

State of Kuwait
Series of Publications of
Islamic Organization For Medical Sciences
Islam and Recent Medical Problems

Proceedings of the International
Seminar on
"INTEGRATION OF TRADITIONAL
MEDICINE (COMPLEMENTARY/
ALTERNATIVE MEDICINE) AND
MODERN MEDICINE"

Shaban 6-9, 1423 H
October 12-15, 2002
CAIRO



Supervised by

Dr. Abdul Rahman A. Al-Awadi

President
Islamic Organization
for Medical Sciences,
Kuwait

Edited by

Dr. Ahmad Rajai El-Gendy

Secretary General Assistant,
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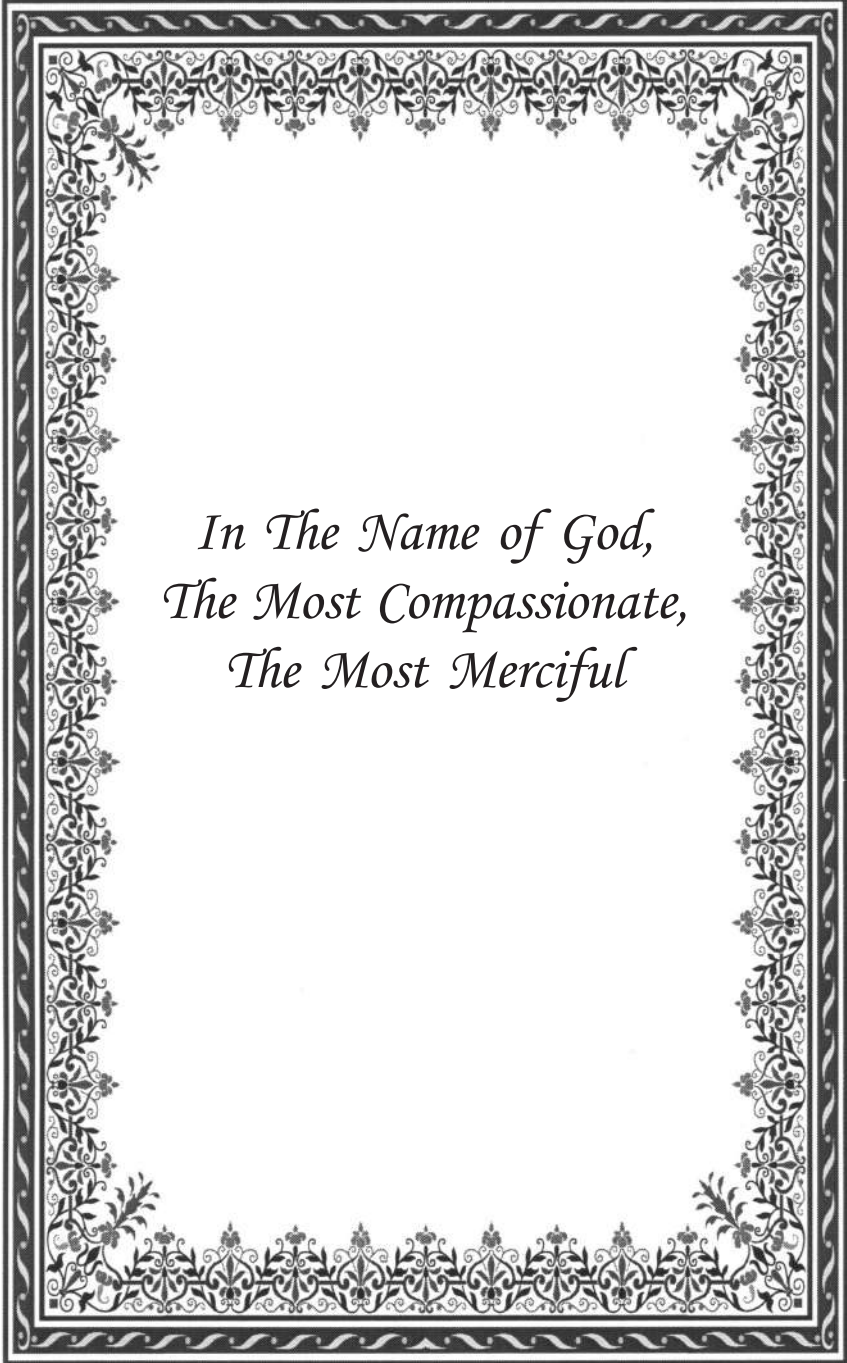
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*In The Name of God,
The Most Compassionate,
The Most Merciful*

CONTENTS

- Foreword	11
Dr. Abdul-Rahman Abdulla Al-Awadi	11
- Introduction	15
Dr. Ahmad Rajai El-Gindy	15
- Programme of the Conference.....	35
- Address by Minister of Health and Population, Egypt	47
H.E. Dr. Mohammed Awad Afifi Tag-El-Din	47
- Address by the Director General of ISESCO	53
H.E. Dr. Abdul Aziz Al-Tewajry	53
- Address by the Director of EMRO (WHO)	59
H.E. Dr. Hussain Al-Gezairy	59
- Address by the President of IOMS	65
H.E. Dr. Abdul Rahman A. Al-Awadi	65
- <i>Plenary Lecture</i>	
- Integration of Complementary and Alternative Medicine with Mainstream Medicine: An Islamic and Cultural Point of View.	71
Dr. Ezzeddin Ibrahim (U.A.E.)	71

First Session: An Overview of CAM

1. Integrating Traditional & Complementary Medicine into National Healthcare: Learning from the International Ex- perience.	79
Prof. Gerard Bodeker (U.K.)	79
2. Traditional Medicine and Its Challenges at the turn of the New Millennium.	123
Dr. Kin Shein (Japan)	123
3. Overview of Traditional Medicine (Complementary/Alterna-	

tive Medicine) with Special Reference to EMR Countries. Dr. Ahmed R. El-Gindy (Kuwait)	149
- DISCUSSION	199

Second Session: Fundamentals of CAM

1. Fundamentals of Complementary and Alternative Medicine. Dr. Howard Hall (U.S.A.)	209
2. Medicine as Science and Healing Art: Toward Holistic Care by Integrative Medicine. Dr. Koshiro Otsuka (Japan)	225
- DISCUSSION	261

Third Session: Spiritual Dimension and Its Power

1. Mind-Body Medicine - Magic or Truth? and Its Power for Healing. Dr. James S. Gordon (U.S.A.)	269
2. Spiritual Dimensions in Healing in Islamic Medicine. Dr. Ibrahim B. Syed (U.S.A.)	301
- DISCUSSION	331

Fourth Session: Integration of CAM

1. Why Alternative Medicine? What Conventional Medicine can learn from CAM? Dr. Andrew T. Weil (U.S.A.)	341
2. Key Issues for Better Integration of Traditional Chinese Medicine (TCM) with Conventional (Modern) Medicine: Understanding Infrastructure of TCM System in Terms of Modern Medical Knowledge. Prof. Il-Moo Chang (Korea)	357
3. Regional Policy of Legislation of Traditional Medicine Dr. Peter J. Graaff (WHO/EMRO)	377
- DISCUSSION	391

Fifth Session: Policy of CAM

1. Effectiveness of TRM from a Policy Formulation Perspective. Prof. Vinjar Fonnebo (Norway)	403
2. Cost Effectiveness of Traditional Medicine. Dr. Adrian White (U.K.)	413
3. Research Methods and Efficacy Evaluation in Non-conventional Medicine. Prof. Emilio Minelli (Italy)	427
- DISCUSSION	445

Sixth Session: Clinical Evaluation of CAM

1. The Use of Clinical Trails as a Measurement of Efficacy in Traditional Chinese Medicine. Mr. Paul McCarthy (Ireland)	455
2. What is "Traditional Use Evidence"? Dr. Karin Kraft (Germany)	475
3. Ganoderma Lucidium: the Mushroom and its Spore. Dr. Hu Hai-Yan (Switzerland)	491
- DISCUSSION	501

Seventh Session: Safety, Quality and Regulations

1. Issues of Quality, Safety and Efficacy in the Scientific Integration of Herbal Medicine into Modern Medical Practices and Marketing Botanical Drugs in USA. Prof. Ikhlas A. Khan (U.S.A.)	509
2. Regulations and Legislation for Herbal and Traditional Medicinal Products in the European Union. Prof. Konstantin Keller (Germany)	535
3. Regulations and Legislations of the Complementary and	

Alternative Medicine in Gulf States... general look. Dr. Abdullah Ibin Muhammad Al Bedah (K.S.A.)	545
- DISCUSSION	549

Eighth Session: National Policies

1. National Policies and Regulations on Integration - the United States Experience. Dr. Alan Dumoff (U.S.A.)	559
2. The Status of Traditional Medical Systems in India and Government's Policy towards Health Care Set up. Mrs. Malti S. Sinha (India)	585
3. Registration and Legislation of Traditional Medicines and Practitioners in India. Dr. Suresh Kumar Agarwal (India)	601
- DISCUSSION	611

Ninth Session: Country Experience

1. Expanding Global Horizons of Health Care: An Overview of the National Center for Complementary and Alternative Medicine. Ms. Nancy A. Hazleton (U.S.A.)	623
2. Status of Traditional Medicine in Pakistan and Its Aca- demic and Scientific Value. Hakim Abdul Hannan (Pakistan)	633
3. Experience of Saudi Arabia in the Legislation of Herbal Medicine. Prof. Mansour S. Al-Said (K.S.A.)	649
- DISCUSSION	655

Tenth Session: Country Experience

1. How the Traditional Medicine is Supportive in Conventional Medicine? Herbal Medicine and Experience of Egypt for Herbal Legislation. Prof. Mohammed Younis Haggag (Egypt)	665
2. Iranian Traditional Medicine: Past and Present. Dr. M. Mosaddegh (Iran)	675
3. Prospects of Traditional Medicine in Pakistan. Prof. Anwar-ul Hassan Gilani (Pakistan)	691
- DISCUSSION	705

Eleventh Session: Ethical Issues

1. Ethical Issues of Traditional and Complementary Medicine (TCM) and Registration Requirements for Practitioners - the Malaysian Experience. Dr. Narimah Awin (Malaysia)	713
2. Complementary Medicine: Medical Ethics Dr. Aly Bayoumi Hammad (Egypt)	731
3. Equity as an Ethical Issue in Traditional Medicine. Prof. John H. Bryant (U.S.A.)	737
- DISCUSSION	769

Papers submitted, but not presented in the conference

1. Policies and Programmes of Integration and Mainstreaming of Indigenous Systems of Medicine in India. Prof. Anis Ahmad Ansari (India)	779
2. Preserving and Protecting Traditional Medicinal Knowledge Dr. Xiaorui Zhang (Switzerland)	789
- Recommendations of the Conference	799
- List of Participants	807

FOREWORD

Dr. Abdul Rahman Al-Awadi

President of the Islamic Organization of Medical Sciences,
Kuwait

Foreword

by

Dr. Abdul Rahman Al-Awadi

President of the Islamic Organization of Medical Sciences, Kuwait

Within the past two decades, an important development has occurred in the perspective of the modern method of treatment, which uses the most up-to-date technologies. That development can be summed up as the breaking down and fragmentation of what is already divided in a human being, in order to get to the most minute components of the human body. The cell and its components have been closely scrutinized, and new facts have been discovered about reactions that have not been known before, allowing explanations of things before which science used to stand helpless. Now, man can follow these reactions and predict their future development inside the body and their implications for the various organs. In fact, the new discoveries have gone beyond the wildest imagination. After the discovery of the human genome and the genetic code, it is expected that scientists will know what is likely to befall a human being in the future.

In spite of all these discoveries that were expected to introduce into man's life joy, happiness, and pleasure; to relieve his pain; and to raise his hopes - the result has been contrary to all expectations. The bitter existence that man leads today is the best evidence of that. Depression spreads throughout the world, the rate of suicide is rising, and 35-40% of the new medicines have side effects that are greatly hazardous to human health. Rebellion against every new thing is characteristic of this age, and this is no longer limited to one country, race, religion, or location; the whole world is revolting against the technology that has turned man into a mere number in an equation. The bond of affection between fellow human beings has dissolved due to the spiritual vacuum that man of the twentieth and twenty-first centuries suffers from.

That is the situation in industrial, technologically advanced countries. As for developing countries, the picture may differ. No advanced

equipment, medicine, food, or potable water is available; incomes are low; and people have no alternative other than to return to nature for food, medicines, prevention, and treatment, and for a inclusive perspective that covers spirit, psyche, and body; restores optimism; and regards man as a real human being.

This is not surprising in itself. The majority of the world's population enjoy stability and security through a balanced life; dependence on what the environment yields to man, without going to either extreme; and exploiting all human experience to live a proper and happy life.

For that reason, we have sought to hold this important and comprehensive conference that may predict the future and warn decision makers and education and health planners that what counts is not only the provision of advance equipment and modern medicines. We rather have to dress the wounds of man of the twentieth and twenty first centuries and look at him to see the whole being, body and soul, which are one entity, if one of its organs complains, the others are mobilized sleepless and fevered concern. In other words, we are trying to restore to man his full humanity in which body and soul integrate to achieve equilibrium, stability, and reassurance.

It is for this reason that we have invited the World Health Organization, represented by its regional office, and the ISESCO to share the responsibility with us and help us deliver the message to all people, Muslims or non-Muslims.

Wherever he may be Man is the creature God has blessed above all his other creatures. That is our philosophy in holding this conference, and you have the agenda. We pray God to grant us success, and if not, to forgive us and accept our good deeds.

INTRODUCTION

Dr. Ahmed Rejai El-Gindy

Secretary General Assistant, IOMS, Kuwait.

In the Name of God, the Beneficent, the Merciful

**Traditional (Alternative, Complementary) Medicine:
A World Perspective with Special Focus on
Arab and Islamic Countries**

by

Dr. Ahmad Rejai Al-Gindy

Assistant Secretary General,
The Islamic Organization for Medical Sciences, Kuwait

Medicine is a human heritage, transmitted from one generation to another. It greatly prospered in many civilizations - such as the Ancient Egyptian, Babylonian, Assyrian, Chinese, Indian, Greek, Persian, and Islamic Arab civilizations - reflecting the extent to which they flourished. It was, until the late nineteenth and early twentieth centuries, the means of human survival. It had been the primary source of treatment all over the world, until many theories began to emerge in medicine and therapy, benefiting from old treatment theories, albeit differing with them over many details. By the middle of the twentieth century, traditional medicine began to retreat, giving way to the new theories, with chemistry exercising a great influence. Many instruments and machines have been invented, and they were used to uncover most minute details of life in human cells. The last, but not least, discoveries and innovations include the genetic map, genetic engineering, organ transplants, and cloning. The human imagination continue to toy with further expectations in the attempt to realize man's dream of immortality and everlasting health.

In spite of such undeniable progress and the great achievements in medicine and treatment in the form of producing drugs through genetic alteration that involves animals and plants, and in spite of the eradication, through the discovery of vaccines and antibiotics, of many diseases that used to pose a threat to humanity, such as the plague,

the measles, smallpox, and others - modern medicine has failed in several areas.

For example,

1. Modern medicine has come to be described as medicine of the rich. The poor, under the global circumstances of instability and soaring prices, have no access to decent health care, as the average of annual income in many poor countries does not exceed \$150, which is so low that the majority of deaths are attributed to poor nourishment. As for medicine, it is simply unavailable.

In rich countries, on the other hand, everything is easily available. If a patient's heart is feeble, another heart is available. If a kidney fails to function, a replacement can be found. It is as if spare parts replace faulty ones in the human body, which seems no more than a machine. Any disorder in one of its parts is dealt with successfully one way or another.

2. In spite of these treatment capabilities, twenty-first century man suffers severe depression. World statistics indicate that about 330 million people have depression, and according to World Health Organization (WHO) figures, about 10-20% of the world population will suffer from depression at one point of their lives. Scientists assert that depression will be the main cause of mortality after heart diseases. The annual cost of depression medications amount to some seven billion dollars, with about 44 billions paid by the United States alone for depression therapy.

Pharmaceutical companies that manufacture anti-depression medicines are thriving more than ever. Evidence of this is the profits made by a company that produces a recent medicine for depression, which are estimated as two billion dollars a year.

3. This is getting to be a world for the old; the number of old people, as compared to the young, will increase considerably in the next decade. Consequently, many diseases will coincide: high blood pressure, diabetes, osteoporosis, dental ailments, heart diseases, depression, and negligence. A person may suffer all these disorders simultaneously. Yet, modern medicine has little to offer to confront this situation, which is approaching with accelerating speed.

Old people are estimated to have numbered around 580 millions in 1999, and it is projected that the number will rise to 2,020 millions by 2020. This will pose a heavy burden on health budget; the cost of care for one old person is 15 - 20 times more than it is for a young one.

4. There are diseases that man has made for himself, with his own hands, due to his miscalculation, greed, and disregard of moral standards. Addiction, whether to alcoholics and narcotics, poses the greatest hazard to humanity, threatening what it values most and endangering man's mental stability, as well as his life. The responsibility for this calamity lies with greed, which focuses man's interest only on the material aspects of life, even if his gain will cost the life of a fellow human being. For such people, human life is worth no more than a few dollars, the price of a few grams of narcotics, a bottle of an alcoholic beverage, or few packs of cigarettes.

Another epidemic is spreading like fire in a dry forest as a result of the weakening of religious values and the open proliferation of vice, which is now referred to as the "sex industry," as if it were an activity similar to the pharmaceutical industry, for example. The result of the advent of this newcomer has been a full collapse of the immunity systems which God has given to man. Man has turned into an easy prey, killed by the mildest diseases and disorders. Modern medicine is now helpless in facing this challenge. It may overcome the disease in the future, but this is a warning from the Lord of Creation: "If you persist, We will." All indications, however, suggest that man is persisting in his sins and tyranny. Instead of outlawing and combating adultery and modifying their attitude by restoring the natural concept of family life, as God orders it to be, Western organizations give no heed to it. They rather openly demand "sexual freedom," provided that condoms or diaphragms are used. As a result, the number of AIDS patients is on the increase, with millions dying of it, particularly in African countries, where the rate of infection is up to 40%, and Asian countries, where the rate is also high. Likewise, modern medicine has also achieved little in other areas, such as that of cancer.

This is not meant to put down or underestimate the achievements

of modern medicine or to advocate abandoning it. What modern medicine achieved in the last fifty years in relieving human suffering is much greater than what humanity has achieved throughout its history up to that point.

The problem facing modern medicine lies in its very bases. The first basis was a contribution by Newton, reaffirmed by the Western scientists who followed him, led by Descartes. It is reductionism: in order to know the attributes of anything, it has to be reduced to its smallest unit. This has been regarded as a principle to be respected and observed, and it still prevails in global sciences. In application, man is seen, according to that principle, as consisting of various organs, each of which should be handled separately. The result of that view is reflected in three things.

The first is that great success has been achieved in treating every organ through a specific specialization. This, however, is done at the expense of other organs, as symptoms vary in the degree of their severity from one organ to another. The treatment of one organ may lead to the emergence of other diseases in other organs.

The second point is the great dependence of modern medicine on recently invented equipment, for x-ray pictures and tests, to confirm a physician's diagnosis and treatment.

The third thing is the spiritual vacuum experienced by patients because they receive no personal attention, no attempt is made to explore their personal problems, and, as various equipment is being used, they are rather treated as mere numbers.

This feeling has its ramifications in regards to the speed of recovery and even on recovery itself.

The second principle on which modern medicine is based is invasive intervention against disease, in order to overcome it as quickly as possible, with a direct effort at its eradication. This has placed man's life within a narrow, risky circle, and instead of getting treated, a patient may die.

The third principle of modern medicine is that it seeks treatment, rather than healing. There is a vast difference between the two.

Treatment is the attempt to eradicate the disease, while healing rests on completely different bases.

The fourth principle is the way modern medicine regards disease; it considers it either as a microbe infection or an organ impairment.

Traditional medicine, on the other hand, considers it an internal and external imbalance that is manifested in a certain organ or in the whole body. The remedy then is to restore the balance of a person, his surroundings, and his internal being.

Have the concepts of modern medicine achieved the objectives they are intended to realize? Definitely, as mentioned above, modern medicine has accomplished gigantic achievements. For the last two decades, however, there has been a fallback from those concepts and notions, and this lies behind the great interest in alternative medicine throughout the world, whether in advanced and rich industrial countries, or in developing or underdeveloped ones. Everybody seems to be seeking a means which, in one way or another, would meet his needs, fulfill his desires, and restore his humanity.

It is probably worthwhile to explore the global conditions of alternative medicine in order to realize the extent of the fallback all over the world from modern to alternative medicine.

In the United States, as an example, people pay 27 billion dollars of their own money for alternative medicine treatments, which are not covered by medical insurance. In England, the cost is 2,300 million dollars; in Canada, 2,400 millions; in Malaysia, 500 millions; and in China, 40% of the Health Ministry budget. That is for industrialized countries. In developing countries, no accurate statistics are available, but the extent of alternative medicine popularity is indicated by the fact that 85% of the populations of these countries rely on it.

The expenditure on alternative medicine treatment is not the only thing to take into consideration. Many changes have taken place. Universities have introduced the study of many alternative medicine systems into the curricula of medical schools. Alternative medicine courses are offered for interested practitioners who have had no chance to study it earlier. Many countries have introduced rules and

regulation for practicing alternative medicine, whether by physicians who have studied it or by traditional practitioners.

Many polls of alternative medicine users that aim at determining the type of people who resort to it reveal that the majority are rich people seeking treatment, either to escape the side effects of chemical drugs or to find what they miss in modern medicine: spiritual aspects and a comprehensive perspective that covers the material, psychological, and spiritual aspects.

Moreover, a great number of alternative medicine users and promoters are thinkers, scholars, philosophers, scientists, and educated people, who find it consistent with their beliefs and their concepts of man's role in life, the complex relationships that link him to his internal and external environment, and the psychological and spiritual implications of all this, which inevitably influence man's career and his physical condition.

On the other side of the world, alternative medicine is the main source of treatment in many developing and poor countries. About 90% of the population of Ethiopia rely on it. 60% of the people of India have no source of treatment other than folk medicine. The percentage of traditional medicine users is 71% in Chile, 40% in Columbia, 42% in the United States, 50% in Sweden, and 70% in Canada.

The way alternative medicine is used differs in poor countries from that in rich ones. In poor countries where the annual income is below \$150, alternative medicine is the only option available for patients. Its practitioners charge reasonable fees and accept payment in kind, rather than cash, which makes it easier for the patients. Moreover, the treatment prescribed is unlikely to be expensive.

Furthermore, alternative medicine is part of the folk heritage of these countries and, therefore, remains closer to their hearts and souls. Practitioners most often belong to the same class as the patients, and, therefore, the two sides find no difficulty in dealing with and trusting each other.

In addition, practitioners of modern medicine are usually located

in metropolitan cities, where urban life offers more amenities and luxury. Consequently many villages in those countries are deprived of the health services provided by modern physicians, who are poorly represented there, if at all.

After these details, do we need a new concept of health care? To answer this question, we must study the example of a rich country with high expenditure on health care. Let us take the United States. Although the annual health care expenditure is about \$4,000 per capita, the highest in the world. The total expenditure is \$1.3 trillion, representing 14% of the gross national income. In spite of this, the United States ranks as the 37th country in the world in health service coverage; 43 millions of its population are currently without such coverage.

Regardless of this enormous expenditure, the outcome of health care in the United States calls for reconsideration. For example, two million people suffer from the serious side effects of drugs prescribed to them every year. 20—30% of U.S. patients receive un-prescribed and unneeded treatment. 44,000 - 98,000 people die every year due to malpractice. 106,000 die due to wrong diagnosis. 4—8% of all out-patients suffer from side effects. Because of all these factors, about 77 billion dollars are added to the annual health care expenditure in the United States.

Perhaps all this is due to:

1. the high number of specialists and shortage of general practitioners;
2. the increased dependence on highly costly technology which requires special skills and is fatal when mistakes are made; and
3. the concept of Western medical treatment which is remedial and eradicated, and this has dangerous and sometimes fatal consequences for patients.

TREATMENT ECONOMICS IN MODERN AND TRADITIONAL MEDICINE

We have two models representing rich countries and developing countries.

-
- A. In Japan, an industrial country, it is established that the daily cost of folk medical treatment per patient is about \$6 less than the cost of medical treatment in Western countries. For a hospital with 200 beds, this means an annual saving of about \$438,000.
- B. The population of China (a developing country) amount to some 22% of the world population, while its health care expenditure represents 1% of the world's total.

Thus, in spite of its high cost which is expected to rise year by year, the health care concept has not realized the ambitions of care providers and recipients. An alternative has to be sought in the hope that it would overcome the obstacles confronting medicine.

A number of philosophers, scientists, and researchers in various fields have recognized the predicament of modern medicine. Work teams have been formed to make studies of this issue and determine how much benefit can be derived from alternative medicine in order to straighten the course of modern medicine on various levels, particularly the spiritual level and the comprehensive, integrated perspective that looks at man as a human being and seeks to bring him happiness and overcome the problems and worries that affect his life and humanity in general.

Since various terms are used, it is worthwhile to define the various concepts. For example, the terms folk, alternative, and complementary medicine are used, so how do they differ.

First, folk medicine is defined as a set of medical practices, inherited by one generation after another and stemming from customs, traditions, values, precepts, and beliefs, whether they are man-made or derived from divine religions. Their aim is to maintain health through nutrition and other means of disease prevention. Medicine is described as traditional folk medicine when it is practiced in its original home country, but when it is practiced somewhere else, it is referred to as alternative medicine if used as a substitute for modern medicine, and as complementary medicine if used to supplement modern medicine.

The origin of acupuncture, for example, in China and Korea,

where it is regarded as traditional medicine. When it is practiced in other countries, it is either alternative or complementary medicine.

The types of traditional medicine may be grouped in two major categories:

- The first is pharmaceutical medicine, in which herb, animal and mineral based medicines are used.
- The second is non-pharmaceutical medicine, which depends on manual techniques and exercises, such as massage, splinting, hypnosis, relaxation, energy, body and mind interaction, and other techniques that involve no use of medicines.
- Still, what is the reason that prevents traditional medicine from thriving more than it does? There are many reasons that can be summed up as follows:
 1. The attitude of modern medicine towards folk medicine is indifferent, if not outright hostile.
 2. Modern medicine claims that folk medicine is unscientific and has no explanations based on any scientific authority.
 3. There is hardly any academic research in the field of folk medicine and the little that is made is of poor quality, published in un-refereed journals.
 4. Physicians practicing modern medicine demand that folk medicine should be subject to the same standards and criteria as modern medicine, which is not feasible, as the two disciplines have different bases and there are practices in folk medicine that cannot be measured. Therefore, new criteria may have to be established for folk medicine, quite different from those of modern medicine, although they have a scientific basis.
 5. The allocations for folk medicine research are meager. However, this situation changed in the last decades due to the great public demand for this type of medicine, which prompted authorities to take measures to protect consumers against (1) the risks that cost many lives because of misusing the materials common in folk medicine, which follows no

regulations, and (2) charlatans and false folk-medicine healers. Moreover, developing countries are reexamining their heritage to benefit from their natural resources and potentials, and to consider the possibilities of recruiting human resources in health care.

Major countries have been showing interest in this subject; specialized centers have been set up for research in this field and a liberal budget has been allocated for that purpose. There are now refereed journals specialized in alternative medicine, specialists in modern medicine have begun to pay attention, and a series of research papers is being published in international scientific journals. Likewise, the World Health Organization has a special department for traditional medicine to serve as a coordinator for interested people and set recognized scientific principles for the registration of herbal medications, as well as regulations for practicing folk medicine that do not conflict with world principles. The department also offers help and advice in this field for countries that request them.

This has been a glimpse of the status of folk, alternative, or traditional medicine throughout the world. There are many types of folk medicine, such as the Chinese, Hindu, Greek, and others that stem from the heritage, beliefs, and cultures of various nations.

One of these is Islamic medicine.

Although the term Islamic medicine has given rise to considerable controversy over the concept it implies, my conviction of the importance of this topic makes me more convinced than ever that Islamic culture has had its own medicine that should be called after it.

Islamic Culture was productive in every field over five centuries. George Sarton, a great Western historian, made a sketch of human civilization to give a rough picture of its history, and he assigned fifty years to each civilization, but gave Islamic civilization five centuries and called it the civilization of Al-Razi, Ibn Sina, Ibn Rushd, Omar Khayyam, Ibn Al-Haitham, and others. Even after it began to wane, it continued to be productive not only in the field of religious studies and the humanities, but also in encyclopedias of Islamic history and civilization.

Moreover throughout the history of Islamic civilization, there is no mention of a scientist or scholar who was killed, burned, exiled, or tortured because of his scientific views. Actually, Islam promotes learning, and recommends it to be sought. There are many traditions of the Prophet to that effect, and there are Quran verses that recommend research as something necessary. This attitude is not restricted to religious disciplines; natural sciences have received their share of interest and meditation. Muslims have excelled in all natural sciences: medicine, pharmacology, geometry, algebra, mathematics, astronomy, physics, navigation, and all others with no exception.

Our pride in being Muslims comes from Islam's permission of medicine and treatment and prohibition of quack medicine, augury, and fortune telling. It keeps intruders out of medical practice and sets scientific rules for it. The Prophet, blessings and peace be upon him, ordered his Companions to seek treatment: "God's servants, seek treatment. God has created no ailment without creating a remedy for it, known to some and unknown to others." He also set another principle: "Whoever practices medicine and is not known to have medical knowledge bears liability." This means that only an expert may practice medicine, and there is no room for quack doctors. Meanwhile, preventive medicine was the Prophet's first concern, and in many traditions of his, he urged his Companions to take precautions by refraining from urinating into running water and avoiding the three curse-invoking locations [for evacuating their bowels].

Islam prohibits drinking directly from the mouth of a container and calls for personal hygiene in clothes, food, drink, bath, teeth brushing, nail and hair trimming, and other things. It promotes the cleanliness of houses and the need for them to be aired and for the sun to get in. It commands us to have great ecological awareness so that the environment may not be a source of diseases.

Islam points out what is permissible and what is forbidden in food and drink, and even in Muslims daily behavior. It sets healthy patterns, which makes the Muslims who abide by them physically, psychologically, and spiritually strong.

Islam is the first religion to lay down bases for infection prevention to protect human lives.

There is much more to say about Islam's role in disease prevention and treatment and in setting ethical systems to guarantee the right attitude in confronting the pervasiveness of modern medicine and its new discoveries. Islam has its own say as to the extent to which these innovations are permissible or prohibited.

From the brief review above, it is clear that "Islamic medicine" is a term with a scientific basis that derives its legitimacy from

1. the Glorious Quran,
2. the gracious Tradition of the Prophet,
3. Islamic civilization, and
4. Islam's attitude towards medicine.

In the early days of the Islamic medicine project, some colleagues expressed reservations. Those people can be divided into two groups.

The first was afraid the Islam would be forced into secular practices and that any error would be falsely attributed to Islam. The answer is very simple. Every person is responsible for his own actions, and if he makes a mistake, he has to be held accountable for it. To admit the principle of this group's argument means to divest Islam of all its secular interests, when it is in fact a religion that combines the spiritual and the secular, without either overshadowing the other. Thus, it does not have the monasticism innovated by some Christians nor the materialism in which Jews are plunged. Islam adopts the best course: the mean.

Is There Any Benefit in Islamic Medicine?

To answer this question we have to reconsider the following:

- First, does the Arab and Islamic nation have real achievements in Islamic medicine?
- Second, does the income of an individual make treatment affordable?

- Third, does an individual's allocation for treatment allow him to get the needed treatment?
- Fourth, does Islamic medicine have treatments that can serve as substitutes in treating many diseases?
- Fifth, is Islamic medicine recognized in Islamic countries?

Does the Arab and Islamic nation have real achievements in Islamic medicine?

It is known that Islamic civilization contributed for human progress for five centuries and was productive in all aspects of life, including medicine. This productivity is reflected in the modification of many concepts, such as Al-Razi's distinction between the measles and smallpox, the discovery of pulmonary circulation and the absence of ligation between the upper and lower jaws, the theories of vision and of infection, and other achievements. Muslim scientists also added considerably to the information about medical herbs and diagnosis techniques. Ibn Al-Bitar added over 200 herbs to the ones discovered by his predecessors. Many herbs were written off after it was demonstrated that they had no use or had too many side effects on human patients. Al-Dainori and other botanists excelled. Al-Razi proved himself a giant of medical science with his clinical encyclopedia, the first in history, which is based on scientific criteria similar to the ones employed today in modern medicine.

There are many other, wonderful contributions by Islamic medicine, but time does not allow more elaboration. History and heritage books testify to that fact, which is further demonstrated by the translation of that great heritage to many European languages to serve as major references during the Western civilization's Renaissance. It was from that point that Europe went forward to turn science fiction into reality, while Islamic scientific progress in general was halted.

But is Islamic medicine recognized by the citizens of Islamic countries?

To find the answer it is sufficient to cast a look on the social, health, spiritual, psychological, and economic conditions in Islamic countries.

In spite of the many fierce attempts and the various claims and arguments in the Islamic World to separate the state from religion and base it on secularism, the ordinary citizen still has strong ties with Islam and resists all attempts to alienate him from it. He continues to accept zealously everything related to the Islamic religion. Legitimate incantations are still popular within the rich and poor, educated and illiterate, sections of society. In spite of the controversy over the Prophet's medicine, whether to follow or abandon it or only use it for blessing, it still holds its position for many people. Medical herbs are still used. While each herb requires certain climate conditions to bloom and develop its healing characteristics, Islamic countries enjoy varying climates, ranging from desert to farmland, from hot to cold regions. This fact can be exploited by establishing a joint medical herb market by Islamic countries, where materials and farming and manufacturing expertise can be exchanged.

Although the volume of trade in medical herbs is not as desired and their use for treatment is not highly regarded in many Islamic countries, with the exception of those in East Asia (Pakistan, Afghanistan, Indonesia, and Malaysia), consumption of these substances is constantly on the rise. In recent days, it has exceeded its previous rates. There has been a great interest in Islamic countries in benefiting from this divine gift to treat many diseases. An additional factor is the low average of income in many Islamic countries, where individuals are hardly capable to secure the food they need. Moreover, health care allocations in most Islamic countries are well below international standards.

For most citizens of Islamic countries, treatment, being so costly, is unaffordable. Therefore, the only thing they can do is to use and gain benefit from the medical herbs God has given them and to seek the services of folk healers, particularly since medical herbs have the potential to treat all diseases if administered soundly. They are easily available, cost less than chemical drugs, and have fewer complications.

The mosque continues to play an important role in many aspects of life, particularly in promoting healthy, Islamic living, which would allow Muslims to have a pleasant life and enjoy sound spiritual, mental, psychological and physical health. Islam regards its followers

with a comprehensive viewpoint and offers them a preventive approach in all aspects of life. Once they follow it, they would lead a good life and be healthy and strong. Islam, for one thing, permits and encourages marriage, prohibits and severely punishes adultery and all what leads to it, thus protecting society from sexually-transmitted diseases, the most recent of which is the acquired immunodeficiency syndrome (AIDS). It also prohibits intoxicants, narcotics, smoking, and all other health damaging substances, all of which are afflictions that cause suffering to those who permit and encourage them. In East and West, millions of dollars are lost as a result of taking these forbidden substances.

Islam promotes sanitation and personal hygiene and considers cleanliness a major part of belief. Poor sanitation causes problems from which many Islamic countries are now suffering, with the spread of diseases that can be overcome by following the hygienic way of life encouraged by Islam. In fact, Islam distinguishes between sanitation and ritual cleanliness (taharah), the latter being an idiom denoting a very different concept for which there is no equivalent in Western languages and culture.

In addition, Islam defines the relationship between an individual and his Lord. It enjoins four rites of worship: “the testimony that there is no deity other than God and that Muhammad is God’s Messenger, prayer performance, alms-giving (payment of zakah), fasting in Ramadhan, and pilgrimage to the House for those who can afford the journey.” Each of these is a basic element, discussed in many profound scholarly works and studies which emphasize its importance for individuals in this life and the Hereafter, as it refines, guides, and redeems the soul. In establishing objective principles for man’s relationship with his Lord, Islam refines man’s conscience and enables him to be content and reassured. He is thankful for favorable things that befall him and endures unfavorable things. He feels that there is something good in everything that happens to him. This strong faith in God and His Prophet is reflected in the Muslim individual’s life within his community. Mutual sympathy and compassion prevail in such a community, so that when one member suffers, all others lend

their support. The community resembles a compact structure in which the parts support each other. Justice, safety, and security prevail, and people have a tranquil life, enjoying a balance of the soul, psyche, heart, and body, none of which dominating another and upsetting the balance. This is how a Muslim understands the philosophy of his religion. He accepts his mission on earth as God's deputy, with the task of settling and developing it. Everything maintains a delicate balance and everybody seeks good in his work and aims at pleasing his Lord.

The well-balanced Islamic philosophy produced a strong cohesive society in which the members did not worry much about the material world, nor held it as the end of their knowledge. They rather did good deeds that would be assets for them in the Hereafter.

This has been a brief account of alternative or traditional medicine, with a brief note on the Islamic Organization for Medical Sciences and Islamic Medicine. Hopefully, officials in Islamic countries will not allow this medicine to be neglected. It is our own product, re-exported to us. Nobody else in East or West can claim credit for it. The whole credit goes to Islam. It is hoped that Islamic medicine will be one of the methods of providing health care services to those underserved, with the least possible cost, particularly now that the intellectual property (TRIPS) agreement is about to be implemented with an expected doubling of medical costs, which neither citizens nor the state will be able to afford.

Can Islamic countries take a step forward by doing the following?

1. Can they take advantage of their natural herb resources to set up an herbal pharmaceutical industry supported by a common pharmaceutical market?
2. Can human resources be exploited through proper training to be qualified and serve as a first defense line, providing assistance for simple cases in the remote areas that have no physicians? This has to be supervised by health officials in Islamic countries or by the governments themselves.
3. Can the millions of advocates and of mosques be used to promote health awareness among citizens, emphasizing the sound patterns

of healthy Islamic life, thus fulfilling the mosque's role of being a source of enlightenment in all aspects of life?

4. Is it possible to make all levels of school and college education an extension of the mosque's promotion of the sound patterns of healthy Islamic life, particularly offering Islamic-oriented sexual education for adolescents, warning them against the hazards young people are exposed to in connection with sex, alcoholic beverages, and drugs, with an explanation of the causes of these hazards and the way to avoid them?

We have been especially interested in inviting participants from Western countries - the United States, Britain, Germany and Italy - as well as Japan and Malaysia. We have tried to invite two participants from China, but have been unable to do so due to poor communications. We have also invited representatives of Pakistan and India, as well as Arab countries.

In doing this we want to send a message to people who oppose or question traditional medicine, saying that this is not an invitation to return to the past or an expression of lack of faith in the present or the future. Nor is it a movement of poor countries. It is rather international in its character, particularly since all the participants from the West have high degrees in their fields of specialty and hold distinguished positions. It is sufficient to point out that the president of the United States has formed a committee to study this subject and the chairman of that committee, a dean of an American medical school, is one of our participants, along with others.

We are urged to be very careful and patient as we explore this field, to use scientific criteria, and to choose for each Islamic country the methods most suitable to it and most likely to serve its urgent needs.

Our early, upright predecessors used to learn ten verses of the Glorious Quran at one time and do not move to the ones that follow before they have implemented fully the injunctions of those verses. Those people were masters of the world in their knowledge, morality, and deeds, thus deserving God's description of them: (You are the best nation that has been known by Mankind. You enjoin justice and censure evil, and you believe in God((III: 110).

PROGRAMME

FIRST DAY:
Saturday, 12 October 2002

Inaugural Session **9.00 - 10.25**

- * Recitation from Holy Quran 9.00 - 9.05
- * Address by Minister of Health and Population, Egypt
H.E. Dr. Mohammed Awad Afifi Tag-El-Din 9.15 - 9.25
- * Address by the Director General of ISESCO
H.E. Dr. Abdul Aziz Al-Tewajiry 9.25 - 9.35
- * Address by the Director of EMRO (WHO)
H.E. Dr. Hussain Al-Gezairy 9.35 - 9.45
- * Address by the President of IOMS
H.E. Dr. Abdul Rahman A. Al-Awadi 9.45 - 9.55

Distribution of IOMS Prizes, provided by KFAS

Plenary Lecture

- Integration of Complementary and Alternative Medicine with
Mainstream Medicine: An Islamic and Cultural Point of View.
Dr. Ezzeddin Ibrahim (U.A.E.) 9.55 - 10.25
- **Coffee Break** **10.25 - 11.00**

First Session: An Overview of CAM **11.00 - 13.00**

- This session will be devoted to discuss the ways that CAM can support and improve Conventional Medicine, and challenges to Traditional Medicine at the turn of the new millennium. Also, an overview of TM/CAM will be discussed.

Chairman : Prof. Ibrahim Badran

Rapporteur : Prof. Mansour S. Al-Said

Speakers

- Integrating Traditional & Complementary Medicine into National Healthcare: Learning from the International Experience.
Prof. Gerard Bodeker (U.K.) 11.00 - 11.30
- Traditional Medicine and Its Challenges at the turn of the New Millennium.
Dr. Kin Shein (Japan) 11.30 - 12.00
- Overview of Traditional Medicine (Complementary/Alternative Medicine) with Special Reference to EMR Countries.
Dr. Ahmed R. El-Gindy (Kuwait) 12.00 - 12.30
- **DISCUSSION** 12.30 - 13.00
- **Break and Prayer** 13.00 - 13.30

Second Session: Fundamentals of CAM

13.30 - 15.00

This session will be devoted to discuss the fundamental issues related to the Complementary and Alternative Medicine (CAM), and the importance of developing the holistic insight to make effective, synergistic combination of both areas of medicine (integrative medicine), beyond the reductionism based on the biological mechanic model of human beings.

Chairman : Dr. Hussain Al-Gezairy

Rapporteur : Hakim Abdul Hannan

Speakers

- Fundamentals of Complementary and Alternative Medicine.
Dr. Howard Hall (U.S.A.) 13.30 - 14.00
- Medicine as Science and Healing Art: Toward Holistic Care by Integrative Medicine.
Dr. Koshiro Otsuka (Japan) 14.00 - 14.30
- **DISCUSSION** 14.30 - 15.00
- **Lunch Break** 15.00 - 16.30

Third Session: Spiritual Dimension and Its Power 16.30 - 18.00

This session will be devoted to discuss the major principles of mind-body medicine based on studies on psychological influences on health and illness, and touch on the ways that mind-body therapies can change practitioners’ approach to self and their patients, and also the role of spiritual dimensions in healing particularly in relation to Islamic health practices, health behaviours, code of ethics and framework of Islamic perspectives in caring and spirituality.

Chairman : Dr. Abdul Rahman A. Al-Awadi

Rapporteur : Prof. Anis Ahmad Ansari

Speakers

- Mind-Body Medicine - Magic or Truth? and Its Power for Healing.
Dr. James S. Gordon (U.S.A.) 16.30 - 17.00
- Spiritual Dimensions in Healing in Islamic Medicine.
Dr. Ibrahim B. Syed (U.S.A.) 17.00 - 17.30
- **DISCUSSION** 17.30 - 18.00
- **Proceed to Official Dinner by bus**

SECOND DAY:
Sunday, 13 October 2002

Fourth Session: Integration of CAM

8.00 - 10.00

This session will discuss the policy, regulation and strategy of preserving and protecting Traditional Medicine knowledge, and the policy framework for integrating Traditional and Complementary Medicine into national healthcare in the light of international experiences. Also, the key issues for better integration of Traditional Chinese Medicine with Conventional Medicine will be discussed.

Chairman : Dr. James S. Gordon

Rapporteur : Prof. Emilio Minelli

Speakers

- Why Alternative Medicine? What Conventional Medicine can learn from CAM?
Dr. Andrew T. Weil (U.S.A) 8.00 - 8.30
- Key Issues for Better Integration of Traditional Chinese Medicine (TCM) with Conventional (Modern) Medicine: Understanding Infrastructure of TCM System in Terms of Modern Medical Knowledge.
Prof. Il-Moo Chang (Korea) 8.30 - 9.00
- Regional Policy of Legislation of Traditional Medicine
Dr. Peter J. Graaff (WHO/EMRO) 9.00 - 9.30
- **DISCUSSION** 9.30 - 10.00
- **Coffee Break** 10.00 - 10.30

Fifth Session: Policy of CAM

10.30 - 12.30

This session will be devoted to discuss the priorities and factors that are pivotal of policy formulation and dimensions of effectiveness measurement of Traditional Medicine, its cost effectiveness, and also

the research methods and efficacy evaluation in non-conventional medicine.

Chairman : Dr. Adrian White

Rapporteur : Dr. Abdullah Ibin Muhammad Al-Bedah

Speakers

- Effectiveness of TRM from a Policy Formulation Perspective.
Prof. Vinjar Fonnebo (Norway) 10.30 - 11.00
- Cost Effectiveness of Traditional Medicine.
Dr. Adrian White (U.K.) 11.00 - 11.30
- Research Methods and Efficacy Evaluation in Non-conventional Medicine.
Prof. Emilio Minelli (Italy) 11.30 - 12.00
- **DISCUSSION** 12.00 - 12.30
- **Break and Prayer** 12.30 - 13.00

Sixth Session: Clinical Evaluation of CAM	13.00 - 15.00
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This session will be devoted to discuss the use of clinical trials as a measurement of efficacy of Traditional Chinese Medicine (TCM), the traditional use evidence of Traditional Medicinal Products and the issues in assessment of therapeutic effects of TCM.

Chairman : Prof. Gerard Bodeker

Rapporteur : Dr. Narimah Awin

Speakers

- The Use of Clinical Trails as a Measurement of Efficacy in Traditional Chinese Medicine.
Mr. Paul McCarthy (Ireland) 13.00 - 13.30
- What is "Traditional Use Evidence"?
Dr. Karin Kraft (Germany) 13.30 - 14.00
- Ganoderma Lucidium: the Mushroom and its Spore.
Dr. Hu Hai-Yan (Switzerland) 14.00 - 14.30
- **DISCUSSION** 14.30 - 15.00

- **Lunch Break** **15.00 - 16.30**

Seventh Session: Safety, Quality and Regulations **16.30 - 18.30**

This session will be devoted to discuss the issues of quality, safety and efficacy in the scientific integration of herbal medicine into modern medical practices and the marketing of botanical drugs in U.S.A., and the regulations and legislations for herbal and Traditional Medicinal Products in the European Union, and of CAM in Gulf countries.

Chairman : Dr. M. Haitham Al-Khayyat

Rapporteur : Prof. Anwar-ul Hassan Gilani

Speakers

- Issues of Quality, Safety and Efficacy in the Scientific Integration of Herbal Medicine into Modern Medical Practices and Marketing Botanical Drugs in USA.
Prof. Ikhlas A. Khan (U.S.A.) 16.30 - 17.00
- Regulations and Legislation for Herbal and Traditional Medicinal Products in the European Union.
Prof. Konstantin Keller (Germany) 17.00 - 17.30
- Regulations and Legislations of the Complementary & Alternative Medicine in Gulf States... general look.
Dr. Abdullah Ibin Muhammad Al Bedah (K.S.A.) 17.30 - 18.00
- **DISCUSSION** **18.00 - 18.30**

**THIRD DAY:
Monday, 14 October 2002**

Eighth Session: National Policies **8.00 - 10.00**

This session will be devoted to discuss the national policies of integration of Traditional Medicine/Complementary and Alternative Medicine (TM/CAM) in U.S.A., and India

Chairman : Dr. Abdul Aziz Saleh

Rapporteur : Dr. Peter J. Graaff

Speakers

- National Policies and Regulations on Integration - the United States Experience.
Dr. Alan Dumoff (U.S.A.) 8.00 - 8.30
- The Status of Traditional Medical Systems in India and Government's Policy towards Health Care Set up.
Mrs. Malti S. Sinha (India) 8.30 - 9.00
- Registration and Legislation of Traditional medicines and Practitioners in India.
Dr. Suresh Kumar Agarwal (India) 9.00 - 9.30
- **DISCUSSION** **9.30 - 10.00**
- **Coffee Break** **10.00 - 10.30**

Ninth Session: Country Experience **10.30 - 12.00**

This session will be devoted to discuss the policy of legislation of Traditional Medicine in the Eastern Mediterranean Region, an overview of the National Centre for Complementary and Alternative Medicine in U.S.A., status of Traditional Medicine in Pakistan and its academic and scientific value, and the experience of Saudi Arabia in the legislation of herbal medicine.

Chairman : Prof. Konstantin Keller

Rapporteur : Prof. Mohammed Younis Haggag

Speakers

- Expanding Global Horizons of Health Care: An Overview of the National Center for Complementary and Alternative Medicine.
Ms. Nancy A. Hazleton (U.S.A.) 10.30 - 10.50
- Status of Traditional Medicine in Pakistan and Its Academic and Scientific Value.
Hakim Abdul Hannan (Pakistan) 10.50 - 11.10
- Experience of Saudi Arabia in the Legislation of Herbal Medicine.
Prof. Mansour S. Al-Said (K.S.A.) 11.10 - 11.30
- **DISCUSSION** 11.30 - 12.00
- **Break and Prayer** 12.00 - 12.30

Tenth Session: Country Experience	12.30 - 14.00
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This session will be devoted to discuss the status of Traditional Medicine/ Herbal Medicine in Egypt, past and present of Iranian Traditional Medicine, and the prospects Traditional Medicine in Pakistan.

Chairman : Prof. Ahmed Fouad Basha

Rapporteur : Prof. Ikhlas A. Khan

Speakers

- How the Traditional Medicine is Supportive in Conventional Medicine? Herbal Medicine and Experience of Egypt for Herbal Legislation.
Prof. Mohammed Younis Haggag (Egypt) 12.30 - 12.50
- Iranian Traditional Medicine, Past and Present.
Dr. M. Mosaddegh (Iran) 12.50- 13.10
- Prospects of Traditional Medicine in Pakistan.
Prof. Anwar-ul Hassan Gilani (Pakistan) 13.10 - 13.30
- **DISCUSSION** 13.30 - 14.00
- **Lunch Break** 14.00 - 15.00

Eleventh Session: Ethical Issues **15.00 - 17.00**

This session will be devoted to discuss the Ethical issues of Traditional and Complementary Medicine and the Registration Requirements for Traditional Medicine Practitioners, and the Equity.

Chairman : Dr. Andrew T. Weil

Rapporteur : Prof. Ali Abdul Monem Mustafa

Speakers

- Ethical Issues of Traditional and Complementary Medicine (TCM) and Registration Requirements for Practitioners - the Malaysian experience.
Dr. Narimah Awin (Malaysia) 15.00 - 15.30
- Complementary Medicine: Medical Ethics
Dr. Aly Bayoumi Hammad (Egypt) 15.30 - 16.00
- Equity as an Ethical Issue in Traditional Medicine.
Prof. John H. Bryant (U.S.A.) 16.00 - 16.30
- **DISCUSSION** **16.30 - 17.00**
- **Break** **17.00 - 17.30**
- **Panel Discussion** **17.30 - 19.30**
- **Break** **19.30 - 20.00**
- **CLOSING SESSION** **20.00 - 21.00**

FOURTH DAY:
Tuesday, 15 October 2002

Sight-Seeing Programme

(VISIT TO DIFFERENT HISTORICAL SITES IN CAIRO)

**SPEECH OF
DR. MUHAMMAD AWAD TAJ AL-DEEN,**
Minister of Health and Population, Egypt

The Speech of His Excellency, Egyptian Minister of Health and Population, Dr. Muhammad Awad Taj Al-Deen, delivered on behalf of him by Deputy Minister Dr. Mahmoud Abu Al-Nasr

Professor Hussein Al-Gazaeri,

Professor Abdul Rahman Al-Awadi,

Ladies and Gentlemen,

I am pleased to share you this meeting and greet you all in this seminar that raises a vital and persisting issue and constitutes a significant step on the way of safety and public health in the countries of East Mediterranean Region. You agree with me that the issue of treatment and therapy is one that belongs to public opinion, which is of interest to all people, the rich and the poor; the young and the old; the literate and the educated alike. You also agree with me that the Health Ministry is the body responsible for citizens' health. In addition to providing citizens with therapeutic and preventive care and health services as constitutions state, it is responsible for supervising health service units whether they are governmental or private, affiliated to authorities or individuals, as well as setting disciplines and mechanisms that ensure regular service and obtainment of desired outcomes. It is also responsible for defining safety factors and following them up to save citizens from harm and check safety in all procedures related to public health and individuals.

Ladies and Gentlemen,

Medicine is the other face of the health coin as it is necessary for the patient to recover. Egypt's Ministry of Health and Population is greatly interested in developing drug industry and keeping up with latest advancements and technologies in this regard, while it focuses on big challenges posed by the New World Order. However, we must admit at the same time that medicine converts to a fatal poison if it is wrongly or inappropriately used.

Ladies and Gentlemen,

Popular medicine and alternative medicine, so to speak, are kinds of medication that had been vastly used in the past. Not a small category now depends basically on it as medicine for them. Another category may resort to it when traditional medicine fails and leaves patients desperate. Moreover, popular medicine is the basis on which modern medicine has been established, as herbal medicines at one time were almost the only drugs used. Studies indicate that alternative medicine is widespread in many world countries including western ones. About 80% of Africa's population, 65% of the Indian people rely on alternative remedies, and not a few number of westerners use alternative medicine. In Germany, 77% of pain relief clinics use acupuncture, compared with 90% of these clinics in the United Kingdom. Though there are many forms of therapy through alternative medicine, starting from herbs and ending with acupuncture and the various aspects in between, herbal medication remains the most popular among Egyptians. This is a natural result of culture accumulation with which the Egyptian people have been influenced, beginning with the civilization of the Pharaohs, passing by ancient Greek civilization and Islamic civilization. Use of herbs and so-called popular medicine are widespread in many crowded quarters. Furthermore, druggists' recipes are quite well known in Egypt's history and used by both the educated and illiterate people. Herbal remedies are not the only common type of alternative popular medicine in Egypt, but there is also spiritual medication and remedy through the Quran and other forms of alternative medicine, which do not depend on drugs but rather deal with the patient's psychological side.

Ladies and Gentlemen,

Egypt's Ministry of Health and Population encourages research and innovation and praises novelty provided it adheres to the Ministry's criteria and disciplines aimed at protecting citizens and public health, and boosting drug industry. It is no secret that prices of modern medicine will rise several times with the coming of the World Trade Organization. At that time, herbal remedies will be one of the important options before the masses as an acceptable alternative to costly modern medication, provided it is prescribed by a professional physician who is responsible for his patients, and not by unqualified individuals who

inherit such a trade from their forefathers and whose harm exceeds their benefits. But we should design a system for distributing such medications according to established rules in this context. The Ministry registered during past years many drugs produced by Egyptian companies, whose contents are derived from natural herbs, through mechanisms applicable at the Planning and Medicinal Policies Centre and the Public Authority of Control and Medicinal Research in Egypt. A committee of novel remedies was formed at the Ministry, which is tasked with probing all therapy methods and remedies referred to it, and testing their efficacy and safety.

Finally the Ministry welcomes the discussions and recommendations in this field concluded by WHO Regional East Mediterranean Committee in its forty-ninth session in Cairo. These discussions and recommendations have stressed that popular medicine has an important role to play as an alternative aspect of treatment. This development came in response to current circumstances represented in increasing pressures resulted from world changes, trade globalization and intellectual property rights. The committee has also urged conducting more scientific research to ensure the efficacy and safety of this kind of medicine, and underlined the registration and preservation of the region's plants and products for the welfare of the region. This can be done via countries' support of setting effective regulatory mechanisms for registering herbal medicines and ensuring their quality.

