicated that children under 10 years did not take part in visits. Most visitors were between 21 and 40 years (61%) and were women (62%). They were less educated compared to the general population in the area. The main reasons given for attending traditional healers were treatment (60%) and blessing (26%).[13]

In Mali, men are more likely to prefer traditional treatments for malaria than women,[14] and more boys than girls believed in herbal medicine in a survey in the Sudan.[15] It has been suggested that women are less likely to be treated at modern facilities, and are more likely to resort to traditional medicines.[16]

People with a serious health condition may seek THC before accepting modern medical services. In Malawi, 37 per cent of TB patients reported attending a traditional healer prior to attending the health service. By the time a final diagnosis of TB was made, most patients had visited several different care providers: private practitioner (69 visits), village clinic (64)

Table 1. Adult conditions taken to indigenous healers from Shai-Mahoko (1996)

Condition	No. of respondents [healers]	Percentage
Infertility	32	91
Septic sores	31	89
Impotence	30	86
STDs	28	80
Deliveries	28	80
Asthma	23	66
Mental illness	21	60
High blood pressure	20	57
Palpitations	15	43
TB	14	40
Alcoholism	12	34
Diabetes	9	26
Cancer	9	26

and traditional healer (40), and 32 patients reported taking some form of traditional remedy at home.[17]

Travel time can be a factor in the choice of traditional over modern medical services.

Among comments made by traditional midwives in South Africa, in a study by Troskie (1997),[18] was that "the nearest hospital is 20 kilometres far". Similar responses were recorded from clients. In Kwale district, Kenya, which has one health service facility for 12,000 people, it has been estimated that 24 per cent of the population has a health facility within two kilometres distance, 58 per cent within five kilometres and 83 per cent within 10 kilometres.[(18)] By contrast, THC services are readily available. Every village has a number of traditional healers and birth attendants, each with their own specializations.[19]

Similarly, in India, rural women in Gujarat were more likely to use services which were closer to home, other things being equal. The "travel" variable (including time and travel costs) is a more important factor determining the use of modern and traditional services among women in the study area than the actual direct costs of the service.[20]

In the case of malaria, selection of first-line treatment varies from area to area. Sometimes, herbal remedies are given at home as the first-line treatment,[21,22] especially in mild cases of malaria.[23,24] Sometimes, herbs are the second line after treatment with chemotherapy has failed.[25,26] Munguti (1998) found that in a rural area of Kenya, seven per cent used herbs as the first choice of treatment, 17 per cent as the second choice, and 14 per cent as the third choice.[27]

There can be contrasting patterns of use across countries and regions. Whereas young children in Sudan were found not to attend traditional healers, in Kenya 40 per cent of sick children were taken to the *mganga* [traditional healer] and 55 per cent to the clinic; 26 per cent of the mothers said that both sources of treatment were consulted.[19]

There are usually differences between urban and rural populations in their use of TRM and modern medicine. While 95 per cent of urban women who attended modern medical clinics in South Africa strongly advocated mixing traditional and western antenatal care, only 63 per cent of rural clinic attenders found this practice acceptable. All groups favoured Western over traditional care in cases of serious pregnancy complications.[28]

Asia

In India, it has been found that the influence of family structure is significant. The presence of the mother-in-law is associated with a greater use of traditional healers.[20]

Inadequacies in and scarcity of modern medical services can contribute to the use of traditional health services. Less than half (44%) of Chinese immigrants studied in the USA had used Western health services in the US within the previous 12 months; 20 per cent reported that they had never used them. Chinese physicians stated that many Chinese patients are not satisfied with American doctors because of the inflexibility of appointments, short visit, long waiting, distrust and miscommunication.[29]

In a study of health service utilization in four villages in India, the most common complaint by a majority of those surveyed was that "medicines are never available" at the primary health centre, followed by discourteous behaviour of the staff and health personnel, "doctors never available", "doctors demand money for

better treatment", and so on. Almost a quarter of the women initially tried homoeopathic treatment, followed by nine per cent who administered Western medicine at home, and two per cent opted for traditional home remedies for cure and treatment, before visiting and consulting a trained medical practitioner. Medical pluralism was found to be flourishing as people switched from one medical system to another depending on affordability and time.[30]

In Sri Lanka, two patterns of health care seeking which cut across modern and traditional medical systems were identified. The first involved patients who searched for a medicine which could cure or served as a commodified fix for health. The second pattern involved the search for a practitioner who had the power of the hand to cure one's illness through an affinity to their person.[31]

Medical pluralism is common worldwide as consumers practise integrated health care, irrespective of whether or not it is present at the formal level. In Taiwan, 60 per cent of the public have been found to be users of multiple healing systems, including modern Western medicine, Chinese medicine, and religious healing.[5]

Medical insurance coverage for TRM influences the utilization of traditional health services. Most Taiwanese (86%) support the coverage of Chinese medicine by the National Health Insurance and 79 per cent indicated that they would use Chinese medicine if that becomes the case.[5] In the USA, whereas older Chinese/Korean immigrants are more likely than younger ones to use TRM, the most significant difference in the use of traditional practitioners appeared between insured and uninsured individuals. Only 24 per cent of the uninsured used traditional practitioners, compared with 59 per cent of persons with Medicaid only and 71 per cent of those with other types of insurance including Medicare and Medigap coverage. It is likely that the insured are those who also had more disposable income available to pay for traditional forms of health care.

Packaging herbal medicines in the Institute of Traditional Medicine, Sri Lanka.

Indigenous communities

Indigenous communities with a history of colonial conquest have patterns of use of TRM which may vary according to the degree of official support, the spiritual needs met by healers, and the strength and intactness of their healing traditions.

In Australia, *The 1987 Review of Rehabilitation Services in the Northern Territory* found that traditional Aboriginal medicine is widely practised in the Northern Territory.[32] In most regions of the Northern Territory, more than 22 per cent of indigenous people had used bush medicine in the last six months when surveyed.[32] The decreased use of bush medicine seems to be because Western medicine is easier to access, not because of a lack of faith in its efficacy.[32] Examples of bush medicine include herbal preparations, diet, rest, massage, restricted diet and external remedies such as ochre, smoke, steam and heat.[32]

Of native American patients attending an urban Indian Health Service clinic in Wisconsin, the mean age of patients was 40 years and the sex distribution was 68.7 per cent women and 31.3 per cent men; 38 per cent of patients see a healer, and of those who do not, 86 per cent would consider seeing one in the future. Most patients report seeing a healer for spiritual reasons. The most frequently visited healers were herbalists, spiritual healers and medicine men. Sweat lodge ceremonies, spiritual healing, and herbal remedies were the most common treatments. More than a third of the patients seeing healers received different advice from their physicians and healers. The patients rate their healer's advice higher than their physician's advice 61.4 per cent of the time. Only 14.8 per cent of the patients seeing healers tell their physician about their use.[33]

Policy Points

(1) There is much variation in patterns of use of THC services across communities, regions, age and gender groupings, income levels, and according to access to other health care services.

(2) Utilization studies are a sound starting point for traditional health service development. Good studies can identify categories of need, target groups, geographical priorities, and potential areas of partnership between traditional and modern medicine.

Formalization of Traditional Health Services

The term **'integration'** has come to be widely used to express the formalization and official incorporation of TRM into national health services. However, the term has a more specific meaning.

Historically, the relationship between modern and traditional medicine has taken four broad forms

- A *Monopolistic* situation, where modern medical doctors have had the sole right to practise medicine;
- A *Tolerant* situation, or one of *Co-Existence* where traditional medical practitioners, while not formally recognized, are permitted to practise in an unofficial capacity;
- A *Parallel* or dual health care model, as in India, where both modern and traditional medicine are separate components of the national health systems;
- An *Integrated* model where modern and traditional medicine are integrated at the level of medical education and practice (e.g. China, Vietnam).

In this discussion, the term 'formalization' will be used to characterize both the last two forms, given above.

Asia has seen the most progress in incorporating its traditional health systems into national health policy. Most of this development began 30–40 years ago and has accelerated in the past 15 or more years. In some Asian countries, the development has been a matter of official policy, e.g., China, while, in others, change has come about as a result of a process of politicization of the TRM agenda, e.g., India and South Korea.

In China, the process of integrating traditional Chinese medicine (TCM) into the national health care system began in the late 1950s and was, in significant part, in response to national planning requirements to provide comprehensive health care services. Prior to this, TCM had been viewed as part of an imperial legacy to be replaced by a secular health care system.

The process of integration was guided by health officials trained in modern

medicine, and harmonization with modern medicine was the goal of integration from the outset. This was accomplished by a science-based approach to TCM education and an emphasis on research into TCM, both supported by a substantial organizational infrastructure. Integration and development of TCM was managed via a process of centralized national planning.

More than 40 years on, the State Administration of Traditional Chinese Medicine in China now comprises eight functional departments. The departments are:

- Office. Responsible for overall coordination;
- Department of Personnel, Labour, Laws and Regulation. Devises organizational structures; formulates technical standards for TCM professionals; administers qualifications; studies and formulates the guiding principles, policies and development strategy of TCM; drafts laws and statutes; organizes research; coordinates publications and media, etc.;
- Planning and Financial Department. Formulation of development programme; administers the State's special funds and loans for TCM; import and export activities; regulates overall balance;
- Medical Administration Department. Directs implementation of development plan for TCM in urban and rural areas. In charge of macroscopic administration and technical development in all kinds of TCM institutions, including state, collective, private and jointly owned hospitals of TCM; hospitals combining TCM and Western medicine, etc.;
- Production and Circulation Department. In addition to directing/supervising production, trade, packaging, storage, etc., it also administers protection of wild medicinal resources (including medicinal resources in imminent danger);
- Department of Quality of Traditional Chinese Drugs. Formulates quality standards and technical standards for TCM products; supervises and inspects production;
- Scientific, Technical and Educational Department. Directs construction of scientific research institutes and laboratories; organizes research, development, appraisal and academic exchanges, etc.; directs protection of intellectual property rights (IPR); administers proficiency examinations in TCM, etc.;
- Foreign Affairs Department. Administers and directs state technical and economic cooperation and academic exchange of TCM with foreign countries.[34]

In 1995, the total production of herbal medicines in China reached 17.57 billion Chinese yuan in value, an increase of 212.6 per cent since 1990. In that year, sales of herbal medicines accounted for 33.1 per cent of the drug market in China (Source: WHO SE Asia).

In 1980, China was the first country to negotiate a component for TRM within a World Bank health sector loan. A more recent World Bank-financed expansion of hospital beds included provision that 20 per cent of these would be in hospitals of TRM.[35]

In addition to formal integration of modern and traditional medicine in China, the public are pluralistic in their health care utilization, rendering integration a reality at the grassroots level. A survey carried out in two village health clinics in Zheijang Province, China, showed that children with

upper respiratory tract infections were being prescribed an average of four separate drugs, always a combination of Western and Chinese.[36] A challenge of integrated health care is the need to conduct research to determine which illnesses are best treated through one approach rather than the other. The Zheijang study reported that, in practice, simultaneous use of both types of treatment is so commonplace that their individual contributions are hard to assess.

In South Korea, the parallel operation of two independent medical systems along the lines of Western biomedicine and oriental medicine (OM) is one of the prominent aspects of the health care service. This was established by law in 1952.

In 1996, there were 9299 licensed OM practitioners compared to 59,399 Western practitioners. OM doctors operate in the health care services in the same way as other medical care providers, with some notable differences. The private sector is dominant in OM, with almost all OM hospitals and primary clinics being privately owned and operated. The great majority of OM doctors work in self-employed private settings at the primary care level. In 1995, the concentration in urban areas of OM clinics and hospitals (95.1%) was higher than that of Western medical clinics (90.6%) and hospitals (86.4%). Political conflict between the OM and modern medical sectors has been high during the 1990s over issues of fees, ability to sell and prescribe traditional herbal medicines and licensing of traditional practitioners.

The level of coverage of OM in the National Medical Insurance is low and, as noted in the section on *Finance*, there is reluctance on the part of most OM practitioners to provide insurance cover for OM.[37]

A policy guideline on OM was adopted for the *Seventh Project of the 5-year Economic and Social Development Plan in Korea (1992–1996)*. The guideline set a goal for full integration of Western and Oriental medicine by the year 2001. A number of short- to medium-term measures were recommended to improve the quality of OM care: promotion of clinical cooperation, training of OM consultants and lifting the customary ban on OM doctors' employment in the public hospital sector. An OM care unit was set up for the first time in the National Medical Center in 1991.[37]

In India, the Parallel Model of formalization of indigenous medicine was adopted when the Central Council of Medicine Act was promulgated in 1970. India's formalization of its indigenous systems of medicine came after a century of committees had unsuccessfully attempted to create this outcome. The election to Parliament of the President of the All-India Ayurveda Congress, Pandit Shiv Sharma, and the election of a tradition-oriented Prime Minister, Morarji Desai, combined to create the conditions for a political solution when policy reform had been unsuccessful. The Act set up a Council to oversee the development of Indian Systems of Medicine and to ensure that standards of training and practice were developed according to both traditional requirements and Government standards of good clinical practice. Training would be in separate colleges, of which there are now well over one hundred.

Current priorities of the Department of ISM include education, standardization of drugs, enhancement of availability of raw materials, research and development, information, education and communication and larger involvement of ISM in the national health care delivery system including Reproductive and Child Health (RCH). Due to the high cost and unavailability of modern medical services in rural areas of India, the Indian Government has undertaken to add 10 medicines from the Ayurvedic and Unani systems into its national family welfare programme. A pilot project, designed to last till 2003, is currently being implemented in seven Indian states for Ayurveda while Unani medicines are being introduced in four cities. The RCH project is co-funded by the World Bank and the Indian Government. The medicines, which are all traditional herbal formulations, will be for anaemia, oedema during pregnancy, post-partum problems such as pain, uterine and abdominal complications, lactation-related problems, nutritional deficiencies and childhood diarrhoea. Also included are massage oils for babies and mothers that are already used routinely in Indian households. Concurrent evaluation and monitoring will be done to oversee acceptance levels and to ensure quality in drugs administration and storage and to monitor the sustainability of the programme.

Under Taiwan's current health care system, Chinese medicine is reported to have a subordinate role to Western medicine,[5] more characteristic of the *Tolerant* or *Coexistence* model described at the beginning of this section. This is apparent in three ways:

- Limited participation of Chinese medicine practitioners in any public health policy-making and programmes;
- Small proportion of Government medical resources allocated to the training, research and practice of Chinese medicine;
- Loose licensure system for Chinese physicians.

Two parallel licensure systems for Chinese physicians exist in Taiwan:

- The Chinese Medicine Physician License Exam (CMPLE)
- The Chinese Medicine Physician Special License Qualifying Exam (CMPSLQE).]

The CMPLE is offered only to persons with medical degrees in Chinese medicine. One medical college in Taiwan offers formal training and a medical degree in Chinese medicine. The CMPSLQE has no educational or training prerequisites and any citizen of Taiwan may apply for the first

level of the Qualifying Examination. After passing, they can proceed to the second level of Special License Examination. On passing the second level of examination, graduates can obtain the Chinese Medicine Physician (CMP) license. The two licenses, CMPLE and CMPSLQE, carry the same privileges and there is no way for patients to distinguish between the two.[5]

Debate in Taiwan on improving Chinese medicine focused on whether the Government should begin with research or build a medical school. Characteristic of many governments, research was given priority and the Government established the National Chinese Medicine and Drugs Research Centre. Establishing a Chinese medical school was left to the private sector. The resultant China Medical College – established in 1958 – is the only such college in Taiwan and has been considered to have been under-funded and inadequately equipped.

Recommendations made by The Commission on Health Research for Development,[39] for strengthening essential national research, such as the support and cooperation from industrialized nations, should also extend to the area of research in TRM and its integration. It has been argued that the global community should promote cooperation and information exchange centred on integration strategies.[5]

In Africa and the Americas, traditional and indigenous medicine is informal, in some cases operating under a *Monopolistic* situation controlled by orthodox Western medicine. In others, a more *Tolerant* situation exists, but in the absence of official recognition or health sector investment in development. The same applies to indigenous medical traditions in Australia.

> "Healers have for long been treated like trees on savanna farms - not formally cultivated, yet valued and used, particularly by women and children".
>
> Last & Chavanduka (1986) *in The Professionalisation of African Medicine.*

Traditional Medicine and the Formal Health sector in Africa

There has been a long-reported willingness on the part of traditional healers in Africa to collaborate with the formal sector and to establish joint training. Burnett, et al., (1999) note that 37 of the 39 traditional healers (94%) and 14 of the 27 formal health workers (52%) interviewed in a Zambian study were keen to collaborate in training and patient care relating to HIV/AIDS.[40]

However, this is not generally a reciprocal view. Although one per cent of nurses in South Africa are reported to be traditional healers, rural nurses in Swaziland perceived themselves as being teachers to healers, but not learning from healers. They saw themselves as a source of referral for healers, but not the reverse.[41]

One view is that it may be more appropriate to work towards a system of cooperation between two independent systems, with each recognizing and respecting the character of the other.[(42)] This has been the policy in Botswana, where parallel development has been encouraged, since it is felt that one or other of the two systems might suffer in the process of integration.[40]

WHO policies of the late 1970s and 1980s have promoted the establishment of associations of traditional healers in Africa. During the 1990s, NGOs of traditional health practitioners – associations, small groups, clinics, etc. – have grown exponentially in Africa, playing a partnership role in HIV/AIDS education and care,[43] in

delivering child survival messages and in managing endemic disease in partnership with modern health care workers.

There is now an emerging momentum to begin a process of formalization of traditional medicine in Africa.

In Uganda, new legislation is being developed to ensure a role for TRM in national health care, in part as a result of the successful engagement of traditional healers in combating the AIDS epidemic in the country.

South Africa's parliament, on 5 August, 1998, proposed that a statutory council be set up to regulate the 350,000 traditional healers. A report by a parliamentary committee on social services proposed that the council should present its recommendations within three years [by 2001] for the drafting of final legislation.

A Parliamentary Committee on Social Services in South Africa proposed that the profession of traditional healing should be divided into four categories: the *inyanga* (traditional doctors or herbalists); the *sangoma* (diviner); birth attendants or midwives; and traditional surgeons who mainly do circumcision. Spiritual healers were not included because their training and accreditation was considered "unclear" and "ill-defined".[44]

In South Africa, many traditional healers are members of well-organized national organizations that are seeking formal recognition from the Government. In one instance of WHO-sponsored collaboration, it has been recognized that the rapid increase in TB caseload, especially in African countries heavily affected by the HIV epidemic, requires a search for effective ways to treat patients outside hospital. As a component of WHO's Community Care for Tuberculosis in Africa Project, Wilkinson, et al. (1999), studied the potential role for collaboration between the health service and traditional healers, especially as TB treatment supervisors, and examined what precedent and potential exists for traditional healers to act in this role.[17]

Before commencing collaborative effort in health care between modern and traditional sectors, a careful assessment of potential benefits and obstacles should be made. The medical services utilization patterns of the communities need to be ascertained and the specific role of traditional health practitioners considered. In such efforts the ideas of healers themselves about possible collaboration are crucial.[19]

Ghana has recently passed the Traditional Medicine Practice Act 2000, Act 595, to establish a Council to regulate and control the practice of TRM. The primary draft of this act originated from the traditional healers themselves. The Act defines TRM as "practice based on beliefs and ideas recognized by the community to provide health care by using herbs and other naturally occurring substances", and herbal medicine as "any finished labelled medicinal products that contain as active ingredients aerial or underground parts of plants or other plant materials or the combination of them whether in crude state or plant preparation." It is arranged into four sections, namely the establishment and functions of the Traditional Medicine Practice Council; registration of practitioners; licensing of practices; and miscellaneous provisions.

Ghana's Ministry of Health has incorporated a Traditional Medicine Unit since 1991, and in 1999 this was upgraded to the status of a Directorate. The Ministry, in collaboration with the Ghana Federation of Traditional Medicine Practitioners Associations (GHAFTRAM) and other stakeholders, has now developed a five-year strategic plan for TRM. This plan

outlines activities to be carried out from 2000–2004, and will be reviewed every two years. It proposes, among other aspects, the need to develop a comprehensive training in TRM from basic and secondary to tertiary levels.

A 'Ghana Herbal Pharmacopoeia', containing scientific information on 50 medicinal plants, has been published. A second volume is currently in preparation. Efforts are being made to integrate TRM into the official public health system and it is expected that by the year 2004, certified and efficacious herbal medicines will be prescribed and dispensed in hospitals and pharmacies. The Ghanaian Government has set aside the third week of March every year as a Traditional Medicine Week, starting from the year 2000.

In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) has taken steps to regulate and control TRM products with a view to ensuring their safety, efficacy and quality. In consultation with traditional healers and researchers, NAFDAC has developed guidelines on regulating herbal medicines. Recently, the Government of Nigeria approved a national policy on a Traditional Medicine Code of Ethics. Draft legislation has been prepared to establish national and state Traditional Medicine Boards to enhance the regulation of TRM practice and promote cooperation and research in TRM.[45]

Clearly, planning for the formalization of traditional health services has many dimensions that need to be addressed, depending on the state of current sectoral development, level of political will, budget resources available, training infrastructure, the model of formalization suitable to and preferred by the country and by the traditional health care community. It has been argued that, underlying the general proposition for a mix of traditional and modern medicine is an agenda of incorporating the former into the political-economic arena and cultural hegemony of biomedicine.[46] Clearly, if TRM is to be given a formal place in national health care, this process needs to be done not only in close consultation with the traditional health sector, but taking direction from them as to appropriate models of partnership, formalization and training.

One commentator has outlined six recommendations for effective integration that cover many of the major salient issues:

- Promotion of communication and mutual understanding among different medical systems that exist in a society;
- Evaluation of TRM in its totality;
- Integration at the theoretical level and the practical level;
- Equitable distribution of resources between traditional and modern Western medicine;
- An integrated training and educational programme for both traditional and modern Western medicine;
- A national drug policy that includes traditional drugs.[5]

Recognizing the need for a policy to reflect public health care demands and patterns of use, the 12th Commonwealth Health Ministers' Meeting in November 1998 established a Working Group on Traditional and Complementary Health Systems[47, 48] (Nelson, 1998; Bodeker, 1999). The Working Group was commissioned to develop an action plan to promote and integrate traditional systems of health and CM within national health systems, giving consideration to:

- Policy Framework, including:
  - provision of services
  - conservation of medicinal plants and related intellectual property rights;

- Training of traditional and conventional practitioners;
- Development of standards of practice;
- Mechanisms for enhanced sharing of experiences in the Commonwealth;
- Regulation and safety, involving practitioners of TRM in the process;
- Research – evidence-based research to promote mutual understanding and confidence, and establish efficacy;
- Management of the integration of traditional and conventional medicine.

Health Ministers representing most of the 54 countries of the Commonwealth noted that TRM should be seen as 'complementary' rather than 'alternative', indicating the need for collaboration and partnerships with conventional medicine.

Cost Considerations

In many Western countries, including the US, debates on health-care reform are now dominated more by the language of efficiency and cost than the spirit of caring and equity.[49]

As governments begin to consider developing formal health services in TRM, the question inevitably arises as to whether these will result in cost-savings and whether consumers will be willing to pay for formal services in TRM. These issues are similar to those underlying the justification of modern medical services, and the debate on traditional health services is also shifting from a language of equity and quality of care to one of efficiency and cost.

In the industrialized countries, where almost half of the population regularly uses CM, insurance coverage for this is still relatively new.[2] Major American medical insurers now routinely cover CM services– a trend which is emerging in Britain as well.

In the developing world, the cost of modern medical services may be one important reason for people turning to the services of TRM. In a rapid community survey in Boga, Zaire, 56 per cent of households reported that the price of treatment was the greatest obstacle to their receiving medical care. Fees and other factors will inevitably deter some people from using the health services, and they may use traditional healers or drug sellers instead, or alternatively receive no treatment at all.[50]

This shift can be exacerbated by macro-economic factors such as devaluation of currencies. Structural adjustments, which have been accompanied by the introduction of user fees for Government health services, can result in a substantial shift from modern to traditional medicine, even in urban populations. In an African Development Bank study of 800 households in Abidjan, Cote D'Ivoire, devaluation of the Ivorian franc was associated with a concurrent shift from modern to traditional medicine by 13.5 per cent of households. This was even higher (16.7%) in women-headed households, where poverty is greater.[51] Personal communications with medical personnel in Tanzania suggest that the introduction of user fees for previously-free Government outpatient clinics resulted in a substantial shift away from modern medical services towards TRM. Simultaneously, traditional healers in the Kilimanjaro region reported that they had experienced a substantial increase in demand for their services at the time that user fees were introduced for Government health services.[52]

The effect of user fees on health care utilization and health outcomes has been a subject of considerable debate in the 1990s. Much of this debate has centred on the ability and willingness of households to make larger out-of-pocket payments for health care.

Many studies in developing countries indicate that health care utilization rates among both poor and non-poor individuals would not be significantly affected by small increases in user fees.[53] In addition, many studies suggest that health care utilization would actually increase if increased user fees are accompanied by improvements in service.[53]

However, other research indicates that the price elasticity among the poor is substantial, which suggests that user fee schemes would have a regressive distributional impact.[53]

In many developing countries people are expected to contribute to the cost of health care from their own pockets. As a result, people's ability to pay (ATP) for health care, or the affordability of health care, has become a critical policy issue in developing countries. It is particularly urgent where households face combined user fee burdens from various essential service sectors such as health, education and water. Research and policy debates have focused on willingness to pay (WTP) for essential services, and have tended to assume that WTP is synonymous with ATP. However, this assumption has been questioned and it has been suggested that WTP may not reflect ATP.[7] As noted in the introductory section of this chapter, households may persist in paying for care, but to do so may sacrifice other basic needs such as food and education. This in turn can have serious consequences for the household and individuals within it. In terms of a social benefit analysis, the opportunity costs of payment make the payment "unaffordable" because other basic needs are sacrificed.

In this regard, research into the economics of health care utilization should shift the focus of attention from the health facility – including Government and private TRM clinics – to the household. It is in households that decisions are made on how to allocate limited resources to health, education and other essential commodities.

In Vietnam there is a rural expression that TRM can be paid for with one chicken, modern medicine can cost one cow and hospitalization can cost a family its herd of cows. Translating this into immediate and downstream income benefits, such sacrifices by poor families may be made at the expense of their future livelihood.

Fees charged by traditional healers vary greatly and can also be high. In South Africa, for example, where payment is not exclusively monetary, the healer may receive a cow on curing the patient. The treatment for a condition such as *umtsebulo* – presumed soul loss – can cost US$ 125.[54]

An approach to ATP, founded on basic needs and the opportunity costs of payment strategies (including non-utilization), has been proposed. Common household responses to payment difficulties have been found to range from borrowing to more serious "distress sales" of productive assets (e.g., land), delays to treatment and, ultimately, abandonment of treatment. Although these strategies may have a devastating impact on livelihoods and health, few studies have investigated them in any detail. In-depth longitudinal household studies would develop an understanding of ATP and could inform policy initiatives which might contribute to the development of affordable models of THC services.

Potential Conflicts Arising from Allocation of Resources to Traditional Health Care Services

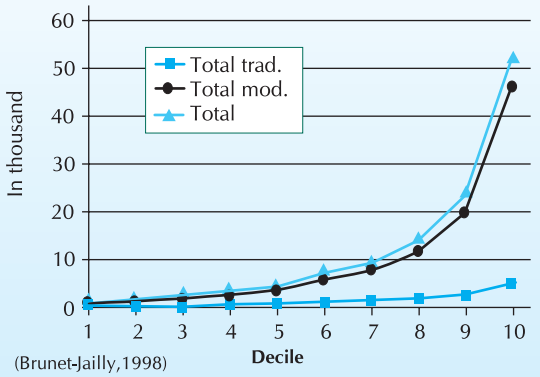
Resentment can arise from under-funded sections of the modern medical sector when resources are allocated to the development of traditional medicine. A

traditional birth attendant (TBA) training in Nigeria attracted resentment from under-funded rural midwives as resources were given to birth attendants when maternity centres lacked equipment.[56]

Another potential conflict is that if THC services are made available under medical insurance schemes, those who can afford to pay for insurance will be the greatest beneficiaries of TRM. The poor may be relegated to purchasing unregulated drugs from unlicensed street vendors, as already happens in so many poor countries. This would stand in contrast to the customary role of TRM serving as the first and last resort for available health care for the poor.

A further risk is that primary health care services in TRM may remain marginal and under-funded due to the tendency of national health budgets favouring tertiary care. In Cote D'Ivoire, the rich receive more assistance than the poor, because the poorest patients rarely use anything but primary care, whereas the Government provides generous subsidies for the tertiary level, which in practice serves the richest patients.[57] Average per capita spending on consultations differs by a ratio of 1:300 between the first and tenth deciles. The spread is extreme (1:3000) in the case of expenditures on hospitalization. It has been argued that there is injustice in the high allocation of resources to tertiary care, when household expenditures on TRM and modern medicine indicate the demand and need at the primary care level (see Figure 3).

Fig. 3: Average Household Expenditure (in CFAF) on Health, per person and decile: 1993



(Brunet-Jailly,1998)

Differential allocation of resources to areas of high priority might be one solution

> An older woman I knew in Papua New Guinea did not perform any visible economic activity, being old and weak. On the surface she consumed rather than produced resources; thus there was little incentive to spend still more on maintaining her health.
> But what of the value of her knowledge and wisdom in the resolution of family conflicts?
> What of her value in the education of the children through myths, storytelling and personal history?
> What of her knowledge of herbal and household remedies for common illnesses?
> How to assess in monetary terms the fact that she can call upon the support of other community members in times of hardship, just as she has assisted them in times past?
> These are vital contributions to the continued health of her community, but we have a long way to go before we can cost them.
> Too often the economic spotlight is turned upon the more straightforward task of assessing the cost of her arthritis or her chronic obstructive lung disease: inevitably, she shows up as a negative item on the balance sheet.
>
> (Hill, 1997)[55]

for building relevant and viable traditional health services. In Sri Lanka, Aluwihare (1997) has examined sets of figures on such indicators as infant mortality and women in the labour force. His finding is that national aggregate data do not help in the appropriate targeting of resources. Rather, the best way would be to target the parts of the country where the figures are the least satisfactory, as a dollar there would have produced a better effect than 10 dollars in an area which had better parameters.[58] The use of data that are disaggregated by place and time is a more effective way of identifying "weak" points where specific action is needed. This would require that TRM utilization studies be incorporated into national health service research as well as studies on the availability, quality and cost of traditional health services on a region-by-region basis.

Health insurance for traditional medicine

As noted in the section on *Utilization*, health insurance coverage can lead to a substantial increase in the use of TRM services. In a Korean immigrant population in Los Angeles, 24 per cent of the uninsured used traditional healers, compared with 59 per cent of persons with Medicaid only and 71 per cent of those with other types of insurance including Medicare and Medigap coverage.

In China, although traditional health services are covered by health insurance, only about 12 per cent of the population has comprehensive medical insurance that covers the cost of hospitalization, and the proportion of uninsured people may be as high as 50 per cent.[59, 49] In hospital settings, insured patients are more likely to receive TCM.[59] This is due to the fact that one of the primary sources of a hospital ward's profit, under the market model of health care provision that is in place, is the 15–25 per cent mark-up for prescribed medications, so the changed incentive system has become associated with increased polypharmacy.[59]

Under the market system, many TCM hospitals in China operate at a deficit, as better equipped Western hospitals attract more patients. As TCM is largely an outpatient, low technology specialty, most of the income of traditional hospitals comes from the sale of drugs. Even with the 25 per cent mark-up allowed, it is hard to cover operational costs. While Government subsidies currently ensure survival, there is no surplus for improving services and further market reforms may threaten this subsidy system.[36]

The experience in Taiwan is that insurance coverage for TRM would more than double the use of TCM. Whereas 35.4 per cent of Taiwanese reported using TCM regularly, 86 per cent of the public would support the coverage of Chinese medicine by the new National Health Insurance and 79 per cent would use Chinese medicine if it does.[5]

High profitability of TRM can lead to its custodians resisting moves to provide insurance coverage for their services and products. In Korea, where the profit margin of herbal medicines is variously estimated to be 100–500 per cent compared to their basic cost,[37] the population utilize herbal medicines on a large scale.[37] The amount of reimbursement for herbal medicine under the National Medical Insurance (NMI) scheme was approximately 50 billion Korean won in 1993. This was estimated to be only a small portion of total expenditure on herbal medicines.[37] The high returns on herbal medicine boosted the socio-economic status of TRM doctors to the extent that about two-thirds (64%) of

them did not want herbal remedies to be included in the NMI scheme at all.[37]

In New Zealand, which has a long tradition of universal insurance for medical and hospital services, a number of Maori organizations signed contracts with regional health authorities to provide primary health care, resulting in an increased number of Maori-controlled services throughout the country. New Zealand has allowed the registration of more than 600 Maori traditional healers and the Government reimburses their services under health insurance schemes. It has been argued that the New Zealand experience showcases the importance of a funder-purchaser-provider separation and shows that this can be beneficial to indigenous health services.[60]

In Australia, Easthope et al. (1998) show that since the introduction of a Medicare rebate for acupuncture in 1984, use of acupuncture by medical practitioners has increased greatly.[61] By analysing Health Insurance Commission data on claims by all non-specialist medical practitioners for Medicare Benefits Schedule items for an attendance where acupuncture was performed by a medical practitioner, they showed that 15.1 per cent (about one in seven) of Australian GPs claimed for acupuncture in 1996. Claims rose from 655,000 in the financial year 1984–1985 to 960,000 in 1996–97, and Medicare reimbursements to doctors for acupuncture rose during this period from $7.7 million to $17.7 million. Acupuncture was more likely to be performed by male practitioners, by those aged 35–54 years, and by practitioners with an overseas primary medical qualification. A survey of general practices in Hobart showed that although only 15 per cent of the GPs provided acupuncture, it was available in 31 per cent of practices.

Cost-Benefit Research

Taking into account the bias towards higher income groups among medical insurance enrollees, evaluating the health insurance records of TRM/CAM users can be an effective way of estimating cost-savings of using traditional or complementary health care for certain sectors of society. A Canadian study provides an example.

A retrospective study of Quebec health insurance enrollees compared a group of Transcendental Meditation (TM) practitioners with non-meditating controls.[62] Earlier research had highlighted positive individual and group health effects of this meditation, which derives from India's *Vedic* tradition. This study aimed to determine whether these health benefits translate into savings to the Government in terms of possible reductions in payments to physicians for the medi-tating group.

The study involved a total of 2836 health insurance enrollees from Quebec. Of these, 1418 were volunteers who had been practising the TM technique for an average of six years, and 1418 were controls of the same age, sex, and region who were randomly selected. Using data provided by RAMQ (Régie de l'Assurance-Maladie du Quebec), Herron and associates first established a baseline by going back 14 years and gathering information on the total amount of money paid to physicians for this group. Adjustments for inflation were made using the medical cost component of the Canadian Government's Consumer Price Index (CPI). The scientists were able to determine a typical subject's rate of change in expenditure over the period using robust statistics.

Researchers found that before starting meditation, the yearly rate of increase in payments between the TM group and the control group was not significant. However, after learning meditation, the TM group's

mean payments declined one to two per cent each year, while the control group's mean payments increased up to 12 per cent annually over six years. Thus, there was a mean annual difference between the two groups of about 13 per cent. The research team estimated that this could translate into savings of as much as $300 million per year for the Province's health insurance company, the Régie de l'Assurance-Maladie du Quebec.

A recent example of comparative research of a traditionally used herbal medicine and the main equivalent conventional medicine has cost-benefit implications that are important. The study, on mild to moderate depression, compared St. John's Wort (*Hypericum perforatum*), with the recommended dose (150 mg) of imipramine, one of the most commonly used tricyclic antidepressants. Hippocrates, Pliny and Galen had all described the use of *Hypericum* for the treatment of mental disorders. An Randomized Clinical Trial (RCT) was conducted involving 324 outpatients with mild to moderate depression. The study found that *Hypericum* extract is therapeutically equivalent to imipramine in treating mild to moderate depression, but that patients tolerated *Hypericum* better.[63] Two years of treatment with Prozac (20 mg/day) will cost US$1,250 in China, about the annual income of an urban worker.[49] A TCM equivalent of *Hypericum* would result in substantial cost savings and, if similar to *Hypericum*, may be better tolerated by patients. Cost savings could be calculated on an annual, national basis, as could economic and social costs arising from reductions in side-effects. Cost-benefit analysis of this type would assist countries in making informed choices about the selection of treatments to be incorporated in integrated health care services.

Conclusion

Rising consumer demand for THC services, the unavailability of conventional services in many areas of the developing world, and the move by governments to integrate THC into national health services, all combine to create a new set of issues regarding TRM that extend beyond the long-established themes of safety, efficacy, standardization of medicines and training of traditional health practitioners. While these issues are at the core of quality control in traditional health services, planners are assuming that if quality is indeed controlled, a new set of questions arise. At the forefront of these are questions of the comparative cost of conventional and THC and treatments.

In drawing together the basic five-point framework for economic analysis outlined in the Introduction and the complex issues that actually occur in real-life setting, a number of policy issues can be identified and distilled as providing the context for the development of cost-effective THC services.

With respect to the economic valuation of TRM, it is necessary to recognize that in the developing world, the cost of modern medical services can be a factor in people choosing TRM. Programmes to develop and formalize traditional health services should not overlook this point. The risk in doing so is of depriving the poor of services that have historically been their first and last resort for health care. Accordingly, economic policies on TRM should aim to keep any user fees affordable – including those of THC practitioners in the community.

Significant investment is a prerequisite for the development of effective THC services. Under-investment risks perpetuating poor standards of practice and products and also contributes to main-

taining old stereotypes of inferior services and knowledge in TRM. If health insurance coverage is provided for TRM, national schemes should be weighted in support of continued access by the poor to TRM.

A necessary backdrop to economic analyses is a social analysis which examines the extent to which there is demand for traditional health services, who the clients are, what the conditions are that they bring for treatment, and how they rate the quality of both traditional and conventional health care services. Political priorities can frame and set the pace of formalization of THC. The traditional health sector is, can and should be part of this equation in the interests of ensuring appropriate developments in policy, regulation, accreditation, service development, standards of practice, training and research.

A comprehensive yet flexible infrastructure is necessary to address the diverse areas within the THC sector. These include: legislation, regulation, financing, research, product development, education and training , and sustainable medicinal plant production.