Ladies and Gentlemen,

We look forward to seeing the outcomes of your thoughts and studies and the conclusions of this important and purposeful meeting. Your results will greatly assist in boosting the efforts targeted at protecting public health and citizens. Egypt's Health Ministry is always pleased to cooperate (with others) in order to safeguard coming generations and saves no effort to achieve this aim. Please accept my thanks and appreciation.

Allahs Peace, Mercy and Blessings be upon you,,,

**SPEECH OF
H.E. DR. ABDUL AZIZ AL-TEWAIJRY**
Director General of ISESCO

INAUGURAL SPEECH

by

H.E. Dr. Abdul Aziz Al-Tewaijry

Director General, ISESCO

In the name of Allah, the Most Compassionate, and Merciful. Praise be to Allah Almighty and prayers and peace be upon His Messenger Prophet Mohammad, his kith and kin.

Excellency Dr. Al-Gezairy, Director, EMRO

Excellency Dr. A.R. Al-Awadi, Chairman of IOMS

Ladies and Gentlemen, peace be upon you.

I have the pleasure to welcome you to this international symposium on "Integration of Alternative Medicine and Modern Medicine", to express my personal satisfaction to have this symposium held here in Cairo, the place of science, thoughts and cultures. I would also like to express my heart-felt thanks to my brother Prof. A.R. Al-Awadi, Chairman of the IOMS, to His Excellency brother Dr. Hussain Abdul Razaq Al-Gezairy, EMRO Director and I would avail myself of this opportunity to come under fruitful cooperation between the ISESCO, the IOMS and the EMRO/WHO.

I would also like hail the distinguished efforts of Prof. A.R. El-Gindy, Secretary General Assistant of IOMS along with his colleagues in convening this international symposium.

Ladies and Gentlemen,

At the dawn of the third millennium, the Islamic world is standing in a critical situation, at the cross roads, facing formidable civilizational challenges. It eternally longs for a standard of progress, commensurate with its capacitatives and the level of natural and the human resources. But it suffers, at the same time, from numerous difficulties, hampering its advancement in other fields specially, the economic, scientific areas, and the general development in the scienti-

fic, technological and industrial fields. And then, we had the September 11 events and its subsequent developments that have yet added dilemma of the Islamic world enabling those wide open before enemies to reach anti-Islam campaigns.

Today, the world is going through a critical chapter. Unlimited industrialization is assuring humanity into new era of technological progress, marked by profound unprecedented developments.

At the same time, globalization is steadily progressing, bringing nations close together, but unfolding aggressive attempts to impose immoral ethics over the whole world. The scientific and technological gap between the developed and developing countries is widening day after day. The new world, though they amplified these disparities in order to the burden of under developed, while the information technology brought the radical changes of new patterns of behaviour and economic activities, and technological standards of the world.

The 20th century, indeed, has witnessed steady progress in the different medical fields, rapid phase of development in modern technology. Novel therapeutic methods have been developed especially, during the last three decades. And, the humanity has embarked on the visualization of biotechnology and genetic engineering to heal diseases and even to intervene on genetic disease during the future periods. But, given the high cost of treatment by modern methods and techniques, high technology is not and will not, in the near future, be affordable by the vast majority of people. Notably in the Muslim countries, most of whose populations are living under the poverty line. It is, therefore, particularly the duty of Muslim physicians and Muslim scientists who are in frontline of scientific and technological advancement in these areas to assemble and address themselves to this issue to come-up with solutions. I mean that it would be appropriate, practical inexpensive forward treatment and preservation, not only for Muslims, but also all humans at large, just as our forefathers did throughout the rich and remarkable history. People in many of our Muslim countries often resort to traditional medicine for treatment, for purely economic reasons. And, some have even taken-up this medicine as an occupation without real knowledge, without real experience. It is consequently

most urgent to lay down rules and regulations for the profession of traditional medicine. Because, integrating traditional treatment in modern medicine, undoubtedly will create benefits to all Muslims and to mankind as a whole.

Excellencies, Ladies and Gentlemen,

The ISESCO, the IOMS and the EMRO/WHO have a set of prime objectives and goals for this international symposium. These are the following:

1. Introduction of Alternative Medicine, its importance in related research, and documentation.
2. Overview of Alternative Medicine in the world.
3. Interactions between Alternative Medicine and Modern Medicine, pharmaceuticals considerations of countries that proved successful in integrating Alternative Medicine into Modern Medicine.
4. Economical integrating of Alternative Medicine into Modern Medicine, legal and regulatory aspects of traditions and this type medicine.

This is a general framework of the objectives submitted by the symposium seeking to present to the Muslim individuals with clarity, to spell the perplexities and confusions, sound evidence and ground for the use of Alternative Medicine and Modern Medicine for the sake of his own welfare and for the welfare of whole mankind.

Excellencies, Ladies and Gentlemen,

I would like to reiterate my thanks and I pray Allah the Almighty to guide our steps and bless our endeavours to achieve the welfare of our Muslim Ummah! And I would like to address my thanks in particular to the IOMS, WHO/EMRO and indeed, to all those who have collaborated with us in convening this international symposium. Allah blesses you! Assalam-o-alaikum!

**SPEECH OF
H.E. DR. HUSSAIN AL-GEZAIRY**
Director of EMRO (WHO)

INAUGURAL SPEECH

by

Dr. Hussain Al- Gezairy

Director, EMRO/WHO, Cairo

In the Name of Allah and Prayers and Peace be upon His Messenger

Ladies and Gentlemen- Dear Colleagues,

First, I would like to express my gratitude to the Islamic Organization for Medical Sciences headed by His Excellency, Dear Brother, Dr. Abdul Rahman Al-Awadi, as well as the Islamic Educational, Scientific and Cultural Organization (ISESCO), chaired by Respected Brother, Dr. Abdul Azeez Al-Tuwaijry. I thank them for their efforts in the fields of public health and welfare of this region's population. Then, let me express my wishes and expectations that popular medicine would be an integrated part of future medicine on grounds of the past's expanded knowledge. Popular medicine has been and will be an important ingredient of providing health care in our region and all over the world. Virtually, we are entitled to be proud that the so-called Greek medicine or the Islamic Arab medicine represents one of the most famous and prevailing systems of popular medicine. The increasing demand of both governments and patients on popular medicine and natural medical treatments is clear evidence of the high status enjoyed by popular medicine compared with other health care options.

As a third of the world population is denied regular access to basic drugs, we can easily notice that a big proportion of the population of developing countries, which reaches 80% in some rural areas, depends on popular medicine as the main source of treatment. Meantime, a rising rate of the population of industrial countries has converted to popular medicine or alternative medicine as a complementary medical aspect, after it has suffered the limited western medicine. However, this does not mean that there are no problems threatening the future of

popular medicine. In fact there are common problems facing most countries at world and regional levels. These include:

- First: Many national health care systems do not officially recognize popular medicine and its practitioners, thus encouraging its practice outside their framework and giving a chance to practitioners of legerdemain to play their role.
- Second: Absence of regulations and legislation related to herbal products and other public treatments on the basis of scientifically acceptable safety and quality criteria, or non-application of these regulations and legislation, if there are any, in most countries.
- Third: Governments and academic institutions alike do not pay enough attention to research, education and training in the field of popular medicine.

Ladies and Gentlemen,

In the light of the above-mentioned problems and out of the World Health Organizations desire to meet the requests of their member states in the domains of information, training and policies, the WHO has decided to be committed to its lead role in the sphere of data collection and multiplication. It will also continue setting rules required for using popular medicine that is considered modern medicines partner, in a complementary and reasonable way. Whenever popular medicine provides real opportunities, and it actually does in many cases, for boosting health care, we will support its integration or incorporation into the predominant health care model, or at least seek its coexistence with such a model. I would like to seize this occasion to refer to two issues associated with herbal medicines, which enjoy a special importance in my viewpoint. These two issues need the solidarity of all the WHO countries. It is necessary that all the region states move to face as quickly as possible the effects of globalization, particularly issues of intellectual property rights that may have negative consequences on national legacy and biological diversity of our popular knowledge as regards possession, practice and production.

We at WHO pay great attention to correct regulation and appropriate usage of herbal medicines, which is embodied in the items of the

organizations regional programme that aims at assisting world countries to incorporate herbal medicines in their national medicinal policies when appropriate. WHO also helps countries to establish registration and inspection systems for ensuring the quality of these medicines, cement suitable exploitation of herbal medicines through providing guidebooks, criteria and technological methodology, and finally facilitate exchange of information among member states.

Dear Colleagues,

Achievement of incorporation and integration means that popular medicine is officially acknowledged and fully inserted into all fields of health care system including national policy, regulation and registration of practitioners, treatments, practice at all levels, insurance coverage, research and education.

Up till now a few number of countries have really inserted popular medicine in national health care systems. I am sorry to say that the list does not include a single state from the region. However, there is still a ray of hope represented in the issuing of legislation that supports and strengthens research and regulation bases by some region states including Kuwait, the headquarters of the Islamic Organization for Medical Sciences. It is no doubt that this international seminar with its rich scientific agenda and its participants of famous world experts in all aspects and forms of popular medicine, will greatly contribute to safeguarding this positive dialogue.

It is to my pleasure in this regard to tell you that Their Excellencies Ministries of Health in WHO East Mediterranean Region, during meetings of the regional nutrition committee held about two weeks ago, have recognized the important role still played by popular medicine in ensuring the health of their peoples. They also underlined major challenges faced by popular medicine in different field, as well as the continued need for the protection of popular medicine knowledge and the preservation of its natural resources. They endorsed a resolution calling upon all the member states in the region to apply the WHO strategy of popular medicine during the period from 2002 to 2005, as a framework for preparing and developing national pro-

grammes of popular medicine. The application of this strategy is also aimed at ensuring the implementation of national policies and regulation related to popular medicine and complementary and alternative medicine, in order to boost their proper usage and take procedures required to protect and preserve knowledge associated with popular medicine, safeguard national plant wealth and maintain natural resources.

I learn that many dear participants in this international seminar have contributed to setting and reviewing our strategy of popular medicine. Here I express my deepest gratitude for the efforts you have put into the preparation of this significant document that will be an example to all of us and to health ministries in the region in particular, on the way of seeking the common goal represented in strengthening activities of popular medicine as an important ingredient of good health. I wish you good luck in all your discussions.

Allah's Peace, Mercy and Blessings be upon you,,,

**SPEECH OF
H.E. DR. ABDUL RAHMAN
ABDULLAH AL-AWADI**

President, IOMS, Kuwait

INAUGURAL SPEECH

by

H.E. Dr. Abdul Rahman Abdullah Al-Awadi

President, IOMS, Kuwait

In the name of Allah, the Most Compassionate, and Merciful. Peace be upon the Prophet of Allah and peace be upon you all!

My dear brothers Dr. Hussain Al Gezairy, Regional Director of EMRO, Mr. Tuwajiry, Director General of ISESCO, Ladies and Gentlemen, and Dear Colleagues,

It is a pleasure to take the floor today in this meeting in Cairo in order to talk subsequently about this subject of traditional medicine. And to start with, I would like to apologize to the simultaneous interpretations. I am apologizing because, I have not prepared any written paper, I therefore, ask for the interpreters to bear with me.

First of all, I would like to address my thanks to the Prime Minister of Egypt Dr. Atef Ebeid, for having pleased to hold this conference under his patronage. Of course, we do understand the difficulties for him to be present with us here at this moment, so understandably busy. We would love to have him with us, because we know, how strongly he believes in this particular topic. Today, as we know, gathering here in this beautiful conference hall that is called Kuwait Hall. Thanks to the efforts of Dr. Gezairy, because Kuwait has contributed to the building of these premises and this conference room has been named after the country, State of Kuwait. So, Dr. Hussain Al-Gezairy is warmly thanked for all of his efforts, indeed, anyone who is paying attention to these health matters. And Dr. Gezairy is a colleague for long time. We are living in one region of the world, where there is so much traditional medicines. But, unfortunately, not enough attention is being paid and we have to figure out that in such age. We are not alone, we are here in Egypt today in this country. We don't know yet how ancient Egyptians were

mummifying? That has inspired our institutes, the greatness of sciences that has existence in the past. This is not fully past, fortunately. This makes our world crippled, when establishing a link with its past. Past is culture, it is a science that we have to fully grasp to go into the future. And, we cannot claim that we have reached our utmost limits. We may have discovered the human genome, may have discovered so many things in terms of analysis. But we are trying, we in this symposium will be trying to collect all the bits and pieces of knowledge, because, man is not just a body, just a part of body. Even, there is sub-specialization that have marvelous progress in some aspects, yet it tends to forget that we are living, dealing with a wholesome of body and soul, not body alone. And, therefore, many have thought wrongly that Traditional Medicine and we modern doctors have not been able to collect all the bits and pieces. We, here, in this symposium, will be trying to do so. We will try to establish proper links and make of human a complete, a whole picture living and coexisting in its complete form. Without such co-existence, without such complementarity, we will never be able to cope with human. Because, modern human being is more complex, because of complexity of science, complexity of knowledge. And, we will listen to many presentations that will review all of the dimensions whether in the developed and developing countries. If look at country such as America, US\$27 billion are being spent on traditional medicine, that is alternative medicine, complementary medicine. All of these are names and we did not settle for one single name. What is the future of such medicine? How are we going to merge all of these dimensions together the authentic concept that have proved and made for proofs? Years and centuries ago, how could we make fusion to merge these two medicines modern and traditional? We know that a country such as America spends a lot of money on Alternative Medicine, but in many poor countries, people can hardly find enough to eat, to drink. So, how could we possibly ask these countries to resort to Modern Medicine that would not cope with their customs, traditions, understandings and the way of living? So, we have to get the best out of rich experiences, useful experiences. India, Pakistan, Malaysia and Indonesia are the countries that have gone a long distance and that have gathered

experience for such place and now they can rest on their knowledge. We have to recognize the performance and the achievements of Modern Medicine, but we must not forget Traditional Medicine. We did not come from the sky or from the vacuum. We came from deeply rooted past experience and living, because, if we don't understand our past, we will never be able to progress in future. This is one of the objectives of our meeting. I won't take much of your precious time. I know that many specialists and scientists will take floor and share experience with us. What we will try to do here, is to try to reach a very simple thing, namely, how to establish a link between both medicines, traditional one that has manifested and showed its fruits throughout the ages and Modern Medicine? How to merge between both of them in order to give the human being their full place or picture for physical and soul together? This is not, of course, a first meeting of WHO/EMRO. We have held so many other symposia. We have cooperated with WHO. We have many studies on the use of traditional medicine, herbal medicine and like. Today, we are gathering here in order to complete, what we already started. We are not starting from scratch, we have got already a basis to build upon such conditions that have to exist in the practicing of traditional medicine. As was said earlier, many have taken advantage of the vacuum existing and they have used an old form, in the absence, of course, of rules and regulations. We need a framework. In China, India, Pakistan, well-known societies for such medical practitioners exist. In this row, we have to discuss the centers that have to coordinate and how these medical centers operate in order to be efficient in everything, in other words that would be discussed here to re-examine the whole picture and trace or draw the clear lines for such traditional medicine. We also have to stress the ethical aspects of traditional medicine, to concentrate on moral and ethical issues and see how we should reach safety, quality and excellence. We have to have rules and regulations, so as to guarantee traditional medicine is of the highest possible quality. I am sure, you will reach many of these objectives and I would like to address my thanks again to my brothers and sisters in the Arab Republic of Egypt and Prime Minister of this country Dr. Atef Ebeid, and indeed, Dr. Abdul Aziz Al-Tuwaijry from

ISESCO which has had so many contributions in such matters. This symposium would not have been possible without the efforts exerted by the WHO/EMRO, the IOMS and ISESCO. We hope, therefore, that all of us together, will be able, in the best possible conditions, to reach our objectives. It is a must for us to pay tribute to the organizers of this meeting. I hope, we will continue cooperating together. I do not want to say about the staff of WHO/EMRO. These are all like unknown soldiers and like unknown soldiers, they do resort to military methods whenever necessary in order to reach the best possible objectives. Once more, I thank you all!

PLENARY LECTURE

**INTEGRATION OF COMPLEMEN-
TARY AND ALTERNATIVE MEDI-
CINE WITH MAINSTREAM
MEDICINE: AN ISLAMIC AND CUL-
TURAL POINT OF VIEW**

Dr. Ezzeddin Ibrahim (U.A.E)

**Integration of Complementary and Alternative
Medicine with Mainstream Medicine: An Islamic
and Cultural Point of View**

By
Dr. Ezzeddin Ibrahim
(Abu Dhabi, UAE)

Points of Lecture

- I. History and Justification
- II. Expansion and Precautions
- III. Drawing attention to: Herbal & Unani Medicines and Spiritual Treatment
- IV. Islamic Medicine
- V. Reliance on Traditional Medicine in Developing Countries
- VI. Thesis recommended: Controlled Integration of all Modalities

I. History and Justification

1. Five Systems in question: Mainstream, Complementary, Alternative, Traditional and Integrated
2. (CAM) recognised only recently
3. Justifications:
 - Historical studies
 - Limitations of Allopathic medicine
 - Favourable assessments of CAM
 - Costs
4. Precautions: for efficacy, safety, competent practitioners, pace and cost

II. Herbal, Unani and Spiritual Modalities

1. Herbal: the Alpha and the Omega
2. Unani:
 - i.e. Greco-Arab Medicine
 - Constituted mainstream medicine for 12 centuries
 - Verified and accredited in India and around
3. Spiritual:
 - Clear of superstition
 - Mystical powers are isolated cases
 - Prayers, supplications and meditation

III. Islamic Medicine

1. Realistic and Pragmatic attitudes towards: Illness, Health, medical treatment and surgery
2. Spiritual practices are complimentary to synthetic medicine
3. Link between Greco-Arab era and Western renaissance with its own contributions
4. Smooth integration with modern medicine

IV. Traditional and Local Medicine in Developing Countries

1. Alma-Ata International Declaration 1978
2. Recommendations:
 - Scientific assessments
 - Legislation
 - Safe and effective practice
 - Avoidance of commercialisation
3. High costs of medicalisation remains unsolved problem

V. Thesis Recommended: Controlled Integration

1. Integration: obvious conclusion
2. International exchange of information
3. Control on: choice, practice, development and cost

First Session
Saturday, 12 October 2002
An Overview of CAM

Chairman : Prof. Ibrahim Badran
Rapporteur : Prof. Mansour S. Al-Said

Speakers:

- 1 - Prof. Gerard Bodeker (U.K.)*
- 2 - Dr. Kin Shein (Japan)*
- 3 - Dr. Ahmad Regai El-Gindy (Kuwait)*

**INTEGRATING TRADITIONAL &
COMPLEMENTARY MEDICINE INTO
NATIONAL HEALTHCARE:
LEARNING FROM THE INTERNA-
TIONAL EXPERIENCE**

Prof. Gerard Bodeker (U.K.)

INTEGRATING TRADITIONAL & COMPLEMENTARY MEDICINE INTO NATIONAL HEALTHCARE: LEARNING FROM THE INTERNATIONAL EXPERIENCE

Gerard Bodeker

Global Initiative for Traditional Systems (GIFTS) of Health,
Green College, University of Oxford, Oxford, UK

ABSTRACT

Consumer demand for traditional and complementary medicine has outpaced the capacity of policy makers and funders to keep abreast with coordinated knowledge generation and policy development

Yet international experience is growing and it is possible to draw on this experience as a reference for planning the integration of these services within conventional healthcare systems. To facilitate this, an overarching policy framework is proposed which discusses international experience in the following eight categories: equity; ethics; governance; financing; knowledge production; knowledge management & utilisation; capacity development; research environment.

INTRODUCTION

As the global public's use of traditional and complementary medicine increases, governments are being challenged to develop sound policies, regulations and trade standards (Bodeker 2001). Public access to their healthcare system of choice and public safety are both important dimensions of the policy challenge.

In this paper, an attempt is made to survey salient issues relevant to policy, as so many countries are now grappling with the policy dimensions of the ever-increasing demand from the public.

(Author's note: This paper draws on work done in previous papers: the first, Bodeker G (2001a) 'Planning for Cost-effective Traditional Health Services', WHO Kobe, Japan, (2001) for which support from WHO Kobe

Center is gratefully acknowledged; also, Noller et al., 2001, for which support from the Commonwealth Foundation is gratefully acknowledged; and a presentation at the Malaysian Complementary Healthcare 2001 Conference held in Kuala Lumpur, September 2001, for which support for the British Council is gratefully acknowledged. An abridged version of this paper is published as Bodeker G & Kronenberg F, " A public health agenda for complementary and traditional (indigenous) medicine ", in the American Journal of Public Health, Oct 2002)

TRADITIONAL ORIGINS

In most developing countries, traditional health systems are grounded in long-standing cultural and spiritual values and it is important that policy reflect and support this rather than attempt to replace tradition with science alone.

Traditional health knowledge extends to an appreciation of both the material and non-material properties of plants, animals and minerals. Its classificatory systems range in scope from the cosmological to the particular in addressing the physiological makeup of individuals and the specific categories of materia medica - the materials used for therapeutic purposes in traditional health systems - needed to enhance health and well-being. Mental, social, spiritual, physical and ecological factors are all taken into account.

A fundamental concept found in many systems is that of balance - the balance between mind and body, between different dimensions of individual bodily functioning and need, between individual and community, individual/community and environment, and individual and the universe. The breaking of this interconnectedness of life is a fundamental source of dis-ease, which can progress to stages of illness and epidemic. Treatments, therefore, are designed not only to address the locus of the disease but also to restore a state of systemic balance to the individual and his or her inner and outer environment (Bodeker 2000).

The cosmologies of traditional health systems ascribe life, spiritual value and interconnectedness among all life forms to the aspects of the

natural world used in the process of promoting human health and well-being.

In establishing policy it is important that these fundamental theoretical underpinnings of traditional health systems be respected and perpetuated in order to ensure their continuity in an intact form.

A POLICY FRAMEWORK

Clearly, global demand has led to a situation where it is now recognized that policy must be developed to ensure safe and high quality traditional and complementary health services to a public which is already integrating medical services on its own accord.

In May 2002, the WHO World Health Assembly (WHA) saw the initiation of two significant policy initiatives in complementary and traditional medicine. Commonwealth Health Ministers, at their Pre-WHA meeting, agreed to establish a Global Information Hub on Integrated Medicine. The Hub will be hosted by Malaysia, which has put up US\$10 million to establish the project. It is being designed as a central information resource on complementary and traditional medicine for use by policy makers, clinicians, researchers, the public and industry. Reflecting patterns of consumer use and a wider trend towards mainstreaming, Ministers elected to use the term "integrated medicine" rather than "complementary medicine".

At the time of the WHA, the World Health Organisation launched its new Traditional Medicines Strategy 2002-2005 on 16th May. The strategy, through regulation, research, training and sectoral development, is designed to mainstream the traditional and complementary therapies used by the majority of the world's population. To achieve this, WHO has outlined a framework for action aimed at enabling these approaches "to play a far greater role in reducing excess mortality and morbidity, especially among impoverished populations" (Ramsay, 2002).

With respect to policy action, country experience can be organised into eight broad areas of principle:

1. Equity. 2. Ethics. 3. Governance. 4. Financing. 5. Knowledge pro-

duction. 6.Knowledge Management & Utilisation. 7.Capacity Development. 8.Research Environment.

This framework draws on that developed by the Council on Health Research for Development (COHRED) and it served for the policy recommendations on traditional medicine made at the COHRED conference on health research priorities for the coming decade, held in Bangkok in October 2000 (Bodeker et al 2001).

1. Equity.

Research into patterns of use of modern and traditional medicine has found that the general public throughout the world use both systems according to sets of priorities that may reflect the availability of each system, its affordability, their belief in its efficacy at the symptomatic as well as etiological levels, and the cultural familiarity of the various approaches.

Research in India has found that medical pluralism was flourishing as people switched from one medical system to another depending on affordability and time. (Bandyopadhyay & MacPherson, 1998). Rural women in Gujarat have been found 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 use of modern and traditional services among women in the study area than the actual direct costs of the service. 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 (Vissandjee et al, 1997).

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 U.S. had used Western health services in the US within the previous twelve months. 20% 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 (Ma, 1999).

With respect to the use of traditional medicine by indigenous

groups, of Native American patients attending an urban Indian Health Service clinic in Wisconsin, 38% of patients see a healer, and of those who do not, 86% would consider seeing one in the future. Most patients report seeing a healer for spiritual reasons, reinforcing the point made at the beginning of this paper that traditional health systems are grounded in cultural and spiritual values that must be preserved if equity and access to high quality traditional services is to be ensured.

Clearly, in planning the development of traditional health services, access of those who most rely on traditional medicine for their daily health needs must be ensured - namely rural people, women headed households and indigenous and other ethnic communities.

India has succeeded in attracting World Bank funds to the development of traditional medical services in rural areas in a manner that will ensure that poorer sectors of society are equitably served.

Due to the high cost and unavailability of modern medical services in rural areas of India, the Indian government has undertaken to add ten medicines from the Ayurvedic and Unani systems into its national family welfare program. A pilot project, designed to last till 2003, is currently being implemented in 7 Indian states for Ayurveda while Unani medicines are being introduced in 4 cities. The reproductive and child health 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.

Political factors are again associated with the advancement of indigenous medicine in India. After decades of under-funding, the current pro-tradition BJP Government doubled the budget for ISM in the previous financial year (The Lancet, April 8, 2000).

2. Ethics.

Clinical Research

A basic starting point in clinical research into traditional and complementary medicines and therapies is that the Helsinki Declaration which governs the use of human subjects in research is the definitive international agreement against which clinical research standards are set. Informed consent is a key element of these standards.

While humans subjects issues remain constant, certain ethical issues also vary from the clinical evaluation of conventional drugs. For example, the ethics of providing a plant with known safety but unknown clinical effects are different in a prevention study as opposed to a treatment study. WHO guidelines for the evaluation of herbal medicines allow that in the case of traditional medicines with an established history of use, it is ethical to proceed from basic animal toxicity studies directly to Phase 3 clinical trials.

Other ethical issues include the need to protect intellectual property rights, obtaining informed consent from the community; devising ways to share benefits, and return findings to the community.

Intellectual Property (IP)

Exploitation of traditional medical knowledge for drug development without the consent of customary knowledge holders is not acceptable under international law, as set out in the International Convention on Biological Diversity (CBD). Benefit sharing agreements should be negotiated in advance of R&D being commenced. Clinical trials on herbal medicines should be conducted in full accord with the Helsinki Agreement.

The Convention on Biological Diversity (CBD)

The CBD is the only major international convention that assigns ownership of biodiversity to indigenous communities and individuals and asserts their right to protect this knowledge.

Article 8 (j): State Parties are required to “respect, preserve and

maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices.”

Article 18.4: Contracting Parties should “encourage and develop models of co-operation for the development and use of technologies, including traditional & indigenous technologies.”

The CBD competes for influence with the far more powerful Trade Related Aspects of Intellectual Property Systems (TRIPS) of the World Trade Order.

TRIPS, the key international agreement promoting the harmonisation of national IPR regimes, covers four types of intellectual property rights:

1. Patents
2. geographical indications
3. undisclosed information (trade secrets)
4. trademarks

Despite the CBD’s emphasis that any product that has been in customary use is de facto a holder of a patent for use, TRIPS makes no reference to the protection of traditional knowledge. Nor does TRIPS acknowledge or distinguish between indigenous, community-based knowledge and that of industry.

TRIPS instead makes provision "for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof." (Art. 27(3)(b)). This, of course applies to medicinal plants and products based on these.

IPR & Traditional Medical Knowledge

In a celebrated case, the Indian Government’s Centre for Scientific and Industrial Research filed a re-examination request with the US Patent and Trademark Office, seeking revocation of a 1994 patent

issued to the University of Mississippi (Patent, 5,401,504), which claimed the use of turmeric for promoting wound healing. The Indian government argued that turmeric is a well known traditional medicine used in India, and written about by Indian researchers as early as the 1950s. In the US Federal Appeals Court, India secured a revocation of the patent, thus raising the patenting of traditional medical knowledge to a high profile internationally. Through the Dept of Biotechnology, the Government of India is now recording on a set of CD Roms all of the national medicinal plant knowledge. This will be distributed to patent offices world-wide to provide a data base of previously existing knowledge (known in legal terms as 'prior art') on Indian traditional medicinal knowledge. India is also pursuing a comprehensive legal strategy to seek revocation on non-Indian patents on Indian life forms.

There have also been high profile cases of international exploitation of African medicinal resources in flagrant violation of the OAPI Agreement, such as the unauthorised over-harvesting of bark for *prunus africana* in Cameroon by Spanish and French companies for use as a herbal medicine for benign prostatic hypertrophy. Legal challenges have also been mounted by the Zimbabwe National Traditional Healers Association (ZINATHA) against a Swiss company for alleged violation of the IP rights of ZINATHA members in the commercialisation of a plant medicine used traditionally in Zimbabwe. A recent court action in South Africa has raised the profile of patenting of indigenous medical knowledge in a case against the South African Government by the Sand people (formerly referred to as the Bushmen) of the Kalihari region of Southern Africa. The South African Government had investigated the bark of a shrub used by the Sand as an appetite suppressant when in the desert for extended periods and had patented the active molecule from this and sold the licence to a British herbal medicine manufacturer Phyto Pharm which, after some further research and development, sold on the rights for development to Pfizer as a potential anti-obesity drug. In March 2002, there was a legal settlement made which accorded prior ownership to the Sand people and reached a mutually agreed contractual basis for benefit sharing from any products derived from this knowledge.

In February 2002, member countries of the WTO, in recognition of this disparity, instructed the WTO to work with the CBD and the World Intellectual Property Organisation to develop a means of harmonizing TRIPS and the CBD. This process is now underway and its final outcome is awaited.

FUTURE

1. Debate over patenting will hinge much on what constitutes prior informed consent. A central issue is how to determine who represents a community, what represents full consent.
2. In the case of dispute over State vs. Community ownership of indigenous knowledge, there is a question as to whether states should receive royalties from knowledge that originates from communities within those states. Or whether royalties should go direct to the traditional knowledge holders.
3. Disputes over patents on herbal products - these may have an impact on local herbal use and developing country exports of herbals. The context for these kinds of disputes is the burgeoning market. The World Conservation Union estimated in 1997 that the annual global market for herbal products was in the vicinity of US\$60 billion. The World Bank estimates that by 2050, the market will be valued at US\$5 trillion.
4. More examples similar to the case of S. African AIDS drugs - with herbals. "Patent rights v. Patients' rights".
5. Restrictions on collaborative research (e.g. India's Biodiversity research approval committee now requires Central Govt approval for all collaborative research with international partners).
6. Developing country alliances (e.g. ASEAN) working to combat prejudicial aspects of TRIPS.

3. Governance.

Self-regulation by traditional health practitioners is central to the establishment and maintenance of standards of best practice. Regulation should be designed to preserve and strengthen traditional knowl-

edge systems and practice rather than to constrict their expression and availability.

An important example is the case of New Zealand which has allowed the registration of more than 600 Maori traditional healers who provide services within the wider health system. The government reimburses their services under health insurance schemes.

In the United Kingdom, osteopaths and chiropractors have been registered as official health professions through an Act of Parliament and the basis for maintenance of professional standards is that of self-regulation. The same principle is being applied to medical herbalists and acupuncturists, both of which professions are on track for registration in Britain.

In Britain, where the professions of osteopathy and chiropractic have already been licensed as full health professions under Acts of Parliament, the House of Lords Select Committee on Complementary and Alternative Medicine (CAM) in its 2001 report signalled that acupuncture and herbal medicine also constitute “principal disciplines” in CAM.

The Lords Committee observed that while CAM practitioners are “currently subject to a range of statutory and non-statutory controls”, professional regulation is lacking for herbal medicine. The report signalled that herbal medicine and acupuncture are now the next therapies on track for statutory regulation under the Health Act 1999. The Health Act of 1999 offers two regulatory options for professions or therapies:

1. to apply for statutory regulation, or
2. to join a health professional council for title protection.

An example of the process required for regulation of a CAM profession can be found with herbal medicine. Here, the Lords Committee identified the regulatory body likely to work on coordinating statutory formalisation and professional practice as the European Herbal Practitioners Association (EHPA), which was established in 1993 to unite the major registering herbal organisations. The EHPA aims to “publish a common core curriculum, common continuous

professional development scheme, single code of ethics and disciplinary procedure.” The EHPA has established a board of accreditation which now evaluates educational institutions which offer courses in herbal medicine. The EHPA is also working with the UK Department of Health to effect statutory regulation of all British herbal medicine practitioners.

Recognising the professional development process entailed in such an exercise and acknowledging the basic principle of self-regulation, the UK Department of Health has outlined their objectives as being “to put in place, as far as possible, the policies, organisation, infrastructure and legislation that the UK herbal medicine profession will need to operate statutory self-regulation.” Both the Department of Health and the Lords Committee have recognised that such processes are long and costly, as has been the case with both regulation of the professions of chiropractic and osteopathy.

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 politicisation of the traditional medicine agenda - e.g. India and South Korea.

In China, the process of integrating traditional Chinese medicine (TCM) into national healthcare system began in the late 1950s and was, in significant part, in response to national planning requirements to provide comprehensive healthcare services. Prior to this, TCM had been viewed as part of an imperial legacy to be replaced by a secular healthcare system.

The process of integration was guided by health officials trained in modern medicine, and harmonisation with modern medicine was the goal of integration from the outset. This was accomplished by a science-based approach to TCM education, an emphasis on research into TCM, both supported by a substantial organisational infrastructure. Integration and development of TCM was managed via a process of centralised national planning.

More than forty years on, the State Administration of Traditional Chinese Medicine in China now comprises eight functional departments and investment in the sector has more than quadrupled over a 15 year period (State Administration of Traditional Chinese Medicine, 1997).

However, elsewhere in the region, under Taiwan's current health care system, Chinese medicine is reported to have a subordinate role to Western medicine (Chi, 1994). This is apparent in three ways:

- (1) limited participation of Chinese medicine practitioners in any public health policy making and programs;
- (2) small proportion of government medical resources allocated to the training, research and practice of Chinese medicine: and
- (3) loose licensure system for Chinese physicians.

One commentator has outlined six recommendations for effective integration that cover many of the major salient issues:

1. Promote communication and mutual understanding among different medical systems that exist in a society.
2. Evaluate traditional medicine in its totality.
3. Integration at the theoretical level and the practical level.
4. Equitable distribution of resources between traditional and modern Western medicine.
5. An integrated training and educational program for both traditional and modern Western medicine.
6. A national drug policy that includes traditional drugs (Chi, 1994).

4. Financing.

A fundamental working principle of sectoral development here is that dedicated government funding is needed to ensure that the traditional and complementary health sector develops as needed.

In the industrialised countries, where almost half of the population regularly uses complementary medicine, insurance coverage for this is still relatively new. Americans and Australians typically pay out of pocket for CM services. Americans spend more out of pocket on CM

than on all US hospitalisations (Eisenberg, 1993; Astin, 1998). Australians spend more on CM than on all prescription drugs (MacLennan et al., 1996). Major American medical insurers now routinely cover complementary medical services - a trend which is emerging in Britain as well.

The effect of user fees on health care utilisation 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 pay larger out-of-pocket payments for health care. Research indicates that the price elasticity among the poor is substantial, which suggests that user fee schemes would have a regressive distributional impact (Gertler & van der Gaag, 1990; cited in Hotchkiss et al., 1998).

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.

Potential Conflicts Arising From Allocation of Resources to Traditional Healthcare Services

Resentment can arise between 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 (Matthews et al., 1995).

Another potential conflict is that if traditional healthcare services are made available under medical insurance schemes, those who can afford to pay for insurance will be the greatest beneficiaries of traditional medicine. 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 traditional medicine serving as the first and last resort for available healthcare for the poor.

A further risk is that primary healthcare services in traditional medicine 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 (Demery et al., 1995; cited in Brunet-Jailly, 1998). 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 traditional medicine and modern medicine indicate the demand and need at the primary care level.

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. 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 traditional medicine utilisation 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 coverage can lead to a substantial increase in the use of traditional medical services. In a Korean immigrant population in Los Angeles, 24% of the uninsured used traditional healers, compared with 59% of persons with Medicaid only and 71% 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% of the population has comprehensive medical insurance that covers the cost of hospitalisation and the

proportion of uninsured people may be as high as 50% (Xhu, 1992; cited in Phillips et al., 1997; World Bank, 1997, cited in Lee, 1999). In hospital settings, insured patients are more likely to receive traditional Chinese medicine (Phillips et al., 1997). This is due to the fact that one of the primary sources of a hospital ward's profit, under the market model of healthcare provision that is in place, is the 15-25% markup for prescribed medications, so the changed incentive system has become associated with increased polypharmacy (World Bank, 1992, cited in Phillips et al., 1997).

Under the market system, many TCM hospitals in China operate at a deficit, as better equipped Western hospitals attract more patients. As Traditional Chinese Medicine is largely an outpatient, low technology specialty, most of the income of traditional hospitals comes from the sale of drugs. Even with the 25% markup 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 (Hesketh & Zhu, 1997).

The experience in Taiwan is that insurance coverage for traditional medicine would more than double the use of TCM. Whereas 35.4% of Taiwanese reported using TCM regularly, 86% of the public would support the coverage of Chinese medicine by the new National Health Insurance and 79% would use Chinese medicine if it does (Chi, 1994).

High profitability of traditional medicine 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% compared to their basic cost (Cho, 2000), the population utilise herbal medicines on a large scale (Han, 1997; cited in Cho, 2000). 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 (Moon et al., 1997; cited in Cho, 2000). The high returns on herbal medicine boosted the socio-economic status of traditional medicine 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 (Lee, 1993a; cited in Cho, 2000).

In New Zealand, which has a long tradition of universal insurance for medical and hospital services, a number of Maori organisations 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. (Scrimgeour, 1996).

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. 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% (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% of the GPs provided acupuncture, it was available in 31% of practices.

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 (Herron and Hillis, 2000). Earlier research had highlighted positive individual and group health effects of this

mental, which derives from India's Vedic tradition. This study aimed to determine whether these health benefits translated into savings to the government in terms of possible reductions in payments to physicians for the meditating 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 1 to 2 percent each year, while the control group's mean payments increased up to 12 percent annually over six years. Thus, there was a mean annual difference between the two groups of about 13 percent. 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.

An 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 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 (Woelk, 2000). Two years of treatment with Prozac (20 mg/day) will cost US\$1,250 in China, about the annual income of an urban worker (Lee, 1999). 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 healthcare services.

POLICY IMPLICATIONS

1. Cost of modern medical services can be a factor in people choosing traditional medicine. Programs to develop and formalise 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 healthcare.
2. Policy should aim to keep any user fees affordable - including those of THP's in the community.
3. Significant investment is a prerequisite for development of effective traditional healthcare services. Under-investment risks perpetuating poor standards of practice and products and also contributes to maintaining old stereotypes of inferior services and knowledge in traditional medicine.

5. Knowledge production.

The decision taken by the US Congress a decade ago to establish an Office of Alternative Medicine at NIH has led to a focussed program of research through the re-named National Center for Complementary and Alternative Medicine (NCCAM). The NCCAM focus on clinical trials and basic research is now seen internationally as the gold standard of how nations might proceed in investing in knowledge generation in this sector.

While this focus on the efficacy and mechanisms of action of

complementary modalities is of great significance, there is also a need for a public health agenda to be added to this focus on the generation of clinical and experimental evidence for CM modalities. Other areas worthy of investment include research into prevention, studies of quality of life resulting from CAM interventions, and the healthcare utilisation patterns of various sectors of society, including vulnerable sectors such as women headed households, the poor, ethnic minorities, the handicapped, etc. Also worthy of detailed analysis is the trend for distinctly different patterns of CAM use to occur for different diseases. Finally, the economic dimensions of CAM and traditional medicine use are awaiting serious study, as policy makers, insurers, industry and consumers are all calling for guidance in this field (Bodeker, 2002).

Comparative research should be promoted, where modern and traditional approaches to managing the same conditions are compared in terms of clinical outcomes and cost. Clinical research should follow national and international health priorities - e.g. cancer, cardiovascular disease, diabetes, TB, malaria, HIV/AIDS, etc., and mainstream research funds should encourage a component of research into traditional means for treating specific conditions.

In order to ensure a rational basis for the use of plant-based medicines, priority is needed for infrastructure development in traditional medicine. This will include:

- * Research oriented to the safe and effective production of herbal medicines as a central feature of public health programs in non-industrialized as well as industrialized countries
- * education and training for both traditional and orthodox medical practitioners, and
- * research policy which promotes observational and clinical studies.

To justify necessary national, bilateral and multilateral investment, a new generation of micro- and macro-economic analyses of the traditional medicine sector is needed.

Section 8, Research Environment, addresses research policy in detail.

6. Knowledge Management & Utilisation.

In order to ensure sound standards of practice based on recognised levels training and the use of therapies that are safe and effective, information is needed on best practice across a wide range of professional and industrial issues. A coordinated development strategy with multiple national and international partners will be required to develop such an information resource to inform and support national policy development in natural healthcare.

There are many challenges. Current on-line material currently accessible online is limited in scope. Much of it consists of commercial sites containing information related to specific products being marketed. Only a small number of databases (e.g. MEDLINE, AMED, etc.) allow free access to information published in a limited number of scientific journals. Most other relevant scientific databases are accessible only on a fee-paying basis. Much of the material on policy and on trade in traditional and complementary medicine does not exist in digital form or is currently not accessible online. Each database is compiled in its own unique format and style. Data structure, indexing methods and terminology used for data retrieval are also widely different as each database is compiled to suit specific user groups. Much of the material on Asian traditional medicine is not available in English. Identifying common strands between these data sources and devising data retrieval methodology applicable to all will be the fundamental requirement of any integrative exercise. There is also the question of financial arrangements required to ensure access and continuous input of new material from these sources.

A coordinated development strategy with multiple national and international partners will be required to develop such an information resource to inform and support national policy development in natural healthcare.

Such a resource was called for by Commonwealth Health Ministers representing the 54 countries of the Commonwealth when they called for a mechanism for sharing policy experience among Commonwealth countries (Reuters, 2001). This has now been developed as the Global Information Hub for Integrated Medicine and will be hosted by

Malaysia which has provided an establishment fund of \$10 million for the project.

7. Capacity Development.

Capacity of the traditional sector must be strengthened in the following areas: Safety, efficacy, standardisation, current utilisation, cost-effectiveness, customer satisfaction, and priority diseases (TB, malaria, AIDS, etc.), prevention of disease

Safety

A primary concern regarding traditional and complementary therapies is "Are they safe?" Recent studies in the UK have found that there has been adulteration with steroids of some traditional Chinese dermatological preparations. In an analysis of Chinese herbal creams prescribed for dermatological conditions, Keane et al., (1999) found that eight of eleven creams analysed contained steroids. Clearly, policy gaps need to be plugged and effective regulation of herbal medicines is needed, while ensuring that regulation is not simply a means of limiting public access to these preparations. Limiting access through professional controls and regulatory means can be seen as constituting monopolistic trade practice.

Safety must be the starting point for national drug development strategies for herbal medicines. While most of the published research on herbal medicine is pharmacological, WHO's 1993 *Guidelines on the Evaluation of Herbal Medicines* consider that clinical evaluation is ethical where drugs have long been in traditional use. Roy Chaudhury has offered a model for the clinical evaluation of herbal medicines:

1. Toxicity testing of the plant in two species of animal for acute and sub-acute toxicity.
2. A modified, shorter toxicity testing if the plant has already been used in man or is in such use now.
3. Administration of the total extract or combination of plants, if used, in exactly the same way as it is prepared and used by the population.

The differences between this approach and that of conventional drug evaluation methodology are that:

- * efficacy testing is carried out on humans rather than on animals, human studies are undertaken subsequent to modified, shortened toxicology studies having shown that the substance is not toxic in animals:
- * the duration of the toxicity studies is reduced to six weeks for plants that are already in common use:
- * the plant or mixture of plants is administered to subjects in the same manner in which it is used in traditional medicine (Roy Chaudhury, 1992).

Research should consider best evidence for safety, including evidence for adverse effects from treatments (including magnitude, percent of people so affected, etc.), as well as from inappropriate applications of traditional therapies. Postmarket surveillance studies can provide information on adverse effects of botanical herbal preparations. Pharmacognostic and pharmacological research can provide information on the quality, efficacy, safety or toxicity of botanical/herbal medicinal preparations.

More broadly, a basic question in addressing safety in herbal medicines is "Safe with respect to what?" Research has found that in the US, 51% of FDA-approved drugs have serious adverse effects not detected prior to their approval. 1.5 million people are sufficiently injured by prescription drugs annually that they require hospitalization (Moore, 1998). Once in hospital, the problem may be compounded. The incidence of serious and fatal adverse drug reactions (ADRs) in US hospitals is now ranked as between the fourth and the sixth leading cause of death in the United States, following next after heart disease, cancer, pulmonary disease and accidents (Lazarou, et al., 1998).

Clearly, the safety of and risks associated with medical interventions is an issue across all categories of health care.

In developing health systems for traditional medicine, safety and quality control of herbal medicines go hand in hand. A case in point

is the development of new standards of safety and quality for herbal medicines produced in India. New regulations were introduced in India in July 2000 to improve the standard and quality of Indian herbal medicines. Regulations will establish standard manufacturing practices and quality control.

The new regulations outline requirements for infrastructure, manpower, quality control and raw material authenticity and absence of contamination. Of the 9,000 licensed manufacturers of traditional medicines, those who qualify can immediately seek GMP certification. The remainder have two years to come into compliance with the regulations and to obtain certification.

The government is also setting up ten new drug testing laboratories this year for ISM and upgrading existing ones to provide high quality evidence to licensing authorities of the safety and quality of herbal medicines. This replaces an *ad hoc* system of testing that was considered by the Dept of ISM to be unreliable.

Randomised controlled clinical trials of selected ISM prescriptions have been initiated to document their safety and efficacy and to provide the basis for their international licensure as medicines rather than simply as food supplements (Sanjay Kumar, *Reuters*, July 13, 2000).

The Australian model of risk management of herbal medicines constitutes an important model of legislation and policy in this field.

The Office of Complementary Medicines of the Australian Therapeutic Goods Authority has responsibility for the regulation of drugs and other medicinal substances. The Office does not, however, regulate complementary health professionals as this is done by the various state governments of Australia.

Under the Therapeutic Goods Act of 1989 the Therapeutic Goods Authority (TGA) established a special office for the regulation of complementary medicines, covering:

- * Herbal Medicines
- * Vitamins
- * Minerals
- * Nutritional Supplements

- * Homeopathic Medicines
- * Aromatherapy oils

Whereas most countries regulate complementary medicines as foods, in Australia, complementary medicines are regulated as medicines. The approach of the TGA in managing risks covers:

- * Licensing of manufactures
- * Pre-market assessment of products
- * Post-market regulatory activity.

The TGA position is that managing risk requires a balance between the pre-market evaluation and post market vigilance. If the pre-market evaluation is too little, post-market vigilance is required. Conversely extensive pre-market evaluation means less risk to manage and less post-market vigilance.

Accordingly, the TGA follows two paths:

- a. Licensing of manufactures; and
- b. Pre-market assessment of products

In the case of registered the following key steps are followed:

- * Quality based on good manufacturing practice
- * Safety through a product by product evaluation; and
- * Efficacy via a product-by-product evaluation

The TGA requires the following for listed medicines of lower risk:

- * Quality based on good manufacturing practice
- * Safety through a substance-by-substance evaluation; and
- * Efficacy via sponsors holding evidence to support claims and indications.

Post-market regulatory activity covers the following steps:

- * Post-market review of products
- * Monitoring and surveillance in the market place
- * Problem reports and recalls
- * Laboratory testing; and
- * Adverse reaction reporting.

The risk assessment framework for complementary medicines covers the following steps:

- a. Characterisation of substance
- b. History and patterns of previous human use
- c. What, if any, adverse reactions have arisen from use
- d. Biological activity
- e. Toxicology
- f. Clinical trials
- vii Conclusions and recommendations.

(F. Cumming in Noller et al, 2001)

Emerging European Regulation on the Safety of Herbal Medicines

The European Community definition of a medicinal product is:

- (i) Any substance or combination of substances presented for treating or preventing disease in human beings or animals;
- (ii) Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or restoring, correcting or modifying physiological function in human beings or in animals is likewise considered a medicinal product; and
- (iii) Any medicinal product requires a product licence

Directive 65/65 must show through toxicology and pharmacology tests that the potential toxicity of product and any dangerous or undesirable toxic effects under proposed conditions of use. Specifically, Directive 65/65 requires:

- * Single dose toxicity
- * Repeat dose toxicity
- * Reproductive toxicity
- * Teratogenicity/embryo/foetal toxicity
- * Mutagenicity
- * Carcinogenicity
- * Pharmacokinetics

-
- * Pharmacodynamics
 - * Local Tolerance
 - * Clinical Trials:
 - * adverse events
 - * assessment of relative safety
 - * Post marketing experience

For products that have been in long established use, the following is required:

- * Ingredients used for 10 years in Europe
- * Requirements as 65/65 but:
- * Can replace toxicity, pharmacology and clinical trials by reference to published reports.
- * Missing evidence requires additional tests
- * Must show recognised efficacy and safety in normal use

The EC's Traditional Medicines Directive makes use of the following information:

- * Used in Europe for 30 years (or combination Europe and another country)
- * Bibliographic review of safety data
- * Expert report
- * Additional assessment/tests may be required
- * Post-marketing surveillance required
- * Monographs to be developed
- * Committee to provide list of acceptable ingredients
- * The EC recognises the following sources of information:
 - * Adverse reaction reporting schemes
 - * Poisons Centres
 - * Drug Information Units
 - * Post marketing surveillance
 - * Clinical Trials
 - * Prescription Event Monitoring

- * Existing medical and scientific literature

In Britain, where only 20% of herbal medicines are licensed, there are efforts to ensure the safety of traditional and herbal medicines via new information centres. These include:

The Chinese Herbal Database brings together existing data for:

- * Translation of reports of toxicity from Chinese and other literature
- * Production of monographs/safety reviews
- * Provision of information/training to medical professionals at Guy's & St Thomas' Hospitals
- * To be extended to other traditions of medicine
- * There is a new project at the Medical Toxicology Unit, funded by Guy's & St Thomas' Hospital Trust
- * Collaboration with Chinese Medicines Unit, UWS

Prescription Event Monitoring

- * Pilot study to evaluate use of PEM in monitoring adverse events associated with herbal medicines
- * Grant application submitted
- * Collaboration Drug Safety Research Unit, Southampton University, National Institute of Medical Herbalists, Medical Toxicology Unit

Chinese Medicinal Plant Authentication Centre, Kew

- * Set up because of lack of quality control of Chinese medicinal herbs used in the UK
- * Identification from authenticated voucher specimens collected in China
- * Drug material from plants from same collection as voucher specimens
- * Drug finger-prints - TLC, HPLC, LC-MS, DNA
- * Not looking for active compounds

- * Independent and confidential enquiry service for practitioners, academics, suppliers, regulatory authorities

Doctors and patients need to be aware of potential for toxicity in order to identify and make reports. (D. Shaw in Noller et al, 2001). For this, information is needed and this should be on-line and global in nature. The Global Information Hub on Integrated Medicine is currently working to develop such a resource.

The Australian National Centre for Environmental Toxicology in Brisbane is setting up the information component requested by Commonwealth Health Ministers on the safety of herbal medicines. No such international information resource currently exists. The International Safety of Herbal & Traditional Medicines Project was launched at a symposium held in Brisbane, 7 July 2001 (Noller et al, 2001).

The Safety project has been conceived to:

- * Bring together global information on herbal medicines and their safety. Through this, provide a one-stop resource for people seeking information on the safety of herbal medicines.
- * Provide protocols, advice and training in the methodologies required to evaluate safety
- * Offer toxicology services to countries, companies and communities via the Australian hub and through a number of linked regional centres.

Generate publications - hardcopy and electronic in this field - possibly a journal, a news bulletin, and regular conferences or symposia at international toxicology conferences.

PRIORITY DISEASES

There is a prevailing prejudice that traditional and complementary medicine is useful for chronic low-level conditions, whereas mainstream medicine is useful for acute and infectious disease. The development of multi-drug resistant strains of malaria and TB have challenged such views of late and there is anew search for benefits in ancient approaches.

Malaria

The two most effective drugs used in conventional medicine to treat malaria originate from plants: quinine from bark of the Peruvian *cinchona* tree, and artemisinin from the Chinese antipyretic *Artemisia annua* L. Other plants are likely to contain as yet undiscovered antimalarial substances. While much research has focused on trying to isolate and purify these from plants, there is concern that conventional isolation and extraction methods may miss synergistic mechanisms of action found in traditional antimalarials.

Currently, modern pharmaceuticals are not available in constant supply in areas most affected by malaria - particularly in sub-Saharan Africa and in South and SE Asia. With increasing drug resistance and the high cost of drugs, the use of herbal antimalarials in these regions is popular. Despite growing policy interest in traditional medicine, there has been almost no research into the clinical effectiveness of herbal remedies as they are used in real life.

At a December 1999 meeting in the Kilimanjaro region of Tanzania, a Research Initiative on Traditional Antimalarial Methods (RITAM) was established to develop a strategy for more effective, evidence-based use of traditional medicines for malaria. RITAM is a joint undertaking of The Global Initiative for Traditional Systems of Health (GIFTS) at Oxford University and WHO's Tropical Disease Research Programme (TDR) (Bodeker & Willcox, 2000).

RITAM members have developed four specialist groups to implement a research strategy designed to make a significant contribution to malaria control programmes:

1. Policy, advocacy and funding
2. Pre-clinical studies
3. Clinical development
Repellence and Vector Control.
(Willcox et al., 2001)

HIV/AIDS

In Africa and in much of Asia, the high cost and scarcity of many

essential drugs as well as anti-retroviral drugs has led the majority of people living with HIV/AIDS to use traditional herbal treatments for a variety of HIV-related conditions including opportunistic infections (OI). Indeed, in view of widespread use, traditional medicine is in a real sense carrying the burden of clinical care for the AIDS epidemic in Africa, a trend largely overlooked by health ministries, international agencies, and donors.

At the 1998 Bangalore meeting, Medicinal Plants for Survival, Dr. Donna Kabatesi, cited clinical data on Ugandan herbal treatments effective against herpes zoster, and HIV-associated chronic diarrhea and weight loss. Research being conducted by Professor Charles Wambebe, head of Nigeria's National Institute for Pharmaceutical Research and Development, has shown that a Nigerian herbal medicine has produced steep increases in CD4 levels and improvement in HIV-related illness. Controlled clinical trials are now being conducted. The Tanga AIDS Working Group is conducting research into the efficacy of Tanzanian herbal treatments for HIV-related fungal infections.

In view of these trends, a regional Task Force on traditional medicine and AIDS in East and Southern Africa was inaugurated in Kampala, Uganda, on 10 April 2000. The Task Force co-ordinates activity related to the widespread use of traditional medicine by people living with HIV/AIDS (PLWHA) in Africa and the role of traditional healers in contributing to AIDS prevention and support.

A network of researchers and institutions is developing a research programme which will identify, evaluate and develop safe and effective local treatments for HIV-related illnesses. The programme will use simplified but controlled clinical protocols to conduct rapid evaluations of promising treatments. It will build data bases for information sharing on successes and failures of local treatments. It will be grounded in an intellectual property rights framework to protect the rights of local knowledge holders, learning lessons from a few existing programmes in Africa. Recognizing the global, unsustainable pressure on wild stocks of medicinal plants, sustainable horticulture will be promoted for priority species (Bodeker et al, 2000).