Priority areas for collaboration include diseases such as TB, malaria[64] and HIV/AIDS.[(65)] Here new sets of economic questions present themselves and these must include the ethics of not evaluating the medicines that the public uses for home-treatment of serious diseases.

A mechanism is needed for sharing experience in policy and service development both within and between countries. Communication and mutual understanding should be promoted among different medical systems that exist in a society. In evaluating TRM, this should be done as a system in preference to selecting single therapeutic modalities to be evaluated for a specific effect. Integration of health services should be coordinated at the theoretical and practical levels. Governments and inter-national organizations, such as WHO, should work to ensure that there is equitable distribution of resources between traditional and modern Western medicine.

An integrated training and educational programme is needed for both traditional and modern Western medicine. And finally, there is a need for a national drug policy that includes traditional drugs.

Economic analysis of TRM is necessary. As we have seen, there are five broad means of conducting such research: cost descriptions; cost-comparison studies; cost-effectiveness analysis and cost-utility analysis. The selection of methodology will depend on who is asking the question – Government, insurer, consumer advocate, etc. A necessary starting point is transparency in stating the priorities lying behind the research and the research question, e.g., cost-savings, quality of life improvement, etc., in order to enable a balanced interpretation of the outcomes of the research.

Cost-benefit research is needed and, increasingly will be done. While comparing outcomes and costs of traditional and conventional interventions, care is needed to avoid the charge that is sometimes made that cheap medicines are being produced for poor people, with some disregard for quality and efficacy.

As this is a nascent field, it would benefit from the emergence of a specialized group of researchers who are linked, potentially via the internet, to share experience, models of research and findings. Such a group would work to develop priorities in an international research agenda, refine evaluative methodologies and articulate ethical and cultural perspectives to broaden the scope of economic analyses.

Clearly, for formalization of THC services to be achieved in a climate of competition for scarce resources, it will be vital that programme administrators and custodians of traditional medical knowledge conduct cost-related research. The potential is the development of a new basis for ensuring that traditional health knowledge is put on sound footing alongside conventional medicine.

References

1. Eisenberg D.M., et al. Trends in alternative medicine use in the United States. Results of a follow-up National Survey. *JAMA*.1998; 280 (18): 1569–75.
2. MacLennan A.H., Wilson D.W. and Taylor A.W. Prevalence and cost of alternative medicine in Australia. *Lancet*. 1996; 347:569–72.
3. White A. and Ernst E. Economic analysis of complementary medicine: a systematic review. *Complementary Therapies in Medicine*. 2000; 8:111–18.
4. Astin J.A. Why patients use alternative medicine: results of a national study. *JAMA*. 1998; 279 (19): 1548–53.
5. Chi C. Integrating traditional medicine into health care systems: examining the role of Chinese medicine in Taiwan. *Social Science and Medicine*. 1994; 39 (3): 307–21.
6. Robinson R. Economic evaluation and healthcare: what does it mean? *BMJ.* 1993; 307: 670–73.
7. Russell S. Ability to pay for health care: concept and evidence. *Health Policy and planning*. 1996; 11(3): 219–37.
8. Stephens C. Training urban traditional birth attendants: balancing international policy and local reality. Preliminary evidence from the slums of India on the attitudes and practice of clients and practitioners. *Social Science and Medicine.* 1992; 35 (6): 811–17.
9. Bannerman R.H. Traditional Medicine and Healthcare Coverage. *WHO,* Geneva.1993.
10. Shai-Mahoko S.N. Indigenous healers in the North West Province: a survey of their clinical activities in healthcare in the rural areas. *Curationis.* 1996; 19(4): 31–34.
11. Shiferaw T. Illness burden and use of health services in a rural community. South-western Ethiopia. *East African Medical Journal*. 1993; 70 (11): 717–20.
12. Oskowitz B. Bridging the communication gap between traditional healers and nurses. *Nursing RSA.* 1991; 6 (7): 20–2.
13. Ahmed I.M., et al. Characteristics of visitors to traditional healers in central Sudan. *Eastern Mediterranean Health Journal*. 1999; 5 (1): 79–85.
14. Traore S., Coulibaly S.O., Sidibe M. *Comportements et couts lies au Paludisme chez les femmes des campements de pecheurs dans la zone Selingue au Mali,* Institute National de Recherche en Sante Publique. Bamako, Mali. WHO: TDR/SER/PRS/12.1993.
15. Elzubier A.G., et al. Knowledge and misconceptions about malaria among secondary school students and teachers in Kassala, Eastern Sudan. *Journal of the Royal Society of Health*. 1997; 117 (6): 381–5.
16. Tanner M., Vlassoff C. Treatment-seeking behaviour for malaria: a typology based on endemicity and gender. *Social Science and Medicine*. 1998; 46: 523–32.
17. Wilkinson D., Gcabashe L. and Lurie M. Traditional healers as tuberculosis treatment supervisors: precedent and potential. *International Journal of Tuberculosis and Lung Diseases*. 1999; 3 (9): 838–42.
18. Troskie T.R. The importance of traditional midwives in the delivery of health care in the Republic of South Africa. *Curationis*. 1997; 20 (1): 15–20.
19. Boerma J.T., Baya M.S. Maternal and child health in an ethnomedical perspective: traditional and modern medicine in coastal Kenya. *Health Policy and Planning.* 1990; 5 (4): 347–57.

20. Vissandjee B., Barlow R. and Fraser D.W. Utilization of health services among rural women in Gujarat, India. *Public Health*. 1997; 111 (3): 135–48.
21. Agyepong I.A., Manderson L. The diagnosis and management of fever at household level in the Greater Accra Region, Ghana. *Acta Tropica.* 1994; 58: 317–30.
22. Ruebush T.K., Kern M.K., Campbell C.C., Oloo Aj. Self-treatment of malaria in a rural of western Kenya. *Bulletin of the World Health Organization*. 1995; 73: 229–36.
23. Miguel C.A., Manderson L., Lansang M.A. Patterns of treatment for malaria in Tayabas. The Philippines: Implications for control. *Trop. Med. Int. Health.* 1998; 3 (5): 413–21.
24. Miguel C.A., Tallo V.L., Manderson L., Lansang M.A. Local knowledge and treatment of malaria in Agusan del Sur, The Philippines. *Soc. Sci. Med*. 1999; 48: 607–18.
25. Muela H.S., Ribera J.M., Tammer M. Fake malaria and hidden parasites – the ambiguity of malaria. *Anthropology and Medicine*. 1998; 5 (1): 43–61.
26. Bitahwa N., Tumwesigye O., Kabariime P., Tayebwa A.K.M., Tumwesigye S., Ogwal-Okeng J.W. Herbal treatment of malaria – four case reports from the Rukarawe Partnership Workshop for Rural Development (Uganda). *Tropical Doctor*.1997; (Suppl1): 17–9.
27. Munguti K.J. Community perceptions and treatment seeking for malaria in Baringo District, Kenya: implications for disease control. *East African Med J*. 1998; 75 (12): 687–91.
28. Varga C.A., Veale D.J.H. Isihlambezo: utilization patterns and potential health effects of pregnancy-related traditional herbal medicine. *Social Science and Medicine*. 1997; 44 (7): 911–24.
29. Ma G.X. Between two worlds: the use of traditional and Western health services by Chinese immigrants. *Journal of Community Health*. 1999; 24 (6): 421–37.
30. Bandyopadhyay M., MacPherson S. Women and health: tradition and culture in rural India.1998.
31. Nichter M. Ethnomedicine: diverse trends, common linkages. Commentary *Medical Anthropology*. 1991; 13:137–71.
32. Maher P. A review of “traditional” aboriginal health beliefs. *Australian Journal of Rural Health.* 1999; 7 (4): 229–36.
33. Marbella A.M., Harris M.C., Diehr S. Use of Native American healers among Native American patients in an urban Native American health center. *Archives of Family Medicine*. 1998; 7: 182–95.
34. State Administration of Traditional Chinese Medicine of the People’s Republic of China. Anthology of policies, laws and regulations of the People’s Republic of China on Traditional Chinese Medicine. Shangdong: Shangdong University. 1997.
35. Hesketh T., Zhu W.X. Health in China. Traditional Chinese medicine: one country, two systems. *British Medical Journal*.1997; 315: 115–17.
36. Hesketh T.M., Zhu W.X. Excessive expenditure of income on treatments in developing countries. *British Medical Journal*. 1994; 309: 1441.
37. Cho H.J. Traditional medicine, professional monopoly and structural interests: a Korean case. *Social Science and Medicine*. 1999; 50 (1): 123–35.
38. India. Ministry of Health and Family Welfare. Indian systems of medicines and homoeopathy: annual report. 1999–2000. (http://mohfw.nic.in/ismh/).
39. COHRED. Proceedings of the International Conference on Health Research for Development. 1990.
40. Burnett A., et al. Caring for people with HIV in Zambia: are traditional healers and formal health workers willing to work together? *AIDS care*. 1999; 11 (4): 481–91.
41. Upvall M.J. Nursing perceptions of collaboration with indigenous healers in Swaziland. *International Journal of Nursing Studies*. 1992; 29 (1): 27–36.
42. Last M., Chavanduka G. The professionalisation of African medicine. 1986.

43. Kabatesi D. Use of traditional treatments for AIDS associated diseases in recourse-constrained setting. In: *Health in the Commonwealth: challenges and solutions 1998/99* (ed. L. Robertson, K. Bell, L. Laypang & B. Blake). London: Kensington Publications. 1998.
44. Baleta A. South Africa to bring traditional healers into mainstream medicine (news). *Lancet.* 1998; 352: 554.
45. Osuide, G.E. Regulation of herbal medicines in Nigeria: The role of the National Agency for Food and Drug Administration and control (NAFDAC). Paper presented at the *International Conference on Ethnomedicine and Drug Discovery, Silver Spring MD*. 1999; Nov 3–5.
46. Kagwanja P.M. Women and the political economy of traditional medicine in Kenya: a historical perspective. Curare Special Issue: *Women and Health*. 1997; 11 (97): 29–38.
47. Nelson T. Commonwealth Health Ministers and NGO's seek health for all. *Lancet*. 1998; 352: 1766.
48. Bodeker G. Traditional (i.e. indigenous) and complementary medicine in the Commonwealth: new partnerships planned with the formal health sector. *Journal of Alternative & Complementary Medicine*. 1999; 5 (1): 97–101.
49. Lee S. Diagnosis postponed: *shenjing shuairuo* and the transformation of psychiatry in post-Mao China. *Culture, Medicine and Psychiatry*. 1999; 23 (3): 349–80.
50. Goodman H., Waddington C. *Financing health care.* Oxford: Oxfam. 1993.
51. African Development Bank/UNICEF. Les strategies d'adaptation socials des *populations vulnerables d'abidjan face a la development et a ses effets*. *African Development Bank.* 1995.
52. Tanzania, Lambheni Traditional Healers' Association, personal communication. 1997.
53. Hotchkiss D.R., Rous J.J., Karmacharya K., Sangraula P. Household health expenditures in Nepal: implications for health care financing reform. *Health Policy and planning.* 1998; 13 (4): 371–83.
54. Kale R. Traditional healers in South Africa: a parallel health care system. *British Medical Journal*. 1995; 310: 1182–85.
55. Hill E. Over the edge: health care provision, development, and marginalisation. In: *Development for Health*, ed. Hill E. Oxford: Oxfam Publication. 1997: 6–13.
56. Matthews M.K., et al. Training traditional birth attendants in Nigeria – the pictorial method. *World Health Forum*. 1995; 16: 409–14.
57. Brunet-Jailly J. AIDS and health strategy options: the case of Cote d'Ivoire. *AIDS Economics Online Conference 1998*. http://www.worldbank.org/aids-econ/arv/index.htm.
58. Aluwihare A.P.R. Ethics and Practical decision-making. *World Health Forum.* 1997; 18: 120–24.
59. Phillips M.R., Lu S. and Wang R. Economics reform and the acute inpatient care of patients with schizophrenia: the Chinese experience. *American Journal of Psychiatry*. 1997; 154 (9): 1228–34.
60. Scrimgeour D. Funding for community control of indigenous health services. Australian and New Zealand. *Journal of Public Health*. 1996; 20 (1): 17–18.
61. Easthope G., et al. Acupuncture in Australian general practice: practitioner characteristics. *Medical Journal of Australia*. 1998; 169: 197–200.
62. Herron R.E., Hillis S.L. The impact of the Transcendental Meditation program on government payments to physicians in Quebec: an update. *American Journal of Health Promotion* 2000; 14(5): 284–91.
63. Woelk H. Comparison of St. John's wort and imipramine for treating depression: randomized controlled trial. *BMJ.* 2000; 321 (2 Sept.): 536–39.
64. Bodeker G. & Willcox M.L. New research intitiative on plant-based antimalarials. *The Lancet*. 2000; Feb. 26: 355,761.
65. Bodeker G., et al. A regional task force on traditional medicine and AIDS in East and Southern Africa. *The Lancet.* 2000; April 8.

Development of training programmes for traditional medicine

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Introduction

The systems of traditional medicine in South-East Asia are amongst the most evolved of all the ancient systems of medicine known to mankind. There is a rich tradition of recorded and unrecorded literature on their usefulness and use in most countries of South-East Asia. Practitioners of traditional medicine are heirs to a rich heritage of knowledge and skills, handed down from one generation to the next with great dedication. The social goal of Health for All, with primary health care as the key approach, was adopted by the Member States at the World Health Assembly in 1978. Traditional medicine was identified as an essential component of the overall response for its achievement, particularly in the developing world. It has been clear to most health administrators, for over two decades, that this exalted goal of "Health for All by the year 2000"[1] would not be realized without the use of all available health resources, particularly traditional medicine and its practitioners.

However, the actual experience has not been totally encouraging in most countries and the incorporation of traditional medicine into the organized public health systems, especially at the district health level, has been very erratic and non-productive, to say the least. This token acquiescence of Member States of the World Health Organization in galvanizing traditional medicine to achieve this collective goal has meant that the health status of the poor, especially the rural poor, has continued to be compromised. The prevailing economic hardships facing most developing countries of the Region have further complicated the picture for the urban poor.

Although reliable statistics are not available for some of the countries of the Region, there is a wide gap between the health status of people in the urban areas and those in the rural areas of the Region. Life expectancy at birth and infant mortality, and maternal mortality, another useful index of the level of health, continue to be unacceptably high in many countries. Infectious and parasitic diseases continue to sap the energies of the people. Some children receive no preventive immunization for crippling diseases of childhood. Many more suffer from severe malnutrition of one deficiency or another.

In many countries, only a few city dwellers have access to organized health and other social services at prices that they could afford. The majority of the population

are left to their own devices which often means recognized traditional health practitioners and/or charlatans. This situation highlights one facet of the social injustices that are being perpetrated, knowingly or unknowingly, by policy-makers and administrators in most developing countries.

Most, if not all, traditional medicine practitioners are inadequately trained for the tasks that they perform in their communities. In spite of this, licensed and unlicensed practitioners continue to be readily available to the sick in rural and peri-urban settings, prescribing ethical and non-ethical as well as rational or irrational modern medical drugs to those they see in their daily practices. In the main, their activities are restricted to curative practices only.

The education and training of traditional practitioners becomes a crucial issue in this context. Of course, it is also a fact that education and training responses *per se* will not address, let alone solve, many of the problems and issues related to the incorporation of traditional medicine to complement the modern systems of medicine in our countries. This paper outlines some of the contextual issues in the integration of traditional medicine with the general health care services, and suggests a rational framework and some practical guidelines for the development of human resources in traditional medicine. Therefore, the list of issues and the suggestions offered in this paper do not pretend to be exhaustive. However, taken together, they are key questions and issues to be answered before designing any meaningful education and training programme for traditional medicine, including defining the role of traditional health practitioners in the district health system.

Some lessons and questions from past experiences

To place education and training as a sub-system in the health system in South-East Asia, it is useful to examine some of the relevant experiences that have been accumulated and which are of direct relevance to these countries. A small number of these experiences have been extracted and summarized here as it would help in the elaboration of national health policy related to traditional medicine.

We have useful lessons from a number of African countries that have attempted to bring traditional medicine into the mainstream of the health services, often without much success. For example, one country, at independence, tried to correct the situation inherited by adopting policies and promulgating legislation that were encouraging to traditional practitioners but, at the same time, alienated them from the formal health personnel.[2] Consequently, the existing gap between the two types of practitioners further widened.

Cooperation and collaboration should be brought about as a purposeful part of the overall development of the national health policy and not as a result of injudicious or hasty adoption of policies to promote traditional medicine which, in fact, have often tended to discredit it. The identification and categorization of the various traditional practitioners should be a national undertaking with the intention of improving health benefits for the people, as has been done in China, India, Mexico, Sri Lanka and Thailand.

A good policy should be the ultimate expression of a consensus and, therefore, the necessity of involving traditional medical practitioners at all stages of this process cannot be overemphasized. Such consultation is most easily achieved when there is

a national association of traditional practitioners and when the representatives of such an association can be brought into direct relationship with the health authorities.

Sri Lanka is the only country where there is a separate ministry for indigenous medicine. In India and China, there are Departments and Bureaus of traditional medicine within the ministries of health. Regional and national associations exist in these countries as well as in most African countries. All people value good health and traditional practitioners continue to exist because people believe in them and their practices, which have values that are derived from and are consistent with their own culture. In most instances, these practitioners would be willing to participate in health-promoting activities, provided they were convinced that they could be effective and knew how.

All too often, however, the opportunity to participate has not been afforded them by the health services, and legislation in some cases endorses this negative stance. Experience shows that restrictive legislation remains unenforceable and people continue to utilize their traditional systems of medicine. For example, a restrictive law forbidding traditional practitioners to issue certificates in respect of their patients was repealed in one country. However, it should be noted that no enabling law has been introduced in its place, and people continue to patronize their practitioners. In many instances, health services are influenced by technocrats bent on achieving and maintaining a set of "international medical standards".[2] These may not necessarily reflect nationally acceptable training curricula that meet local manpower needs, thus further accentuating the brain drain of qualified staff.

Traditional medicine is to a large extent culture-specific and therefore practitioners tend to stay in their own communities. Successful attempts to utilize traditional medicine are characterized by the ability of health personnel to understand local traditional practices. China and India are examples of countries that have developed their traditional systems of medicine to the extent that they now command some respect from practitioners trained in Western or modern medicine. They have succeeded in making health personnel aware of the place of traditional medicine in their culture, its strengths and weaknesses, and the use that may be made of it in formal health care.[3]

Education in the classical systems of medicine such as Chinese traditional medicine, Ayurveda and Unani, already includes an appreciable amount of instruction in Western medicine. In the case of traditional systems, where remedies are handed down from generation to generation by word of mouth, arrangements have to be made to provide practitioners with additional knowledge. Examples include the ability to identify and encourage existing beneficial practices (e.g., breastfeeding), as well as competence in certain modern methods of prevention and cure (e.g., the care of infants with diarrhoea or acute respiratory infections). The creation of a learning situation, where health personnel actively work with traditional practitioners and the communities in identifying health needs, organizing health care activities, managing their implementation and evaluating the results achieved, would also promote a healthier climate for all.[4]

In an ideal situation, personnel of the formal health system and traditional practitioners should be encouraged to work together as teams in clinics and health centres. Research in traditional medicine and in the utilization of traditional

practitioners in district health care, with traditional health practitioners themselves as principal investigators, could greatly enhance development in this field. To take another example, making available simple multipurpose kits containing appropriate therapeutic agents and basic instruments that could be handled by traditional practitioners in their own practices, as is done in some countries, could do much to improve the quality of their work. Traditional medicine activities must, of course, be adequately funded and external and internal funding agencies and non-governmental organizations should be coopted into this endeavour.

Some guiding principles for developing a training system in traditional medicine

The above experiences and questions provide the overall context for establishing and improving education and training programmes in traditional medicine. The more immediate context for policy and action will be the structure and the function of the human resources development sub-system in the particular country.

WHO advocates that each level of the health system should be the responsibility of the most suitably trained health professionals, and not necessarily the "most highly" trained staff. The support such "suitably trained" staff need must be provided by the higher levels of staff. This would be a critical requirement to "integrate" the traditional medicine practitioners in the general health care system and place them in a position of maximum use to the community.

WHO also believes that the three main components of the human resources development process – planning, production and management or utilization – should be functionally integrated, and these, in turn, should be integrated with overall health systems development. In this scenario, ideally education and training in traditional medicine should be articulated within this system. But reality is often otherwise. Many of the efforts in the education and training of traditional medicine practitioners in the countries are made on an ad hoc basis outside the mainstream of human resources for health development and do not constitute an integral part of the education and training of health professionals. The reasons for this state of affairs are multiple, but they originate mainly from two generic problems that are inherent in our health systems. One is the place of traditional medicine in the health system, the types of issues that were identified in the earlier part of this paper. The other is an attitudinal and hierarchical problem wherein the practitioners of the modern allopathic system of medicine do not recognize the practitioners of traditional medicine to be on par with them. The years of dominance of the allopathic system, and the technological advancement it has achieved, supported by public perception and demand, have combined to create this situation and it will be narve to expect it to change overnight. But this is a fundamental problem that needs to be recognized and addressed appropriately in many of our countries.

None of the three processes in human resources development – planning, education and management – can function independently of each other. They have their own cycles, though.

- Human resources planners acting independently of production and management become paper planners only;

- Educators and trainers acting in ignorance of planning and management have abandoned the logic of purposeful education and the relevance of their programmes to the needs of society;
- Health services managers who act independently of plans and education and training have given away their most important management tools, including the influencing of the health personnel they want to utilize.

Defining the characteristics of graduates of educational and training programmes

It seems obvious that the roles to be fulfilled by graduates of educational and training programmes should serve as a basis for determining the content and methods of learning, yet this process is seldom given careful attention. Most often, the roles are taken for granted, based largely on outmoded recollections, or on the assumption that graduates can adapt to the situation in which they find themselves. Furthermore, the training institutions often do not even consider it necessary to train students for well-defined roles and functions. When graduates complain that their preparation was not adequate, the programmes are only occasionally modified.

To ensure the relevance of health manpower preparation, it is necessary that there is a full understanding of the personal and professional competencies, including the intellectual and practical skills, values, and attitudes required if health workers are to function effectively in the settings to which they are assigned.[5] The development of such an understanding involves several problems:

- The roles to be filled may not yet exist but are planned; this is a common occurrence in evolving health systems;
- The roles have social and managerial as well as technical aspects that require an interdisciplinary approach to role definition and training;
- The roles of each health worker include establishing and maintaining important relationships with others, and this requires consideration of the overall function of a team as well as training for teamwork;
- The roles involve close interaction with communities, which requires not only an understanding of the nature of that interaction, but also calls for the participation of communities in the process of role definition.

Key questions/issues and some answers

(1) How can the formal health services work with traditional practitioners for the benefit of the population? Why?
Because so far, traditional practitioners have been excluded from exercising any responsibility in most national health services.

(2) How can a traditional medicine infrastructure be created? Why?
Because, without a clearly defined infrastructure, through which traditional health practitioners themselves could be heard and which could be a regulatory body in relation to ethical and professional matters, there is likely to be chaos.

(3) How to sensitize, orient and use health professionals and others so that they may support the national traditional medicine programme? Why?
Because, if they are brought into a constructive relationship with the programme, they will continue with their biases and hamper Government efforts to put traditional medicine on a sound footing.

(4) How to review health legislation concerning traditional medicine? Why?
Because, most of the present legislation in this field is outdated or irrelevant and needs to be revised to conform with the new policies adopted. In any case, a reasonable and enforceable legislation would greatly enhance the implementation of traditional medicine activities.

(5) How to define the role of bilateral and multilateral assistance? why?
Because, any external support should be consistent with Government policies and priorities; otherwise, it may lead to unnecessary and wasteful investment in esoteric projects which have no direct relevance to the people's health needs.

(6) How to develop a national drug policy that includes traditional medicine? Why?
Because, importing drugs is always very costly and consumes scarce foreign currency. Developing traditional remedies of proven efficacy and quality will not only promote self-reliance but will also encourage research workers to investigate other traditional remedies more carefully.

(7) How to formulate up-to-date research and development policies in traditional medicine? Why?
Because, at present research policies in most countries do not reflect the role of traditional medicine in health services. New research and development policies could greatly assist

institutions in addressing the critical problems now being faced.

(8) How to finance traditional medicine activities? Why?

Because, the introduction of traditional medicine activities will require adequate budgetary appropriations. A sound programme and budget that maximizes the effective use of all available resources needs to be evolved.

(a) There is no single or simple approach to the problem of how to involve traditional practitioners in national health systems, especially at the primary health care level. Dedicated and sincere action on the part of all concerned will be required to foster a collective effort to generate and implement policies best suited to any given country.

(b) The first step could be the establishment of a National Council for Traditional Medicine, that could be charged with responsibility for preparing a national strategy of laying down a broad plan of action to be followed by the Government. The Council should be multidisciplinary and multisectoral in nature, with appropriate representation of the different types of traditional practitioners involved.

(c) Major policy issues need to be identified quickly, priorities determined and mechanisms established to propose the various options and courses of action open to the Government, with ad hoc groups being formed to tackle specific issues.

(d) Adequate finance should be assured under the Government's regular budget for the support and promotion of traditional medicine activities. External finance should be considered as only supplementary to the Government's main effort.

(e) In parallel with the work outlined above, it will be necessary to undertake a survey of the national situation in respect of the practitioners, the population's preferences and needs, resources, special problems, etc., upon which a sound national health plan reflecting the role of traditional medicine may be formulated. Practitioners of traditional medicine should be engaged in these activities and the results should be made widely known to the general public as well as to the health professions.

(f) The institution of practical, low-cost traditional medicine activities need not await the results of these surveys. One of the first activities should be the generation of a public debate that should include special educational efforts for the public (press, TV and radio), distribution of information on traditional medicine, and short courses for traditional practitioners and conventional health personnel, as an initial step, to secure their involvement.

There are three basic changes and reorientations that are needed in the education and training programmes in traditional medicine. Firstly, more attention must be paid to problem-solving skills as the current curricula are overburdened with the pursuit of knowledge and information, much of it is irrelevant to the priority tasks needed to meet the health problems of communities. The curricula also need to be more problem-oriented and community-oriented, if not community-based. In addition, appropriate teaching and learning strategies need to be developed for traditional medicine practitioners to work in teams.

Secondly, the education and training programmes in traditional medicine need

to develop appropriate teaching and learning materials and promote the wider use of audiovisual, self-instructional and simulation techniques which have proven value. The challenge is to adapt these to the specific requirements, especially to students and learners in rural areas, where many of them are. Some of the knowledge may not be documented and will need to be elicited from the practitioners themselves.

The third major change is in the evaluation of the education and training programmes. Evaluation should not only determine whether the students (and the teachers) have achieved their objectives (often called student assessment), but also the quality of the whole teaching and learning process. It should determine whether the learners have achieved the objectives, and if so, to what extent; whether the objectives are relevant to health care needs; whether the curriculum and methods are relevant to the objectives and if the evaluation is valid and objective. In other words, this should be a self-controlling process.

Training of teachers

The changes in education and training envisaged in traditional medicine hold important implications for the training of their teachers. This, of course, is possible in those instances where institutional cases are available. The traditional practitioner who works independently would not be able to do these. Perhaps the most basic aspect of teacher training is that they understand their role as teachers, i.e., to promote the process of learning by guiding the students to achieve the learning objectives. The second would be for them to understand that the role of their training institutions is to prepare personnel for health systems that meet the health and social needs of their communities. As promoters of learning, teachers need more than a sound grasp of their own health disciplines. They need to know the needs and demands of their communities, and the intersectoral activities that are most likely to contribute to health development. It is by pursuing such a wider agenda that the teachers of traditional medicine will develop the respect and the self-confidence to interact with their counterparts in schools of Western medicine. It is accepted in recent times that training in educational principles and processes in teaching and learning methodology would be essential for teachers of all health personnel. By this count there is a great dearth of teachers of traditional medicine with such knowledge and skills. It would therefore take a considerably long time before a majority (or even a sizeable number) of teachers are in these areas, but the process must begin now.

Continuing Education

Education of traditional medicine practitioners should not be seen as a one-time event. Initial learning experiences should be improved continuously, and higher levels of competence achieved. Improved work performance, enhanced competencies, more positive work attitudes, and greater productivity should not be left to chance. They should be pursued through continuing education that seeks to enhance the performance of health workers through a system of planned educational programmes relevant to service needs. Most of the countries in the Region still do not have any continuing activities, leave alone having in place well-coordinated, systematic continuing education programmes. In the best sense, modules or units of continuing education

should be sequential and progressive, and specific learning objectives should be derived from the competencies required for more effective and efficient performance.[6] Here, there are greater opportunities than with basic-level programmes to pursue multi-professional or team-and-problem-oriented approaches to education.

Since the purpose of continuing education is enhanced job performance in the health services, it must be associated with other factors that contribute to high levels of staff morale and productivity. Continuing education is, therefore, not only a part of the training component of human resource development, but of human resources management as well. In China these aspects are reasonably well-articulated in the continuing education of traditional medicine practitioners. It requires cooperation between the trainers and the health service managers.

Orientation of medical students and practitioners in traditional medicine

In order to foster and generate an atmosphere of cooperation between the practitioners of modern and traditional medicine, one requirement would be to orientate the students and practitioners of Western medicine in traditional medicine. This should therefore be taken up as a parallel activity. In India, for example, it is now compulsory for medical students to have a certain number of hours of instruction dedicated to traditional medicine. This is a good start and, later, it may be possible to incorporate some assessments also into this. It would be desirable to similarly orientate the practitioners of Western medicine in traditional medicine, but this would be a much more difficult exercise as there would be few available ways of generating interest among them in this subject. It would be easier when, and if, the two systems are available to the community in some integrated or coordinated manner so that the practitioners communicate regularly with each other.

Conclusion

Many years have passed since the World Health Assembly first urged interested governments to give adequate importance to the utilization of their traditional systems of medicine with appropriate regulations as suited to their national health system (Resolution WHA30.49). So far no clear picture as to how this was to be implemented in many countries has evolved and many public health administrators look on traditional medicine with continued cynicism. Without a proper understanding at Government level of the issues involved and the creation of an informed body of opinion on the subject among the health profession and the public, there will be no significant move to utilize traditional medicine in national health systems.

One tends to speak as if the traditional forms of medicine and their practitioners are each homogeneous entities. It is, however, important to distinguish between the “formalized” traditional systems of medicine, such as Ayurveda, Unani, and Chinese traditional medicine and the practice of those practitioners who are recognized by their communities as being competent to provide health care. These practitioners serve a long apprenticeship and their knowledge is handed down from generation to generation, mainly by word of mouth.

There are also various types of healers whose practices are based on spiritual or moral convictions and others more difficult to define but who, nevertheless, are

recognized healers within their communities, such as exorcists and spirit media, who employ special healing arts associated with the supernatural. Their methods and beliefs are so diverse as to preclude their incorporation in any formal system. Individual governments will have to decide on what place, if any, to accord them.

Countries' primary concern should be to encourage the utilization of those elements of traditional medicine which are of value in their national health services. In this modern age, the rich heritage of traditional medicine should not remain the exclusive or esoteric interest of only a few.

References

1. Primary Health Care. Report of the International Conference on Primary Health Care. Alma-Ata USSR. 6–12 September 1978. Geneva. World Health Organization. 1978 ("Health for All" Series, No. 1).
2. Stephan, J. "Legal Aspects: patterns of legislation concerning traditional medicine." In: Bannerman, R. H. et al. ed. *Traditional medicine and health care coverage: a reader for health administrators and practitioners*. Geneva. World Health Organization. 1985.
3. Akerele, O. "Towards the utilization of traditional Medicine in National Health Services" In: *American Journal of Chinese Medicine*. Vol. XIV. Nos.1–2. 2–10.
4. Report of the Regional Consultation on Development of Traditional Medicine in South-East Asia region. World Health Organization. New Delhi. 14–17 September, 1999. Regional Office for South-East Asia. 1999.
5. Health Manpower Requirements for the Achievement of Health for All by the Year 2000, through Primary Health Care. Technical Report Series 717. Geneva. World Health Organization. 1985.
6. Guilbert, J.J. Educational Handbook for Health Personnel. World Health Organization. Geneva. 1981.

Technical issues

Legislation and regulation of traditional systems of medicine - systems, practitioners and herbal products

Dr. D.C. Jayasuriya
Dr. Shanti Jayasuriya

Standardization, pre-clinical toxicology and clinical evaluation of medicinal plants, including ethical considerations

Prof. Ranjit Roy Chaudhury
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Protection of traditional systems of medicine, patenting and promotion of medicinal plants

Prof. Carlos M. Correa

Research, drug development and manufacture of herbal drugs

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Legislation and regulation of traditional systems of medicine – systems, practitioners and herbal products

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Just as much as we have "traditional foods" or "traditional dresses", every society has medicines and practitioners that have come to be labelled as "traditional".

When does a type of medicine or practitioner become "traditional"? Given that "traditional" is a relative term, and that each country's experience is unique, a precise date cannot be easily determined. Generally, it is the date of recognition accorded, either by legislation or through practice or official patronage, to a certain type of medicine and practitioner thereof, that serves as the cut-off date for the demarcation of what we describe as "western" or "modern" or "allopathic" medicines and practitioners as against "traditional" medicines and practitioners. In practice, it is through an evolutionary process that each system has emerged to, or retained, its position of dominance. Socio-historical and anthropological studies[1] illustrate that this process continues notwithstanding the legal status because perceptions, beliefs and practices of people are not easily amenable to change through the force of law.

In considering the role of regulating traditional medicine, two areas need to be addressed:

- The regulation of traditional medicinal products;
- The regulation of traditional medical practitioners.

Before these aspects are considered, it will be useful to examine what "traditional medicine" is.

"Traditional Medicine" has been defined in various ways; in most contexts, however, its content and parameters are understood even without a definition. A recent statutory definition is to be found in the Public Health Code of Burkina Faso of 1994:[a]

"Traditional medicine means the aggregate of all knowledge and practices of a physical or non-physical nature, whether explicable or not, used in order to diagnose, prevent, or eliminate physical, mental, psychological, and social disequilibrium, and based exclusively on past experience and knowledge passed on from generation to generation, either orally or in writing."

[a] Law No. 23/94/ADP of 19 May 1994 promulgating the Public Health Code (IDHL, 1995, 46 (4), 452).

This definition captures many salient features of most non-Western systems of medicine that look at the human body and the multifarious ailments from a holistic perspective. In a few countries, including several South-East Asian nations, traditional medical education is organized on a well-structured basis; the definition does not specifically exclude this aspect but the way it is formulated may tend to create the impression that instruction in traditional medicine takes place in an informal context. Another possible limitation is contained in that part of the definition which speaks of traditional medicine being based *exclusively* on past experience and knowledge. There is a growing, albeit relatively slowly, body of empirical evidence of the properties of some herbal medicines looking especially at *inter alia* long-term toxicity.

A broader definition is to be found in the law of Guinea. "Traditional Guinean medicine is the sum total of all technical knowledge involving the preparation and utilization of substances, measures, and practices in use, whether explicable or not at the current state of the art, resulting from the sociocultural and religious foundations of Guinean communities, which is based on practical experience and on traditions handed down from generation to generation, whether verbally or in writing, and which is used in the diagnosis, prevention or elimination of an imbalance of well-being of a physical, mental, social or spiritual nature".[b] This definition includes within its scope the religious and spiritual dimensions of traditional medicine. In some countries, traditional medical practice is closely connected with both religious as well as spiritual practices.

Regulation of Traditional Medicinal Products

Before the advent of synthetic compounds and preparations, medicinal plants provided the most diverse and potentially most effective means of treating many illnesses, and the tradition of using plants was passed from one generation of traditional healers to the next.[2]

While no precise figures are available, estimates suggest that some 80 per cent of the world's inhabitants remain extensively reliant for their primary health care needs on traditional medicines, including those manufactured from plant extracts or purified active ingredients.[3] Such products are not by any means confined to developing countries. Use of herbal products and alternative systems of medicine is widespread in many developed countries. In 1990, for instance, the sales of over-the-counter (OTC) herbal medicines in Germany alone have been claimed to be of the order of US$ 1.5 billion.[c]

Moreover, plant substances continue to provide the basis for many modern medicines. In the United States, for instance, a 1993 estimate indicates that some 25 per cent of prescription drugs and 60 per cent of non-prescription drugs include one or more naturally-derived substances and in 1990 the sales of such products amounted to some US$ 15.5 billion.[4]

In addition to being the sources of active constituents for many therapeutic products, plants frequently provide the starting materials for potent synthesized drugs, as well as providing models for the development of related, pharmacologically

[b] Law No. L/97/021/AN of 19 June 1997 (IDHL, 1999, 59 (2), 162).

[c] Kuipers C.E. et al. Herbal medicines – a continuing world trend (draft manuscript available with the Programme).

active compounds. Conservation of plant species consequently operates to the advantage of populations in both developed and developing countries. The imminent extinction of perhaps as many as 20,000 of the 40,000 to 75,000 plants potentially valuable to medicine,[5] is a cause for concern worldwide and action has already been broached in some countries to regulate their harvesting and exportation.[6] The United Nations Convention on Biological Diversity, states, *inter alia,* that: "conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential."

Species of medicinal value are specifically cited in the Convention as being among the categories of plants that need to be identified and scheduled as a prerequisite to assuring both conservation and sustainable use.

The policy context of regulation

It is estimated that only some 5000 plant species have so far been studied for biological activity and possible medical application, and few of these – or their component substances – have been comprehensively screened for toxicity and specific pharmacological activity.

This holds importance, not least because the aphorism is now demonstrably fallacious that the safety of herbal substances becomes apparent as a consequence of extensive use over many generations. In general, this thesis is applicable only to dose-related, acute toxic effects. It is less reliable when applied to immunologically determined effects, and largely irrelevant to the identification of long-range consequences of exposure. Several recently commissioned investigations of the potential toxicity of naturally occurring substances widely used in herbal preparations have revealed "a previously unsuspected potential for systemic toxicity, carcinogenicity and teratogenicity".[7]

In recognition of the value of the world's resources of medicinal plants and the need for discernment in their use, the Fortieth World Health Assembly, in adopting resolution WHA40.33, called upon Member States:

- To initiate comprehensive programmes for the identification, evaluation, preparation, cultivation and conservation of medicinal plants;
- To ensure quality control of drugs derived from traditional plant remedies by using modern techniques and applying suitable standards and good manufacturing practices.

Similarly, the Forty-second World Health Assembly, in resolution WHA 42.43, urged Member States:

- To make a systematic inventory and assessment (pre-clinical and clinical) of the medicinal plants used by traditional practitioners and by the population;
- To introduce measures for the regulation and control of medicinal plant products and for the establishment and maintenance of suitable standards;
- To identify those medicinal plants, or remedies derived from them, which have a satisfactory efficacy/side-effect ratio and should be included in the national formulary of pharmacopoeia.

The WHO Secretariat has responded to those resolutions by formulating general guidelines for the assessment of herbal medicines and research guidelines for

evaluating the safety and efficacy of herbal medicines.

Terminology and scope of regulatory control

Some national drug laws refer specifically to medicinal plants and/or herbal remedies, but there is no consistency in the terminology employed to identify or describe them for regulatory purposes. In the international sphere, only the Single Convention on Narcotic Drugs, 1961, as amended by the Protocol of 1972, which is concerned only with a limited number of plant substances, and particularly those with some therapeutic value and a high potential for abuse offers precise definitions.

In a more general context, the 1965 EEC Directive on Medicinal Products[d] lends precision to general definitions. The word "substance" is defined as applying to any matter "irrespective of origin". "Vegetable substance" is established as a general definition that comprises "plants" and "parts of plants".

Some national laws subsume medicinal plants into the definition of "substance" (e.g., the Netherlands); "medicament" (e.g., China); "traditional drug" (e.g., Indonesia), "herb" (e.g., Rep. of Korea), "herbal remedy" (e.g., United Kingdom); "traditional medicine (e.g., Singapore); or "herbal substance" (e.g., Australia).

In some countries, medicinal plants are embraced within national drug legislation by virtue of being listed in a pharmacopoeia (e.g., France) or in a national formulary (e.g., the Philippines).

The term "herbal remedy" is similarly subjected to a variety of legal definitions. In the Medicines Act, 1968, of the United Kingdom, "herbal remedy" has been defined as

"a medicinal product consisting of a substance produced by subjecting a plant or plants of drying, crushing or any other process or of a mixture whose sole ingredients are two or more substances so produced, or of a mixture whose sole ingredients are one or more substances so produced with water or some other inert substance".

The Australian Therapeutic Goods Regulations, 1990, has a broader definition of herbal substance:

"all or part of a plant or substance (other than a pure chemical or a substances of bacterial origin): (a) that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and (b) that is not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form".

The WHO guidelines for the assessment of herbal medicines propose a definition which is subsidiary to the term "plant preparation":

"Finished, labelled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant material or combination thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential oils, and any other substances of this nature. Herbal medicines may contain excipients in addition to the active ingredients. Medicines containing plant material combined with chemically defined active substances, including chemically defined, isolated constituents of plants, are not considered to be herbal medicines."

[d] Council Directive 65/65/EEC of 26th January 1965, as subsequently amended.

A different definition – similarly dependent upon the concept of prepared or processed ingredients – is preferred in the recent WHO guidelines for evaluating the safety and efficacy of herbal medicines:

"A plant-derived material or preparation with therapeutic or other human health benefits which contains either raw or processed ingredients from one or more plants. In some traditions, materials of inorganic or animal origin may also be present".

In formulating such a definition, two considerations are important: the ways in which related concepts and terms have been already defined, both within national statutes and international texts, and the particular aspects that it is intended to regulate.[8] Thus, some definitions of herbal remedies are drafted in terms that cover medicinal plants, while others specifically exclude them.

Registration/Approval

Any attempt to apply broad generalizations to the wide variety of national approaches to the registration of plant-based medicinal products can be misleading.[e] National control systems have evolved in different and unique ways, and these distinctive influences continue to be reflected in the regulatory provisions currently in place. In many instances, such products have been either included or excluded for assessment and registration purposes through exemptions inspired by any of a wide variety of factors. The piecemeal evolution of regulatory requirements which in part is attributable to difficulties in defining terms and validating claims regarding efficacy and safety is more evident with regard to plant-based products than other medicinal products.

Different national laws apply various criteria to the scheduling of herbal or traditional products for purposes of registration. These criteria cover the following considerations:

- Whether or not the product is included in an official pharmacopoeia or formulary;
- Whether or not the product is to be sold as a prescription product;
- Whether or not a therapeutic effect is claimed;
- Whether or not the product contains an ingredient or substance that is either scheduled in an international convention or subjected to prescription control;
- Longevity of use (described as 'well established' or 'long-term' use) determined in relation to a stipulated date or classified as a 'new drug within the traditional system';
- Some countries draw a distinction between "officially approved" products and "officially recognized" products. This is an important distinction in practice since the intention is to enable the latter to be legitimately marketed without formal assessment or registration.

At the risk of oversimplification, it is possible to classify legislative approaches into three groups:

- All medicinal products are subjected to the same regulatory provisions;
- All or some herbal and/or traditional medicines are exempted from all regulatory provisions;
- All or some herbal and/or traditional medicines are exempted from specified regulatory provisions.

[e] WFPMM, Self medication: progress built on tradition (Swiss Pharma 11a/91), pp. 54–91; *Drug Information Journal,* Vol. 27, 1993, pp. 145-168; and Chaudhury, R.R. *Herbal medicine for human health,* New Delhi, WHO, 1992

The extent to which elements of Good Manufacturing Practices are applied to the manufacture of plant-based medicinal products is varied.

Different national statutes require different types of information and data to be submitted with applications for registration of herbal products. Some countries, including Turkey and the Philippines, require information on the registration status of the product in other countries, and in case of the latter, information on the manufacturing operations and facilities.

Manufacture, Import, Export, Sale and Dispensing

In most countries, the manufacture, import, export, dispensing and sale of medicinal plants are not specifically regulated. Depending on the scope of the law these may be governed by provisions applicable to medicinal products in general or, alternatively, this field of activity may remain essentially *laissez-faire*. Hence, it is not usual to establish by law separate mechanisms to deal specifically with certain aspects of medicinal plants. Regulatory competence in nearly all countries is vested in the national drug authority. France is among the few countries in which a separate authority has been established: the National Interprofessional Office has certain statutory powers and responsi-bilities with regard to plants, parts of plants, and the products of initial processing of these materials.

China features prominently among countries that have issued regulations specific to traditional herbal medicines. Detailed provisions have been promulgated on their preparation which specify standards and requirements to be maintained in manufacturing facilities and by personnel. In Indonesia, traditional medicines can be manufactured only under a licence granted by the Ministry of Health. Hungary permits the marketing and processing of only those medicinal plants that have been inspected by the Medicinal Plants Research Institute and for which a certificate of inspection has been granted. In Singapore, the statutory requirements concerning manufacture do not apply to products prepared exclusively by drying, crushing or comminuting plants or parts of plants.

The extent to which elements of Good Manufacturing Practices are applied to the manufacture of plant-based medicinal products is varied. Insofar as the European Community is concerned, guidelines for the manufacture of herbal medicinal products were drafted in 1990 under the aegis of the Committee for Proprietary Medicinal Products.

These guidelines are intended to supplement the EC text of good manufacturing practices.

Statutory provisions bearing specifically on the import of medicinal plants are uncommon. Countries that require registration of herbal medicinal products generally have the power to regulate their import; any restrictions applied specifically to medicinal plants are usually set out only in regulations.

A number of countries have recently reported that some imported herbal products have been found to contain non-labelled substances that are potentially harmful to health. Malaysia, for instance,

reported[f] the presence of several scheduled poisons and controlled substances, including betamethasone, dexamethasone, chlorpheniramine, mefanamic acid, phenylbutazone, and dexachlorpheniramine, in both domestically produced and imported herbal medicinal products. This resulted in the confiscation of stocks and the banning of these products from domestic markets.

Approaches to the export of medicinal plants

A few countries require all exports to be regulated. In Spain, for instance, the export of medicinal plants is subject to the issuance of a certificate of guarantee by the competent pharmaceutical inspectorate.

Other countries which cultivate medicinal plants have sought to promote exports by specifying the competent regulatory authority in the legal text. In Mali, for instance, one of the statutory responsibilities of the Office of Pharmacy is to promote the export of products of its own research and manufacture, particularly drugs based on medicinal plants. Similarly, the National Pharmaceutical Office of Benin is required to promote the export of medicinal products.

In some countries, however, specific restrictions are applied to the export of protected plants. In Mali, prior authorization of the Director-General is required for any activity involving the collection of medicinal plants for export. In 1976, a WHO expert group on traditional medicines[9] called upon countries to regulate the export of medicinal plants for commercial purposes – a call that remained largely unnoticed until the elaboration of the United Nations Convention on Biological Diversity.

The dispensing and sale of medicinal products and medicinal plants are governed not only by the laws dealing specifically with drug regulation but also by those dealing with the health-related professions. Statutory provisions relating to medicinal plants, where they exist, are based on a range of different approaches and modalities. In France, for instance, certain essential oils derived from plants may be sold or supplied to the public only by pharmacists. In the Republic of Korea, herbal practitioners – a category of health professionals who need to pass an examination to be granted this status – may sell herbs by preparing them in accordance with the specifications in oriental medical books or prescriptions of oriental medical doctors.

In the United Kingdom, herbal remedies are sold on a retail basis by shopkeepers (e.g., 'health foods' shops, supermarkets, grocers); herbalists (i.e., persons who make and sell herbal remedies to persons who consult them); and pharmacists. In Bulgaria, only persons in possession of medical qualifications may receive authorization by the Ministry of Health to prescribe medicinal plants. In Brazil, medicinal plants may be dispensed only within pharmacies and herbalists' shops. Lesotho has a system – administered by the Universal Medicinemen and Herbalists Council – of licensing medicinemen and herbalists. In Morocco, there is a statutory prohibition on the simultaneous practice of the profession of physician, dental surgeon and midwife, on the one hand, and that of a herbalist, on the other, even if the latter is otherwise qualified to practise any of the other professions. Those licensed as a herbalist may sell any medicinal plant and parts of any such

[f] Annon. Contaminated herbal medicines in Malaysia. SCRIP, No. 1892, 28 January 1994, p. 19.

plant, with the exception of those plants included in the list of poisonous substances, and no herbalist may store or sell any other pharmaceutical preparation or speciality.

Labelling, Advertising and Promotion

Few regulatory texts have specific provisions concerning the labelling, advertising and promotion of medicinal plants. Those that do address these issues tend to extend to herbal medicines the general provisions applied to other medicinal products. A few countries do have discrete and specific provisions

Norway requires herbs and blended herbs available over-the-counter (OTC) to carry the following warnings

"The medicinal effect of this preparation has not been assessed by the public authorities responsible for the control of medicaments".

Brazil requires the botanical classification of the medicinal plant to appear on labels and wrappers. No proprietary name is required in China either for medicinal plants or for decoctions prepared in accordance with Chinese traditional medicine. Indonesia requires that traditional drugs intended for clinical trials must be labelled with the words "intended for Clinical Trials; Not for Sale".

Gambia prohibits all advertising of products derived from plants cultivated in the country and used as traditional medicines, unless specific approval has been obtained from the Medicines Board.

Research and Institutional Mechanisms

Several African countries provide for further research on medicinal plants. The National Pharmaceutical Bureau of Burundi, the Central Laboratory at Mototo in Guinea, the National Institute for Medical Research of Tanzania, the Institute of Medical Research and Medicinal Plants of Cameroon, and the National Institute for Research on the Traditional Pharmacopoeia and Traditional Medicine of Mali have a statutory responsibility to undertake research relating to medicinal plants.

Conclusions

Despite increasing pressures for the introduction of controls, relatively few countries have enacted specific legislative measures to control either the use of medicinal plants or of herbal preparations derived from them in respect of which there is only limited data concerning their quality, safety and efficacy. Legislative texts of those countries that have developed systems for the scientific and technical assessment of the quality, safety and efficacy of medicinal plants, as well as guidelines formulated under the aegis of the World Health Organization, define the criteria for assessment and the procedures to be followed in undertaking such assessments.

As the assessment of medicinal plants cannot be guided by systematic or long experience, it is important that drug regulatory authorities wishing to regulate medicinal plants as well as assess them make the maximum use of the accumulated wisdom of those authorities with more experience in this relatively unchartered territory. The new United Nations Convention on Biological Diversity offers a stimulus to countries that wish to review the control of medicinal plants within a framework that maintains a balance between reasonable exploitation and conservation.

Traditional Medical Practitioners

Traditional medical practitioners exist in almost every society; not all prefer to be

called as "traditional medical practitioners" because with the advent of the Western system of medicine, Western medical practitioners have come to enjoy an almost monopolistic position, with the attendant status, privileges and concessions. In some countries, by law there are restrictions in the use of the term "medical practitioner" or "doctor', thus placing traditional medical practitioners at a disadvantage. It has never been easy to establish the precise role and status of traditional medical practitioners. Community acceptability, political patronage and perception as a source of last resort when practitioners of other systems have failed to provide relief are some of the factors that come into play in determining the recognition to be accorded to them. Attempts have been made by some countries to initiate a process of dialogue and consultation with a view to arriving at some compromise. Mauritania, for instance, established a working group on medicine and the pharmacopoeia:

"to determine the situation of traditional medicine and the traditional pharmacopoeia in Mauritania and, in particular:

- to examine the most appropriate and realistic ways and means of establishing an honest dialogue between the official health services and traditional practitioners in the spirit of the objectives of health for all by the year 2000 through primary health care;
- to propose the most appropriate mechanisms for identifying traditional medical practitioners who are amenable to such a dialogue in order to determine and acknowledge the part that they can play in the system of comprehensive health care (health promotion, prevention of disease and disability, diagnosis and early treatment of disease and rehabilitation."[g]

A definition of a traditional health practitioner is found in the Public Health Code of Guinea of 1997:[h] "A traditional health practitioner is a person recognized by the community in which he lives as competent to carry out diagnoses with local sociocultural foundations and contribute to the health and physical, mental, social, and spiritual well-being of the members of the locality concerned." In addition to this definition, there are separate definitions of traditional therapists; traditional midwives; herbalists; and, medico-druggists. These are reproduced below:

Traditional therapist	A person recognized by his locality as being competent to carry out diagnoses and dispense health care based on the concepts of disease and disability that prevail in that locality;
Traditional midwife	A person recognized as competent to provide health care to women and newborns before, during and after delivery, on the basis of the concepts prevailing in the locality concerned;
Herbalist	A person who has a knowledge of the customs and sells medicinal plants;
Medico-druggist	A person who has a knowledge of the customs and sells

[g] Decision No. 1831 of 9 December 1981 establishing a working group on medicine and the pharmacopoeia (IDHL, 1983, 34 (1), 122).

[h] Law No. L/97/021/AN of 19 June 1997 (IDHL, 1999, 59 (2), 162).

medical substances other than plants, of animal or mineral origin.

The practice of traditional medicine is defined as covering consultative, diagnostic, and care procedures that make exclusive use of traditional methods.

What is significant about the above definitions is that they underline the importance of community recognition and understanding of the local situation. Concepts of disease and treatment vary from system to system and from society to society; the expected role of traditional practitioners is to provide treatment in accordance with these concepts. The ability to adapt these concepts in accordance with scientific advances will considerably enhance their potential; they are best placed to gradually introduce into otherwise conservative cultures modern methods and modern drugs.

A historical perspective

Legislative provisions relating to the status of health practitioners can be best understood only by considering the evolution of such provisions in each country. The reason for this is that each country has approached the issue in a way that is unique and often dictated by considerations that are not readily comprehensible or logical. Historically, with the increasingly strong presence of those trained in Western medicine, there was a movement to entrench their role and position by providing for a virtual monopoly status. Every society has had persons – often without any formal education – with the requisite knowledge and skills to treat the sick and the disabled. They were popular because of their easy accessibility, use of language that was simple to understand and the provision of treatment at minimal or no cost. Success stories of treating those who had found no relief after taking Western medicaments and the belief that someone who is closer to one's own environment and religion is better placed to provide treatment were additional factors. In other words, traditional medical practitioners have always been a force to be reckoned with. In drafting legislation governing health practitioners, a compromise had to be reached because it was simply not politically or culturally acceptable to overlook or dismiss the important role played by traditional medical practitioners. Legislative approaches relating to the regulation of traditional medical practitioners basically fall into four categories:[10]

- The exclusive (monopolistic) system;
- The tolerant system;
- The inclusive system;
- The integrated system.

Each of the above systems are briefly described below:

The exclusive (monopolistic) system

Under this system, Western medical practitioners were the only ones to be legally recognized, at least at one point of time. Other practitioners were simply not mentioned in the legislation or the legislation clearly excluded them from functioning as medical practitioners. Examples are available from European countries, the most notable being France, and the Americas of legislation conferring a monopolistic status on university-educated physicians and allied professionals such as dentists, pharmacists and nurses. Some laws made it a specific offence to engage in medical acts contrary to the law. In certain instances, even when concessions were made, the provisions

were specifically formulated to protect the monopoly. For example, Czechoslovakia issued Ministerial Instructions in 1976 and 1981 to regulate the practice of acupuncture but only physicians with special training were permitted to use this method.

The Tolerant System

A few countries with advanced health care systems, such as the United Kingdom and Germany, do not prohibit healing by persons without the necessary qualifications specified in the law for registration as a physician of what is commonly known as "western system" or "modern system" of medicine. What the law often states is that it is an offence for anyone who is not duly licensed as such to claim to be a physician or to use the title reserved for such a person. In the United Kingdom, for instance, under the Medical Act of 1956 "any person who willfully and falsely pretends to be or takes or uses the name or title of physician, doctor of medicine… surgeon, general practitioner…or any name, title, addition or description implying that he is registered…" is guilty of an offence.

Under this system, while practising medicine is not prohibited, traditional medical practitioners nevertheless suffer from certain disabilities under the law. For instance, in the United Kingdom, only registered practitioners enjoy, under the law, the following privileges:

- Entitlement to recover in the courts fees for treatment and advice;
- Employment by and dispensing of treatment under the National Health Service;
- Holding appointments in public hospitals and other public establishments;
- Issuing such medical certificates as are required by law;
- Issuing prescriptions in respect of certain drugs as provided for by the Medicines Act 1968.

A few countries have moved towards the tolerant system by expressly mentioning in the legislation that non-modern scientific systems are permissible. For instance, the Medical Act of 1971 of Malaysia states that "…nothing in this Act shall be deemed to affect the right of any person, not being a person taking or using any name, title, addition or description calculated to induce any person to believe that he is qualified to practise medicine or surgery according to modern scientific methods, to practise systems of therapeutics or surgery according to purely Malay, Chinese, Indian or other native methods, and to demand and recover reasonable charges in respect of such practice." Another example is to be found in the Medical and Dental Practitioners (Amendment) Act 1981 of the Republic of Kiribati. It states that "nothing in the Medical and Dental Practitioners Ordinance shall affect the right of any I-Kiribati to practise in a responsible manner Kiribati traditional healing by means of herbal therapy, bone setting and massage, and to demand and recover reasonable charges in respect of such practice: provided that a person so practicing shall not take or use any name, title, addition or description likely to induce anyone to believe that he is qualified to practise medicine or surgery according to modern scientific methods." Systems of medicine exempted from the application of the law are mentioned in the Medical Council Act of 1988 of Mauritius which states that the Act does not prohibit the practice of systems of therapeutics according to homoeopathy, Ayurvedic and Chinese traditional methods.

The Inclusive System

This system is found in countries such as Bangladesh, India, Pakistan and Sri Lanka where the law recognizes two parallel systems, the traditional and the modern. The law provides for the registration and recognition of traditional medical practitioners and regulates matters pertaining to medical education, practice, and ethics.

In most countries traditional medical practitioners originally came from families where they were taught by their elders. Knowledge was transmitted from one generation to another; secret remedies remained a closely kept secret that was not recorded in writing. Universities, schools and colleges for training the different categories of traditional medical practitioners were set up much later. In the early stages, the laws governing medical practice recognized a category of practitioners without formal educational qualifications but who had been in active practice for a defined period of time. This was a legislative technique that is generally not found in laws governing Western or modern practitioners. Through this device, it was possible to bring into the mainstream of traditional medical practice thousands of practitioners who might otherwise have not been eligible for registration had formal qualifications been a statutory requirement.

In almost every society, traditional medical practitioners gained recognition through a struggle; each country has its own story of the battles that were fought. In many instances, traditional medical practitioners emerged as a strong and influential political force to be reckoned with – even though they were numerically not large, they had their supporters in large numbers. State patronage has always played an important role. The creation of a separate Ministry of Indigenous Medicine in Sri Lanka, for instance, was an important turning point in the country's medical history.

The Integrated System

The integrated system represents a stage where the inclusive system has evolved into a system that provides for the two professions – western or modern medical practitioners and traditional medical practitioners – to work together as one team.

China provides the best known example of this integrated system. In South Asia, Nepal can be described as having adopted this system. The Chinese system, with the well-known example of barefoot medical doctors, can be best understood only within the country's complex political context. Indeed, there are concerns as to whether the Chinese system can be easily tried out elsewhere with the same degree of success.

An integrated system offers an opportunity for each system to offer its best for the welfare of the patient. In actual practice, however, some problems can arise. For instance, drug interactions are not well-studied and in prescribing medicines a choice would almost invariably have to be made between a Western drug and a herbal product, for instance.

Conclusions

This review of traditional medical practitioners highlights that different countries have approached the issue from different perspectives and that there is no single legislative model prevalent throughout the world or any particular geographical region. Each country has a fairly complex body of laws, regulations and codes of conduct applicable to traditional medical practitioners. It is not possible to comment on these laws unless they are examined in the light of the laws, regulations and codes

of conduct applicable to modern or Western medical practitioners.

Towards the Future

It cannot be gainsaid that for the vast majority of the population in most rural societies traditional medical practitioners will continue to provide the only source of medicine that is easily available at a reasonable cost. While exclusion, through experience and practice, of products on the basis of evidence of short-term toxicity will continue to operate as a safety valve, the need for assessment based on appropriate criteria has to be met sooner or later by all countries. Guidelines produced by WHO exemplify that such assessments are not unrealistic even in countries with limited resources. The challenge is to devise "appropriate criteria" using cost-effective methods. There must be a dialogue leading to consensus and traditional medical practitioners themselves must be in the vanguard of the movement to rationalize the traditional medicine market.

It augurs well for the future that the WHO Regional Office for South-East Asia, in particular, has been promoting the integration of traditional medical practitioners into the district health system (DHS). From a regulatory perspective, the integration of traditional medical practitioners and traditional medicine products into the district health system (DHS) must be based on the following guiding principles:

Principle 1: The DHS must recognize that plural systems of health care exist and that each system must be accorded recognition.

Principle 2: Recognition of plurality is not necessarily inconsistent with the obligation to ensure that those basic principles of public health and safety are not compromised.

Principle 3: The determination of the respective role to be assigned to each system must involve consultations with recognized practitioners of each system and consumer groups or community leaders representative of users. Such consultations must be based on the premise that health-care products must conform to acceptable standards of quality, safety and efficacy, and that the numbers who use such products or the political patronage extended to such products or the practitioners thereof are irrelevant to the scientific process that must necessarily take place to determine quality, safety and efficacy. Unsafe products or those of doubtful quality must be eliminated from the market; the support of relevant groups must be mobilized to ensure that such products are no longer marketed or used. There must be an appropriate legislative basis to mandate the process of evaluation and to authorize products to be marketed or to be eliminated from the market. Through a phased-in approach all products can be assessed on a systematic basis. Even countries with limited manpower have been able to progress by making extensive use of the experience of countries with more manpower. Unless genetic and other factors dictate otherwise, a product approved by many countries must be assumed to be suitable for inclusion in the list of essential medicines for community use.

Principle 4: Products that are permitted to be used must be made available through appropriate channels, not excluding those that have been devised for a particular type of product. Where an integrated approach to distribution is feasible, such an approach must be developed through a process of consultation and collaboration. Practitioners of each system must respect the

strengths and limitations of each system and the need to supplement delivery systems devised for each system. Managers of DHS must assume the responsibility for ensuring that the delivery system can meet the demand. A management committee must be in place to ensure that products are made available to the extent possible. Where health insurance or social reimbursement schemes exist, traditional medical products must be considered as eligible products.

In this first year of the new millennium we must have the modesty to recognize that no single system can meet all our health-care needs and the courage to ensure that products that are not safe must not be permitted.

References

1. Wolffers I. Traditional practitioners and western pharmaceuticals in Sri Lanka. *The Context of Medicines in Developing Countries.* Amsterdam. Klluwer Academic Publishing. 1988: 47–56.
2. Nakajima H. Our earth and our health. *Natural resources and human health-plants of medicinal and nutritional value.* Amsterdam. Elsevier. 1992: 1.
3. Akerele O. Nature's medicinal bounty: don't throw it away. *World Health* Forum. 1993; 390.
4. Reid W.V., et al. A new lease on life. *Biodiversity prospecting: using genetic Resources for sustainable development.* Washington D.C. World Resource Institute. 1993: 7.
5. Kobe Conference. Plants of medicinal and nutritional value. *Natural resources and human health.* Amsterdam. Elsevier. 1992: xi.
6. De Klemm C. Medicinal plants and the law. *Conservation of medicinal plants.* Cambridge. Cambridge University Press. 1991: 265.
7. WHO. Guiding principles for small national drug regulatory authorities. In: *WHO Expert Committee on Essential Drugs: Fifth report. WHO Technical Report Series.* Geneva. World Health Organization. 1992; 825: Annexure.
8. Jayasuriya D.C. The regulation of pharmaceuticals in developing countries: legal issues and approaches. Geneva. World Health Organization. 1985.
9. WHO. African traditional medicine. Brazzaville. WHO. 1976; (TRS No. 1):20.
10. Stepan J. Legal aspects. Traditional Medicine and Health Care Coverage. Geneva. WHO. 1983: 290–313.

Standardization, preclinical toxicology and clinical evaluation of medicinal plants, including ethical considerations

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Inadequate standardization of medicinal plants, unacceptable preclinical toxicology studies and inappropriate uncontrolled and badly designed clinical trials form the triad of constraining factors which have held back the use of medicinal plants for health development and belied the longstanding hopes that research on medicinal plants would lead to a host of new drugs.

Standardization

When a medicine is administered to a patient, the doctor who prescribes the medicine needs to be certain that the medicine contains the correct amount of the right substance and does not contain any impurities. Only then will the medicine induce its therapeutic effect and not induce any toxic effect due perhaps to contaminants. This is only possible if the herbal medicine has undergone a process known as standardization. It is this lack of standardization of herbal remedies which acts as a constraint to the use of these medicines in allopathic hospitals. It is also one of the constraints preventing an increase in the export of traditional medicines from third world countries with the unique heritage of abundant unlimited biodiversity. Only if herbal medicines are well standardized will countries purchase such medicines. Only if the allopathic doctors are convinced that every sample of a herbal drug contains the same amount of active constituents will they prescribe such medicines.

The need for proper standardization has also been recognized by practitioners of the traditional systems of medicine. At the 3rd International Congress of Traditional Asian Medicine held at Mumbai from 4–9 January, 1990, this point was repeatedly highlighted by a large number of participants who did not belong to the allopathic system.[1] A group of Ayurvedic research workers stressed the importance of developing good methods for standardizing crude extracts, decoctions and compound formulations which consist of different ingredients. It was clearly stated that the technology available at that time, 10 years ago, was not able to develop suitable quality control criteria for mixtures and compound preparations.

There are several factors which have acted as constraints in the development of appropriate methods for standardizing herbal medicines. Some of these have

been clearly brought out by Handa in his contribution to the Regional Consultation on Development of Traditional Medicine in South-East Asia Region held in New Delhi from 14–17 September, 1999.[2] Bottlenecks in the standardization of herbal drugs include dependence on wild sources for the plants leading to variation in quality, adulteration and substitution of the active plant material by inactive, cheaper varieties of non-medicinal plants, and in many cases incorrect identification of the plant itself. This is because the same plant may have different local names at different locations while sometimes different plants have the same local name. A good example of the latter is that the plant which is commonly known as *Punarnava*, a quality-of-life enhancer, is collected under the botanical name of Boerhaavia diffusa and also collected under the name Trianthema portulacastrum (*Vishakarpara*). This would certainly lead to problems in standardizing Boerhaavia diffusa if some Trianthema portulacastrum is also contained in the sample.

The loss in medicinal plants due to ecological degradation has led to a shortage of the actual plants and substitution by other non-medicinal plants. One example is the preparation of a herbal drug from the bark of the plant Caesalpinia sappan (*Patranga*). When this bark is collected, the bark from other plants such as Pterocarpus marsupium (*Vijayasara*), Gluta travancorica and Toona ciliata (*Nandivriksha*) or Cedrela toona are substituted for Caesalpinia sappan. Other examples which have been found in India relate to the substitution of the bark of Saraca indica (*Ashok*) by the bark of Trema orientalis (*Jivanti*) and substitution of the plant Holarrhena antidysenterica (*Kutaja*) by the plant Wrightia tinctoria (*Asita kutaja*). Similar instances of adulteration can be seen in many countries of South-East Asia.

The need for standardization has long been recognized. The World Health Organization organized an Inter-Regional Meeting on Standardization and Use of Medicinal Plants at Tianjin in China in November 1980.[3] Participants clearly pointed out the problems relating to standardization of herbal medicines and the tremendous need for immediate work in this field. A second conference, also organized by the Western Pacific Regional Office of the World Health Organization at Tokyo in 1986, identified three areas of priority research.[4] Research on standardization was one of these areas. Standardization, it was stressed, means standardization of the raw material, standardization of the method of production and quality control of the final product. The Regional Consultation at New Delhi held in 1999[2] again highlighted the need for standardization but added some new features to this issue.

Parikh[2] in his presentation at the New Delhi meeting organized by the World Health Organization made a strong plea for cultivation of medicinal plants rather than collection from the wild. Standardization of herbal preparations from plants which are cultivated would be easier for the following reasons. The availability of the plant material would be assured and the supplies could be controlled. The quality of such plants would be reliable, identification totally accurate and adulteration would not be an issue. Further, in this system the environment would be maintained. Other possible advantages would be the possibility, in these controlled conditions, of carrying out agronomic manipulation and genetic improvement.

A reference was also made by Parikh[2] to the global market for medicinal plant

products which had been estimated to be of the order of five trillion dollars in 2050. Only those countries which invest immediately and well in setting up standardization of herbal products could hope to exploit this worldwide growth in the need for herbal products. Countries will, in the years to come, not allow products which are not standardized to be sold.

Another major constraint in setting up standardization procedures is the non-availability of standards against which products could be assessed by chemical or bioassay methodology.

Advances have been made in the last 10 years in the standardization of herbal products. It is expected today that the following macroscopic, microscopic, physicochemical and biological tests should have been carried out before any plant material is released for use.

- Macroscopic examination;
- Microscopic examination;
  e.g. Anatomical structure
  Detailed study of fragments;
- Physiochemical testing
  e.g. Boiling point;
  Freezing point;
  Absorption coefficient;
  Loss on drying;
  Ash value;
  Refractory index;
  Optical ratio;
  Water/alcohol soluble solid;
  Spectroscopic analysis;
  Thin-layer chromatography – R.F. value;
  Gas liquid chromatography.
- Biological testing where appropriate
  e.g. Digitalis bioassay.

A big step forward towards improved standardization of plant medicines was the publication in 1998 of the "Quality control methods for medicinal plant material"[5] by WHO Geneva, which followed the 1992 document "Quality control methods for medicinal plant material". Investigators interested in details of the methodology proposed for use are requested to study the publication brought out in 1998.

Another positive development has been the publication of Herbal Pharmacopoeas which have laid down the standards for the different procedures. WHO has recently brought out its first Pharmacopoea containing standards for plants. Other pharmacopoeas available include the British Herbal Pharmacopoea (1990), Japanese Standards for Herbal Medicines (1993), Ayurveda Formulary and Standards for Ayurvedic Formulations (1978), the Central Council for Research in Indian Medicine "Pharmacopeal Standard for Ayurvedic Formulations (1987), the Ayurvedic Pharmacopoea of India (1989), the Unani Pharmacopoea (2000), National Formulary of Unani Medicine – Part I (1984) and Part II (2000), the Pharmacopoea of the People's Republic of China and the Indian Herbal Pharmacopoea (1998), volumes one and two.

In spite of these advances, standardization of herbal preparations needs to be given a big boost by governments in the Region if the tremendous potential of ancient heritage and biodiversity is to be used for the people of the countries for delivering improved health care. Herbal medicines would be much more widely used nationally and internationally, would be much more accepted and would tremendously enhance health care if improved standardization provides credibility to the quality of the medicines used. Unfortunately, there are very few centres for standardization of herbal products in the Region, too few qualified and trained experts in this area of expertise, and a lack of sustained funding for standardization

activities. These shortcomings need to be corrected.

Preclinical Toxicology

Preclinical toxicology studies in animals are carried out to determine the safety of medicinal plants and herbal preparations before administering these to humans for the purpose of evaluating clinical effectiveness. The quantum of toxicity tests to be carried out is defined in national laws, and the drug regulatory agencies of the countries ensure that acute, subacute and chronic studies in animals are carried out and the results carefully assessed. These requirements were, till recent years, the same for new synthetic molecules never before administered to man and for herbal medicines used for generations and, in many instances, even being actually used at this time.

It was only in 1980 that the first author, in his keynote address at the First World Conference in Clinical Pharmacology in London, stated that extensive preclinical animal toxicology studies for synthetic drugs were not necessary for herbal medicines used for generations and even being used at the present time.[6] He proposed a shorter, six-week toxicology model on two species of animals which would be realistic, save time and resources and prevent unnecessary animal sacrifice. Although there was considerable concern as regards the ethical implications of this shortened toxicology testing model, it has been accepted by and large by the regulatory authorities of a large number of countries including India, and by the World Health Organization.

Another decision by the Swedish drug regulatory agency helped in the acceptance of reduced toxicology testing for medicinal plants. The authorities approved clinical evaluation, in a limited number of human subjects, of a plant Zaopatle – *Montanoa tomentosa* – for its luteolytic effect and possible use as a contraceptive. The animal toxicology tests carried out before clinical evaluation were:

- Thirty rats were administered the decoction at three doses for four weeks;
- Four female monkeys were administered the decoction once daily for 30 days;
- Four adult dogs were given the concoction for 12 weeks. The usual toxicology profile after administration of the substance was studied in these three species.

The reason for the Swedish authorities putting zaopatle on the fast-track reduced toxicology profile was the great need for early development of a contraceptive and the fact that zaopatle had been used for its antiovulatory effect as a herbal tea in Mexico. Such use was first described by the Spanish monk Fray Bernadino de Sahagun in 1575.[7] In recent years, drug regulatory authorities of several countries have allowed clinical evaluation of plants for the treatment of HIV/AIDS with very minimal toxicological studies.

The World Health Organization first accepted the fact that traditional medicines may need shorter preclinical toxicological evaluation 10 years after the Chandigarh proposal at a WHO Consultation on Traditional Medicine[8] and AIDS in 1990 when the report of the Consultation stated: "The range of preclinical tests available for evaluation of a synthetic drug, before beginning clinical trials, is well known. What is not known, however, is whether such preclinical tests need to be so extensive for herbal remedies". The group suggested that herbal remedies were not really new drugs and that these had been

used for a long time and information regarding its use was available. They concluded that a more limited range of preclinical tests may be adequate for traditional remedies and that this limited testing would be justified by the remedy's previous use in human disease. They left it to individual countries to define their own needs but even suggested that some herbal remedies could be directly approved for clinical evaluation without preclinical toxicological tests.

It is interesting to note that, to a large extent, this shortened toxicology profile was accepted because of the urgent need to discover a new contraceptive or an anti-HIV herbal remedy.

WHO thinking on this subject was further consolidated when it published[9] in 1991 the WHO Guidelines for Assessment of Herbal Medicines. The principle enunciated here was that "if a traditional medicine has been used without harm, no specific restrictions or regulatory action should be undertaken" unless there is a reason for it.

The WHO "Research Guidelines for evaluating the Safety and Efficacy of Herbal Medicines"[10] brought out in 1993 by the Western Pacific Regional Office in Manila reiterates that not all tests are required for every herbal medicine. A list of tests to be carried out has been provided.

What generally comes out in a later WHO document published in 1996[11] is that if adequate study of the published literature demonstrates lack of harmful effects of a herbal remedy, then clinical evaluation can be undertaken without undertaking animal toxicology studies. If, however, the literature survey does not document long-term use without harm, then animal toxicology studies should be undertaken before clinical evaluation. It makes the very interesting statement that "prolonged and apparently uneventful use of a substance usually offers testimony of its safety". The document again stresses the importance of literature search and the absence of side-effects after long-term use. It, however, for the first time, brings out the need for tests for systemic toxicity, carcinogenicity and teratogenecity as it may not be easy to document the absence of these from the long-term use of herbal remedies.

In recent years, drug regulatory authorities of several countries have allowed clinical evaluation of plants for the treatment of HIV/AIDS with very minimal toxicological studies.

A few important points will be made at this stage before delineating a toxicological profile for herbal remedies. All the recommendations cited above are for herbal remedies used as such for generations. If the method of preparation is changed, or if a product – a chemical entity – is being sought to be clinically evaluated, or if two new mixtures or products are combined, then it becomes a new drug – not a traditional medicine. All the requirements for a new drug would apply and the drug regulatory authorities would require the full range of toxicity studies to be carried out. Thus, while only very limited studies were needed for the use of *Picrorhiza kurroa* as a hepatoprotective substance, the full range of toxicology tests had to be performed for Picroliv– the compound obtained from *Picrorhiza kurroa*.