In India, a conference on HIV/AIDS and Indian Systems of Medicine was jointly hosted by the Delhi Society for the Promotion of the Rational Use of Drugs (DSPRUD) in November 2000. The Commonwealth Working Group on Traditional & Complementary Health systems and GIFTS of Health were international partners in this. This meeting brought together researchers, traditional practitioners, and policy makers to identify what work is being done in this field in India and to chart a way forward. A research agenda has been developed and a network established. A clinical trial protocol has been published to establish standard operating procedures for the clinical evaluation of herbal medicines for HIV related illness (Chaudhury 2001).

8. Research Environment

Research into traditional medicine is needed at both national and international levels. If this need is to be met, dedicated funding will be required to be allocated by international funders and governments.

Research priorities. In order to ensure a rational basis for the use of plant-based medicines, priority is needed for infrastructure development in traditional medicine. This will include:

Research oriented to the safe and effective production of herbal medicines as a central feature of public health programs in non-industrialized as well as industrialized countries education and training for both traditional and orthodox medical practitioners, and research policy which promotes observational and clinical studies.

Efficacy and beyond: Research methodologies for traditional and complementary medicine and Consumer satisfaction is of importance in evaluating health services. Satisfaction with care is one component of well being, which has in turn been identified by WHO as a marker of good health. Our own research at Oxford University suggests that a search for satisfaction in the treatment of chronic disease is the primary reason why people in Britain - particularly women - seek the services of complementary health care providers. Consumer satisfaction studies merit a high place in national researches into complementary and traditional healthcare (Ong et al., 2002).

There is an international call for evidence of what constitutes best treatments. The preferred method is through a formal approach to gathering and synthesizing research data. Evidence Based Medicine (EBM) has become a worldwide movement in clinical medicine. Such high standards are now being called for by established medicine in evaluating the claims of traditional complementary health practitioners. The core of EBM is the randomised controlled clinical trial (RCT), and EBM methodology is centred around determining therapeutic effects of specific treatments via meta-analyses of clusters of RCTs.

RCTs, the unit from which the meta-analyses of EBM are built, have also been challenged as being limited in both principle and procedure (Black, 1996). RCTs are seen by some as an inadequate tool for measuring infrequent adverse outcomes such as infrequent adverse effects of drugs. They are also, due to limitations in study size, unable to evaluate interventions designed to prevent rare events, such as accident prevention schemes. And they are unable to adequately evaluate the long-term consequences of therapies - e.g. oral contraceptives, HRT to prevent femoral fractures, and the loosening of artificial hip joints for which a 10 to 15 year follow-up is needed.

In order to address areas not readily studied using RCT methodology, and also to correctly design and interpret RCTs, observational, or cohort, studies are receiving new attention. Observational studies are based on quantitative epidemiological methods and quantitative sociological methods in which data are collected through observation. In traditional medicine, it may be assumed that a natural experiment is already taking place - practitioners are prescribing, patients are using. Observational research of existing practice allows for a first line of data to be collected without the ethical difficulties of assigning subjects to novel treatments. No one is assigned, data is gathered on what is actually happening and what the outcomes are from these interventions.

It has been suggested by Arthur Margolin of Yale University that the validity and ultimate value of RCTs of complementary therapies would be diminished if they were conducted without preliminary foundational studies. Foundational studies should investigate such

issues as the reputed efficacy of the active treatment or the reputed non-efficacy of the control treatments (Margolin, 1999).

As noted, the RCT does not provide data on the effects of a treatment over time. Clinical observational studies are called for here. Population studies are needed to look at patterns of utilisation, expenditure, benefits and adverse effects.

While evidence of mechanism of action is clearly not needed to promote utilisation or to achieve consumer satisfaction - this is happening of its own accord - basic research into the physiologic links and molecular bases of therapeutic outcomes and mechanisms of action is needed in the longer term. Where employed, basic research methodologies need to be generated to sensitively capture aspects of CM practice and theory that may appear intangible - e.g. energy (*prana, qi*) etc.

The needs of interest groups in special situations - e.g. women, children, the poor, the elderly and those with special medical conditions - must be recognized and given priority in the development of national research agendas into CM and THC. Our own research indicates that older women with chronic conditions are the most frequent users of CM providers (Ong, Bodeker et al., in press). And ethnic minority groups in the UK, for example, prefer to use their own traditional forms of medicine, such as acupuncture and traditional herbal medicine, to such Western CM systems as chiropractic and osteopathy. The specific needs, health status and utilization patterns of special interest groups should be addressed. Also of interest are diseases for which current treatment regimens are unsatisfactory, e.g. many cancers and chronic debilitating conditions.

Prevention of disease is an area of fundamental importance in complementary health systems. Dietary and nutritional approaches to prevention provide opportunities for the study of prevention, as does the use of herbs and traditional forms of exercise (e.g. yoga) in promoting a balanced state of health. Accordingly, systematic research should be conducted into effective prevention practices

In all therapeutic settings, western and traditional, belief and attitude have an influence on treatment outcomes. A "placebo", or

"meaning response," effect is an important component of many therapies. The extent to which therapeutic outcomes are based on expectancy is an important area of study.

WHO's Quality of Life Assessment includes spiritual dimensions in assessing an individual's quality of life. Here, "spiritual" relates to the sense of meaning regarding the self or extending beyond the self. The spiritual dimension of life and well being is central to many traditional and complementary health systems. In Britain, 12% of those who use CM providers in use the services of 'spiritual healers' (Ong, Bodeker, et al., in press). This trend, its origins and outcomes are important areas of research.

There is a need for comparative evaluation of both CM and conventional medical methods for treating the same condition to identify safe and efficacious treatments that are locally available. This may also include the study of cross- cultural/cross-geographic healing practices to identify common treatments and/or to combine evidence for a specific herb or treatment regimen. Comparative studies could assess feasibility, cost-effectiveness, and environmental impact as well as specific biomedical outcomes.

Combination therapy should also be studied. For example, traditional and modern medicine are often used simultaneously in the treatment of certain chronic diseases in Asian medical systems, such as the Ayurvedic medical system of India and Traditional Chinese Medicine. In addition, patients often combine modern and traditional treatments. Caution should be exercised to address cultural bias in the assumptions, methodologies and concepts employed in comparative research.

A range of methodologies, then, can and should be employed in evaluating traditional and complementary therapies. These should be applied in a manner that is sensitive to the theoretical and clinical assumptions of the modality being evaluated in order to ensure that the research design adequately measures what is being studied.

A national research agenda into complementary and traditional medicine should promote research on the individual, the family and community, the wider population, and the ecosystem/ environment.

Both political and scientific will are needed to support such an agenda. Legislators in industrialised countries are coming to recognise that the use of complementary medicine is linked to votes - votes of the wealthier and more educated sectors of society. In poorer countries, the search for effective and affordable treatments for such epidemics as malaria and opportunistic infections associated with AIDS is driving renewed policy interest in traditional medicine.

In each case, substantial increases in research funding are needed. And new directions in clinical evaluation must be forged by researchers who are able to transcend limitations in research orthodoxy in the interests of providing sound information to the public on what constitutes good healthcare.

POLICY POINTS

1. Safety is the starting point in the evaluation of traditional medicines and procedures. A model for rapid toxicity testing of herbal medicines has been developed by WHO SEARO and should be examined with a view to widespread application.
2. National testing centres are needed - appropriately funded.
3. There is a concurrent need for self-regulation by THP associations, focussing on peer supervision and enforcement of standards of professional practice and conduct.
4. RCTSs are a powerful and costly tool for evaluating therapeutic efficacy. Other methods also exist for determining this. These should be used as components of a repertoire of evaluative strategies used in determining what works, what works best, and works best over time.
5. Research should be attuned to cultural concepts and issues. This is required out of respect for the traditional being studied and in view of the possibility that traditional explanatory models may provide new insights into diagnosis, disease progression, individual differences, and treatment strategies.

CONCLUSION

As governments grapple with the complexities of establishing regulatory and policy frameworks that will ensure safety and quality of complementary and traditional health services, it is proposed that an overarching framework for addressing policy is a beneficial means of ensuring an adequate coverage of key health policy dimensions.

In this paper, the COHRED framework has been used, encompassing, as it does, equity, ethics, governance, financing, knowledge production, knowledge management and utilisation, capacity development and the research environment.

All of these areas require attention in order to ensure that public demand for access to safe and familiar complementary and traditional health services and products is met within the context of national goals for health sector development.

A vital requirement in ensuring that policies become reality is an adequate level of sectoral investment. Recent World bank investment in the traditional health sector in China and India suggests that previous disinterest by international funders in the traditional health sector is now slowly being replaced by interest in an evidence based approach to the development of this sector in the context of universal healthcare coverage and health sector reform.

This trend suggests that the way forward in policy development in this field is via a combination of concerted local consultation with all relevant interest groups, matched by an exchange of information and experience with international partners who have developed some perspectives or have experience in one or more areas of policy relevance.

In order to ensure that this occurs in the best interests of traditional and complementary medicine and their use by a public that wants reliable access to such services, it will be essential to establish canons of best practice within the traditions, build services around the principle of self-regulation, and for partnerships between professional bodies and regulatory agencies to be open and equitable, free of power

politics associated with dominance of the sector by one or more medical interest groups.

Such a strategy has the potential to eventually lift traditional medicine and policy related to this from marginal status to a strong and internationally-accepted component of comprehensive health sector development.

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**TRADITIONAL MEDICINE AND ITS
CHALLENGES AT THE TURN OF
THE NEW MILLENNIUM**

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TRADITIONAL MEDICINE AND ITS CHALLENGES AT THE TURN OF THE NEW MILLENNIUM

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General Introduction

Mr Chairperson, distinguished participants, colleagues, ladies and gentlemen.

It is an honour to be here today to present information on Traditional Medicine (TRM) and Its Challenges at the turn of the New Millennium.

I convey the best wishes from Dr Yuji Kawaguchi, Director of the WHO Centre for Health Development (WHO Kobe Centre), to this International Seminar. We wish to express our sincere thanks to the Organizers of this meeting and especially to Dr Al-Awadi and Dr El-Gindy for their kind invitation to the WHO Kobe Centre for participation at this meeting.

In presenting this paper, I reflect some of the views of all those who were involved in the development and preparation of the WHO Traditional Medicine Strategy 2002 to 2005; particularly Dr Zhang and her team in WHO/HQ, Regional Advisers responsible for Traditional (Complementary and Alternative) Medicine (TCAM) programmes in the WHO Regional Offices and all those experts in TCAM who were involved in the development of the strategy. I participated in the preparation of the Strategy while I was stationed at the WHO Regional Office for South-East Asia in New Delhi.

This presentation will touch upon the following topics:

- WHO programme in the area of TRM.
- Some aspects of the present global status in TCAM.

- Current challenges in TCAM; and
- Selected WHO publications for TRM development.

WHO programme in TRM

The WHO is aware that many therapies and practices in TCAM are beneficial to the health of the people, while others are not and some can even be harmful to health. Because of increasing use of TCAM worldwide, eight resolutions have been passed at the World Health Assembly since 1969 covering topics such as TRM and modern health care, medicinal plants, human resource development, pharmaceutical production, training and research in order to ensure, among others, the quality, safety and efficacy of the traditional remedies and their practitioners.

These resolutions form the basis for WHO's work in TRM for the Eighth General Programme of Work globally for the period 1990 to 1995 and the Ninth General Programme of Work for the period 1996 - 2001. A basic aim of the WHO collaboration with the Member Countries is that where TRM is widely accepted and used, its possible role in the national health care system would be identified and incorporated where appropriate [1]. WHO has also been assisting Member Countries in identifying and using safe and effective traditional remedies at the primary health care level.

As early as in 1991, the 44th World Health Assembly passed resolution No. WHA44.34 on TRM and modern health care. It urges Member States: (1) to intensify activities leading to cooperation between those providing traditional medicine and modern health care, respectively, especially as regards the use of scientifically proven, safe and effective traditional remedies to reduce national drug costs; and (2) to introduce measures for the regulation and control of acupuncture methods. In the area of medicinal plants, the Forty-first World Health Assembly passed Resolution number WHA41.19 since 1988 urging Member States: (1) to examine the situation with regard to their indigenous medicinal plants; and (2) to take effective measures to ensure their conservation and encourage their sustainable use.

These two World Health Assembly resolutions and other six

resolutions in the area of TRM, promote WHO collaboration with the Member Countries in the following five areas; namely: (1) National programme development. (2) Health systems and operational research. (3) Clinical and scientific investigations. (4) Education and training; and (5) Exchange of information [1]. Support was provided by WHO to the Member States in the above areas according to priorities of the individual Member Country.

Some aspects of current global status on TCAM

Traditional medicine has been observed to be beneficial in areas such as prevention of disease, the treatment of a number of non-communicable diseases, improvement of quality of life for the elderly people and mental health. In view of the shift from communicable to non-communicable diseases in many countries, the concomitant global epidemiological transition and increase in the number of elderly people following demographic changes necessitate identification and use of effective and safe traditional remedies especially where conventional pharmaceutical preparations are not readily available [5].

Certain generalizations can be made on the present status of TCAM. (1) The majority of the world's population in developing countries depends on traditional medicine for primary health care. (2) The work force represented by practitioners of traditional medicine is a potentially important resource for the delivery of health care; and, (3) medicinal plants are of great importance to the health of individuals and communities. [1]

The current interest in Traditional/Complementary and Alternative Medicine in both developing and developed countries is based, *inter alia*, on the following reasons:

1. The purported “holistic approach” of Traditional/Complementary and Alternative Medicine in maintenance of health and in treating illnesses.
2. Most therapies used in the traditional way are considered to be safe and without serious untoward side effects.
3. A number of important allopathic pharmaceutical products are derived from medicinal plants and are effective in a variety of

diseases such as cerebral malaria (artemisinin), management of pain (morphine), gout (colchicine), heart ailments (digitalis), leukemia (vincristine) and many others. This led to the realization that TRM containing medicinal plants have great potential to contribute to health; and,

4. A growing trend for self-care and personal responsibility in maintenance of one's own health and prevention of disease. This has been a fundamental reason in the use of traditional remedies for hundreds of years.

Popular Systems of Traditional/Complementary and Alternative Medicine

Traditional/Complementary and Alternative Medicine is often regional and country specific or indigenous and can be grouped into two major categories. Those employing medicinal preparations of herbal, mineral and/or animal origin and those, which are not using medication in treatment.

Therapies employing medications include African medicine, Arabic Unani medicine, Indian Ayurveda, Chinese medicine, Herbal medicine, Homeopathy, Indonesian medicine (Jamu), Siddha medicine, Traditional and indigenous medicine of Bhutan, Japan, Mongolia, Thailand, Tibet and Viet Nam, among others.

Therapies that do not use medicines internally are Acupuncture, Chiropractic, exercise (e.g. T'ai-chi), manual therapy (e.g. Shiatsu), and others.

Therapies that are being used worldwide include Chinese Medicine, Indian Ayurveda, Arabic Unani Medicine, Homeopathy and Naturopathy. Medicinal plants are commonly used in all of the above therapies.

Therapeutic techniques such as Acupuncture, Chiropractic and Osteopathy are used in many parts of the world [2].

Some information on status of TRM in developing countries

In the developing countries Traditional Medicine is being used in the maintenance of health as well as in the prevention and treatment

of physical and mental illnesses for centuries. The majority of the population in developing countries continues to use Traditional Medicine for their primary health care needs.

In Africa, about 80% of the population in countries of the Region use Traditional Medicine. This includes deployment of traditional birth attendants, mental healers and others. A number of these countries in Africa have training programmes to improve the skills of traditional birth attendants in their primary health care knowledge and practices. Doctors, nurses and pharmacists of conventional medicine receive Traditional Medicine training in some of these countries.

TRM practitioners are much more readily available than allopathic medical doctors in Africa. Ratio of TRM practitioners to population is usually 1:200—1:400 in countries such as Tanzania, Uganda and Zambia. The availability of allopathic practitioners is usually about 1 for 20 000 population. In sub-Saharan Africa, the traditional practitioners are 100 times more numerous than allopathic practitioners. Furthermore, allopathic practitioners tend to be located in the urban rather than in the rural areas. Hence for many rural populations, TRM practitioners are relied upon for taking care of their health problems [5].

TRM is basically ingrained in the belief of the people that it is good for their health and thus it continues to be an integral and important part of the peoples' lives. The care of TRM practitioners is sought not only in the prevention and treatment of various diseases but also for relief of HIV/AIDS and related opportunistic infections in sub-Saharan Africa. UNAIDS is advocating collaboration with TRM practitioners in prevention and care of HIV/AIDS in the region.

The statistics of many countries of Asia show that, Traditional Medicine continues to be widely used by preference even though allopathic medicine is often available. Kampo medicines in Japan are prescribed by 60 — 70% of the allopathic doctors for their patients. The traditional forms of Malay, Chinese and Indian medicines are used extensively in Malaysia. Traditional Medicine accounts for about 40% of all health care delivered in China and are used to treat approximately 200 million patients annually. For Latin America, about

70% of the population in Chile and 40% of the population in Colombia have used Traditional Medicine.

The growing number of national TRM research institutes in developing countries is also a sign of the growing importance of TRM. Countries such as China, Ghana, the Democratic Peoples Republic of Korea, the Republic of Korea, India, Mali, Madagascar, Nigeria, Thailand, Indonesia, the Lao Peoples Democratic Republic, Sri Lanka and Viet Nam, among others, have establish institutes devoted to research in TRM.

Some information on status of CAM in developed countries

There has been a resurgence of interest in TCAM in many developed countries. Herbal medicine and acupuncture are gaining popularity while acupressure, massage and exercise (e.g. T'ai chi) and Yoga are also being accepted and taken up. The percentage of population that uses Complementary and Alternative Medicine at least once in their lifetime is: Australia - 48%, Canada - 70% and France - 49% [2]. A survey of 610 Swiss doctors showed that 46% had used some form of Complementary and Alternative Medicine, mainly homeopathy and acupuncture. In the United Kingdom, about 40% of all general allopathic practitioners offer some form of Complementary and Alternative Medicine referral or access. In the USA, use of Complementary and Alternative Medicine was about 40% in 1997 and at present exceeds the number of visits to all conventional primary care physicians [5].

Among the traditional therapeutic techniques, Acupuncture is now used in 78 countries or more. The World Federation of Acupuncture-Moxibustion Societies has estimated figures of 50 000 and 15 000 acupuncturists in Asia and Europe respectively. These figures represent traditional acupuncturists as well as allopathic doctors who practice acupuncture. The acupuncture treatment in Belgium is administered by 74% of allopathic doctors. 77% of pain clinics in Germany also administer acupuncture treatment. 46% of allopathic doctors in UK either recommend patients for acupuncture treatment or treat their patients with acupuncture themselves. In the USA, practice of acu-

puncture is legal in 38 states and six states are developing acupuncture practice policies. USA has 12 000 licensed acupuncturists [5].

According to the United Nations Conference on Trade and Development (UNCTAD), the world herbal medicines market is approximately US\$ 60 billion. In the USA alone, herbal sales increased by 101% within a two-year period from May 1996 to May 1998. The herbal products that are popularly used include *Ginkgo biloba* (to improve blood flow to the brain, hence to improve brain function such as memory); *Hypericum perforatum* (St. Johns wort for elevating mood in the management of mild to moderate depression), *Echinacea* (commonly used to stimulate immune system in treating common cold), ginseng (used to improve body's resistance to stress), and garlic (to reduce cholesterol and triglycerides).

Factors other than tradition and cost account for increased use of CAM in many developed countries. The adverse effects of chemical drugs, greater public access to health information on CAM, taking charge of ones own health and well-being are some of the other contributing factors.

The growing use of TRM/CAM resulted in development of regulations by governments in several countries. In the case of Chiropractic, 24 countries already have such regulations while others are in the process of developing it. For herbal medicines, the number of WHO Member States with regulations increased from 52 in 1994 to 64 in 2000. In 2000, regulations on herbal medicines were developed by Australia, Canada and the USA. In a number of countries, structures, budget and training in TRM/CAM are increasing steadily [17].

The CAM research is increasing in a number of developed countries. The National Health Service of the United Kingdom has supported two trials of acupuncture for treating chronic pain with positive results. The USA has a number of programmes for CAM research at the Columbia University in New York, Harvard University in Massachusetts, the Memorial Sloan-Kettering Cancer Center in New York, the University of Maryland, among others. The Cochrane Library alone contains almost 50 systemic reviews of CAM research.

One of the reviews is on the use of *Hypericum perforatum* (St Johns wort) in mild to moderate depression. It includes 27 trials involving more than 2000 patients. It revealed that *Hypericum perforatum* was better than placebo and similar in potency to tricyclic antidepressants with fewer adverse effects.

WORK OF INTERNATIONAL ORGANIZATIONS IN TCAM

A number of UN Agencies, international organizations, non-governmental organizations, international and national professional associations and specific initiatives are involved in the TCAM development. Most of these organizations are dealing with various aspects of herbal medicines. The following are some aspects of the work that these organizations are undertaking.

(1) Convention on International Trade in Endangered Species of Flora and Fauna (CITES)

This UN Organization of 125 Member Countries was established in 1975. It has set up an endangered species list of flora and fauna and bans their commercial exploitation. It also regulates and monitors trade in other flora and fauna species that might become endangered through unscrupulous trade.

(2) Food and Agriculture Organization of the United Nations (FAO)

The long-term strategy of FAO is on conservation and management of natural resources. One of its activities is on non-wood forest products including medicinal plants. National policies, conservation and research on medicinal plants are being developed.

(3) United Nations Conference on Trade and Development (UNCTAD)

UNCTAD is dealing with protection of traditional knowledge relating to food and health care products that enter into commerce in the process of globalization. Plant genetic resources and biodiversity found in developing countries are important for these products - thus influencing trade, investment, development and income.

(4) United Nations Industrial Development Organization (UNIDO)

UNIDO works in the area of herbal medicines including research,

development and their distribution in health care systems of developing countries. It supports industrial use of medicinal plants, which include building capacity for production, improving technology and factory production of herbal medicines.

(5) *World Intellectual Property Organization (WIPO)*

WIPO deals with intellectual property and traditional knowledge. Its areas of involvement include intellectual property rights and sharing of benefits arising from use of medicinal plants and associated TRM knowledge. It is developing Traditional Knowledge Digital Library, which now has 50 medicinal plants, and associated traditional knowledge.

(6) *Commonwealth Secretariat*

The Commonwealth association of 54 countries is promoting cultivation, conservation and production of affordable herbal medicines for Anglophone African countries. It has published “*A Guide to the European Market for Medicinal Plants and Extracts*” giving practical information for producers and exporters of medicinal plants.

(7) *European Agency for the Evaluation of Medicinal Products (EMA)*

EMA’s work in the area of herbal medicinal products is to ensure their quality, safety and efficacy. It also facilitates exchange of information and experiences relating to herbal medicines.

(8) *European Scientific Cooperative on Phytotherapy (ESCOP)*

ESCOP has published 15 monographs on medicinal uses and safety of plants that are used for humans and animals. It also publishes summaries of product characteristics on individual plant drugs including clinical pharmacodynamics, pharmacokinetics and data on preclinical safety.

(9) *European Union (EU)*

This union of 15 independent countries in Europe focuses on two aspects of TRM/CAM - policy and regulation and research into non-conventional medicine. It called upon its Member States to promote official recognition of CAM in medical faculties, to encourage its use

in hospitals, and to encourage allopathic doctors to study CAM at the university level.

(10) World Bank

The World Bank assists developing countries with policies and strategies for medicinal plant conservation, cultivation, processing and marketing. It operates Indigenous Knowledge Programme, which uses indigenous/traditional knowledge in agriculture, health care, food preparation, education and natural resource management.

(11) World Trade Organization (WTO)

The WTO administers the Agreement on Trade Related Aspects of Intellectual Property Rights also known as TRIPS. This Agreement covers various issues relating to intellectual property and traditional knowledge and traditional medicines.

(12) Cochrane Collaboration

An area of Cochrane's work is on preparing, maintaining and dissemination of systematic reviews of the effects of health care interventions including systematic reviews of CAM. A recent CAM work of Cochrane is on the topic of acupuncture.

(13) Ford Foundation

The Foundation's work in TRM supports the work of traditional healers and TRM organizations in finding solutions to HIV/AIDS epidemic in Africa.

(14) Association for the Promotion of Traditional Medicine (PROMETRA)

The Association is based in Dakar, Senegal and has offices in twelve countries of Africa and one in USA. Its work is to advance the use and acceptance of TRM/CAM.

(15) World Wide Fund for Nature (WWF) and World Conservation Union (IUCN)

These two organizations work to conserve the integrity and diversity of nature worldwide. They promote the use of natural

resources in equitable and ecologically sustainable manner. One of their areas of work is medicinal plants.

(16) International Homeopathic Medical League (LMHI)

LMHI is involved in education, documentation of homeopathic practices and research. Securing legal recognition of homeopathy is one of its objectives.

(17) World Federation of Acupuncture-Moxibustion Societies (WFAS)

One of the WFAS aims is to develop the science of acupuncture-moxibustion (AM). It strengthens international academic exchanges, promotes understanding and cooperation among AM groups.

(18) World Federation of Chiropractic (WFC)

WFC promotes high standards of chiropractic education, research and practice. It also collects information on regulation and registration of the practice of chiropractic in the countries.

(19) World Self-Medication Industry (WSMI)

WSMI promotes understanding and development of responsible self-medication. Many of the over-the-counter drugs are herbal medicines. WSMI is therefore involved in developing guidelines for assessing herbal medicines and methodology for their research and evaluation.

(20) Islamic Organization of Medical Sciences (IOMS)

IOMS has a Centre for Research on Herbal Medicine in Kuwait. It gives services to those who wish to have treatment with herbal medicines and some other TRM therapies.

(21) Global Initiative for Traditional Systems (GIFTS)

GIFTS is located at the Oxford University. It promotes policy development and awareness of traditional health systems. It develops linkages between traditional health systems, conservation of biodiversity and economic development.

(22) *Research Initiative on Traditional Antimalarial Methods (RITAM)*

RITAM is an initiative of WHO, GIFTS, Oxford University and others who are interested in developing and validating local herbal medicines for prevention and treatment of malaria.

There are many TRM professional associations in Africa, Asia and other continents that have long been established in many countries. Some of these associations are on Ayurveda, Unani, Siddha and Homeopathy.

Challenges in Traditional (Complementary and Alternative) Medicine

In recognition of the growing interest and needs in the area of TRM/CAM, TRM/WHO/HQ and Regional Advisers responsible for TRM/CAM from Regional Offices entered into consultations with various authorities in TRM/CAM over a period of more than two years to identify the pressing needs of the Member Countries. These consultations lead to the development of WHO Traditional Medicine Strategy 2002 - 2005. The strategy identified four areas of work in TRM/CAM; namely - (1) Generate sound evidence in ensuring quality, safety and efficacy. (2) Increase access to safe and effective TRM. (3) Improve proper use of TRM preparations of assured quality through education, training and appropriate information (rational use). And, (4) Define the role of TRM/CAM in national health systems where appropriate and in the health sector reform where necessary. In doing so, a national policy on TRM/CAM is needed to ensure that necessary regulatory and legal mechanisms are in place for ensuring effectiveness of remedies and practices. This would safe guard the health and well being of the patients and consumers. The four main areas are shown in Table 1.

Table 1.
Present challenges in TCAM*

National policy and regulatory frameworks	<ul style="list-style-type: none"> * Lack of official recognition of TRM/CAM and TRM/CAM providers * TRM/CAM not integrated into national health care systems * Lack of regulatory and legal mechanisms * Equitable distribution of benefits of indigenous TRM knowledge and products * Inadequate allocation of resources for TRM/CAM development and capacity building
Safety, efficacy and quality	<ul style="list-style-type: none"> * Lack of research methodology * Inadequate evidence-base for TRM/CAM therapies and products * Lack of international and national standards for ensuring safety, efficacy and quality control of TRM/CAM therapies and products * Lack of adequate regulation and registration of herbal medicines * Lack of registration of TRM/CAM providers * Inadequate support for research
Access	<ul style="list-style-type: none"> * Lack of data measuring access levels and affordability * Need to identify safe and effective therapies and products * Lack of official recognition of role of TRM/CAM providers * Lack of cooperation between TRM/CAM providers and allopathic practitioners * Unsustainable use of medicinal plant resources
Rational use	<ul style="list-style-type: none"> * Lack of training for TRM/CAM providers and on TRM/CAM for allopathic practitioners * Lack of communication between TRM/CAM and allopathic practitioners, and between allopathic practitioners and consumers * Lack of information for public on rational use of TRM/CAM

* Table reproduced from WHO Traditional Medicine Strategy 2002 - 2005.

The objectives, components and expected outcomes of the WHO Traditional Medicine Strategy from 2002-2005 to meet challenges in TRM are shown in Table 2.

**Table 2. WHO Traditional Medicine Strategy
2002-2005 - objectives, components and expected outcomes***

Objectives	Components	Expected outcomes
POLICY: Integrate TRM/CAM with national health care systems, as appropriate, by developing and implementing national TRM/CAM policies** And programmes	1. Recognition of TRM/CAM Help countries to develop national policies and programmes on TRM/CAM	1.1 Increased government support for TRM/CAM, through comprehensive national policies on TRM/CAM 1.2 Relevant TRM/CAM integrated into national health care system services
	2. Protection and preservation of indigenous TRM knowledge relating to health Help countries to develop strategies to protect their indigenous TRM knowledge	2.1 Increased recording and preservation of indigenous knowledge of TRM, including development of digital TRM libraries
SAFETY, EFFICACY AND QUALITY: Promote the safety, efficacy and quality of TRM/CAM by expanding the knowledge-base on TRM/CAM, and by providing guidance on regulatory and quality assurance standards	3. Evidence-base for TRM/CAM Increase access to and extent of knowledge of the safety, efficacy and quality of TRM/CAM, with an emphasis on priority health problems such as malaria and HIV/AIDS	3.1 Increased access to and extent of knowledge of TRM/CAM through networking and exchange of accurate information 3.2 Technical reviews of research on use of TRM/CAM for prevention, treatment and management of common diseases and conditions 3.3 Selective support for clinical research into use of TRM/CAM for priority health problems such as malaria and HIV/AIDS, and common diseases

	<p>4. Regulation of herbal medicines</p> <p>Support countries to establish effective regulatory systems for registration and quality assurance of herbal medicines</p>	<p>4.1 National regulation of herbal medicines, including registration, established and implemented</p> <p>4.2 Safety monitoring of herbal medicines and other TRM/CAM products and therapies</p>
	<p>5. Guidelines on safety, efficacy and quality</p> <p>Develop and support implementation of technical guidelines for ensuring the safety, efficacy and quality control of herbal and medicines and other TRM/CAM products and therapies</p>	<p>5.1 Technical guidelines and methodology for evaluating safety, efficacy and quality of TRM/CAM</p> <p>5.2 Criteria for evidence-based data on safety, efficacy and quality of TRM/CAM therapies</p>
<p>ACCESS: Increase the availability and affordability of TRM/CAM, as appropriate, with an emphasis on access for poor populations</p>	<p>6. Recognition of role of TRM/CAM practitioners in health care</p> <p>Promote recognition of role of TRM/CAM practitioners in health care by encouraging interaction and dialogue between TM/CAM practitioners and allopathic practitioners</p>	<p>6.1 Criteria and indicators, where possible, to measure cost-effectiveness and equitable access to TRM/CAM</p> <p>6.2 Increased provision of appropriate TRM/CAM through national health services</p> <p>6.3 Increased number of national organizations of TRM/CAM providers</p>
	<p>7. Protection of medicinal plants</p> <p>Promote sustainable use and cultivation of medicinal plants</p>	<p>7.1 Guidelines for good agriculture practice in relation to medicinal plants</p> <p>7.2. Sustainable use of medicinal plant resources</p>
<p>RATIONAL USE: Promote therapeutically sound use of appropriate TRM/CAM by providers and consumers</p>	<p>8. Proper use of TRM/CAM by providers</p> <p>Increase capacity of TRM/CAM providers to make proper use of TRM/CAM products and therapies</p>	<p>8.1 Basic training in commonly used TRM/CAM therapies for allopathic practitioners</p> <p>8.2 Basic training in primary health care for TRM practitioners</p>

	<p>9. Proper use of TRM/CAM by consumers</p> <p>Increase capacity of consumers to make informed decisions about use of TRM/CAM products and therapies</p>	<p>9.1 Reliable information for consumers on proper use of TRM/CAM therapies</p> <p>9.2 Improved communication between allopathic practitioners and their patients concerning use of TRM/CAM</p>
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* Table reproduced from WHO Traditional Medicine Strategy 2002-2005.

** With the exception of China, the Democratic Peoples Republic of Korea, the Republic of Korea and Viet Nam, such integration has nowhere taken place.

This underlines the fact that in some countries national assessment is needed to ascertain which TCAM modalities can be best integrated with the national health care system.

The WHO has published a number of documents to assist in the development of TRM. Information on some of these publications are given below.

Ensuring safety, efficacy and quality of TCAM

These publications are mainly in the area of medicinal plants and research.

Guidelines for Appropriate Use of Herbal Medicines. WHO Regional Office for the Western Pacific published the document in 1998 [6]. It covers topics such as national policy development, development of national programme on herbal medicines, regulation of practitioners, regulation of manufacture and distribution of medicinal herbal products and regulation of herbal medicines.

Quality Control Methods of Medicinal Plant Materials. WHO, Geneva published the document in 1998 [7]. It contains recommended test procedures for assessing the identity, purity and content of medicinal plant materials. Test procedures are intended to support the development of national standards and reliable methods for quality control.

WHO Monographs on Selected Medicinal Plants. Volumes 1 and 2.

WHO Geneva published these documents in 1999 [8] and 2001 respectively. Volume 3 is under preparation. The publications provide scientific information on safety, efficacy and quality control of widely used medicinal plants in order to facilitate their appropriate use. They also provide models for developing national monographs or formularies on herbal medicines.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines. WHO Regional Office for the Western Pacific published the document in 1993 [9]. It covers topics such as herbal medicine research in general and specific research studies including protocol preparation, quality specifications of plant materials, non-clinical studies and clinical trials, evaluation of herbal medicine research and technology transfer and education.

Rational Use: Proper use of TRM preparations

The WHO has published a number of documents that are useful in developing rational use of TCAM. They cover areas such as conservation of medicinal plants, selection and use of therapies, training and good practice and acupuncture nomenclature. Some of these publications are as follows:

Natural Resources and Human Health: Plants of Medicinal and Nutritional Value. Proceedings of the First WHO Symposium on Plants and Health for All: Scientific Advancement. Kobe, Japan, 26-28 August 1991. Amsterdam, Elsevier Science Publishers, 1992 [10]. The book highlights the vital role plants play in the health of people everywhere. It underscores the importance of natural resources for human health, encourages development of new approaches to valuing natural resources of importance to human health and to upgrade the quality of natural resources through the application of biotechnology.

Conservation of Medicinal Plants. Proceedings of an International Consultation, Chaingmai, Thailand, 21-27 March 1988. Cambridge, UK, Cambridge University Press, 1991 [11]. The WHO, IUCN (The World Conservation Union) and the WWF (World Wide Fund for Nature) and the Ministry of Public Health of the Royal Thai Government convened the meeting. This book is on conservation of

medicinal plants dealing with the problems, the experiences of countries in conservation and future direction, which countries and various organizations must take to ensure conservation of the medicinal plants in the world.

Guidelines on Basic Training and Safety in Acupuncture. Geneva, World Health Organization, 1999 (WHO/EDM/TRM/99.1) [12]. This publication consists of guidelines on basic training and safety in acupuncture. The basic training covers use of acupuncture in national health systems and training programmes for acupuncture practitioners, qualified physicians, and for primary health care personnel. Safety in acupuncture covers topics such as prevention of infection, contraindications, accidents, untoward reactions and requirements for safe use of acupuncture.

National policy

The WHO has published a number of documents to assist in developing national policies and national programmes on TRM. Some of these publications are as follows:

Development of National Policy on Traditional Medicine. Manila, WHO Regional Office for the Western Pacific, 2000 [13]. This publication covers concept, scope and role of traditional medicine in countries of the Western Pacific Region. Steps in the development of national policy on traditional medicine as well as the contents of a policy are included. Difficulties in developing a national policy and programme in TRM as well as solutions are identified.

Traditional Medicine: Its Contribution to Human Health Development in the New Century. Kobe, WHO Centre for Health Development, 2000 (WHO/WKC/SYM) [14]. This publication gives perspectives of traditional medicine as a potential contributor and resource for developing better and fairer health and welfare systems and improving human health in the new century.

Traditional Medicine: Better Science, Policy and Services for Health Development. Kobe, WHO Centre for Health Development, 2001 [15]. This publication highlights consistent themes that emerged throughout the Symposium. They were: (1) the need for a high degree of

government and WHO commitment and investment if traditional medicine is to move beyond its marginal status within the health sector; (2) regional and national variations in the interpretation of the terms 'integration' and 'harmonization', and the importance of developing locally-relevant models; (3) the need for a repertoire of appropriate models of research to be agreed upon as a framework around which national and international research agendas can be constructed; (4) diverse models of training in traditional medicine - for both traditional and conventional health workers; and (5) the importance of ensuring sustainable and ethical production of herbal medicines by ensuring the protection of medicinal plant biodiversity and of the intellectual and cultural property rights of customary holders of traditional health knowledge.

Traditional and Modern Medicine - Harmonizing the Two Approaches, Manila, WHO Regional Office for the Western Pacific, 2000 [16]. This publication covers changes in trends of TRM usage, integration of TRM with modern medicine (MM) and the need for harmonization of TRM and MM. It also identifies issues that would be important in harmonization of TRM and MM. They include evidence-based approach, promotion of mutual respect between the two practitioners, dissemination of information on herbal medicine and acupuncture research to improve the confidence of conventional medical doctors in TCAM.

Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review. Geneva, World Health Organization, 2001 [17]. This publication reviews the legal status of TCAM in 123 countries worldwide. It provides information on situation in the utilization of TCAM and identifies widely used TCAM such as Ayurveda, Chinese traditional medicine, Chiropractic, Homeopathy and Unani Medicine.

Report of the Inter-regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine. Geneva, World Health Organization, 2001 (WHO/EDM/TRM/2001.1) [18]. This publication covers the role of intellectual property rights in relation to traditional medicine. It gives perspectives in globalization, the TRIPS Agreement,

intellectual property rights and protection of traditional knowledge, innovations and practices. Problems and gaps in traditional medicine in relation to modern patent laws are identified.

Traditional Medicine and Health Care Coverage. Geneva, World Health Organization, 1983 [19]. This well-known book on TRM provides information on systems and practices of TRM worldwide. Other topics include herbal medicines and profiles of traditional practices in the six Regions of WHO. Organizational and legal aspects of TRM as well as the role of TRM in primary health care are described.

Traditional Practitioners as Primary Health Care Workers. Geneva, World Health Organization, 1995 (WHO/SHS/DHS/TRM/95.5) [2]. This publication gives step by step guidelines for training of Traditional Health Practitioners. It includes planning for the training, content of training, determining training method, selection of training materials, training of trainers and evaluation of training.

Closing remarks

I wish to end this presentation by reminiscing two parts of the Awaji Declaration on TRM that succinctly highlights the theme of this International Seminar on “*Integration of Traditional (Complementary / Alternative) Medicine and Modern Medicine*”.

The Awaji Declaration on TRM, was promulgated in September 2000 at the end of the WHO Kobe Centre’s International Symposium on TRM with the theme: Better Science, Policy and Services for Health Development held on Awaji island in Japan [14]. The relevant parts of the Declaration is highlighted below:

“We the international participants at Awaji International Symposium on Traditional Medicine:

Celebrate the people-led movement in health care and the spirit of progress made in Awaji, and

Declare the importance of Traditional Medicine in creating and nurturing health for the peoples of the world, and

Request all people to promote the use of Traditional Medicine and integrate it into their health systems to benefit those in need,

Through a satisfactory method of health care that builds on time-tested cultural knowledge to alleviate suffering, and

Assist people in establishing balance in their lives in a closer relationship with nature, and for the health of the Earth, our Mother.”
Unquote.

We hope that the statements of the Awaji Declaration would complement the theme of this International Seminar in putting TCAM in proper perspectives for further development in the Member Countries of WHO.

Thank you for your attention.

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- 2 - *Traditional Medicine - Growing Needs and Potential*. WHO Policy Perspectives on Medicines, Geneva, World Health Organization, No. 2, May 2002.
- 3 - *Traditional Practitioners as Primary Health Care Workers*. Geneva, World Health Organization, 1995 (WHO/SHS/DHS/TRM/95.6).
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- 16 - *Traditional and Modern Medicine - Harmonizing the Two Approaches*, Manila, WHO Regional Office for the Western Pacific, 2000.
- 17 - *Legal Status of Traditional Medicine and Complementary/Alternative Medicine; A Worldwide Review*. Geneva, World Health Organization, 2001 (WHO/EDM/TRM /2001.2).
- 18 - *Report of the Inter-regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine*. Geneva, World Health Organization, 2001 (WHO/EDM/TRM/2001.1).
- 19 - *Traditional Medicine and Health Care Coverage*. Geneva, World Health Organization, 1983.

**OVERVIEW OF TRADITIONAL
MEDICINE (COMPLEMENTARY/
ALTERNATIVE MEDICINE) WITH
SPECIAL REFERENCE TO
EMR COUNTRIES**

Dr. Ahmed Regai El-Gindy

(Kuwait)

1



Overview of CAM With Special Reference to EMR Countries

*Dr. Ahmed Regai El-Gindy,
Secretary General Assistant, IOMS.*

2

Achievements of Modern Medicine



3



Measles



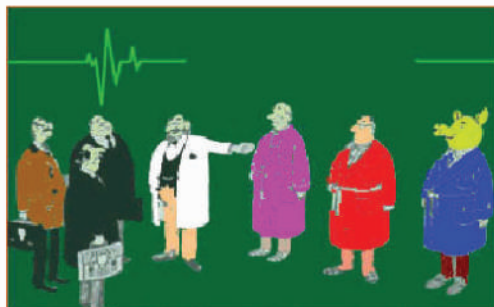
Smallpox

4



Test Tube Baby

5



Mr Smith got the liver, Mr Jones the kidneys - but Mr McTavish is our real triumph!

Organ Transplantation

6



Cloning



DNA

A complex block containing several elements: a diagram of a cell with a nucleus and organelles; a flowchart showing a tree-like structure of cells; and a poster with Arabic text and a corn cob illustration. At the bottom, a person in a red suit is shown in a dynamic pose.

Gene Therapy

7

The Areas where Modern Medicine did not have an Impact.



8



AIDS

No. of Cases in 1993 - 15 million

No. of Cases in 2000 - 40 million

9



Cancer

The USA President’s Cancer Panel was told in 1993 that “the decade of war against Cancer have been an unqualified failure”. There has been a 43.5% increase in the incidence of Cancer since 1950, with a slight improvement in the 5 year survival rate after treatment.



10

Public health policies & medical sciences have enabled people in affluent cultures to survive acute threat to health, only to go on to suffer chronic physical & psychiatric illness irrespective of its quality.



The number of people reaching old age is increasing.

1999	580 million people [Over 60 years]
2020	1000 million people [Over 60 years]
2050	2000 million people [Over 60 years]

1999	66 million people [Over 80 years]
2050	370 million people [Over 80 years]

1996	7 million people disabled in USA
2050	17 million people disabled in USA

40% of Aged Europeans are suffering from depression



11



Depression



- In **December 1998** there were **330** million people suffering from **depression**
- **10 – 20%** of the global population will develop depression at some points.
- According to **WHO**, **depression** will be the world's second most debilitating illness by 2020
- The cost of the antidepression drugs is about \$ 7 billion
- Eli Lilly earned \$2.7 billion from prozac in 1998.
- **USA** depression costs society **\$44** billion per year of which
 - \$12.4 billion for **treatment**
 - \$7.5 billion for **economic** cost of **suicide**
 - \$24 billion cost of **lost productivity**

As **Cancer** is a **malignant** growth, so **depression** is a **malignant** sadness

12



Suicide

Suicide costs the Economy in USA \$7.5 billion

The percentage of suicide is high in Aged Persons.

13



Pollution

14



Paradoxically, the highest incidence of Heart Attacks, Cancer & Depression are in developed countries where they have the most sophisticated equipment and tools for diagnosis & treatment.

There is something wrong; how to stop this bleeding....?

15



Smoking

16



In spite of the tremendous medical achievement in modern medicine, it is estimated that one-third of the world's population lacks regular access to affordable essential drugs. Yet, even in remote areas, TM is often widely available and widely used.

17

In spite of the tremendous achievements and developments in the Modern medicine, both consumers and practitioners are dissatisfied. So they tried to find other alternative. The only system available is Traditional System.

What is traditional medicine?

WHO defines traditional medicine as including diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness.



18

However, the **definition** is not comprehensive:

1. It should include that all these practices are derived from the different cultures, beliefs or religion, indigenous to different cultures.
2. The definition omits the main difference between TM and Allopathic System, which wholism (holism).
3. Also, the definition should include that these practices are part of the culture whether it is explicable or not.



19**Complementary and alternative medicine**

The terms “**complementary**” and “**alternative**” (and sometimes referred to as “non-conventional” or “parallel”) are used to refer to a broad set of health care practices that are not part of a **country’s** own tradition, or not integrated into its dominant health care system.

But **alternative** means that the traditional medicine can replace the orthodox medicine.

**20****Types of Traditional Health Systems**

WHO has defined three types of health system to describe the degree to which TM/CAM is an officially recognized element of health care.

1. **Integrative** system TM/CAM is officially recognized and incorporated into all areas of health care provision. TM/CAM is included in national drug policy; providers and products are registered and regulated. TM/CAM therapies are available at hospitals and clinics (both public and private) in People’s Democratic Republic of Korea and Viet Nam.



21



2. **An inclusive system** recognizes TM/CAM, but has not yet fully integrated it into all aspects of health care. It is available in **developing** countries such as India, Pakistan, Equatorial Guinea, Nigeria and Mali and **developed** countries such as Canada and the United Kingdom & USA.



3. **Tolerant system**, the national health care system is based entirely on allopathic medicine, but some TM/CAM practices are tolerated by law.



22

Expenditure of TM

The world market of herbal medicine is US\$ 60 billion.

Malaysia	US\$ 500 Million
USA (Out of Pocket)	US\$2700 Million
UK	US\$2300 Million
Canada	US\$2400 Million
Australia	US\$1000 Million
China	40% of all health care delivered.



23

In India, government figures show that indigenous systems of medicine, which provide health coverage to over **2/3rd** of the population in different ways, share only **2%** of the total health budget of the nation. The rest of the expenditure (**98%**) is incurred by the western modern medical infrastructure, which serves only **one-third** of population of the country.

TM/CAM is still the principal source of the world's primary health care of over 60% of the world population, particularly in the developing countries.

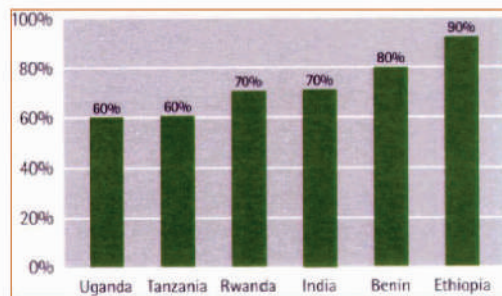
Patients voted for their out of pocket expenses for the utilization of CAM.

24

The global situation of TRM (Traditional Medicine) :

The No. of consumers in some selected countries.


Use of Primary Health Care is Extensive in some Developing Countries



Sources: Compiled from government reports to World Health Organization.

25 Percentage of population, which has used CAM at least once in selected Developed and Developing Countries

Chile	71%
India	60% [TM is the only access to health care].
Colombia	40%
USA	42% [No. of visits to CAM providers now over exceeds the no. of visits to all primary care physicians in the US]
Sweden	50%
Belgium	38%
Australia	48%
France	49%
Canada	70%



26


In China, TM accounts for major healthcare delivery which is reflected by the following:

No. of Worker in TM Hospital	-	350 000
No. of Hospital of TM	-	2500

In addition, 95% of the general hospitals have the units for TM.

Rural doctors who can provide conventional and CAM 50%

No. of practitioners of TM in China 525 000



27

TM accounts for 30 – 50% of total consumption Health Resources

No. of manufacturer of herbal products	800
Total annual output	US\$ 1,800 Million
No. of farmers who cultivate Medicinal Plants	340 000
Total planting area for medicinal herbs	348 000 acres
No. of Research institutions across the country	170

India:

TM is widely used in India, especially in rural areas where 70% of the Indian population lives.

No. of hospital providing TM	2860
No. of beds	45720
No. of dispensaries of TM	22100
No. of Registered TM Practitioners	587536

28

The Orthodox physicians put claims against TM that it is not effective, not safe, bad in quality and not scientific

If so,

Why Patients Use Traditional Medicine (CAM)?

In spite of the tremendous development, high technology, treatments and saving lives from threatening diseases, the orthodox system failed to make the mankind happy and satisfied. People try to find happiness else where, by paying out of their pocket.

29

1. Astin in 1998 published a report about why patients use TRM, after his survey he concluded that along with being **well educated, the majority had professional or technical occupations reporting** poor health status, the majority of alternative medicine users appear to be doing so not so much a result of being dissatisfied with conventional medicine, but largely because they find these health care alternative to be more congruent with their own values, beliefs and philosophical orientations towards health and life.

2. **More accessible and affordable:**

The Physician:Patient Ratio

In Tanzania, Uganda and Zambia -

1:200 or 1:400 of TM practitioners

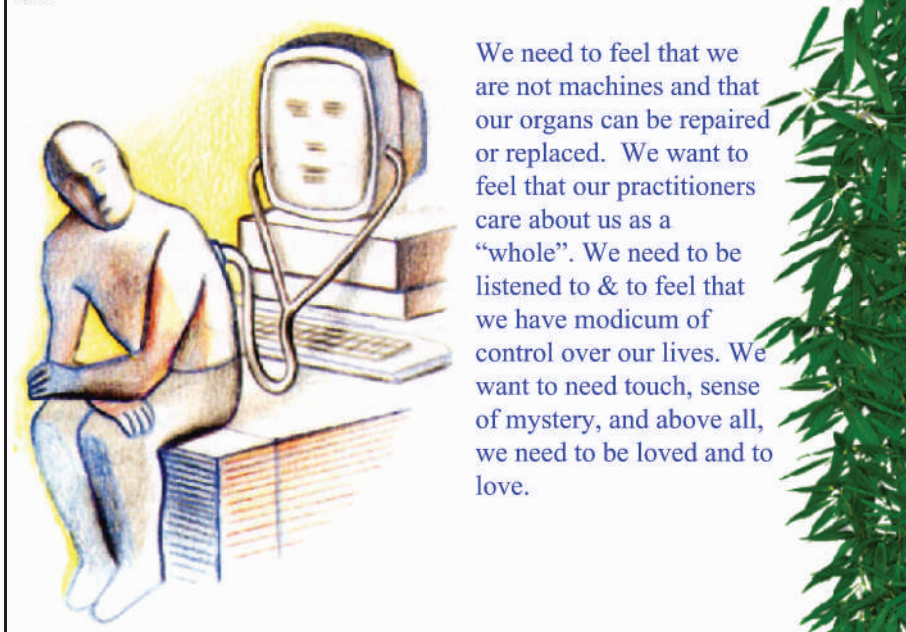
While 1:20 000 Allopathic Practitioners

And in Sub Saharan Africa -

100 TM Practitioners: 1 Allopathic Physicians.

Not only this but the Allopathic Physicians are always in urban areas.

30



We need to feel that we are not machines and that our organs can be repaired or replaced. We want to feel that our practitioners care about us as a “whole”. We need to be listened to & to feel that we have modicum of control over our lives. We want to need touch, sense of mystery, and above all, we need to be loved and to love.

31

3. TM is often embedded in wider belief systems and continues to be an integral and important part of many people’s lives.
4. In addition, concerns for the adverse effects and escalating costs of conventional health care are fueling the search for alternative approaches to the prevention and management of illness.
5. The levels of expenditure by private individuals are considerable in developed countries. There is wide spread recognition of the growing financial, social and personal cost involved and the need for a less fragmented and more participative human approach.
6. Biotechnological approaches – pharmaceutical and surgery often have a limited amount to offer with chronic degenerative or stress related disease, mental disorders or addiction.

32

Conceptual Differences and Commonalities Between Biomedicine and Traditional Medicine.

Traditional Medicine

Holism (Spirituality, Mind-body)

Healing

Individuality

Health Manifestation

Vital Energy (relating to global)

Touch and Compassionate

Low Technology

Orthodox Medicine

Reductionism

Treatment

Non Individuality

Disease Oriented

Materialism

Mechanical

High Technology

33

Continuation.....

<u>Traditional Medicine</u>	<u>Orthodox Medicine</u>
Not Invasive (Gentle)	<i>Invasive</i>
Low Cost	<i>High Cost</i>
Natural Drugs	<i>Chemical and Pure Compounds</i>
Accessible and Affordable	<i>Difficult in Accessibility and Affordability</i>
Low Side Effects	<i>High Side Effects</i>



34

Commonalities Among Traditional Health-Care Systems

Traditional health care systems represent philosophical approaches to managing health and disease that differ substantially from conventional medicine.

The question of what is common to these traditional systems has been largely over looked but:

1. **Spirituality is an integral part of each.**
2. **Vital Energy or “vital force”**
3. **“Belief in Unity” or holism (Wholism)**



35**4) Healing:**

This was used by the Muslim physicians where they established special hospitals for those who are suffering from psychosomatic diseases. These hospitals include a very big garden with flower fountains, Holy Quran recitation, music, group prayer and Lessons in faith. They gave salaries for healed person after discharge from the hospital. They call these places as Healing Hospitals.

Also, in Islam there is what we call “Roquiah”, a reading of some Quranic Verses, and giving him some advise for his course and stories from the Islamic history about the faith and how he can overcome his misfortune or catastrophe. Also there is Haj (Pilgrimage), Ramadan Fasting, Omrah and Zakat.

36

In the Holy Quran, we have many verses about the types of disease that can be divided into body disease and heart disease, the last can be subdivided into disease of the heart as organ and psyche as psychosomatic disease. Also in Quran we could not find a word ‘treatment’, but instead disease found “Healing”.

37 Changing attitude towards TM

Under the pressure of the consumers and the high consumption by the people & interested allopathic physicians and upon their desires to give a chance for TM, there are many changes in the attitude towards the TM System. This can be classified into the following:

Acupuncture:

1). It is no more limited to TM practitioners. But allopathic physicians are either trained or refer their patients to acupuncture clinics. It is now used in at least 78 countries and practiced not only by TM practitioners but also by allopathic physicians.



38 Belgium -

74% of acupuncture is practiced by allopathic physicians.

Germany-

77% of pain clinics use acupuncture

UK-

46% allopathic doctors either use acupuncture or recommend it.

Asia-

50,000 Acupuncturists

Europe-

15,000 Acupuncturists including Allopathic doctors

USA

12,000 Licensed Acupuncturists
 38 States are practicing Acupuncture legally
 6 States are developing acupuncture practicing policies.



39**2) Education:**

In USA 64% of the medical schools offer courses in CAM. In Europe 43% of medical schools offer courses on unconventional medicine.

3) British Medical Association:

Acknowledges that CAM systems are full systems, that they are here to stay, that doctors must learn about them even at the under-graduate level and if a doctor wishes to study them, then he or she must undertake a full course of instruction.

40

- 4) Polls of doctors have shown that 3/4th of British general practitioners, trainees and nearly half of those in practice want to learn one or more of CAM.
- 5) 24 countries have regulations for chiropractic.
- 6) 64 countries have regulations for herbal medicines
- 7) Some countries have structures, budgets and training in TM/CAM and are growing steadily.
- 8) Growing numbers of national TM research institutes in both developing and developed countries (China, India, Korea, Mali, Megasese).

41

9) UK :

(a) No. of schools offering training courses in CAM increased by 30%.

(b) The House of Lords requested the Committee on Science & Technology to make a survey of CAM health care.

(c) It is suggested to create a 'Center of Excellence' for CAM.

10) In Japan 60 to 70% of Allopathic Physicians prescribe TM [Kampo].



42

11) USA:

a) A large number of medical schools now have elective classes and CAM seminars.

b) In the USA, in 1992, US Congress established the Office for Alternative Medicine at the National Institutes of Health. The Office becoming the National Center for Complementary and Alternative Medicine (NCCAM) with budget of US\$68.4 million for year 2000.

c) Concurrently in 2000, the White House set up the White House Commission on Alternative Medicine. The Commission is charged with developing a set of legislative and administrative recommendations to maximize the benefits of CAM for the general public. It has ten members, including senators and experts.



43

11 -d) The USA also has a large number of units for CAM research, based at research institutions such as the University of Maryland, Columbia University in New York, Harvard University in Massachusetts, and the Memorial Sloan-Kettering Cancer Center in New York.

12) The European Union (EU) recently completed a Cost (European Cooperation in the field of Scientific and Technical research) project on “unconventional medicine”.

13) Also in Europe, the European Agency for the Evaluation of Medicinal Products (EMA) works on the quality, safety and efficacy of herbal medicinal products. An Ad Hoc Working Group on Herbal Medicinal Products was established by the EMA in 1997.

14) Australia has recently provided federal funds to the Southern Cross University in New South Wales to establish a department of Natural Medicine and CAM.

44

15) This reflects an international movement, as developing and developed countries try to find answers for the crucial questions of safety, efficacy, and quality. In the near future we shall have a new design for RCT, safety, efficacy reliability, scientific, realistic and appropriate.

16) Sri Lanka has a minister responsible for all the traditional medicine systems.

17) Pakistan’s Hamdard have established Bayt Al-Hikmah, which includes the Faculty of Unani Medicine.

18) China has an integrated traditional modern system providing services for about 200 million people.

19) In 1995, the Norwegian Parliament examined how CAM could best be incorporated into the Norwegian health service.

45

Why TM did not develop like orthodox Medicine?

1. Relation between the two systems:
Fighting together :
The orthodox always mentioning that :
TM is not scientific i.e.



Both Orthodox & Complementary medicines are in danger of identifying themselves & their care with tools in their tool boxes - be they drugs or acupuncture needles.

The gap between them is, however, narrowing with the emerging view, backed by the study of placebo & psycho neuroimmunology, that to ignore whole person factors is unscientific & less successful.

46

No studies for safety, efficacy, quality. The results of the TM are not based on the scientific background especially for Randomized Control Trials (RCT), the gold standard.

Quackery :

- * The practitioners of TM are not qualified.
- * They neither have recognized education nor training system.
- * The bases for diagnosis are neither scientific nor quantifiable.

Budget :

Accordingly there is no policy, no support, no budget, no research.

47

2. The Allopathic Physicians insist on evaluating the TM system with their methods, which is unfair. The methods used in the evaluation of the orthodox medicine could not be used to TM, because each system has its own philosophical theory.

But new reliable, realistic and appropriate methods could be used for the evaluation of the TM.

3. The herbal drugs could not be patented thus the international drug manufacturing companies can not invest in this area.

4. In addition to lobbying either from the political side or the chemical drug industry which affects all trials for herbal drugs.

5. So, both systems are trying to evaluate each other with tools in their boxes, be they – drugs or acupuncture.

Both systems are in trouble. The only way is to have a good understanding between both systems is with an open mind and good hopes.

48



But is integration just bolting on the scientifically proved bits of TM to the leaning tower of Pisa of orthodox. To stop would to ignore the fundamental imbalance that TM's rise reflects but cannot fix.



The achievement of TM

They are trying to evaluate it with their own tools, in spite of the fact that both systems are conceptually different. They must first know the language, to go inside, as Shamplion did. He discovered Rasheed's Stone then, he was able to know some of the secrets.

49 **New Paradigm for Health Care**

Are we in need of new Paradigm ?

Lessons from the USA health care crises.

Expenditure of Health care/person	US\$4000 (1997)
Quality rank	37 in the world
The total expenditure of Health care (about 14% of DIP)	\$1.3 Trillion
The No. of uninsured (about 16% of the population)	43 Million (1998)

The emphasis on crisis care has resulted in **development of highly technical invasive treatments and potent drugs** that raise the risk of iatrogenesis. **More than 2 million** American become seriously **ill every** year from reactions to **drugs** that are **correctly prescribed and taken.**

50 **20-30 %** of patients receive **contraindicated** and unnecessary care.

44000 – 98000 of **deaths** due to **medical error.**

106000 deaths a year are attributed to **non-error – adverse effects of medications.**

The adverse effects in out patient care include adverse effects other than death.

* Between **4 – 8%** of patients experience adverse effects in out patient setting.

* These effects results in **116** million extra **physician visits**, **77** million extra **prescriptions**, **17** million **emergency room visits**, **8** million **hospitalisations**, **3** million **long term admissions**, **199000** additional **deaths**, **77** billion in **extra costs.**

51

These may be due to:

- * Too many specialists & too few generalists
- * Too much technology: The more technology, the more treatment, the more adverse outcomes, the more damage is done.
- * These studies shed New Light on Imperatives for Research & New Health Policy to face these harmful interventions.

In UK, in the last 20 years, there has been 50% increase in the percentage of the gross domestic product spent on health. Yet 34% of the population, is suffering from long-term illness, and there is 64% increase in incapacity or days of certified sickness.

This raises a question about Rigorous study and RCT and its efficacy for tracing the side effects.



52

In spite of spending this tremendous amount of money on health care, it fails to restore happiness to the consumer and practitioners.

Also, the latest medical technologies are designated to identify the marker of the disease and then attacking it, so its approach is **very highly invasive, which puts the patient** in the area of danger.



53

Cost Benefit: We have more than one study:

(1st) In Japan (Developed Country): the cost of the western medicine per patient/per day is more than US\$6. For 200 bed, hospital will save US\$438000 / year.

(2nd) Developing Countries

2a Population of China is 22% of the world population. Expenditure for the health is only 1% of world health care budget.



54

2b Peru (Developing)

The study conducted by National program in CAM and the Pan-American Health Organization, to compare CAM practices and allopathic medicine practices by measuring the following markers:

- **Observed clinical efficacy.**
- **User / patient satisfaction.**
- **Reduction of future medical risks associated with life style.**

Treatment was compared for selected pathologies with the same degree of severity.



55 The results were as follows:

- (1) The overall average of direct cost using CAM was less than that of allopathic medicine.
- (2) For each of the criteria evaluated, CAM's efficacy was higher, fewer side effects, higher correlation and higher recognition.
- (3) The overall cost-effectiveness of CAM was 53-63% higher than that of conventional treatment for the selected pathologies.

B3 India :

The expenditure on TM on 60% of the Indian population is about 2% of the total health budget .

(CAM is the only healthcare system available for this 60% of the population).

98% of the remaining health budget goes for the allopathic system drugs and equipments.

56 Overview of TM in EMRO

We can observe the following contradictions for the countries of EMRO:

Although Islam lays emphasis on holism, spirituality, and morality, it is astonishing that the TM (which is partly based on these principles) did not prosper in the EMR inhabited by the followers of this religion.

The tremendous contribution made by scholars from this region to the art of healing is almost forgotten though being practiced in India, Pakistan, Sri Lanka, Malaysia etc.


The EMR countries are either developing or are least developed, with the exception of GCC, where TM could have been cost effective in Health care but the allopathic medicine has become the main remedy.

57

Islam encourages and asserts to search and discover what is beneficial for humankind, and stresses to find proper treatment for ailments yet people in this region have not done much, in the present day, in this respect.

Altogether, there is no TM practice on scientific footing in the EMR and no education/training provided in this area except in Pakistan where Late Hakim Mohammed Said established a University for Tibbi Medicines (Bait-ul-Hikmah).


The only forms of TM available in the region are herbalism (shops of herbs and herbal products prepared under unhygienic conditions), cauterization, cupping, and the recitation of certain pertinent verses from Holy Quran related to patient care.



58 PER CAPITA INCOME AND HEALTH BUDGET/EXPENDITURE

Countries	Per Capita GDP in US\$	Per Capita National Health Expenditure in US\$	Per Capita Annual Budget of MOH in US\$
Afghanistan	160	8.0	0.9
Bahrain	9715	477.0	232.0
Cyprus	13435	755.0	244.4
Djibouti	805	29.0	14.1
Egypt	1380	66.0	10.0
Iran	1460	171.4	71.5
Jordan	1706	116.0	35.0
Kuwait	14545	580.0	410.0
Lebanon	4455	310.0	46.0

Contd.



59

Libya	8220	344.0	292.0
Morocco	1295	48.0	17.5
Oman	8332	218.0	152.6
Pakistan	480	31.0	3.5
Palestine	1484	122.0	
Qatar	28366	469.0	436.0
Saudi Arabia	8485	316.0	107.0
Somalia	168	4.0	
Sudan	282	60.0	3.1
Syria	3500	46.0	18.6
Tunisia	2180	123.4	52.6
U.A.E.	17680	311.0	148.0
Yemen	370	19.0	4.6

60 **Per Capita Income and Health Expenditure/
Budget of Some Selected Countries
(In Descending Order)**

Countries	Per Capita GDP in US\$	Per Capita National Health Expenditure in US\$	Per Capita Annual Budget of MOH in US\$
Somalia	168	4.0	
Afghanistan	160	8.0	0.9
Yemen	370	19.0	4.6
Djibouti	805	29.0	14.1
Pakistan	480	31.0	3.5
Syria	3500	46.0	18.6
Morocco	1295	48.0	17.5

Contd.

61

Sudan	282	60.0	3.1
Egypt	1380	66.0	10.0
Jordan	1706	116.0	35.0
Palestine	1484	122.0	
Tunisia	2180	123.4	52.6

62

Why did TM disappeared from the countries of EMR?

1. There is no definite time that we can say when it disappeared.
2. I think we can mention, approximately, it is the time when it was decided to replace the Arabic language by English in the medical education.
3. During colonisation, a group of students were sent to different European countries, for study and, on their return, they were the leaders of the society. They were always pressing to change every thing in their country to be as close as possible the mirror image of the European countries.

63

(4) Most of them were in influential positions, especially in the executive, media, and education areas. Gradually, they changed the national concept conveying to them that this is the way for development.

(5) At the same time the Islamic civilization eclipsed. These people found the road smooth to incorporate the European culture.

(6) When physicians sent to Europe returned to their mother countries, they became the leading national personalities and they changed completely the Islamic concept about medicine and replaced it with European ideology, which did not reflect the culture and belief of the peoples in these countries because Islam is deeply rooted in the heart of the people.

64

(7) Allopathic physicians were empowered and through executive orders and issued laws that prohibited anyone to practice medicine except those who were qualified from the faculty of medicine. Failing to do so was considered as a criminal offense.

(8) The relation between physicians and TM practitioners were not in good terms. The former considered the latter as Quacks, not scientific – no basis for their therapy. So, no policy, no budget, no support and no research on TM.

(9) As a result, they are working away from the official authority, dispensing the untested and badly prepared medications with raw material not hygienically stored. The patients who paid had to suffer the result of noncooperation between both of them.

65



The same thing with the herbal products. They try to evaluate them like chemicals (Reductionism & materialism).

66

(10) Similarly, the professionals from the faculty of pharmacy who are responsible for drugs and their safety, efficacy, quality and manufacture also belong to the same school of thought i.e. reductionism, materialism and objectivity. Accordingly, they are always asking about what they call active ingredients to study its pharmacology, pharmaceutics and manufacture.

The only forms of TM available in EMR countries, with the exception of Pakistan, are herbalism, (shops for selling herbs and preparations of some herbal products), cauterization, cupping, and recitation of some pertinent verses of Holy Quran regarding patient care; some countries have also introduced acupuncture practiced by orthodox medicine. Some herbal drugs factories are now available. But there is no real practice of TM. So there are many factors responsible for the absence of TM from most, if not all, of the EMR countries.

67

A New Hope Emerged From Kuwait

In 1980, hope emerged from Kuwait to revive Islamic Medicine. In 1984, an Amiri decree was issued to establish “Islamic Organization for Medical Sciences”, to take responsibility for the promotion and progress of “Islamic Medicine”.

Islamic Organization for Medical Sciences (IOMS)

Establishment



LAW NO. 18/1984
FOR ESTABLISHMENT OF
ISLAMIC ORGANIZATION FOR
MEDICAL SCIENCES (IOMS)

68

After reviewing articles No. 12, 14, 15 and 65 of the Constitution and the approval of the National Assembly on the following law, that we have ratified and issued:

Article No. 1

An organization for “Islamic Medicine”, under the name of “The Islamic Organization for Medical Sciences” shall be established, having its own Identity and Independence, for which State of Kuwait is its Residency. It might establish centers for research and study in or out of Kuwait and shall function its activities according to its constitution that will be issued by an Amiri Decree.

69

Article No. 2

Ministers, each within his Jurisdiction, shall see to the implementation of this Decree, effective on date of its publication in the official gazette.

Amir of Kuwait
Jaber Al-Ahmed.

14th February, 1984 A.D.



70



Islamic Organization for Medical Sciences (IOMS)



71**Aims & Objectives****The IOMS aims to achieve the following:**

1. To revive the doctrines of the Islamic Religion relating to the treatment of and protection against various physical and psychological ailments. The Organization also aims to revive Islamic heritage in the domain through a re-reading of research and studies of the pioneer Muslim physicians in the light of modern technological advances in an attempt to find scientifically-based applications of these studies for the service of mankind.
2. To encourage research workers in the field of Islamic medical sciences and join medical and juristic viewpoints to reach a common ground on controversial medical and legal issues in the application of recent medical findings and providing alternative drugs and methods of treatment for those prohibited in Islam.

72**What is Islamic Medicine?**

Islamic Medicine, as its name indicates, derives its principles from the Holy Quran and Prophet's sayings (Hadith) and the diligence of the followers.

Islamic Medicine may include, among many others, all the modalities of modern medicine. It fulfills all the following six criteria: It is excellent and leading among other brands of the healing arts. It is a medicine with faith and Divine ethics. It is guided and oriented. It is comprehensive, paying attention to holism, healing, life style, body and spirit, to the individual and the society. It is universal, utilizing all useful resources, and offering its services to all mankind. And last, but not least, it is scientific.

73

Structure of Islamic Medicine

- Give honour to the mankind.
- Holism, faith healing, spirituality, Body and Mind.
- Islamic Life Style; Prophet's Sayings concerning Health
- Prayer for the sick
- Divine Ethics
- Islamic Heritage



74

Islamic Medicine Center

- Aims and Objectives
- Plan of action
- Selection of diseases to be treated
- Selection of Herbs for treatment of specified diseases
- Quality of Herbs and Herbal Drugs

Aims and Objectives:

- (1) To introduce Islamic TM, starting with herbal medicine
- (2) To control the import of herbs and herbal drugs to Kuwait

Plan of Action:

(A) *Different administrative actions were taken:*

- (i) It is included in the Ministry of Health framework
- (ii) Has a special budget
- (iii) Has its own identity and is directly under the supervision of the Minister of Health



- 75** (iv) Specialists appointed for the Center
(v) Two Hakeems were appointed

(B) *Co-operation between the Center and EMRO to discuss different issues. In this context, three seminars were held.*

- (i) The use of herbs in the primary health care
- (ii) Rational and irrational use of TM
- (iii) Herbal Remedies Act

Selection of Diseases to be treated by Herbal Drugs

1. Should be quantifiable
2. Highly prevalent
3. Preference to chronic diseases
4. Excessive side effects of chemicals used for treatment
5. Non-availability of effective allopathic medicines

76

Selection of Herbs for treatment

The Herbal Medicines Act classified the herbs into three main categories:

- (a) Those which are well known and used by the inhabitants and mentioned in one of the traditional books on medicine
- (b) Those which are mentioned in the standard text books or pharmacopoeias or in the literature.
- (4) Those which are unknown

77

Quality of Herbs and Herbal Drugs

Should conform to:

- 1) Macroscopic and microscopic criteria
- 2) Chemically conform to the official requirements of the pharmacopoeias
- 3) Microbiologically conform to the official requirements of WHO monograph
- 4) Should be free from aflatoxins and the fungus producing the toxins.



78

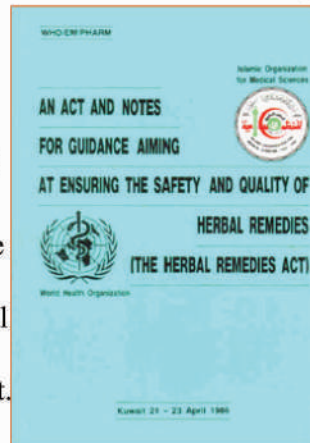
Achievements of the Islamic Medicine Centre

1. Clinical, Pharmacological, toxicological (acute, subacute, chronic, and teratological), phytochemical, pharmacognostic, and pharmaceutical studies have been carried out on several herbs and polypharmaceutical herbal preparations.
2. Fifteen research papers published.
3. Sixteen herbal formulations are prepared following strict GMP regulations. Quality control is a must.
4. Specifications for 90 plants established.
5. Quality assurance for all the imported herbs and herbal products.



79

6. After the issuance of Ministerial order, 76 herbal pharmaceutical products have been registered, 50 are under consideration, and 6 were rejected.
7. Treatment being provided for 16 chronic diseases.
8. Yearly average of patients receiving treatment is approximately 15000.
9. Three seminars have been held in collaboration with EMRO to discuss following issues:
 - i) The use of herbs in the primary health care
 - ii) Rational and irrational use of TM
 - iii) Herbal Remedies Act.



80



Mosque
Mosque

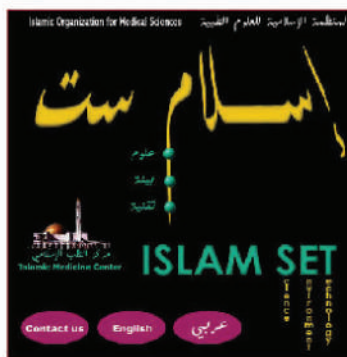


Animal House

81



Center of Information



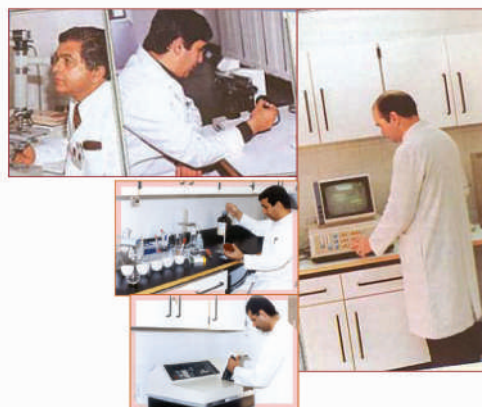
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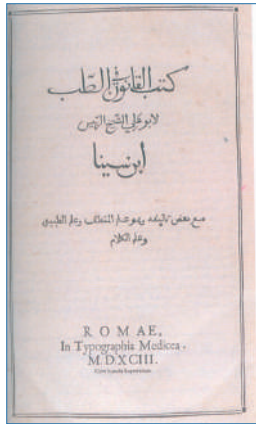
82

LABS



83

Some Achievements of Islamic Era in the field of Medicine



Avicenna's Canon



Avicenna's Treatise on Healing

84



Surgical Instruments by Abulcasis

85



Spiritual Treatments in Islamic Medicine



86



Pharmacy in the Islamic Era: The picture showing the preparation and inspectors supervising the activity.



87

What is needed to be done?

1. Political will
2. Budgetary provision
3. Recognition of TM system
4. Legalization and regulation for TM practitioners and drugs.
5. Mutual understanding between different health care systems.
6. Proper education and training for TM practitioners
7. National Integration System according to the situation of each country.
8. National drug policy that includes traditional drugs.
9. Evaluation, on scientific basis, to make TM realistic, reliable, appropriate, and acceptable.

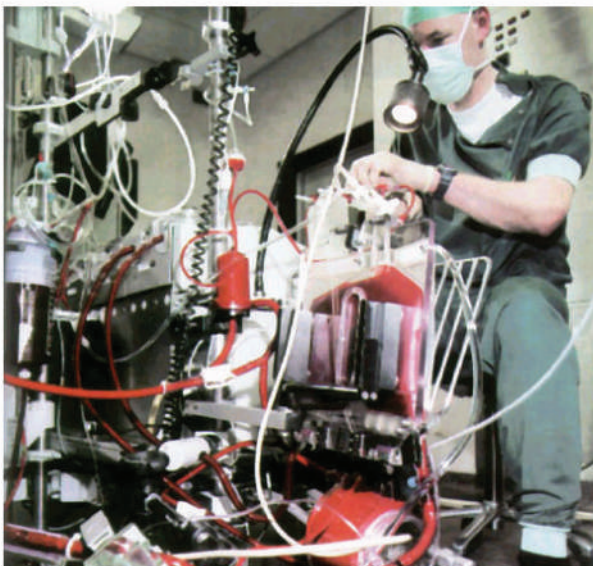
88



Berlin Wall

Can we demolish this wall between the two systems & convince these guards to leave to promote integration as we did with the Berlin Wall.

89



We want to humanize medicine & restore its soul, to enhance human healing.

90



Integration

91



**Medicine with one system
(TM or CONVENTIONAL?)**



**Medicine with both
systems (Integrated)**

92



It would be a tragic loss if traditional human caring had to move to the domain of complementary medicine, leaving orthodox medicine with just the technical management of disease.

I strongly believe that, the way forward is to create a move to an inclusive system that incorporates the best and most effective of both CAM and Orthodox. We must give the patient a choice where appropriate & the best of all world, whenever it is possible.

93

Thank you very much



DR. AHMED REGAI EL-GINDY



DISCUSSION

Discussion of First Session

An Overview of CAM

Chairman: Prof. Ibrahim Badran

Rapporteur: Pro. Masour S. Al-Said

Prof. Ibrahim Badran: Now time for debate. Yes, please.

Participant: Thank you very much. The question is for Dr. Kin Shein and to Dr. El-Gindy. When we are talking about integration, it should be integration of natural types of medicine into the health care system. It is more difficult in modern medical system, but within the healthcare, it is possible. Other issue is that, to be practical, we have to define well organized practical plan to do this. Let us start by cooperation. Each system should recognize the other. Co-ordination should be done before we go into integration. What are these types of traditional, natural remedies?

Dr. Kin Shein: Thank you very much for these useful comments. The word integration is, perhaps, misinterpreted. What the word that I would like is incorporation of Traditional Medicine into the national health care system. Integration may appear to have two systems mixed together and then giving treatment for a common condition. To me, this is not what I advocate. To me, I would rather have the role of Traditional Medicine in health care system and Traditional Medicine can play that role as far they are effective, they are non-toxic and they give beneficial effect for health of a person. Now, with regard to this specificity, in Traditional Medicine we don't know the mechanism of action. With allopathic drugs, you know the mechanism of action. Some one has mentioned that research is very much needed and for research, pharmaceutical companies use as much as US\$300million over a period of ten years to come up with the mechanism of action, toxicities, the pre-clinical studies in various phases and so on. Traditional Medicine does not have that kind of money. Traditional Medicine has been used for generations and it only has an experience by which people can say it is effective or it is non-effective. This is why the scientific validity is very much needed to see which prepara-

tions are effective and in the national programs this sort of comparison has to be made.

Another point in TM is that, if we take them alone, I think Prof. Bodeker has also mentioned that, they may not be effective. If we mix them together and give it, then they will become effective. I remember that one of the Traditional Medicine practitioners has given the example. He compares the Traditional Medicine preparation to a chicken-curry. Chicken-curry contains Masala, Chicken, Onion, Garlic and so on, and so, also oil. When we have that mixture, it becomes tasty. If we take individually, you know that what I mean taking alone, I think Traditional Medicine has somewhat this example, when we have to make sure of the various ingredients. A lot of examples about potentiation, synergism is there in allopathic medicine.

Dr. Ahmed Regai El-Gindy: I will speak with all frankness. We are speaking of a citizen in a country where US\$4 a year is allocated as national health expenditure, which is not sufficient even to purchase panadol or aspirin. We have two things. We have developing countries, which have to pay a great attention to this topic, because things will be cheaper. I think the experiment, and examples given by Dr. Bodeker from Africa provides good answer.

If we want to introduce traditional systems to US, or to other rich countries, I agree with you that there has to be comprehensive studies. They assess each other. The two systems should find the short-comings of each other. We have to lay down the scientific standards, which are adequate for this purpose. We should not do comparison between the herbal plants or herbal therapy or Traditional Medicine and equally validate to those in Modern Medicine. We are opening a new stage or phase, which should not perturb the scientific basis or scientific standards.

Participant: I thank the speakers. Dr. El-Gindy has encouraged me to speak in Arabic. I thank the speakers Dr. Shein, Dr. Bodeker, Dr. El-Gindy. Now, I would ask Dr. Bodeker for the slide, which shows Manhattan, because I will be giving a lecture in Jeddah. I want to speak on this point. Dr. El-Gindy, I agree with you. Your lecture was outstanding, particularly with the lecture in Arabic. Separating active

ingredients are very important that you may prove the effectiveness and efficacy of the drug.

Participant: Thank you Mr. Chairman. The three panelists have mentioned introduction to the subject, and Dr. El-Gindy has raised so many questions based on this introduction and yet questions remain unanswered. We are hearing the countries of this region are at cross roads strategically. We will hear the experience of countries of other regions, and let us hope we will reach co-relation that will be adequate for countries of Mediterranean region. I would like to remind you of documents that were distributed telling us please do not over use definitions or abuse definitions, because of time factor and because we want to make out of best experience of experts. We have traveled from very far to come here, we have come from the UK, USA, Japan, Pakistan, and India etc. So, I hope during the next coming days, we have recommendations such as the establishment of working group to see a best method for our region. Because our region is very much liking Traditional Medicine. Our region does not want to adopt fully Traditional Medicine and does not want to learn fully Modern Medicine. So, what would be the best methods? Perhaps, the working group could come out with vision that may convince all of legislators, professors who teach medical sciences to represent future generations. We have to think about the most adequate ways and means for us and the methods for over coming next 50 years.

Participant: My experience in the subject is by attending about 30 such conferences/symposiums. There is no real debate such as acupuncture, homeopathy, but what I am saying, are the Arab health ministers caring more about their people than their counter-parts in Europe, America? If these countries have allowed practicing traditional medicine, and I invite the WHO to frame some adequate legislation for Middle Eastern Mediterranean region so that we make surities concerning homeopathy, acupuncture and see the situation in Europe and US as well. - Thank you!

Prof. Ibrahim Badran: I would like to thank you for these questions and contribution. We are only left with couple of minutes. So, Prof. Gerard, please.

Prof. Gerard Bodeker: I think this has been very constructive session stimulating those questions on American structure and in the direction of federal action towards stimulating primary change. Two points I would like to talk about, on the very worthwhile observations made. One was the comment that my colleague from India made about the educational need. This is a very great point. In Vietnam, this experience was very successful. All the Vietnami Medical students have to do 16 courses in Traditional Medicine, as part of medical education. In India, Ms. Shailaja Chandra was successful in introducing at least an agreement to begin Ayurveda taught in the medical curricula syllabus. It is too working. In Oxford Medical School, I am responsible for Complementary Medicine Course. We have been teaching complementary medicine to Oxford Medical students. I came straight from a class to Middle East yesterday. Students were learning about medication. It is well established. The General Medical Council in Britain has instructed the deans of Medical Schools to introduce complementary medicine, not so that they become practitioners, so they know that what patients are doing. They like complementary medicine whether they disagree with that. They have to learn because half of the patients are doing that. So, I think your point is very fundamental one in respect of integration. Education at the level of medical curriculum is vital.

My final comment, last commentator talking about Arab Health Ministers in political lobbying in the action. I would just like to mention two cases where political-will actually globalized by the constituencies themselves. One in India. The India Medicine Central Council active in 1970 came about after over 100 years. Over 100 years committees meeting to talk commissioned by government with distance of political will to make recommendation, nothing happened with integration. The All India Ayurveda Congress nominated its president Pandit Sharma to stand for election and he was elected to Lok Sabha and pushed through legislation to establish this council, to establish the form of base way to the Indian systems of medicines. They set up the council, money began to flow and so it is on a political lobby.

In US same thing happened, where this lobby sent congressmen who worked to introduce legislation in the US congress to establish the Office of Complementary and Alternative Medicine, its International Center from where Ms. Nancy Hazleton represents.

I think on the political will side, ministers, they may say that they support it, but ball back in the court of the complementary and traditional organizations to translate that political will into serious introduction. - Thank you!

Dr. A. R. El-Gindy: There were two points; one is raised by Dr. Hai, another by Dr. Yousuf.

Prof. Ibrahim Badran: Yes, the recommendations in your files, emails we sent you, invited you to convey to the organizer of the symposium that any recommendation you may wish to give. You said that you wish to see in this room the opposition, opponent to this idea. Well, we have people with us, we don't have the opposite point of view represented as such here. All right, the active ingredients now, of course, we could reach an understanding, but it needs a very high technology, it needs a lot of work, lot of experience. But, if we take it along as a topic, it could be OK. At the end of this very rich session, I think I have taken much of your energy, much of your precious time. I wish to address my thanks to Prof. Bodeker from UK, Dr. Kin Shein from Japan, and to Dr. A.R. El-Gindy from Kuwait and also to Prof. Mansour Al-Said for his assistance as a Rapporteur for this session.

Second Session
Saturday, 12 October 2002
Fundamentals of CAM

Chairman : Dr. Hussein A. Gezairy

Rapporteur : Hakim Abdul Hannan

Speakers:

1 - Dr. Howard Hall (U.S.A.)

2 - Dr. Koshiro Otsuka (Japan)

**FUNDAMENTALS OF
COMPLEMENTARY AND
ALTERNATIVE MEDICINE**

Dr. Howard Hall

(U.S.A.)

ALTERNATIVE AND COMPLIMENTARY MEDICINE PRACTICES AND SUFISM

Howard Hall

Case Western Reserve University,
Rainbow Babies & Childrens Hospital
Cleveland, Ohio, U.S.A.

Introduction: Alternative Medicine Use

The 1990's witnessed a "silent revolution" for some of the wealthiest and most highly educated citizens of major industrialized countries of the world, from the United States to Europe. In the United States Einsenber et al (1993) conducted a survey that revealed that Americans made about 427 million visits to alternative medicine practitioners compared to 388 million visits to all primary care physicians for chronic non-life threatening conditions. By 1997, the number of visits to "alternative medicine practitioners" continued to increase (629 million visits) eclipsing the number of visit to all US primary care physicians (386 million) (Einsenber et al., 1998). When this data was examined in terms of percentage of people using unconventional medicine, for the 1990 survey about 34% individuals interviewed had used at least 1 of 16 alternative therapies in the previous year. By 1997 this number was up to 42%. The nature of these alternative therapies ranged from: relaxation techniques, hypnosis, biofeedback, imagery, herbal medicines, chiropractic manipulations, to such healing practices, as acupuncture, Homeopathy and Folk remedies (Einsenber, et al. 1993). The amount of money Americans spent on alternative medical practices was staggering. For example, in 1990 around \$15 billion was spent on services for alternative medicine practitioners and by 1997 this figure had increased to over \$21 billion.

The revolution or paradigm shift within mechanistic medicine:

Larry Dossey (1993) described medicine moving through three

distinct eras: beginning with Era I: Mechanical, Material, or Physical Medicine. This was the Newtonian view of the world and the human body operating like a machine. Era II: was the Mind-Body Medicine movement. In the United States one can place the alternative medicine movement with relaxation and meditation approaches within this era. Finally, Era III: represented what might be described as “spiritual healing” or “energy type of healing approaches” which Dossey called Non-Local or Transpersonal Medicine. Sufism (Islamic mysticism) will be discussed within this context.

Through out human history up until today we have seen the tension between mechanistic versus vitalistic approaches in explaining healing and the world around us. With advancing technology, mechanistic approaches held out the promise of explaining healing through the laws of chemistry and physics. Vitalists look toward some mysterious life force as an alternative means of explaining the world. A scientific treatment of viatalistic healing approaches can be found in James Oschmans (2000) pioneering book “Energy Medicine: The Scientific Basis.”

It is interesting to reflect back on western history before the Era one mechanistic/scientific period. Similar to Era III, but without the subsequent scientific developments, pre Era I saw the world as operating solely on spiritual principles. As described in Redfields (1993) *The Celestine Prophecy*:

“....every aspect of the Medieval world is defined in other-worldly terms. All the phenomena of life-from the chance thunderstorm or earthquake to the success of crops or the death of a loved one-is defined either as the will of God or as the malice of the devil. There is no concept of weather or geological forces or horticulture or disease. All that comes later. For now, you completely believe the churchmen; the world you take for granted operates solely by spiritual means.” (Page 32) Era I displaced this Western God Centered view of the world with science and natural laws. Thus the body and the universe were now seen as operating under natural and scientific principles (mechanistically).

Roots of Era II Mind-Body Medicine

Emotions and cancer

Galen (second century C.E.) noted a relationship between Melancholy women and breast cancer versus Sanguine women. In the popular culture Woody Allen in the movie Manhattan noted after breaking up with his girl friend:

- I don't get angry.
- I have a tendency to internalize.
- I cant express anger.
- I grow a tumor instead.”

Psychoneuroimmunology (PNI): (A bridge between Mechanical Medicine with Mind-Body Medicine) (Ader, 1981; Ader, Felton, & Cohen, 1991).

Robert Ader (1981) demonstrated that the immune system in rats could learn via classical conditioning. This was the taste aversion learning paradigm, where a conditioned stimulus (CS) (novel saccharin drinking solution) was paired with an unconditional stimulus (US) (immunosuppressive drug cyclophosphamide) which resulted in conditioned immunosuppression to the sugar water.

Not only has conditioning been found to alter immune activity, but also psychology stress and hypnosis. It is now accepted that stress can lower host resistance via its impact on immune activity (Boyce, et al., 1995). Hypnosis has also been associated with inhibition of allergic skin reactions, (Hall, 1983).

Clinical Psychoneuroimmunology

Self-Regulation of Immune Activity:

In a series of studies involving children, adolescents and adults my research team examined the impact of hypnotic inductions with imagery on changes in immune activity (Hall et al., 1992a; 1992b; Hall, Minnes, & Olness, 1993; Hall, Papas, Tosi, & Olness, 1996). We observed:

- * Increased lymphocyte responses to stimulation with Pokeweed mitogen.
- * Both increases and decreases in the stickiness of Neutrophils or (Adherence).
- * Simple relaxation without immune imagery was associated with increases in neutrophil adherence.
- * Active imaging of adherence changes, whether increased stickiness or decreased stickiness, resulted in decreased neutrophil adherence.

Thus our laboratory demonstrated that directional changes could be produced by humans, but not simply as a means of conscious volition. Instead, behavioral operations such as relaxation or active imaging resulted in such alterations.

Evidence-Based Era I Medicine:

The later part of the 20th century saw the rise of “Evidence-Based Medicine” (the Conscientious and judicious use of current best knowledge in making decisions about the care of individual patients, often from well-designed, randomized, controlled trials) (Kennell, 1999). For centuries, in Mayan native villages, young mothers had continuous female support during labor and delivery (i.e. Doula) (Kennell, 1999).

Evidence-based randomized control studies observed the presence of a Doula (female labor support person) significantly shortens labors, decreases the need for analgesia, and reduces the likelihood of high tech. medical interventions, such as cesarean delivery (Kennell, 1999).

Evidence Based Era II Mind-Body Medicine

NIH Technology Assessment Panel on Integration of Behavioral and Relaxation Approaches into the Treatment of Chronic Pain and Insomnia, JAMA (1996): concluded:

“A number of well-defined behavioral and relaxation interventions now exist and are effective in the treatment of chronic pain and insomnia.” (Page 313)

My clinical work as a behavioral psychologist is in the area of

Mind/Body medicine. I work in the department of Pediatrics in the division of Behavioral Pediatrics and Behavioral Medicine at Rainbow Babies and Childrens Hospital, University Hospitals of Cleveland, and The Otis Moss Health Center. My clinical interventions involve employing relaxation-based approaches for the following conditions:

- * Headaches, Insomnia, Stress disorders, Performance and Test Anxiety, Chronic and Acute Pain problems, Enuresis in children, Habit Disorders, and the removal of warts employing relaxation-based hypnotic procedures.

ERA III Energy Medicine/Spiritual Healing (Non-Local, Transpersonal Medicine or Vitalism)

The Silent revolution or paradigm shift of the 1990's incorporated global healing traditions from other cultures that were over thousands of years old. These non-western practices involved non-mechanistic/whole person approaches to healing. Example of such global healing traditions included: Ayurveda medicine of India with its various yogas (Zysk, 1996) and Chinese Medicine with Acupuncture (Ergil, 1996) and Qigong (McGee, Sancier, & Chow, (1996). Within Western Religious traditions there was intercessory Prayer and Distant Healing Intention research (Dossey, 1993).

Evidence basis for ERA III Medicine

Daniel Benor, MD (practicing holistic psychiatrist) wrote: "Spiritual Healing: Scientific Validation of A Healing Revolution" (Benor, 2001). As he addressed the question for the evidence-basis of spiritual healing:

"Does spiritual healing work? Does research confirm that healing is an effective therapy?" An impressive number of studies with excellent design and execution answer this question with a "Yes. If we take a broad view, out of 191 controlled experiments of healing, close to two thirds (64.9 percent) of all the experiments demonstrate significant effects." Page 371. Spiritual healing effects can be demonstrated on animals, plants, single-celled organisms, bacteria, yeasts, and DNA.

Along similar lines, cellular biologist and physiologist James Oschman, Ph.D. wrote “Energy Medicine: The Scientific Basis.” (Oschman, 2000). “Medical research is demonstrating that devices producing pulsing magnetic fields of particular frequencies can stimulate the healing of variety of tissues. Therapists from various schools of energy medicine can project, from their hands, fields with similar frequencies and intensities. Research documenting that these different approaches are efficacious is mutually validating. Medical research and hands-on therapies are confirming each other. The common denominator is the pulsating magnetic field, which is called a biomagnetic field when it emanates from the hands of a therapist.” (Page XIV)

Western Medicine is alternative medicine for many countries around the globe where spiritual/energy healing practices are the mainstream practice. Acupuncture (ERA III) was virtually ignored by Western scientists until about 25 years ago with Nixon 1971 visit to China. This non-ERA I approach to healing claim that inserting a needle in various distal parts of the body, such as the little toe of the right foot for example, would impact the visual cortex. High tech. research demonstrated that the visual cortex would light up on fMRI when that acupuncture point was stimulated (A. Z. Cho, 1998).

Why wouldn't western medicine embrace evidence from other global healing traditions?

Thomas Kuhn in his classic text on “The Structure of Scientific Revolutions” (Kuhn, 1970) noted that:

“Normal science, for example, often suppresses fundamental novelities because they are necessarily subversive of its basic commitments. Nevertheless, so long as those commitments retain an element of the arbitrary, the very nature of normal research ensures that novelty shall not be suppressed for very long.” (Page 5)

The above study by Jones, Cho, et al. with fMRI and ZH.67 acupuncture point was rejected from “Nature” and “Science” without even a review (Roy, 2002).

(Evidence for ERA III) Advance AIDS and Distant Healing, Sicher, et al., 1998.

Forty AIDS patients and 40 healers from different religious traditions were randomized in a double-blind study. After 10 weeks of distant healing experimental subjects at 6 months demonstrated significantly fewer AIDS-related illnesses ($p < .04$); Lower severity of illness ($p < .02$); Fewer visits to the doctors, less hospitalizations, and less days in the hospital. These effects were additive with protease and triple-drug therapies (Sicher, Targ, Moore, & Smith, 1998). Why didn't this study make national headlines?

Prior to being published in 1998 and noted in the proceedings from the Harvard University Intercessory Prayer & Distant Healing Intention meeting: "Despite these significant findings, with a disease representing a major global health problem, for which there is no cure, these results have not yet been published in a peer-reviewed journal. It has twice been turned down and is under consideration with a third journal." (Page 36)

Roy (2002) argued that the process of peer-review in science: "has become a "defender of the faith", a conserver of to-day's theories.... accurately characterized as the paradigm-police." Roy argues that peer review simple tests new results by how well they conform to current theory (i.e.. the true faith). He goes on to argue that Peer-review has failed dismally keeping out "bad" or "pathological sciences" e.g. Poly-water and cold fusion were products of peer reviewed journals.

Thomas Kuhn, noted: "Perhaps the most striking feature of the normal research problems we have just encountered is how little they aim to produce major novelties, conceptual or phenomenal." Kuhn (1970) (Page 35)

Peer review/paradigm policing in other fields

The father of sleep medicine, William Dement, MD, Ph.D. had his first paper on rapid eye movements (REM) sleep in cats rejected 5 times before it was finally published and later became one of the most cited scientific papers in biomedical research.

As Dement (1999) noted: "The journal editors' mistake is really not so surprising, in light of the history of sleep research. The idea that the brain is active during sleep, not turned off, flew in the face of

thousands of years of prejudice. People reacted as if I were claiming that we don't need air to breathe." (Page 41)

Dement also noted regarding the failure of other sleep researchers to observe REM in infants that: "I think it says something about how strongly preconceived ideas can affect perception... I might have fallen prey to the same blindness, but once the scales of dogma had dropped from my eyes the rapid movements were completely obvious." (Page 39)

Does scientific evidence guild the practice of Western medicine? Even with clear evidence for decreased risks, standard obstetrical practice does not include the use of a Doula (or labor support person) Kennell (1999). On the other hand, there are medical procedures today that millions of patients have received, such as pulmonary artery catheterization with little scientific evidence that it is associated with improved patient outcomes (Dalen, 1998).

Contrary to popular opinion that mechanistic/reductionistic/ High tech. U.S. medicine under a managed care model, being the best in the world, there is much evidence to the contrary. Thus, this might explain some of the reasons that educated people are making other choices about health care for chronic non-life threatening health conditions. For example, managed care has failed to keep health costs down, and failed to reduce racial health disparities, and has allowed 39 million Americans to be without insurance along with 9 million children (Ross, 2002). Even more troublesome are the risks of big business high tech medicine. In 1998 the U.S. Western Scientific Medicine System observed over 108,000 deaths form drug interactions (the 4th Leading cause of death). Also between 44,000 and 98,000 Americans die each year from physicians and surgeons' mistakes, totaling about 200,000 deaths a year from U.S. Western based medicine (Institute of medicine, 1999). In addition, between 20-25% of the total days are Iatrogenic based hospital stays from hospital caused infections. (Roy, 2002).

Thus it should come as no surprise that the most educated, informed, and affluent persons from industrialized countries are

moving away from mechanistic/high tech. approaches for chronic non-life threatening medical conditions.

With the silent revolution, people are moving toward whole person health and global healing traditions as noted by leading health expert, Andrew Weil (1983). One global healing tradition that has received very little attention from the West is Sufism, or non-traditional Islamic mysticism. The rapid wound healing from deliberately caused bodily injuries from one major Sufi school will be introduced as a practice that can unify Dossey's three eras.

“Deliberately caused bodily damage phenomena” (DCBD)

The extraordinary Instantaneous Healing of “Deliberately caused bodily damage phenomena” (DCBD), has been reported by the Tariqa, Casnazaniyyah School of Sufisms (Hussein, Fatoohi, Al-Dargazelli, and Almuchtar, 1994a,b, c; Hussein, Fatoohi, Hall, and Al-Dargazelli, 1997). Followers (dervishes) of this Sufi school have been observed to demonstrate instantaneous healing of deliberately cause bodily damage (DCBD). For example, dervishes have inserted a variety of sharp instruments such as spikes and skewers into their body; hammered daggers into the skull bone and clavicle; and chewed and swallowed glass and sharp razor blades without harm to the body and with complete control over pain, bleeding, infection, as well as rapid wound healing within 4-10 seconds (Hussein, Fatoohi, Al-Dargazelli, and Almuchtar, 1994a,b,c). Researchers report that such extraordinary abilities are accessible to anyone and not restricted to only a few talented individuals who have spent years in special training. These unusual healing phenomena have also been reproduced under controlled laboratory conditions and are in no way similar to hypnosis (Hall, Don, Hussein, White, & Hostoffer, 2001).

From a spiritual perspective, this type of healing is described in terms of healing energies (Hussein, Fatoohi, Al-Dargazelli, and Almuchtar, 1994a,b, c). This “higher energy” is alleged to be instantly transferable based upon a spiritual link from the dervish to the current shaikh of the Tariqa Casnazaniyyah Sufi School (Hussein, Fatoohi, Hall, and Al-Dargazelli, 1997). Followers of this Sufi school describe

the ability to accomplish DCBD as an “others-healing phenomena” which goes beyond traditional mechanistic and psychological factors that influence healing. It is argued that hypnosis or altered states of consciousness as an explanation for DCBD have little logical, theoretical, or empirical support (Hall, 2000).

Sufism as a unified theory of Era I, II, and III:

Traditional Islamic theology recognizes that Allah (God) created a world that can apparently operate under mechanistic/Newtonian principles. As noted in the Holy Quran (Surah 6: 95-99) it states that Allah (God) created order in this world causing seed to sprout, the rising and setting of the sun, rain to fall, etc... Such is the judgment and ordering of (Him) the exalted in Power, the Omniscient.” (6:96).

This is consistent with the mechanistic (Newtonian) view of the world and humans. Thus there is no rejection of mechanistic views from traditional Islamic philosophy. Sufi philosophy goes further noting that mechanistic views can also be explained within a vitalistic perspective. From this point of view, Sufism can predict both mechanistic and energy-based DCBD healing phenomena in ways that Newtonian models cannot explain.

As explained by Sufi Shaikh Gaylani in his book *Jila al-Khatir: Purification of the Mind* (Edited by al-Casnazani al-Husseini, 1998).

“The belief of the followers of the Book and the Sunna of the Messenger of Allah (Salla Allah taala alayhi wa sallam) is that the sword does not cut because of its nature, but it is rather Allah (‘Azza wa Jall) who cuts with it, that the fire does not burn because of its nature, but it is rather Allah (‘Azza wa Jall) who burn with it, that food does not satisfy hunger because of its nature, but it is rather Allah (‘Azza wa Jall) who satisfies hunger with it and that water does not quench thirst because of its nature, but it is rather Allah (‘Azza wa Jall) who quenches thirst with it. The same applies to things of all kinds; it is Allah (‘Azza wa Jall) who uses them to produce their effects and they are only instruments in His hand with which He does whatever He wills.”

(Page 42)

Thus, most of the time the world operates by mechanical laws (allowed by Allah (god) but, interventions by a Sufi Shaikh based upon the Shaikh's nearness to Allah and through Allah (god), would allow for fire not to burn, a knife not to cut, etc. The Goal of the Sufi (and all spiritual paths) is nearness to God. In Sufism this is done via Jihad (or struggling against the lower self or nafs). It is the lower self that keeps humans distant from God. Islam and Sufism is about surrendering to the will of God through following the path. Once near God, alterations of mechanistic laws can occur.

Conclusion

Western high tech. medicine can be helpful for medical and surgical emergencies. Western high tech. medicine cannot be as helpful for chronic non-life threatening conditions. Thus, as noted in the beginning, people are making wise decisions, moving toward holistic/global approaches. Sufism is one of the least studied approaches that offered an integration of Era I, II, and III. The SUFI Way: (Universal path for spiritual traditions) prayer, fasting, meditation, avoiding intoxicants, pork, sex outside of marriage and jihad, or battle against the lower self.

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**MEDICINE AS SCIENCE AND
HEALING ART: TOWARD HOLISTIC
CARE BY INTEGRATIVE MEDICINE**

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MEDICINE AS SCIENCE AND HEALING ART: TOWARD HOLISTIC CARE BY INTEGRATIVE MEDICINE

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1. Problems of Modern Western Medicine... Disease-oriented Medical Science, based on Mechanistic Model

In the long history of medicine of humankind, Modern Scientific Medicine has greatly contributed to the cure of numerous diseases especially for these nearly 150 years. Clearly Modern Scientific Western Medicine is a powerful Disease-oriented Medicine, mainly by allopathic approaches of treatments. Modern Western Medicine has strongly developed high medical technologies so rapidly, aiming at conquering or overcoming diseases by attacking them.

The major premise of Modern Western Medicine is based on the mechanistic model, regarding human body as something mechanical, which can be fixed or repaired as perceived by reductionistic science. In short, Reductionism in Science means a paradigm, separating objects into small pieces of small parts almost endlessly and analyzing each small part to understand the reality of a whole complex existence. Human genome project is also based on this reductionistic science. But can that reductionistic and mechanistic model of a human being be really enough to understand the dynamic whole reality of a living human being? In fact, the reality of a human being remains far beyond a simplified mechanistic model, so we need to consider the holistic, dynamic model of a human being, which has physical, psychological, and spiritual aspects, also together with the understanding on cultural and religious aspects.

Is Modern Scientific Western Medicine truly enough to understand

a real human existence and to take care of a living human being as a whole?

2. What is the true essence of Medicine? - Medicine is Art and Science.

Obviously Medicine is not just Science only, and also Art for healing patients. Disease-based Medical Science is not necessarily equaled to Medical Care & Human Hospitality to heal patients from heart.

Truly Medicine is both Science and Healing Art. If we put patients first in priority above all in Medicine, probably Art comes first in medicine. So Medicine is Art first and Science second.

But what is the essence of medicine anyway? What is Medicine? To investigate and explore the true meaning of medicine, we need to go back to the root of medicine. To clarify the point, let us go back to the root of Western Medicine and focus on it.

Was the root of Western Medicine historically similar to the way of Modern Disease-oriented Medicine by Disease-based Science? And were the approaches for healing in the root of Western Medicine also similar to the way of allopathic treatments to attack and suppress the symptoms of diseases?

3. The Root of Western Medicine (1)-The Essence of Asklepios' Medical Art

The root of Western Medicine can go back to the ancient Greece around the times of Asklepios (Asclepius). Almost 3000 years ago, in ancient Greece, Asklepios, or God of Medicine had been worshiped for several hundred years. During that time, the faith healing by worshipping Asklepios, God of Medicine, asking for supernatural healing power from God is the major healing art.

All over the ancient Greece, more than 100 temples for Asklepios, called "Asklepieions" had been built as the healing retreat centers for patients. Patients had visited and stayed at those temples to heal themselves. One of big Asclepieions holds the place for worship, the

sanctuary, the memorial gate, the big bathing pool, the accommodation place, the gymnasium, and the outdoor open theater, and it looked like a huge complex of natural healing retreat center. The famous, typical and huge Asklepieion is the one, situated in Epidaurus, Greece.

Most of the healing temples were situated in wonderful and extraordinarily beautiful natural environment. Very pure, good natural air and water had been abundantly available there, filled with refreshing vital energy of nature.

In the atmosphere of profound serenity and also in that natural healing environment, patients had been gradually healed. Together with the main faith healing by the worship to Asklepios, Diet Therapy, Hydrotherapy, Exercise, Massage, and Herbal Remedies had been conducted in the healing-complex-like temple of Asklepios. So the Asklepios Temple Complex had a perfect healing environment, meaning that “Nature heals patients.”

This healing environment of the healing temples looks completely different from that of today’s modern medical hospitals.

Priests of the temples were physicians for patients. Patients worshiped, donated their offerings, took baths regularly, and prayed for God in the temples. And patients took good and peaceful rest, and slept well at night. Patients’ everyday life had been based on religious faith to God of Medicine, Asklepios.

In that faith healing, the dreams of patients sometimes were comprehended as God’s messages in the process of healing, and those symbolic messages had been used for patients’ care by priests. The temple priests were very skillful psychosomatic healers, who used very effectively the techniques of the power of suggestions to pull out the innate healing abilities of patients. That means those priests already knew how to use the principle of Mind/Body Interactions to activate one’s natural healing potentials, using patients’ inner strong belief systems by the name of God.

Interestingly, the topic of Mind/Body Interactions is one of the highlight topics of today in the field of Complementary, Alternative,

and Integrative Medicine in this 21st century. The fact shows amazingly that the principle of Mind/Body Interactions had been already used very effectively and successfully in the Asklepios' Medical Art during the times of ancient Greece.

But the faith healing approach very often caused some strange, religious superstitions, in which we tended to get caught easily as our psychological traps. That means diseases were considered as illnesses, caused by Gods or Demons. Especially during those ancient times, "Epilepsy" was firmly believed as Sacred Disease, which was the suffering from Gods.

4. The Root of Western Medicine (2)-The Essence of Hippocratic Medicine

The person who courageously and completely denied that "Sacred Disease" is Hippocrates (BC460~375), "The Father of Western Medicine" in the ancient Greece of almost 2500 years ago. He stated clearly and strongly this way: the "Sacred Disease", or Epilepsy is nothing to do with Sacred at all, and that common sense of such belief is just superstition, and this disease is not caused by Gods or Demons, but it is just caused by natural force by natural law. Hippocrates successfully released humans and healing arts from superstitions, magics, and demons. Therefore, he is called The Father of Western Medicine, as the beginning of Rational and Scientific Medicine.

Hippocrates conducted careful and holistic observation precisely over through patients, health, and diseases, and discovered and developed the profound insight that exactly the same Nature's function also works in the body of a patient. He called it "physis" in Greek. That "physis" always functions and balances the environment of a human body.

He says in his famous classic Hippocratic Collections (Corpus Hippocraticum); "The body's nature is the physician in disease. Nature finds the way for herself, not from thought. For example, blinking, and the tongue offers its assistance, and all similar things. Well trained, readily and without instruction, nature does what is needed."(-*Hippocrates*. Epidemics Vol.6, Section 5)

By observing and understanding the function of nature, or “physis” in a body, Hippocrates made the most of patients’ innate healing abilities to balance and heal themselves for the cure of diseases. Because of that profound insight by careful and accurate observation, Hippocrates was greatly famous for precise “prognosis” with amazing accuracy.

Later, the internal nature’s healing power was called by his disciples as “vis medicatrix naturae” in Latin, meaning “the healing power of nature”.

From the term, “physis”, the term, “physkos” in Greek came out, and later from this term, “physicus” in Latin also came out. Then, from this term, “physicus”, the term in English, “physician” was born. That originally means “natural healer”, or “nature’s helper”, because “physician” was originally the person, who healed patients by the help of nature’s law and function. Therefore, the role of physicians does not originally mean to attack and fight against diseases, or to give a repair to a patient’s body like fixing a broken machine. The original meaning of “physician” is to balance the internal natural environment, by using the healing power of nature within a patient. Obviously this approach is very different from the dominant allopathic approach by today’s physicians.