Another point which needs discussion is to examine the tenet that if no harm has been found after the use of a herbal medicine for generations and there is no

documentation of such an effect, then the preparation can be used clinically. Lack of documentation of a side-effect or a harmful effect does not always mean that there is no such effect. It may not have been observed or, even if observed, it may not have been documented. In fact, the WHO publication[13] on "General Guidelines for methodologies on research and evaluation of traditional medicine" makes this point when it states clearly "Absence of reported or documented side-effect is not an absolute assurance of safety of herbal medicine. However, a full range of toxicology tests may not be necessary. Tests which examine effects that are difficult or even impossible to detect clinically should be encouraged. Suggested tests include immunotoxicity, genotoxicity, carcinogenicity and reproductive toxicity". This latest WHO Guideline (2000)[13] does not take a step backward but takes a broader perspective on the need for toxicological evaluation of herbal remedies. It still reiterates that: "Only when there is no documentation of long historical use of a herbal medicine or when doubts exist about its safety, should additional toxicity studies be performed". There appears to be some anomaly between the two quotations from the same document but then this field is full of anomalies. It is noteworthy that due to a resurgence of interest in traditional medicines much thinking is going on and will continue to go on in this area of herbal medicine preclinical toxicology. The need for WHO to assist countries in regulating the use of traditional medicines regarding their safety and efficacy was one of the specific recommendations made by the Ministers of Health of the WHO South-East Asia Region at their meeting held in New Delhi in September 1998.[12]

What comes out very clearly is that there has to be flexibility in the toxicological requirements for herbal medicines and that no rigid framework, as has been prepared for synthetic drugs, will ever be possible. So much depends on the way the extract or plant is administered, the duration of use, the dose and so many other factors that the framework established by the Chandigarh group in 1980 and broadly accepted by the Indian Council of Medical Research and the World Health Organization can remain only a framework. The actual requirements may have to be slightly altered from plant to plant. The actual tests to be carried out in the Chandigarh model and the duration have been described in Tables 1 and 2. The tests recommended by WHO are given in Table 3. This has been given in detail in the 1996 document of the Western Pacific Region of WHO.[11] Another point which needs to be made is that evaluation of literature does not mean only anecdotal information that a plant has been used for centuries without inducing any side-effect. This sort of information has very limited value. However, if some clinical studies have been carried out then the value of absence of side-effects is enhanced. These clinical studies should, however, be looked at carefully especially with regard to the study design, the number of patients, the specific diagnosis, the dose used, the duration of administration of the herbal medicine, and the criteria used for assessing the treatment.

Researchers, public health administrators and drug regulatory agencies are interested in developing guidelines for toxicological assessment of herbal remedies which would, on the one hand, ensure that patients are not subjected to the toxicity of the remedies and, on the other, not hamper the development and use of these medicines. The modified Chandigarh model[14] being used in several countries could be a starting point. This

Table 1. Tests required for subacute toxicology studies

Liver function	Serum Albumin/Globulin, Total proteins Alkaline phosphatase Bilirubin SGOT/SGPT
Renal function	Blood Urea Serum Creatinine
Haematology	Haemoglobin RBC, WBC – Total and Differential, ESR, PCV
Others	Cholesterol Glucose

Table 2. Duration of toxicity studies

Single administration or repeated administration for less than one week	2 weeks to 1 month
Repeated administration from one week to four weeks	4 weeks to 3 months
Repeated administration between one and six months	3 to 6 months
Long-term repeated administration for more than six months	9 to 12 months

Table 3. Toxicity profile recommended by WHO for herbal medicines[10]

Acute toxicity	Tests should be performed on two species – one rodent and one non-rodent. Males and females from one species at least. Five animals per group per sex in rodents and at least two animals per sex in non-rodents. Oral route orally or route of intended administration Different dose levels
Observation studies	Toxic signs, reversibility of signs. Animals to be observed for 7–14 days. Autopsy of any animal which dies with histopathology of organ showing macroscopic changes at autopsy.
Long-term toxicity	Two species – one rodent and one non-rodent. Both sexes to be used. Rodents – 10 male and 10 female. Non-Rodents – three males and three females. Route – expected route of clinical use. Administration period will vary with expected period of clinical use. Three different dose levels administered seven days a week.
Observation studies	General signs, body weight, food and water intake - Haematological examination - Renal and hepatic function tests.
Other tests of appropriate period of administration recommended	E.C.G.; Visual and Auditory tests.

consists of the usual acute toxicity studies complemented by six-week subacute toxicology studies with three doses in two phylogenetically different species like the rat and the rabbit species and a control series. The following observations are made daily: weight, food intake, water intake and general behaviour. The following tests for looking at haematological, hepatic and renal effects specially need to be carried out before and at the end of six weeks before sacrificing the animal.

An autopsy has to be carried out on every animal at the end of the study and on any animal which died during the course of the study. Histopathological studies need to be carried out on every organ at the autopsy both for control and herbal remedy-treated animals on the high dose. If the animals on the high dose show histopathological changes then the same histopathology should be carried out on animals administered the intermediate dose.

Other tests could be added on if thought necessary. These are tests for immunotoxicity, carcinogenicity, genotoxicity and reproductive toxicity. Teratology studies should also be carried out, as has recently been completed[15] for a combination of *Embelia ribes* (*Vidanga*), *Piper longum* and borax which is now being evaluated in Phase II clinical trials as a contraceptive. Such an effort was described in ancient textbooks of Ayurveda 2500 year ago.

Earlier studies have also shown that this model is effective in detecting toxicity. *Semecarpus anacardium* (*Bhallatak*) was going to be clinically evaluated as a contraceptive but the six-week toxicity study demonstrated an effect on the white blood count which was not acceptable.[16] The plant was therefore not investigated further.

It is hoped that this review would help investigators to fashion the toxicology requirements for specific plants depending on their earlier use, experimental results and the manner in which it is sought to be used.

Clinical Evaluation

Clinical trials in the past have been carried out largely by clinicians and clinical pharmacologists with experience in clinical trial methodology of synthetic drugs but no background of herbal or traditional systems of medicine, or by traditional medicine practitioners and experts who have very little idea about the conduct of clinical trials according to modern concepts of clinical pharmacology.

The results of such trials are therefore not acceptable to the larger scientific community and the practitioners of the modern system of medicine, allopathy, who need clear-cut evidence of efficacy and lack of side-effects of herbal remedies in well-conducted clinical trials before they would consider use of such medicines.

An important challenge for clinical researchers in the 21st century is to conduct clinical evaluation of traditional medicines within the specific framework of rigorous clinical pharmacological principles without ignoring or trampling on the concepts and practices of traditional systems of medicine (Chaudhury, 1992).[14] Fortunately, more and more multidisciplinary centres are being developed with this objective in mind. It is also salutary that specialists and practitioners of the Chinese Traditional System of Medicine in China and specialists in Ayurvedic and Unani medicines in India have no objection to the use of modern concepts of the methodology of clinical trials in evaluating the efficacy and side-effects of herbal preparations used in these traditional systems (Chaudhury, 2001).[17] Conside-

rable effort has been made in the past two decades to develop a herbal contraceptive keeping in perspective the concepts of Ayurveda and the traditional systems of medicine.[18] Again, the Indian Council of Medical Research has taken the plant *Pterocarpus marsupium* from its use in folklore and Ayurvedic medicine to Phase III clinical evaluation for the treatment of diabetes mellitus using well-accepted clinical pharmacological principles.[19] It is now being handed over to industry for pharmaceutical development and marketing.

The basic principles in the clinical evaluation of herbal remedies are, of course, the same irrespective of whether a synthetic compound or a herbal preparation is being evaluated. However, there are also very important differences which need to be kept in mind. In the next few pages these basic concepts will be delineated. The differences inherent in clinical evaluation will then be described with examples from the Indian programme, which has taken note of these differences and modified the clinical trial methodology accordingly. Finally, the grey areas still awaiting clarification and elucidation will be discussed.

Before any drug is administered to a human subject or a patient for purposes of clinical evaluation, the approval of the national drug regulatory authority has to be obtained. While this is mandatory and essential for all synthetic drugs, the national Government may, in some circumstances, allow traditional medicines to be evaluated without formal or informal approval of the regulatory authority. This has to be clearly spelt out. In India, for example, the Office of the Drugs Controller General allows, without further need of approval, plant preparations described for their therapeutic effect in 27 ancient books and treatises. However, the preparation needs to be made and administered in exactly the same way as has been described in those books. A synthetic or traditional medicine cleared for use for a certain disease condition needs fresh approval if it is to be used for a different condition or if it is to be administered by a different route, or if it has excipients not stated in the ancient books referred to earlier. A product or a new combination of herbal medicines will be treated as a new drug and will have to be approved for clinical evaluation.

In addition to approval of the national drug regulatory agency, an investigator has to obtain the clearance of the Institutional Ethical Committee and, if necessary, clearance of the National Ethical Committee or the Ethical Committee of the agency supporting the clinical evaluation. Thus, when *Vicoa indica* was clinically evaluated as a herbal contraceptive based on observations made by public health personnel on its use in a tribal community, ethical approval was obtained from three agencies – the local Institutional Ethical Committee at the Postgraduate Institute of Medical Education and Research, Chandigarh, where the trial was conducted, the Ethical Committee of the Indian Council of Medical Research, New Delhi, and the Ethical Committee of the Population Foundation of India, which supported the clinical trial. (Chaudhury, 1983).[20] This is not the place to describe the composition and functioning of Institutional Ethical Committees or the different nuances of obtaining informal consent of each person who enters the trial, although a little more will be mentioned about informed consent when discussing some ethical aspects of clinical evaluation of herbal products.

Once informed consent is obtained, then clinical evaluation could begin. The

chief investigator is solely responsible for the trial and can stop the trial any time he/she feels that it is not in the interest of the patients to further carry on the trial. This could be due to serious adverse effects being observed or could even be because results at some other centre published recently had clearly shown the benefits of a particular treatment. In such circumstances, it may be difficult to continue a trial which would provide perhaps the same result two years later. The reader is referred to the Ethical Guidelines for Biomedical Research on Human Subjects published by the Indian Council of Medical Research in 2000.[21]

Clinical evaluation of any synthetic or plant product is carried out in five phases.

Phase I

The objective of Phase I of a clinical trial is to determine the safety of the maximum tolerated dose of the herbal product in healthy adults of both sexes. At least two subjects should be administered each dose to establish the safe dose range, pharmacodynamic effects, and adverse reactions, if any, with their intensity and nature. An investigator trained in clinical pharmacology should carry out these studies and clinical emergency help and resuscitation facilities must be available at the centre where the Phase I trials are being carried out. Such a Phase I study has recently been carried out with a herbal preparation being evaluated for its contraceptive effect (Chaudhury, 2000).[18]

Phase II

These are controlled studies conducted in a limited number of patients of both sexes to determine therapeutic effects, effective dose range and further evaluation of safety. Normally, 20–25 patients should be studied for assessment of each dosage. The studies are usually limited to 3–4 centres. The studies should be carried in a randomized double-blind manner unless this is not possible. However, a well-planned and well- conducted single-blind study in certain circumstances, particularly with herbal medicines, could also yield unequivocal and scientifically valid conclusions.

Phase III

The purpose of these trials is to obtain adequate data about the efficacy and safety of drugs in a larger number of patients of both sexes in multiple centres, usually in comparison with a standard drug and/or a placebo if a standard drug does not exist for the disease under study.

Phase IV

After approval of the drug for marketing, usually given after assessment of the results of Phase III trials, the Phase IV studies or post-marketing surveillance is undertaken to obtain additional information about the drug's risks, benefits and optimal use. A rare side-effect or a side-effect not recorded in strictly controlled trials could be discovered in Phase IV studies.

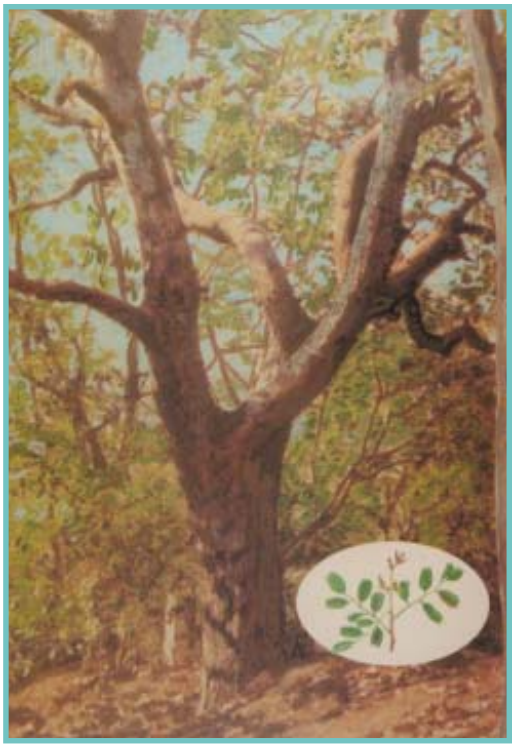
Phase V

These are studies in which the drug is used as it would be used in the community. The strict monitoring of Phase II and Phase III clinical trials and the follow-up inherent with post-marketing surveillance would both be absent in these Phase V clinical trials. The efficacy and side-effects of the drugs would be seen in field conditions.

Multicentric trials

Reference has been made earlier to multicentred studies. It is important to carry out such studies and yet it is not easy to organize, coordinate and conduct these

studies. The same protocol should be used and the trials should be conducted at the same time. All methods, whether laboratory methods or methods for the recruitment of subjects or methods even for asking questions to elucidate information, should be standardized. There should be centralized data management and analysis. There should be a Coordinator or a Clinical Trials Monitor who would visit each centre where the trial is being carried out to confirm that at each centre the trial is being conducted as it should be. Otherwise laxity in following inclusion and exclusion criteria during recruitment of subjects, different ways of dealing with drop-outs at different centres or using different reagents and kits at different centres would vitiate the trial and render months of hard work unacceptable.



Vijayasar - developed as an anti-diabetic drug in India.

Randomization

It is accepted today that all Phase II and Phase III trials should be randomized so as to rule out bias. As far as possible this should be followed. Randomization is possible in nearly every comparative clinical trial and, while there may be problems in carrying out double-blind studies, there should be no problem in carrying out randomized Phase II and Phase III clinical trials.

Blind Studies

It is again generally accepted that well-planned and well-conducted clinical trials should always be double-blind studies. Such trials increase the confidence of the scientific community and clinical fraternity in accepting the results of these studies. A double-blind study is one in which neither the doctor carrying out the trial nor the patient knows who is receiving what drug. A single-blind study is a study where either the investigator or the patient – one of these – does not know which is the drug and which is the standard for comparison. Usually the doctor recording the condition of the patient knows the drug group but the patient does not know what he is receiving. However, it could be the reverse also – the doctor not knowing who has received what drug while the patient is aware of this. It needs to be clearly brought out that the gold standard of double-blind, randomized multicentred clinical trials is not the only way to determine the effectiveness, particularly of traditional medicine, and that very useful results can be obtained in single-blind and even, in preliminary investigations, in open studies. Thus, at one stage, an open trial of the plant *Pterocarpus marsupium* had to be carried out and formed a vital link leading to double- blind, flexible dose, randomized clinical evaluation of the plant.[19] Similarly, the therapeutic effect of a thread coated

with extracts of these plants was found as effective as surgery in anal fistula in an open, randomized, multicentred trial.[22]

However, it is a challenge for the clinical pharmacologist to plan, as far as possible, double- blind randomized multicentred clinical trials even with traditional medicines. The double-blind flexible dose, randomized, multicentred trial of *Vijayasara*, *Pterocarpus marsupium*, in diabetes mellitus was one such study.[19]

Another ongoing study is a double-blind, randomized, multicentred trial of *Pipallyadi Vati* as a herbal contraceptive.[18]

Use of a placebo

The use of a placebo is decreasing in comparative clinical trials because in most clinical conditions there already exists a treatment. The new drug should therefore be compared against that existing drug. It would be unethical to give a placebo, i.e., a similar looking, smelling tablet containing no medication to one group of patients for a disease when a known remedy exists. A placebo still has a role in conditions where no cure exists. In such conditions an open trial with objective laboratory and clinical measurements to record the effects of a new drug as compared to a placebo may also be justified.

Single-Case Studies

In addition to open, single-blind and double-blind clinical trials, it is also possible to obtain information from single-case studies for the evaluation of the efficacy of a herbal medicine. This has been particularly pointed out in the WHO Document "General guidelines for methodologies on research and evaluation of traditional medicine", which was discussed at a WHO meeting in Hong Kong in 2000.[13] The report states "Such studies, i.e., single-case studies, are appropriate for the development of research hypotheses, testing those hypotheses in daily clinical practice and referring clinical techniques". To be meaningful, single-case designs should have a common protocol which could be the basis of collaborative research between practitioners.

Observational Studies

Another approach which could be used is to carry out Observational Studies. The traditional medicine practitioner continues his treatment without modifying it in any way and the clinical investigator observes whether clinical improvement takes place. The data are recorded by the traditional medicine practitioner and separately by the investigator carrying out these studies. More studies of this type should be carried out. It could provide a valuable model for studying both the efficacy and the safety of herbal medicines. Such a study is in fact being coordinated by the first author in Mumbai where the allopathic doctors at a well-known allopathic hospital are working together with traditional medicine practitioners in a leading Ayurvedic hospital. The protocols are prepared jointly but patients are being treated at an Ayurvedic hospital. The Ayurvedic physi-cians give the treatment for bronchial asthma and arthritis according to an agreed protocol. The results of the treatment are assessed separately by the physicians of the modern system of medicine and by the Ayurvedic physicians. These are then compared as regards the effectiveness of the treatment and the side-effects seen.

Indian Council of Medical Research Network

In the past 12 years, the Indian Council of Medical Research (ICMR) has set up a unique network throughout the country for carrying out controlled clinical trials of

herbal medicines. The programme, first described by the author at a meeting on Alternative Medicine organized by the National Institute of Health in Washington in August 1977, is monitored by a Scientific Advisory Group consisting of persons from the Allopathic, Ayurveda and Unani systems of medicine. This group also contains experts in pharmacognosy, toxicology, pharmacology and clinical pharmacology as well as clinicians and experts in standardization and quality control.

The infrastructure consists of the core group at the ICMR Headquarters at New Delhi, three Advanced Centres in Traditional Medicine and different expert groups for every condition being studied. There are, for example, at this time special expert groups for bronchial asthma, arthritis, hepatitis, benign hypertrophy of the prostate, filariasis and cancer. The three Advanced Centres are at the Central Drug Research Institute, Lucknow (Pharmacology and Clinical Pharmacology), the National Institute of Epidemiology, Chennai (Preparation of protocols, randomization and monitoring of results), and at the Regional Research Institute, Jammu (Standardization). There are specialized centres in the network such as the Institute of Himalayan Ecology at Palampur for the study of special features of medicinal plants needing study, the National Institute of Education and Pharmaceutical Research, Chandigarh (Bioavailability Studies) and the Central Indian Medicinal Plants Organisation at Lucknow (growing medicinal plants). In addition, there are more than 25 clinical trial centres spread throughout the country for carrying out multicentred studies.

The trials are planned and protocols prepared by the whole group. All trials are comparative, controlled, randomized and double-blind unless there is reason for carrying out a single-blind study. No compromise is made on the quality of the scientific clinical trials. Although the trials are planned by the multidisciplinary central group, they are carried out at the foremost centres of allopathic medicine in the country. This is the reverse of the Mumbai studies where the clinical evaluation is being carried out at the Ayurvedic hospital. The Chief Investigator of any one study is always an outstanding clinical researcher in the field. The results obtained are monitored by the whole group. Only standardized preparations with predetermined markers are used for these trials.

Using this network, the Council has demonstrated that a medicated thread coated with *Euphorbia neriifolia (Snuhi), Achyranthes aspera (Apamarga*) and *Curcuma longa* is as effective as surgery for the treatment of anal fistula.[22] The Council has also shown that *Picrorhiza kurroa* is effective in hepatitis[23] and that *Pterocarpus marsupium* is again an effective anti-diabetic drug.[19] *Pterocarpus marsupium* will soon be handed over to the industry for marketing. The results of these clinical trials will be acceptable to clinicians at allopathic hospitals because of the sophisticated clinical pharmacological methodology used in these trials with only well- standardized products.

Selection of patients

In any clinical trial the right drug has to be given to the right patient. In allopathic medicine all cases of asthma, arthritis, hepatitis or diabetes of a particular variety are considered as one entity and the cases are divided into two groups by randomization procedures. One group is given the standard drug and one the new drug. While this concept and methodology is appropriate for synthetic drugs, it need not always be appropriate for herbal medicines

used in traditional systems of medicine such as Ayurveda and the Unani system of medicine.

This important issue was first highlighted by the first author at the WHO meeting on "General Guidelines for methodologies on research and evaluation of traditional medicine" held at Hong Kong in April 2000, at the Global Conference on Research for Health Development at Bangkok on 10 October, 2000, and subsequently in the *British Medical Journal* in 2001.[17]

In many of these systems, the *Prakriti* (Ayurveda) or *Mijaj* (Unani Medicine) determines the effectiveness of a particular traditional medicine. This could be described as a temperament or the psychomotor character of the individual.[24, 25] A person could have predominantly any of the following temperaments: *Vata, Pitta* or *Kapha*. A hypertensive patient with *Vata* or *Kapha* temperament should be treated with *Samirpannaga rasa*, but this will not work in a patient with a *Pitta* temperament. He needs to be treated with *Tagaradi Churna*. Another simple example is the treatment of fever of the malarial type (*Vishama jwara*). A combination of the bark of *Azadirachta indica*, *Zingiber officinale* (*Sunti*) and *Piper nigrum* (*Maricham*) would be effective in the *Kapha* type of individual but not in the *Pitta* or *Vata* type. There are two preparations containing *Commiphora wightii (Gum Guggulu)* for the treatment of arthritis. *Mahayograj Guggulu* is used in *Kapha* patients while *Yograj Guggulu* is used in *Pitta* patients. This perspective should therefore be kept in mind when designing clinical trials with Ayurvedic or Unani medicines.

Sometimes a traditional medicine useful for one type of patient is actually harmful when administered to a patient with the same disease but having a different temperament. *Kanaka* is effective in patients of bronchial asthma with a *Kapha* temperament but will cause congestion in patients with a *Pitta* temperament. The fresh juice of *Momordica charantia* will be effective in diabetic patients with a *Kapha* or *Pitta* temperament but should be avoided in patients with a *Vata* temperament. *Rasona Kalpa* is very effective in arthritis patients with a *Vata* and a *Kapha* temperament but should be avoided in patients with a *Pitta* temperament.

A second issue is that in the traditional systems of medicine, the medicine may be different if the patient has another concomitant symptom. An asthma patient with gastrointestinal disturbances will respond to one medicine while another patient without gastrointestinal disturbances would need another medicine. The clinical pharmacologist should be wary of entering all cases of asthma into a clinical trial without taking these factors into consideration (Chaudhury, 1992).[14]

The third issue is the importance given, unlike in allopathy, to the vehicle which contains the active traditional medicine. The vehicle may accelerate or enhance the effect of the medicine or may counteract the side-effects induced by a particular constituent in the combination of plants. Some substances commonly used as vehicles are honey, molasses, butter, buttermilk, ghee, juice of ginger and juice of betel leaf (*Piper betle*). Finally it is very common, in a combination of three plants, to have the second plant to enhance the effect of the first plant while the third plant would counteract the side-effects induced by the second plant. Attempting to determine which of the many plants in combination is the effective one would be, in the circumstances, an exercise in futility.

These concepts have been kept in mind and the protocols developed for the

Mumbai study, perhaps for the first time in modern clinical trial methodology, stratified the subjects of asthma according to whether gastrointestinal symptoms are associated with the asthma and Ayurvedic drugs administered accordingly. In any clinical trial of asthma, all patients would have been included and then divided into groups. The result of such a trial would not be accepted by the pratitioners of traditional medicine.

Another important feature of medicinal plants is that many of them induce an immunostimulant effect without exerting any specific therapeutic effect. In ordinary clinical trials this is difficult to measure. However, it would be well worth measuring when clinical trials of herbal remedies are planned. In addition to studying the efficacy of the plant and the side-effects induced by it, the amount of Satisfaction felt by the patient and the Quality-of-Life Parameters could also be studied. This is particularly important when a herbal remedy is being assessed alongside a synthetic compound.

Ethical Considerations

Several of the ethical considerations which need to be kept in mind when planning and conducting clinical evaluation of traditional medicines have already been discussed. These are aspects of clinical trials such as the need for clearance from the Institute Ethical Committee and Informed Consent. The responsibilities of the Chief Investigator apply equally to clinical evaluation of synthetic drugs or herbal medicines.

There are, however, some special features when traditional medicines are being evaluated. These will be discussed below.

When clinical trials of herbal drugs used in traditional systems of medicine such as Chinese Traditional Medicine, Ayurveda or the Unani System of Medicine are to be carried out at an allopathic hospital by a practitioner of the allopathic system of medicine, then it is incumbent on him to have as a coinvestigator a physician from the traditional system in which that remedy is used. This principle would also hold good if an Ayurvedic physician wants to evaluate an allopathic drug. An allopathic physician would have to be taken on as a coinvestigator.

When a folklore medicine is ready for commercialization after it has been found effective, then, as stated in the Indian Council of Medical Research Ethical Guidelines, the legitimate rights/share of the tribe or community from whom the knowledge was gathered, should be taken care of appropriately while applying for the Intellectual Property Rights and Patents for the product.

The preclinical toxicological requirements before clinical trials have already been considered from a regulatory and legal point of view. Ethically it may not be necessary to carry out such studies if much is known about the plant from ancient literature and if the plant is already in use provided it is to be evaluated in the same form. When an extract of a plant or a compound from a plant is to be clinically evaluated for a new therapeutic effect, it should be treated as a new entity and the full range of acute, subacute and chronic toxicity data will have to be generated as required by the national drug regulatory authority.

Is it ethical to add on a traditional medicine to the standard allopathic treatment to assess whether the dose of the allopathic drug could be reduced or whether the side-effects induced by the allopathic drug brought down? Normally it would not be justified to combine

treatment with medicines of different systems and use these concurrently on a patient. The effect of one of the medicines could be reduced by the other or indeed the side-effects of one could be increased by the second drug. It is also possible that there could be a serious interaction between the two. However, when a great deal of information is known about a plant – its mechanism of action, lack of toxicity in animal studies, lack of side-effects when used widely as a single drug – then it may be ethically acceptable to carry out a clinical trial of that plant drug with an allopathic drug. It would, however, be safer if some limited animal studies are carried out administering both the allopathic drug and the medicinal plant at the same time.

Normally the pharmacokinetics of a synthetic drug and its breakdown products are known before it is administered for Phase I studies to humans. This is not possible for herbal products as it is very difficult to obtain this information. It will therefore be ethically justifiable to conduct Phase I clinical trials without having this data till such time when it is possible to carry out bioavailability studies on herbal remedies and medicinal plants.

Conclusion

It is hoped that the information provided in this chapter will help the reader to appreciate the complexities of studying medicinal plants and the difficulties inherent in this type of study. The advances made in recent years have also been described and should help investigators to plan clinical trials of medicinal plants which would respect both the concepts of the traditional systems of medicine and those of modern clinical trials methodology.

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References

1. Proceedings of Third International Congress of Asian Medicine. Mumbai. 1990.
2. Report of a Regional Consultation on development of Traditional Medicine in South-East Asia Region. WHO-SEARO. New Delhi. 1999.
3. Report of an Inter-Regional meeting on Standardization and Use of Medicinal Plants. WHO. WPRO. Manila. 1980.
4. Report of a consultation on medicinal plants. WHO. WPRO. Manila. 1986.
5. Quality control methods for medicinal plant material. WHO. Geneva. 1998.
6. Chaudhury, R.R. (1980), Controversies in clinical evaluation of antifertility plants. *Clinical Pharmacology and Therapeutics*. 474. P. Turner, (Ed.) Macmillan. New York.
7. Gallelos, A.J. (1983). The Zoapatle 1 – A traditional remedy from Mexico emerges to modern times. *Contraception*. 27, 211.
8. Report of a WHO Consultation on Traditional Medicine and AIDS : Clinical Evaluation of Traditional Medicine and Natural Products. WHO. Geneva. 1990.
9. WHO Guidelines for Assessment of Herbal Medicines. WHO. Geneva. 1991.
10. Research Guidelines for evaluating the safety and efficacy of herbal medicines. WHO. WPRO. Manila. 1993.
11. WHO Technical Report Series No. 863 on “Guidelines for assessment of herbal medicine”. WHO. 1996.

12. Report of Sixteenth Meeting of Ministers of Health. WHO South-East Asia Region. New Delhi. WHO. 1998.
13. General Guidelines for methodologies on research and evaluation of traditional medicine. WHO. Geneva. 2000.
14. Chaudhury, R.R. Herbal medicine for human health. WHO-SEARO. New Delhi. 1992.
15. Roy Chaudhury, M., Chandrasekharan and Mishra, S. (2001). Embryotoxicity and teratogenecity studies of an Ayurvedic Contraceptive. *Pippalyadi Vati*. *J. Ethnopharmacology*. 74, 189.
16. Vaishnav, R., Sankaranarayanan, A., Chaudhury, R.R., Mathur, V.S., and Chakravarti, R.N. (1983). Toxicity studies on proprietary preparation of Semecarpus anacardium. *Indian Journal of Medical Research*. 77, 902.
17. Chaudhury, R.R. (2001). Commentary: Challenges in using traditional systems of medicine. *Brit.Med. J*. 322, 164.
18. Chaudhury, R.R. (2000). Proceedings of Symposium on Current Status of Fertility Regulation. C.M. Gupta and Chaudhury S.R. (Ed.) Central Drug Research Institute. Lucknow. 11–21.
19. Chaudhury, R.R. (2001). Antidiabetic effect of Vijayasar – Pterocarpus marsupium. *Pharmacology and Therapeutics in the New Millennium*. S.K. Gupta (Ed.) Narosa. New Delhi. 355–356.
20. Chaudhury, R.R. (1983). Plant contraceptives: translating folklore into scientific application. 5: 58. *Advances in Maternal and Child Health.* Jelliffe, D.B. and Jelliffe, E.F.P. (Ed.) Oxford University Press. Oxford.
21. Ethical Guidelines for Biomedical Research on human subjects. Indian Council of Medical Research. New Delhi. 2000.
22. Shukla N.K. et al. Multicentric randomized controlled clinical trial of Ksharasootra (Ayurvedic medicated thread) in the management of fistula-in-ano. *Indian Journal of Medical Research* (B) 94. June 1991. 177–185.
23. Indian Council of Medical Research. Annual Report. New Delhi. 1994.
24. Verma, V. Ayurveda – a way of life. Samuel Weiser Inc. New York . 1995.
25. Majumdar, A. Bioregulating Principles: Tridoska in Ayurveda – The Ancient Indian Science of Healing. Wheeler Publishing House. New Delhi. 1998.

Protection of traditional systems of medicine, patenting and promotion of medicinal plants

Carlos M. Correa

Introduction

Traditional Medicine (TM) serves the health needs of a vast majority of people in developing countries, where access to "modern" health care services and medicine is limited by economic and cultural reasons. TM is broadly used in such countries,[i] often being the only affordable treatment available to poor people and in remote communities. The relevance of TM in developing countries may increase in the future in a context of growing poverty and marginalization and, particularly, in view of the high prices generally charged for patented medicines.[ii]

TM also plays an important role in developed countries, where the demand for "herbal medicines" has grown in recent years. Moreover, many pharmaceutical products are based on, or consist of, biological materials. These include compounds extracted from plants and algae as well as human proteins obtained by extraction or through genetic engineering techniques (e.g., interferon, erythropoietin, growth hormone). Plants, in particular, are an indispensable source of medicines.[iii]

The protection of TM under intellectual property rights (IPRs) raises two types of issues. On the one hand, an important question is the extent to which TM may be protected under existing IPRs or new modalities thereof. Certain aspects of TM may be covered by patents or other IPRs.[iv] There have also been many proposals to develop *sui generis* systems of protection. Such proposals are often based on considerations of equity: if innovators in the "formal" system of innovation receive a compensation through IPRs, holders of traditional knowledge should be similarly treated.

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i For instance, the per capita consumption of TM products is, in Malaysia, more than double that of modern pharmaceuticals. TM is even significant in more advanced developing countries such as South Korea, where the per capita consumption of TM products is about 36% more than that of modern drugs (1, p. *iii*).

ii The TRIPS Agreement has imposed the obligation to recognize product patents for pharmaceuticals.

iii See, e.g., 2, p. 1.

iv In particular, trade secrets protection, which relates to undisclosed information of a commercial and technical nature, may apply to different components of TM .

On the other hand, the appropriation of such knowledge and/or the related biological materials under IPRs by unauthorized parties has raised significant concerns, particularly in developing countries where there is a long and significant tradition in TM. Those concerns have been generated by several cases of patenting in developed countries, of plants, their compounds or uses derived from TM, without fair compensation to those who have preserved and made available such knowledge.

This chapter examines the extent to which patents may be utilized to protect certain aspects of TM or the materials used in traditional treatments. It considers, first, the concept and components of TM. Second, the patentability of different modalities of TM is examined, including products, processes and uses. Third, the nature of alternative modes of protection is briefly described and some measures to promote the use of TM are discussed.

The concept of "traditional medicine"

In order to examine the application of IPRs to TM, a first essential step is to clarify the meaning of this concept, and its different components. TM is a very broad term, comprising indigenous or "tribal" people's knowledge, farmers' or "rural" traditional knowledge and regionally bound traditional knowledge about the "healing".

According to the definition provided by WHO's Traditional Medicine Programme, TM is:

"The sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance and relying exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing".[v]

TM thus encompasses different types of knowledge. Distinctions can be made on the basis of its subject matter, the level of codification, the individual or collective form of possession, the usability and commercial value, and the degree of prior disclosure of the relevant information. As discussed below, these factors may have important implications with regard to the extent to which patents can be applied in this area.

Subject matter

The subject matter of TM may basically refer to different categories of knowledge:

a) The properties of certain biological materials used in isolation, in their wild form, or as part of a preparation or mixture. Such materials include *phyto-medicines* or "*herbal medicines*", as well as animal parts and minerals. Though the concept of TM is often linked to plant-based medicines, animal-based medicines have played a significant role in the healing practices, magic rituals, and religions of indigenous and Western societies. In fact, of the 252 essential medicines selected by the World Health Organization (1999), 11.1 per cent come from plants and 8.7 per cent are derived from animals.[4, p.6] A large number of medicinal plants are used in the folk traditions as well as in other systems of TM.[vi]

[v] See 5.

[vi] It has been estimated that around 7500 plant species are utilized in indigenous medicine, many of which (such as indigo) have multiple uses. see, e.g., 6, p. 170.

b) Methods of diagnosis and treatment, including physical, mental and spiritual therapies, which are influenced by the culture and beliefs dominant in a particular community.[vii] The traditional therapies may encompass the use of certain biological materials, including dosage and forms of administration thereof, and rituals applied by healers as part of their traditional healing methods.

Codification

The codification of TM varies significantly. A distinction can be made, particularly in Asia, between the *codified* systems of 'traditional medicine' and the *non-codified* medicinal knowledge, which includes "folk", "tribal" or "indigenous" medicine. Thus, in India, the system of medicine consists of two major tendencies: the folk and the codified traditions. Folk traditions are handed down orally from generation to generation. The codified tradition consists of medical knowledge with sophisticated theoretical foundations expressed in thousands of manuscripts covering all branches of medicine. Examples are Ayurveda, Siddha, Unani and the Tibetan tradition.[7]

The Ayurvedic system of medicine, in particular, is codified in the 54 authoritative books of this system. In contrast, the "folk" medicine is based on traditional beliefs, norms and practices based on centuries-old experiences of trials and errors, successes and failures at the household level. These are passed through oral tradition and may be called, "people's health culture", home remedies or folk remedies. They have a vital place in primary health care in developing countries.[1]

Individual/collective possession

TM may be possessed by individuals ("individual knowledge").[viii] In some cases, for instance, healers use *rituals* as part of their traditional healing methods, which often allow them to monopolize their knowledge, despite disclosure of the phytochemical products or techniques used.[8]

In other cases, knowledge is in the possession of some but not all members of a group ("distributed knowledge"). There is, hence, asymmetric information between groups but not within a given group of persons, even though the latter may not be aware that others share the same knowledge.[11]

Finally, a certain kind of knowledge may be available to all the members of a group ("common knowledge"), such as in cases of knowledge on herbal-home remedies which is held by millions of women and elders.[ix]

Commercial value

TM may encompass commercial value when its application, and notably the delivery of TM products, can be made trough commercial channels. While some TM can be used and understood outside its local/traditional/ communal context, this is not always the

[vii] Physical methods of treatment involve muscle manipulation and massage. Mental methods of treatment involve self-discipline in the form, for instance, of a strict diet. Spiritual methods of treatment involve prayers and use of holy water (9, p. 167).

[viii] Reviews of anthropological literature reveal that concepts close or equivalent to individual forms of IPRs are quite common in indigenous and traditional proprietary systems (see, e.g., 10, p. 69).

[ix] For an alternative classification of modalities of knowledge possession based on the concept of "negative" and "positive" community, see 15, p. 185).

case. There are spiritual components in the TM peculiar to each community. Knowledge that cannot be utilized beyond its communal context has little or no commercial value, despite the value that such knowledge may have for the communal life.[3]

Herbal medicines and other TM products may be commercialized domestically or internationally, subject to compliance with national sanitary laws. There is no limit, hence, to their commercial exploitation. A major issue, still unresolved, is the sharing of benefits with the individuals/communities which provided the relevant knowledge.[12]

Disclosure

Most TM is of a non-contemporary nature. It has been used for generations and in many cases collected and published by anthropologists, historians, botanists or other researchers and observers.[3] Disclosure erects an important barrier for the application of some forms of intellectual property protection, notably patents.

However, there are cases in which TM is being kept secret. In specialized areas, in particular, for example bone-setters, midwives or traditional birth attendants and herbalists, knowledge of different plants and healing techniques is restricted to certain classes of persons, and the healing properties of particular plants are often undisclosed.[9]

Moreover, like other types of traditional knowledge, TM is not a static body of information; it continues to evolve with the practices of the individuals/communities that held and use it.[13] This evolution may give rise to *new* knowledge, which may meet, as described below, the requirements for protection under intellectual property rights.

Can TM be patented?

Patents protect *inventions*, that is, new, non-obvious technical solutions. Patents are granted by a Government authority and confer the exclusive right to make, use or sell an invention generally for a period of 20 years (counted from the date on which the application for the patent was filed). In order to be patentable, an invention usually needs to meet the requirements of absolute novelty (previously unknown to the public), inventive step or non-obviousness, and industrial applicability (or usefulness). Patents may be granted for all types of processes and products, including those related to the primary sector of production, namely agriculture, fishing or mining.

Patents are conferred in many countries to protect inventions based on or consisting of natural substances (including genetic materials), plants and animals. Patents, as discussed below, can also be granted in respect of the *use* of a product and of methods for diagnostics as well as for surgical and therapeutic treatment. Though there are important differences among national laws on the subject matter of patent protection, at least in principle patents may be applied to different components of TM, provided that the above-mentioned patentability requirements are met.

There are, however, several major obstacles to affording patent protection to existing TM. One such obstacle stems from the legal standards established by national laws to acquire patent rights.