The influence of Hippocrates was crucially important for the history of Western Medicine, and reading through the volumes of “Hippocratic Collection” (Corpus Hippocraticum), overall the essence of Hippocratic Medicine can be pointed out as follows; 1. Humanistic Medicine ----- (1). Doctor-Patient Relationship, (2). “Help, or at least not to harm.” or “First, do no harm.” (Primum Non Nocere.): In Hippocratic Medicine, the importance of Doctor-Patient Relationship and of the safe care to patients was strongly emphasized. 2. Lifestyle Medicine ----- Hippocratic approach was mainly Lifestyle approach, emphasizing Diet Therapy. 3. Natural Medicine ----- Hippocratic approach was holistic Natural approach, based on Diet Therapy to recover patients’ humoral balance, considering patients’ body constitution types, with other additional natural therapies, such as Hydrotherapy, Massage, and Herbal Remedies. Good Air, Good Water, and

Good Natural Environment were crucially important in Hippocratic Natural approach. 4.Environmental Medicine ----- Hippocrates was called as The Father of Environmental Medicine, too. Because he carefully observed and understood how natural environment affects human health strongly and crucially, and he also developed the careful insight on the relationship between human health and environment. 5. Rational Medicine ----- Hippocrates set humans free from meaningless fear and anxiety, which was based on the belief and superstition; such as diseases are caused by Demons and capricious Gods. He stated clearly diseases are caused by natural forces by natural laws. So Hippocratic Medicine is Rational approach, eliminating any kinds of occult and superstition. Rational diagnosis and treatment were followed by his logical reasoning, based on careful observation to patients under the natural law. So some people says this showed the dawn of scientific western medicine. 6. Healing-oriented Medicine ----- For Hippocrates, health means the harmonious balance among internal and external forces of nature. His major medical philosophy is “Let Nature (Physis) work and heal.” Therefore, “Balance” is the key word for Hippocratic healing, and Hippocratic Medicine, originally the real root of Western Medicine is based on Healing-oriented Medicine rather than Disease-oriented Medicine. Disease-oriented Medicine usually tries to attack and destroy diseases as enemies by militaristic allopathic treatment, not focusing on ones dynamic balance of healing mechanism.

5. The Similarities of Traditional Western and Eastern Medicines

Looking back through the root of Western Medicine and the essence of Hippocratic Medicine, surprisingly we can naturally find out that the essential wisdom of Traditional Western Medicine looks very similar to the one of various Traditional Eastern Medicines. For long years, it has been said that Western Medicine is completely different from Eastern Medicine, so they are incompatible and contradictory. But as we have seen so far, at least for me, the essential

wisdom of the roots of both Traditional Western and Eastern Medicines looks very similar in the way of observation and insight.

Let me point out some similarities among Hippocratic Medicine and Traditional Eastern (Asian) Medicines; such as Traditional Indian Ayurvedic Medicine, Traditional Tibetan Medicine, Unani Medicine, and Traditional Chinese Medicine.

Western Hippocratic Medicine and other Traditional Asian Medicines all emphasize the following key points similarly; 1. Lifestyle Health, 2. Wellness and Prevention of Disease, 3. Healing Power of Nature, 4. Humoral Balance, 5. Environmental Connection in Health, 6. Individual Uniqueness: “Each Person is Different.”

Of course, there are many cultural, historical, and environmental differences in the expression of the knowledge through these traditional Western and Eastern medicines, but ignoring the details of differences in each knowledge, I just focus on the essential similarities of wisdom for health care and healing only.

Especially the expressions on humors are different, but if we can regard “humors” as some symbolic images to understand the dynamic reality of body constitution and mental temperament of a human being, many different types of expressions can be possible to describe one dynamic reality of a human being.

In the field of General Semantics, Alfred Korzybski pointed out about the recognition of reality as follows; “The symbol is not the thing symbolized. The word is not the thing. The map is not the territory it stands for.” (*Science and Sanity: An Introduction to Non-Aristotelian Systems and General Semantics*)

So the various symbolic expressions might be possible to understand the reality of a patient’s internal balance. That is why I dare to ignore the detailed differences of expressions on “humors”. Through the symbolic humoral understanding, we have to explore what is going on in a patient’s body. That means Traditional Western and Eastern Medicines both require intuitive holistic understanding on patients, together with rational and logical thinking.

Overall, interestingly both Traditional Western and Eastern Medi-

cines are Healing-oriented, “Balance-recovery” Medicines, which are very different from Disease-oriented, allopathic medicine, which dominates today’s Modern Western Conventional Medicine.

6. Why Western Medicine became Allopathy-dominated Modern Western Medicine later in its history?

If traditionally both Western Medicine and Eastern Medicine had similar essential wisdom in history, why Modern Western Conventional Medicine became so different?

Interestingly, the characteristics of both areas of traditional medicines in the East and West are; 1. Wellness Medicine rather than Disease Medicine, 2. Healing-oriented Medicine, or Balance-oriented Medicine, 3. Environmental Medicine, or Ecological Medicine. They are not Disease-attacking Medicine to conquer diseases by the military force of medical medications and technologies, and obviously they are more peaceful, healing-focused medicine. These are the fundamental characteristics of both Traditional Western and Eastern Medicines

Amazingly, those essential wisdoms of the origin of medicines had strongly been succeeded in the history of medicine from the ancient times of Hippocrates to Thomas Sydenham (1624~1689) in the 17th century, so the fundamental wisdoms of medicines had been specifically alive for more than 2000 years.

Thomas Sydenham was called, “English Hippocrates”. His clinical practice was based on the theory of humoral balance by Hippocrates. He greatly contributed to the progress and development of clinical medicine by his careful, precise, and comprehensive observation on patients and diseases. In his practice, exactly like ancient Hippocrates, he regarded the healing power of nature and vital force as the crucial keys to recovery.

But, later, Gionvanni Batista Morgagni (1682~1771), a professor of anatomy, wrote a book, “The Place of Disease and its Cause” in 1761, pointing out that the place and the cause of disease exist locally. In the point of view of anatomy, disease mostly shows visible abnormal tissues locally, so he came to believe “Disease is local”, and the cause

of disease is also observed there together as visible evidence. And he denied the theory that disease is caused by humoral imbalance. In other words, very near-sightedly, he believed only visible appearance of disease is the place and the cause of the disease. He stuck too much on visible aspects of disease. If disease is local and just a visible thing, then if we can remove it, it means we can eliminate the place and the cause of the disease. After Morgagni, medical professionals were strongly obsessed with the visible matters of disease to find out how to eliminate and destroy them. So disease was becoming something wrong or evil to be removed or destroyed. Highly probably human feelings of strong fear against disease also helped this kind of view to be acceleratedly expanded, mainly focusing on visible factors of diseases.

Finally, Louis Pasteur (1822~1895) and Robert Koch (1843~1901) made a very crucial view in the history of Western Medicine. Louis Pasteur invented vaccination and Robert Koch discovered the germs of Tuberculosis and Cholera. After them, the study of Bacteriology and Microbiology had been developed so rapidly. And also by the great influence of Industrial Revolution, the pharmaceutical drugs to attack or destroy the visible targets of disease had been abundantly developed by the rapid growth of the pharmaceutical industry. And that pharmaceutical industry acceleratedly had gained powerful influence to the politics in the field of medical industry.

Whereas, Claude Bernard (1813~1878) and Max von Pettenkoffer (1818 ~ 1901) had quite different views on the cause of diseases during that time. They admitted the fact that the visible germs might be the primary triggers for diseases, but they emphasized the points that the visible germs are rather secondary cause, and the most crucial cause of diseases lies in abnormal imbalance of the Vital Force of the internal environment (*milieu interieur*) of our body.

Claude Bernard is called as The Father of Physiology, and Max von Pettenkoffer is called as The Father of Public Health.

In the debate with Robert Koch, very surprisingly Max von Pettenkoffer himself drank the strong extract of cholera germs directly by his own experiment, but he did not suffer from any symptoms of Cholera at all and had no problem.

Louis Pasteur did not understand why some silkworms suffer very easily and others do not suffer easily under the same condition in his experiments. If the germ is the real cause of disease, all of them have to suffer equally, but they do not necessarily so. Because of this serious question, when he was dying, he said, “ Claude Bernard is right. I could not understand why this difference happened under the same condition. If I can start my study again, I want to study with the ideas of Claude Bernard. “It is told that this is his last honest words.

Obviously it is not the “Either-Or ” issue, but probably it is the both sides of a coin. Therefore, both sides will be gradually connected again, highly probably by the immunological point of views through the rapid development of Immunology.

The one stream of the direction, fighting against morbid matters which cause disease had gradually accelerated, probably because of psychological fear from human nature to protect oneself against enemies to survive. This force of direction has been strongly empowered by the raising pharmaceutical industries as the main authorities of medical industries after the age of the Industrial Revolution. Politically it has dominated the most areas of medicine as drug-oriented allopathic approaches together with the study on too professionally classified diseases. That is why the allopathic medicine has been dominating the world of modern conventional medicine since then. Probably in human history, it was not avoidable indeed, but the huge main stream power means the political power, governing the world of medicine nearly these 150 years so strongly.

7. A Holistic Healing Model Case - A Healing Art of Traditional Tibetan Medicine

Here, let us take a careful look at a specific example of healing art of Traditional Tibetan Medicine.

In 1989, at the First International Conference on Holistic Health and Medicine, which was held in Bangalore, India, I had a rare chance joining the workshop to learn on Traditional Tibetan Medicine for several days directly from a Tibetan doctor. His name is Dr. Tenzin Chodrak, a senior physician to His Holiness The Dalai Lama.

In that workshop, very fortunately, I had a good opportunity watching the demonstration of their healing arts of Tibetan Medicine. One of my great interests is the Tibetan Golden Needle Treatment.

In the actual demonstration session, a female patient suffering from migraine appeared. She looked more than the age of 50 years old. Dr. Tenzin kindly consulted the patient nearly for 30 minutes. Then Dr. Tenzin and other Tibetan doctors started measuring the some length of her each hand with a thread, and using the thread of that length, they measured very carefully to find out her exact point on her head and put a golden needle at the point. That was a very interesting process to find her precise acupuncture point, probably paying careful attention to the individual differences of the body size. Then, he put some amount of moxa at the top of the long & thick golden needle. And he put fire at the top quietly.

The other young Tibetan doctors and Dr. Tenzin surrounded her like a human circle and suddenly started the chanting of Tibetan Buddhism. The lady closed her eyes looked so relaxed in relief, without any anxiety, probably also in belief for healing.

Until the moxa burned all up, the chanting in the rhythm like music continued. Several minutes passed. She opened her eyes. Her migraine headache was completely gone. She smiled.

As I watched the whole process, I found out, if we just focus on the golden needle treatment itself, then we might miss some crucially important keys for its healing. Obviously the treatment itself worked actually. But together with the treatment or beyond the treatment, there worked a holistic care for healing effectively in the whole process.

Dr. Tenzin created rapport, or good psychological connection with the patient first very naturally. He set up a good healing relationship with the patient. The good Doctor-Patient Therapeutic Relationship in strong trust is the invisible key for recovery.

Then along with the transmission of the heat of the burning moxa down at the point on her head, the rhythm of mantra of Tibetan Buddhism surrounded her like a circle and guided her into deep

trance, or altered state of consciousness. With that all process, it is highly probable that her strong belief system on Tibetan Buddhism and her expectation for healing was synergistically getting accelerated with the heat and the circulating sounds in rhythm.

The function of Mind/Body Interactions was really effectively working there in the successful healing environment. So I found it this approach of traditional healing art is really psychosomatic, Mind/Body approach for recovery. So the technique of the golden needle treatment itself is also important, but using that technique, this traditional approach conducted truly as a holistic approach for healing. You cannot separate the whole process. This is a crucially important point to understand the holistic and comprehensive systems of various Traditional Medicines.

Probably you can test Tibetan golden needle treatment just only for itself objectively and separately by Randomized Controlled Trials (RCT), but you might miss the crucial essence of the whole picture about the holistic system of the traditional healing art, which is tremendously important as the core of healing.

In the recent past, the study on Mind/Body Interactions clearly reveals that Nervous System, Endocrine System, and Immune System are not the independent systems, but they are very closely interrelated and interacted each other. The area of this study is called Psychoneuroimmunology, and it is one of highlight topics in the field of Complementary & Alternative Medicine (CAM) and Integrative Medicine.

For your information, the similar insight on interactive Mind/Body Connection is nothing new in the traditional wisdom in the long history of Japan and of Islamic countries. In Japan, Hakuin Zen Monk(1685~1768) and Master Tenpu Nakamura(1876~1968) already taught the great importance of Mind/Body Unification for radiant health and happy fulfillment of life with strong vitality. Also in the history of Islamic medicine, Ibn Sina (Avicenna: 980~1037)already had his clear insight about the effect of the mind to the body and its strong psychosomatic influence, in the historically famous medical textbook,"The Canons of Medicine ". So the wisdom on Mind/Body

Interactions is nothing new in both cultures of long history, but it is beneficial to recognize the fact that the further scientific study will reinforce more the rightfulness of those traditional insight and wisdom with scientific evidences in the future.

8. Health, Healing, and Spirituality

(1). Power of Prayer

Considering the phenomenon of healing in the case of the Tibetan golden needle treatment, if the chanting was not based on Tibetan Buddhism, and if the chanting was from a different religion, for example, from the choir of a Catholic Church, would it be similarly effective to this Tibetan migraine patient? Probably Not. So here, we have to find out and observe the great importance of ones psychological, cultural belief systems, mostly deeply connected with religions.

Is our health closely related with religion? What is the relationship between health and spirituality? Is Medicine of Spirituality possible in this highly technological modern society? These topics are very big issues to discuss, but also very important for the soul of humankind. Dr. David Larson, MD, who was the President, National Institute for Healthcare Research in USA, scientifically confirmed the strong connection or interrelationship between health and spirituality. In short, spiritual aspects of life, the matters of spirituality affect human health clearly and strongly.

To pursue some aspects of these issues on this occasion, let me give you some interesting examples, related with the influence of spirituality to our health.

In all religions since humankind had appeared on this planetary earth, there has always been Prayer with us and our life together. Does Prayer work as medicine?

“Prayer works.” says Dr. Larry Dossey, MD, who is a famous scientific physician and author in USA on spirituality and medicine. He wrote “*Healing Words--The Practice of Medicine*” and “*Prayer Is Good Medicine*”, introducing the scientific evidences on the power of prayer this way;

“Prayer works. More than 130 controlled laboratory studies show, in general, that prayer or prayerlike state of compassion, empathy, and love can bring about healthful changes in many types of living things, from human to bacteria. This does not mean prayer always works, any more than drugs and surgery always work but that statistically speaking, prayer is effective.” (Larry Dossey, MD, *Prayer Is Good Medicine*; page 49)

And Dr. Larry Dossey, MD introduced and explained to me an amazing test case on the healing power of prayer this way;

“Byrd studied 393 patients in the coronary care unit of San Francisco General Hospital. All were given modern medical care, but approximately half were assigned to a group receiving prayer. The prayer groups were from all over the United States. This was a double-blind, controlled study, meaning that nobody knew who was being prayed for and who was not. The doctors, nurses, and patients did not know. The prayed-for group did better in several days. There were fewer cardiac arrests in the prayed-for group, and they had fewer cases of pulmonary edema (filling of the lung with fluid). This study is important because it shows that you can test prayer in the hospital like you can test drugs-in a double-blind, controlled way.”

(* Randolph Byrd. 1988. Positive therapeutic effects of intercessory prayer in a coronary care unit population. *Southern Medical Journal*. 1988; Volume 81, Number 7, pages 826-9.)

And he introduced another test case on the effect of prayer as follows;

“Another good study was by Sicher and Targ, looking at the role of distant healing and prayer in patients with advanced AIDS. Everyone was treated with conventional medications, but half were given distant healing or prayer. Again, this was a double-blind, controlled study. The prayed-for AIDS patients had fewer AIDS-related illnesses such as pneumonia, sepsis, encephalitis, and so on. The “healing” looked like a powerful medicine.”

(* Sicher F, Targ E, Moore D, Smith HS. A randomized double-blind study of the effect of distant healing in a population with

advanced AIDS - report of a small-scale study. *Western Journal of Medicine*. 1988; 169(6): 356-363)

But Dr. Larry Dossey, MD also knows the fact that Prayer and the matter of spirituality are also beyond the paradigm of Science. He also says; “Science cannot measure the unmeasurable.” (Prayer Is Good Medicine; page 21) and his definition of prayer is “Prayer is communication with the Absolute.” (*Prayer Is Good Medicine*; page 84)

These words guided me toward some profound meaning of religious mind and heart, and that reminded me one of my best friends in Saudi Arabia, Prof. Mansour Al-Said, Ph.D, who kindly taught me some teachings of Quran several times when we talked.

Then my intuition told me the ancient Islamic wisdom has something great and still very new in its teachings, is related with the matter on spirituality and health, which can be applied to today’s modern world and the future.

(2). Islamic Lifestyle Wisdom for Spirituality, Healing, and Health

Honestly saying, I am just the beginner, who is just learning about Islamic culture and religion, so my knowledge is very limited. My major interest is not just the knowledge, but the wisdom of Islamic culture. Fortunately I had some good opportunities visiting Islamic countries in the Arabian Peninsula, such as Saudi Arabia and U.A.E., and I experienced and touched some aspects of Islamic life and culture. My impression is Islamic life is strongly based on the teachings of Quran and Prayer. Prayer is the essential rhythm of Islamic peoples daily life like breathing the air.

My friend, Prof. Mansour Al-Said, Ph.D and his friends kindly showed me the way of praying during my stay in Riyadh, and that was beautiful. That impressed me a lot because their behavior of praying recalled me the importance of humble and sincere attitudes with appreciation toward invisible Something Great beyond humans, which maintains all the balance and invisible order of this world and the universe. Even the amazing structure of DNA and human genome in precise design of order cannot be created by humans. When we

forget these clear facts with too much technological knowledge, we human beings might become very selfish and arrogant, and probably humans might become the most dangerous animals on this planetary earth.

In Islamic life, I feel Prayer IS their everyday life. If prayer is Islamic everyday life, that prayer is just like our consistent breathing. Mostly we all forget the importance of breathing, but if we stop breathing too long, definitely we cannot survive. Probably so is prayer in Islamic spiritual daily life.

And especially from the viewpoint of healthy lifestyle and spirituality, it seems to me that Islamic lifestyle has some great wisdom, which is still new and meaningful in this 21st Century.

In my observation, Islamic Lifestyle has 3 major great wisdoms as Lifestyle Medicine; They are 1. Prayer, 2. Meditation, 3. Fasting. They look so traditional and simple from the ancient times, but now they will be another new light as a holistic approach for ones preventive health maintenance and healing, coping together with conventional medicine, through the new fields of study, such as Mind/Body Interactions, Psychoneuroimmunology, and Nonlocal Intercessory Distant Healing, and Diet Therapy.

First, as we already see it previously, Prayer is truly effective as therapeutic healing. Probably we cannot precisely explain why it works and how it works, but now we know it really works, supported by scientific, statistical evidences. Prayer is not religious superstition at all. Dr. Larry Dossey, MD points out the fact that Prayer is nonlocal, spontaneous, distance-free phenomenon. He described the characteristic of prayer this way; “ prayer is an attitude of the heart--a matter of being, not doing --- As an attitude of heart, it can be invisible, silent, still. “ (*Prayer Is Good Medicine*; page 83)

Obviously, 1. Prayer is; Spiritual, Nonlocal, Mental, and Mind/Body Interactive. Equally 2. Meditation is; Spiritual, Nonlocal, Mental, and Mind/Body Interactive, too. So Prayer is Meditation, and Meditation is Prayer. 3. Fasting: Regular Fasting, called Ramadan clearly has Spiritual value, too, and at the same time, Fasting has Physical, Physiological, and Body/Mind Interactive process of Detox-

ification and Purification in one's body. Traditionally Japan also has profound wisdom on Diet and Fasting.

I call these lifestyle wisdom of Islamic culture as “The Islamic Golden Rules of Wisdom for Spirituality, Healing, and Health Care”. They look so simple, that is why modern highly technological human beings tend to miss this tremendous importance of these Lifestyle Wisdoms.

In the nearest future, we will be able to prove more on the tremendous power and effectiveness of these ancient, traditional lifestyle wisdoms by advanced science and high technology.

I want to encourage all Islamic countries should conduct big, new scientific researches on this potential area of traditional wisdom. Surely you will discover another many new scientific evidences under the new light. So it means that those Islamic ancient and traditional lifestyle wisdoms will be highly reevaluated and revived strongly in the future of this 21st Century all over the world.

“Ask the Old, Find Out the New. ”---These simple words show the way for the future of Islamic Wisdom beyond modernization and westernization. My intuition clearly tells me Islamic lifestyle traditional wisdom is very old indeed, and still very new and valuable for the future of humankind

9. Modern Versions of Hippocratic Medicine - US and Japan

(1). Modern Version of Holistic Approach as Lifestyle Medicine

Can traditional low-tech intervention of lifestyle approach be clinically effective with scientific evidence?

One of the most successful cases of lifestyle medicine is probably the Dr. Dean Ornish's Program for Reversing Coronary Heart Disease.

Dr. Dean Ornish, MD is the President & Director of Preventive Medicine Research Institute, University of California, San Francisco, USA and he successfully proved the fact that atherosclerosis can be reversible by changing lifestyle fundamentally without using any drugs.

His research was reported in *Lancet*, 1990 as the scientific research papers, entitled, “*Can lifestyle change reverse coronary heart disease?*” (*Lancet* Vol.336: p.129 - 133, 1990). And it brought him some remarkable reputation and sensation in mass media. But amazingly his approach of lifestyle change looks very simple. I will try to summarize the essential key points of his program.

The key points of the important essence in Dr. Dean Ornish’s Program are as follows; 1. Stop Smoking, 2. Low-Fat Vegetarian Diet, 3. Stress Management, 4. Moderate Exercise 5. Group Emotional Support. ----- That’s all.

In this Low-Fat Vegetarian Diet, the fat intake must be less than 10% of the total calories and cholesterol from food should be less than 5 mg per day. And No animal food.

As for the Stress Management, Meditation and Guided Imagery with visualization are conducted for the effect of relaxation response. Obviously Meditation holds spiritual meaning beyond just the technique of relaxation.

For Moderate Exercise, patients do Yoga and Walking. And clearly Yoga has the effect of relaxation response. Walking has to be moderate and enjoyable. Those physical exercises should never be competitive.

In Group Emotional Support, patients naturally share their own experiences and encourage each other. So patients can eliminate the feeling of isolation. Patients are walking together for the better toward a new transformation of life. It also creates healing environment for patients naturally. And this process also can be Meaning Therapy to explore the meaning of life.

Here, the crucially important thing is that you cannot separate these key factors. It is “one holistic package” approach, so you cannot separate it into parts. For example, if you just apply only the part of Low-Fat Vegetarian Diet to patients, it cannot make successful results. The Low-Fat Vegetarian Diet is important, but it is Not everything. The whole system of one-packaged holistic approach IS important, and it works effectively. This is the key.

It is clearly similar to the principle of holistic healing by the Golden Needle Treatment of Traditional Tibetan Medicine. The Golden Needle Treatment itself is important, but that is Not everything. It also worked as the whole system of one holistic approach. There is no separation in holistic healing.

Overall, Dr. Dean Ornish's Lifestyle Medicine approach looks like the modern version of ancient Hippocratic Medicine.

Surprisingly the clinical result of this traditional low-tech intervention was much better than the result of modern allopathic conventional medicine. The Lancet report says 82 % of the low-tech experimental group patients acquired remarkable improvement after only 1 year. (*Lancet* Vol.336: p.129 - 133, 1990) And, compared with the high medical cost of bypass surgery, Dr. Dean Ornish's Program may save approximately US \$ 50,000 per patient and also save the hospitalization cost.

Because of this clear, realistic result of cost-effectiveness, Mutual Omaha and other health insurance companies (over 40 companies) decided to apply their insurance to Dr. Dean Ornish's Program for the reimbursement.

The interesting thing is the fact that the effect of this low-tech intervention was proved by very high medical technology together with the result of clear cost-effectiveness.

And Dr. Dean Ornish, MD got the idea of this lifestyle approach originally from ancient, traditional, Asian wisdom of Yoga, when he came across his identity crisis at his medical school.

Why don't you try to prove the effectiveness of Islamic traditional lifestyle wisdom to reevaluate it and revive it strongly in this modern, materialistic society?

As I told, Ask the old, Find out the New.

(2). The Concept of Integrative Medicine and its Clinical Education

As we have seen so far, we can find out the new value of Traditional Wisdom. Complementary and Alternative Medicine (CAM), and Traditional Medicine---they are the great resource of

holistic wisdom for holistic care. Then is allopathic modern conventional medicine not useful at all? I do not think so, either. I think there are the benefit of CAM approach and also the benefit of modern conventional medical approach. They can be complementary to each other because they are different, therefore they can help each other to help patients for the patients' best interest.

Dr. Andrew Weil, MD, the famous author of "*Spontaneous Healing*", the Program Director, Program In Integrative Medicine, and the Clinical Professor of Medicine, University of Arizona, clarifies the crucial points on the relationship between Conventional Medicine and Unconventional Medicine (CAM and Traditional Medicine). He says Conventional Medicine works very effective as Crisis Medicine for trauma and surgical emergency. Yes, he is quite right because it is not reasonable, or not a good idea for you to go to an herbalist when you got injured seriously by a traffic accident. Absolutely you'd better go to conventional medical hospital, which can cover emergency care.

Dr. Andrew Weil, MD successfully clarifies the different roles of both Conventional and Unconventional Medicines as follows in his book, "*Spontaneous Healing*";

Conventional Medicine CAN: 1. Manage trauma better than any other system of medicine, 2. Diagnose and treat many medical and surgical emergencies, 3. Treat acute bacterial infections with antibiotics, 4. Treat some parasitic and fungal infections, 5. Prevent many infectious diseases by immunization, 6. Diagnose complex medical problems. 7. Replace damaged hips and knees. 8. Get good results with cosmetic and reconstructive surgery, 9. Diagnose and correct hormonal deficiencies.

And Conventional Medicine CANNOT: 1. Treat Viral infections, 2. Cure most chronic degenerative diseases, 3. Effectively manage most kinds of mental illness, 4. Cure most forms of allergy or autoimmune disease, 5. Effectively manage psychosomatic illnesses, 6. Cure most forms of cancer.

(Andrew Weil, MD, *Spontaneous Healing*: pages 225-226)

The area of "Conventional Medicine CANNOT" can be the

potential area for CAM and Traditional Medicine, which probably have the strong capacity for solving those problems by applying them. The role of CAM and Traditional Medicine is there to explore and investigate their potentials.

So Dr. Andrew Weil, MD prefers the term of Integrative Medicine to Complementary & Alternative Medicine, meaning to combine the best choices of both medicines effectively and harmoniously for the patients' best interest. Clearly the issue of Conventional and Unconventional Medicines is not either-or issues. This has to be both-and, and beyond both of them.

Dr. Andrew Weil, MD already started the Fellowship Program In Integrative Medicine for the 2 year medical educational training of MDs and DOs, at University of Arizona, and the first fellow doctors started the training course in 1998 and graduated in 2000. Also under the name of Associate Fellowship Program, the 2 year course of Internet-based, Distributed Distance Learning Program In Integrative Medicine started in 2000.

The Core Curriculum of the Fellowship Program In Integrative Medicine is as follows; 1. Philosophical Foundations---(1). Healing-oriented Medicine (2). Philosophy of Science (3). Medicine and Culture (4). Art of Medicine (5). Research Education (6) Ethics, 2. Lifestyles Practices---(1). Mind/Body Medicine (2). Nutritional Medicine (3). Spirituality & Medicine (4). Lifestyle Practices & Illness Prevention, 3. Therapeutic Systems & Modalities---(1). Botanical Medicine (2). Manual Medicine (3). Chinese Medicine (4). Homeopathy (5). Energy Medicine (6). Guided Imagery & Hypnotherapy, 4. Personal Development & Reflection---(1). Meditation (2). Relaxation (3). Self-Examination, 5. Clinical Integration---(1). Art of Integration (2). Personal Integration, 6. Forwarding the Field/Implementation---(1). Leadership, Medicine & Society (2). Physicians as Agents of Change

(For more specific information on Program In Integrative Medicine at University of Arizona, check this Web-site: <http://integrativemedicine.arizona.edu/>)

I think this is the very first realistic medical training course for clinicians on Integrative Medicine as challenging trials. Fortunately

Dr. Andrew Weil, MD has been a good friend of mine for more than 10 years, so I visited him directly in Tucson, Arizona to see the Integrative Medicine Clinic and the Program activities.

The Integrative Medicine Clinic at the medical center was different from the ordinary clinics at the medical center. More green plants are in the waiting room, and relaxing CD music is being played in a room. The first interview of a new patient is at least 1 hour, and, from the second interview, it will be about 30 minutes. Not just 3-5 minutes typical hospital interview after waiting for a long time in the waiting room at the University medical center. Patients have to make a reservation in advance. Community Medicine is emphasized, so community people have first priority for the consultation. Each Program Fellow doctor reported to Dr. Andrew Weil, MD about the diagnosis of one's patients after the interview.

Every Monday afternoon, there is a clinical discussion session on each patient's case. The session conductor is Dr. Andrew Weil, MD, and Pharmacist, Homeopath, Nutritionist, Psychotherapist, Hypnotherapist, Guided Imagery Specialist, Traditional Chinese Medicine Specialist, Acupuncturist, Osteopath, Herbalist and other Fellow MDs gathered, sit down together around a table, and discuss each patient's case one by one. It is just like a brain storming session. The session goal is very clear. They get together to find out the best solution for each patient. Therefore, each participant in discussion is very open-minded, and tries to listen carefully to each other's comment of various perspectives. So there is no conflict of bias and opinions. They just focus on how to help patients in a best way. That is the only goal to reach. I was very much impressed by that scene. In that session, there is no contradictive conflict between Conventional Modern Medicine and Unconventional CAM. Sometimes their views are different, but they just try to find out the best solution for each patient. If a patient comes really first in priority, there is no contradiction for helping a patient in actual practice. That is really amazing. That is what the way of Integrative Medicine is all about, and this is a good, cooperative team work for Integrative Care towards one clear

goal: “Help and Heal patients. ” Actually this is the real essence of all medicines.

In addition, personally I call my friend, Dr. Andrew Weil, MD as “Modern American Hippocrates”, who is the father of modern, clinical Integrative Medicine.

(3). A Japanese Holistic Care Hospital for Cancer Patients

Let me introduce some information on what is going on in Japan about Complementary & Alternative Medicine and Integrative Medicine.

In the long history of Japan, the term, Oriental Medicine has been very close to us, so many people, including medical and health care professionals in Japan tend to feel strange about the term, Complementary and Alternative Medicine. It is very western words, which regards Conventional Western Medicine as the center of domination.

Especially Kampo medicine is very familiar to most of Japanese people, including medical and health care professionals. Kampo means, in short, the Japanese-arranged, traditional Chinese herbal formulas, which are applied to the natural environment of Japan and the Japanese people’s body constitution. Kampo medicine is so familiar with us Japanese, so if you ask, “Is Kampo Alternative Medicine?”, then many Japanese people will say “No.” Then if you ask “Is Kampo Oriental Medicine?”, then most of Japanese people will say “Yes.”

According to the recent survey of Dr. Jiro Imanishi, MD, Ph.D, who is the professor of Kyoto Prefectural Medical College, 73 % of clinic-based medical doctors in Kyoto prefecture accept Kampo as one of the effective medical agents. Especially for clinicians, Kampo is a naturally acceptable medical intervention. But the problem is most of physicians did not learn the essential theory of Kampo and Oriental Medicine, so many doctors tend to use Kampo like allopathic drugs. On the other hand, acupuncturists and other Oriental Medical experts cannot prescribe Kampo medicine to their patients, even they know the theory of Kampo and Oriental Medicine better than conventional

medical doctors. Legally only conventional medical doctors can prescribe any kinds of medicine, including Kampo.

One of the advantages of the Japanese National Health Insurance Policy is that this National Health Insurance covers many kinds of Kampo herbal Medicine. In fact, it covers 152 kinds of Kampo herbs, and 147 kinds of Kampo formulas. Compared with the health insurance policies of other countries on CAM, this Japanese Health Insurance system looks very advanced in a sense. But, on the contrary, the Japanese Ministry of Health and Labor is still very rigid and conservative about CAM. Paradoxically, under the name of Evidence-based Medicine, the Japanese Ministry of Health and Labor tends to try suppressing more on Kampo Medicine and CAM.

Under this very paradoxical, ambivalent, and complicated situation on CAM in Japan, there is one very exceptional hospital, which focuses on holistic and integrative care to cancer patients. The name of the hospital is the Obitsu Sankei Hospital, founded by Dr. Ryoichi Obitsu, MD in November, 1982. Dr. Obitsu, MD is originally a surgeon and oncologist, and the overall structural information about this hospital is as follows;

The hospital has 99 beds, and the outpatients are approximately 250 patients per day. This hospital has approximately 120 staffs. There are 14 MDs; 7 regular doctors and 7 irregular doctors. And there are 67 Nursing staffs; 45 nurses and 22 nursing assistants. And there are 10 nutritionists, 3 acupuncturists, 5 pharmacists, 2 psychotherapists, 2 aroma therapists, and others.

In this hospital, mainly serious or terminal cancer patients are being treated by the choices of conventional approach, Diet therapy, Kampo, Nutritional Supplements, Chi Gong, Guided Imagery, Tai Chi, Tanden abdominal breathing, Aromatherapy, and Homeopathy, and so on. Each medical doctor tends to play the role of a guide for a patient. The patients mostly can make the best choice of treatments and they can select the treatments they want. In this hospital, most of the patients are the serious cases of cancer, but those patients are very positive and active with strong hope for life and healing. They focus

on the now and today to live it fully with the sense of fulfillment in life.

There is one story telling us about the attitude of the patients of the Obitsu Sankei hospital. Dr. Carl Simonton, MD, who is a very famous doctor and expert of Guided Imagery to cancer patients in USA, once visited this Obitsu Sankei Hospital, and he was very welcomed by the big applause of all the serious cancer patients, who had been waiting for him. Because of the warm, pure, and bright energy from the heart of those serious cancer patients, Dr. Simonton was so much moved very deeply and strongly, and got into tears with warm, heartfelt sensation.

The Obitsu Sankei Hospital emphasizes the holistic and integrative care to cancer patients, and the way of their living as humans. In reality, the National Health Insurance of Japan cannot apply to most of the CAM treatments at the Obitsu Sankei Hospital, but it does not matter much for Dr.Obitsu, MD. His smile is beautiful like the vast, blue sky over the land of Mongolia, where he likes best.

(4). Japanese Organizations on CAM and Integrative Medicine

As for the organizations on the activities on CAM and Integrative Medicine in Japan, one is the Japan Holistic Medical Society (JHMS), which was established in 1987, and I am one of the founders. The JHMS is mainly the activities of grassroots health care movement for the philosophy of Holistic Medicine. This 2002 is our 15th anniversary year, and the JHMS was officially recognized as Non-Profit Organization(NPO) in this 2002. The JHMS now holds 2000 members in Japan. The objective is more focused on the information network and lifestyle preventive health care by education for health care professionals and the general public.

More professionally, the Japanese Association for Alternative, Complementary, and Traditional Medicine (JACT) was established in 1998, especially for medical professionals by the effort of Dr. Kazuhiko Atsumi, MD, Ph.D. Dr. Kazuhiko Atsumi, MD, Ph.D is an internationally famous medical doctor of Conventional Medicine, in the field of advanced medical technology. He is the top frontier of

Laser Surgery, Computer Medicine, and Artificial Organs in Japan. And especially he has the world record of the animal survival by his Artificial Heart. But he found out the limitation of Conventional Medicine, so he bravely shifted his way to focus on the field of CAM and Integrative Medicine. He connected 10 different kinds of associations, related with CAM and Oriental Medicine in Japan, and is trying to make this CAM field a bigger main stream in Medicine, by educating medical professionals. As the President of JACT, Dr. Atsumi, MD, Ph.D established in 2000 another connected association, the Japanese Society for Integrative Medicine (JIM), which aims at focusing more on academic research and conference, connected with other international conferences and institutes on CAM and Integrative Medicine in overseas. Now the JACT has approximately 1100 members (mostly medical and health care professionals), and the JIM has 400 members (mostly medical professionals and researchers). Dr. Atsumi, MD, Ph.D had been the professor of medical engineering at Tokyo University, Faculty of Medicine for 25 years. And he is a very influential person as one of the executive board members for the Scientific Council of Japan. And he was nominated for Nobel Prize in the past, and recently he predicts strongly, by saying “Definitely the Integrative Medicine will be the future of medicine in this 21st Century.”

Dr. Atsumi, MD, Ph.D and JACT executive board member staffs are planning to organize the World Congress on CAM and Integrative Medicine in the near future of 2006 for the global meeting of the East and the West in Tokyo, Japan.

10. Beyond Evidence-based Medicine

Recently the trend of Evidence-based Medicine is coming up strong in all areas of Medicine. Surely Evidence is important in all areas of Science, and so is in Medical Science.

Obviously, in the flood of too much abundant professional knowledge and information in medicine, Evidence-based Medicine is crucially important for all medical and health care professionals to let

them make more accurate & precise choices of treatments and its applications for the better patients' care.

On the other hand, as we have seen, Medicine originally covers a very comprehensive and holistic area, which needs both Science and Healing Art. Patients need more human touch for healing by holistic care, together with the accuracy and safety of treatments, informed by Evidence-based Medical Science.

Whereas, as we have seen, originally traditional medical approach mostly cannot be divided into separable parts of treatments. So is other CAM approach. Because the system of traditional medicine is mostly a holistic and comprehensive approach to the whole being of a patient, who is the inseparable living entity of the physical, psychological, and spiritual being. Also a good Doctor-Patient Relationship itself can be a very powerful therapeutic relationship, which can be very effective as the art of healing, not only for the patient but also for the doctor oneself.

Evidence-based Medicine is strongly based on Reductionistic Science, asking for the Quantity of data first, which usually cannot explore the meaning of Quality and neither the synthesized meaning of inseparable connections and interdependent relationships in the process of healing.

It is often told that the Gold Standard of Evidence-based Medicine is Randomized Controlled Trials (RCT).

Randomized Controlled Trials (RCT) are totally based on one major premise that one drug, or one treatment should be equally effective to most of (or, statistically significant numbers of) people. This major premise is based on the concept that each person is equal or similar.

Whereas, the major premise of Traditional Medicine and other Complementary & Alternative Medicine(CAM) is mainly based on the concept that each person is different.

Therefore, logically speaking, very clearly RCT has some crucial limitation to evaluate the systems of Traditional Medicine and CAM. This RCT evaluation approach is appropriate and effective for the

judgment of allopathic drugs and treatments, but RCT cannot judge everything as the Gold Standard.

And the problem is RCTs usually cost too much, and take very long time. The fact is the large scale of RCTs is possible mostly by big pharmaceutical companies and by government institutions. So No money, No RCTs. This is an evident fact. That is why big pharmaceutical companies and other big medical industries come out very strong, almost dominating the RCT researches because of the money. And it is inevitable that those medical industries obviously tend to pay for the RCT researches mainly for the benefits of their business. That is the problem. If medical commercial business initially governs the direction of RCT researches, then how can we trust it? So consumers should be alert.

More than the Quantity-based research, we need more the Quality-based research to understand the systems of CAM and Traditional Medicine. And we need to pay more attention to patients themselves and explore their own innate healing abilities. How our healing system works? - this crucial question has to be explored more deeply and strongly. This is more important than the questions to find out some new allopathic drugs for the countless numbers of diseases, with which we are often getting nowhere.

Additionally, we need to explore more the Quality of medical and health care services from the viewpoint of Patient-oriented, holistic care with human touch & heart, which are probably immeasurable. Do not forget the word of Dr. Larry Dossey, MD, "Science cannot measure the unmeasurable."

Evidence is important, but the most important is the patients, who need medicine, medical care, and healing. In medicine, if patients come first above all, obviously scientific evidence should be beneficial first for the patients, not for the business purpose of pharmaceutical industries.

If patients come first, then patients' healing should be the central issue to be the base of medical care. Evidence just supports the patients' healing by the proof of safety and efficacy of medical and therapeutic interventions. So Evidence-based Medicine (EBM) is not

essentially the suitable words, because it gives us the impression that Evidence always comes first, more than the reality of a living patient. If too much Evidence-dependent doctors are just focusing on reading scientific papers of evidence on the desk, and not paying much attention to observe a living human patient directly in front of him/her, then those doctors might conduct cold, mechanic malpractice, with no human touch and heart. So, in my definition, if patients really come first in medicine for healing them, it should be beyond Evidence-based Medicine, it must be Evidence-supported, Healing-based Medicine (EHM).

11. The Essence of Integration of Medicine—Toward Holistic Care & Healing by Integrative Medicine

The Integration of Medicine obviously does not mean the modern westernization of Traditional Medicine and CAM. If Western Conventional Medicine just wants to use some partial techniques of Traditional Medicine and CAM as easy & handy supplements, which can be attached to the Main Stream Medicine, without any respect and real understanding, then it looks quite similar to the way of exploitation or western colonization over Traditional Medicine and CAM. I do not agree to the relationship of “Conventional Western Medicine is always the Master, Traditional Medicine and CAM are always the Servants, and vice versa.” It is not fair.

As we have seen, the root essence of both Eastern and Western Medicines is quite similar, and modern conventional western medicine has just gone too far, so quickly with medical technologies, away from the original root philosophy of Medicine for these 150 years. Originally the essence of all Medicines is similar in the East and the West.

In fact, Modern Conventional Western Medicine and Traditional Medicine & CAM ---- Both systems and approaches look very different and contradictive, representing each system as a totally different paradigm. That is why we need to remember that the root philosophy of both medicines is similar.

When a patient needs help and expects the best possible medical care, which is safe, clinically effective, cost-less, and preventive, it is

very logical and reasonable to make the best choices of both areas of medicine for the patients' best benefit.

If the mission of medicine is to help the patients first of all, we can set up a clear goal that the purpose of medical care is "for the patients best benefit".

Analogically saying, when a person is being drowned in a river, asking for help, do we waste our time, arguing which way of approach might be right or wrong? Obviously, beyond race, religion, and nationality of the person, we just try our best to find out the best and quickest way from all possible choices to help and save a living human being safely. This is what the essence of clinical Integration of Medicine is all about.

The reality of a patient is in front of us, then for the patient's best benefit, those different systems and approaches can work together complementarily like Yin and Yang, or like the marriage of female and male, as a holistic care by Integrative Medicine. The core idea is that they are different, that is why they can help and work together to reach one clear goal: "Help and Heal a patient".

But we cannot force both areas of medicine to combine directly.

Let me give you a specific analogical example. It is like the relationship of Oil and Water. Usually Oil and Water CANNOT be mixed up. Many western scientists have been trying to *force* them to be mixed up as emulsion fuel for the practical use nearly for 30 years, but they could not make any success. But the only exception is a Japanese scientist, Dr. Osamu Yamanaka, Ph.D. He did not force Oil and Water to be mixed up. Instead, he used some catalyzers to *harmonize* the conditions of both of them, after clearly understanding the whole differences of both characteristics, and finally he made a very successful, practical emulsion fuel from the mixture of Oil 50% and Water 50%, which burns completely *without* Oxygen and produces *quite* less Carbon Dioxide. Personally I had a chance to watch the burning experiment. It is really surprising, but it is true.

The key of successful Integration is *Not to force them* to combine

directly, but *to harmonize them naturally* through the effects of the catalysis. We cannot be against natural law.

I feel strongly the same principle for the Integration of Medicine analogically. For the successful Integration of Medicine, beyond modern westernized globalization, we need such kinds of catalyzers to harmonize the both areas of medicine. The catalyzers must be discovered through our flexible creative thinking, with multiple value perspectives, considering various cultural diversities, cultural belief systems, religions, and also the matters of spirituality.

In my observation, the catalyzers for the successful Integration of Medicine are mainly human quality factors, which contain; 1. Patient-oriented Goal, 2. Wisdom, 3. Philosophy, 4. Fair Open-mindedness, 5. Humanity, and 6. Insight for Complexity Science. Without those ingredients of the catalyzers, the trials for the Integration of Medicine will remain contradictive.

Dr. Truong Thin, MD, the Director of Traditional Medicine Institute, Ho Chi Minh City, Vietnam, kindly explained to me the structure of Traditional Medicine. He says that the structure of Traditional Medicine is; 1. Philosophy, 2. Ethics, 3. Art, 4. Technology, 5. Science. I was very much impressed and moved by his clear thought. Not only for Traditional Medicine, this is the structure of balance and the essence for all medicines, which we should not forget.

If we keep that wisdom in mind and heart, then we can go forward to explore the meaning and application of holistic care and healing for patients by Integrative Medicine.

Lastly, I firmly believe that Islamic traditional culture embraces profound wisdom and insight for the future of health care and medicine of all humankind. So let us ask and explore the Islamic old traditional wisdom to discover the new. Please be proud of your own traditional wisdom, which is very old and very new. And please keep the wisdom strongly alive for the future of health and spirituality of all humankind.

Thank you very much for your attention.

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- 12 - *Is Integrative Medicine The Medicine of The Future?: A Scholarly
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DISCUSSION

Discussion of Second Session Fundamentals of CAM

Chairman: Prof. Hussein Al-Gezairy

Rapporteur: Hakim Abdul Hannan

Prof. Hussein Al-Gezairy: We would like to give chance for some questions now. Yes, please.

Participant: While in the morning, we spoke of Alternative/ Complementary Medicine, a number of questions were raised in my mind. Treatment with herbal medicinal plants and therapy to those subjected to in CAM, there is an important aspect namely spiritual or belief or the relationship with the religions and therapy. I would like to clarify very briefly the concept of Islam in treatment. Islam is a practical religion, which does not deny that God has created illness and treatment and Prophet (SAW) said that you can cure your patient with invocation and supplication. In this field, I think relationship between religion and complementary medicine required specialized seminar and number of researches are required, but to speak of Sufism and exaggerate Sufism and we leave Science, I think this would be tantamount to exaggeration. Thank you!

Prof. Hussein Al-Gezairy: I believe that one of the lectures this morning spoke up all that is required. I agree with you on what you said.

Participant: I would like to thank the IOMS for having organized the seminar. We are in a need to examine Alternative Medicine in our region. There is only difference between reality and imagination, to exaggerate in killing the human body to uphold the spirit is not accepted by Mohammed. Some one said I will not sleep tonight, but Prophet (SAW) said “God has created morning to work and night to sleep”, to exaggerate to killing the human body and to give important role to spiritual sight will be counter against nature. We would like to come to an end to these superstitious and meta-physical things. We wanted to put an end to that.

Dr. Howard Hall: When I started research on Sufism, it was much

understood that many orthodox Muslims had much antagonism against such concepts. I do appreciate that. I do what you understand that there is no harm done during these practices from a scientific point, these are very remarkable, the people hear, there is no pain or sufferings. And as a scientist from the west, I felt compelled to explore this.

Prof. Hussein Al-Gezairy: I am sure Dr. Hall, nobody is going to ask you not to follow it. But it is important and I think, this does happen as we have heard also from Dr. Otsuka that in other religions. So, it cannot be called Sufism or should not be directly linked to Islamic teachings. Yes, please..

Dr. Ibrahim Farooq: I am a Journalist in Al-Ahram. I would like to thank the organization for having sponsored this kind of seminar, which is of tremendous importance to put facts and to make difference between Complementary and Modern Medicine. In Islamic Medicine, there is something that could be scientific or put in a scientific setting. Haggama is of Islamic origin, we could use it. We could put it in scientific framework. I think, we should have a database, for Complementary Medicine that could be placed in a scientific setting and framework.

Participant: Thanks to Dr. Hussein and to my colleagues who presented their lectures. I would like to magnify one thing. There is something mentioned by Dr. Koshiro. The issue of prayers which is linked between the supplication and remembrance of God. It could be either prayer or anything else, if as I think we believe in that, means to impose Sufism in therapy. It may be useful to remember, what was said at the beginning of the conference. The objective suits from this meeting, but it is required for us to know how and to what extent we can include some old traditional medicine with Modern Medicine, so that we can secure health benefits and minimize cost.

Dr. Ali Haeri: Because it is a sensitive and critical issue, I would like to re-emphasize what my colleagues say that Almighty Allah orders us to do research and follow science. And “*Allajeena yatafakkaruna fee khalkis samawati wal Arz*”. Many other verses of the Holy Quran orders the human to be, I think, a researcher, scientist and

knowledgeable. “*Innamaa yagshallaha min ebaadihi walama*” and so on. At the same time, there are all secrets of revelation that we are not quite aware of. Science may reveal according to certain phases of human knowledge and evolution. They reveal some secrets, still we don’t know if they are these secrets. “*Wama Vudeetu minal Ilmi illa Qaleela*” (Whatever knowledge you may have is little). So, what we do is that we try to explore and explain the phenomenon and the nature through our knowledge of science and research. But, if we want to correlate that absolutely, that is the deed of God or this is what Islam has absolutely mentioned or solely this is the solution/result of the answer. I would like to emphasize here that all these are deeds of God, no doubt. But co-relation and relativity and relationship of these phenomenons and physics are the secrets of their creation, it still remains to be fully understood and I think time will come where God has promised that this will happen. “*Sanuriya hum aayaatina fil afaaki wafee an-fusihim hatta yatabayyana lahum annahul haqq*”. But until we reach there, because many people say a lot of things about fasting, it is true, but that is not the secret of having fasting. Many people talked about the prayers, there are many hadiths and many things that makes us understand why prayers are good, but that does not mean that it is the secret of revelation of prayer. - Thank you very much!

Prof. Hussein Al-Gezairy: We request Dr. Al-Awadi to chair the last session of today. - Thank you!

Third Session
Saturday, 12 October 2002
Spiritual Dimension
and its Power

Chairman : Dr. Abdul Rahman A. Al-Awadi

Rapporteur : Prof. Anis Ahmad Ansari

Speakers:

1 - Dr. James S. Gordon (U.S.A.)

2 - Dr. Ibrahim B. Sayed (U.S.A.)

**MIND-BODY MEDICINE:
MAGIC OR TRUTH? AND ITS
POWER FOR HEALING**

Dr. James S. Grdon

(U.S.A)

Mind-Body Medicine: Magic or Truth? Yes

James S. Gordon, M.D.

Director, The Center for Mind-Body Medicine

42% of all Americans Using CAM in 1997

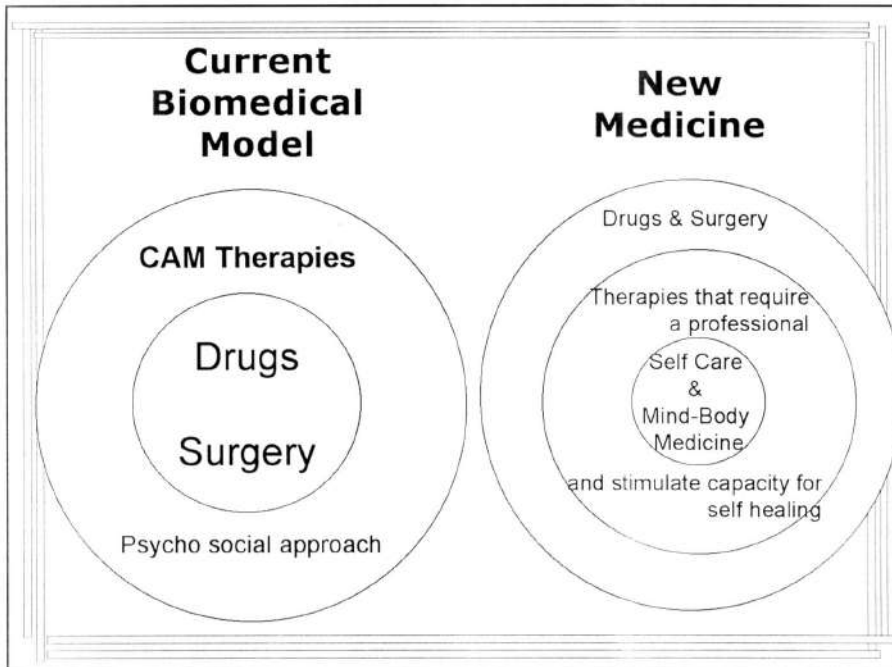
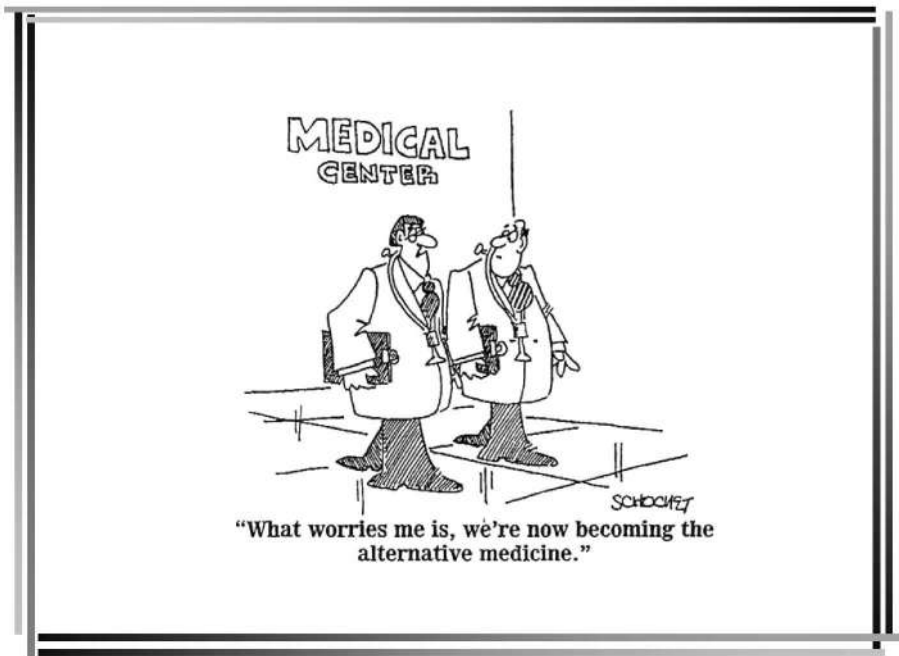
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Self Care and Mind-Body Medicine are the Heart of All Health Care

- Self-Awareness
- Relaxation
- Meditation
- Imagery/Self-Hypnosis
- Exercise
- Nutrition
- Prayer

Truth and Magic

The transforming power of belief,
expectation and attitude.

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The Central Role of Self-Care and Mind-Body Medicine

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B. DRAWINGS

C. MOVEMENT and EXERCISE

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The Central Role of Self-Care and Mind-Body Medicine

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Group Support

- A universally applicable approach
- The research is as good as that for many standard treatments

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Group Support (cont.)

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The Work In Kosovo







Post Traumatic Stress Syndrome Criteria for Diagnosis and Treatment

Re-experience of the Original Trauma

- Intrusive Recollections
- Nightmares
- Flashbacks
- Intense Distress at Reminders of the Trauma





Post Traumatic Stress Syndrome Criteria for Diagnosis and Treatment

Avoidance Responses to Alleviate Anxiety

- Avoiding Trauma-Related Thoughts and Feelings
- Avoiding Trauma-Related Activities and Situations
- Psychogenic Amnesia
- Diminished Interest in Significant Activities
- Feelings of Detachment and Estrangement
- Restricted Range of Emotion
- Sense of Bleak Future



Post Traumatic Stress Syndrome Criteria for Diagnosis and Treatment

Persistent Increased Arousal

- Sleep Disturbance
- Irritability
- Concentration Impairment
- Hypervigilance
- Exaggerated Startle Response
- Heightened Physiological Increased Heart Rate
 - Sweating
 - Reactivity





Mind-Body Medicine

The understanding and the
experience of the interconnection,
indeed,
interpenetration and inseparability,
of mind and body.