Novelty

The *universal* novelty requirement, as applied in most countries, prevents the patentability of an information which belongs to the “prior art”, that is, which has been published in a written form or

has otherwise been made available to the public, for instance, through public use, *in any country* before the date of filing of a patent.

"Prior art" generally includes any publication of the invention prior to the date of the patent application. This concept may be defined so as to also include precedents that have not been divulged before that date, but which demonstrate that a third party had previously reached the same invention. This approach has been followed in some US decisions, based on *Corona Cord Tire Co. vs. Dovan Chem. Corp.* (US Supreme Court, 1928), where a prior invention of another party, not publicly known, was deemed as destructive of novelty for a second invention. Likewise, novelty may be destroyed in certain cases by the information contained in previous patent applications.[x] [14]

The novelty requirement will generally impede the patentability of TM knowledge that has been openly used for many years, and, in some cases, published in different forms. This is likely to apply to a large part of TM.

In order to destroy novelty, however, the prior use must generally be such that access to the information would have allowed a third party to execute the invention, without significant further research. There may be situations in which novelty may not have been lost despite the fact that the relevant TM knowledge has been previously used, even for long periods. One example would be the case of a traditional knowledge used in a small community, when the information has not been diffused beyond the community's members. There are also cases in which the traditional healers have kept confidential[xi] certain aspects of their treatment and associated medicines, a practice that may be more frequent than often believed.

An important issue is whether the identification of the chemical srtucture of an active substance which is responsible for the therapeutic effect of a known product, may lead to the granting of a patent or whether it should be deemed that no novelty exists. In the case *Merrill Dow Pharmaceuticals v. Norton & Co.* (1996) the court held that it was not necessary for an active substance to be identifiable or reproducible for it to have been made available to the public.[xii]

The novelty requirement may not be an obstacle to obtaining patents on TM in countries where a *relative* novelty standard is applied. In the United States, for instance, according to article 102 of the Patent Law,

A person shall be entitled to a patent unless:

(a) *the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the*

x In Europe, however, the information contained in a prior, non-published, patent application is not considered for the purposes of considering the existence of "inventive step".

xi In the Mobil case, for instance, the Enlarged Board of Appeal of the European Patent Office decided that the word "available" carries with it the idea that, for lack of novelty to be found, all the technical features of the claimed invention in combination must have been communicated to the public, or laid open for inspection. Under the European Patent Convention, a hidden or secret use, because it has not been made available to the public, is not a ground for objection to validity of a European patent (*Mobil/Friction-Reducing Additive* (1990) O.J. E.P.O. 93; (1991)(see 9, p. 166).

xii Lord Hoffmann exemplified this situation with the case of Amazonian Indians, who believed that the effect of the cinchona bark on malaria was due to "the spirit of the bark". The Indians, however, should be said to have known about quinine even though they did not know its chemical structure (9, p. 166).

invention thereof by the applicant for patent, or

(b) *the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States... (35 United States Code No.102).*

This means that TM knowledge which has been published in a written form in the United States or in any other country is not patentable. But if such knowledge was publicly used but not documented in a foreign country, novelty is not lost.

As a result of the relative novelty requirement of the US, several patents have been granted to researchers or firms from developed countries by the US Patent and Trademark Office relating to or consisting of genetic materials or traditional knowledge acquired in developing countries.[16, 17]

This appropriation (or "biopiracy") has involved resources protected "as is", that is, without any further improvement (e.g., US patent No. 5.304.718 on quinoa granted to researchers of the Colorado State University) and on products based on plant materials and knowledge developed and used by local/indigenous communities, such as the cases of the neem tree, *kava*, *barbasco*, *endod* and turmeric (see below), among others, etc.[18]

A telling example was the case of *ayahuasca*,(*Banisteriopsis caapi*), a plant native to the Amazonian rainforest that thousands of indigenous people of the region use in sacred religious and healing ceremonies, as part of their traditional religions. The US Patent and Trademark Office (PTO) issued a patent to a US citizen for the "ayahuasca" which was subsequently revoked by the same Office in November 1999. The PTO based its rejection of the patent on the fact that publications describing *Banisteriopsis caapi* were "known and available" prior to the filing of the patent application.[xiii]

As discussed below, in order to prevent the appropriation by third parties under patents of traditional knowledge, there have been initiatives to develop proper written documentation of such knowledge. It is assumed that if the material/knowledge is documented, it can be made available to patent examiners the world over, so that prior art in the case of inventions based on such knowledge is readily available to them.

It should be noted, finally, that in some countries (United States, Argentina, Mexico) the publication made by the inventor within one year prior to the date of application for a patent does not destroy novelty. This "grace period" is particularly useful for the protection of research results obtained in universities and other public institutions, where researchers are usually under pressure to promptly publish their findings. A possible way to allow for the patentability of TM may be to establish a special "grace period" for inventions pertaining to this field whenever claimed by the communities or individuals that legitmately developed or possessed them.[8] This would certainly expand the scope of patentability in cases where it would have been excluded by the application of the novelty requirement standard.

[xiii] The PTO's decision came in response to a request for reexamination of the patent by the Coordinating Body for the Indigenous Organizations of the Amazon Basin (COICA), the Coalition for Amazonian Peoples and Their Environment, and lawyers at the Center for International Environmental Law (CIEL).

Inventive step

While in some cases, such as when a certain TM knowledge has been kept undisclosed, the novelty of the information may have been preserved, an additional standard of patentability must be met in order to acquire patent rights. The "inventive-step" or "non-obviousness" requires that the claimed invention be non-obvious for a person with average skills in a given technical field. This means that, even if novel, a piece of knowledge will not be patentable if it is proven obvious or lacking inventive step.

Obviousness is judged in the United States on the basis of the determination of i) The scope and content of the "prior art", ii) The differences between the claimed invention versus the prior art, and iii) The level of ordinary skill in the art.[19] In Europe and other countries, emphasis is given to the extent that the invention solves a technical problem. This "problem-and-solution" approach makes the inquiry on inventive step more objective than in the United States.[14]

The fact is, however, that thousands of patents are granted each year in the major countries for minor, sometimes purely trivial developments.[20] In 1999, for instance, the United States Patent Office granted over 160,000 patents, twice the number granted 10 years ago. This is partially the fruit of an excessive flexibility of the Patent Office in assessing the inventive step and of shortcomings in the examination procedures.[xiv]

The flexibility with which the inventive step/non-obviousness is judged allows for the patentability of technical solutions of an incremental nature or which represent a relatively minor advancement in relation to previously available information. This is clearly undesirable from the point of view of public policy and the preservation of the freedom to use knowledge in the public domain.

What can be protected?

Natural products

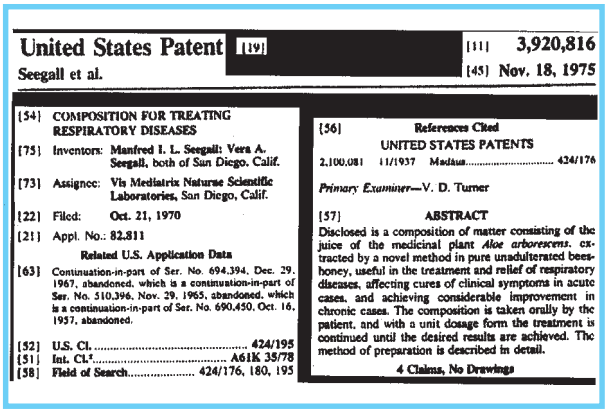
TM include plants, animal and mineral materials, extracts, mixtures, condiments and herbal preparations. Obstacles for the patentability of such medicines may arise when they consist of or are based on *natural* materials which have not been processed or modified.

One of the basic problems is the extent to which a substance which exists in nature, but for which a certain use has been identified, may be deemed to be an "invention" or a mere "discovery". Such use may have been identified with regard to a product the properties of which were not known, or in respect of products of known properties and for which the "invention" would be the determination of its chemical or genetic structure.

Patent protection of biological materials, including cells and genes, has been accepted in many countries. This remains, however, a controversial issue, particularly with regard to the patentability of materials that pre-exist in nature and are just isolated, purified, or slightly altered, in order to be claimed as an "invention". In some jurisdictions (e.g., the United States) an isolated or purified form of a natural product, including genes, is patentable.[22, 23, xv] The European Directive

[xiv] For example, less than 50 per cent of the examinations conducted by said Office refer to relevant background bibliography; the examination is by and large limited to analysing previous patents. See, 21.

[xv] The extent of patentability of biological materials in the USA has not been addressed yet, however, by the Supreme Court.



United States Patent [19]

Seegall et al.

[11] 3,920,816

[45] Nov. 18, 1975

[54] COMPOSITION FOR TREATING RESPIRATORY DISEASES

[75] Inventors: Manfred I. L. Seegall; Vera A. Seegall, both of San Diego, Calif.

[73] Assignee: Vis Medistrix Naturae Scientific Laboratories, San Diego, Calif.

[22] Filed: Oct. 21, 1970

[21] Appl. No.: 82,811

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 694,394, Dec. 29, 1967, abandoned, which is a continuation-in-part of Ser. No. 510,396, Nov. 29, 1965, abandoned, which is a continuation-in-part of Ser. No. 690,450, Oct. 16, 1957, abandoned.

[52] U.S. Cl. 424/195

[51] Int. Cl.[2] A61K 35/78

[58] Field of Search 424/176, 180, 195

[56] References Cited

UNITED STATES PATENTS

2,100,081 11/1937 Madaus 424/176

Primary Examiner—V. D. Turner

[57] ABSTRACT

Disclosed is a composition of matter consisting of the juice of the medicinal plant *Aloe arborescens*, extracted by a novel method in pure unadulterated bees-honey, useful in the treatment and relief of respiratory diseases, affecting cures of clinical symptoms in acute cases, and achieving considerable improvement in chronic cases. The composition is taken orally by the patient, and with a unit dosage form the treatment is continued until the desired results are achieved. The method of preparation is described in detail.

4 Claims, No Drawings

Example of a United States Patent

on Biotechnological Inventions (No. 96/9/EC of March 11, 1996)[xvi] adopts a similar approach. The Directive, essentially declaratory of long-standing law throughout much of Europe,[xvii] establishes that "biological material" and substances isolated from nature (such as new antibiotics) will be considered patentable.[23]

In some countries, however, the patentability of existing biological materials, unless they are genetically altered, has been contested or excluded. Thus, in the United Kingdom the High Court of Appeal held that the isolation of gene sequences constituted a mere discovery and, hence, was not itself patentable. The Court held that although the amino acid sequence of t-PA had not previously been determined, one cannot patent a known substance just by being the first to determine its structure.[(24)]

The Mexican law (1991/1994) excludes the patentability of all genetic materials. The Argentine patent law (1995) and the Andean Group Decision 344 (1993) do not allow, in principle, the patentability of materials existing in nature. The Brazilian patent law (1996) stipulates that no patents shall be granted with respect to living beings or "biological materials found in nature", even if isolated, including the "genome or germplasm" of any living being.

Despite the exclusion of certain biotechnology-based products from the patent domain, patents may still be granted for the process used to obtain them. This may be the preferred option for countries prioritizing medicine affordability and access, or where the patentability of such substances is deemed contrary to basic cultural and ethical values.[xviii] The ability to do so may be limited, however, by the provision of the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS Agreement") which requires the patentability of micro-organism (Article 27.3.(b)).

Some developing countries may, however, worry that excluding substances found in nature from patentability could conceivably hinder investment in some local activities, including activities that might otherwise lead to patents on products derived from traditional knowledge or specific local skills or know-how. For those that seek intellectual property protection for TM, limiting the patentability of natural materials may convey negative consequences. It must be borne in mind, however, that the developing countries that possess TM knowledge often lack the financial resources and the research and industrial capabilities to scientifically identify and

xvi "Biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature" (article 3.2).

xvii See, e.g., 23, p. 213.

xviii See, the proposal for review of article 27.3. (b) of the TRIPS Agreement submitted by Kenya on behalf of the African countries (WT/GC/W/302, of 6 August, 1999).

isolate the compounds that explain the therapeutic effects of certain traditional medicines. In addition, traditional healers and communities generally lack the skills and resources necessary to follow the complex procedures of patents systems and, in particular, to face the costs of registration both locally and abroad.[xix]

It should also be noted that since the granting of patents is dependent on each *national* law, the non-patentability in one country does not mean that "pieces" of TM could not be patented in another country. If protection were obtained without the authorization of the healers/communities that developed or possessed them, it would be possible to request the nullification of the patent in the foreign country.[xx]

Extracts and formulations

While, as mentioned, the patentability of natural products may be limited by patent rules, it is possible to obtain protection (if the patentability requirements are met) for extracts or formulations of natural products.

Examples of patents of this type include US 4178372 on hypoallergenic stabilized *Aloe vera* gel: US 4725438 on an *Aloe vera* ointment; US 4696819 on anorexic material extracted from coca leaves; and EP 0513671 on "*Commiphora mukul*" extracts.

Combinations

Patents may be obtained, if the patentability requirements are met, for combinations and preparations. This is normally the case with modern pharmaceuticals, both in cases where a composition is a simple mixture of diverse components and where there is some chemical reaction between them.[23]

Many examples of patents granted on combinations of plants for therapeutic purposes can be mentioned, for instance, EP 0519777 relating to formulations made out of a variety of fresh plants; and WO 93/11780 on a skin therapeutic mixture containing cold-processed *Aloe vera* extract (with yellow sap and aloin removed).

Production and extraction processes

Many TM products are obtained through fractionation, purification or concentration. The processes for obtaining such products, if novel and non-obvious, may also be patented.

There are numerous examples of patents relating to extraction and other processes for the preparation of medicines based on natural products, such as ES 475.812 on a process for the extraction of organic compounds with therapeutic activity from plants; ES 2010127 for the preparation of a medicine for skin reparation; EP 0530833 on a process to prepare hard gelatine capsules containing Chinese herbal extracts; ES 8801986 for preparation of a jus or gel of *aloe*; ES 393347 on a process for the extraction of an active ingredient from *anacardium occidentale*; and US 4956429 on a method of making a coca leaf flavour extract.

[xix] The costs for the international protection of an invention are somewhere in the range of $ 40,000–$ 50,000, including registration and maintenance fees.(25)

[xx] Examples were the actions initiated by the Government of India in relation to a patent on *turmeric* granted in the United States, and the already referred action against the *ayahusaca* patent. In both cases, the USPTO finally revoked the patents.

Methods for Treatment and Diagnostics

Most national patent laws exclude the patentability of diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Patents on such methods are not granted due to ethical reasons or to difficulties with actually enforcing those patents. In addition, a method that is applied to the human body is not considered industrially applicable and, hence, does not comply with one of the key patentability requirements of most patent laws. However, in the United States patent practice increasingly favours the patenting of medical methods if they satisfy the definition of process and the other conditions of eligibility.[xxi]

Article 27.3.(a) of the TRIPS Agreement explicitly allows Members not to grant patents for methods for therapeutic and surgical treatment and for diagnostics.

TM includes a large variety of methods of treatment. Traditional methods of treatment are usually specific to a particular country or to a particular community in that country, although some of them, such as acupuncture, are used worldwide. The protection of such methods under patents would be possible if allowed by national law and viable under the patentability requirements. However, it may be quite difficult to enforce patent rights obtained, since it may be extremely costly and complex to identify and prosecute a large number of possible infringers. In addition, the patentability of such methods, if possible, would restrict the use of TM rather than promote it.

Patentability of uses

An important issue in relation to the protection of TM is the extent to which the "use" of a known product can be subject to patent protection. This may occur, for instance, when the therapeutic properties of a natural product are identified and claimed. Patent applications on the therapeutic use of a known product are usually written as instructions to the physician on how to employ a certain substance to treat a particular disease, and may be deemed as non-patentable either as a "discovery" or as a therapeutic treatment, whenever the latter is not eligible for protection under the domestic law.

In countries which admit the protection of inventions, claims may be either a *product* claim or a *process* claim, depending on the context.[xxii] Some national laws treat the new use as a *process* patent claim of one of two kinds: "use" claims (such as "the use of X as an antihista-minic") or claims on one or more actual process steps (e.g., "a method of preventing ….").[xxiii] The patenting of use inventions depends on whether the purpose of the use is novel and non-obvious. Method inventions may be judged independently of the purpose. Even if intended for a novel purpose, the key consideration in determining the patentability of a method invention is whether it could be anticipated by other methods.[xxiv]

xxi A bill enacted in 1996 (amending US patent law, 35 USC 287.c) determined, however, that the use of patented surgical procedures cannot be subjected to infringement suits. See, e.g., 23, p. 220.

xxii Thus, in Europe, *first medical indications* have been dealt with as a product claim, whereas the *second medical indication* (that is, when a new use is discovered for a product that already had pharmaceutical use) as a process claim.

xxiii See, e.g., 23, p. 208.

xxiv See, e.g., 26, p. 120.

One example of a patent on a therapeutic *use* of a natural product is afforded by the patent granted in March 1995 by the US Patent and Trademark Office on "Use of Turmeric (Curcuma longa) in Wound Healing". It was awarded to the University of Mississippi Medical Center. The claim covered "a method of promoting healing of a wound by administering turmeric to a patient afflicted with the wound", such wounds including surgical wounds and body ulcers.

The powder of the turmeric plant was a classic "grandmother's remedy" in India. It had been applied to the scrapes and cuts of children for generations.[10] On 14 August 1997, the US Patent and Trademark Office invalidated the patent upon request of India's Council for Scientific and Industrial Research, in the context of a growing protest by many developing countries against "biopiracy".[xxv]

In Europe, a legal provision allows the patentability of a known product for a new specific indication.[(27)] Under article 54(5) of the European Patent Convention, the identification of the first medical indication of a known product may suffice to get a patent on the product.[xxvi] The United States, by contrast, has adopted a more restrictive approach, confining patents on uses to a particular "method-of-use." Such method-of-use patents do not encompass protection of the product as such.[14]

Under the TRIPS Agreement, WTO Member Countries seem free to decide whether or not to allow the patentability of the use of natural and other known products.[xxvii] Many patent laws recently adopted in developing countries make no specific reference to the availability of patents for uses, leaving unclear whether the protection for processes covers "uses" and "methods of use."

Countries concerned about "biopiracy" may wish to exclude the patentability of the use of known products in order to prevent the appropriation under patent rights of biological materials. It would seem logical, in particular, that a country that broadly excludes methods of medical treatment also broadly excludes new therapeutic uses for known products. Nevertheless, given the territoriality of the patent system, a country that prevents the patenting of uses under its national law cannot force other countries to follow the same approach. In the absence of international rules on the matter, nothing will prevent other countries from declaring as patentable (if the legal requirements are met) what is not deemed protectable in a particular country.

Policy options: Protecting or promoting TM

The previous sections have indicated the scope available for the patenting of different components of TM. However, there are divergent opinions on the desirability of extending IPRs protection to such knowledge, as well as on the modalities to be applied therefor. These different views arise from different philosophical and ethical perceptions, as well as from

xxv *SUNS*, No, 4050, 8.9.97

xxvi The Technical Board of Appeal of the EPO has ruled that such claims should be deemed as covering all therapeutical uses of the product like in the case of claims on a pharmaceutical composition. Infringement of such claims would only take place when the product is commercialized for direct therapeutic use, and not in bulk.

xxvii Because patents protect inventions but not discoveries, the discovery of a new purpose for a product cannot render a known product patentable *as such* under general principles of patent law. Unless in connection with the new purpose the product is forced to be present in an amended new form.

diverging considerations on the socio-economic implications of IPRs protection, including the danger of distortion to indigenous systems.[28]

Developing a sui generis regime

Many proposals have been elaborated, by scholars and NGOs, to protect traditional knowledge (including medicinal use) through a *sui generis* regime.[xxviii] This is the case, for instance, in respect of proposals relating to "tribal", "communal" or "community intellectual rights",[xxix] and "traditional resource rights", among others.[xxx] Some proposals aim to develop *new* forms of protection as an independent category of intellectual property,[9] or as a component of the broader body of "traditional knowledge". In many cases, however, the rationale for the proposed protection is unclear.[13]

A few countries have started to address the complex conceptual and operational problems involved in the recognition of communities' rights on traditional knowledge. For instance, "collective" intellectual property rights have been recognized by the Constitution of Ecuador (1998). The Biodiversity law of Costa Rica (1998) protects "**sui generis** community rights" (article 82), and a draft law in Brazil (Bill No. 306, 1995) recognizes the rights of local communities to collectively benefit from their traditions and knowledge and to be compensated by means of intellectual property rights or other measures. At the international level, the Council of TRIPS has under its consideration the possible review of article 27.3(b) of the TRIPS Agreement. Such review is regarded by some developing countries as an opportunity to harmonize the TRIPS Agreement with the CBD,[xxxi] and to develop rules for the protection of traditional knowledge.[xxxii] The proposed approaches differ, however.

Thus, for the African Group the review of article 27.3(b) should preserve the room existing to develop specific modalities of protection for traditional knowledge (including TM) at the national level.[xxxiii]

Venezuela[xxxiv] has gone a step further. It has proposed the development of binding *international* rules on the matter. It has suggested

"*to establish on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous communities, together with recognition of the need to define the rights of collective holders" (WT/GC/W/282).*

Though the viability of this latter proposal in the framework of the TRIPS Agreement is still uncertain, it addresses one of the problems that countries that opt for protecting traditional knowledge may

[xxviii] For a review of literature on the matter, see x.

[xxix] See, e.g., 29, p. 38.

[xxx] See, e.g., 30.

[xxxi] See, e.g., the submission by Egypt, WT/GC/W/136.

[xxxii] See, in particular, the submissions by India (WT/GC/W/147)and by the African Group (WT/GC/W/302 of 6 August, 1999).

[xxxiii] The OAU has developed a "Model law on Community Rights and Control of Access to Biological Resources" (1999).

[xxxiv] Under Decision 391 of the Andean Pact, the Member Countries thereof are bound to develop legal regimes for the protection of communities' knowledge. A constitutional provision to that effect has been adopted in Ecuador. None of the Andean countries, however, have so far developed such regimes.

face. Due to the principle of territoriality, protection at home would not prevent the misappropriation of the protected knowledge in other countries or that such knowledge would continue to be considered as belonging to the public domain.

Developing countries (notably Latin American and Caribbean) have also actively promoted the increased involvement of the World Intellectual Property Organization (WIPO) in the discussion and development of a "sui generis" regime for traditional knowledge.[xxxv]

Curbing "biopiracy"

Despite the general agreement in the developing world about the importance of obtaining a recognition for traditional knowledge, the main concern of some countries has been to avoid the "biopiracy" of traditional knowledge and to ensure benefit sharing (as provided for under articles 15 and 16 of the CBD), rather than the establishment of a system of positive appropriation. Thus, the Government of India has stated that

"*In the recent past, there have been several cases of biopiracy of traditional knowledge (TK) from India. For preventing such instances in the future there is a need for developing digital databases of prior art related to herbs already in the public domain. Following patents on brinjal, etc., in India, an exercise has been initiated to prepare easily navigable computerized database of documented TK relating to use of medicinal and other plants (which is already under public domain) known as TK Digital Library (TKDL). Such digital databases would enable Patent Offices all over the world to search and examine any prevalent use/prior art, and thereby prevent grant of such patents and biopiracy".*[12]

Among the projects initiated in India to impede the consideration of such knowledge as "new" and, therefore, patentable in some jurisdictions, "Gene Campaign" has undertaken work on documentation of biodiversity and knowledge relating thereto aimed at three tribal populations: the Munnars in South Bihar (in the Chotanagpur region); the Bhils of Madhya Pradesh, and the Tharus of the Terai region. Medicinal plants and knowledge related thereto was sought to be documented with the help of educated tribal youth. Elders in the village, medical practitioners and traditional healers were consulted in the collection and understanding of the information.[12]

The documentation of traditional knowledge, in the Indian Government's views, permits not only the prevention of "biopiracy"; it may also provide a basis for the sharing of benefits arising out of the use of such knowledge, though documentation *per se* will not facilitate benefit sharing with the holders of such knowledge.[12]

In addition, Section 36 (iv) of the Indian Biodiversity Bill provides for the protection of knowledge of local people relating to biodiversity through measures such as registration of such knowledge, and development of a *sui generis* system. For ensuring equitable sharing of benefits arising from the use of biological resources and associated knowledge, Sections 19 and 21 stipulate prior approval of the National Biodiversity Authority (NBA) before their access. While granting approval, NBA will impose terms and conditions, which secure equitable sharing of benefits. Section 6

[xxxv] A proposal for the establishment of a Committee to deal with these issues was submitted to the WIPO Governing Bodies in September 2000.

provides that anybody seeking any kind of IPR on a research based upon biological resource or knowledge obtained from India needs to obtain prior approval of the NBA, which will impose benefit-sharing conditions. Section 18 (iv) stipulates that one of the functions of NBA is to take measures to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource.

In the Patent (Second Amendment) Bill 1999, the grounds for rejection of the patent application, as well as revocation of the patent, include non-disclosure or wrongful disclosure of the source of origin of biological resource. It has also been made incumbent upon patent applications to disclose the source of origin of the biological material used in the invention in their patent applications.

The Andean Group Decision 391 has already established that any IPR or other claims to resources shall not be considered valid, if they were obtained or used in violation of the terms of a permit for access to biological resources residing in any of such countries, as regulated under that Decision.

Improving access to TM

A possible negative impact on the access to health care of the strengthening of IPRs in developing countries has been stressed in recent analyses, including some studies by the World Health Organization.[31] The recognition or establishment of new types of IPRs on TM may reduce, rather than enhance, access to medicines and health treatment, particularly by the poor. In dealing with TM, developing countries should, therefore, very carefully balance the expected benefits from a possible IPRs-like protection of TM, with the costs that are likely to arise from the limitations on access to TM treatments that the exercise of such rights would entail.

While an option to deal with TM is to work within the sphere of IPRs, governments should aim to *promote the use* of TM for preventive and curative health care rather than to *protect* it under rights that may restrict its diffusion. An example is provided by Act No. 8423 (1997) of the Philippines, which aims "to accelerate the development of traditional and alternative health care" by improving the manufacture, quality control and marketing of traditional health care materials (Section 3.d).

This promotional approach may be combined with a misappropriation regime aimed at avoiding the monopolization of TM and related biological materials. Such a regime – just as in the case of trade secrets – would not be based on the granting of exclusive rights (i.e, on a *ius prohibendi*) but only on the right to prevent or require a compensation for the use of traditional knowledge when it has been acquired, for instance, in a manner contrary to legitimate rules and practices on access.[13]

The promotion of TM requires much more than defining the appropriate framework for IPRs protection. Attention should be paid to research and development (R&D) and to the condition for the use of such knowledge.

Developing countries only account for a minor part (around 4 per cent) of world R&D,[32] and a significant part of the scarce resources devoted thereto are applied to issues that have been defined by and are of primary interest to developed countries.[33] Though the technical capacity to undertake clinical trials in order to establish the safety and efficacy of TM products exists in many developing countries, this is a costly endeavour for

which considerable financing is necessary and generally unavailable, even to test TM used locally to treat common diseases in those countries, such as malaria.

Pharmaceutical companies have shown considerable interest in acquiring and developing TM, as illustrated by the Bioprospecting Program of the Instituto Nacional de Biodiversidad (INBio) of Costa Rica and the recent agreement between Extracta (a Brazilian company) and Glaxo-Wellcome to investigate on natural compounds that may be used as antibiotics and tropical diseases, such as dengue.[xxxvi] In some cases, pharmaceutical companies have obtained considerable benefits from the exploitation of TM.[xxxvii] There are, however, signs that the interest of such companies may be fading out, due in part to the prospects of newer methods of drug development and genetic engineering.[xxxviii]

The promotion of TM should also consider the need for an assessment of herbal medicines,[xxxix] as well as the training, certification and registration, where appropriate, of traditional healers and practitioners.[1]

Exports of TM products

As mentioned, TM plays an important role in health care in developing as well as developed countries. Though TM methods and products have been originally developed to satisfy local demands within a given community, trade in TM products may be important and provide a new source of income to developing countries. Herbal medicines are currently traded internationally, in many cases without the strict conditions that apply to other drugs.

The export of such products may, however, face many regulatory and commercial barriers. Pharmaceutical products are subject to health regulations in order to establish their safety, efficacy and quality. The tests required to prove those conditions are, as indicated above, time consuming and very costly. Though, in general, prolonged use of a TM offers testimony of its safety, in a few instances WHO has warned:

"investigation of the potential toxicity of naturally occurring substances widely used as ingredients in these preparations has revealed previously unsuspected potential for systematic toxicity, carcinogenicity and teratogenicity".[34]

In some cases, herbs, which are in fact drugs, are sold in several countries as dietary supplements and, therefore, they fall outside the regulations on medicines, which are generally stricter than those related to such supplements. In other cases, there is no control or monitoring over the advertising and promotion of herbal medicines.[1]

The granting of patents on herbal medicines or natural compounds may also create trade obstacles. Besides any consideration on the unfairness of "biopiracy", the patenting of TM products or substances can be used to prevent the import of such products, even – paradoxically – where supplied from their

[xxxvi] *Jornal do Brasil*, 30 July, 1999.

[xxxvii] An often cited case is the use of the Madagascar rosy periwinkle plant by Eli Lilly for the treatment of Hodgkin's disease (a type of lymph cancer) and childhood leukaemia.

[xxxviii] *Health 24 News*, Volume 1, Issue 49, 7 July, 2000. This article reports that one of the most active firms in exploring the use of TM, *Shaman Pharmaceuticals*, abandoned its multimillion-dollar effort to bring new drugs from the rainforest.

[xxxix] WHO has developed Guidelines for this purpose (see 34).

country of origin. Patent owners enjoy, in effect, the right to prevent any commercialization, including imports, of a patented product.[xl]

A similar problem may be faced if the *plant varieties* used to produce a TM product were protected under breeders' rights in the country of import. Breeders' rights are a type of intellectual property rights that are exercised in respect of propagating materials of plant varieties. The UPOV (Union for the Protection of Plant Varieties) Convention provides an international framework for the protection of such varieties. The TRIPS Agreement has obliged all WTO Member Countries to provide a patent or an effective "*sui generis*" protection (or a combination of both).

If breeders' rights were obtained by unauthorized parties on plants used for TM, the countries of origin thereof would also find a serious barrier, since breeders' right-holders enjoy a similar set of exclusive rights with regard to imported products.

Finally, it should be borne in mind that many medicinal plants face extinction or severe genetic loss. Overexploitation of such plants in order to satisfy export demands can aggravate these risks. Hence, governments should control trade in medicinal plants in the framework of broader policies for the conservation and sustainable use of such plants. Peru, for instance, passed a law in July 1999 which bans the non value-added export of some botanical species with known healing properties, which had become the target of massive extraction by foreign laboratories. The law covers the two best-known medicinal plants in Peru's indigenous pharmacopoeia: 'cat's claw' and '*maca*'; and legislators are considering expanding the norm to cover other products ('*yacun*' and '*para-para*').

Conclusions

TM plays an important role in the health care systems of developing countries. The diffusion of TM products is also significant in developed countries. The commercial value of TM has raised divergent views on the need and scope for protection of TM under IPRs. Some governments, scholars and NGOs have voiced the need to protect TM under existing or new forms of IPRs protection, as a means to recognize and compensate the creators and possessors of such knowledge. Others object to that possibility for ethical, economic or other reasons. However, there is, in general, agreement on condemning "biopiracy", that is, the unauthorized appropriation under Western IPRs systems of traditional knowledge and biological materials.

The concept of TM embraces different categories of knowledge that may be subject to various types of IPRs, if the conditions for protection are met. Several components of TM, including products and processes and, in some countries, uses and methods of treatment, can be covered by patent rights. In fact, a large number of patents have been granted in relation to natural products, combinations, extracts and preparations thereof, as well as processes of production. The application of patents to TM, however, faces important obstacles, in particular due to the novelty requirement and to the costs and complexity of procedures before patent offices.

While designing national policies on TM, a careful assessment of the possible objectives and implications of IPRs

[xl] See article 28 of the TRIPS Agreement.

protection of TM should be made. Their establishment may provide a basis for the recognition of traditional and indigenous healers and communities. Nevertheless, due to the very nature of IPRs, they may limit rather than increase access to medicines that are essential to millions of people in developing countries. A balanced policy may be based on a restrictive approach towards the patentability of naturally occurring products and uses of existing products, as well as in the application of strict patentability requirements, particularly with regard to novelty.

Governments may also adopt measures to promote the use of TM for the affordable treatment of national and regional priority diseases, and may also seek to preserve and expand export opportunities for TM products. IPRs granted in foreign countries may pose obstacles to such exports, particularly in countries where patents are granted on the basis of a criterion on relative novelty.

Some developing countries have proposed development of international rules on the IPRs protection of traditional knowledge, including TM, particularly in order to curb "biopiracy". Given, however, the considerable conceptual divergences still existing on these issues, it does not seem likely that an international consensus on the objectives, scope and content of possible rights to be recognized in relation to such knowledge will be reached soon. This is a difficult task at the national level itself, as evidenced by the small number of countries that have just started, but not yet accomplished, the establishment of a system of protection in this area.

In a scenario in which developing countries will have to pay more for needed medicines after the full implementation of the TRIPS Agreement, what part TM will play as a component of a public health strategy has become an urgent and crucial issue. Governments and the World Health Organization should be encouraged to clarify the implications of different policy options, including the protection under IPRs, and to define the role that TM is called upon to play in the health systems of such countries.

References

1. Balasubramanian, K. (1997). *Herbal Remedies: Consumer Protection Concerns*. Consumers International. Penang.
2. Lambert, John; Srivastava, Jitendra and Vietmeyer, Noel. (1997). *Medicinal Plants. Recuing a Global Heritage*. World Bank Technical Paper No. 355. Washington D.C.
3. Koning, Martine. (1998). "Biodiversity prospecting and the equitable remuneration of ethnobiological knowledge: reconciling industry and indigenous interests". *Intellectual Property Journal*. No.12.
4. Medeiros Costa Neto, Eraldo. (1999). "Traditional use and sale of animals as medicines in Feira de Santana City, Bahia, Brazil". *Indigenous Knowledge and Development Monitor*. Vol.7. Issue 2.
5. Zhang, Xiaorui. (1998). "Significance of Traditional Medicine in Human Health Care". Paper presented at WIPO Asian Regional Seminar on Intellectual Property Issues in the Field of Traditional Medicine. New Delhi. India. October 7–9.
6. Shankar, Darshan. (1996). "Tribal and rural farmer-conservers". In: *Agrobiodiversity and Farmers' Rights.* Swaminathan Research Foundation. No.14. Chennai.

7. Shankar, Darshan; Hafeel, Abdul and Suma, T. (1999). "Cultural Richness of Green Pharmacy". *Compas Newsletter*. No. 2.
8. Bhatti, Shakeel. (2000). "*Intellectual property rights and traditional medicines*". Prepared for WHO-ASEAN Meeting on the TRIPS Agreement and its Impact on Drug Supply. Jakarta.
9. Koon, Ong Chui. (1999). "Intellectual property protection of traditional medicine and treatments in Malaysia". Blakeney, Michael (Ed.). *Perspectives on Intellectual Property. Intellectual property aspects of ethnobiology*. Vol.6. Sweet & Maxwell. London.
10. Dutfield, Graham. (2000). *Intellectual property rights, trade and biodiversity*. IUCN. London.
11. Bonabeau, Eric and Theraulaz, Guy. (Ed.) (1994). *Intelligence collective*. Hermes. Paris.
12. Government of India (2000). "Protection of biodiversity and traditional knowledge. The Indian experience". WT/CTE/W/156. 14 July.
13. Correa, Carlos. (2000). "In situ conservation and intellectual property rights". in Brush, Stephen (Ed.). *Genes in the field. On-farm conservation of crop diversity*. IPGRI/IDRC/Lewis Publishers (p. 242).
14. Merges, Robert P. (1992). Patent law and policy. Cases and materials. Contemporary Legal Educational Series. Boston.
15. Drahos, Peter. (1997). "Indigenous knowledge and the duties of intellectual property owners". Intellectual Property Journal. No.11.
16. Correa, Carlos. (1999). *Access to plant genetic resources and intellectual property rights*. Background Study Paper No. 8. FAO. Rome.
17. The Croucible Group. (2000). *Seeding Solutions*. Vol. 1. IDRC-IPGRI. Rome.
18. Mooney, Pat. (1998). "The parts of life. Agricultural biodiversity, indigenous knowledge and the role of the third system". *Development Dialogue*. Special Issue. Uppsala (pp 152-154).
19. Wegner, Harold. (1994). Patent law in biotechnology, chemicals & pharmaceuticals. Stockton. Chippenham (p. 224).
20. Barton, John. (2000). "Reforming the patent system". *SCIENCE*. Vol. 287. 17 March.
21. Aharonian, Greg. (2000). "Patent examination system is intellectually corrupt". *Patnews*. 1 May.
22. Bent, S., Schwab, R., Conlin, D., and Jeffrey, D. (1991). Intellectual property rights in biotechnology worldwide. Stockton Press. New York.
23. Grubb, Philip. (1999). *Patents for chemicals, pharmaceuticals and biotechnology. Fundamentals of global law, practice and strategy*. Clarendon Press. Oxford.
24. Thurston, J. and Burnett, Hall. (1988). "Genentech Inc. vs. The Wellcome Foundation Ltd. How important is the decision for the biotechnology industry". E*uropean Intellectual Property Review*. No. 2.
25. Hofinger, S. (1996). "Determinants of an Active Patent Policy – An Empirical Study". *European Patent Convention*. No. 3.
26. Hansen, Bernd and Hirsch, Fritjoff. (1997). *Protecting inventions in chemistry. Commentary on chemical case law under the European Patent Convention and the German Patent Law*. WILEY-VCH. Weinheim.
27. Stieger, Werner. (1982). "Article 54 (5) of the Munich Patent Convention: An Exception for Pharmaceuticals". *International Review of Industrial Property and Copyright Law*. Vol. 13. No.2.
28. Blakeney, Michael. (2000). "Protection for indigenous or traditional works (e.g. folklore): Has the Time Come?". Fordham University School of Law. International Property Law & Policy. Annual Conference. April.