Mind-Body Medicine

Mind-body medicine uses a variety of approaches

- self-awareness, relaxation, imagery, meditation, exercise, yoga, qi gong and self-expression
- to mobilize the mind to affect and transform itself and the body, and to mobilize the body to affect and transform the mind.

Mind-Body Techniques and Self-Care

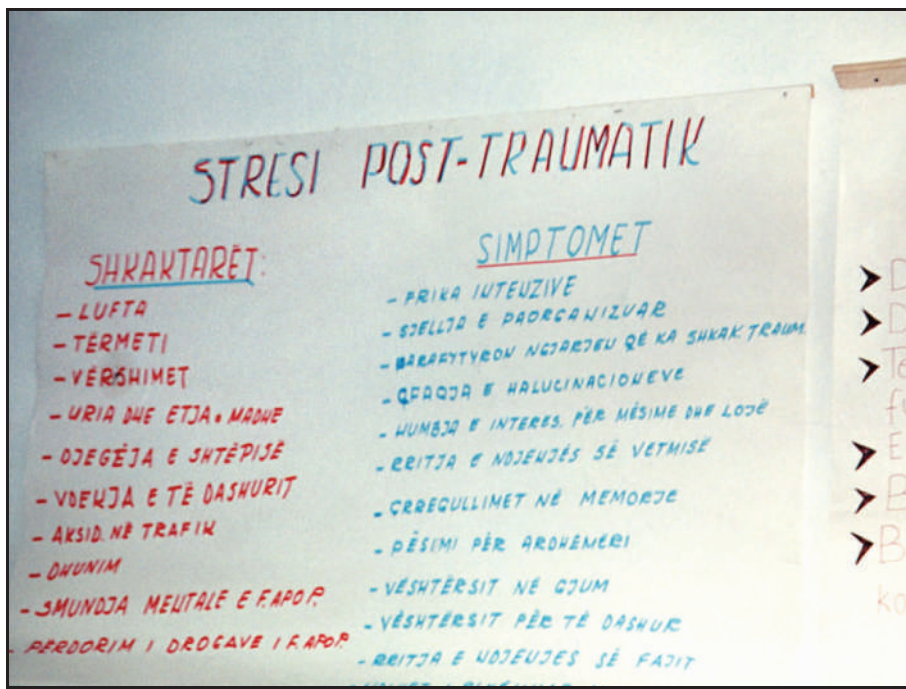
- Self-awareness
 - Journals
 - Drawing
 - Genograms
- Relaxation
- Autogenics and Biofeedback
- Meditation
- Imagery
- Exercise
- Nutrition

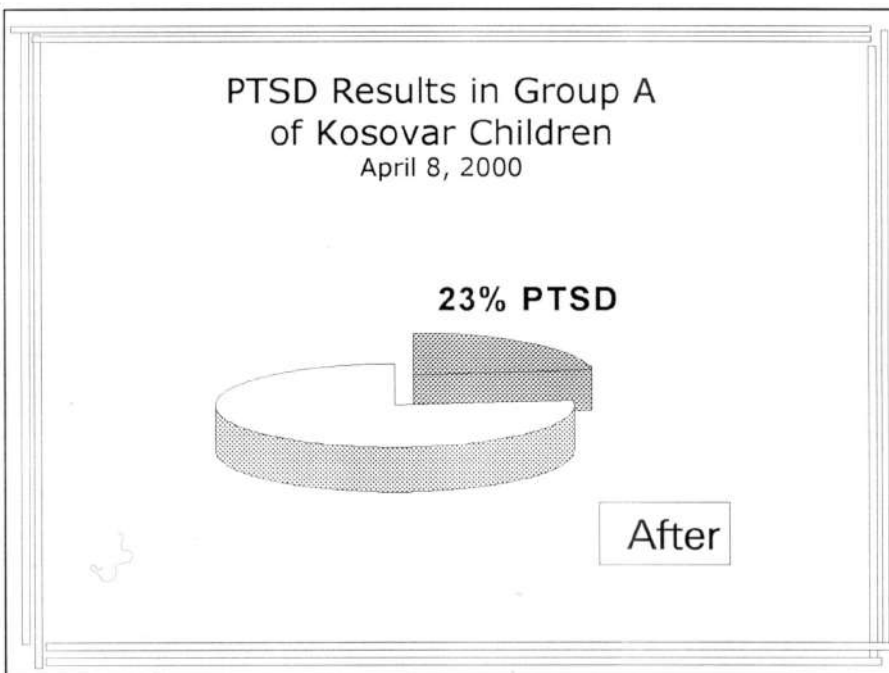
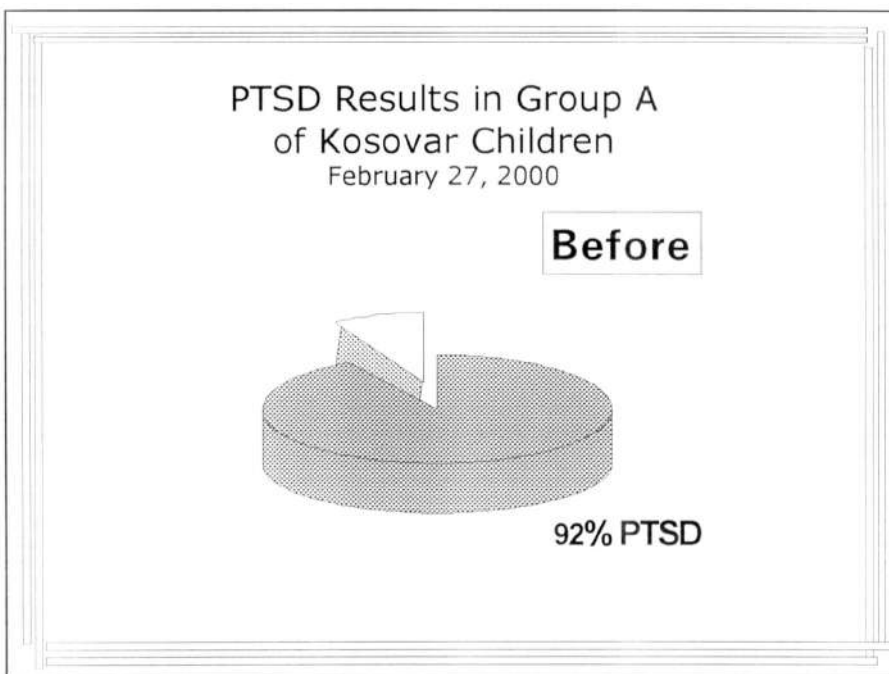
Dealing With Trauma in a Group

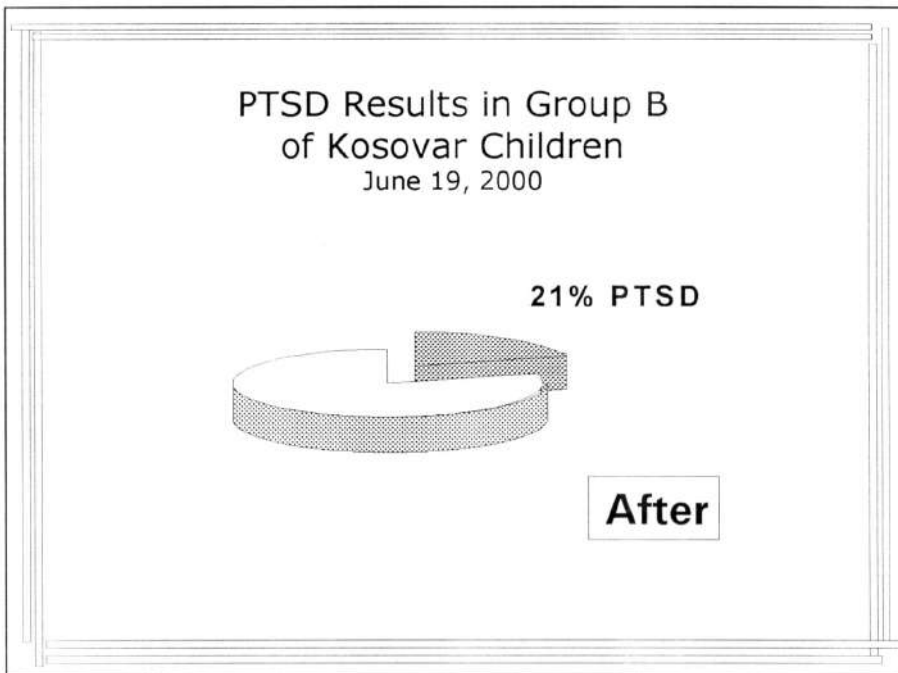
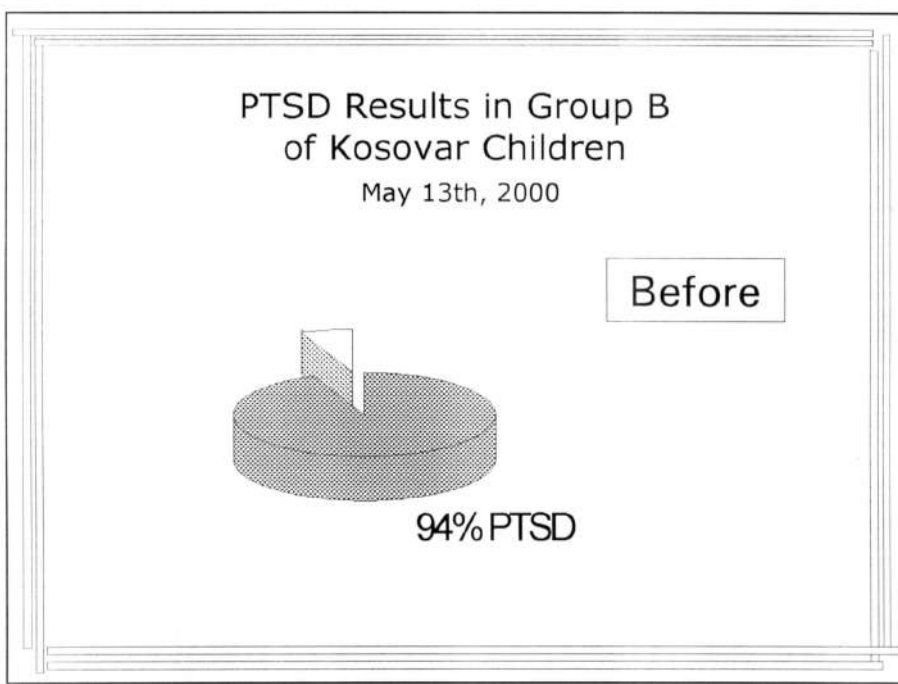
Mind-Body Skills Groups are Designed to Create a Safe Place in which to Learn Techniques to:

- Engage people in helping themselves
- Restore sense of control
- Give a new perspective on, and some distance from, traumatic events
- Quiet physiologic arousal
- Decrease intensity of re-experiencing trauma
- Allow, not force, self-expression and sharing
- Help people shift their focus from past trauma to present experience
- Provide a context for understanding trauma
- Provide an opportunity to use lessons from one's own healing to help others









Comments from students after completing the group work

"I come from the village of Reshtan, which was isolated for two years because of the war. The Serbs killed my father and burnt down my house. That's what made me feel so upset about my destiny. After a talk with the psychosocial groups, the test and the treatment the things changed quickly to me. Now I love the life again and I'm quite hopeful for a better future."

- *Sami Bytyqi (16 a)-Reshtan Students of the III year Gymnasium*

"Jeta e Re"-Suharekë, KOSOVË

Comments from students after completing the group work

"My name's Albulena Berisha. I'm from Suhareka. I'm attending the VIII grade of elementary school "7 March" Suhareka. The war murdered some of my classmates and it made me feel awfully, have nightmares. I hardly could eat anything.

Meeting the social -psychologists and their methods of work brought a great positive change in my personality. Now I feel much better, and keep practicing the same way at home.

I appreciate the methods of James Gordon whose advises, I had the luck to be given personally."

- *Albulena Berisha (14 a)
Suharekë, Kosovë*



Center for Mind-Body Medicine

- **MindBodySpirit Medicine: A Professional Training Program.** Panama City, Florida. November 10 - 16, 2002.
 - for health professionals who want to learn how to incorporate mind-body medicine into their work with individuals and groups.
- **Food As Medicine: Integrating Nutrition into Clinical Practice and Medical Education.** Panama City, Florida. March 2 -8 2003.
 - for physicians in practice, medical school faculty, residency faculty and other health professionals.
- **Comprehensive Cancer Care 2003: Integrating Alternative, Complementary and Conventional Therapies.** Washington, DC. April 9 - 13, 2003.
 - an annual conference evaluating the newest, most promising CAM therapies worldwide in the fight against cancer.

Center for Mind-Body Medicine

- **CancerGuides™.** Berkley. California June 22 – 28, 2003.
 - for health professionals who want to learn how to advise patients on the best ways to integrate complementary and alternative therapies into individualized programs of comprehensive cancer care.
- **Healing the Wounds of War.**
 - an on-going program to teach health and mental health professionals to deal with the trauma and stress caused by war and civil strife and to help them teach the populations they serve.

www.cmbm.org

Books

by James S. Gordon, M.D.



***Comprehensive Cancer Care: Integrating
Alternative, Complementary and Conventional
Therapies.***

by James S. Gordon, M.D. and Sharon Curtin,
Perseus Books, 2000.



***Manifesto for a New Medicine: Your Guide to
Healing Partnerships and the Wise Use of
Alternative Therapies.***

by James S. Gordon, M.D., Perseus Books, 1996.

**SPIRITUAL DIMENSIONS IN HEAL-
ING IN ISLAMIC MEDICINE**

Dr. Ibrahim B. Syed

(U.S.A)

SPIRITUAL DIMENSIONS IN HEALING IN ISLAMIC MEDICINE

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West Shefford Lane, Louisville, Kentucky, U.S.A.

INTRODUCTION

Alternative medicines such as acupuncture, homeopathy, herbal treatments, folk remedies, prayers and other religious practices, massage and other "alternative" therapies have become increasingly popular in the last decade, both with patients and with doctors. A survey showed that the number of Americans who use such therapies rose from about 33 percent in 1990 to more than 42 percent in 1997 (1). In addition, Americans spent over \$27 billion on these therapies that year, more than was spent on out-of-pocket expenses for all U.S. hospitalizations. The U.S. government has also increased its financial interest in alternative medicines, increasing available funding for National Center for Complementary and Alternative Medicine (NCCAM) from \$2 million dollars in 1993 to 68.7 million in 2000. This funding represents congresss dedication to developing and supporting quality, scientific research in the safety and efficacy of these alternative medicines, and to provide the public with reliable information. The National Center for Complementary and Alternative Medicine (NCCAM- was established by Congress in 1998.) is 1 of the 27 institutes and centers that make up the National Institutes of Health (NIH). NCCAM's primary areas of focus is to integrate scientifically proven CAM practices into conventional medicine, NCCAM announces published research results; study ways to integrate evidence-based CAM practices into conventional medical practice; and support programs to develop models for incorporating CAM into the curriculum of medical, dental, and nursing schools (2). As early as in 1977, the WHO (World Health Organization) held a meeting in Geneva discussing the topics of "utilization of traditional medicine in national

health care systems", "Integration of traditional medicine and modern medicine" and on other relevant topics (3).

The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) has recognized the influence of spirituality on hospitalized patients by requiring a hospital chaplain (Imam) or access to pastoral services in the standards for accreditation of all hospitals (4). According to the JCAHO, a spiritual assessment should be performed on every patient, identifying, "at a minimum," the patient's denomination, beliefs, and spiritual practices.

Interest in Spiritual Medicine

Recently there is a tremendous surge in interest and publications in the field of spiritual medicine in the United States. An abundance of articles, books, and conferences in recent years have addressed the impact of spirituality on patient, physician, and health care (5-12). For example Dr. James S. Gordon, MD who is the founder and Director of the Center for Mind-Body Medicine at Georgetown University, Washington, D.C. published "MANIFESTO FOR A NEW MEDICINE: Your guide to healing partnerships and the wise use of alternative therapies (13). Dr. Gordon wrote that medical education is long on technical mastery but short on issues of personal and spiritual growth. Dr. Gregory Plotnikoff, MD who is the medical director of the University of Minnesota's Center for Spiritual Care and Healing advocates care for the body and the soul (14). In "Timeless Healing: The Power and Biology of Belief," by Herbert Benson, M.D. (15) draws on Benson's work at Harvard's Mind/Body Medical Institute. Benson's prescription for doctors and patients contains three ingredients: 1) identifies each others important beliefs and motivations, 2) discuss and act on those beliefs, and 3) let go and believe. Religious belief and faith are the vehicles for his prescription.

The late Dr. David Larson, MD who was the president of the International Center for Integration of Health and Spirituality (ICIHS), Rockville, Maryland awarded five \$10,000 grants in 1996 to Medical Schools to incorporate classes on Religion and medicine into their Curricula. Dr. Dean Ornish, MD has documented the reversal of coronary artery occlusion by diet and meditation.(16).

This message-that health care has a spiritual component-flies in the face of modern Western health care culture, which holds to a biomedical model for healing and recovery. However one should not forget that advanced sciences like quantum physics have led to the development of transistors, lasers, CT Scanners, MRI scanners, computers and other technologies. Science itself proves that science cannot prove everything. The recent discoveries authenticate that a recursive or self-regard incongruity always contradicts the harmony of any system of ordinary sound reasoning or science.

Quantum physics shows a reality that is not mechanistic and cause-and-effect universe of classical physics. Extensive research has demonstrated that quantum weirdness is, indeed, the nature of reality. Physicists agree about the quantum nature of consciousness. From the quantum activity of the electrons in the brain arises the human mind, which is in another dimension, a domain beyond the physical. It is at this quantum interlace of wave-particle duality that matter becomes spirit. Hence one can argue that healing of the human body is a quantum phenomenon. Physicians try to understand the mind-body connection with the ordinary mechanistic cause-and-effect science. But in reality mind-body healing is illogical, that it occurs external of the logical perception and that it does not follow the normal scientific anatomical and physiological pathways.

Mike Denny, MD. PhD, says, "We have forgotten that the healing function of the human unconscious, as it emerges through the imagination into consciousness, does not speak the language of mathematics and science. It expresses itself in a metaphor and is perceived through intuition. It speaks to the conscious mind in poetic images which, like quantum particles, can be in more than one place at the same time, are not present until they are observed, move from one place to another without traversing the intervening space and can affect one another nonlocally, at a distance. It is at this mystical interface that mind-body medicine becomes soul-body medicine. It is here that human beings experience the divine. The quantum physicists of the 20th century, all of them, experienced the divine. They acknowledge the discontinuous, self-referential paradox demonstrating that

science proves that science can never give a full representation of reality. And so it is that by bringing our science up-to-date and into the 21st century we can experience soul-body healing as a portal to uniting science and spirituality in the medical healing arts." (17).

Spiritual Medicine has two components: Distant Healing and Self-care (that is healing by patient's own efforts). Distant healing is defined as any purely mental effort undertaken by one person with the intention of improving physical or emotional well being in another. In clinical practice, healing may involve a mental effort in or out of the healer's presence, with or without his or her awareness, and with or without touch. This broad definition would also include petitionary prayer or Du'a in which the practitioner generates a mental request for a particular outcome or that Gods "will be done."

WHAT IS SPIRITUALITY?

Spirituality involves the recognition and acceptance of a God beyond our own intelligence and with whom we can have a relationship. This God can provide an experience of inspiration, joy, security, peace of mind, and guidance that goes beyond what is possible in the absence of the conviction that such a power exists. The word "spiritual" refers to the divine nature of the energy, which healers agree comes from one external, invisible intelligent source.

Spirituality vs. Religion

Robert C. Fuller, Professor of Religious Studies at Bradley University, and is the author of 'Alternative Medicine in American Religious Life (18), Says, "Spiritual" and "religious" are really synonyms. Both connote belief in a Higher Power of some kind. Both also imply a desire to connect, or enter into a more intense relationship, with this Higher Power. And, finally, both connote interest in rituals, practices, and daily moral behaviors that foster such a connection or relationship. The word spiritual gradually came to be associated with a private realm of thought and experience while the word religious came to be connected with the public realm of membership in religious institutions, participation in formal rituals, and adherence to official denominational doctrines.

Religiousness, is associated with higher levels of interest in church attendance and commitment to orthodox beliefs. Spirituality, in contrast, is associated with higher levels of interest in mysticism, experimentation with unorthodox beliefs and practices, and negative feelings toward both clergy and churches. Those who see themselves as "spiritual, but not religious" reject traditional organized religion as the sole-or even the most valuable-means of furthering their spiritual growth. Many have had negative experiences with churches or church leaders because they may have perceived church leaders as more concerned with building an organization than promoting spirituality, as hypocritical, or as narrow-minded. Some may have experienced various forms of emotional or even sexual abuse. They typically view spirituality as a journey intimately linked with the pursuit of personal growth or development.

Spirituality exists wherever we struggle with the issue of how our lives fit into the greater cosmic scheme of things. This is true even when our questions never give way to specific answers or give rise to specific practices such as prayer or meditation. We encounter spiritual issues every time we wonder where the universe comes from, why we are here, or what happens when we die. We also become spiritual when we become moved by values such as beauty, love, or creativity that seem to reveal a meaning or power beyond our visible world. An idea or practice is "spiritual" when it reveals our personal desire to establish a felt-relationship with the deepest meanings or powers governing life (18).

Spirituality can be seen as being distinct from religion. Different world religions have proposed various doctrines and belief systems about the nature of a God and humanity's relationship with it. Spirituality, on the other hand, refers to the common experience behind these various points of view. It is an experience involving an awareness of and relationship with something that transcends your personal self as well as the human order of things. This "something" has been given various names ("God" being the most popular in Western Society) and defined in ways that are too numerous to count. We call it simply as the God.

Many have experienced major turnarounds in their condition as a result of cultivating their spirituality. They feel that developing a relationship with their God provided the moral support, courage, hope, and faith for them to follow through with their personal recovery program. It provided them with a sense that they are not alone in the universe, and that there is a source of guidance and support that is available at times of confusion and discouragement.

An individual has biologic, psychologic, and social dimensions and yet there is a spiritual dimension, which connects to all of these and contributes to an individual's sense of wholeness and wellness. Experiences such as joy, love, forgiveness and acceptance are manifestations of spiritual well being. Imbalance in one of the several dimensions led to disease and exacerbating illness. It is known that the spiritual elements also play an important role in the recovery process from acute or chronic sickness. Spiritual healing techniques frequently can support or complement conventional health care modality (7).

Spirituality is often defined as the experience of meaning and purpose in our lives—a sense of connectedness with the people and things in the world around us. For many, this connectedness encompasses a relationship with God or a higher power. Florence Nightingale (19) is considered the founder of modern nursing believed that spirituality is a dimension of human nature and that it is the highest level of human consciousness. Religion, according to Nightingale, is a means of expressing and developing spirituality, as can be all aspects of life. Science is necessary for the development of a mature concept of God, who regulates the universe thorough law as opposed to caprice. For many American, spirituality is experience and expressed through religiousness. The terms “religiousness” and “spirituality” often are used interchangeably. Religiousness is adherence to the beliefs and practices of an organized place of worship or religious institutions. Spirituality provides a sense of coherence that offers meaning to one's existence as a human being. Sometimes a patient may experience states of consciousness that have profound spiritual and transformative impact, including near-death experiences, mystical states, and delirious states associated with alterations of brain chemistry. These events may have a positive impact on the individual or they may lead to distress. Reassurance and legitimization of the experience by a health care provider can be very therapeutic (20).

Physicians are helping patients look beyond the physical dimension to find comfort, answers, and cures. The vast majority of Americans believe that spirituality influences their recovery from illness, injury, or disease, says one recent poll. Two thirds of the respondents indicated they would like physicians to talk with them about spirituality as it relates to their health or even to pray with them.

Specific Benefits of Developing Spirituality are Security and Safety as one will feel increasingly safe when one believes that there is a source one can always turn to in times of difficulty, and in trusting Him to take care of. There is much security to be gained through the understanding that there is no problem or difficulty that cannot be resolved through the help of God. Secondly it is the Peace of Mind.

Peace of mind is the result of feeling a deep, abiding sense of security and safety. The more reliance and trust one develops in God, the easier it becomes to deal without fear or worry with the inevitable challenges life brings. One turns to God when one feels stuck with a problem in living and don't know how to proceed. Learning how to let go when solutions to problems aren't immediately apparent can go a long way toward reducing worry and anxiety in one's life. Peace of mind is what develops in the absence of such anxiety. The third benefit is self-confidence. One comes to realize that God is the creator who has found something good in the believer. Every human being is a part of the universe. This realization can improve the way one looks at oneself and boost self-confidence. Man is created to be inherently good and worthwhile.

PRAYERS- Western Studies

Relaxation Response (21)

Dr. Herbert Benson (Associate Professor, Harvard Medical School and Director of the Mind Body Medical Institute of Harvard University and author of 'Relaxation Response' conducted scientific experiments to determine efficacy of prayer. Benson believed that there is no magic to prayer. He taught people to meditate using the word *one* or any other phrase they felt comfortable. Initially, all these mantras worked equally well in invoking the relaxation response and

stimulating the healthful physiological changes in the body as a result of it. But Benson also found *that those who used the word one or similar simple phrases that had no particular spiritual meaning did not stick with the program whereas those who used prayers continued because of their belief.* It has also been scientifically shown that to be effective, the person using the prayer has to have an unqualified faith that it will work. This is described by the scientists as intrinsic belief, characterized by profound spiritual commitment, devotion and quest for a truly transformed life. Thus, religious component in the spirituality is certainly very useful, and in fact may be needed, before the full benefits of spiritual healing can be realized. There is much healing and benefit to be obtained by cultivating one's spiritual life. A personal spiritual commitment is the most important ingredient. Spiritual awareness and growth can effect a transformation in one's whole being. It can help one to develop a basic trust and faith that is unshakable. The relaxation response, according to Benson, is the opposite of the familiar "fight or flight " response; it is accompanied by a decrease in hear rate, ventilation rate, etc., The body and mind generally slow down, or relax, a process that conveys significant positive effects on one's well-being. The relaxation response, Benson suggests, is the common thread amongst most positive spiritual practices and may be the root of the health benefits of spirituality. Patients want and benefit from attention to their spiritual needs. Both clinical researchers and clinical practitioners should appropriately incorporate spirituality into their work in order to fully understand and take advantage of the health benefits that seem to be related (21).

For centuries people have turned to prayer in times of bad health. It was one thing to use prayer to help trigger the physiological response of relaxation. A patients' belief in prayer is a powerful resource that might enhance the healing power of a wide range of medical treatments. Belief is very important in healing. Initially physicians called it the placebo effect,(it's all in your head, it's a dummy pill, and what have you), whereas in 50% to 90% of many diseases, belief can heal.

When a new drug comes it is appropriate to test it against a

placebo. And let's assume as is often the case, both come out to be 50% effective. The so-called new drug will be dropped because it's no better than a placebo. The question that could have been asked and should have been asked is what's going on in the 50% who get better with the placebo. There's an enormous literature that one can draw upon as to the power of belief in healing, in this case it's the belief in a placebo, belief in an inactive drug. Well for many people in the world (and this differs in various populations around the world) but for example in America, 95% of people believe in God. That particular belief system is one that is a Powerful one that should be tested. In Benson's latest study there's actually a double placebo effect. He's testing both the power of belief in prayer and the power of prayer itself. In this study the patients are not doing the praying themselves, others are praying for them as they recover from surgery (15). Modern neuro-science is showing us that the mind is inseparable from the body and the body from the mind. They interact. And it's foolish to disregard this kind of healing simply because we use such catchall phrases which don't fit any more, such as the placebo effect.

With thousands of patients already abandoning proven treatments in favour of alternative medicine, there's a worry some might find Benson's message too easy to swallow. Everything cited by Benson is scientifically proven and published in peer review literature.

It would be foolhardy for a patient to ignore these awesome cures of modern medicine which work whether you believe in them or not. The penicillins, the hormone replacements for hormone deficiencies, anesthesia, cataract replacements for blindness, these work and they're marvellous. It is hard to find a person abandoning them. It makes much more sense for physicians to recognise that belief can be used and add it to the already existing proven cures where belief doesn't work. (15). In the West, health professionals are less religious than the general public. Of 212 studies examining the effects of religious commitment on health care outcomes that Matthews and Larson reviewed (1995), 160 (75 %) demonstrated a positive benefit of religious commitment while 37(17 %) revealed a mixed or no effect, and 15 (7 %) demonstrated a negative effect (22).

Healing is maximized when the full potential of five faculties of the mind are fully developed and tapped for their therapeutic power. The five faculties are addressed by: cognitive healing techniques, analytical meditation for healing disorders, affective meditation for healing disorders, imaginal meditation, and creative meditation.

Origins of Islamic Spiritual Healing

Seeking Help with Prayers

The word "prayer" in the English language is generally understood as an act of addressing God with reverence, offering praise, giving thanks, affirming and confirming one's total dependence on God, and asking His grace, mercy, and help. In Islam, the equivalent word is supplication or in Arabic "Du'a," literally meaning to call upon, to invoke, and to supplicate. "Du'a" can be individual or collective, and is an essential element of both Islamic worship and Salaat or daily ritual prayers. Genuine and earnest "Du'a" is seen in Islam as a reality rather than a placebo, magic, or just a psychological construct. Prayer in Islam is both the essence and existence of life. The purpose of life is prayer and the effect of prayer is life. The Qur'an states: *"And your Sustainer says, 'Call unto Me and I shall respond to your prayers (Du'a). Verily, those who scorn My service, they will enter hell, disgraced."* Qur'an, 40: 60. Again we read in the Qur'an, *"And if My servant ask thee about Me, behold, I am nearer. I respond to the call of everyone who calls, whenever one prays to Me. Let them, then, pray to Me, and trust in Me, so that they may follow the right way."* Qur'an, 2:186. In Islam there is no life without prayer and faith.

Imam Ghazali (d 1111 CE), has said, "Illness is one of the forms of experience by which man arrives at a knowledge of God or illness increases faith and brings man closer to God." The Qur'an confirms *"O you who believe, seek help with patience and prayers, as God is with those who patiently persevere"* (Quran 2:153).

Prophetic Medicine

Islam developed "Prophetic Medicine" on the basis of the Hadith (Prophetic traditions). Prophetic medicine encourages medical treatment, stating, "There is a medicine for every ailment; when a right medicine hits the corresponding disease, health is restored by God's permission." In addition, prophetic medicine gives broad principles of preventive cure, emphasizing the discipline of diet and the use of honey and certain herbs.

The traditional Islamic medical system contains a mixture of spiritual and physical elements, including the use of natural substances and certain Islamic supplications for healing and cures. It includes preventive measures, curative medicine, mental health problems healing, surgery, and most importantly, spiritual cures for both the body and soul.

Prophetic medicine also encourages the recitation of the Qur'an, Dhikr or remembrance of God, repentance from sins, giving charity (Zakah, Sadaqa), and making continuous prayer to God for healing. There is no doubt in the efficacy of prayer. However, prayer works along with the best and most appropriate medical treatment, not at the expense of it. In the Islamic view, prayer does not work by itself without God's will and permission. Illness or sickness is seen as an anomaly, an imbalance in God's created order, and a test from God. Restoration of wellness is found through both the proper treatment and prayers. Believing in the efficacy of any medicine or drug or in the expertise of any surgeon or physician while ignoring the will and permission of God in that regard would correspond to disbelief and denial of God. Without prayers to God, a Muslim cannot find restoration of health, nor is there meaning and purpose in a healthy life that is devoid of prayers to God. At every affliction or calamity, disease or death, loss or distress, the Qur'an teaches the believers to proclaim "*Verily to God we belong and verily to God we return.*" (Qur'an, 2: 156)

On visiting the sick persons Prophet Muhammad (pbuh) used to comfort them and say the following prayer (Du'a):

"O Allah remove the hardship, O Lord of mankind, grant cure for

You are the Healer. There is no cure but from You, a cure which leaves no illness behind."

Spiritual healers inherited the methods that God's messengers were using, and from one generation to another have practiced these methods up to the present time. In the Islamic tradition, healers utilize both medicinal remedies and spiritual means. The spiritual techniques follow scientific principles, which utilize the patient's latent energy, and the power contained in the devotions and supplications and meditations of the prophets, messengers, and "wise men" of God. (23). Prophet Muhammad (peace be upon him) was once in a session where he was curing people through spiritual methods when he was asked whether or not remedies should be sought from medicines. He said, "Yes, you must seek remedy from medicine, because whatever disease God has created in this world, He has also created its remedy as well. But there is one disease for which He has not created any remedy, which is old age."

Each and every prescribed Quranic verse has its unique healing property, which differs from those of other verses. The following are some examples of verses used in spiritual healing.

The Qur'an contains Six Verses of Healing: "Ayaat Al-Shifa" in Arabic (six verses of Qur'an in which the word 'Shifa" or healing occurred).

- (1) **"And [God] shall heal the breast of the believers."** Tauba 9:14
- (2) **"Mankind there has come to you a guidance from your Lord and a healing for (the diseases) in your hearts, and for those who believe a guidance and a mercy."** Yunus 10:57
- (3) **"There issues from within the bodies of the bee a drink of varying colors wherein is healing for mankind."** An- Nahl 16:69
- (4) **"And We sent down in the Quran such things that have healing and mercy for the believers."** Bani Israel 17:82
- (5) **"And when I am ill, it is [God] who cures me." A supplication(Du'a) of Prophet Abraham(Ibrahim) Ash-Shu'ara 26:80**
- (6) **"And declare (O Muhammad) that [the Quran] is a guidance and healing for the believers. Ha Mim 41: 44**

HISTORY OF SPIRITUAL MEDICINE IN ISLAM

In Islam Spiritual medicine can be used to mean two different things, although both are allied and sometimes confused. One refers to the belief in a spiritual or ethical or psychological cure for diseases that may be physical or spiritual (or psychic). Thus, a physical illness may be cured, for example by recitation of the Qur'an or other prayers (Du'a). Most medical men of Islam even in the scientific tradition of medicine recognized this belief to an extent.

Ibn Sina is credited with psychic cures. Muslim physicians practiced various forms of psychotherapy such as shock or shame-therapy in the treatment of mental illnesses and this treatment was original. A famous Persian work titled *The Four Essays (Chahar Maqala)*, written about 1155 CE for the ruler of Samarqand by his court-poet, Nizami-Ye 'Aruzi discusses administrators, astronomers, poets and physicians. Each chapter gives definitions of an ideal person in each category followed by ten illustrative anecdote (24). Ibn Abi Usaibi'a narrates about the treatment by Jibra'il ibn Bakhtishu' of a beloved slave-girl of the caliph Harun al-Rashid through shock-treatment (25).

Part of spiritual medicine in Islam is devoted to ethical well being, but from a practical point of view. Thus Abu Bakr al-Razi wrote *al-Tibb al-Ruhani* (Spiritual Medicine) which has been translated into English as *The Spiritual Physick of Rhazes*. (26). In this work, al-Razi describes in detail the moral diseases and discusses with acute perception how these affect human behavior.

The Moghul emperor Jehangir once suffered from some illness, which his doctors were unable to cure. Frustrated, he repaired to the tomb of the Saint Mu'in al-Din Chishti at Ajmer and was cured. Ever since then he wore earrings in the name of the saint as a token of being his follower (27).

Volumes of spiritual prescriptions for cures exist. Most prayers and amulets contain verses from the Qur'an, to which high curative powers were ascribed. Very frequently, the recommendation is made that the patient shall write down certain Qur'anic verses on a piece of paper or on a glass (ceramic plate) and after soaking these writings in water

drink the water. In south-east Asian countries, sick people stand outside the mosques and the believers who are coming out of the mosques after performing the salaah, recite certain Qur'anic Surahs and blow air on the sick people.

Khawass al-Quran (Miraculous Properties of the Qur'an): The "miraculous properties" of practically each passage of the Qur'an are discussed including their curative properties for various diseases. It is said that when Surah 38 (Saad) is recited on a sleeping person it cures breathing problems; when written down and read during a patient's waking hours, it cures illness. A person who continuously recites it will be immune from all troubles at night (28)

Sufi Shaikhs or *pir* are said to cure the following ailments (29):

- * Sickness
- * Infertility
- * Problems with one's job
- * Alleviate fear of failure in an exam
- * Demonic possession (mental illness)

Al-Dhahabi (d.1348 CE)(30) says the benefits of the Islamic ritual prayers (salaah), which involve certain changing physical postures, are fourfold: spiritual, psychological, physical, and moral. He further says:

- * Prayers cause recovery from pain of the heart, stomach, and intestines.
- * Prayers produce happiness and contentment in the mind; they suppress anxiety and extinguish the fire of anger. They increase love for truth and humility before people; they soften the heart, create love and forgiveness and dislike for the vice of vengeance. Besides, often-sound judgment occurs to the mind (due to concentration about difficult matters) and one finds correct answers (to problems). One also remembers forgotten things. One can discover the ways to solve matters worldly and spiritually. And one can effectively examine oneself-particularly when one strenuously exercises oneself in prayers.
- * Salaah is a divinely commanded form of worship

- * Psychological benefit: prayers divert the mind from the pain and reduce its feeling.
- * Besides the concentration of the mind, salaah is exercise of the body: postures of standing upright, genuflexion, prostration, relaxation, and concentration; where bodily movements occur and most bodily organs relax.

Al-Muwaffaq 'Abd al-Latif narrates in his book *Kitab al-Arba'in* that a number of people who led lazy lives because of their wealth, who nevertheless had preserved good health. The reason is they were given to frequent prayer and also regular *tahajjud* (midnight prayer) (31).

Mechanism of Spiritual Healing (32)

Spiritual healing is when energy is transmitted to the person who needs it. The treatment works on the body, mind and spirit, which are seen as one unit that must harmonize for good health. If a separate healer is involved, the healer will place the hand on the person being treated to channel the energy from the Higher Source. The spiritual healing can help mental and emotional problems and physical conditions such as a frozen shoulder.

The channeling of healing energy from its spiritual source to someone who needs it is called spiritual healing. The channel is usually a person, whom we call a healer, and the healing energy is usually transferred to the patient through the healer's hands. The healing does not come from the healer, but through Him (the source of healing energy). On the other hand, one does not need a healer to take advantage of spiritual healing. One can pray. The healing energy from this source is available to all.

Healers see the body, mind and spirit as one interdependent unit and believe all three must work in harmony to maintain positive health. Any problem - be it a broken leg or depression needs the power of healing to restore the balance of the whole person. It is felt that sickness often starts in the mind, or at the deeper level of the spirit, and it is often here that healing begins.

The spiritual healing technique involves the energy field that exists around each of us. Everyone has an energy field or an aura that

surrounds and interpenetrates the physical body. This field is intimately associated with the health of the human being.

In different cultures, energy is known by different names. The word "energy" is referred to as: *Ki* in Japanese, *Chi* in Chinese, *Prana* in Hindi, *Qudra* in Arabic.

Energy is the life breath transmitted to us from the Existing, Everlasting Superpower that overlooks human beings and all creation. Energy regulates our thought patterns and emotions. It is the source of our life force and is the animating factor in all-living beings. It circulates through our bodies and can be harnessed for healing. It is the source of all movement in the universe. This energy is never lost and exists without the secret of its nature being understood by science and modern medicine.

This energetic spiritual life force holds the organs, blood vessels, and all body parts in place. When the body's life force diminishes, the anatomic relations of the body's organs are altered and disrupted, which leads to pain, organ dysfunction and an overall deterioration of health.

The spiritual energetic life force creates an energy field around itself like a highly charged magnet or electrode. This force reflects its energy throughout the human body and becomes the driving life force behind all of its activities and processes. The life force not only energizes the body but also gives it its identity. As its constituent electrons, protons, and neutrons--which are also its energy components--define an atom, so too does the spiritual life force give energy and identity to the physical body.

The healing spiritual energy is analogous to a waterfall. If a waterfall is channeled in the right way, it can be harnessed to produce energy and give light. Similarly, if our blood flow is properly channeled through a balanced, equilibrated system, the driving force of that energy will augment the energy of the weak organs.

In those organs where the life force has been weakened and dissipated, spiritual healing will increase and activate these vital forces.

The spiritual healing technique allows the life energies to be exponentially expanded to activate the ill member and heal it.

Spiritual healers harness and activate the life force within the patient. Much in the same way that contemporary physicians direct lasers to heal affected areas of the body, spiritual healers access a similar chain reaction of the body's existing energy, channeling it to the affected areas to heal pain and suffering. When one organ begins to heal, the other organs use the released energy to activate and release their own inherent energy, which in turn promotes physiological equilibrium and relief from pain.

The Three Phases of Spiritual Healing (32)

Universal force--or cosmic energy--includes the energies of the planets, stars and galaxies, and whatever is around us of propagating energy fields. This vast, all-pervading force nourishes the soul, the spirit and the energy within each individual and in every living creature. Through the meditative process of spiritual healing, one can access this driving energy which exists in every living cell in the body.

The energy is channeled to the cerebral cortex, which is the processing center of our thoughts. The concentration of energy in the brain comprises the first phase of spiritual healing. This process in turn stimulates the vagus nerve to send electrical impulses down the heart's conduction system to the sinoatrial node, through the inter-nodal tracts, through the atrioventricular node, down the Bundles of His, out the Purkinje fibers and into the myocardial wall to begin systole. This migration of energy, which fills the heart, is the second phase of spiritual healing. Conditions such as angina, congestive heart failure, cardiomyopathy and hypertension, in addition to many other related cardiac diseases, are healed and the patient can then find health and relief from pain. The energy is then pumped with the blood out of the heart into the vascular system and delivered to the entire body in the third phase of spiritual healing. A major focus of phase three is the aorta, which is the conduit for the healing waves of energy that are carried by the blood.

As the blood flows from the heart, it is first channeled back to the

heart via the coronary arteries in a chain reaction that sustains and increases the energy in the heart itself, much in the same way that the sun increases its light through its own nuclear reactions. This cycle produces more and more energy, which pours out into the vascular system with foci in the major arteries, supplying the brain via the carotid arteries. It also travels through the subclavian arteries to the upper extremities, the splanchnic circulation to the abdomen, through the renal arteries to the kidneys, and through the iliac vessels to the lower extremities.

A healthy heart will sustain a weak body, but when the heart is weak and diseased--even in a young person--the body will not be healthy or live long. Therefore, maintaining the heart is the first priority for spiritual healers. Furthermore, maintaining the brain is also another important priority to keep the flow of messages functioning properly.

How Energy Relates To Disease (32)

Kabbani says, "Spiritual healers symbolize the flowing of the driving life force in the body and in the universe as vortices of energy made up of a number of smaller spiral cones of energy. These are known in Islamic terminology as "*Lata'if*", meaning subtle manifestations or layers. The *Lata'if* (sing. *lateefa*) are the points of maximum energy intake and are very important focal points of balance within the energy system. Disease and illness occur if a *lateefa* is unbalanced.

Lataif in adults have a protective screen over them. In a healthy system, these *Lata'if* spin in synchronized rhythm with the others, drawing energy from the universal energy field into their center for use by the body. Each one of them is tuned to a specific frequency that helps the body to remain healthy. However, in a diseased system these vortices are not synchronized. The energy of the *Lata'if* that make up these vortices may be fast or slow, jerky or lopsided. Sometimes breaks in the entire energy pattern can be observed in which a *lateefa* may be fully or partially collapsed or inverted. These disturbances are related to dysfunction or pathology of the physical body in that area."

Meditation and The Focal Point Of Treatment

In Islam meditation covers, Salaat, Dhikr or remembrance of God, recitation of the Qur'an. In spirituality, good health requires intensive striving by the patient and personal change. Personal change to develop patience, contentment, gratitude, cheerfulness, joy, love, sharing, courage, benefaction, recognition of good deeds, forbearance, and courtesy will improve spirituality and energy flow.

Without personal change in the body's energy flow, one will eventually create other problems which leads back to the source that caused the disease in the first place. Thus, dealing with the source of disease is the focal point of treatment. This search stimulates the deeper part of ourselves that is sometimes called the "higher self" or the "spark of divinity" within us. This divinity within us, the deeper part of ourselves, sends us information about what type of sickness needs to be treated and what type of contact points need to be touched through our meditation. Meditation is a tool which gives deep relaxation and to quiet the mind. This helps to alleviate stress, and therefore enable the internal chemical and hormonal system to regain their equilibrium (21).

Medical tests have shown that there are definite measurable physiological changes in meditating subjects. The brain itself undergoes changes in the type of electrical waves generated. By using an electroencephalogram (EEG) there is an increase in the generation of alpha waves and sometimes also in the number of theta waves. These indicate a shift of consciousness into a tranquil state of awareness quite different from that of sleep. This state is therapeutic and very restful although the patient is both fully conscious and functional (21).

The body demonstrates the effects of meditation in various ways. The breathing pattern slows, as does the heart rate, and there is a marked decrease in the level of oxygen consumption and carbon dioxide elimination. However, the physical effects of meditation last longer than the meditation period itself. This is demonstrated by the fact that sufferers of hypertension and many other diseases have, through meditation alone, made such clinically-measurable improvements that they have been able to discontinue their medications. This

is very well noted and recorded in spiritual healing books and manuscripts (6, 11, 12, 13).

Healing Through Meditation

Meditation elicits many descriptive terms: stillness, silence, tranquillity, peace, quiet, calm. All counter stress and tension. All promote physiological health and well-being.

The feeling of pain can be completely cured by meditation wherein the dormant energy of a sick body is activated by a spiritual ignition produced by the meditative process (32).

As a scientist shoots a laser, the spiritual healer emits the light and energy that he receives from the universal force. The healer massages the affected areas and this combination of heat from the hand and light from the forehead immediately begins the healing process.

The healer also prescribes that the patient sit alone for a few hours each day fully relaxed, repeating several thousand times different holy names of God in a special format for the duration of treatment. These holy names are like energy sparks which ignite more flow from the universal energy source. This ignition also activates the focal points of the body causing heat to be generated in the body of the patient. This heat is considerably less than the immense power transmitted by the healer, but it is sufficient to cause the patient to break out into a sweat.

At this time, the patient goes to the healer who transmits more energy as before, advancing the patient's treatment. As the moon reflects the light of the sun onto the earth, so too does the healer reflect the universal energy through his body to the patient. This produces a state of immense heat and spiritual interaction between the healer and the patient. This process is repeated for several days or even weeks until the patient recovers (32).

As he recovers, the patient begins to experience a psychological effect from the dynamic, synergistic interaction between himself and the healer. This psychological effect of recovery and relief from pain induces the endocrine glands to secrete hormones which balance the whole system and begin to cure the ill organs, raising the patient to

higher levels of health and spirituality than would be possible in the former painful, diseased condition.

As the surgical patient is anesthetized, so too is the spiritual patient put in a pain-free state in which the spiritual healer can work on him in the way he finds suitable (32).

Meditation has several practical benefits, which are described by Dr. Dean Ornish, a cardiologist known for his treatment program for heart disease based on diet, exercise, group support, and meditation. First, meditation can increase your powers of concentration. Second, it increases awareness of what is going on inside you ('insight'). Third, meditation helps you become more aware of what's going on around you ('outsight'). Fourth, meditation helps clear quiet the mind, enhancing the clarity of our perceptions. Fifth, meditation can give us a clear and relatively undistorted view of ourselves. Sixth, meditation helps you focus on the present moment, rather than the past and future. (33)

Meditation program may do the following (34, 35):

- * Reduce stress
- * Reduce high blood pressure
- * Reduce substance abuse
- * Increase both creativity and intelligence
- * Improved psychological health
- * Improve memory and learning ability
- * Increase energy
- * Increase inner calm
- * Reduce insomnia
- * Increase happiness and self-esteem
- * Reduce anxiety and depression
- * Improve health
- * Promote a younger biological age

Integration of Traditional Medicine and Modern Medicine

Physicians and scientists are all acquainted with this unquantifiable life force, but are unable to interact with it directly except through its vehicle, the physical body. For that reason, scientists look intently to the outward existing body and invent procedures and techniques to keep the body in homeostasis, striving to keep the vital life force in the body as much as possible and to keep the body free of pain. The contemporary physician is concerned primarily with the physical body as well as the psychological aspects of human existence. Therapeutics for illness are largely physical, whether in the forms of medication, surgical intervention, or otherwise.

Spiritual healers, on the other hand, use an inward approach to healing by applying spiritual techniques and methods to utilize the body's own energy. The difference between the spiritual healers and the physician healers is that the former is healing from inside-to-outside while the latter is healing from outside-to-inside. Each are doing good for their patients and both meet on the common ground of curing disease and relieving pain and suffering.

There are some in the Muslim Ummah, particularly those in rural areas with limited access to modern medical facilities, who completely reject modern medicine, prefer to rely on a combination of supplications and traditional medical treatments. It is common to find traditional healers and Hakims (Unani doctors) who continue to rely on a mixture of Qur'anic verses, water, local herbs, oil, or honey for their medical treatments. There are some countryside healers who are not medically trained and who become involved in superstitious practices that contradict Islamic norms and values. There are some secular Muslims who have little knowledge of Qur'an and Sunnah, who prefer to rely completely on modern medicine. The vast majority of Muslims, however fall somewhere between the spectrum of these two groups. They believe that Salaat, Du'a, Qur'anic recitations and Dhikr (remembrance of Allah) play an important role in healing and recovery along with the benefits of modern medicine.

Islamic Medicine is an Integrated Medicine

Defining Islamic Medicine El-Kadi (36) says, "Although Islamic Medicine may include, among many others, all the modalities of modern medicine, it differs from modern medicine in that it fulfills all the following six criteria: It is excellent and leading among other brands of the healing arts. It is a medicine with faith and Divine ethics. It is guided and oriented. It is comprehensive, paying attention to body and spirit, to the individual and the society. It is universal, utilizing all useful resources, and offering its services to all mankind. And last, but not least, it is scientific.

While modern medicine proclaims these criteria, i.e. to be excellent, ethical, oriented, comprehensive, universal and scientific, it has failed to fulfill any of them. The big question is: Can Islamic Medicine overcome all the problems of modern medicine, and can it provide its missing ingredients? The answer is a confident "yes". In all the problem areas of modern medicine listed in this paper, the deficiencies are either lack of ethical and moral guidance, lack of standardized value system, disregard of certain restrictive or instructive rules related to ingested materials, or disregard of certain hygienic and social guidelines governing human relations and social life. These missing items, are the very one abundantly provided by Islamic teachings.

The detailed elaboration on the correlation between various Islamic teachings and the course or development of various diseases is beyond the scope of this paper and will be the subject of separate investigations. The combination of Islamic teachings and the existing technological advances, which are fully supported by the Islamic teachings, produces a unique blend of healing arts which qualifies as Islamic medicine, a medicine which is most up-to-date and progressive while in full harmony with divine teachings and guidance. The basic Islamic teaching asserting that there is a cure for every illness (and it is up to us to find it) is an unbeatable stimulus for study and research towards unparalleled progress and achievement. The establishment of such a healing art entails the total reevaluation and revision of all existing basic and clinical sciences. In addition to providing the new medical foundation, the revised texts and restructured curricula will reflect the

link between the creator and His creation thus reinforcing the concept of oneness of God (Tawheed) and automatically improving the faith of the student through his own professional study. These texts and curricula will also reflect the oneness of creation by showing how the various systems of animated and non animated creatures follow very much the same laws of nature, or better stated, laws of God, thus broadening the horizon of the student which will in turn make him a better scientist and a better person. It will be a monumental task to establish, but a task worth undertaking."

Conclusion

Modern medicine has been tremendously successful and we must be grateful to it for a whole range of extraordinary advances that leave us far better off than our ancestors. Ideally, traditional and alternative medicine should co-exist in harmony - perhaps even practiced by the same doctor.

Physicians and other caregivers should consider patients' spiritual needs. The prominent role of religious commitment and spirituality in patients' private lives can have a tremendous impact on medical decision-making and coping with serious medical illness. Spiritual inquiry is justified by the need to obtain important medical information and explore the patient's privacy, confidentiality, and autonomy. Integrating traditional medicine into modern medicine is to effectively integrate spiritual sensitivity into clinical practice which could be a challenge that should be addressed by all physicians and clinical care providers. Muslim physicians practicing modern medicine should make Du'a with the patient or for the patient. Performing Salaat, Dhikr and recitation of Qur'an greatly augment the healing process.

Eighty percent of the people living in developing countries use traditional medicines and hence there is a need to ensure that such medicines were validated for safety, efficacy and quality. Some of the problems facing the integration of traditional medicine and modern medicine are: inadequate policies; insufficient evidence on safety and efficacy, a lack of research on knowledge, attitudes, practices and behaviors; a lack of standardization of dosage regimens; the sheer

amount of hard cash behind drug companies promote; mutual distrust between Western-trained and traditional health practitioners; poor documentation.

Burkina Faso is a good example of a developing country which has strengthened and developed traditional medicine and also improved partnerships between modern medicine and traditional systems of medicine so as to enhance the integration of traditional medicine into national health systems for the benefit of its people (37).

In America as many people now consult alternative medicine practitioners as do regular doctors.

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DISCUSSION

Discussion of Third Session Spiritual Dimension & Its Power

Chairman: Dr. Abdul Rahman A. Al-Awadi

Rapporteur: Prof. Anis Ahmad Ansari

Dr. A. R. Al-Awadi: Thank you Dr. Ibrahim for very good lecture. Now, time for questions. Only very good questions without recommendations, please.

Participant: Dr. Ibrahim, you spoke about lack of research and yet you maintained that Du'a the doctor should do for the patients.

Dr. Ibrahim B. Syed: It is a recommendation for other modalities. What I am talking about Alternative Medicine or Complementary Medicine, there are so many, I am addressing that apart from the spiritual medicine. Is it clear to you?

Dr. Gamal, Kuwait: I would like to thank you Mr. Chairman for the opportunity to attend this symposium and I want to emphasize two points regarding Dr. James. You mentioned something about personal insight, about Lung Cancer. In Islamic heritage, we have this. When a man came to the Prophet (PBUH) with fever and told him, he tried to put him at ease, but the man refused. Then, the Prophet (PBUH) told him "go with your own thoughts", this is a famous hadith. The other point regarding the prayer for some body else, we have it in Islam. You can pray for somebody else just in this way. - Thank you!

Dr. James Gordon: I want to make a couple of comments. There are so many studies on specific kinds of medical practices, among some of those are general approaches, techniques and kinds of meditations. I would say the evidence is good as that the most of standards of allopathic treatment. One of the things I want to add about faith. There is very interesting scientific studies. There is a researcher who has died, his name is George Soleman, who is a pioneer researcher. He also did some very interesting studies on people who expect to live. Most of the people by cancer and some other diseases. Another aspect is they tended to be religious or spiritual

people and they had very strong sense of faith. Third aspect is that they took charge of their own health care. The fourth is that they had very strong connection both with healers, professionals whether western or traditional healers and also with family members.

George Soleman wrote also a book called “Remarkable Recovery”, which is a popular book that talks about several thousand cases. I think it is really an interesting field.

Dr. A. R. Al-Awadi: Thank you! Any other question please?

Prof. J. H. Bryant: I want to thank both the speakers, particularly Gordon for when, he brought the science base together with these practices. Your describing is impressive. Also, I want to mention that I have procured, I think would be delighted to White House Commission, then Callahan Editor “The Role of CAM Accommodating Pluralism”. I particularly like that.

Dr. James Gordon: The issue of pluralism is important and I appreciate that. The point in history, my work as Dr. Syed mentioned manifest of new medicine and I recommend of Ayurveda. It is one of the reasons, I call it a new medicine, is because for the first time in the history of human being, we have access to the traditions for the more, over the world. We also have the opportunity to bring scientific methodology to understanding that tradition and this is an amazing turning point, and a turning point in medicine.

I also like to add some thing else. I think at a time when there is so much misunderstanding and conflict, medicine and healing, indeed, conferences like these bring together people from different cultures to address the common concern for healing, really very important, in helping to bring about mutual understanding and hope for greater peace and accepted compassion for one another. I think, we have a great powerful public role, all of us to play in to the planetary peace process. Thank you!

Dr. A. R. Al-Awadi: Thank you! Any other question?

Dr. Ali Haeri: Thank you very much. I appreciate the material by both the speakers. Just a very minor comment I would like to make. I consider it very delicate issue. The human psychology is like a

fingerprint. I agree with you, individuality is very important. But as a Muslim, I believe that it is a balance between individuality and living in a group of social life. I can give an example like a spoon-full of sugar crystals. Each crystal has the same character, as a human like other humans, but you cannot sweeten a cup of coffee with one crystal of sugar. You have to use whole spoon in order to sweeten your coffee. So, it is a balance between being individual. I agree, we have to deal with patient exactly as what he wants and feels, and the same time we cannot separate him from the society or group of living in. So, it is balance between these two. - Thank you!

Dr. James Gordon: I agree with you, as this is a very important point. I am working in Kosovo during the war and after the war. It is the incredible power of family and community. They help people to heal. I think that something we have not importantly in the west, we lost many of those connections. We need to once again appreciate that there is a balance between individuality and that connection to others that belonging to them. -Thank you!

Dr. Ibrahim B. Syed: Just, I like to comment on that the Muslims feeling that praying alone is not enough. The Prophet (PBUH) said if you pray with Jamath you will get 27 times more blessings than you pray alone.

Dr. A. R. Al-Awadi: Any other comments. What I would like to say, not the recommendations, but some words. No doubt, we are going back to now what we call the proper life style. I am glad that we got back to our centre of culture. We have left that for long time. That was the major short-coming of the civilization. How advanced we are? We are forgetting that extra whatever we call it that nature, there is something.

In Islam, we say foreword “There is God, you subdue yourself to Him”. That’s all. You don’t care for the next. Islam means subduing to God. You subdue yourself completely to GOD. There is no other argument. That’s why the Al-Salath (The Prayer). The Al-Salath (Prayer) in Islam means the connection. Because you are always with your God, five a times a day. If you can actually manage that thing, it is great spiritual obligation. I personally have seen that. I am some-

times very tense in conferences and arguments, I always break for prayer and in fact, you feel that you are a very different person. If you really pray for 5 minutes, you have good connection and concentration for a very long time. We have this life style changed. Because all what we are seeing now, all the diseases and mother diseases are man made. We got the drugs, we got the AIDS, Alcohol. These are all man made. We are the defectors. It is not the bacteria, it is not the mosquito, but it is we, who endowed with bad kind of life-style and we really destroyed ourselves. At this time, in our society we are going to put that man back, very interested to bring him down to earth. It was very strange. We did a little study. Dr. Khalid is here. Yes Dr. Khalid, if you give the experience of the Quranic Clinic for the Cancer patients. They forgot death. They told that there is no death. So, Dr. Khalid is a Cancer Specialist. He can speak of some of his experiences.

Dr. Khalid: Bismillah Hirrahma Nirrahim! Actually, because we have psychological problems, we are discovering that Cancer is a killer disease in our thought and most of the patients coming, they fight to death. We think that we can give more relief for our patients. This may help them from frustrating and continuing the treatment. Secondly, for giving enough faith to face this difficult disease either because of the disease itself or because of the management of disease. So, we started this 3 years ago and called Quranic Clinic. Most of our patients if they like to see Sheikhs who are reading Quran, give him more faith to face this disease according to their way, they visit regularly to the Sheikh and we discovered (this is just an observation because we are in need of collecting data), that before this clinic around 30% of the patients escaping from treatment because of scaring, which is end by depression. Now, this prepared them for continuous treatment. So, during this observation, we noted actually that most of our patients don't do that any more, they are going to visit the Sheikh, they have strong faith, good understanding for our religion and because of this understanding, they know that *Allah Suhhana Wata Aala* asks them to continue the treatment who have all the facilities, which is created by man. So, now we don't face any escape from treatment.

Second observation is, actually these people are not any more scaring and, which we believe, that the psychological or spiritual support improves the immunity for patient, and since it is working in a procedure to prevent or to help the patient to spreading of the disease. So, also we noted that patient also having good cure rate, good local control rate, and good survival. But, it is, as I mentioned a preliminary result. We are still in a stage of collecting data, evaluating these procedures to prove this scientific approach. - Thank you very much!

Dr. A. R. Al-Awadi: It only shows that at that stage, it is very important. A lot of them refused, then generally back to life. Then, lot of them even reduced the medication. As Dr. Khalid said, we are going to publish that study. It can show that once you are in, you can really benefit from a huge space of spiritual code. Tranquility to soul in our religion is very important. The soul and body interact to give the result. Dr. Abdul Aziz, please.

Dr. Abdul Aziz: I would like to make one comment after listening these excellent presentations. I suggest one to refer to our definition upheld that also we would think that this kind of approach would be very useful not only for treating diseases but what we call promoting health and protecting health. I would also just like to return to the concept of health potentiality that has been clearly developed by our scholar Dr. Haitham Al Khayat. These kind of approaches can increase the potentials of healthy people, so when they are exposed to any risk, they can really protect themselves from these risks. I also feel that these kinds of risks would be very useful not only for sick people but also for normal people to promote the potentiality of health. I may even go for that listening to the approach by our colleague that he went to areas. There are sufferings both in Kosovo and Palestine. May be we are now discussing within UN, the concept of human security, health security. We are trying to promote this concept so that we decrease the suffering. One of the main components of promoting health security is justice as well as equity. So, again we need to include this kind of holistic approaches to emphasize the concept of justice to

promote health and human security as well as the concept of equity for promoting human health and security. - Thank you!

Dr. James Gordon: I really appreciate the comment. Good deal about my work at the mind-body medicine is training health professionals in these approaches. I agree with you completely. We work very intensively and I invite any of the people who are interested to participate with us in this work. We work very intensively to train health professionals, especially physicians in self awareness, care, mind-body medicine and bringing our programs into medical schools in the US for training medical school faculty who, in turn, are teaching too. I think this is quite fundamental and I appreciate the comment about the work in worst situations.

Dr. A. R. Al-Awadi: I think there are no more comments. - Thank you very much!

Fourth Session
Saturday, 13 October 2002
Integration of CAM

Chairman : Dr. James S. Gordon

Rapporteur : Prof. Emilio Minelli

Speakers:

1 - Dr. Andrew T. Weil (U.S.A)

2 - Prof. H-Moo Chang (Korea)

3 - Dr. Peter Graaff (WHO/EMRO)

**WHY ALTERNATIVE MEDICINE?
WHAT CONVENTIONAL MEDICINE
CAN LEARN FROM CAM?**

Dr. Andrew T. Weil

(U.S.A.)

WHAT CONVENTIONAL MEDICINE CAN LEARN FROM CAM?

Andrew T. Weil

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Tucson, Arizona, USA

Summary

We are witnessing a tremendous rise in complementary and alternative medicine (CAM) throughout the world. Although many users and practitioners of CAM are opposed to the theories and practices of conventional medicine, there are many ways that CAM can support and improve conventional medicine. First, many CAM treatments are more natural, less risky, and less expensive than conventional drugs and surgery. Patients want such treatments, which can help lower the high cost of health services, especially in developing countries. Second, by emphasizing the importance of lifestyle choices and self-care. CAM stimulates the development of real preventive medicine, which can further cut health care costs. Third, by treating patients as whole persons - as mental-emotional beings, spiritual entities, and community members, as well as physical bodies - CAM opens up other avenues for intervention that extend the power of conventional medicine, especially in areas where conventional medicine is not very successful. Fourth, by focusing on the innate healing abilities of the human organism, CAM can restore a perspective to conventional medicine that has been lost in the past century in our enthusiasm for external, technological solutions to all health problems. This can further enhance the power of conventional medicine and reduce dependence on costly treatments. Fifth, some CAM therapies, if proved to be efficacious, might force us to expand the current scientific paradigm in ways that would make conventional medicine more effective. For all of these reasons a marriage or synthesis of the best ideas and practices of conventional medicine and CAM should be a logical goal.

Full Text

More people than ever are using complementary and alternative medicine - surveys consistently document the trend worldwide. In the United States between forty and fifty percent of patients go to CAM practitioners.⁽¹⁾ Most significantly, the amount of money they spend on these visits exceeds the amount spent on visits to primary care physicians.⁽²⁾ Clearly, CAM is not only popular, it has also become a powerful market force that can no longer be ignored by healthcare providers and policymakers.

The reaction of conventional medical practitioners and institutions to CAM has changed with its rising popularity and influence. For much of the twentieth century CAM was ignored by the conventional medical community. More recently it has been viewed as a threat, possibly because of the economic competition it represents and possibly because its underlying philosophies are seen as incompatible with modern science. Many medical practitioners and publications denounce CAM as unscientific or even anti-scientific and devoid of any evidence base. They call CAM practices worthless or dangerous, and they accuse CAM practitioners of offering false hopes of cures to patients with serious diseases.

Now at the turn of the century, another reaction is evident. Some medical practitioners and publications have begun to suggest that aspects of CAM should be integrated into conventional medicine, that a synthesis of the best ideas and practices of conventional medicine and CAM is a logical goal.⁽³⁾ One expression of this movement is the appearance of Integrative Medicine in the US and of Integrated Medicine in countries as diverse as the United Kingdom and China. For the past seven years I have directed a Program in Integrative Medicine at the University of Arizona College of Medicine in Tucson,

(1) Eisenberg, DM, Roger, BD, Ettner, SL et al. Trends in alternative medicine use in the United States, 1990-1997. *J Amer Med Assoc* 1998;280:1569-75.

(2) Ibid.

(3) *Brit Med J* 2001;522:passim.

Arizona; therefore, I consider myself one of the growing number of physicians with this new perspective on CAM

Underlying the concept of Integrative Medicine is the assumption that CAM has something of value to offer standard medicine. I should say at the start that I am far from being an uncritical proponent of alternative medicine. I have spent many years studying CAM around the world, and I find it to be a very uneven collection of ideas and practices that range from the reasonable and useful to the ridiculous and dangerous. One of main tasks of integrative medicine is to sort through all of this material, separating out what is valuable and worth integrating.

I note several broad areas in which CAM differs from conventional medicine in ways that are worth our attention. First, CAM makes use of many treatments, like herbs, which are more natural than conventional drugs and may have better safety and efficacy profiles. Some of these treatments may also be less expensive than standard drugs and surgery. Many patients today want natural therapies, and bringing them into wider use might lower the high cost of health services, especially in developing countries. Second, by emphasizing the importance of lifestyle choices and self-care, CAM tends to have more of a preventive focus than conventional medicine. If more physicians worked from this perspective, we might be able to improve public health significantly and cut health care costs even more.

Third, CAM often views patients as whole persons not just as physical bodies. It pays attention to them as mental-emotional beings, spiritual entities, and community members and looks for the relevance of these other dimensions to health and illness. By doing so, it opens up other avenues for intervention than the purely physical approaches of conventional medicine and may increase our effectiveness with diseases that the standard system does not have much success with.

Fourth, by focusing on the innate healing abilities of the human organism, CAM represents a perspective that conventional medicine lost in the twentieth century in its enthusiasm for external, technological solutions to all health problems. Restoration of it can enhance the power of conventional medicine and reduce dependence on costly

interventions. And, finally, what appear to be “unscientific” aspects of CAM may, in some cases, turn out to be legitimate challenges to the dominant scientific paradigm. Investigating them could result in an expanded paradigm that might improve medicine and healthcare.

I would like to consider these five areas of difference between CAM and conventional medicine in more detail in order to support my contention that a synthesis of the best ideas and practices of these systems is a logical goal.

With regard to CAM treatments that are more natural and may also be safer and more effective than conventional drugs and surgery, I would ask you to consider the example of botanical remedies. My professional training is in botany as well as medicine, and I have a long career interest in the study and use of medicinal plants. I have recommended plant remedies to patients over many years, never with any adverse results. One of the great differences between whole plants and isolated compounds is concentration. Plants are dilute forms of natural drugs, with concentrations of active compounds often in the range of less than one percent of their dry weight. Pharmaceutical drugs, by contrast, are very concentrated.⁽¹⁾

Whenever we concentrate pharmacological power, we inevitably increase toxicity as well as therapeutic potential, because there is no difference between a drug and a poison except dose. (All drugs become toxic in high enough dose, and some poisons become useful therapeutic agents in low enough dose.) For many drugs in common clinical practice, the margin of safety between the effective dose and the toxic dose is small; one consequence is the tremendous number of adverse drug reactions produced by conventional medicine, many of them serious. One estimate is that 100,000 deaths occur annually in hospitalized patients in the U.S. alone as direct results of adverse drug reactions.⁽²⁾ Significantly, most of these did not involve errors in

(1) Weil, AT. *Health and Healing*. 3rd ed. Boston. Houghton Mifflin, 1995; 96-111.

(2) Lazarou, J, Pomeranz, BH, Corey, PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *J Amer Med Assoc* 1998;279:1200-5.

prescribing; the right drugs were given to the right patients for the right indications, and nonetheless these disasters occurred.

In my experience there are great safety advantages in using dilute, natural forms of drugs. Bringing that option into conventional medicine would help reduce the amount of direct harm caused by exclusive reliance on potent, isolated compounds. (Of course, concentrated extracts of plants, now often sold over-the-counter, may pose greater risk.) And there is another important difference between herbs and pharmaceuticals: plants are complex mixtures of bioactive compounds.⁽¹⁾ Western science uses reductionism to manage the complexity of nature; in pharmacology this habit leads us to assume that the properties of a medicinal plant can be equated with those of its isolated “active principle.” This is a false assumption. The therapeutic effects of botanicals result from a synergism of many components, and a new science of complexity is necessary to understand them. I will return to this point in discussing paradigm shift at the end of this talk. In many cases the complex natural mixtures of drugs interact with the body in ways that produce better results than do single compounds.

For example, some herbs used in Chinese medicine can raise low blood pressure and lower high blood pressure. Apparently, they contain compounds with opposite effects, and which effect predominates in an individual patient may have to do with which receptors are available for binding. In a sense, this gives the body an active choice in determining the end effect, and it may explain the “normalizing” action of herbs that can bring disturbances of physiology back to normal whether they are represent underactivity or overactivity. Conventional pharmacology cannot explain such paradoxical actions, and the isolated drugs it relies on prod the body in only one direction at a time.

In addition to the advantages of much better safety and possibly better efficacy, herbal remedies are much cheaper than pharmaceuticals, an important consideration for most of the worlds population. Of

(1) Weil, op.cit.

course, there are great problems of quality control of herbal products and hard questions of how to regulate and study them, but these are practical matters that can be managed. The fact is that botanical medicine represents a broad field of therapeutics that is prominent in many systems of CAM, such as Ayurveda, traditional Chinese medicine, naturopathy, and ethnomedicine, a field that has been mostly ignored by contemporary conventional medicine and pharmacy. It offers the promise of improving outcomes while reducing both the harm and costs of conventional drug treatment. And this is just one example of a CAM modality that deserves attention. Others I might mention are dietary adjustment, manual medicine (manipulation, massage, etc.), hydrotherapy, and music therapy.

The next area for discussion is the possibility of strengthening the preventive aspects of health care by adopting CAM's emphasis on lifestyle choices and self-care. I do not think this requires much elaboration. We know that the diseases that kill and disable people prematurely and that absorb most of our health care monies are diseases of lifestyle. They result from poor dietary choices, lack of exercise, stress, habits like smoking and the use of intoxicants, etc. Conventional doctors spend little time discussing these behaviors with patients and helping them make changes. The field called "preventive medicine" mostly deals with immunizations and public sanitation rather than with the fundamental issue of lifestyle choices and their role in health and illness.

By contrast, CAM practitioners often place great emphasis on healthy living or living in harmony with nature and some of them are better trained to motivate patients to change. Ayurveda, the ancient medical system of India, is really a science of healthy living that looks at all aspects of lifestyle from diet to mental state to physical environment. Because lifestyle choices are made early in life and are often difficult to change in older people, it seems to me most important to get good information to young children about better and worse kinds of food, the importance of exercise, ways of neutralizing stress, and so forth. In my view, this is an area of failure of conventional medicine, where the contributions of CAM would be most welcome.

By the way, I also believe that physicians should be role models of healthy living. They should teach patients by example. Unfortunately, the process of conventional medical education makes it unlikely that men and women will come out of it with healthy lifestyles. I feel strongly that development of tools for healthy living should be an integral part of medical education and training.

Whole-person medicine, the next area in which CAM has much to contribute, has to do with all the variables that affect health other than those associated with the physical body. Because I do not have time to discuss this subject fully, I will take one example: mind/body medicine. This is probably the best-researched field of CAM, with an abundance of data demonstrating mind/body interactions and a range of therapies that take advantage of those interactions.⁽¹⁾ Hypnosis is one such therapy; it has cycled in and out of medical favor over the years. Hypnosis is an altered state of awareness marked by increased intensity and focus of concentration and heightened suggestibility. In individuals with high capacity for this state, it is easy to see that suggestions can affect physiological processes that appear involuntary and beyond the reach of consciousness in ordinary waking states. For example, hypnotized subjects can divert blood flow from one hand to the other, can prevent formation of blisters in response to thermal injury or produce them in response to no injury.⁽²⁾

These observations merely hint at the range of possibilities afforded by hypnosis and other mind/body interventions (including guided imagery, biofeedback, breath control, meditation, and so forth). It is well documented, for example, that various aspects of immune function can be conditioned and modified by these methods.⁽³⁾ Despite decades of positive research and the availability of a

(1) Pelletier, KR. Sound mind, sound body: mind/body medicine comes of age. In: Pelletier, KR. *The Best of Alternative Medicine: What Works? What Does Not?* New York. Simon & Schuster, 2000.

(2) Rossi, EL. *The Psychobiology of Mind-Body Healing: New Concepts of Therapeutic Hypnosis*. New York. WW Norton, 1986.

(3) Ader, R. *Psychoneuroimmunology*. New York. Academic Press, 1981.

number of time- and cost-effective therapies for influencing the body through the mind, these methods are very much underutilized in conventional medicine and usually considered part of CAM. Greater use of them could extend our ability to treat diseases that do not respond well to standard approaches, such as autoimmune diseases and all of the conditions that represent unbalanced functioning of the autonomic nervous system, including hypertension and irritable bowel syndrome.

And mind/body medicine is only one aspect of the whole-person approach, which also considers spirituality and sociocultural influences on health. The restricted focus of conventional medicine on the physical body works when we can identify specific mechanisms of disease; it is not so helpful when we cannot. What rheumatologist would not rather treat gout than fibromyalgia? What gastroenterologist would not rather treat peptic ulcer disease than irritable bowel? The whole-person approach of many CAM modalities might make these and other difficult diseases much easier to manage.

Next I will talk about the emphasis of many CAM practitioners on the innate healing ability of the human organism. Twenty-five hundred years ago, Hippocrates urged physicians to respect the *vis medicatrix naturae*, the healing power of nature, and until recently, most physicians did so. Now, natural healing power is not even mentioned in medical schools. Yet this very old idea is still alive and well in most CAM traditions. Homeopathic doctors give remedies to elicit healing responses from the body. Doctors of osteopathy and chiropractic manipulate body structure to restore normal nerve function and blood circulation in order to allow healing to occur. Practitioners of Chinese medicine modify the flow of energy through the body to allow restoration of the innate balance that is health. These systems make a clear distinction between treatment and healing. Treatment comes from the outside; healing comes from within. At best, treatment facilitates healing.⁽¹⁾

(1) Weil, AT. Spontaneous Healing. New York. Alfred A. Knopf, 1995.

Here is an example I often use with medical students. Consider a patient with acute bacterial pneumonia who is critically ill. You hospitalize the patient, administer powerful antibiotics, and in forty-eight hours, the crisis is past. What has happened? Many conventional doctors and patients will believe that the antibiotics caused the cure. I would suggest a different interpretation. What antibiotics do in this circumstance is reduce the numbers of invading germs to a point where the patient's immune system can take over and finish a job it was unable to do because it was overwhelmed. The ultimate cause of cure is the activity of the body's own innate healing system. I find this interpretation to be more useful, both as a practitioner and as a patient.

As a practitioner I find it comforting to know that nature is at my side as an ally, that the body wants to be healthy, and that if I can identify and remove obstacles to healing, nature will accomplish the rest. As a patient I find it comforting to know that my body has a remarkable ability to self-diagnose, to repair itself, to regenerate. That knowledge increases my self-reliance and reduces the likelihood of my becoming unnecessarily dependent on external interventions. Even when disease is advanced or incurable, the body's healing system can help it adapt to its condition. Patients can even die in a healed state - that is, in peace and with acceptance of death.

I regret that conventional medicine has drifted so far away from its roots in nature and has become so unmindful of the wonderful potential for healing we are born with. I believe one of the benefits promised by the thoughtful integration of CAM into conventional medicine could be a renewed understanding of the true nature of healing. A practical result might be willingness to save costly, high-tech interventions for those instances when they are really needed and to explore first simpler, less expensive ways of facilitating healing from within.

Finally, I have suggested that some of the more controversial areas of CAM might, if taken seriously, lead to expansion of the current paradigm of science and medicine. Again, in the interests of time, let me talk about just two features of the current paradigm that seem to

me limiting: reductionism and materialism. I have already referred to the reductionistic nature of pharmacology, but this is equally true of most conventional science and medicine. Assuming that the part equals the whole certainly makes experimentation and explanation easier, but, increasingly, a new science of complexity is coming into being. In mathematics and physics, chaos theory and other complex models are proving to be much better than classical ones for understanding natural phenomena, from the shapes of coastlines and clouds to predicting the weather. Medicine has so far shown no movement toward embracing these new models, even though the human body is an ultimately complex system. The reductionistic approach of medical science may severely limit our ability as physicians to interact with it and help it out of conditions of disease.

Many CAM systems embrace complexity. Traditional Chinese medicine (TCM) is a good example. A typical Chinese herbal prescription might include a dozen different herbs to be boiled into a tea. TCM practitioners are happy to have Western scientists analyze these remedies, but they are quite uninterested in the Western obsession with finding “the active principle” of the brew. In their view, therapeutic benefit is the result of a synergistic action of all the ingredients; they do not even care to know which herb may be the most active, let alone which component of it is. Moreover, a typical TCM treatment protocol will also include dietary change, acupuncture, massage, and energy work (*qigong*). Conventional medical research would attempt to isolate each separate modality to assess efficacy. The TCM researcher would study all of it together

I would argue that the reductionistic model of conventional medical science simply might not be adequate to understand or assess many CAM systems. If we begin to integrate CAM with conventional medicine, we may be forced to question the usefulness of reductionism in understanding health and healing, disease and treatment. I would welcome that kind of questioning.

Materialism is the belief that only that which is perceptible or measurable is real. Materialism postulates that all effects in physical systems must have physical causes. Nonphysical causation of physical

effects simply cannot happen in a materialistic paradigm. In conventional medicine, it is just this belief that limits our ability to see, understand, and make practical use of mind/body interactions. It is the obstacle to full acceptance of therapies like hypnosis. It is the reason for the lopsided emphasis on the physical body to the exclusion of the other dimensions of human life. And, most unfortunately, it leads us to regard placebo responses as nuisances that muddy our experiments rather than value them as true healing responses elicited by belief.

Of all the systems of CAM, homeopathy is the one that most challenges the conventional scientific paradigm.⁽¹⁾ How can remedies diluted beyond the point that any of the original molecules are present possibly convey information to the organism? If they do - that is, if the clinical successes of homeopathic medicine cannot be explained away as placebo responses -- then the conventional paradigm must change. Vigorous research in this area should be a priority.

Another area of CAM that runs up against the materialism of conventional science is the whole field of energy medicine. Many practitioners of it exist, with many different styles of practice. There are formal systems like Therapeutic Touch and Reiki, and individual "hand healers," who either touch patients or do not touch them but claim to somehow channel energy to them to facilitate healing. I have experienced this myself more than once, and the sensation I felt coming from the hands of a skilled practitioner was not subtle. It was strong and obvious, and I'd like to know what it was. If this kind of intervention can be shown to affect the structure or function of the body, again the influence of materialism in the conventional paradigm will diminish. I would make research on this kind of treatment another high priority.

Paradigm shift does not come about easily in any scientific field and certainly not in medicine.⁽²⁾ Some of the tension between proponents of CAM and adherents to conventional medicine may

(1) Weil, AT. *Health and Healing*, 1-38.

(2) Kuhn, TS. *The Structure of Scientific Revolutions*. 3rd ed. Chicago. University of Chicago Press, 1996.

come from a sense that so much is at stake. But I am sure that continued evolution of the scientific paradigm from which medicine operates can only increase our understanding and effectiveness as physicians and improve the well being of patients.

Given the significant contributions that CAM can make to conventional medicine, it seems to me that we must proceed with integration as a goal. Although many individual practitioners have begun to learn forms of CAM and offer them to patients along with standard treatments, the real work of integration must happen in the education and training of our health professionals: doctors, nurses, pharmacists, and all of the allied professions as well.

I am a founding member of a US group, the Consortium of Academic Health Centers for Integrative Medicine that now includes a number of leading medical schools. To join, an institution must qualify as an academic health center (university-based with a medical school and at least one other professional school) and must have an ongoing program in integrative medicine with full institutional support; in addition, the dean or chancellor of the institution must participate in the meetings. The Consortium now has twelve member institutions, with more wanting to join.⁽¹⁾ It is our hope that this group will eventually represent enough academic power to call for the necessary reforms in health professional education.

In my own institution, the University of Arizona Health Sciences Center, I am working to train physicians, medical students and residents, pharmacy students, and others by exposing them to the theory and practices of CAM, helping them to evaluate these modalities critically, and giving them practical instruction in integration. My colleagues and I are also developing curriculum in various areas of integrative medicine that we hope will one day find their place

(1) Member institutions include: Albert Einstein-Yeshiva University, Columbia University, Duke University, Georgetown University, Harvard University, Jefferson University, Stanford University, and the Universities of Arizona, California (San Francisco), Maryland, Massachusetts, Michigan, and Minnesota. For information contact vmaizes@ahsc.arizona.edu

in professional schools. For information on the activities of the Program in Integrative Medicine, please visit our website: <http://www.integrativemedicine.arizona.edu> I extend invitations to you to visit us in Arizona and see the progress we are making in turning out the first of a new generation of physicians, trained in a much more comprehensive way to better fulfill the needs of today's patients.

**KEY ISSUES FOR BETTER
INTEGRATION OF TRADITIONAL
CHINESE MEDICINE (TCM) WITH
CONVENTIONAL (MODERN)
MEDICINE: UNDERSTANDING
INFRASTRUCTURE OF TCM
SYSTEM IN TERMS OF MODERN
MEDICAL KNOWLEDGE**

Prof. Il - Moo Chang

(Korea)

KEY ISSUES FOR BETTER INTEGRATION OF TRADITIONAL CHINESE MEDICINE (TCM) WITH CONVENTIONAL (MODERN) MEDI- CINE: UNDERSTANDING INFRASTRUCTURE OF TCM SYSTEM IN TERMS OF MODERN MEDICAL KNOWLEDGE

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ABSTRACT

In the light of medical history so far recorded, the traditional Chinese medicine (TCM) seems to be one of leading and orthodox medicine over the world till 17 century, and even now, more than one third of total population of mankind including Chinese, Korean, Japanese and Vietnamese are taking an advantage of TCM therapy along with modern medicine. Since last decade, growing interests from public sectors in western world, especially U.S. people, in Complementary and Alternative Medicine (CAM) have brought huge changes in medical research trend, because public sectors like to take benefits and advantages from it. Nowadays many policy makers and researchers in medical fields get interested in a main issue: How can traditional medicines as a part of CAM integrate into the modern medicine? In this regard, we have heard frequently rhetoric of medical investigators: “evidence-based therapy” for CAM. It sounds very reasonable and agreeable in order to assure effectiveness and safety of traditional therapies. But how and who will verify the evidence? It is also fact that most of conventional medical investigators do not have knowledge of traditional medicine, and even they cannot access to information of particular traditional medicine, e.g. most of TCM literatures were written in Chinese alphabet. It is obvious for them not to understand

the traditional Chinese medical descriptions without knowledge of classical Chinese literature and language. In this regard, I believe in that the pre-requisite step of verifying the evidence-based therapy of TCM in particular is to provide mutual understanding of the infrastructure of TCM system in terms of modern medical terminology.

Based on my academic experience in respect to studying TCM herbal therapy, several criteria of infrastructure of TCM system should be interpreted and understood by modern medical terminology as follows;

- 1) Difference of human anatomy in view of TCM system: acupuncture and moxibustion therapies can be understood. Modern anatomy cannot prove invisible flow of Qui and meridian points yet, even though their clinical effects reveal.
- 2) Disease Classification: nearly 4,000 diseases were classified till 17 C, and very detailed symptoms and prognosis of disease were described.
- 3) TCM herbal therapy: nearly 100,000 formulas reported and two third of them are poly-pharmacy type (combination of several herbs). How such poly-pharmacy type formulas act, and why Chinese people prefer them?
- 4) Pretreatment of herbal materials using traditional methods to reduce toxicity of medicinal plant materials

To discover wisdom of TCM therapy using acupuncture and herbal formulas, I believe, it is desirable that at least the above four major issues are understood before getting into insight of TCM world. Then using modern medical techniques to verify its effectiveness and safety can assess each therapy. Throughout about 2,000 years medial history in Chinese culture, tremendous numbers of herbal formulas and medical treatments have been developed, however, current TCM therapy can be characterized into two main therapeutic methods: one is TCM herbal therapy and the other is acupuncture/moxibustion. In addition, it can not be said that all of herbal formulas are good enough for treating certain diseases, since safety matters should be

more considered. Throughout long time of history, many herbal materials are wrongly used by the view of modern botanical science. However, there are still a large number of valuable formulas that can exhibit significant effects on certain diseases, e.g. shizandrin and artemisin derived from TCM herbs.

A Journey to Traditional Chinese Medicine (TCM)

I. Historical Aspects

When the human race appeared on the face of the earth, bacteria, germs and viruses causing diseases were already in existence and caused great suffering and death. Treatment for illness, although primitive, must also have existed, even though there is a lack of material proof. To look for the origin of such treatments, we must keep track on the written records of ancient human societies in history.

Egyptian papyri and Chinese manuscripts from the time around 2,500 BC to 1,500 BC provide accounts of credible treatments on a variety of ailments, and it is reasonable to assume that this is the earliest verifiable period of using traditional medicines. During this time, there were distinct ethnic groups with different cultures worldwide that developed their own therapies with available natural herbs nearby. These remedies have been passed down and systemized through generations. As many civilizations rose and fell, there was a great deal of interchange among different peoples worldwide. Exchange of ideas including information on medical treatment for various ailments was evidently accompanied by increases in trade. A substantial number of Indian herbal remedies were imported into China, as were Persian remedies via the ancient “Silk Road”, the trade route from the Mediterranean cultures to China by the way of many other Asian countries; India’s traditional Ayurveda and Chinese herbal medicines are typical examples of exchange. In much the same way, some herbal remedies from Latin America and from Africa, all but extinct today, were encroaching into Western medicine.

Worldwide, there are several common traits in the development of

traditional medicines, consistent with the advancement of society. Firstly, religious and shamanistic treatments among more primitive groups of humans had a big influence on the development of traditional medicines, some of which remains today. Secondly, there was a tendency for traditional medicine systems to take advantage of the adaptability of the human body to changes in the environment to stimulate self-healing. This was highly evident in Western medicine during Hippocratic time, around 460 BC. However, from the Renaissance period onwards through the Industrial revolution, as Western medicine was making a progress practically and its religious aspects were getting totally irrelevant, it became a more structured scientific subject looking at single therapy for each specific disease. The discoveries of X-rays, the microscope and infectious micro-organisms, the subsequent development of vaccines and identification of disease-causing organisms, all made within the last 100 to 200 years, were great leaps forward for the art of medicines. Western medicine has made tremendous steps forward in eradicating infectious diseases, especially reducing the infant mortality.

On the other hand, traditional oriental medicine, widely practiced in China, Korea, Japan and other Asian countries continued its development using a more conceptualized approach, and now following detailed analysis, the value of herbal medicines and acupuncture/moxibustion has been realized and their efficacy were proved clinically. A decade ago, the WHO recognized traditional medicine as an invaluable adjunct to Western treatment methods in a special program to integrate the two for the benefit of humans. Many traditional herbs are now purified and produced like their Western counterparts. For example, morphine, reserpine, artemisin are cases of the merging of Western and traditional medicine to develop effective treatments for pervasive diseases. The merging of the diverse medical traditions and disciplines has been widely carried out in China under the name of “Integrated medicine” for about the past two decades, and currently similar treatments are practiced in Korea and Japan as well.

In the West, the importance of traditional medicine, especially traditional Chinese medicine (TCM) is rapidly being appreciated and

its use is expanding, with many acupuncture centers in France, The UK, Germany and other countries. In the United States, the National Center for Complementary and Alternative Medicine within the framework of the National Center for Complementary and Alternative Medicine (NCCAM) of the National Institute of Health has been set up in 1998 that is diverged from the office of alternative medicine in 1992.

II. Development

To begin with, it is necessary to take a look at the formation and development of the traditional Chinese medical science and medicines according to times and area. The Chinese medical science and medicines have been handed down in the forming respective cultural areas of a vast land in China by different peoples, and since 3,000~4,000 years ago up to date, a unique and systematic traditional medicine was established. The traditional Chinese medical science, medicinal therapy and acupuncture, which have been combined with each other from original forms developed in different areas, are called 'Chinese medical science and medicines'.

A cultural area is regionally divided into 'Northern cultural area' (Yellow river area), "Middle cultural area (Long river area), and Southern cultural area (Tropic/sub-tropic area). In the northern area, acu-punctures or moxibustion are customarily applied rather than medical plants due to the cold and rapidly changing weather and majority resident nomads raising cattle. In this area, it was ordinary to live through the cold weather, therefore, the adaptability to the nature and the observation ability were acquired, which gave birth to the hypothesis of Yin-Yang and Five Elements to which Indian medical science and Buddhism affected. Yellow Emperors Classic of Internal Medicine would be a basis of an old medical book referring to this hypothesis. In Long river cultural area, a medication was more popular. Recuperation method and medicines of eternal youth were targeted with the introduction of 'immortal thoughts' and 'Taoist thoughts', and a tonic medicine or various hygienic methodologies appeared since this area was a center of politics and the economy in

ancient Chinese imperial nations. An ancient “Materia Medica” called in Shen-Nong-Pen-Tso is probably an origin of old Chinese herbal therapy. In a southern area, a variety of virulent epidemic were often spread due to the hot and humid weather. However, a unique herbal therapy was developed, especially effective to many infectious diseases. *Shang-Han-Lon*? written by Zhang, J.K., is typical among old medical classics in late-Han dynasty. All medical knowledge and techniques having been originated and developed from different areas were put together, which makes current TCM today.

III. Theoretical Background for Traditional Chinese Medicine

1. Grand Hypothesis; Yin-Yang and Five Elements

The theoretical background of Chinese medical science, origin of oriental medical science starts from Yin-Yang and Five Elements. Yin-Yang and Five Elements, as a hypothesis, possesses oriental philosophy on universe and nature. This hypothesis has been referred to demonstrate human physiology and symptoms according to the concept that the human body is governed by the nature because it is born, grown, and dying back to the nature. In fact, the hypothesis is rooted to ordinary life and language in Asia. For example, moon (month) and sun (day) symbolize yin and yang respectively, and five elements represent a week; Tuesday, Wednesday, Thursday, Friday, Saturday. ‘Qui’, as an often-mentioned word, has several meanings; sense, consciousness, energy. Thus, the hypothesis is related with the culture and ways of life, and has an effect on the way of thinking for long time. Keep in mind the following lists below in order to understand the relationship between the hypothesis and the rationale of TCM.

- (1) Yin-Yang and Five Elements is a hypothesis explaining the generation of the universe, the creation of heaven and earth, and occurrence living creatures in the nature.
- (2) It is not empirically proven but theoretical, deduced rational, and 4-dimensional with concepts of time and space.
- (3) It simplifies the nature in a macroscopic and comprehensive view.

Based upon the above lists, the hypothesis of Yin-Yang and Five

Elements is shortly explained. Yin & Yang hypothesis, which sees the world before the birth of universe as the Great Absolute, is one of the hypotheses that dominate the nature of universe. In other words, it believes that the movement of the Great Absolute in empty space has created Yang. We have to bear in mind that the characteristic of Yang is based upon dynamic movement. However, different from Yang, in case of Yin, it is the stillness that has created Yin. Heaven has the character of Yang, whereas earth has the character of Yin, and the universe came to existence through them. Such thought has been enlarged and eventually has become the principle of analyzing and explaining the state of nature. For example, Yang is stronger during the daytime whereas, Yin has power over Yang during the nighttime. Such conception implies that the occurrence in the nature is due to the inter-transformation between Yin & Yang, which eventually makes harmony and balance. Like transmigrationism in Buddhism, Yin & Yang becomes the basic principle of Oriental way of thought in culture, which believes that the relationship between birth and death brings balance and harmony. Thus, the specific hypothesis Yin-Yang and Five Elements brings us to the path of transmigrationism. Such path leads to the cycle of birth and death through inter-transformation. For example, tree burns to be fire, and when fire fades away, it transforms into ash. And during this process water is created. Ash eventually returns to earth (soil), and water evaporates to become cloud and rain that helps the growth of tree. The hypothesis of Five Elements was added to that of Yin-Yang in order to perceive the inter-transformation of nature. They are believed to compose the Earth; tree, fire, soil, metal, and water. The process of these transformations is dominated by two basic properties; compatibility (mutual inclusiveness) and incompatibility (mutual exclusiveness). The principle of compatibility believes tree creates the fire, fire creates the soil (ash), and soil creates the metal. Water gives nutrition to tree. The principle of incompatibility believes that tree is over soil (it absorbs the nutrition of soil), soil is over water, water is over fire whereas fire is over metal and metal is over tree. The Five Elements additionally introduce the time concept to these two principles. “Seasons of Five Elements” offers the idea that a year is composed of 5 seasons; spring, summer, long summer, autumn and winter. Herein, the change of

heaven greatly influences the seasons, where the factor for the change of heaven, known as “five spirits” is introduced. Five Elements are the basic substances that compose Earth. “Five tastes” concept is also connected with the characteristics of each substance; sour, bitter, sweet, hot, and salty. Tree tastes sour, fire bitter, earth sweet, metal hot, and water salty. Taste seems to be a very reasonable approaching method because it was the only way to illustrate the characteristics of substances in the ancient times. The hypothesis of ‘Five Transformation’ established the theoretical background of TCM as a guide to comprehend the human body and physiological functions.

2. Extension of The Hypothesis of Yin-Yang and Five Elements to Human Body

The hypotheses above introduced gave birth to ‘Five Organ Hypothesis’ which means human’s most important internal organs comprise five. The five organs are the liver, the heart, the spleen, the lungs, and the kidney. And the five tastes are related deductively to five organs. Sour taste is helpful for the liver, bitter for the heart, sweet for the spleen, hot for the lungs, and salty for the kidney. This concept could be expanded to five sub-organs; the muscles, the blood, the flesh, the skin and the bone marrow, ultimately, which compose the whole human body. The following also explains the relationship between the above five sub-organs of the body and five organs. In other words, the liver controls the muscle, the heart generates the blood, the spleen makes the flesh, the lungs make the skin and hair, and the kidney makes the bone marrow, respectively. Supposed the hypothesis of ‘Yin-Yang and Five Elements’ is applicable to some organs of the body, five organs fit to Yin, and ‘six parts (gall, stomach, large/small intestine, urinary bladder, three energizers)’ fit to Yang. The six organs, different from five organs, are called six parts which is also connected with the ‘Five Elements’. They generally support the physiological functions of the five organs, and help the human body maintain the total function. There exist three energizers not recognized even with the modern anatomy but defined by traditional medical science.

In a view of modern medical science, some concepts above sounds

reasonable, but the process and the function of human body explained by the rest may be hardly convincing. It is because the western medical science resulted from the actual proof of anatomy whereas the traditional sciences are originated from ‘the hypothesis of Yin-Yang and Five Elements’, which is deductive and abstract to explicate the phenomena of the human body.

3. Factors and functions of the vital force

Let’s take a look at the factors necessary for maintaining the vitality of human body. The four factors Nutrition, Defensive power (e.g. immune function), Qui, Blood and Essence, Spirit, Body fluid can control the human physiology and maintain the vitality.

- 1) ‘Nutrition’ means when the body ingest the food, ‘Essence’ is generated by five organs and six parts, and then it moves to the whole body through the vessels.
- 2) ‘Defensive power’ indicates ‘protection’. Just like ‘nutrition’, ‘immunization’ is created when the grain is digested and absorbed. Then ‘immunization’ circulates through the outside of the vein, and range all over the skin and mussels.
- 3) ‘Qui’, indicating bio-energy, can be explained in two ways; The Heaven Qui is the air for breathing by the lungs, and the other is Earth Qui acquired by grains.
- 4) ‘Blood’ circulated all over the vessels, and provide five organs and six parts with the nutrition. ‘Nutritional Qui’ secretes ‘body fluid’, and ‘body fluid’ turns into ‘blood’ when it gets into ‘pulse’. That is, as ‘Nutritional Qui’ is ‘Essential Qui’ of grain, the origin of ‘blood’ can be ‘Essential Qui’ of grain too.
- 5) There are two meanings of ‘essence’. One is that of five organs and six parts, and the other is that of reproducing function.
- 6) ‘Spirit’ is the word indicating every thinking ability and consciousness condition. So, it maintains the normal physiological activities of human body. To make short, essence, spirit, qui could play roles as indicators for vitality.
- 7) ‘Body fluid’ is divided into ‘Jin’ and ‘Ak’. ‘Jin’ come under

‘Yang’, and decentralized by the Immune Qui. ‘Ak’ is under ‘Yin’, followed by nutrition and blood, and circulated by ‘meridian point’. So, nutrition, immunization, qui, blood, essence, spirit, and body fluid have functions that control the physiological action and maintain the vitality.

- 8) Meridian: The human body needs a way supporting nutrition to every part of our body, and circulating all kinds of body fluids, to keep vitality. Every pathway the energy and blood moves through is ‘meridian’. Meridian is divided into two parts; ‘Channels’ and ‘Collaterals’. ‘Channels’ flows upward and downward, and ‘collaterals’ is connected with ‘channels’ just like a branch. Meridian is connected with many organs and makes it possible for every physiological function to go on smoothly. There are 12 major channels (2 more channels-Doc-channel and Im-channel). These are connected with ‘five organs and six parts’, and each ‘hole in channels’ is allocated to them. 12 channels are classified into two categories, Yin and Yang. We call the ones which flow the side and the back of the body ‘Yang-channel’, and the ones flow the abdominal region, hands and feet ‘Yin-channel’. Channels and Collaterals meet at a point called ‘hole’, which sometimes could be a target of medicinal therapy and acupuncture. We should notice that a disease can permeate from the exterior of the body through this point. Observation of an abnormal condition through a permeated disease plays a role as an indicator for a diagnosis. In Oriental medical science, ‘channel and collateral’ is considered to be very important whereas the vessel to be trivial; for instance, it is used for feeling the pulse, or known as the pathway of blood flows. Up to date, we did not make it clear yet where the channel and collateral is in our body, but the function of it, especially that of ‘hole’ is proved in indirect ways.

IV. Disease Concept based on Traditional Chinese Medicine

1. Cause of Disease

In the view of traditional medical science, the thought of ‘Disease’

is far from that of modern medical science, which is based on actual proof and pathology. The Chinese concept of disease is derived from the imbalance between Yin and Yang states in human physiology. When pathogenic factors of either external (bad Qi, or called in Sa) or internal factors (the seven emotions) alter the human body, Yin and Yang are said to be out of balance. To restore balance, a TCM doctor will select herbs with Yang or Yin properties. When illness results from too much Yang, a doctor prescribes an herb with Yin properties or vice versa. Referring to disease-causing factors by the view of Shang Han Lon introduced about 1,000 years ago (late-Han dynasty), it was believed that external factors could cause disease. 'External factors' are the factors that attack our body by penetrating from the outside. When these alien and unnecessary substances get into our body, these were thought as the cause of the disease. 'External factors' can be a shapeless material such as 'fever', 'chilliness', and 'humidity'. In fact there wasn't any idea and necessity that the cause of disease could be microorganisms with life. This is because the 'hypothesis of Yin-Yang and Five Elements' simplifies the broad and natural phenomenon. 'Shang-Han' is the diseases generated from the outside of the body. Shang-Han is brought on by the intrusion of 'exogenous factors (fever, paralysis, chilliness, humidity, xenobiotics)' from the heaven energy to 'meridian hole point'. These cases are acute, feverish, and infective. It was believed that all these diseases occur when imbalance between Yin and Yang in body (e.g. defensive power is lowed) reveals.

2. Disease Classification

Based on our literature research up to 17 century, nearly 4,000 kinds of diseases were classified and recorded. Each disease was explained its symptom in details from start and prognosis. Such detailed description of disease symptoms made modern pathologists estimating accurate disease classification in terms of modern medicine. Of 4,000 diseases, two third of diseases described in terms of TCM can be converted into modern terminology by the W.H.O. disease classification (about 15,000 diseased classified). Even though the number of 4,000 looks much less diseases in comparison with the

W.H.O. classification, those 4,000 diseases cover almost all diseases. But the title of disease such as hepatitis in terms of TCM was just not divided into more detailed types of hepatitis such as hepatitis A, B, and C, etc.

3. Diagnosis

There are 4 ways of diagnoses performed in traditional medical science; Watching (complexion, skin color, the pupil color, and the condition of tongue), Listening (the hearing ability and sense), Communicating (by asking the patient), Palpation (the finger sense by feeling the pulse and examining the abdominal region). Through the many experiences, even 30 or more types of pulse could be distinguished.

Three standards for estimating disease are as follows;

- 1) The part where disease outbreaks: We classify the diseases into 3 groups; 'external side', 'internal side', and 'Ban-Pyo-Ban-Li (side between the external and internal)'. And 3 different disease-causing factors also make a classification; 'the external factors' (six symptoms expressed in the whole body after intrusion of 'exogenous' outside of the body; paralysis, chilliness, humidity, fever, dehydration, and fire), 'internal factors' (diseases of five organs and six parts caused by seven emotions: happiness, anger, anxiety, thought, sadness, fear, and surprise) and 'Bul-Whae-Bul-Nae' (an external wound and addiction).
- 2) The condition of disease: diseases are classified by 'insufficiency/excessiveness', 'movement/stillness', 'cold/fever'. For an example, there are expression such as 'Yang-Excessiveness', 'Yin-Insufficiency' by the degree of response and strain of the body. 'Movement' means when the disease turns acute, 'stillness' means when it goes slow or chronic, 'cold/fever' is assorted according to the temperature the patient feels.
- 3) The disease progress time: it is assorted into 6 session: three Yang such as Tai-Yang, Shao-Yang, Yang-Myung, and three Yin such as Tai-Yin, Shao-Yin, Kwul-Yin. Tai-Yang is the beginning of

the disease and Kwul-Yin is the end of the disease, which means death.

By these 3 factors, we can tell how the diseases can be specifically diagnosed and classified. The term of the Jung is a way of expression of disease in terms of TCM.

Wisdom of TCM Herbal Therapy

I. Pre-treatment of Herbs and Polypharmacy Formulas (Combination of several herbs)

Most traditional medicines, including Chinese medicines, have relied on herbs and the majority does to higher plants. There are few kinds of drugs using animals and minerals. But in some specific area, like Tibet and Mongolia, lots of minerals are used as crude drugs. The early period of herbal therapy, perhaps, the concept of *Similia similibus* is applied and the similar effect was expected when the medicinal herbs or animals with similar shapes are used. For instance, because the shape of Ginseng is just like that of a human, ginseng has been thought to work as a good tonic. Because a root of a bellflower is white, it has been thought to possess a cold attribute to lower down the fever. The tastes of lots of medicinal plants are tested to categorize each one corresponding to five tastes. Based on these experiences, there are already around 365 plants written in the Chinese oldest book on medicinal herbs 'Shen-Nung-Pen-Tso', and they are classified into 3 groups; High, Middle, and Low herbs. As High herbs are free from toxicity, this kind of medicine can be used for long time, and even frequently used as health food. Middle one can be a little toxic that it can't be applied for long period. Low one is toxic and used for specific treatments that it should be used just for a short time very carefully. We realize that even about 2000 years before, both the effect and the toxicity of the medicines have already been established.

In the development of TCM herbal therapy, Korea contributed Ginseng and Aconiti Tuber to China. And as well as many other countries such as India, Vietnam, Malaysia, and even Persia introduced some medical plants to China.

It is interesting to note that about 500 herbs should be pre-treated (sometimes process method) before use by special and traditional ways. By doing such pre-treatment, toxic natural substances are eliminated without the loss of major pharmacological activities in particular herbs. For example, when fresh *Pinellia* tuber was treated with lime-licorice-ginger, mutagenic substance was removed without the loss of anti-emetic effects⁽¹⁾.

The vast numbers of polypharmacy herbal formulas are a characteristic feature of TCM herbal therapy. Of approximately 100,000 formulas so far recorded at the present time, two third of them are polypharmacy type. Only one third of formulas comprise a single herb in TCM herbal therapy. Of the polypharmacy type formulas, approximately two third of formulas consists of 5-6 herbs, while the remaining one third have more than 5-6 herbs. Polypharmacy formulas generally exhibits holistic effectiveness by exerting activities to multi-target organs (organ systems) according to the Five elements hypothesis; the hypotheses of five tastes and five energies that are derived from Five Elements Hypothesis are also introduced to identification of the effects of herbal medication. 'The properties of herbs' indicates understanding the attributes of possible drug actions. Based on the 'properties of herbs', using several kinds of medical plants together to improve the effect and making them suitable to patient's symptoms. Although the polypharmacy is a bit used in traditional Indian medicine, this could be the main characteristic of TCM herbal therapy. Considering complexity of polypharmacy type of herbal therapy, many Western scientists become dismayed and wonder what specific pharmacological effects can be studied if any in a mixture of several herbs, sometimes even more than a dozen herbs in a formula.

To help understand these complexities of polypharmacy, herbal materials in a particular formula can be divided into four criteria according to their function.; King, Vassal, Assistant, and Delivery servant herbs. The King herb(s) plays a role of major pharmacological actions. The Vassals exhibit additive action, similar in activity to the Kings but with different herbs. Assistants usually perform a detoxifying activity. When we consider that each herb contains a variety of

constituents, both helpful and harmful to the patients, the Assistants act to nullify that harmful activity. The Delivering servants help transport the active ingredients existing in the King and Vassal herbs to target organ. In addition, TCM doctors frequently combine two different polypharmacy formulas-one to treat a specific organ, e.g., liver, and the other to treat a related aspect such as bile. By prescribing this way, the combined polypharmacy formula can exhibit multiple treatments to several organs. This is one of reasons why the TCM herbal remedies are believed to show holistic effects. Pharmacological information on the King herbs in certain polypharmacy formulas has drawn the attention of modern medical-pharmaceutical scientists, because there is a higher possibility of finding and isolating active constituents from TCM herbal materials identified as King herbs⁽²⁾. Ephedrine, Artemisin and Shizandrin are such a case.

To make it short, the most specific features what TCM herbal therapy has are; First, understand the drug's nature. Second, most of the medicines are supposed to undergo the 'pre-treatment'. Third, most of the prescriptions are polypharmacy.

II. Safety and Toxicity of TCM Herbal Materials

We generally assume that 'traditional medicines are safe because they have been used as medicines for several thousand years, which justifies the long time application'. This kind of idea sounds reasonable but very dangerous. Referred to the classification of medicines - High, Medium, and Low herbs, medium and low-leveled medicines mentioned in previous part could possess toxicity, even though most of them were pre-treated. Traditional medicines are, nonetheless, usually less toxic. This idea seems convincible because they should often be taken for longer period than western medicines. The therapeutically available time of effective ingredients from highly evolutionary herbs is usually short. The therapeutic time of the both effective and adverse effects can be even shorter because the ingredients mostly achieve pharmacological attributes after activation by human enzymes.

According to the clinical reports for recent 30 years at TCM Research Centers in Shanghai, there are a lot of toxic/adverse effects

in TCM herbal materials⁽³⁾. Especially, the precise dose-application is critical in that there exists many liver toxicity, and aplastic anemia. Special cautions should be exercised that some Chinese herbs such as *Aristolochiae Fangji* showed carcinogenic activities. Most importantly, when a drug has a same name but is from different herbal sources among three countries-Korea, China, and Japan, examination on the safety is necessary⁽⁴⁾.

III. Access to Information on TCM Herbal Therapy-TradiMed Database

In Korea, Japan and China, vast numbers of old medical classics have been in existence for several hundreds years. Referring to the Union Catalogue published by the Institute of Information, the Academy of TCM, approximately 12,000 books are listed, and almost all the books are written in Chinese alphabets.⁽⁵⁾ When we attempt to integrate TCM with Western medicine, the first step seems to gain access to those medical classics. However, it will require inordinate time, even though you have enough knowledge of Chinese language and literature. Assuming illiteracy in Chinese language, it is impossible to access to the information on TCM.

In this situation, I like to refer to the TradiMed Database (Traditional Oriental Medicines Database). This database contains vast amount of information on TCM herbal therapy. Six groups of information can be retrieved by using CD-ROM title, and Internet Web service (www.tradimed.com) as follows;

- 1) Formulas; total 12,000 formulas with indication, composition of herbs, dosage, caution, and contra-indication.
- 2) Botanical-Pharmacognosy; more than 2,000 herbal materials and botany, list of official compendia such as pharmacopoeia and national standards, and color photos of materials and plants.
- 3) Phytochemicals; constituents with chemical formula, molecular weights, common name of constituents, chemical structure images, analytical data such as melting points, spectroscopic data with UV, IR, nmr (proton and C13), mass spectrometer data. References sources, and safety-toxicity data are available also.

- 4) Disease Classification; more than 4,000 diseases classified in terms of TCM and modern pathology.
- 5) Pre-treatment/processing; traditional methods of pretreatment of more than 500 herbal materials.
- 6) Clinical Case Studies; more than 800 case report using TCM treatment and Western treatments simultaneously.

All these information are serviced in Korean (Year 2,000), English (Year 2,001), Japanese (Year 2002), and Chinese (Year 2004) versions.(service years).

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**REGIONAL POLICY OF
LEGISLATION OF
TRADITIONAL MEDICINE**

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REGIONAL POLICY OF LEGISLATION OF TRADITIONAL MEDICINE

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Introduction

Traditional medicine (TM)⁽¹⁾ includes the diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness. In countries where the dominant health care system is based on modern Western medicine or where traditional medicine has not been incorporated into the national health care system, traditional medicine is often termed “complementary”, “alternative” or “non-conventional” medicine (CAM).

Any discussion of TM, including that on legislation, therefore has to take into consideration the following areas:

- * Products and techniques
- * Practitioners; and
- * Protection of knowledge and heritage

Appropriate use of herbal medicines of guaranteed quality and efficacy is a culturally accepted, safe, and cost-effective way of treating a specific range of diseases. Herbal medicines are widely used in many countries of the Eastern Mediterranean Region for treatment of a variety of disorders and are hence the focus of WHO’s Eastern Mediterranean Regional Office (EMRO) work in the area of Traditional Medicine, and this paper. WHO/EMRO attaches great impor-

(1) As defined by WHO

tance to the proper use of herbal medicines as a mechanism to increase access to health care services.