29. Berhan, Tewolde and Egziabher. (1996). «A case of community rights». In: Tilahun, S. and Sue, E. (Ed.). *The movement for collective intellectual rights*. The Institute for Sustainable Foundation/The Gaia Foundation. Addis Ababa.
30. Posey, Darrell and Dutfield, Graham. (1996). *Beyond Intellectual Property. Toward Traditional Resource Rights for Indigenous Peoples and Local Communities*. International Development Research Centre. Ottawa.
31. Velásquez, Germán and Boulet, Pascale. (1999). *Globalization and access to drugs. Perspectives on the WTO/TRIPS Agreement*. WHO. WHO/DAP/98.9. Geneva.
32. UNDP. (1999). *Human Development Report 1999*. New York.
33. Arunachalam, Subbiah. (1995). "Science on the periphery: can it contribute to mainstream science?". *Knowledge and Policy*. Vol. 8. No. 2.
34. WHO. (1996). "Guidelines for the assessment of herbal medicines". *WHO Technical Report Series*. No. 863 (p. 180).

Research, drug development and manufacture of herbal drugs

B. B. Gaitonde

Introduction

Concept of Diseases and Drugs in Traditional Medicines

Two-thirds of the world's population depend upon herbal resources for their primary health care needs. Furthermore, a large number of modern drugs are either derived from plant material or conceived, modelled and discovered based on the practice of traditional medicine. Most people, particularly from rural areas in developing countries, have their access first to traditional herbal medicines to relieve or cure their ailments.

Traditional health practices are based on many years of experience acquired by humans in their journey in evolution. Primitive man sought remedies for illnesses from his surrounding animal, vegetable, and mineral kingdoms. Some of these remedies were based on mistaken beliefs or mysticism. However, as civilization progressed, particularly in Asia and notably in China, Egypt, India and the Middle East, the rich treasure of knowledge on herbal remedies was systematically preserved, collated and written about, based on the prevailing concepts of health and disease. This resulted in the development of different systems of medicine like the Chinese system, Ayurveda, Unani and Siddha. *Ebers Papyrus* of ancient Egyptians, or the *Samhitas* of Ayurveda were veritable treasurehouses of human knowledge on herbal remedies and ethno-therapeutics.

The origin of Ayurveda, the ancient system of medicine of the Indian subcontinent, can be traced to the *Vedic period*, i.e., about 1500 B.C. The *Atharv-veda* of the Aryans, composed during their migration to the Indian Subcontinent, described medicinal plant remedies for ill-health as well as for rejuvenation of the body and mind. The use of medicinal plants progressed into the period of the *Samhitas*, notably *Charak* and *Sushruta Samhitas*, wherein one finds the "healing science" emerging from the "magico-religious" state to a truly empirico-rational medicine. The *Samhitas* have elaborate treatises on recognition of plants based on their botanical characteristics, description of the parts of the plants, appropriate agronomic conditions for their cultivation (soil, manure, etc.), classification based on medicinal use (Charaka mentions more than 50 plant groups); collection, conditions for preservation, and the use of different parts of plants such as bark, stem,

leaves, flowers, fruits, seeds and roots. There are also elaborate descriptions of the methodology for the preparation of medicines (dosage forms) and methods of detoxification of mineral products.

Most fascinating are the descriptions of the pathogenesis of diseases based on the concept of *Tridosha*: *Vata*, *Pitta*, *Kapha*. It is postulated that the human body is composed of five elements (*Panchmahabhutas*) and is in perfect health when the "Three Doshas" are in a state of equilibrium. Disease produces imbalance of *Doshas* and, depending upon the nature and extent of imbalance, an appropriate management strategy is employed to bring back the body to its original equilibrium.[1]

Ayurveda describes very methodically the pharmacology of "Drugs and Diet", both being accorded equal importance in the management of a patient. Charaka's classification of plants was based on their therapeutic uses and properties. Each medicine and also dietetic article have in them what Ayurveda describes as *Rasa* (taste) *Vipaka* (alteration or metabolism in the body), *Virya* (potency) and *Prabhava* (specific action/potential which is beyond the *rasadi* attributes of the drug). Thus, in Ayurveda drugs are prescribed to treat an individual and not just his disease, depending upon the predominant property of the medicament and the *Prakriti* (*Vata*, *Pitta* or *Kapha*) of the patient.

In the Chinese system of traditional medicine, the human body is considered as a single entity. Normal body functions are a result of the harmonious, balanced behaviour of elemental forces called *Yin-yang* and *Wuxing*. Other concepts are *Zang fu* (internal organs) and *Jing luo* (channels and collaterals), and Qi, a vital force circulating in the body. Continuous circulation of Qi is believed to promote health, while interruption of Qi in any organ leads to disease. Acupuncture is said to stimulate *Yin* or *Yang* and restore the normal flow of Qi.

Numerous herbs or medicaments made from animal parts are thought to help in restoring the balance of *Yin* and *Yang* when disturbance manifests as disease. It describes measures to remain healthy and prevent or treat disease. Traditional Chinese medicine has produced over 10,000 medical books, and described over 5000 herbal drugs. Most countries in the Western Pacific Region have been influenced by traditional Chinese medicine.

These medicines are complex mixtures of plants, animal parts or products, minerals and metals. However, plants and plant products form the dominant part of the *materia medica* of traditional medicine practised in different parts of the world and in particular in Asia, especially China, India, Korea, Philippines, Indonesia and Tibet. In India, for example, the *Charaka Samhita* (treatise), dating back to 900 BC, lists 341 plants and plant products for medicinal use. Susruta, who practised surgery about 600 BC, described 395 medicinal plants. Vagbhatta practised Ayurveda in Sindh (now in Pakistan) around the 7th century AD and wrote an unrivalled treatise on the principles and practices of medicines called *Ashtangahridaya* which provides systematic descriptions of medicinal plants and mixtures of plant products, minerals or metals. *Bhavaprakash*, written by Bhavamishra in about 1550 AD, describes 470 medicinal plants. It is thus evident that traditional medicines offer a wide range of herbal medicines, often classified therapeutically.

Research Policy

Most countries in the South-East Asia Region (SEAR) have a political commitment

to give priority to research and development of traditional medicines. The health policy of China aims at integrating modern medicine with the traditional Chinese medicines and conducting research in traditional practices in a rational way. India has set up the Central Council for Research in Ayurveda and Siddha (CCRAS) and Unani systems to investigate a number of herbal medicines to establish the scientific basis of their use. The Indian Council of Medical Research has established a programme of Composite Drug Research (CDR) whereby herbal drugs are investigated by a team of traditional and modern medicine practitioners, a botanist, a phytochemist and a pharmacologist in a coordinated manner.

More than a hundred medicinal plants used in Ayurveda have been investigated in the CDR scheme and have provided some promising leads for further investigation. In some cases, the therapeutic claims made by Ayurveda practitioners have been justified by pharmacological studies. The plants selected in CDR have been botanically identified and their pharmacognostic data have been reported. Phytochemical studies have yielded some novel chemical structures.[2] Thus, the *Satavari* (*Asparagus racemosus*) root used in Ayurveda as a galactogogue was studied in experimental animals and reported to possess galactogogue and anti-oxytosic activities.[3,4] The plant is reported to contain *Shatavarin* having a specific pharmacological action. *Picrorhiza kurroa* has been reported to posses hepatoprotective activity and its active principles have been identified as Picrocytes. *Butea frondosa*, which is used in Ayurvedic preparations as an anthelmintic, has yielded an active principle called palasonin. *Guggulisterone* from *guggul* resin has been isolated.[2] The resin is used extensively by traditional practitioners in the treatment of inflammation of joints, obesity, lipid disorders, etc., on the basis of the description of *Medorog* (Lipid disorder) by Susruta. Chemical investigation has yielded two active compounds, namely *z-Guggulsterone* and *e-Guggulsterone.*[5] It is evident that such a composite approach in the investigation of medicinal plants is likely to be more rewarding in establishing the therapeutic claims of traditional remedies and obtaining novel chemical entities.

Thailand, Indonesia, Vietnam, Sri Lanka and Nepal, have all given priority to research in traditional medicines in their health and drug policies. Several countries have established pharmacopoeias of traditional medicines and established institutes to undertake research in all aspects, including standardization and quality control of herbal medicines.

Objectives of Research in Herbal Medicines

The hallmark of modern medicine is the scientific approach in promoting health, preventing diseases and curing ailments. Scientific methodology consists of the following approaches:

- Astute observation;
- Formation of hypothesis;
- Experimentation to prove or reject the hypothesis;
- Acceptance and incorporation of the results of research in modern medicine.

Since most herbal medicines used in traditional practices are based on empiricism, there is a need to separate chaff from the grain and prove, beyond reasonable doubt, the efficacy, safety and cost-effectiveness of herbal medicines. Such an approach not only enriches modern

medicine but the empiricism, if any, of traditional medicine also gives way to rationality.

In the context of primary health care, the major objective of such research would be the utilization of local resources in a more rational manner in meeting the health care needs of the vast majority of the population who are beyond the reach of modern medicine.

Policy and Organization

Several countries in SEAR have formulated national policies and strategies for research and development of traditional medicines. The overall developmental objective is the utilization of indigenous resources for the health and well-being of the populations. Specific objectives are:

- To evaluate, on a scientific basis, the prevailing health practices and adopt those in primary health care;
- To complement and enrich modern health practices by the experiences of traditional practitioners.

In order to implement the national policy on herbal medicines, there has to be a multidisciplinary organization. In such an organization, the key role of traditional practitioners must be emphasized. The organizational structure for such an integrated approach would involve a national committee for policy decision or a high-power board, consisting of botanists, pharmacologists, pharmacists and physicians of modern medicine along with an enlightened practitioner of traditional medicine, drug manufacturers and representatives of the drug regulatory agency.

Having verified the therapeutic claim of herbal medicines, the next step would be to develop methods of standardization, quality control and appropriate dosage forms.[6,7]

Drug Research

Research on herbal drugs as conceived in modern parlance consists of observations, discussions and literature review/search, animal experimentation, chemical fractionation and clinical evaluation. Opinions differ on whether it is appropriate to employ such a scheme for "Plant to Drug" in case of traditional medicines. Most traditional systems aim at a holistic approach for the cure of diseases and therefore most of their medicines are mixtures of plants, metals and minerals rather than a single drug as in modern medicine.

Furthermore, such a drug combination is conceived by taking into account the pathogenesis based on the concepts of health and disease in traditional medicine. Several drugs are combined with a view to enhancing the potency of each other or to mitigate or obligate the adverse effects of others. Most traditional practitioners have scant interest in research in herbal medicines since they firmly believe that such type of research is not necessary or because it will perhaps serve to enrich modern medicine rather than traditional medicine.

In spite of such views, there is a constant search for medicines from herbal sources. In the last two centuries, several drugs having a high therapeutic value have been derived from plants, for example, digoxin from digitalis, eserine from calabar beans, reserpine from the roots of *R.serpentina*, etc. Such drugs have not only entered the therapeutic armamentarium of modern physicians but also have served as tools to understand the physiology and pathogenesis of diseases.

"Plant to drug" research has often proceeded according to the following scheme:

Composite Drug Research

India and other countries in Asia, notably Thailand, Nepal, Myanmar and China, have adopted national policies aimed at research and development of national herbal resources and traditional medicines. One of the strategies adopted in India for research in the Ayurvedic, Unani and Siddha systems of medicine was the establishment of "composite drug research units". Each unit consists of a traditional practitioner, a crude medicinal plant collection centre with a pharmacognosist for establishing the botanical authenticity of the sample, a clinician of modern medicine, a phytochemist and a pharmacologist. Each unit has been allocated medicinal plants for investigation. As mentioned earlier, the major obstacle in such a study is that the traditional practitioners do not believe in using a single plant but a combination of plants with or without mineral or animal products. Elaborate methods of preparation of such a medicament are described. For example, *Celastrus paniculatus,* which has been prescribed in Ayurveda for improving

memory and intellectual performance, has an elaborate method of preparation of the oil from the plant.

Another problem encountered in research on herbal medicine relates to seasonal variations in the activities of plants. It has been reported that some plants, when collected only in a particular season, show activity. Samples collected in other seasons are devoid of active principles and therefore biological activity.

Ethno-Pharmacognostic Research

Although there are elaborate descriptions of medicinal plants using various synonyms, in the ancient treatises there are hardly any botanical descriptions as in modern pharmacognosy. The usual practice in ancient times seemed to be for a practising physician to collect plants from his surroundings and prepare the drugs himself for use in his practice. It is not unusual to find that a herbal medicine used in different parts of a country for a particular ailment contains plants widely varying in botanical characterizations. For example, it has been reported that samples of *Shankha Pushpi (Convolvulus pluricalis),* used by traditional practitioners in different parts of India, contain widely varying plant species. It is therefore necessary to study the ethno-practices in different parts of SEAR countries, collect samples of medicinal plants, and subject them to pharmacognostic studies employing modern methodology. In such a study it would be important to collect information not only on the plant itself but on the time of collection, cultivation, harvesting, the mode of preservation, conditions in which it is used (fresh or dried), parts of the plant in use (whole plant, leaves, stems, bark, flowers, shoots, fruits, seeds, or roots, etc.). It would also be necessary to study the method of preparation of dosage forms used in traditional practices, treatment formulae, dose and mode of administration to patients.

In this connection, a rational model developed in China is the use of retrospective data on plants or animals to analyse the rationale of their use in Chinese medicine. Thus, 248 plants and animal drugs used in over 700 polypharmacy prescriptions were studied for their rationale, if any, based on the published reports of their pharmacological actions, complete with any available folklore claims. If there was any correlation between reported pharmacological effects with use in Chinese medicine, it was presumed that there is a rational basis for its use.

Another important consideration given by the Chinese is what is described as “Conversant evolution”. If a particular traditional medicine is used for the same purpose by peoples widely separated by geographical distances or belonging to different religious, ethnic or cultural backgrounds, a strong possibility of its being “really effective” was accepted and further research was undertaken.

Ethno-botanical studies involve macroscopic and microscopic descriptions, preparation of plant specimens for a herbarium and also a preliminary chemical analysis to identify chemicals such as alkaloids, glycoside, terpenes, sesquiterpenes, etc.

Napralert Database

A computerized database on the chemistry and pharmacology of natural products is now available at the University of Illinois, USA. This department is now headed by Dr Fong. The database covers over 4595 genera of plants, animals and micro-

organisms. It provides useful information on plants used in traditional medicines and can be used for literature search before planning an elaborate research programme.[8]

It is possible to obtain from the database names of plants of a specific country or area: plants with pharmacological data on specific activity, i.e., hypoglycaemic, antitumour, antifertility, etc.

Agrobotanical Research

Such research is necessary for the identification and evaluation of the natural distribution of the plant species. Research on conditions of soil, weather, or type of manure used for cultivation of the plant and the effect on seasonal variations in the growth and properties of the plant would also form a part of such agrobotanical studies. Such studies are important for undertaking the cultivation of medicinal plants and making herb gardens.

Pharmacological Studies

Modern pharmacology has made remarkable progress in the last four decades. From the early days, when pharmacodynamic studies were done to determine the effects of drugs on systems and tissues, i.e., on circulatory or nervous systems, etc., the scientists working in this field are now involved in identifying the molecular basis of drug action, interactions with receptors (both extra and intracellular) effects on transmission mechanisms or interaction with cytokines. With the cloning of receptors through recombinant DNA technology, research methodology has been further refined.[2]

Classical pharmacological studies on experimental animals, using crude or refined plant extracts, have yielded some fruitful data. On a global basis, about 130 drugs, all single entities extracted from higher plants or modified chemicals, are currently used in modern medicine.[2]

However, such a classical "phyto pharmacological" approach has not been cost-effective. In fact, out of 200 new chemical entities (NCE) introduced in medicinal chemistry globally, only about 2 per cent were based on higher plants.[(2)] The National Cancer Institute (USA), beginning in 1959, screened over the next 25 years, 180,000 plant extracts covering

Table 1. Drugs from ethnotherapeutic field

Drugs	Ethnotherapeutic information
Morphine	Opium used by ancient Egyptians and Sumarians
Atropine	Used by Babylonians
Ephedrine	Used by the Chinese for respiratory ailment (2700 BC)
Quinine	Used by Peruvians for fever
Emetine	Used by Brazilians and South Americans for dysentery and to induce vomiting
Digoxin	Used in England in the 17th century for heart illness
Tubocurarine	Used as arrow poison by Red Indians
Reserpine	Rauwolfia serpentina used as 'folklore' remedy for mental diseases in Bihar (North India)
Artemisin	Used in ancient Chinese medicine for fever

* Modified for Table 1 in reference: Sukh Deo

3500 plant genera but this tremendous effort did not yield a single marketable drug.[2] This has weaned major pharmaceutical companies away from plant research and instead made them go in for synthetic drugs. In synthetic drug research, once any innovative breakthrough occurred, several "me-too" drugs flood the market. Several examples can be given about the success of this approach, such as NSAID, ACE, inhibitor, B-lactamase inhibitors, quinolones and B-blockers. This has no doubt proved cost-effective.

In spite of what has been said above, it must be emphasized that the ethnotherapeutic use of traditional medicines provides clues for searching for plant drugs, identifying their active principles, synthesizing their analogues, and leading to their introduction in modern therapeutics. The following Table (adapted from Sukh Deo, 1997)[2] gives examples of some important remedies which are the result of such investigative approach.

From the Table, it is evident that traditional medicines offer investigative leads to undertake further studies to assess and establish their therapeutic utility in a number of clinical conditions, especially those diseases in which modern medicine offers very limited therapy. In Ayurveda, for example, there is a group of drugs called "*Rasayana*" or life promoters or rejuvenators, which can be investigated in terms of modern physiological parlance, as anti-inflammatory, antioxidants, immunomodulators, antiaging, etc.[8]

Specific Screening Models

Experimental pharmacology offers several screening models to screen crude or semi-

Table 2. Some plants with notable therapeutic activity[(2)]

Botanical name	Probable therapeutic activity
Acorus calamus	Tranquillizer
Asparagus racemosus	Galactogogue: uterine sedative
Bacopa monnieri	Improves memory
Boerhaavia diffusa	Diuretic
Curcuma longa	Anti-inflammatory
Phyllanthus niruri	Hepatoprotective
Picrorrhiza kurroa	Hepatoprotective
Celastrus paniculatus	Immunomodulator, antioxidant
Ocimum sanctum	Antistress
Gymnema sylvestre	Hypoglycaemic
Momordica charantia	Hypoglycaemic
Hibiscus rosa-sinensis	Hypoglycaemic
Plumbago zeylanica	Antifertility
Commiphora mukul	Hypolipidemic
Withania somnifera	Tranquillizer, immunomodulator
Terminalia chebula	Antiaging
Convolvulus microphyllus	Neural regeneration and synaptic plasticity
Panax ginseng	Antifatigue, adaptogenic, antistress

purified herbal drugs for therapeutic activities based on traditional usage.[9,10] Some of the models used in the screening programme are discussed.

The criteria for selection of plants mentioned under each of the activities can be summarized as follows:

- Plants are in use by traditional practitioners in a particular clinical condition;
- Preliminary pharmacological studies have yielded promising leads;
- Plants are mentioned in the ancient texts as useful in certain diseases, particularly those for which there are no effective or safe drugs in modern medicine, e.g., diabetes, arthritis;
- Ancient texts providing leads for selection of plants for screening for such conditions as cancer, stress, rejuvenation.

Anti-inflammatory, Analgesic-Antipyretic Activities

Several herbal remedies have been screened for anti-inflammatory, analgesic and antipyretic activities using appropriate screening models. A simple and commonly used method to study anti-inflammatory activities, though not ideal, is carageenin-induced oedema of rat paws. Analgesic activities have been studied in animal models to assess pain relief in acid-induced writhing in mice or by tail clip method in rats. Antipyretic activity has been studied in animals with induced fever.

Several plants have shown anti-inflammatory activities in a number of screening models and would need further studies. Thus, *Randia dumetorum* contains orionic acid 3 B-glucoside, which was reported by Ghosh, et al (1983), as possessing anti-inflammatory activities in the exudative and proliferative phases of inflammation in rats.[11] B-sitosterol isolated from *Cyperus rotundus* possesses anti-inflammatory activity comparable to hydrocortisone.[12] *Tinospora cordifolia* was reported by Pendse, et al (1981), as possessing anti-inflammatory activity against both acute and chronic inflammation comparable to non-steroidal anti-inflammatory agents.[13]

Potassium embelete, a quinone obtained from *Embelia ribes*, was reported by Atal, et al (1984), as a potent, centrally acting analgesic. It was reported to possess a highly therapeutic index and lack abstinence syndrome.[14] Similarly, *Solanum melangena* was reported by Vohra, et al (1984 a), as possessing non-narcotic analgesic activity.[15] Petroleum ether extract of *Abutilon indicum* was shown to possess analgesic activity against acetic acid-induced writhing in mice and has a good margin of safety.[16]

Antiallergic Activity

Several plants are used in traditional medicines for treating allergic conditions such as bronchial asthma, urticaria, eczema and allergic rhinitis. These are usually screened in animal models on the basis of their antihistaminic or antiserotonin activities in isolated tissue systems such as isolated intestine and isolated lung perfusion. Other models used are passive cutaneous anaphylaxix in rats (PCA), histamine contents, or release by antigens.

Plants showing some antiallergic activities are:

- Piper longum;
- Tylophora indica.

Dry fruits of *Piper longum* reduced PCA in rats and also prevented histamine-induced bronchospasm in guineapigs.[17] Similarly, *Tylophora indica* alkaloids were found to posses activity comparable with

disodium cromoglycate.[18] Because of their extensive use in Ayurvedic preparations and supportive experimental evidence, both the plants would need further evaluation.

Hypoglycaemic Activity

Diabetes mellitus has been described in ancient texts on traditional medicine both in China and India. In Ayurveda, Charaka has given an elaborate description of the disease and has prescribed the dietetic regime and drug treatment.

Following are some of the herbal remedies screened for diabetes. The most often used screening model is alloxan-induced hyperglycaemia in rats and rabbits. Some plants screened for the hypoglycaemic activity are:

- Acacia catechu;
- Gymnema sylvestre;
- Momordica charantia;
- Leucaena leucocephala;
- Hamiltonia suaveolans;
- Pterecarpus marsupium.

Gymnema sylvestre is used in combination for the control of diabetes and was reported to regulate blood sugar in experimental animals by affecting insulin-dependent enzymes.[19] *Momordica charantia* contains a polypeptide posse-ssing hypoglycaemic activity[(20)] and the plant was shown to be effective in both juvenile and maturity onset diabetes, probably due to increased insulin release from pancreas.

Diabetes is a complex metabolic disorder which, according to the traditional medicine concept, needs management of diet, physical activity, emotional problems and appropriate drug combinations.

Diuretics

Drugs of this class are used in several clinical conditions, such as dropsy, hypertension and acute left ventricular failure. Diuretic activity has often been studied in rats primed with saline and measuring urine output in a fixed time period. A dose response study is planned, and the effect on sodium or potassium excretion can also be assessed.

Plants showing diuretic activity are:

- Milingtonia hortensis;
- Toddalia asiatica;
- Cucumis trigonus.

Millingtonia hortensis showed a significant natruratic effect without affecting potassium excretion to any great extent.[21] *Toddalia asiatica* was reported to contain coumarins which possess diuretic activity though less potent than hydrochlorothiazide.[22] Similarly, *Cucumis trigonus* was also reported to possess some degree of diuretic activity.[23]

Spasmolytic Activity

These drugs are used to relieve spasm of smooth muscles as in bronchial asthma, renal colic or colicky pain in abdomen. Several test systems have been used to assess the spasmolytic activity of the plant extracts. Commonly used ones are isolated guineapig ileum, spasm induced by acetyl chloline or histamine and tracheo-bronchial tree of guineapigs. Since histamine has been implicated in bronchial asthma, its release or that of other cytokines, induced by histamine releasers or stabilization of mast cell granules, has been studied to assess the effects of plant extracts on various local hormones.

Some of the plants screened for spasmolytic activity are:

- Clausena pentaphyla;
- Corydalis meifolia;
- Symplocos spicata;
- Corchorus tridens;
- Selaginella rupestris.

Patnaik and Dhawan (1982) have reported extensively on several species of *Clausena*[24] *Clausmerin*-produced relaxation of smooth muscles. This compound seems to possess a high safety margin. Bhakuni and Chaturvedi (1983) reported on the spasmolytic activity of *Corydalis meifolia.*[25] The active compound was not as potent as papaverine. *Symplocos spicata*[26] *Corchorus tridens,*[27] and *Selaginella rupestris*[28] show varying degrees of spasmolytic activity in experi-mental models.

Ocimum Sanctum - antistress, adaptogenic plant used in India

Central Nervous System Activity

A large number of herbal remedies are used in traditional medicine to influence the functions of the nervous system. While some enhance or depress CNS non-specifically, others are used to influence behaviour abnormalities, sleep pattern, improvement of memory or in the treatment of mental disorders like depression, schizophrenia or dementia.

Most studies are conducted in rats or mice for exploring the effects of plant extracts on motor activity, exploratory behaviour, amphetamine-induced agitation, conditioned reflexes, drug-induced convulsions, phenobarbitone-induced sleeping time, behavioural responses, natural or acquired, etc. Several investi-gators have studied a number of plants mentioned in traditional medicines for their effects on different functions of the nervous system using very sophisticated techniques like stereotaxic stimulation, estimating neurohormones in different parts of the brain, etc.

The following are a few plants screened for their activities on the CNS:

- Melia azadirach;
- Hydrocotyle asiatica;
- Salvia haematodes;
- Calophyllum inophyllum;
- Taxus baccata.

Amongst these, *Bacopa monnieri* has been investigated extensively by Singh and Dhawan (1982, 1985) who have confirmed the claims made in Ayurvedic texts on memory and performance in experimental models.[29,30] *Melia azadirach* was shown by Srivastava, et al (1981), as an anorexogenic.[(31)] Agrawal (1981) reported on the neuroleptic activity of *Hydrocotyle asiatica*, showing promising results.[32]

Adaptogenic Activity

Ayurveda has described a group of complex remedies called *Rasayanas* or life promoters. Some of these can be described as antistress, immunomodulators, preventives of memory loss or cognitive functions, etc. They provide a challenge to modern pharmacologists to devise screening models for establishing an appropriate activity as described in ancient texts.

The effects of drugs have been studied on stress-induced pathological changes in mice or rats, such as increased endurance of swimming mice, stress-induced gastric ulcers in rats, milk-induced leucocytosis in mice, stress-induced increase in the weight of adrenal glands in mice, and isoprenaline-induced myocardial damage in rats. More recently, with the advances in

molecular pharmacology, investigators in this field have looked afresh at some of the plants utilizing receptor-binding or/and enzyme-inhibition techniques. These have provided encouraging clues and would need further probing.

Plants described in traditional medicines as possessing antistress activity are:

- Allium sativum;
- Acorus calamus;
- Celastrus paniculatus;
- Centella asiatica;
- Convolvulus microphyllus;
- Nardostachys jatamansi;
- Ocimum gratissimum or sanctum;
- Pluchea lanceolata;
- Terminalia chebula;
- Withania somnifera;
- Emblica officinalis.

Dahanukar, et al (1997), in a series of experiments, have reported the beneficial effects of aqueous extracts of several of the above-mentioned plants in experimental animals in doses comparable to those used in humans.[33] All of these were found to produce immuno-stimulation. *Emblica officinalis* seems to strengthen defence mechanisms against free radical damage induced by stress. Sambulingum, et al (1997), have shown the antistress effects of *Ocimum sanctum* especially in noise pollution-induced stress.[34]

Such leads provided by traditional medicines call for further studies in this important area, particularly with a view to elucidating the mechanism of action of the drugs vis-à-vis the pathogenesis of stress.

Anticancer Activity

Several plants and plant extracts have been studied as anticancer agents, chemo-preventive, radio sensitizers, or immunity enhancers. Test systems are cancer cell lines or *in Vivo* tumors. Alkaloids from *Vinca rosea* have already been used in the treatment of human cancers for over a decade. The following herbal products have shown some anticancer activity:

- Centella asiatica;
- Salacia oblonga;
- Janakia arayalpathra;
- Podophyllum hexandrum.

The plants mentioned above have been reported to posses either direct anticancer activity in experimental models or have radiosensitizing or immunostimulant effects. These have been reviewed by Dahanukar, et al (2000).[35]

Nutraceutics

There is an emerging trend to use dietary substances for the prevention or cure of diseases. People are becoming more and more health conscious and wish to pick and choose “diets” which promote health and avoid “those” which cause harm. Scientists all over the world are studying the scientific basis of such a line of thinking or dietary practices. Some of the “dietetic substances” studied are the following:

- Edible oils;
- Spinacia oleracea (Spinach);
- Momordica charantia (a vegetable);
- Curcuma longa (condiment);
- Trigonella foenum graecum (seeds);
- Murraya koenigii (curry leaf);
- Brassica juncea (mustard seeds/ leaves);
- Mentha spicata (mint leaf);
- Allium cepa (Onions);
- Allium sativum (Garlic);
- Myristica fragrans (Nutmeg);
- Piper nigrum (Black pepper).

In traditional medicine, diet plays a major role in health and disease. In Ayurveda, dietetic articles are described as

ushna (hot) or *sita* (cold) and the patients, depending on their *Prakriti*, are advised to take or avoid one or the other. Sarkar, et al (1996), have reported on the clastogenic and non-clastogenic effects of Indian spinach.[36] *Momordica charantia,*[36] edible oils,[37,38] *Curcuma longa,*[39] Fenugreek,[40,41] and *Mentha spicata.*[42]

Anti-peptic Ulcer Activity

Acid peptic disease is treated with remedies which restore equilibrium of humors in the body. There is, therefore, no appropriate test model to assess the activity of herbal medicines in this disease complex. However, commonly used models to test antipeptic ulcer activity are experimentally produced ulcers in rats by pyloric ligation, or immobilization, and prednisolone or histamine-induced ulcers in guineapigs. Herbal drugs proposed for this condition are:

- Tectona grandis;
- Andrographis paniculata.

Ethanol extract of the bark of *Tectona grandis* was studied by Pandey, et al (1982), and showed anti-ulcer activity in rats and guineapigs.[43] Vishwanathan, et al (1981), reported a similar activity of a flavone isolated from *Andrographis paniculata.*[44] Several such plants used in combination by traditional practitioners in gastric disorders should provide leads from animal experimental studies for clinical evaluation.

Hepatoprotective

Modern medicine does not offer any specific hepatoprotective drugs. Viral hepatitis or liver cirrhosis is treated symptomatically and by diet rather than drugs.

Traditional medicine, in particular Ayurveda, offers several medicinal plants with possible hepatoprotective activity. Experimental test models which are commonly used include hepatic damage induced by carbon tetrachloride in rats, both as acute and chronic hepatic injury.

Alcohol, isoniazide, pyrazinamide or paracetamol-induced hepatic injury in rats has also been used to produce hepatic injury. However, there is no animal model to simulate chronic progressive hepatitis or cirrhosis.

The following are commonly used herbal medicines as hepatoprotectives:

- Tinospora cordifolia;
- Acacia catechu;
- Piper longum;
- Phyllanthus niruri;
- Eclipta alba;
- Picrorhiza kurroa.

Rege, et al (1984b), have reported that chronic liver damage was prevented by *Tinospora cordifolia.*[45] Similarly, *Acacia catechu* prevented chronic damage of liver but not the acute variety. *Piper longum* is a drug most commonly advocated in Ayurveda for the treatment of liver disorders. However, in studies by Rege, et al (1984c), it only seems to restrict fibrosis.[45] *Picrorhiza kurroa* and *Eclipta alba* have been extensively investigated for hepatoprotective activities (Pilankar, Ph.D thesis submitted to Mumbai University).[46] These drugs form important ingredients of Ayurvedic preparations such as Liv 52 or Liv 100 marketed in India for liver disorders. Vaidya, et al (1996), have reviewed experimental and clinical research relating to the hepatoprotective effects of Ayurvedic formulations.[47] Saraswathi, et al (1998), have reported on the hepatoprotective activities of Liv 52 and Liv 100, which are mixtures of herbal drugs extensively used in liver disorders such as progressive hepatitis, and cirrhosis.[48] It was shown that hepatic enzyme activity was protected by these preparations.

Antifertility Activity

The serious problem of population explosion and the limitations of modern drugs used in the control of conceptions have attracted the attention of several scientists sufficiently for them to investigate medicinal plants for antiinfertility activity in both females and males.

The test models usually employed are anti-implantation study in rats, litre size, estrogenic or anti-estrogenic or abortifacient activity in rats, study of the response of isolated rat uterus induced contracture, *in vitro* spermicidal activity, etc. In males, the test models are the effects on testes in male dogs, the effect on spermatogenesis in dogs, mating behavioural study, etc.

Some of the plants screened for antifertility activities are:

- Bupleurum marginata;
- Embelia ribes;
- Thespesia populnea;
- Hibiscus rosa-sinensis;
- Plumbago zeylanica;
- Xeromphis spinosa;
- Annona squamosa;
- Lygodium flexuosum;
- Adhatoda vasica;
- Azadirachta indica;
- Trichopus zeylanicum.

Kamboj and Dhawan (1982) have presented a review of medicinal plants screened for antifertility activity in experimental animals.[49] Embelin isolated from berries of *Embelia ribes* was reported by Prakash (1981) as possessing significant anti-implantation activities.[50] *Hibiscus rosa sinensis* flowers have been used in traditional medicine as antifertility agents. They have shown both anti-fertility and aborticacient activities in rats.[51] *Plumbago zeylanica* was studied by Chowdhary, and reported to possess some degree of activity. *Lygodium flexuosum* was studied by Gaitonde, et al, on the basis of its use in folklore practices among *Adivasis* in Maharashtra, India. The plant extracts showed significant anti-implantation activities in three species of animals and the effect was reversible.

Chemotheapeutic Agents

The chemotherapeutic era started with penicillins isolated from molds. Thereafter, several compounds possessing antimicrobial, antifungal, antiviral and antiparasitic activities have been studied and introduced as chemotherapeutic agents. The test system is to note the effect of the plant product on the *in vitro* culture of micro-organisms or to study the effect in experimental animals infected with the organisms. Some of the plant products showing such chemotherapeutic activities are:

- Clausena anisata;
- Cassia alata;
- Semecarpus anacardium;
- Cinnamomum zeylanicum;
- Azadirachta indica.

Antiviral Activity

This is shown by the following plants:

- Phyllanthus amarus;
- Glycyrrhiza glabra.

Antimalarials

- Artemisia japanica;
- Artemisia maritima;
- Azadirachta indica.

Most investigators in this field have used standard *in vitro* assays. *Clausena anisata* was active against both gram-positive and gram-negative bacteria.[52] Annona glabra was reported to possess a substantial anti-microbial, anti-fungal and moderate degree of insecticidal activities.

Semecarpus anacardium was shown to be bactericidal *in vitro* against gram-negative organisms such as *S.typhi* and *Proteus vulgaris*. The growth of *Vibrio cholerae* was inhibited by the acetone extracts of *Cassia alata*. Agnihotri and Vaidya (1996) have studied a number of plants for their antibacterial properties and found *Thymus vulgaris* to posses substantial antibacterial activity.[53]

Azadirachta indica was shown to be very active against clinical isolates of dermatophytes. Similarly, essential oils obtained from *Santolina chamaecyparissus* showed a significant activity *in vitro* against *Candida albicans*. Rai screened 17 medicinal plants (1996) for anti-mytotic activity and reported that maximum activity was present in *Eucalyptus globulus* and *Catharanthus roseus.*[54] *Ocimum sanctum* was also found to be effective as an antimytotic.

Phyllanthus amarus was reported to be effective against Hepatitis-B virus at cellular level.[55] *Glycyrrhiza glabra* has been tested against both DNA and RNA viruses *in vitro,* particularly on DNA viruses. Premnathan, et al, have also carried out *in vitro* screening against HIV-infected MT-4cells. Some plant extracts were found to inhibit the adsorption of HIV virus into the cells.[56]

With the resurgence of malaria, several plants have been studied for antimalarial activity on the basis of leads provided by either folklore use or ancient texts of traditional medicines. Both *in vivo* and *in vitro* screening models have been used and several species of *Artemisia* were reported to possess varying degrees of antimalarial activities.

From the above discussion it becomes evident that further research, in particular clinical studies based on specific pharmacological properties, would prove rewarding.

Phytochemical Research

Chemical processing of the plant or its parts involves the following steps

- Crude Plants/parts;
- Dried – sometimes fresh;
- Solvent extraction.

Step I

Identification of active chemical constituents:

- alkaloids, glycosides, terpenes, sesquiterpenes (terpenoids)
- oleoresins, steroids, coumarins, etc.;

Step II

Further purification using:

- Thin-layer chromatography or ion exchange, or gas,
- Chromatography,
- Coupled with mass spectrometry,
- High-performance liquid chromatography (HPLC);

Step III

- Determination of chemical structure.

Chromatography is a powerful tool used primarily for separating the components of a sample. The components are distributed between two phases, one of which is stationary and the other mobile. The sample, when introduced into the mobile phase, undergoes a series of partition or adsorption interactions as it moves through the chromatographic system.

It is expected that the differences in the physical and chemical properties of the individual components determine their relative affinity for the stationary phase and therefore the components would migrate through the system at differing rates. This permits separation, isolation, identification and also quantification of the chemical constituents in a mixture. Each of the

purified components can, after elution, be tested for biological activity in an appropriate test system. Thus, by such highly sophisticated methodology it is possible to proceed from "plant to drug".[2]

Drugs derived from plants as pure chemicals have been in therapeutic use for almost a century. Some of the plant constituents have yielded novel chemical entities, leading to their synthesis and the preparation of their analogues or derivatives. Some examples of such drugs derived from plants are given in the following Table.

Table 3. Drugs derived from plants

Source Plant	Active Constituent
Digitals lauata	Digoxin
Ephedra vulgaris	Ephedrine
Rauvolfia serpentina	Reserpine
Cinchona bark	Quinine
Artemesia annua	Artemisinin
Commiphora mukul	Guggulusterones
Asparagus racemosus	Shatavarin
Picrorhiza kurroa	Picroside
Adhatoda zeylanica	Vasicine
Atropa belladona	Atropine
Papaver somniferum	Morphine

Plant Culture

This is a recent addition to bio-technology in plant research. *In vitro* plant cultures under varying experimental conditions result in bioproducts with novel chemical structures and biological activities.

Structure-based Designs

Having identified a chemical structure, organic chemists are engaged in intensive computerized drug design exercises. This requires computer graphics, software for molecular visualization, and docking programmes to screen and find out which compounds satisfy the appropriate stereo-structure. Computer modelling has already yielded a number of compounds of herbal origin with therapeutic possibilities.

Molecular Approach to Drug Development

In recent years there have been tremendous advances in understanding how drug molecules modify cell functions. After Paul Ehrlich postulated that drug molecules interact with specific areas on cell membrane or inside the cell called "receptors", such receptors have now been identified and their stereo-chemistry studied. With advances in genetic engineering the receptors have even been cloned. It is now possible to study drug receptor interactions and their kinetics and therefore it is possible to evaluate the therapeutic potential of several naturally occurring phytochemicals derived from higher plants.

While most investigators in this area of drug development would prefer to work on synthetic drugs, the potentials of herbal medicines offering interesting chemical entities are enormous. This type of development can only be undertaken by the pharmaceutical industry. Considering that their annual turnover exceeds US$ 200 billion globally and the R&D inputs of some dominant pharmaceutical companies is in the vicinity of 10–15 per cent of their turnover, it is possible for such frontline industrial houses to invest in R&D on the basis of leads provided by *materia medica* and practices of traditional medicine.

Research on Quality Control Methodology and Standardization

Quality control and standardization are essential to ensure safety and efficacy. Most

herbal drugs are complex combinations and are often prepared by a variety of methods described in the ancient texts. Very often these methods are not well-standardized and therefore the end-product may not yield consistent results. The tests on the final product or dosage forms are not often available in the old treatises. It is therefore essential to undertake extensive research and development for quality control and standardization.

Herbal preparations contain active ingredients of plant parts or materials in a crude or processed form. India, China, Thailand and Indonesia have prepared pharmacopoeias of herbal medicines which describe the botanical characteristics or pharmacognosy of individual plant materials, their chemical characterizations, including the spectrum of active ingredients, both quantitative and qualitative, methods of preparation, and some tests on the final product. However, much more research is needed in this field, particularly for developing methods for quality control to be used by the authorities for regulatory control and for their harmonization and improvement by different countries in the South-East Asia Region.

The combination of scientific studies and traditional knowledge should be the hallmark of such research. Scientific methods presently used include studies on botanical characteristics and chemical studies using instrumentation analysis such as neutron activation techniques. Since this type of research would require adequate resources, both human and financial, it can best be undertaken either by commercial companies or through international collaboration.

Variations of plant material harvested from different geographical areas in different seasons pose a serious problem in standardization. In order to obtain uniform and high quality raw materials which are fundamental for quality assurance, the trend is towards domestication of plants (herbal gardens), genetic improvement or use of plant-culture techniques.

Safety of Herbal Medicines

Any medicinal preparation, whatever its origin, has to be safe for human or animal use. Since traditional medicines, particularly of herbal origin, have been in use over several centuries, these are presumed to be free from toxic effects. These presumptions do not seem to be valid in all cases considering that medicinal plants contain highly toxic chemicals such as glycosides, alkaloids, or saponins and cytotoxic agents. There is a likelihood that herbal medicines in general have overall less toxicity than synthetic compounds. Furthermore, the traditional methods of preparation of dosage forms and combinations of several plants are supposed to reduce or eliminate toxicity and make the final product safe for therapeutic use.

Elaborate toxicity studies prescribed by regulatory authorities for “New Drugs” are not required for those herbal medicines which are either described in ancient treatises or are in use as folklore for several centuries. However, most regulatory authorities would require some toxicity data in two or more species of animals before allowing such drugs to be adopted in national pharmacopoeia or in therapeutic practice.

Once the active principles from a herbal drug are isolated in chemically pure form and their analogues are prepared, such “New Drugs” would require elaborate toxicity studies.

There are a few reports on adverse reactions to herbal medicines. Very often there is a lack of proper observation in

patients and of documentation. In order, therefore, to assess the extent of adverse reactions, it is desirable to undertake multicentric studies on the adverse effects of some commonly used herbal medicinal preparations in the field situation, in particular at primary health care, level through a judicially devised open-ended questionnaire. Such a study would throw more light on the problems of safety of herbal medicines.

Efficacy: Clinical Research

Since herbal medicines have been in use over several centuries, they are regarded as useful and efficacious in the treatment of ailments. While the original herbal remedy may often have been found by chance, several substances of doubtful merit have no doubt entered traditional practices. Some of the ancient recipes contain such amazing and often preposterous substances like pearls, musk, crocodile's dung, horns of antelopes, extracts of ants and so forth. It is therefore necessary to separate the grain from the chaff.

Most physicians in the past millenium have relied upon traditional *materia medica* based on empiricism. There is a possibility that for every therapeutic regimen of some significance, there would be several others, acceptable to the practising physicians of those times which may appear incredible to the present-day scientific community. The modern scientific community may raise such questions as how to differentiate the good from the bad and how to differentiate a truly effective therapeutic remedy from misguided enthusiasm.

Applying modern concepts and methodology, the basis of all treatment regimes should be experimentation. The essential elements of all scientific evaluation are critical observations, hypothesis, carefully designed experimentations and valid conclusions. Through this process alone can rational therapeutics progress.

Application of the science of statistics to clinical experimentation is now recognized as essential for valid conclusions from experimentations. In most instances, patients vary in their responses to the same medication. The disease process itself may have such wide variation. Prof. Bradford Hill therefore put forward the concept of controlled clinical trials which demands, i) Two or more groups of patients observed at the same time and differing in the treatments, ii) Constructing the groups by random selection (randomization), iii) Use of placebo or inert medication, and iv) Comparison of two or more types of treatment or treatment regimens by applying appropriate statistical methods.

The objectives of the clinical evaluation of herbal medicines are, i) Establishing scientific validity for herbal medicines used by traditional practitioners, ii) Studying plants considered medicinal and available locally in abundance, and iii) Searching for drugs from medicinal plants for chronic, refractory or specific diseases for which there is no satisfactory treatment presently available in modern medicine. Some examples of such diseases are atherosclerosis and hyperlipidaemia, bronchial asthma, immunological disorders, rheumatoid arthritis, urolithiasis, metabolic disorders like diabetes mellitus, acid peptic disease, ulcerative colitis, liver diseases, fertility control, malignant malaria, mental diseases, rejuvenation of the elderly (cognitive disease), including Alzheimer's disease, etc.[8]

In the case of the first objective, clinical evaluation using conventional scientific methods is all that is necessary to prove the claims of herbal medicines. There is no

need for elaborate preclinical studies. The modern-medicine clinician should work with a traditional practitioner for evaluating the clinical efficacy of the drug therapy, using dosage forms used by the traditional practitioners. This is important because there are examples where dosage forms of herbal drugs prepared by modern pharmaceutical methods may not yield the expected results.

Having established efficacy and "Clinical Safety", the next step would be to evaluate dosage forms and the appropriate dose of the medicine, with the objective of adopting these in modern pharmacopoeias. At that stage, drug regulatory authorities should be consulted to find out if it is possible to lay down standard quality control methods and establish large-scale production facilities.

Plants considered medicinal and available locally in abundance will fall into two groups: i) Those described in either traditional or modern literature, either singly or in combination, and ii) Those which are "folklore". In the case of the first group, based on the literature survey, a protocol is prepared for clinical evaluation taking into consideration all the available information such as agro-botanical and ethno-pharmacognostic data, phytochemical data, pharmacodynamic studies and acute and subacute toxicity data.

In the case of "folklore" medicines, careful observations and study of "folklore practices", the traditional method of preparation and rituals accompanying the administration of the medicine are prerequisites for planning clinical evaluation. At this stage, the objective is simply to assess

the efficacy of the herbal medicine. Having validated the claim, it would be necessary to plan an elaborate research programme in order to adopt the drug in modern clinical practice.

Research and development of herbal drugs for specific chronic diseases should follow more or less the same approaches as in the case of "folklore" medicines. In this type of research, a careful study of traditional literature, the concepts of health and diseases, descriptions of the pathogenesis of the specific condition, and the mechanisms of drug action as described in ancient treatises, are all important and necessary before embarking on such type of research.

It is also necessary to try to correlate modern concepts of the pathogenesis of disease with the traditional concept. For example, the *Rasayana* drugs mentioned in Ayurveda as health promoters can be conceived to act as "antioxidants" or immunomodulators, and *Celastrus paniculatus* (*jyotishmati*) described in Ayurveda as a promoter of memory could act through receptor activation or regeneration. Sushruta has described treatment of obesity and lipid disorders (*medoroga*) with the use of a gum resin from *Commiphora mukul* called "*Guggulu*" in Sanskrit. Sushruta gives an elaborate description of the etiology and pathogenesis of the disease, which has a considerable resemblance to the modern concepts of atherosclerosis. Dr C. Dwaraknath, the then advisor to the Government of India on traditional medicines (1969), proposed a collaborative study on this plant for its use in atherosclerosis or hyperlipidaemia. This study has led to the isolation, identification, and characterization of a new structural type, *Guggulusterone*. A similar approach has been adopted for herbal drugs in the treatment of liver inflammation and degeneration. *Phyllanthus niruri*, or *Picrorhiza kurroa* are examples of herbal medicines investigated for their effectiveness in liver disorders based on Ayurvedic concepts, and this has led to the isolation of a novel chemical structure. *Asparagus racemosus* is described as galactogogue and used in lactating mothers. Its investigation has resulted in the isolation of *Shatavarin*, a chemical with a novel structure. As mentioned earlier, *Artemesin* and *Aretemesinine* isolated from *Artemisia annua* in China has proved a very valuable drug in the treatment of falciparum malaria. This is based on the use of the plant in fevers mentioned in ancient Chinese medicines.

Pharmaceutical Technology

Herbal medicines, used by traditional practitioners, are administered to patients in several dosage forms. These are prepared according to methods prescribed in ancient traditional treatises. For example, Ayurvedic classics mention elaborate pharmaceutical methods for the preparation of a medicament. Usually the dosage forms prepared according to Ayurvedic texts are distillates (*Arka*) fermented products (*Asavas and Aristas*), Linctuses, (*Avaleha*), powders (*Churna*), incinerated material (*Bhasma*), pills or tablets (*Vati/gutika*), and decoction (*kwatha*).

As mentioned earlier, it is important that traditional pharmaceutical technology is investigated thoroughly before changing over to modern technology. It is possible that the therapeutic properties of the dosage forms are preserved only when these are prepared according to traditional pharmaceutical methods, and this aspect therefore needs investigation.

Standardization and Herbal Pharmacopoeias

Several countries in SEAR have developed methods for the quality control and standardization of herbal medicines. This activity is often undertaken in close collaboration with traditional practitioners utilizing the expertise in ethnobotany, phytochemistry, pharmacology and cell biology. Investigation of this nature has led to the development of monographs on simple or complex herbal medicines. These have been compiled into a National Pharmacopoeia of Herbal Medicines. For example, the 1990 edition of Chinese Pharmacoepoeia enlists more than 784 traditional Chinese drugs.

China, India, the Philippines and Indonesia have published National Pharmacopoeias of herbal medicines listing several local drugs. This is a continuing process and has been going on in order to make additions, deletions, and refinement of methodology. Such pharmacopoeias are yet to gain recognition by drug regulatory authorities in some countries.

Manufacture

Globally, the pharmaceutical industry has grown enormously. In Asia, excluding Japan, China and India have registered a phenomenal growth in the pharmaceutical sector, producing both formulations and bulk drugs. However, in all these efforts, the share of medicinal plants is rather low.

According to Kurup, there are over 4500 pharmacies in SEAR producing herbal medicines.[1] In India, herbal drug production is over Rs. 7000 million annually. While the large majority of traditional practitioners all over the Region continue to prepare their own recipes for use in their practice, several public sector and private manufacturing units have come up in India, China, Indonesia and Nepal to produce herbal drugs in large quantities for sale in the country and for export.

Modern pharmaceutical technology has been used to prepare herbal dosage forms such as tablets, pills, sachets and mixtures. Partial or total automation has been employed. In China, Korea and Thailand, governments have established herbal gardens and the plants are harvested in appropriate seasons. These are then processed according to the directions provided by the ancient texts but, wherever possible, the process is automated using mixers, granulators, fluid bed dryers, tableting machines, coating pans, automatic bottling, labelling and strip packaging, etc.

Several pharmaceutical manufacturers have introduced in their manufacturing activities Good Manufacturing Practices (GMP) as recommended by WHO, wherever possible.

Quality Control is usually done by subjecting the raw materials as well as finished products to i) Physical tests such as colour, taste and disintegration rate, if warranted, and ii) Chemical tests: tests for alkaloids, or glycosides, etc., including chromatographic tests.

All this needs substantial developmental resources which are usually provided by the modern pharmaceutical industry.

Epilogue

Research is the hallmark of progress and rationality. Herbal medicines have been used for centuries and are still patronized by large sections of the people, particularly in the rural areas in developing countries. These remedies have to be evaluated for their efficacy and safety so that their use becomes more rational and they can then be adopted in modern therapeutics

globally. Some higher plants which are of medicinal interest should be carefully investigated in all aspects[57,58] because they offer great possibility for achieving a breakthrough in respect of several diseases for which there is no satisfactory therapy in modern medicine. Countries should therefore provide both financial as well as technical human resources. Technology missions and policy commitment at the highest political level, and international collaboration at national and regional levels, would serve to speed up research and development in the field of herbal drugs.

References

1. Kurup P.N.V. Traditional medicines and health care coverage. Robert H. Bannerman, John Barton and Chen-Wen-Chien (Ed.). WHO publication. *Ayurveda*. 1983; 50.
2. Sukh Deo. Ethnotherapeutic and modern drug development: potential of Ayurveda. *Current Sciences*. 1997; 75 (11): 909.
3. Sabnis P.B., Gaitonde B.B. and Jethmalani M.H. Effect of alcohol extract of Asparagus racemosus (wild) on mammary glands of rats. *Ind.J.Exp. Biology*. 1968; 6: 55.
4. Gaitonde B.B. and Jethmalani M.H. Anti-oxytocic action of saponin isolated from Asparagus racemosus (wild) (Shatawari) on uterine muscle. *Ind. J.Pharmacol*. 1969; 31: 175.
5. Attiso M.A. Phytopharmacology and phytotherapy. Robert Bannerman (Ed.) et al. WHO publication. Geneva. 1983; 194.
6. World Health Organization. Quality control methods for plant material. WHO publication. Geneva. 1998.
7. Fransworth Norman R. The Napralert database as an information source for application to traditional medicine. In: *Traditional medicine and health coverage.* Robert H Bannerman (Ed.) et al. WHO publications. 1983; 184.
8. Lele R.D. New interface between Ayurveda and modern medicine. *The Indian Journal of Clinical Pharmacology and therapeutics*. 2000; 20:1.
9. Patnaik G.K. and Dhawan B.N. Current research on medicinal plants in India. B.N. Dhavan (Ed.). *Indian National Sciences Academy*. New Delhi. 1986; 47.
10. Dahanukar S, Kulkarni R.A and Rege N.N. Pharmacology of medicinal plants and natural products. 2000; 32: 581.
11. Ghosh D. Thejomoorthy P. and Veluchamy. Anti-inflammtaory and analgesic activity of oleonolic acid 3-3 glucoside (RDG-1) from Randia dumetorum. *Ind.J.Parmacol.* 1983; 15: 33.
12. Gupta N.B., Naik R., Srivastava N., Shankar K., Kishore K. and Bhargava K.P. Antiinflammatory and antipyretic activities of B-sitosterols. *Planta Medica*. 1980; 39: 157.
13. Pendse V.K., Mahawar M.M., Khanna N.K., Somani K.C. and Gautam S.K. Anti-inflammatory and related activity of watery extract of Tinospora cordifolia. *Indian drugs*. 1981; 19: 19.
14. Atal C.K., Siddiqui M.A., Zutshi U., Amla V., Johri R.K., Rao P.G. and Kaur S. Non-narcotic orally, effective, centrally acting analgesic from ayurvedic drugs. *J.Ethnopharmacol*. 1984; 11: 309.
15. Vohra S.B., Kumar J. and Khan M.S.Y. Effects of alkaloids of Solanum melongena on the central nervous system. *J.Ethnopharmacol*. 1984A; 11: 331.
16. Bagi M.K., Kalyani G.A., Denmo T.J., Kumar K.A. A preliminary pharmacological screening of abutilon medicine, analgesic activity. *Indian Drugs*. 1984; 22: 69.

17. Dahanukar S.A. and Karandikar S.M. Evaluation of antiallergic activity of Piper longum. *Indian drugs*. 1984; 21: 377.
18. Geetha V.S., Vishwanathan S. and Kameshwaran L. Comparison of total alkaloids of Tylophora indica and disodium chromaglycate on mast cells stablization. *Ind.J.Pharmacol*. 1981; 13: 199.
19. Shanmugsundaram K.R., Panneevselvum G., Samudram P. and Panneeselvim E.R.B. Enzyme changes and utilization in diabetic rabbits: effect of Gymnema Sylvestre R, *Br.J.Ethnopharmacol*. 1983; 7: 205.
20. Kedar P and Chakraborty E.H. Effect of bitter gourd, Momordica charantia seeds and glybenclamide in streptozoticin-induced diabetes mellitus. *Ind. J.Exp. Biol*. 1982; 20: 232.
21. Agrawal V.K. Some pharmacological studies on the stem bark of Millingtonia hortensis. *J.Res.Ayur. Siddha*. 1982; 2: 50.
22. Rastogi R.P. and Dhawan B.N. Research on medicinal plants at Central Drug Research Institute, Lucknow (India). *Ind.J.Med.Res.* 1982; 26: 27.
23. Naik V.K., Agshikar N.V. and Abraham G.J.S. Cucumis trigonus Rox B. II diuretic activity. *J.Ethnopharmacol*. 1981; 3: 15.
24. Patnaik G.K. and Dhawan B.N. Evaluation of spasmolytic activity of clausmarin. A novel coumarin from Clausena pentaphylla. *J.Ethnopharmacol*. 1982; 5: 127.
25. Bhakuni D.S. and Chaturvedi R. Alkaloids of Corydalis meifolia. *J.Nat.Prod*. 1983; 46: 466.
26. Rao Y.V., Dasgupta G., Acharya S.B., Pathak N.K.R. and Biswas M. Preliminary pharmacological studies on glycosides of Symplocos spicata Rox B. *Indian J.Pharmacol*. 1983; 5: 349.
27. Vohra S.B., Khan M.S.Y. and Naqvi S.A.H. Pharmacological and antimicrobial studies on Corchorus tridens. *India J.Crude Drug Res*. 1983; 21: 81.
28. Chakravarthy B.K., Rao Y.V., Gambhir S.S. and Gode K.D. Isolation of a mentoflavone from Selaginella rupestris and its pharmacological activity on central nervous system, smooth muscle and isolated from heart preparation. *Planta Medica* 1981; 43: 64.
29. Singh H.K. and Dhawan B.N. Effect of Bacopa monnieri Linn (Brahmi) extract on avoidance of response in rats. *J.Ethnopharmacol*. 1982; 5: 205.
30. Singh H.K. and Dhawan B.N. Effects of a mixture for Bacosides A and B on mental retention capacity in rats. *Ind.J.Pharmacol*. 1985; 17(Sappl.): 1.
31. Srivastava A.K., Srivastava R. and Dixit V. Pharmacological studies on fruits of Melia azadirach. *J.Res.Ayur. Siddha*. 1981; 2: 260.
32. Agarwal S.S. Some CNS effects of Hydrocotyl asiatica Linn. *J.Res.Ayur. Siddha*. 1981; 2: 144.
33. Dahanukar S.A., Rege N.N., Thatte U.M. "Adaptogenes". In: Ed. Medicinal plants their bioactivity, screening and evaluation: proceedings of international workshop, CDRI, Lucknow (India). 1997; 143.
34. Sembulingam K., Sembulingam P., Namasivayam A. Effects of Ocimum sanctum Linn. on noise-induced changes in plasma corticosterone levels. *Indian J.Physiology & Pharmacol*. 1997; 41: 139.
35. Dahanukar S.A., Kulkarni R.A. and Rege N.N. Pharmacology of Medicinal Plants & Natural Products, 2000; 32: S81.
36. Sarkar D., Sharma A. and Talukdar G. Clastogenic activity of pure chlorophyll & anticlostogenic effects of equivalent amounts of crude extract of Indian spinach leaf and chlorophyllin following dietary supplementation to mice. *Environ, Mol.* Mutagen. 1996; 28: 121.
37. Ghafoorunnisa, Reddy V., Sesikaran B. Palmolein & groundnut oil have comparable effects of blood lipids and platelet aggregation in healthy Indian subjects Lipids. 1995; 30: 1163.

38. Kumar P.D. The role of coconut and coconut oil in coronary heart disease in Kerala, South India. *Trop. Diet.* 1997; 27: 215.
39. Deshpande U.R., Gadre S.G., Raste A.S., et al. Effects of Turmeric (Curcuma longa L.) extract on carbon tetrachloride-induced liver damage in rats. *Indian J.Exp. Biol*. 1998; 36: 573.
40. Khosla P., Gupta D.O., Nagpal R.K. Effects of Trigonella Foenum graecum (Fenugreek) on serum lipids in normal and diabetic rats. *Indian J.Pharmacology*. 1995; 27: 89.
41. Khan B.A., Abraham A., Leelama S. Haematological and histological studies after curry leaf (Murraya koenigii) and mustard (Brassica juncea) feeding in rats. *Indian J.Med.Research.* 1995; 102:84.
42. Sharathchandra J.N., Patel K., Srinivasan K. Digestive enzymes of rat pancreas and small intestine in response to orally administered mint (Mentha spicata) leaf and garlic (Allium sativum) oil. *Indian J.Pharmacol.* 1995; 27: 156.
43. Pandey B.L., Goel R.K., Pathak N.K.R., Biswas M. and Das P.K. Effect of Tectona grandis Linn, on experimental ulcers and gastric secretion. *Indian J. Med Res.* 1982; 76: S.89.
44. Vishwanathan S., Kulanthiavel P., Nazimudeen S.K., et al. The effect of apeigenni 7,4 diomethyl ether, a flavone from Andrographis paniculata on experimentally induced ulcers. *Indian. Pharm.* Sc. 1981; 43: 159.
45. Rege N., Dahanukar S. and Karandikar S.M. Hepatoprotective effects of Tinospora cordifolia against carbon tetrachloride-induced liver damage. *Indian Drugs.* 1984a; 21: 544.
46. Pilankar P.PhD. thesis on Piccorhiza kurruoa and Eclipta alba as epatoprotectives. 1981.
47. Vaidya A.B., Sirsat S.M. Doshi J.C. and Antarkar D.S. Selected medicinal plants and formulations as Hepato-biliary drugs: an overview. *J.Clinical Pharmacol.* Ther. 1996; 7: 11.
48. Saraswathi D.S., Suja R. Gurumurthy P., Shymala Devi C.S. Effects of liv.100. against antitubercular drug-induced hepato-toxicity in rats. *Indian J.Pharmacol*. 1998; 30: 233.
49. Kamboj V.P. and Dhawan B.N. Research in plants for fertility regulation. In: *India.J.Ethnopharmacol*. 1982; 6: 191.
50. Prakash A.O. Antifertility investigations on Embelin as oral contraceptive of plant origin: part 1-biological properties. *Planta Medica* 1981; 41: 259.
51. Singh M.P., Singh R.H. and Udupa K.N. Antifertility activity of a benzene extract of Hibiscus rosa-sinensis. *Planta Medica*. 1982; 44: 171.
52. Chakraborty A., Chowdhary B.K. and Bhattacharya P. Clausenol and clausenine the carbon alkaloids form Clausena anisata. *Phytochemistry*. 1995; 40: 295.
53. Agnihotri S. and Vaidya A.D. A novel approach to study antibacterial properties of volatile components of selected Indian medicinal herbs. *Indian J.Exp. Biol.* 1996; 34: 712.
54. Rai M.K. *In vitro* evaluation of medicinal plant extracts against Pestalotiopsis mangiferae. *Hindustan Antibiotic Bulletin.* 1996; 38: 53.
55. Jairam S. and Thygarajan S.P. Inhibition of HbsAg secretion from Alexander cell line by Phyllanthus amarus. *Indian J.Path.Microbiol.* 1996; 39: 211.
56. Premnathan M., Nakashima H., Kathirasan et al (1996): *In vitro* anti-human immuno-deficiency virus activity of mangrove plants, *Indian J. Med. Res.* 103, 278.
57. Valiathan M.S. Healing plants. *Current Sciences.* 1998; 75: 1122.
58. Chaudhury, R.R. Herbal medicine for human health. WHO-SEARO New Delhi. 1992.

Current status – Country situation

Traditional medicine in the WHO South-East Asia Region

Kin Shein

General introduction

In many countries of the world and especially in the developing countries, traditional medicine (TM) is an important part of health care. In countries of the South-East Asia Region, although modern medicines are now increasingly available throughout different levels of health care, TM has maintained its popularity since it has been used for generations in the past. In recent years, many developed countries have also begun to take interest in herbal medicine, acupuncture and alternative systems of medicine. Consequently, there is increasing trade among countries in medicinal plants and, to a certain extent, traditional remedies as well. It is therefore becoming important that the safety, efficacy and proper use of TM are taken up as among the important areas for development or strengthening in the countries of the Region.

All Member Countries of the South-East Asia Region (SEAR) have been developing and strengthening their TM programmes. Many countries are in the process of introducing TM and traditional medical practitioners (TMP) in primary health care (PHC). However, the potential of services that can be provided by the TMP is far from being fully utilized. TM and TMP have significant potential for contributing to the national health services and for the attainment of the goal of Health for All.

Traditional systems of medicine in South-East Asia Region

Countries of SEAR have a rich heritage of various systems of traditional medicine. Bangladesh, India, Nepal and Sri Lanka have people practising Ayurveda, Unani and /or Siddha Medicine(s). TM known as *Jamu* has flourished in Indonesia. The traditional medicine of DPR Korea is *Koryo* medicine while the TM of Maldives is called *Dhjivehi Beys*. Bhutan, Myanmar and Thai traditional medicines are practised in the respective countries. Thus, systems of traditional medicine in various countries of the Region have a significant role to play in the provision of health care as they are being used by those living in the cities as well as by the majority of the population who live in the rural areas. Apart from these systems, homoeopathy, nature cure and *yoga* are also practised in a number of countries of the Region.

WHO has been assisting the Member Countries in the following areas: National programme development in the various aspects of TM; traditional health systems and operational research; standardization, quality control and proper utilization of traditional and herbal medicines; training of human resources and exchange of information.

The development of various systems of traditional medicine in countries of the South-East Asia Region are described by the national authorities in the ensuing chapters.

Koryo medicine of Korea

Choe Thae Sop

Koryo Medicine, the nation's traditional medicine and precious medical heritage, has contributed to the health promotion of the people and treatment of diseases for thousands of years.

Existing historical works record that in the 5–7th century BC famous Korean doctors were sent for treating the elite on the invitation of the neighbouring kings. Korean acupuncture specialists crossed over to Japan and taught acupuncture skills and trained expatriate trainees in our country. This makes it clear that in those days our *Koryo* Medicine was of a very high quality.

Theories of *Koryo* Medicine were systematized through clinical practices and experiences and, whether big or small, were integrated and published by contemporary medical scientists. These have been preserved and handed down from generation to generation and are even now considered as valuable references in the field of *Koryo* Medicine.

For example, "*Uibangryuchui*" (Medical Encyclopaedia), a world-famous work published in 1443, is an unparalleled masterpiece and consisted of 366 volumes. A prominent Japanese medical historian, Mikisake, highly praised *Uibangryuchui* as the foremost world medical encyclopaedia not found anywhere else.

Although various kinds of theories and therapies of *Koryo* Medicine such as drug prescription, acupuncture and moxibustion have many advantages, (some legendary and non-scientific) scientifically planned clinical trials have been carried out to validate the claim of *Koryo* medicine. *Koryo* medicine products can be combined with allopathic medicine treatment.

DPRK has a well-knit *Koryo* medical service system. In the Ministry of Public Health, *Koryo* Medicine Guiding Section gives guidance on traditional medical services. At the Central level there is a General Hospital of *Koryo* Medicine; all of the 12 provinces have *Koryo* medicine hospitals, and each city and county hospital has a *Koryo* treatment department.

All the *Koryo* Medicine institutions in DPRK are State-owned.

Basic research is also being carried out on *Koryo* medicine – these include identification of the components of herbal medicine, pharmacology of herbs, the principles of meridian practices and acupuncture, and clinical trials with herbal drugs – in combination as well as singly.

The following table gives an idea of the extent of services under *Koryo* medicine in the country.

Traditional medicine system in Bhutan

Pema Dorji

The traditional system of medicine in Bhutan is known as *gSo-ba-rig-pa* and it came into existence in the country during the 16th century. During the reign of Shabdrung Ngawang Namgyel and first Hereditary Monarch, there were some physicians who served as personal physicians and some were private practitioners. Among the physicians, some had been trained in Tibet and the rest obtained knowledge from their forefathers.

Until 1966, this system was not regularized and there existed only private practitioners, but since 1967 it has been regularized and recognized by the Government of Bhutan and is considered as one of the important national health systems under the Health Division. This was done in order to preserve our own tradition as well as to give the general public a choice between the two systems.

Training

As mentioned above, till 1970 there was no regular training for *Dungtsho* (traditional doctor). A training foundation started in 1971 and in 1978 it was institutionalized and a training curriculum (five years) was developed. Since then regular training is being given. After the completion of the five-year course, in line with the national health policy, the students are given practical training in modern medicine (allopathic system) for three months, and thereafter undergo a further three-month attachment course with senior traditional physicians at the Institute of Traditional Medicine Services.

Medicine

Seventy per cent of the raw materials are obtained within Bhutan and these are further categorized as follows

- ***Snogo-smen*** - High-altitude medicinal plants;
- ***Throg-smen*** - Low-altitude medicinal plants;
- ***Sa-smen/Do-smen*** - Mineral origin;
- ***Sog-smen*** - Animal origin;
- ***Tsha-chu*** - Hot spring;
- ***Sman-chu*** - Stone-heated bath with herbal medicated water.

In the preparation of Bhutanese traditional medicine no chemicals are used or mixed; the method is purely natural.

In the past, all the medicines were prepared manually; small-scale mechanized production started only in 1982 with

assistance from the World Health Organization. Now all the products are produced mechanically but strictly in accordance with GMP (Good Manufacturing Practices) regulations, emphasizing quality control. Our products are formulated in different dosage forms like

- ***Ril-bu*** - Pills;
- ***Gor-lab*** - Tablets;
- ***Byugs-smen*** - Medicated ointments;
- ***Tung-smen*** - Syrup;
- ***Shub-lden*** - Capsule.

Hospital

Until 1979, it was functioning as a dispensary and became a hospital only in that year after shifting from Dechenchholing to Kawang Jangsa. It is our plan to establish indigenous units in all 20 districts, and we have now already established 15 units in 15 districts around the country, attached with modern district hospitals. The target is to cover all the 20 districts with indigenous units by the year 2002.

The objective of attaching indigenous units with the modern hospitals is mainly to give a choice to the patients and to cross-check as to which system is more effective for what kind of diseases.

Diagnosis

One of the important aspects of treatment is correct diagnosis. This is done in the following ways:

- Pulse reading;
- Urine analysis;
- Eye and tongue examination;
- Discussion with the patients, mainly on their medical history.

In children, in whom it is difficult to find the radial pulse, diagnosis is made by looking at the blood vessels of the ear lobes.

Treatment

Besides treatment with medicine, patients are also treated with surgical procedures, which are never as invasive as modern surgery practice. These include:

- ***gSer-khab*** - Acupressure with golden needle;
- ***Me-rtsa*** - Moxibustion by herbal compound;
- ***Me-burn*** - Cupping;
- ***Tshug*** - Cauterization, which consists of eight types;
- ***Dugs*** - Applying heat and cold to parts of the body without burning or cauterizing; it consists of two methods:
- ***Grang-dugs*** - similar to cold sponging
- ***Tsha-dugs*** - applying warm poultices;
- ***Byugs-pa*** - Medicated oil massages;
- ***Lum*** - Vapour treatment consists of two methods;
- ***Chu-lum*** - herbal bath
- ***Rlang-lum*** - steam bath;

A nationwide survey is being made to identify the medicinal plants available as well as the hot and cold springs which are used for treatment.

The quality control laboratory is being strengthened for the standardization of medicinal plants.

Traditional medicine in Bangladesh

Md. Aftabuddin Khan
S.K. Chowdhury

Introduction

Traditional medicines have existed in Bangladesh as an important basis of health care since olden times. Because of their potentialities and close association with the culture and tradition of the people, traditional systems of medicine have assumed a unique position in the health care of the people living in even the remotest areas of the country. There are several types of traditional medical practitioners in the country and their spectrum ranges from Unani and Ayurvedic practitioners qualified institutionally or through some years of apprenticeship, to persons who are born into a family of traditional healers and learn traditional medicine from the family.

Present Status: Status of Utilization – by Category

In spite of the development of an extensive network of a modern health care delivery system all over the country, traditional systems still play a significant role in delivering health care at the community level. A recent study conducted in the rural areas of the country on the use of traditional medicine revealed that among the sick family members, one month preceding the day of interview, 37.6 per cent had been treated by village practitioners. Allopathic (MBBS) doctors, *hakims*, *kabiraj*, health assistants (HA) and homoeopathic practitioners provided treatment to 16.7 per cent, 16.2 per cent, 9.5 per cent, 8.6 per cent and 6.8 per cent of cases, respectively. The study also reveals that, of 57 deaths, initial treatment was provided by MBBS doctors in 29.8 per cent cases, homoeopathic in 5.3 per cent cases, Unani 1.7 per cent cases, Ayurvedic 17.5 per cent cases, and village practitioners in 28.1 per cent of the cases before death. A significant proportion of the community members (39 per cent) have knowledge about medicinal plants and 13 per cent of cases with simple ailment were treated by them with herbs. It was also found that community members use various metals, salts, minerals and animal products for self-treatment. This finding reveals the level of confidence of the village community in traditional medicine in the country.

Government Policy on Traditional Medicine and its Development

The Unani and Ayurvedic systems have been recognized by the Government since British rule and, after the liberation of Bangladesh, the Government intensified its efforts for their continuous development and to raise the quality of services. Professional bodies of Unani, Ayurvedic and Homoeopathic medicines have been included in the planning process of national services. A few of the steps taken are described below:

- Administrative set-up for National Programming – The post of Director, Homoeopathy and Traditional Medicines has been created under the Director- General of Health Services to assist him to deal with all matters relating to traditional medicine to plan, implement, monitor and control programmes in traditional medicine. The Director is assisted by a Deputy Director, an Assistant Director and necessary supporting staff at central level;
- Educational facilities and Training of Traditional Practitioners – There are several educational institutes of Traditional Medicine offering diploma courses of four years' duration established in different areas. Five Ayurvedic and 10 Unani Institutes are recognized by the Bangladesh Board of Unani and Ayurvedic system of Medicine. These institutes receive financial and technical support from the Board;
- Establishment of Unani and Ayurvedic Degree College – The Government established a Unani and Ayurvedic Degree College at Mirpur in 1989. This college offers two degrees in the relevant areas – Bachelor of Unani medicine and Surgery and Bachelor of Ayurvedic medicine and Surgery;
- Status of trained manpower (Diploma and Graduate practitioners of Unani and Ayurvedic Medicine) – At present there are more than 1000 registered diploma practitioners of Unani and Ayurvedic Medicine. Nearly 150 Unani and Ayurvedic physicians have graduated till end of July 2000. In addition, more than 3000 *Hakims* and *Kabiraj* have attended certificate courses organized by the Board.

Case Management Facilities with Traditional Medicine – Public and Private Sector

There is only one 100-bed hospital (50 for Unani and 50 for Ayurvedic Systems) working as a teaching hospital for the Government Unani and Ayurvedic Degree College. The hospital can accommodate a maximum of 50 male and 50 female patients. It also provides outdoor medical services.

The Government diploma institution and some of the non-governmental diploma institutions also provide outdoor medical services in Unani and Ayurvedic Medicine.

Currently, 30 Unani and Ayurvedic medical graduates are posted at 30 Government district hospitals. These physicians are providing outdoor services at these hospitals.

Most of the practitioners having a diploma are practising all over the country both in the urban and rural areas. A large number of them are also working in commercial organizations and production units.

Legislation and Regulation

- Control of practices of Unani and Ayurvedic Practitioners – Since the beginning, the Government of Bangladesh has been keen to develop, promote, protect and control the practice of Unani and Ayurvedic Medicine. The Homoeopathic, Ayurvedic and Unani Practitioners Act of 1965 was revised in 1983 and two Acts were enacted in 1983 – the Homoeopathic Practitioners Act and the Unani and Ayurvedic Practitioners Act. The Unani and Ayurvedic Board was formed under these Acts. The Board is responsible for the implementation of Government objectives for the development, promotion and protection of traditional medicine besides supporting research in this field;
- Unani and Ayurvedic Drug and Acts – The Unani and Ayurvedic drug industry had been outside the purview of the Drugs Act of 1940. On 12 June 1982, the Government of Bangladesh promulgated the "Drugs (control) Ordinance, 1982" to control the manufacture, import, distribution and sale of drugs. Section 3(d) of the ordinance reads: "Drug" shall have the same meaning as in the Act and shall also include any substance exclusively used or prepared for use in accordance with the Ayurvedic, Unani and Homoeopathic or Biochemist systems of medicine;
- National Formularies for Unani and Ayurvedic Medicines – The Bangladesh Unani and Ayurvedic Board, under the authority vested in it by the Bangladesh Unani and Ayurvedic Ordinance (Act.) 83, has compiled two formularies, viz., National Formulary for Unani Medicine and National Formulary for Ayurvedic Medicines. These two medical systems have formularies for commercial production. Approximately 50 per cent of these formulae are manufactured in the traditional medicine factories. These traditional preparations are controlled by the Drug Administration Directorate. Registered practitioners can, by virtue of their registration, manufacture on a small-scale the medicines they need for their own patients.

Medicinal Plants

Medicinal plants are the major ingredients of Unani and Ayurvedic medicines. The geographical location, climate and topographic conditions of Bangladesh helps the growth of most of these plants locally in different areas of the country. However, due to continuous massive deforestation, destruction of homestead trees/plantations, frequent natural disasters, commercial mono-culture plantations, etc., the availability of most of these precious medicinal plants will be reduced, and these plants may even be in danger of extinction. If such a trend continues, these plants will scarcely be available locally to meet the needs of the manufacturing plants in the near future.

In Bangladesh there are approximately 5000 plants, of which 1500 to 2000 plants are covered through different ethnobotanical and ethnomedicinal surveys. Conservatively, a minimum of 1000 plants have medicinal value.

Integration into the National Health Care System

The Government of Bangladesh has created facilities to provide alternative medical care in the existing Government hospitals at the district level along with

modern medicine, facilitating integration of traditional medicine in the national health delivery system. The operational activities have been processed under the close supervision of the district health authorities for quality and effective output.

Research and Studies

It has been observed that considerable research has been carried out in Bangladesh during the last few decades.

The Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrinological and Metabolic Disorders (BIRDEM) is carrying out research on anti-diabetes plants. The International Centre for Diarrhoeal Diseases Research, Bangladesh (ICDDR,B) is carrying out research on anti-dysenteric medicinal plants. In the Department of Pharmacy of Jahangirnagar University in-depth work is underway on different aspects of the pharmacology of Ayurvedic medicines.

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The following table gives an idea of the extent of services under *Koryo* medicine in the country.

Indian system of medicine and homoeopathy

L. V. Prasad

India has a rich, centuries-old heritage of medical and health sciences. Some of these systems date back to 5000 years BC. These systems have taken care of the health needs of the people and have survived due to their strengths, efficacy of treatment and drugs. India has the unique distinction of having six recognized systems of medicine under Indian Systems of Medicine and Homoeopathy (ISM&H). The Indian systems are Ayurveda, Siddha, Unani, Yoga & Naturopathy. Within the ambit, however, of Indian Systems of Medicine and Homoeopathy is covered the Homoeopathy system, though it originated in Germany and came to India in the early 18th century. This system has got completely assimilated, accepted and enriched like any other Indian system of medicine.

The Ayurveda system of medicine is of great antiquity and dates back to about 5000 BC Ayurveda is a branch of *Atharva Veda*, which is the repository of and treatise on the knowledge and wisdom of great sages and seers, acquired, tried and handed down to succeeding generations. Ayurveda is not only a system of medicine, but also represents a way of healthy living. It is holistic in approach and enshrines the complete philosophy of health. It is well-documented. The most exhaustive classic on medicine is *Charaka Samhita*; *Sushruta Samhita* is an exhaustive treatise on surgical principles and procedures. *Ksyapa Samhita* exclusively deals with matters of maternity and child health. The four key concepts of Ayurveda which guide the preventive, promotive and curative aspects of the practice of Ayurveda are : *Panch Mahabhutas*, *Tridoshas*, *Sapta Dhatus* and Three *Malas*. Though it is ancient in origin, the system is modern in approach. Undergraduate education in Ayurveda has a course curriculum and training schedule for five-and-a-half years, including clinical exposure. It has eight distinct branches of teaching disciplines corresponding to modern systems. Postgraduate courses are of three years' duration. The training in Ayurvedic medicines and surgery is regulated by a statutory body, namely, the Central Council of Indian Medicine (CCIM). The registration of physicians, practice and ethics are governed by the regulations made by the Council. The drugs are manufactured according to formularies; pharmacopoeial standards have been laid down. Drug manufacture is licensed and regulated under the Drugs & Cosmetics Act,

1940. It uses materials of plant origin for most of its products, which are natural, safe, cost-effective and efficacious. Therapeutics under the Ayurveda system include *Shamana* Therapy, *Shodhana* Therapy, *Satyavajaya* Therapy, *Panchakarma* treatment and *Rasayana* Therapy. Its wide network of physicians and infrastructure of medical institutions, hospitals, dispensaries and manufacturing units make Ayurveda the most widespread Indian system providing health care to the people of India. Some 196 undergraduate and 49 postgraduate colleges are imparting education, and 3,66,812 registered practitioners are engaged in health care. About 8400 pharmacies are manufacturing drugs, both classical and proprietary. Intramural and extramural research and clinical trials, separately and in collaboration with modern institutions with proper protocols adopting scientific parameters, are being conducted extensively to enrich and develop this system.

The Siddha System of medicine is also one of the oldest systems being practised in India for centuries. The principles and doctrines of the *Siddha* system, fundamental and applied, are similar to Ayurveda. It is also holistic in approach. This system emphasizes that medical treatment should be oriented not merely to disease but should also take into account the patient, his environment, sex, age, habits, mental frame, habitat, diet and physical condition. The human body is a conglomeration of three humours, seven basic tissues and waste products of the body. Their equilibrium is good health, and any disturbance or imbalance leads to disease or sickness. In the *Siddha* system, the drug preparation is largely based on plants, but minerals and metals are also used for drug preparation. The educational pattern, regulation of education, registration of practitioners, practice and ethics are governed by the regulations framed by the Statutory Council. Drug standardization, official formularies, licensing and manufacture of drugs are governed by the Drugs and Cosmetics Act, 1940. There are dispensaries, hospitals, pharmacies and research units under the *Siddha* system. Two undergraduate colleges and one postgraduate college are imparting education in the *Siddha* system.

The Unani System of medicine originated in Greece and came to India through the Arabs. It flourished in the country for centuries under the patronage of successive rulers. Today, it is one of the recognized systems of medicine. This system is also holistic in approach and bases its philosophy on the humoral theory. The human body is made up of seven components, such as the Elements, Temperament, Human organs, Spirits, Faculties and Functions. Unani is popular with the masses and is extremely efficacious in certain chronic indications. Undergraduate and postgraduate education, registration of physicians, practice and ethics are regulated by the same Council as for Ayurveda and *Siddha*. Most of the Unani classical texts are in Arabic, Persian and Urdu, but are being translated into English. The diagnosis takes into consideration the temperament, structure, strength of facilities, the type of factors operating on the patient from outside, etc. Unani treatment uses regimental therapy, diet therapy, pharmaco therapy and surgery. In this system, although the general preference is for single drugs, compound formulations are also used in the treatment of various complex and chronic diseases. The drug licensing, manufacture and quality of products are regulated under the Drugs and Cosmetics Act, 1940. There are practitioners, hospitals, dispensaries and pharmacies under the Unani system, in

addition to 40 undergraduate and three postgraduate teaching institutions. A total of 40,478 practitioners of Unani are registered with the Council and 549 manufacturing units are engaged in drug manufacture. Official formularies for Unani drug manufacture have been published and pharmacopoeial standards have been laid down. Extensive and intensive extramural and intramural research, clinical trials, etc., have developed and enriched this system.

Homoeopathy originated in Germany and came to India in the early 18th century. It has been practised in India for about two centuries and has become a popular system of medicine. This system is based on four demonstrable principles: the law of similars, the law of direction of cure, the law of single remedy and the law of minimum dose. Disequilibrium in the functioning of the organs of the body implies sickness. Cure of disease involves restoring the equilibrium. Symptoms are treated as a reaction of the defence mechanism of the body. Treatment through drugs is given to further strengthen the defence mechanism and help it in overcoming the disease. In diagnosis, every case is treated on a uniquely individual basis and patients with the same disease may be prescribed different medicines. The physician has to consider every individual's mental, emotional and physical pathology in order to understand the peculiar ways in which the patient's defence mechanism is reacting. Thus, a very comprehensive and unique individualizing process is involved in making a proper diagnosis. The educational curricula for U.G. and P.G. courses, registration of practitioners, practice and ethics and related matters are governed by the Central Council of Homoeopathy, a statutory council. It follows the same pattern of U.G. and P.G. education. It has a wide network of educational institutions imparting U.G. and P.G. education. Registered physicians, dispensaries and hospitals are providing health care. About 1,89,000 practitioners are registered with the Council. It has 149 undergraduate and 15 postgraduate colleges. Homoeopathy's popularity is greatly enhanced by its cost-effectiveness and the absence of adverse effects if the drugs are administered in prescribed doses. It has evolved pharmacopoeial standards, of which several volumes have been published. Drugs standardization and the quality of drugs manufactured by pharmacies are regulated by the Drugs & Cosmetics Act, 1940.

Homoeopathy's popularity is greatly enhanced by its cost-effectiveness and the absence of adverse effects if the drugs are administered in prescribed doses.

Yoga and Naturopathy are basically drugless therapies. The concept and practice of *yoga* originated in India several thousand years ago. It is one of the six systems of *Vedic* philosophy. It is also holistic and seeks complete harmony among the body, mind and the thinking process. *Yoga* has been found useful in the prevention of diseases, mitigation and cure of diseases and promotion of health. *Yoga* advocates an eight-fold path known as "*Ashtanga Yoga*" for the all-around development of the human personality. These are: *Yama*, *Niyama*, *Asana*, *Pranayama*, *Pratyahara*, *Dharma*, *Dhyana*, and *Samadhi*. These components advocate restraint, observance of austerity,

physical postures, breathing exercises, restraining the sense organs, contemplation, meditation and *Samadhi*. Researches are fortifying and validating the preventive, promotive and curative aspects of *Yoga*.

Naturopathy is a recognized system of medicine. Its philosophy is fully based on the holistic approach. Naturopathy believes that health is the normal and harmonious vibration of the elements and forces comprising the human entity and disease is abnormal or non-harmonious vibration of the elements and forces. The primary cause of disease is violation of the laws of nature. It advocates a natural way of living, and the treatment covers regulation of eating, drinking, breathing, etc., elementary remedies, biochemical remedies, mechanical remedies and mental remedies. Naturopathy advocates diet therapy, hydrotherapy, mud therapy, fasting therapy, massage therapy, etc. Naturopathy treatment has no side or after-effects. These are simple, scientific, easy, cost-effective methods and can be practised by everyone.

There are five degree colleges conducting bachelor courses in Naturopathy and *Yogic* practices of five-and-a-half years' duration. These are affiliated to various universities. A large number of institutions are conducting diploma and certificate courses. There are a number of good *Yoga* and Naturopathy treatment centres. There is the National Institute of Naturopathy, Pune, and the Morarji Desai National Institute of Yoga, New Delhi, under the Central Government, as well as a research council, namely, the Central Council for Research in Yoga and Naturopathy, New Delhi.

All drug-based systems under ISM&H, namely, Ayurveda, Siddha, Unani and Homoeopathy, largely use medicinal plants as raw materials for the preparation of drugs. To develop the medicinal plant sector, this department has set up a Medicinal Plants Board to coordinate all efforts to conserve, cultivate, process and market raw materials with a view to making available standard products relevant to each medical system.

Dhivehibeys in Maldives

Abdullah Waheed

Literally, *dhivehibeys* means Maldivian medicine. It is a unique system of medicine that Maldivians have been practising since time immemorial.

Though the origin of *dhivehibeys* is lost in the dark recesses of history, there are indications that a well-developed medicinal system existed in the country throughout the 800-year known history. Indeed, this would have been a survival necessity in an isolated archipelago nation.

The original *dhivehibeys* depended on locally available ingredients, mostly fresh herbs. Often the practitioners used what they called '*fassangu*', a term that referred to the five main parts of a plant. Things changed when communication with the outside world improved, bringing in fresh ideas and new ingredients. The fresh ideas mostly came from Unani textbooks in Arabic and Urdu. The new ingredients came from Ceylon and India in the form of dry herbs and compounds.

Today *dhivehibeys* reveals strong Unani influences. Thus, the system attributes many diseases to changes in body constitution and associates them with elements such as air, heat (corresponding to fire in Unani) and water that are supposed to flow in the body. Many of the therapies and ingredients are also based on the Unani system. Thus, cupping, cauterization and massage find a place in the local system. Despite these similarities most scholars agree that *dhivehibeys* is distinct from Unani medicine.

The old masters of *dhivehibeys* were experts at feeling the radial pulse and making observations. They, however, lacked a sound basis for analysing them further to identify the underlying conditions. Like many other alternative systems of medicine, *dhivehibeys* had only a vague understanding of diseases and their classification. Therefore, the diagnoses it made were also vague, often equating symptoms with disease. When dealing with external injuries this may not have been a major a drawback, but with internal diseases it definitely would have. Interestingly, *ruggalubeys*, the branch of *dhivehibeys* dealing with bone injury, continued to be popular long after other branches declined.

The modern period of *dhivehibeys* may be said to have begun with Dhon Beyya of Addu Atoll. He wrote a treatise on *dhivehibeys,* which he passed on through his illustrious pupil, Hussein Salahuddeen to Addu Hussein Manikfan. Manikfan, who went on to become a leprosy expert, was

the founder of a family of practitioners, who still continue to be active.

During the first half of the 20th century, *dhivehibeys* flourished and produced many notable practitioners such as Ibrahim Faamuladheyri Kilegefaanu, Naifaru Dhonkaleyfaanu, Ahmed Kaamil and Badeegey Mohammed Didi. They were instrumental in popularizing new concepts learnt from Unani medicine throughout the country and ushering in what can be described as the golden era of *dhivehibeys*. The era ended when modern medicine came during the '50s and gradually weaned patients away from the traditional system.

Along with the decline in *dhivehibeys*, its practitioners also largely disappeared, since not many new entrants came forward to replace the aging masters. Heera Yousuf Fulhu was perhaps the last survivor from the golden era.

Tragically, many aging practitioners died without having an opportunity to pass on their knowledge to the next generation. Centuries of accumulated knowledge in their collective memory was thus irrevocably lost. A monograph on individual ingredients and a few handwritten manuscripts are the only records that survive.

Despite the absence of written texts and the lack of a formal system for sharing information, existing sources of knowledge agree remarkably on the general principles of *dhivehibeys*. However, when it comes to details, different schools of thought represented by traditional families have disagreements. For example, for treating bone injuries all schools agree on the ingredients of the dressing. But for tempering it the *Gaddaduge* school believes in applying strong heat, whereas some others believe in applying only moderate heat with sunlight.

At various times many distinct branches of *dhivehibeys* flourished to cater to the varying needs of the society. In earlier times a priority need was the treatment of battle wounds resulting from recurrent skirmishes with the ubiquitous pirates. Historical anecdotes indicate that the branch of *dhivehibeys* called *kandifaarubeys* (literally, treatment of sword wounds) was highly developed in those days. Another branch of *dhivehibeys* was *lolubeys,* or the treatment of eye diseases. *Ruggalubeys* specialized in treating bone disorders. There were also practitioners who specialized in circumcision.

Dhivehibeys was never far from spiritual healing or *fanditha* as the natives called it. Some of the most successful practitioners were those who could get the right mix of the two. One of the last exponents of this technique was Ihavandhoo Hajee, who successfully combined his potions with charms and prayers.

With the advent of effective Western alternatives some branches such as *kandifaarubeys* and *lolubeys* have virtually disappeared. But some others continue to be popular. A large part of the population still depend on *ruggalubeys* to heal their fractures and the overwhelming majority go to *dhivehibeys* practitioners for circumcision.

In recent years the Government has taken several steps to develop *dhivehibeys*. This includes the appointment of a high-level committee and a chair for *dhivehibeys* at the Faculty of Health Sciences of the Maldives College of Higher Education. The committee has recognized that improving access to herbs is the key to preserving *dhivehibeys*. Otherwise, more and more patients are going to find it not only easier but also cheaper to buy an aspirin at the neighbourhood store than to go searching all over the island for impossible ingredients.

Indigenous medicine in Myanmar

U Kyaw Myint Tun

The regulatory situation

Myanmar's indigenous medicine is based on Ayurvedic concepts and has been influenced by Buddhist philosophy. Prior to the Second World War, certain committees recommended that this system be recognized by the Government, but no action resulted. Four years after Myanmar attained its independence in 1948, the Myanmar Indigenous Medical Committee was formed. It drafted the Indigenous Myanmar Medical Practitioners Board Act, which was promulgated in 1953, with amendments in 1955, 1962, and 1987. It established an Indigenous Myanmar Medical Practitioners Board, whose functions are to advise the Government on, *inter alia*, the revival and development of Indigenous Myanmar Medicine, related research and the promotion of public health; Section 11 specifies as a particular function of the Board "suppression of charlatans or quacks who are earning their living by means of indigenous Myanmar medicine". The Board is also empowered (subject to the prior sanction of the Head of State) to prescribe the subjects for examination in indigenous Myanmar Medicine, to register practitioners, or to remove their names from the register if a defect in character or infamous conduct is established. Section 24 of the Act prescribes that, subject to the provisions of section 23 of the Myanmar Medical Act, in order to sign a medical certificate required by the law to be signed by a medical practitioner, an indigenous medical practitioner must be registered. Similarly, unless he or she has obtained the prior sanction of the Head of State, an indigenous medical practitioner who is not registered may not hold certain specified appointments in publicly supported hospitals and other health facilities.

Section 7 of the Indigenous Myanmar Medical Practitioners Board Rules, 1955, provides for the registration of such practitioners in six classes. The system of classification is essentially based on the division of Myanmar medicine into four branches (*Desana*, Ayurveda, astrology, and *Vizzadara*). In section 9 of the Rules, details are given of the knowledge required for registration in the particular classes. Provision is also made, in section 10, for authors of works on indigenous medicine to be registered in one of three classes; it is indicated in this section that monks may not be registered as medical practitioners.

Under Section 12 of the Rules, the Board is to seek ways and means of

consolidating into a single system the four branches of medicine currently practised; the Board is likewise to undertake studies and research and advise the competent authorities on standardizing the methods of treatment provided in dispensaries operated by the Government.

The Indigenous Burmese Medical Practitioners Board Amendment Act of 1962 introduced new sections 22-A and 28-A empowering the Chairman of the Revolutionary Council of Burma to, (i) Cancel the registration of indigenous medical practitioners, (ii) Prescribe qualifications for registration, and (iii) Terminate the services of any or all of the members of the Board and appoint new members in their place. Under these powers, a new Board was appointed to initiate the re-registration of practitioners. The Department of Indigenous Medicine was established on the 3rd of August 1989.

Education and training

An educational institution known as the Institute of Indigenous Medicine was established by the Ministry of Health in 1976, offering a three-year training programme.

Organization

The second-grade department was formed in mid-1989 by upgrading the branch of indigenous medicine under the Department of Health. The staff strength at that time was about 700. In late 1997, the Department was again upgraded into a first-grade one, expanding the manpower up to 1796 consisting of four main divisions, viz., administration, medical care, research and development, and herbal garden and drug production.

Law and Regulation

To keep abreast with the changing circumstances, the Department reviewed the aforementioned Act and has updated and revised it as the Traditional Medical Council Law, which was enacted on 14 January, 2000, by the Government. At present there are over 8000 traditional medicine practitioners registered under the said law.

In 1996, the Government promulgated the Traditional Medicine Law in order to control the production and sales of traditional medicine drugs systematically. This was followed by a series of notifications concerning registration and licensing, labelling and advertising.

Education and Training in Traditional Medicine

There is one Institute conferring diploma in Traditional Medicine, situated in Mandalay, the second capital of Myanmar. This institute was opened in 1976 and is attached to the 50-bed teaching hospital with the aim of eradicating bogus medical practitioners by producing full-fledged practitioners, to update traditional medicine to modern standards, to carry out research work in traditional medicine, to produce skilled researchers, and to give citizens effective treatment by traditional medicine.

It is a three-year diploma course, followed by a one-year internship. Till the 1997–98 academic year, the number of students awarded diploma totalled 890. The yearly intake of candidates is 100 at present. The Institute has its own medicinal plant garden for teaching demonstrations. The Department is now planning to upgrade the Institute to become a degree-conferring one in the near future.

In addition, the Institute also conducts a one-year course for outside Traditional Medicine Practitioners who have no certificates or licences to treat patients.

Those who are successful in the course will have the licence to practise as Traditional Medicine practitioners.

Medical Care Service

There are two 50-bed traditional medicine hospitals, one each in Yangon and Mandalay, and three 16-bed hospitals in other parts of the country.

For rural and township communities, the Department has established 194 township traditional medicine departments attached with their own outpatient clinics. If necessary, the patients are referred to both Western medical hospitals and the nearest traditional medicine hospitals.

Since 1999 was designated by WHO as the International Year for Older People, primary health care and medical services by traditional means serve the elderly population more by paying greater attention to the diseases prevalent among elderly people such as metabolic diseases, e.g., diabetes.

Registration and Legislation of Traditional Medicine Drugs

According to the Traditional Medicine Law, all the traditional medicine drugs produced in the country have to be registered and the manufacturer must have a licence to produce them. This has been done since 1996 after the promulgation of this law. There are altogether 3962 registered items of drugs and 632 manufacturers have already got the licences for production. Good Manufacturing Practices are considered before giving the licence. In addition, the Department is also involved in the control of advertisements of these commodities.

Cultivation of medicinal herbs and maintenance of herbal gardens

With the main aim of producing enough raw materials for the Department-owned drug manufacturing factories, the Department has been establishing one garden after another for the cultivation of medicinal herbs. Thus, there are now altogether nine gardens with a total area of over 120 acres. Since herbal gardening is still in its infancy, only 20 per cent of the area has been utilized at the moment. They are situated in different parts of the country with different weather and soil conditions, so that different kinds of species can be cultivated, depending on their climate and the nature of the soil.

Traditional medicine manufacturing factories

The traditional drugs used in township traditional medicine clinics and hospitals are provided by two traditional medicine manufacturing factories situated one each in Upper and Lower Myanmar. The yearly production of each factory is 10,000 kgs and the drugs are produced according to the national formulary. In addition, these factories also manufacture 12 kinds of drugs in tablet form for commercial purposes.

Research and Development

The main tasks in this sector are to carry out basic analysis for traditional drugs for registration purposes and standardization of commonly used medicinal plants and quality control analysis for Department-owned drug production factories.

Promotion of the systematic utilization of TM among the people is done by disseminating information through the mass media and by conserving old palm-leaf manuscripts regarding TM which are translated into Burmese for publication.

Traditional medicine in Nepal

Rishi Ram Koirala

Nepal is one of the richest countries in culture, tradition, knowledge of Ayurveda and other traditional medical practices. Ayurveda is a cultural and scientific heritage of this country. Nepal has been free from major foreign invasions in its history and has unique socio-cultural and traditional practices. Both culturally and traditionally, the country has been a bridge between India, Tibet and China. Since pre-historical times, there have been many ethnic groups in Nepal possessing unique cultural and healing practices. These unbroken traditions of healing practices play a big role in Nepal's health care systems.

Traditional Medical Systems in Nepal

The traditional medical systems in Nepal are as follows:

Ayurveda

This is the oldest authentically recorded life-science in existence today. This is a part of the National Health System and has a Government-run network throughout the country.

Institutions and Networks of Ayurveda in Nepal

The main Governmental organizations for Ayurveda are as follows.

Department of Ayurveda

This is the highest institution under the Ministry of Health for Ayurveda in the country. The Department is responsible for Ayurveda Health Policy, implementation, planning, monitoring and provision of services throughout the country. This department was established in 1981 and consists of the following network:

Ayurvedic Hospitals

There are two Ayurvedic hospitals: a 100-bed hospital located in Kathmandu and a 15-bed hospital in Dang district in the Middle-west region.

District Ayurveda Health Centres

There are 50 district Ayurvedic health centres, one in each district, and it is proposed to open five every year till all districts (75) are covered. These institutions are based on the New Ayurveda Health Policy.

Zonal Ayurveda Dispensaries

There are 14 zonal Ayurvedic dispensaries in each zone. It is planned to merge these dispensaries into the district Ayurveda Health Centres.

Peripheral Ayurvedic Dispensaries

There are 211 Ayurvedic dispensaries spread over different parts of the country. These are the only units in the health sector that utilize the local resources of medicinal herbs abundantly available in the country.

Rural Ayurvedic Pharmacies

There are three rural Ayurvedic pharmacies, and an additional pharmacy is planned to be established this year. These pharmacies are managed by and located within zonal and district Ayurvedic dispensaries.

Singha Durbar Vaidhyakhana Vikasa Samiti (SDVKVS)

The SDVKVS was established during the Malla dynasty (355 years ago). This is the only Governmental unit manufacturing Ayurvedic medicines in Nepal. Since 1994, SDVKVS is being run by a Development Board under the Ministry of Health.

Ayurveda Training and Academic Institutions

The following are the academic and training institutions in the country:

Ayurveda Campus

This is the only campus that trains Ayurveda graduates (BAMS, a 5½-year course) in the country. It is a constituent campus of the Institute of Medicine, which is one of the technical institutes of Tribhuvan University. Nearly a decade ago, this campus was conducting pre-university training courses (Ayurveda Auxiliary Course – 15 months – and Ayurveda Certificate-level course – 36 months).

Mahendra Sanskrit University-Affiliated Institutions

Of recent origin are private Ayurveda institutions, affiliated to Mahendra Sanskrit University, that provide Ayurveda certificate-level training courses (30 months).

Council of Technical Education and Vocational Training (CTEVT)

This council has given affiliation to the private sector providing 15 months' training to Ayurveda auxiliary workers for the past four years.

Council of Ayurvedic Medicine

This council has recently been formed by the Ministry of Health. This is a regulatory and legislative body for Ayurvedic courses, manpower, institutions, practitioners and traditional healers in Nepal. Ayurvedic graduates are registered with this council. Similarly, certificate-level trainees (30 months), other trainees (15 months) and traditional healers are also enrolled in this council, which is also responsible for developing a data bank of traditional healers, practitioners and their recipes.

Quality Control of GMP of Ayurvedic Products

Up to now GMP of Ayurvedic products has to be based on Ayurvedic principles. In Nepal, there is no proper unit for quality assessment for Ayurvedic or traditional herbal products.

Traditional Herbal/Spiritual Therapies

A large number of the population is still dependent on these practitioners. Basically, they follow some ethno-traditional, *tantrik*,

spiritual and Ayurvedic knowledge. The estimated number of these practitioners in Nepal is 400,000. Though they are not included in the official system of health care, they are wellknown by different names in different communities.

Homoeopathy

This system has recently been recognized as a national health system and a homoeopathy hospital is run by the Government. The Unani system of medicine is also incorporated in this hospital.

Naturopathy

This is not an official system of medicine, but it has been well-practised by the community. Training in naturopathy is provided by the private sector. There are private hospitals, training centres, clinics and dispensaries in the country.

Amchi

Amchi is a Tibetan medicine or healing practice existing in the upper-Himalayan regions. Though this is not an official system of medicine, there are two types of practitioners in this field. Some of them are institutionally trained and others follow the tradition.

Main Constraints

Qualified, competent and trained manpower is a primary prerequisite for any institutional development. Ayurveda and other traditional systems are facing a severe crisis of manpower development, mobilization and leadership. There is no proper training programme for traditional healers. Academic and other institutions are being run with poor budgetary support, planning, infrastructure and leadership.

Indigenous system of medicine in Sri Lanka

Lal Rupasinghe

Sri Lanka is a country of rich heritage, one of which is its indigenous system of medicine, which has been practised by the people since time immemorial. The Ayurvedic system of medicine from North India, the *Siddha* system of medicine from South India and the Unani system of medicine of the Arabs enriched with contributions from the traditional system of medicine called *Desheeya Chikithsa* is popularly known as the "Indigenous system of Medicine in Sri Lanka".

The Government of Sri Lanka recognized this system as an alternative system of health care by establishing a Department of Ayurveda under the Ministry of Health and Indigenous Medicine. Presently the Ministry of Indigenous Medicine and the Department of Ayurveda are responsible for the development of the Indigenous System, including training, registration, research, hospital care and production of Ayurvedic drugs.

A well-amalgamated health care operating system, made up of the endemic traditional system and the Ayurvedic system, is in operation to suit the requirements of the people of this land.

In 1929, two training institutes for producing doctors in the Ayurvedic system of medicine were institutionalized. The syllabi and subject matter of both consisted of Ayurveda and Traditional Medicine. Thus, at present the country has two sets of Ayurvedic physicians, one set trained by their ancestral teachers, physicians, and the other institutionally trained cadres, both commanding the respect and veneration of the public. Although the modes of practice followed by these two groups are very similar with respect to the systems and principles, there exists considerable difference as to the actual medications used. Institutionally trained practitioners use more of Indian-based medicaments, whereas traditional physicians use more of traditional therapies taught and trained to practise by their ancestral teachers.

They evolved the following highly developed divisions of traditional medicine and these services are still available to the people.

- Fractures and dislocations;
- Snake-bite poisoning and hydrophobia;
- Eye diseases, sinusitis;
- Neurological diseases;
- Mental diseases;
- Diarrhoeal diseases;
- *Kamala* (Hepatitis).

This country enjoys the services of 15,000 traditional and Ayurvedic practitioners, 70 per cent being traditional physicians, trained by their *gurus* and who had acquired knowledge through years of experience as well. The remaining 30 per cent are institutionally trained, obtaining a Diploma or Degree after undergoing a six-year curriculum course, as a part of which they are taught the basics and essentials of traditional medicine on the above-mentioned specialities. In addition to the above-mentioned course, a three-year diploma course is available in the country to train, as physicians, youngsters descended from families whose forefathers were traditional physicians.

The traditional and Ayurvedic system of medicine by Government Policy is recognized as a component of the national health service. Indigenous medical practitioners who fan out throughout the country, especially to the remote rural areas where the Western medical and health care delivery system does not reach, offer invaluable service to the people. Recent surveys conducted revealed that well over 45 per cent of the entire population seeks Ayurvedic and traditional medical assistance in spite of the mere 1.4 per cent of the entire health budget it is receiving annually.

The Department of Ayurveda manages an intricately woven network of health care delivery outlets throughout the country. The details are as follows:

Table Ayurved delivery outlets

• Teaching Hospitals	2
• Central Dispensaries	122
• Provisional Hospitals	46
• Local Dispensaries	231
• Research Institute	1
• National Institute of Traditional Medicine (Teaching and Training only)	1
• Herbal Gardens	5

Sri Lanka is the only country where the traditional medical fraternity together with the Ayurvedic component enjoys the status of a cabinet portfolio in the whole of the South-East Asia Region.

Thai traditional medicine as a holistic medicine

Pennapa Subcharoen

Thai traditional medicine, which has looked after the health of the people for thousands of years, is part of the cultural heritage and wisdom of the country. Our ancestors had accumulated precious experience of holistic health in the fight against disease. The different elements of Thai traditional medicine have been derived from wisdom handed down from generation to generation, from observations, old manuscripts and instructions provided at institutes of Thai traditional medicine. Thai traditional medicine is closely linked to Buddhism. Diagnosis in Thai traditional medicine does not only concentrate on diagnosis of disease but goes into the different theories and hypotheses of disease.

Thai traditional medicine believes that the following six causes are the main source of disease:

- Variation in the elements;
- Seasonal variation;
- Age variation;
- Place variation;
- Time variation;
- Behavioural variation.

Variation in the elements

The body consists of four body elements or *Dhatus*. It is believed that imbalance and disharmony between the four body elements cause disease. The four body elements are:

- The *earth* body element, which refers to any entity that is non-liquid, tangible and visible;
- The *water* body element, which means the fluid composition of the human body, e.g., blood, tears, nasal mucous secretion and urine;
- The *wind* body element, which circulates throughout the body;
- The *fire* body element, which burns the food which is consumed and transforms it into body waste material.

Human disease can be traced back to irregularity and abnormality in these four body elements.

Seasonal variation

The different seasons could cause imbalance of the four body elements. In the rainy season, for example, the wind

body element could be responsible for a fever. Humans should adjust themselves to the diseases which occur in the different seasons. These are given below:

- Summer - Diseases of fire element;
- Rainy season - Diseases of wind element;
- Winter - Diseases of water element.

Age variation

Age can be related to the propensity of a particular disease to occur in a particular person. Different age-groups are correlated with the diseases of a particular element. This relationship is shown below:

- *Primary age (0–16 years)*
  Water element diseases;
- *Middle age (17–32 years)*
  Fire element diseases;
- *Old age (over 32 years)*
  Wind element diseases.

Place variation

The environment has a relationship with the occurrence of a particular disease. Illness can be caused by a different geographical location, extremes of temperature or a new water supply. It is suggested that such an influence could be mediated through the immune system. Information as regards the birthplace of the patient or the actual place of residence may give the physician clues as regards the diseases which are likely to afflict the patient. The correlation between geography and diseases is given below:

- High mountains are associated with diseases of the fire element;
- Rain, water and mud are associated with diseases of the wind element;
- Rainwater, soil and groundwater are related to diseases of the water element;
- Salt water, mud and the beach are related to diseases of the earth element.

Time variation

The time of the day or night has an influence on the different body elements or *Dhatus*. These are described below:

- 06.00–10.00 a.m. and
- 18.00–22.00 p.m.
  Nasal secretion problems or indigestion;
- 10.00 a.m.–14.00 p.m. and
- 22.00 p.m.–02.00 a.m.
  Fever caused by the fire element, stomach ache or hunger pains;
- 14.00 p.m.–18.00 p.m. and
- 02.00 a.m.–06.00 a.m.
  The wind element causes giddiness, feeling of being worn out, exhaustion and fainting in the afternoon.

Behavioural variation

Certain behavioural patterns are associated with disease. Some of these are:

- Having too much or too little food and eating spoilt food; imbalance in activities such as standing, sitting, walking or lying down;
- Exposure to hot or cold weather;
- Going without food, water and sleep;
- Delayed defecation or urination;
- Overwork;
- Excessive sorrow;
- Excessive anger.

Diagnosis

A correct diagnosis is extremely important as a wrong diagnosis would lead to inappropriate treatment, which could be fatal. The method of arriving at the correct diagnosis in Thai traditional medicine consists of two factors – history-taking and physical examination.

History-taking

Attention is paid to the birth date of the patient because it shows the essential elements or *Dhatu* of the patient. The history would also indicate illnesses which occurred during childhood, seasonal illnesses, lifestyle and behaviour which could have related to the illness.

Physical examination

The physical examination consists of confirming the characteristics of the essential elements, palpation of the wrist pulse, checking the body temperature, checking the disordered organ, examination of the blood, using meditation for checking the cause of illness and checking the astrological configuration.

Curative methods

Thai traditional medicine is holistic medicine and takes into consideration several factors which could be associated with the illness. Some of these are given below:

- Factors created by nature, such as the basic elements of the human body, the season and the need for taking herbal food and medicine and altering behaviour;
- Behavioural factors have to be taken into account. The need for exercise and physical stretching (*Ruesee dat Tone*) have to be kept in mind. Thai traditional massage and meditation, which is a principle of the *Dharma* treatment, need to be kept in mind. The treatment could be:
  - Physical treatment such as exercise and body exercises, including body twisting;
  - Moral treatment such as meditation and merit making;
  - Treatment which consists of altering lifestyle so that the four elements and the external environment are in balance.
- Use of herbal food or medicine for adjusting the elements of the body to achieve balance. This consists of using herbal food for adjusting the *Dhatu*, using herbal food according to the season and administering such food for adjusting the *Dhatu* according to the taste of the herbal medicine. These tastes are cool taste (to adjust the fire element), hot food (to adjust the wind element), delicate taste (to adjust the water element) and nine other tastes to adjust the body elements such as astringent, sweet, intoxicating, bitter, creamy, aromatic and sour, spicy and salty;
- The herbal food should be administered according to the body element or *Dhatu*. Examples are given below:

Body element of earth

These persons should have food with astringent, sweet, creamy and salty flavours such as raw guava, mangostein, pumpkin, rambutan, taro, bean, milk and molasses.

Body element of water

These persons should eat food with sour and bitter flavours such as lemon, orange, pineapple, tomato, cavilla fruit, magosa and kiffer lime.

Body element of wind

These persons should eat spicy food such as ginger, galingale, lemongrass, pepper, sweet basil and holy basil.

Body element of fire

These persons should eat food with bitter or tasteless flavours such as morning glory, watermelon, cassia, ivy gonro and tiger herbal.

Healing is carried out by using a single-herb preparation or a mixed medicinal plants prescription. Mixed herb preparations are used for chronic diseases.

Advantages and characteristics of holistic medicine

- Holistic medicine places emphasis on lifestyle, health promotion and disease prevention;
- Holistic medicine creates a warm and empathic relationship between the practitioner and the patient. Proper mental health of the patient is essential for treatment;
- Treatment by holistic medicine lays emphasis on the patients' *Dhatu* or Element;
- Holistic medicine can cure chronic diseases which are induced by stress.

Traditional Thai massage

Thai traditional massage is based on the indigenous wisdom which the Thai people have adopted from their ancestors centuries ago. Massaging is a way of treating sickness; it starts by relieving tiredness or pain by the patient pressing on the pain himself. When he cannot massage himself he should ask somebody to massage him. This pattern has developed from massage by the family to massage at the village-level and later on to massage on a commercial scale.

Two patterns of Thai Traditional Massage:

- Unofficial Thai Massage (Folk Massage);
- Royal Thai Massage.

Unofficial Thai massage

This massage is given by persons to each other in a family or in the village. This type of massage is carried out not only by hand but also by standing on the patient, pushing, pulling and kneeling him by using also the elbow, knee, forehand and edge of the foot. This type of massage relieves tiredness and pain and also develops warm and good relationship among the family members.

Royal Thai massage

This massage is given to the King and the Royal family. In this type of polite massage, only the hand is used. The person carrying out the massage does not come close to the member of the Royal family, does not breathe into the person undergoing the massage and does not turn up his face, as it is disrespectful.

The characteristics of the Royal Thai massage and folk massage are given below:

Royal Thai massage

- Give a massage in a polite manner by walking on knees towards the patient and by not breathing directly on him;
- Start massage from the back of the feet;
- Give the massage only by using the hands, thumbs and fingers. The arms should be straight;
- Give the massage to the patient when he is sitting, lying on the back, lying in a side position but not when he is lying on his stomach;
- The person doing the massage does not bend part of the body of the patient being massaged with force by using his knees or elbows;
- The massage has an effect on the organs and tissues by enhancing the

circulating system and the nervous system. The person who carries out the massage should, therefore, have a knowledge of anatomy and should possess the skill of massaging the blood vessels and nerves.

Folk massage

- Start the massage from the feet;
- Give the massage to the patient while he is sitting, lying on the back, lying in a side position but not when he lies on the stomach;
- Bend the joints and parts of the body with force using the knees and elbows;
- The massage has an effect on the organs and tissues.

Thai traditional massage is a valuable aspect of Thai traditional medicine; it is able to relieve disease and assuage pain. The massage has a beneficial effect on the body systems necessary for maintaining good health. For example, it strengthens the circulatory system, removes wastes, acts as a diuretic, relaxes the nervous system and relieves pain. Some of the types of pain for which it is effective are headache, displaced shoulder joint, neck pain, sprained ankle, backache and kneecap pain. It is effective also in diseases of the elderly such as paralysis, limpness, flatulence, constipation and reduced sexual efficiency.

The benefits of Thai massage and the safety while carrying it out depend on the expertise of the Thai practitioner. He should know the body and the condition of health of the patient. He should know the principle of massage and know what not to do and he should know how much weight he should apply to make it suitable for the patients.

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