Governments and patients alike are increasingly finding a place for the use of traditional medicine or natural medicine therapies among their options in health care. It can be noted on the one hand that, as one-third of the world's population lack regular access to essential drugs, a large proportion of the population in developing countries, indeed up to 80% of people in some rural areas, relies on traditional medicine as its primary, often sole, source of medication. In the industrialized world on the other hand, an increasingly large proportion of the population, in recognition of western medicines limitations, turns to traditional or alternative medicine as a complementary form of medicine.

The countries of our region mirror this global trend with continued, and expanding, reliance on traditional practices and products in some countries as well as a rapid introduction of new services in other, more affluent, countries.

Challenges

However, the future of Traditional Medicine is not assured. Common problems in most countries globally and regionally include the following:

- * Traditional medicine and its practitioners have not been officially recognized by many national health care provision systems and therefore continue to function outside these systems;
- * Regulation and registration for herbal products and other traditional therapies, based on scientifically sound safety and efficacy criteria has either not been established or is not enforced in most countries;
- * Research, education and training in traditional medicine have not received due attention by Governments and Academic Institutions alike;

Only few Member States in the region have a national policy on TRM, or the institutional set-up for national guidance on selection,

regulation and utilisation of herbal medicines. Moreover, traditional medicine practice is insufficiently integrated in, or aligned with, the national health services. Qualification schemes are mostly absent; which makes it difficult for national authorities and consumers to recognize qualified providers of TM/CAM.

To maximize the potential of TM/CAM as a source of health care, these problem areas related to policy; safety, efficacy and quality; access; and rational use must first be acknowledged and then be addressed in a coordinated fashion by all key stakeholders including the government, the traditional practitioners and the general public. This paper focuses on two components, policy and safety, efficacy and quality.

Policy

A review of the regulatory situation of herbal medicine in Member States in WHO Eastern Mediterranean Region two years ago showed that five of the 23 countries have a national policy on traditional medicine.

Other countries, especially those countries where TM/CAM is used as part of primary health care or as a function of complementary and alternative medicine, urgently need to develop their national policy on TM/CAM. This because a national policy provides a sound basis in defining the role of traditional TM/CAM in national health care delivery, ensuring that the necessary regulatory and legal mechanisms are created for promoting and maintaining good practice, that access is equitable and that the authenticity, safety and efficacy of therapies are assured.

Quality concerns

The increasing use of herbal medicines and the expansion of their markets in most countries in the region have led to concerns relating to the safety, quality and efficacy of herbal medicines on the part of health authorities and the public alike.

In the survey referred to above, less than a third of the Member States in the region reported a functioning regulatory system to ensure

However, more and more countries in the region not only recognise the importance of traditional medicine and an increasing number of health authorities are taking action to ensure the safety and efficacy of traditional medicine. For example, the government of Jordan has drafted requirements for the registration of herbal medicines. The governments of Gulf countries are particularly interested to develop their national regulation of herbal medicines and The Secretariat of the Gulf Countries Committee is developing the guidelines for regulation of herbal medicines.

Arguably the most advanced system developed to date in our region is that in Kuwait (see text box).

Kuwait was the first country in the region to recognize Islamic medicine in its constitution and set up the regulation of herbal medicines separate from that for conventional medicines. In 1984, Islamic medicine was recognized by the Constitution of the State of Kuwait. In the law, it described clearly that "An organization for 'Islamic Medicine' called 'The Islamic Organization for Medical Sciences' shall be established, having its own identity and independence, for which the State of Kuwait is the Residency. It might establish centres for research and study in or out Kuwait and shall function according to its constitution that will be issued by an Amiree Decree. The law also states that "Ministers, each within his Jurisdiction, shall see to the implementation of this Decree, effective on date of its publication in the official gazette." In 1986, the law of herbal medicines was promulgated. It supports the development of the safety and quality aspects of herbal medicine. The Islamic Medicine Centre was established in 1985. The Centre works together with the medical doctors, scientists and traditional practitioners and focuses on herbal medicines which have been traditionally used in Kuwait or in Islamic countries. Up to now, 40 types of herbal products have been produced by the Centre for 13 common diseases. An average of 15 000 patients are treated at the Centre each year.

Protecting Traditional Medicine Knowledge

In recent years, the Member States in WHO Eastern Mediterranean region have taken steps to preserve and protect their traditional medicine knowledge for safe and effective use. The establishment of research institutes in Iran and the UAE are examples of national efforts to protect and preserve traditional medicine and traditional medical knowledge. For instance, the Iranian Ministry of Health has developed a national inventory of medicinal plants and has published monographs on over 2500 plants among the 8000 plants whose use has been recorded in the country. The United Arab Emirates's Zayed Complex for Herbal Research and Traditional Medicine is an example of a member state's commitment to the preservation and promotion of traditional medicine, as well as to the promotion of safe and effective traditional medicine into the national health care system.

WHO's programme

In view of the specific issues of importance in the Member States of the Eastern Mediterranean Region described above, the objectives of the WHO programme related to herbal medicine, are therefore to support countries to:

- * Formulate national TRM policies, preferably as part of a national drug policy. It is advocated that such policies give particular emphasis on development or updating of the national legislation for registration and licensing of herbal medicines, as well as for the regulation of traditional medicine practice, as an integral component of the national health system;
- * Promote the proper use of herbal medicines through the development of technical guidelines, standards and methodologies;
- * Exchange relevant information with other Member States.

Specific technical support by WHO focuses on national policy development, regulation and quality control, human resource development, operational research, rational use and curriculum development.

WHO Traditional Medicine Strategy 2002-2005

Since this year implementation of all WHO's activities in the area of Traditional Medicine fall within the framework of the Traditional Medicine Strategy 2002-2005⁽¹⁾. This strategy was developed to meet the numerous challenges and opportunities offered by the integration of traditional, complementary and alternative medical systems in national health care systems. The Strategy has four major objectives:

*** Policy:**

Integrate Traditional and Complementary/Alternative Medicine (TM/CAM) with national health care systems, as appropriate, by developing and implementing national TM/CAM policies and programmes

*** Safety, efficacy and quality:**

Promote the safety, efficacy and quality of TM/CAM by expanding the knowledge base on TM/CAM and by providing guidance on regulatory and quality assurance standards

*** Access:**

Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations

*** Rational use:**

Promote therapeutically-sound use of TM/CAM by providers and consumers

Over the next four years, WHO will focus especially on the first two objectives, development and implementation of national TM/CAM policies, and promoting the safety, efficacy and quality of TM/CAM. This will include work on legislation and regulation of herbal and other TM/CAM products.

(1) WHO/EDM/TRM/2002.1

Policy

Key elements to include in a national policy on TM/CAM, as identified in the Strategy document, include⁽¹⁾:

- * Definition of TM/CAM
- * Definition of the Government's role in developing TM/CAM
- * *Provision for safety and quality assurance of TM/CAM therapies and products*
- * *Provision for creation or expansion of legislation relating to TM/CAM providers and regulation of herbal medicines*
- * Provision for education and training of TM/CAM providers
- * Provision for promotion and proper use of TM/CAM
- * Provision for capacity building of TM/CAM human resources, including allocation of financial resources;
- * Provision of coverage by state health insurance.
- * *Consideration of intellectual property issues*

Main indicator:

Strategy objective	1999 status	2005 target
Member States with national policy on traditional and complementary/ alternative medicine	13%	25%

Safety, efficacy and quality

Key needs in ensuring the safety, efficacy, and quality of TM/CAM include:

At national level:

- * *National regulation and registration of herbal medicines;*
- * *Safety monitoring for herbal medicines and other TM/CAM;*

(1) Those elements which have a direct link to legislation and regulation are entered in italics.

- * Support for clinical research into use of TM/CAM for treating country's common health problems;
- * *National standards, technical guidelines and methodology for evaluating safety, efficacy and quality of TM/CAM.*
- * *National pharmacopoeia and monographs of medicinal plants.*

At global level:

- * Access to existing knowledge of TM/CAM through exchange of accurate information and networking;
- * Shared results of research into use of TM/CAM for treating common diseases and health conditions;
- * *Evidence-base on safety, efficacy and quality of TM/CAM products and therapies*

Main indicator:

Strategy objective	1999 status	2005 target
Member States with laws and regulations on herbal medicines	34%	40%

Specific action

In response to the challenges of promotion of safe and effective use of traditional medicine, particularly focusing on the herbal medicines in the EMRO countries, the following framework for action will be discussed during the 49th session of WHO's Regional Committee for the Eastern Mediterranean (RC49):

Objectives	Components	Specific action
POLICY	Recognition of TM/CAM Assist countries, to develop national policies and programmes on TM/CAM	* Support selected countries to integrate TM/CAM into national health system.
	Protection and preservation of indigenous TM knowledge Assist countries to protect their indigenous TM knowledge	* Support selected countries to record the indigenous TM knowledge and in developing the national inventory of medicinal plants

SAFETY, EFFICACY AND QUALITY	<p>Regulation of herbal medicines</p> <p>Support countries to establish effective regulatory systems for registration and quality assurance of herbal medicines</p>	<p>* Organize regional workshops on national regulation of herbal medicines</p>
ACCESS	<p>Recognition of role of traditional practitioners and TM/CAM in health care</p> <p>Advocate recognition of traditional practitioners and practice</p>	<p>* Organize training workshop of TM/CAM practitioners in selected countries</p>
	<p>Conservation of medicinal plants</p> <p>Sustainable use and cultivation of medicinal plants</p>	<p>* Develop guidelines for good agriculture practice in relation to medicinal plants</p>
RATIONAL USE	<p>Proper use of TM/CAM by health providers</p> <p>Increase capacity of health care providers to make proper use of TM/CAM products and therapies</p>	<p>* Provide basic training for commonly used TM/CAM therapies</p> <p>* Strengthen cooperation between TM/CAM practitioners and other health care providers</p>
	<p>Proper use of TM/CAM by consumers</p> <p>Increase capacity of consumers to make informed decision on use TM/CAM</p>	<p>* Organize regional workshop on proper use of TM/CAM for the consumers and general public</p>

Conclusion

WHO will continue to support its Member States to strengthen Traditional Medicine as an important component of accessible quality health services through implementation of the WHO Traditional Medicine Strategy 2002-2005, and its four components, as adapted to regional and national requirements. During the coming years particular attention will be given to policy development as well as to the establishment of an appropriate legal and regulatory framework.

DISCUSSION

Discussion of Fourth Session Integration of CAM

Chairman: Prof. James G. Gordon

Rapporteur: Prof. Emilio Minelli

Chairman: We have some time for questions and please raise your hands if you would like to begin here.

Prof. John H. Bryant: I am a professor from the Aga Khan University in Karachi, Pakistan, but living in US. I wanted to ask Dr. Andrew Weil a question, but first wanted to say that I have much appreciated his presentation, particularly the health professional education that developed in relation to traditional medicine. And agreed just the fundamental points in both US and globally and see the influence of that spreading rapidly, I hope. I want to ask my curious question. You live and work in Arizona. Arizona has many Native American tribes with deep and rich cultures. I just wonder, if your learning about traditional medicine and doing research has been influenced by your interactions with those cultures. - Thank you!

Dr. Andrew Weil: In my own personal development, I would say interaction with cultures has been very important. In 1970s, I lived in South America and spend much time with South American Indians and learned from their ways of using plants and different traditional healing. At the moment, I am just beginning in the University of Mexico School of Medicine some programmes for the need of healing. They tried to bring the American Healers into the schools and teach about the system. For me, I think the most important thing that I learned from those cultures is the great emphasis on spirituality that disease often originates from spiritual power and then manifests in the physical body. And that enlist the causes of death in that background that work physically. I think that large view of medicine is extremely important and try to bring that perspective into our practice of medicine will be very useful.

Dr. Koshiro Otsuka: In American Medicine, you may have three different symptoms. And they will be treated as distinct. These

symptoms are headaches, muscular cramps, nasal congestion. But in the oriental medicine, these represent one complex. How would be treated with an educational study and naturalized computer systems? Have we lost the holistic way of diagnosing?

Dr. Moo Chang: There is a way of oriental treatment. But as I just said that there are 6800 diseases and symptoms classified in our cultures. But, we made an effort, those in other symptoms and disease in terms of oriental medicine. This converted western terminology. So, when you access to, as you just say nasal congestion and every thing, then you can get the information. When you access to western (terminology) pathology, you can obtain the information on the treatment of that particular disease by using our remedy. So, you can get idea, I cannot explain whole thing, you see in comparison with the western and oriental terminology, you can just get an idea from that.

Participant: You see, what we have, as he says that you are missing some sort of key diagnostic features. In fact, in this traditional approach, they believe that sometimes certain diseases are correlated in a sort of inside as you showed by the arrows. When you have symptoms that sometimes we don't find of that which is the energy and witness for that energy. That means they are aggravating the passage over the other. So, you may have two associations that go under one common 3,4,5 diseases with one side. This is what is missing in the system. This was his question. How can we approach three distinct issues? But these three distinct issues are, may be forty other ones, and may show intercorrelated relations of these five elements. So, it may cover 20 areas of diseases, with certain signs, which are associated.

Chairman: Well, according to my knowledge in Traditional Medicine, there is a base on hypothesis. There is no experimental proof for that. So, you know during my work to convert the oriental disease classification into a modern disease classification, the medical doctors from various fields from dental to internal medicine and surgeons, get together. They analyze symptom accurately. Then they look for the equivalent disease teaching in modern medicine. So, they actually disregard the theory or the hypothesis. There is a trust preached

hypothesis for experimental work in order to prove that. So, when you trust in another, I would say correlation of the oriental with modern medical treatment over diagnosis is often difficult.

Well, I would say that in integrated medicine clinic that I directed at the University of Arizona, we see so many patients who have gone to a series of specialist for treatment of individual problems. And, no one has taken the time to look at whole patient that they see how his problem may be connected, perhaps, through patients lifestyle, through diet, sleep stress and so forth. I think it is very useful to have a broader perspective. They have the time to work with the patient to look at the whole picture to see how different the symptom patterns can be related. I think it would be, I understand, what you are asking, in a way in order to make traditional Chinese medicine understandable to develop a common language to tell it into English. They have computerized format. There is a risk of losing some of that holistic perspective, and to make the system more reductionistic. So, I think that is a potential problem. I think one of the things; which represent a challenge - is how to organize vast available material as Dr. Chang and his colleague are doing. And this is one of the challenges as we work with traditional systems and bring them more evident to the wider world of health care. And I think, we have to really struggle, to see the same thing with every aspect of natural and traditional medicine. In US, for example, there are now integrated medicinal clinics connected to integrated medicinal services, connected to most of the major cultural sectors. The problem is not really integrated into the cultures. All these approaches are widely accepted and had a preserve of the depth of traditional knowledge. We preserve the individual in Canada and to make them part of the knowledge of healthcare system. I think that is a question we need to keep addressing.

Dr. Samir Banoob: Thank you very much! My question and comment is for Dr. Graaff and that is about the economic aspect, what we call in integration? Those of you may have watched CNN this morning with a scene that there is a discovery of a plant milk in Australia, which cures Skin Cancer. And, the cures means cures and

reacts the cancer cells and it preserves the natural tissue that could be a breakthrough. Immediately, it came to my mind, definitely the intellectual property on the indigenous Australian is vast.

Secondly, that medicine will be re-exported to Australia with the cost of US\$50/-. With this what we are going to get from integration like picking up on the good things and then commercialize it. Definitely, the stock of the company will skyrocket. And then go to, my mind, the African traders, well, the pharmaceutical companies are paying US\$700 — 800 per month for treatment of AIDS patient. Now, we can treat for US\$1/- per month. So, the question is, can these kinds of discoveries, belong to the community and being controlled, at least, emphasize by not-for-profitable organizations, such as WHO?

Chairman: Thank you very much! This could be heard about in the topic of legislation and regulation. Because, I think we as an organization agree with you whole-heartedly that what is in the indigenous knowledge is the wealth in the heritage of the people that brought forward the knowledge. And if there are any commercial benefits to be gained from this, they should at least share in this. This requires the respective governments to put in place supportive legislation to make sure that large international companies cannot get away with the type of actions.

Participant: Thank you Mr. Chairman! We used to teach the theory of Hippocrates based on the four main components. And while we were fascinated by the concept, we have to encourage natural healing process. But again the basic principle as history, because it was limited by the knowledge that are there at that time. But listening what is going on, I am thinking, it is time to think of this holistic theories to update them. Now, by that knowledge that we have, we can formulate the holistic theory that can include the old concept as well as the recent knowledge. - Thank you!

Chairman: I think that can be done and should be. I think, it is important to remember that the evidence based allopathic medicine is not as strong as many people believe. In my own practice and teaching, I recommend using sliding scalable evidence. I think this is a

good concept. I think that is a practical concept that we could use. If you look at many of the allopathic techniques, often the potentials for harm is very clear. But the evidence of efficacy is not so clear. For example, the potential of giving estrogen to cause cancer is obvious. This was known for 30 years. The evidence for the benefits of this therapy was very weak. So, we should not suddenly commence a great surprise. We now see that this is not such a good treatment.

Dr. Khalid Assiri: I am Dr. Khalid Assiri from Kingdom of Saudi Arabia. I agree with Dr. Andrew that the medical schools are far away to teach the students about the traditional therapy. With ethical consideration, we should choose the safest method for the people before more dangerous things. Hippocrates said “Leave your medications in the bottles and start by food” as one of the speakers said about the system. When we want to make clinical trial, are we using the diagnosis of traditional Chinese medicine or the diagnosis of modern medicine? I did not see in your system about clinical trial. You did not tell about that measure in efficacy of the formula that you mentioned in your system and you won’t provide the access of the Internet. - Thank you!

Dr. Moo Chang: The web site service will be made available only next year, because that web site service is to be provided by a French Company. There is deal with the medical information. They are going to provide this service next year. But the CD ROM is available. So, you can use them. What I understood is we are using that oriental diagnosis methodology in the practice.

Dr. A. R. Al-Awadi: I want just to talk about more policy issues. We want some thing about integration to find the solution. That should be, I believe tomorrow, we will arrange some time panel discussion on the issue that how do you go about the policy? How do you go about integration? How do you go about this kind of efficacy and quality control? Why I am saying this because, we are now touching in two fields and Mr. Peter Graaff tells very well. We are now very much convinced that now the two can find the solution. We must get the two hands to get in to that, we have seen that very well. I think, tomorrow afternoon, we will try to arrange a panel discussion,

because from here what you describe is how to come up with drug policies? How to go above from here? Now, here is a creedal of a recent Arabic or Islamic Medicine. We don't even deal with it. We have been so much brainwashed that everything West is best. As if we are no more seen in our own self. So I believe, it is possible to motivate how can we really come up? We should gradually lift all this very hates as we put upon the practice due to very few malpractice of some quackery? But 90% of what is happening is not quackery. It is real deep insight to see the people, put the people together. We forget that he is a human being, so many things as possibilities. Now, the west is realizing of rehabilitation. We will welcome to discuss this issue in more integrated way, we should integrate ourselves in discussion. - Thank you!

Dr. Moo Chang, Korea: In another context of integration, in Korea, we have the art of integration instead of using harmonization between the Traditional and Modern Medicines.

Chairman: One thing I should say. One of the great hopes is the education of people, generally about medicine, about science, about research. What I thought even I am working in a very poor population in the US, HIV positives, Drug Addicts for example, who have decided that they can't live, is very eager for information. They actually are extremely sharp about analyzing the oracles to be given to them. Because, many of them have some school education or highly educational knowledge, but for them it is a matter of life and death. And so they got very interested. And I think we can do a lot more work at a national and international level in terms of providing this kind of education to the general population. One of the anti-virus contributions has been newsletters, which is an example of providing information to a lot of people. I think that needs to be provided; the kind of information is to be provided to everybody. I taught in high schools and Jr. high schools in US about CAM and mind-body medicine. And they are very interested, because it is about them. By the health care specially when comes to think you can experience fields of mind-body approaches, exercise, nutrition, acupuncture, becomes very interesting. I think one of the other challenges is how we bring

this kind of education to all of our people? And I think, we will discuss that more.

Dr. Haitham Al Khayyath: I would like to mention an example in support of the notion of Andrew Weil about the difference between treatment and healing. This example is very well known which is Cholera. Cholera is known as a fearful epidemic. When we introduced the oral rehydration treatment, which is a natural treatment as well. When we introduced it, we discovered that it is not necessary to give any medicine to the patient, we just rehydrate him and leave the immunity of the body in two or three days to take care of the bacteria. So, this is a very important example to prove that it is really the healing power of body that works. And even if we give one of the tetracyclines, it is just to support the body in this critical period. Second point, about the referring back to Hippocrates. The Hippocrates that you talk about and we talk about is not the real Hippocrates of course. He is the Hippocrates with an Arabic clock. So, actually we attribute to Hippocrates is a mixture of what Hippocrates got and what the Arab, Islamic physicians added to that. It is our mistake. Unfortunately here the Arab-Islamic World, we didn't go back to the books that are still available, they are really very precious, to understand this whole philosophy, and it is a holistic philosophy as well. And to use it, to try to improve our mother medicine, our mother treatment etc. to give this spiritual touch to what is being done. So, I think it is very important, now I am saying that for myself and to my colleagues here that it is our duty now to go back to these books and try to find out many issues that can be used by any of the west and rest, thereof. And try to integrate or harmonize the medicine that is called modern or allopathic etc. The last small point, we have here, what you call integration or harmonization in Sudan between the traditional healers and the physicians of the modern medicine. Particularly in the psychiatric field, those patients that go to the Sheikh and ask for a treatment, if Sheikh finds that this patient has an epilepsy for example, he sends to the modern physician. And the modern physician gives, I don't know what is the drug, and send back to the traditional healer is the other ways of doing that.

This is a beautiful mixture and it is very successful. I think this is a kind of integration or harmonization that we need to try to extend for other fields of medicine. - Thank you Mr. Chairman.

Chairman: In discussions of Traditional Medicine in US, there is ignorance about Islamic Medicine in my country. This is point of fact that this is a bridge between the ancient medicine of Greece and even of India and the west. I think it would be very useful to try to establish more exchange between the west and the philosophy of Islamic Medicine, which is in my understanding, very consistent with this new model of integration or harmonization. I would work on that.

I want to thank our panelists and Rapporteur. All of you spent a very good discussion. I hope that in future meetings as well as in the rest of this meeting we will be able to continue discussion - Thank your very much!

Fifth Session

Saturday, 13 October 2002

Policy of CAM

Chairman : Dr. Adrian White

Rapporteur : Dr. Abdullah Ibin Muhammad Al-Bedah

Speakers:

1 - Prof. Vinjar Fonnebo (Norway)

2 - Dr. Adrian White (U.K)

3 - Prof. Emilio Minelli (Italy).

**EFFECTIVENESS OF TRM
FROM A POLICY FORMULATION
PERSPECTIVE**

Prof. Vinjar Fonnebo

(Norway)

EFFECTIVENESS OF TRM FROM A POLICY FORMULATION PERSPECTIVE

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Abstract:

TRM is included in the health service in varying degrees in different societies and countries and the forces behind this is complex, of which effectiveness is only one, and may be a minor part. The priorities inherent in policy formulation will influence the possible inclusion of TRM. Three factors are pivotal in policy formulation: choice of provider of health care, the definition of quality standard and the choice of funding responsibility of health care. Several dimensions of effectiveness measurement in TRM are also important: Accessibility, Disease-limiting effect, Acceptability and Disease-specific area of use. The understanding of the complex interaction of aspects of effectiveness and policy formulation will decide what role effectiveness of TRM will influence future policy formulation.

Introduction

The rapid increase in the use of other treatment approaches than the traditionally dominant ones gives rise to challenges for policy-makers around the world. In the so-called developed countries alternative treatment modalities are sought by around 30% of the population for some of their illnesses and ailments. A substantial out-of-pocket payment is channeled into this market. Challenges in the regulation of this development are substantial in countries where consumer interest and protection are taken for granted. Insurance companies are also increasingly being forced to make independent evaluations of coverage for these treatment modalities. In the developing countries, on the other hand, traditional, low-cost, treatment modalities are losing reputation in competition with so-called Western

medicine. A demand of a health care approach beyond the financial resources of the customers poses a tremendous challenge to the concept of universal access to an acceptable level of health care. An interesting scenario has arisen: "Acceptance" of alternative/complementary/traditional treatment approaches in developed countries can facilitate the establishment of a universal, financially acceptable health care service in the developing world. In order to approach the topic of effectiveness of TRM and policy formulation, one has to look somewhat deeper into the many different aspects of the two concepts. I will use my own country to exemplify the discussion.

The policy formulation perspective

The bodies formulating policy with regard to health care at a government level have to address several issues. Most important is that they will always formulate policy on the basis of an already existing health care system of some kind. This is important to keep in mind in understanding that policy makers are not in the situation where they can make a fresh start. Construction of a policy solely based on current ideas of what is the optimal health care without considering the existing system is only theoretically possible after a revolution. I know too little about the Khmer revolution in Cambodia in 1975 to share with you any ideas about whether any attempt was made at that time to do exactly that.

Being in a current situation makes it necessary to consider several factors that are relevant in policy formulation with regard to health care. I think three factors are pivotal: choice of provider of health care, the definition of quality standard and the choice of funding responsibility of health care.

Choice of provider

The provider of health care in a population or nation can be the government itself at the national, county or municipal level, private providers under contract from a governmental level or independent private providers. Choice of provider channel will influence the attitude to TRM, irrespective of documented effect.

When the government itself is the sole provider of health care, the inclusion of treatment modalities will be decided by a body which has to take into consideration many other aspects than treatment effectiveness. Lobby groups representing various political, environmental, cultural and religious groups will attempt to influence this process in addition to the research community. A system with centrally chosen treatment modalities will be resistant to innovations even if effectiveness in a narrow sense of the word has been documented. Not many countries adhere to this level of health care provision.

Private providers under contract

This system which is common in Scandinavia and many other European countries has many similarities to the first one. Policies regarding inclusion of treatment modalities are closely connected to the funding authority. Central political control is still very dominant with all the above-mentioned parties trying to influence the process. However the practicing provider can opt to work for or actually leave the contract with the government enabling it to include and offer other treatment. Professional associations will in this system play an important lobbying role for the regulation of "accepted" treatment modalities.

Independent private providers

If the providers are independent as is common in the USA, there will be a much more diverse possibility for differentiation of accepted treatment modalities. Regulation from the central government will be dependant on what level of detail the politicians encourage. The individual provider will be to large degree governed by the professional organization they belong to. In USA the diversity of accepted treatment modalities illustrates this point.

Quality standard

The quality perspective of policy formulation depends on which treatment values are at the forefront in the society concerned. An axis can be drawn where the extremes are represented by focus on care

quality on the one end, and hard outcome end points at the other. Western societies have in general become so intoxicated by their own outcome success in treating infectious diseases that the general focus in treatment of disease has been put on this aspect of quality standard. Countries and societies accepting more traditional treatment modalities like to present themselves as emphasizing equally the care and holistic approach as measures of a high standard of quality in the health care delivery. Norway is in line with other Western countries in that outcome quality is given highest priority although care quality is gaining ground.

Funding responsibility

The principle in this area is very simple. The power follows the money. If the funder and the provider are the same, the funder decides. If the funder and provider are different, the funder still decides. In a totally free market, the patient will be the person deciding by his/her demand what treatment modalities should be offered. Patients can cooperate through an insurance system. Through the consultation of experts, the insurance companies can give advice to their customers as to what treatment modalities should be offered. When the patients trust government to spend their health care money, they accept a level of governance that has to take many other aspects into consideration. Norway has a system with high government funding, and thereby of course a high level of control.

Effectiveness of traditional medicine

Traditional or alternative/complementary medicine can be considered effective from many standpoints. It is important to discuss these aspects of effectiveness before one tries to evaluate the effectiveness issue combined with the policy formulation perspective.

Accessibility

Effectiveness must always be judged within the accessibility boundaries that are set for the society served. These boundaries can be

geographical, financial, cultural or religious. Norway is a country with very few limitations due to accessibility.

Disease-limiting effect

The most widely accepted measure of effectiveness is the documentation based on rigorous scientific research regarding outcome of disease based on treatment given. Even this concept is, however, not without challenges. The choice of what area to research will heavily influence the available evidence regarding effectiveness. The increasing international focus on evidence-based medicine can actually contribute to a lower level of scientific documentation of other disease limiting effects. All financial resources are put into research on drug treatment of disease because only multinational drug companies have the resources to fund this kind of research. Norway does not give a high priority to government-funded research when compared to other Nordic countries, and we are thereby just as vulnerable to this problem as the rest of the world.

Acceptability

This issue links closely with the accessibility issue. The health care provider must make sure that the treatment modalities offered are in harmony with the values of the society served. The effectiveness will otherwise be seriously jeopardized.

Type of disease

The specter of disease has changed dramatically over the last centuries. An expanding definition and inclusion of unwanted life experiences in the disease concept is combined with a growing potential for the treatment industry. Effectiveness of treatment of yesterday's diseases can therefore be irrelevant for the diseases of tomorrow.

Putting the two together

What is the most effective treatment for this patient

This is the simple question that many of us would like to think

policy makers use as a guide to policy decisions regarding health care provision. As has been demonstrated above there are several aspects of this question that make it much more complicated than it might seem.

...in this culture

If culture is taken into account the provider will have to limit the available options to the ones accepted by the specific culture of the ones with a long tradition in the current culture. Effectiveness will be of relevance in the policy formulation only within the local cultural boundaries.

...with these public resources

The resources allocated to health care are limited in any society. The segment of the health care industry funded by the government will have to relate the effectiveness of TRM to effectiveness of other affordable treatment modalities. This can heavily influence the evaluation of effectiveness. The provision of high-cost health care can be impossible, when at the same time the local population is hesitant to utilize traditional medicine.

...with these private resources

In the privately funded health care sector the policy will mainly be concentrated on limiting treatment modalities that market themselves under unsubstantiated claims. The market decides by itself what is to be the "policy" with regard to effective health care. The development seen in the United States with a dual focus on effectiveness along the lines given above illustrate this point. High-tech, impersonal outcome-effective health care is expanding rapidly alongside treatment modalities concentrated on time, care and holistic approach. The patients/customers want both aspects of effectiveness at the same time. The policy challenge is to ensure a regulation based on the principles of consumer interest.

What is the most effective treatment in global perspective

In a global perspective, lifting the vision from local societies/countries/continents, there is only one effective treatment for the major

diseases of the world. Social injustice must be eradicated and a sustainable economy must be the foundation for every world citizen. Health care approach has probably little influence on the health of the world's population. For the sick and diseased, however, the choice of policy on treatment modalities will be an important factor in deciding both at what level of care they are handled, and what probable outcome their disease will have.

**COST EFFECTIVENESS OF
TRADITIONAL MEDICINE**

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COST EFFECTIVENESS OF TRADITIONAL MEDICINE

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Introduction

It may seem to be self-evident that traditional medicine can offer considerable savings on the cost of providing health services(1). Traditional medicine specifically avoids the cost of high-technology medicine, it uses remedies that may often be safer than drugs, and it encourages self-help and prevention of future health problems. It would seem obvious, therefore, that those responsible for purchasing health care would adopt traditional medicine with enthusiasm. However, they do not: its use is very patchy and inconsistent, and it forms a very small part of the overall health services budget. Why is this? Decision making on health services is a highly complex activity subject to many influences, many of which operate against change. These include professional interests concerning employment and relative roles in the workplace, and industrial interests to do with development of new technologies, workforce employment, investment and balance of payments. The importance of these influences should not be underrated, even if there is a recent explicit trend towards the use of objective evidence in making health decisions. It seems clear that those who promote the value of traditional medicine are only likely to achieve their aims through arguments based on sound evidence that traditional medicines offer potential cost savings over existing health care, particularly in view of the downward pressure on health care resources.

The three foci for evidence-based decision making in policy-decisions on health care are evidence about effectiveness, about safety and about cost. In general, policy decisions that are formed at national (state, region) level would be similar to those made by the individual

clinician who sees his responsibility to apply resources in the most equitable manner possible. An individual clinician who argues the case for special funding for an individual patient is aware that the funding comes from a single budget and his patient's gain is another patient's loss. Nevertheless, patient preference is a powerful factor which usually applies directly at the clinician. Patient preferences may take an increasing role in policy formulation at the level of local health care decisions in the UK in future, with the arrival of primary care trusts with considerable representation by non-medical people.

In the simplest circumstances, it can be seen that a new therapy should replace an existing therapy if it can be demonstrated to be superior in either effectiveness, or safety or cost. This of course is oversimplistic and, for example, takes no account of the costs of change of personnel or fixtures such as clinics and equipment that might be necessary in providing the new therapy. It is the overall picture that governments and insurance companies must take into account. It is much more complex to make decisions about a therapy that claims additional effectiveness but costs more. This scenario is likely to be common in some settings in which traditional medicine might be considered. It may well offer improved health and future savings in health care costs, but traditional medicine may prove to be more expensive in terms of manpower than conventional health care: personnel costs form a large part of any health care budget.

The approach in this paper is to consider the balance of effectiveness, safety and cost in various settings, using whatever best evidence is available. Many of these studies have been included in a systematic review of the literature(2). No study reaches the accepted standards for reporting of economic analysis of health interventions(3). The essential quality questions to apply to these studies are: were the costs measured prospectively? and were the two patient groups that were investigated properly comparable? The evidence falls into 2 groups: Traditional medicine for particular indications, and Traditional medicine for overall health care. Although clear evidence of potential savings cannot be produced, there are still important pointers for the direction of decisions or at least proposals for future research.

Management of individual clinical conditions

a) **Substitution of conventional drugs by herbal preparations.** An increasing number of herbs have accumulated evidence of efficacy that makes them realistic alternatives to conventional drugs. They may be expected to be cheaper since there are few research and development costs to be repaid from sales. For example, saw palmetto is effective for benign prostatic hypertrophy(4). Using estimated costs in the UK, even the cumulative cost of using saw palmetto over many years remains less than the cost of transurethral prostatectomy. This is not the case with all drugs, however. St John's wort is now established as being effective in the treatment of depression, at least mild and moderate forms(5). Its effectiveness is similar to that of both tricyclic antidepressants and selective serotonin re-uptake inhibitors (SSRIs), and its profile of adverse events is rather benign, and much more similar to that of SSRIs than the tricyclic drugs. This may increase the overall effectiveness in practice by reducing the number of patients who stop their treatment because of adverse events. But St John's wort is currently considerably more expensive than those SSRIs which are no longer covered by patents.

b) **Manipulative therapy for back pain**

Back pain has considerable economic impact in many nations. The potential benefits of manipulative therapy have been tested in a number of controlled trials(2). Although one study found that private chiropractic clinics produced a better long-term outcome than out-patient clinics provided by the health service, this could have been due to the effect of the setting(6). When manipulation was compared with other therapies in similar settings, it did not prove superior in either outcome or costs(7,8). In one study it was just as expensive as medical specialist care in out-patients, and both were considerably more expensive than care at basic level(9). In another study, 5 therapies were compared for 250 patients with chronic back pain post-laminectomy who worked for an automobile manufacturer(10). Exercise therapy was superior to any form of manual intervention including physical therapy and spinal

manipulation. The exercise therapy was given in two alternative forms: either with high technology equipment in a special centre, or low technology exercises at home. The latter proved considerably more cost-effective. The message from this group of studies seems to be that, for a complex condition like back pain in which any form of accurate diagnosis is difficult and there is no single clearly effective treatment, the simplest and cheapest intervention is preferred.

c) **Acupuncture for chronic pain**

A study from the UK, was interesting even if not rigorous(11). The costs of providing acupuncture for treatment of chronic pain were measured for 65 patients, who were carefully selected by the acupuncturist for suitability for treatment. The clinical outcome of acupuncture treatment was satisfactory, as nearly four fifths of patients gained 70% pain relief. Costs were then compared retrospectively with the estimated costs of treating the patients in hospital out-patients. The author claimed that acupuncture lead to savings of £260 per patient. However, this study cannot support far-reaching conclusions: there was no real control group, so we cannot compare the effectiveness of the two settings. The costs were not measured prospectively. Costs of acupuncture as provided (per session) were not calculated in the same way as hospital out-patient costs. Nevertheless, there appears to be one important lesson: the patients were carefully selected for acupuncture by a doctor who knew what conditions acupuncture may help and where it is unlikely to. We could call this targeted use of traditional medicine. Individual clinicians who are making decisions on the most cost-effective management of their patients must carefully consider whether the proposed traditional treatment is likely to benefit the individual patient rather than applying it routinely to all patients. This is likely to require new knowledge and skills. Studies that aim to explore the economic benefits of traditional medicine will be most promising when they consider its use in a carefully defined population.

Health care systems

a) Provision of basic care in developing countries

When no health care exists, it seems simplest and most effective to use existing indigenous traditional healers, perhaps in combination with some extra tuition in basic western techniques, to provide an improved level of health care. This was precisely the situation faced by the incoming Chinese government in 1949 and was dealt with by brief training of barefoot doctors who then were able to provide basic health care for some billion population. Questions of value for money are clearly rather theoretical in these circumstances and are overridden by social needs and government priorities.

b) Primary care

Providers of primary care often have a many similarities to Traditional medicine practitioners in their approach, at least in western settings. This is in contrast to, for example, most medical or surgical specialists. These similarities include a willingness to consider the health of the patient in a wider framework than just the medical condition, to include psychosocial aspects; the willingness to work with patients over a period of years in the care of chronic problems, rather than discharging them when no effective therapy can be found in the pharmacopoeia; and recognition of the value of self-help and education. The needs of patients can be expressed in a general way as a hierarchy of needs (Figure 1).

Figure 1: Maslows Hierarchy of Needs

Transcendence - spiritual needs

Self actualisation - fulfilling ones potential

Esteem - respect, recognition, affiliation, to be accepted

Security needs - the need for physical and psychological safety

Physiological needs - freedom from pain, hunger

Medicine that attempts to meet patients higher needs is difficult to assess. The most obvious problem is methodological, i.e. how to evaluate the effect of a therapy on higher needs. For example, providing an explanation in understandable terms to a patient with a

chronic, previously undiagnosed, illness, may afford the patient recognition and restore their self-esteem. Clearly this problem applies to primary care itself as much as to traditional medicine, but primary care is not attempting to gain recognition and acceptance like traditional medicine is. Current measures of quality of life, and the particular measure used for economic analysis, i.e. the EuroQol incorporated into the Quality Adjusted Life Year, only operate at the lowest level of the hierarchy, i.e. in this case the reduction of symptoms. One possible approach that may prove useful is the 'willingness to pay' method(12). This is a generalisable technique which asks patients to put a value on a therapeutic vignette that is described to them, e.g. willingness to pay for a traditional Chinese medicine approach to treatment for migraine.

The second problem is that different practitioners will meet these higher needs to different extents; in other words, meeting these needs is not dependent so much on the therapy as on the therapist. Whether therapists use acupuncture or homeopathy may be considerably less important than their caring approach and interpersonal skills. Results from one practitioner are unlikely to be generalisable.

The third problem is in convincing governments/insurance companies that these higher needs are a matter of concern of a health service. They are likely to argue that patients primarily want their health care attendants to treat their symptoms, and any extra care aimed at meeting higher needs is 'icing on the cake'; and that, while patients are free to purchase traditional medicine for themselves, it is not the government's job to provide it. This could be countered if evidence could be provided that meeting these higher needs successfully reduces patients subsequent demands for health care leading to reduced costs in the long term. There is a suggestive study that transcendental meditation provides stress relief and savings in health costs(13) but the data are not reliable so further research on this important topic is essential.

A further methodological problem in relation to this effect of traditional medicine is the difficulty of selecting a control group. It is one thing to introduce traditional medicine into a primary care setting

and measure the changes that follow. But it is unconvincing to say the changes are due to the traditional medicine, as they could be the effects of other changes. Controlled trials are required: but how is the control group to be formed? In particular, patients who are attracted to traditional medicine will be attracted to the group that provides it. But they will be systematically different from patients who do not choose traditional medicine, for example they might be more likely to be middle aged and female, to have some interest in health lifestyle and so on. No study has yet achieved this ideal control.

A primary care practice in Glastonbury, UK, received funds from a health authority research budget to provide CAM on practice premises, free to the patients and unconstrained by a local budget for health services (fundholding)(14). This report was published privately and not submitted to peer review. The CAM service was provided by 6 practitioners, one of whom was the senior medical partner providing homoeopathic consultations. Two analyses in the report are of particular relevance to economic analysis: changes in referral rates and comparison of health care costs. During the 3 year period for which data on referrals to 4 relevant specialities are available, the rates of referral from the practice remained static. In contrast, the average for other local practices rose over the same period by 33% (see Table 1).

Table 1

Annual rates of referral (per 1000 practice population) to certain departments for the Glastonbury practice offering CAM, compared to percentage changes for other local practices over the same years (14)

Specialist referral	Glastonbury 1993/4	Glastonbury 1995/6	Glastonbury change	All practices in county, change 1993/4 to 1995/6
Orthopaedics	18	19	+6%	+ 28%
Rheumatology	4.3	6.6	+ 54%	+ 48%
Physiotherapy	40	38	-5%	+ 22%
Psychiatry	39	37	-5%	+ 65%

These results are limited by the methodology of the study: referral rates vary widely over time so that 3 years is too short a period to draw firm conclusions. In addition, the practices did not necessarily serve comparable populations.

In order to look at overall cost minimisation, a retrospective analysis was performed of the costs for 41 patients for whom there were data for one year before and after treatment with CAM. Treatment with CAM for this group cost a total of £2570, which is, interestingly, very similar to the estimated reduction in costs of orthodox care, including GP visits, drugs, physiotherapy and counselling, over the 2 years. Some reduction in costs would be likely due to the natural history of the conditions, so it would not be correct to conclude that the savings were entirely the result of treatment with CAM. This report illustrates some of the difficulties in conducting rigorous research in this area but serves to generate interesting hypotheses.

Provision of complete medical services

One attempt at a truly randomised study addressed the question: Does open access to traditional medicine increase or reduce health care costs?(15). A representative sample of 7,500 policyholders in the database of a Swiss health insurance provider were selected at random and offered free access for traditional medicine, as well as their regular health care, for 3 years. The remaining 670,000 subscribers were controls, continuing with normal health care. All claims for the costs of health care over the period were analysed. The expenditure figures for the groups one year before the study and in the final year of the study are presented: average costs of conventional therapy rose from year 1 to year 3 in both groups, with no significant difference between them. The costs of traditional medicine rose from US\$1 to 30 US\$ in the free access group, and from US\$1 to US\$18 in the control group. This is a significant difference. However, using traditional medicine had no impact on overall health costs. In fact, less than 1% of the experimental group used traditional medicine exclusively for any episode of illness. It was always an additional cost. In addition, the

health status of a small proportion of patients was measured before and after the study, using the SF-36 quality of life questionnaire, but the sample was too small to be conclusive.

Unfortunately, this study has serious limitations, which is not surprising considering it is the first of its kind. The people who were offered traditional medicine were not particularly interested in it, and even forgot that it was available. The level of use of Traditional medicine rose to only about 6%, which is much lower than surveys generally find. The patients' and doctors' knowledge about and use of traditional medicine was not optimised. The difference between the use of traditional medicine in the two groups was too small to make any impact on orthodox health care costs. The study duration was too short to permit real changes in usage patterns. The measurement of quality of life was taken on too few patients, it should be measured on whole groups. Other major criticisms have been raised. The message is that the methodology is potentially useful but this particular study does not lead to any conclusions on the effect on health costs providing traditional medicine free.

Conclusion

There is still insufficient evidence to make firm statements about the economic value of traditional medicine in comparison with conventional medicine. Although it is easy to assume that it is cheaper, the very limited evidence suggests that this may not necessarily be true. Some herbal preparations are cheaper than their pharmaceutical counterparts, but not all. Simple therapies for back pain appear more cost-effective than spinal manipulation and physiotherapy. One promising subject for research is acupuncture for the treatment of chronic pain. Further research is well worthwhile into therapies such as meditation for long-term prevention of health care costs. Traditional medicine might need to be carefully targeted. There is no alternative to carefully designed high quality RCTs in determining the cost consequences of Traditional medicine. It should also be noted that economic analysis is just one of several factors influencing decisions on health care, including current practice, the wishes of the public, and vested interests.

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**RESEARCH METHODS AND
EFFICACY EVALUATION IN
NON-CONVENTIONAL MEDICINE**

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RESEARCH METHODS AND EFFICACY EVALUATION IN NON-CONVENTIONAL MEDICINE

Emilio Minelli, Umberto Solimene***

Definitions

The Food and Drug Administration defines non-conventional therapies as “medical interventions that:

- i) lack sufficient documentary support with respect to their safety and efficacy under specific pathological conditions;
- ii) are not generally taught in graduate medicine courses;
- iii) are not generally reimbursed by Insurance Companies” (Eisenberg et al., 1993).

A further definition, proposed in the JAMA issue of November 1998, classifies them as: “a wide set of healthcare practices (i.e. publicly available) other than those intrinsic to the politically dominating healthcare system of a given society or culture” (Sugarman J., Burk L., 1998).

The above highlights the still dominating role that the monopolistic institutional assessment of the biomedical paradigm still plays in the definition of non conventional medicines, besides providing a relevant reference to the scientific biomedical model. On the other hand, in this respect, it is worth mentioning, among others, the disregarded recommendation of the World Health Organization, expressed by the Office for Traditional Medicine Programmes and described in the document “Relations between Traditional Medicines and Official Healthcare

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Systems” of 1983, and inviting Member States to “try and overcome the monopoly, tolerance, or parallel relations between traditional medicines and western medicines, to come up with integration between different disciplines “ (W.H.O., 1993).

No mention is made in the W.H.O. documents of “Non-Conventional medicines”, but Traditional Medicine is widely discussed.

This is defined as a “set of notions based on the history and beliefs of a country, developed a long time before the European medicine and its modern technological development ever took place.” This is one reason why sophisticated theories and complex caring systems of traditional medicines are often expressed and handed down in ways that are sometimes quite alien to modern scientific medicine.

The Burden of Evidence

In the light of the frequent criticism expressed by the opponents to this therapeutic option, claiming substantial lack of evidence on efficacy both with respect to basic techniques and to clinical research, the W.H.O. has repeatedly stated that traditional medicine must ensure evidence of efficacy and safe use equal to that provided by modern western medicine.

In addition, the W.H.O. has repeatedly stated the need for an ethical use of complementary medicines in countries where medical treatment is based on modern medicine, to be supported by evidence on efficacy, assessed through controlled clinical studies (Consultation on Acupuncture, Milan, November 1996). This is why the W.H.O. has expressed the need to operate in view of obtaining validation tools allowing, on one hand, to collect results comparable to those of conventional medicine and, on the other, to take into account the special concepts and applications of complementary medicines. At the same time, these should not prevent the practice and use of the latter, even before reliable disproving evidence has been provided. This position implies a substantially positive evaluation of the data resulting from practising a discipline for hundreds and, sometimes, thousands of years.

Traditional Medicine and Homeopathy

According to the authors, homeopathy may nowadays, for its origin and its long-term use in Europe, be considered as an integral part of traditional European medicine. In this sense, it may be reviewed according to the guidelines provided by the W.H.O. in the survey on traditional medicine. This is why the authors claim that homeopathy may only be assessed starting from clear recognition of the general scope of practice within which it is used, rather than only from an evaluation of the pharmacological value of the remedies used. This implies the need to identify appropriate methods and tools for the assessment of the clinical efficacy of homeopathy, without denying the importance of appropriate basic research allowing a correct evaluation of the homeopathic system as a whole.

The authors thus start with a review of the steps constituting the diagnostic and prescriptive methods of homeopathy (Buckman R. and Lewith G., 1994), in order to identify any additional variables that should be considered in view of investigating the existence of a possible method for assessment of the efficacy of homeopathy. Besides, the peculiarities of homeopathy are highlighted, taking into account the performance of treatments on a daily basis, including treatment term, a possible homeopathic worsening of conditions, the practitioner/patient relation, and the placebo effect.

The Methodological Challenges of Homeopathy

The authors further review the methodological problems affecting the identification of the tools to be used for correct evaluation of the homeopathic practice, while trying to overcome the risk of giving up any evaluations and of applying the traditional research method to clinical homeopathy, through more or less substantial simplifications or distortions of the same (Reilly D.T. et al., 1986; Hart O. et al., 1997; Vickers A.J. et al., 1998).

The methodological issues involved in homeopathy should therefore be considered, including customized therapy, evaluation of treatment failures, evaluation of results and, last but not least, the problems concerning evaluation biases.

Update of Research Methods in the Field of Non-Conventional Medicines

Two positions are currently recorded with respect to the methods to be used for evaluation of non-conventional medicines: while one of these is defined in the work by the W.H.O., the other is summarized in the “Methodological Manifesto” drafted by the National Institute of Health (NIH).

WHOQOL-100 and the Indexes of Quality of Life

The W.H.O. has created WHOQOL-100, a system for evaluation of the effects of complementary therapies on the quality of life, characterized by the ability to determine the effect of a therapy based on its impact on the patient as a psycho-physical entity, rather than on the disease, as the sole available principle for evaluation. The limit of this tool, namely its purportedly universal applicability, does not affect its value and importance.

WHOQOL-100 Scheme	
Spheres	Issues
Physical	Pain, discomfort Energy, weakness Sleep, rest
Psychological	Positive feelings Thinking, learning, concentration Self-esteem Body image, appearance Negative feelings
Independence level	Mobility Daily activities Working ability
Social relations	Interpersonal relations Social support Sexual activity

<p>Environmental</p>	<p>Physical safety Domestic environment Financial resources Health and treatment: value and quality Willingness to acquire new information and skills Participation and openness to entertainment and leisure Physical environment (pollution, noise, traffic, climate)</p>
<p>Spiritual</p>	<p>Spirit / religion / faith</p>

The W.H.O. initiative starts as an original opportunity for synthesis and valorization of widespread methods, the Indexes of Quality of Life (IQL), based on collection of data where subjective issues, highly valued, are combined with objective data. The main characteristic of these research tools, also very useful for clinical studies in homeopathy, is the importance they attach to the evaluation of global actions and of the relevant impact on the patient, considered as a global psychophysical entity. This is why the authors believe that this type of studies are particularly fit for the evaluation of methods like homeopathy, affecting the patients general conditions rather than a given symptom (Liverani A., Minelli E., Ricciuti A., 2000).

Limits of the IQLs

The strong dependence of the individual on environmental and/or psychological conditions is the basic critical issue of these evaluation methods.

The main effort implied by the use of this tools is to restrict the purposes of investigation and the field of observation as much as possible. These limits, however, are combined with substantially flexible use even by individual professionals. From the methodological viewpoint, it should be noted that these tools, subject to the necessary validation process, are relatively simple to set up and implement, provided that their purpose is clearly and precisely stated. If we assume that extending life and improving life quality are clear

indicators of the efficacy of a treatment, the IQLs may indicate the effectiveness of a therapy as much as, or better than, those constituted by other biohumoral parameters.

The Methodological Manifesto of the NIH

The opposite opinion, although not in disagreement, is expressed by outstanding experts. In spite of considerable reserves concerning Randomized Clinical Trials (RCT) and “reductive evaluation approaches”, they still claim that existing methods are widely sufficient for correct evaluation of alternative therapies.

One of the most concise and outstanding statements in this respect was expressed by the NIH Working Group on Quantitative Methods in Alternative Medicines, which drafted a sort of Methodological Manifesto. This points out to a number of methodological guidelines, which anyone involved in CAM research should comply with. The document is basically divided into two parts: part one describes major methodological problems, and part two contains guidelines and recommendations, which may be summarized as follows.

The Methodological Manifesto
<p>Methodological problems</p> <ol style="list-style-type: none"> 1. Complex customized actions 2. Customized therapeutic effects 3. Focus on effects vs. systemic disorders 4. System correspondence and correlations 5. Long-term effects 6. Redefinition of the human body 7. Multi-factor aetiology <p>Methodological Guidelines</p> <ol style="list-style-type: none"> 1. Problems concerning different studies require different methodological and analytical approaches.

2. Researchers should use the strongest possible research schemes and the most appropriate statistical processes for the issues raised by a given study.

A special type of intervention does not necessarily comply with the conventions that are normally considered as the best in medical research (double blind studies, randomized placebo-controlled studies), but other research projects and statistical approaches may be fit to respond to the issues involved by the study concerned.

3. Clinical trials are not the only possible studies.
4. The results of observation studies may support the projects for intervention trials.

Indeed, new medical know-how is more often acquired through observation, both by means of the prospective analysis obtained from mass studies and simple case studies.

5. Alternative therapies: yes; alternative results: no.
For example, a clinical trial could be carried out in homeopathy without considering the multi-factor character of the intervention or how unusual the specified recovery mechanism is, provided that the proposed evaluation variable is a biological parameter uncontrovertibly accepted by biomedical research. This is basically similar to testing of pharmacological agents, whose action mechanisms are not fully known or understood.

6. The existing quantitative procedures are usually fit for research on alternative therapies and complementary medical systems.

7. Complex complementary medical systems may be studied as “gestalts”.

A study on the efficacy of this therapeutic system could consider “homeopathic therapy” as “the treatment”, whatever its individual components (physician-patient relation, choice of remedy, dynamic implementation, lifestyle advice, etc.).

This shows that, whatever the gap between both opinions, substantial perplexity lingers with respect to the main research tools, namely the RCTs.

Limits of Controlled Randomized Clinical Trials

The limits to the use of clinical trials in the “real” world may be divided into three groups as follows:

- i) limits derived from the “pragmatic” foundations of modern clinical research;
- ii) “intrinsic” limits of the method;
- iii) additional limits

i) Six pragmatic limits of randomized clinical trials

1. Exclusion criteria of randomized clinical trials

Each clinical trial, therefore, provides for “exclusion criteria” limiting patient recruitment, in order to minimize the interference of variables that may pollute results.

Hence, several actions are tested on a minority of patients. In practice, exclusion criteria depend on the researchers inclination: either “demanding” (high number of exclusion criteria) or “practical” (low number of exclusion criteria).

2. A relatively short-term observation period in most clinical trials for chronic diseases

In acute diseases, a few months observation period could be enough to assess the efficacy of treatment and observe any side effects. However, in chronic diseases, few months, one year, or few years (the term of most clinical trials) is too short a term to assess the actual efficacy of a treatment correctly.

3. Standard dosage provided for by the protocol and concurrent therapies

Today, many protocols provide for inflexible dosage to ensure “scientific” rigour.

One patient reporting severe GI disorders, caused by a drug judged

effective, is excluded from the study, although a reduced dose, in daily practice, may often allow continuing the therapy effectively without any side effects (the concept of customized therapy: using the highest possible dosage, or the most appropriate dosage, for a given patient rather than the “highest possible dosage” in general terms).

For these reasons, many clinical trials, if designed according to highly “demanding” criteria, may imply the risk of underestimating the efficacy and overestimating the toxicity of one drug. The clinical approach required by inflexible protocols does not reflect daily clinical practice.

4. *Use of markers that are often unfit to highlight the actual progression of the disease*

In a trial lasting one or few years, the long-term outcome of a chronic disease, like death or disability, may not be assessed.

Most markers used in trials for chronic diseases often do not provide reliable information on the overall future progression of the disease, and therefore may not provide valuable hints for achievement of the true practical aims of medical treatment in the long term.

5. *Statistically significant results are not necessarily clinically significant, and vice versa*

Efficacy is assessed in clinical trials based on the statistical significance of the different results of the studied treatment vs. placebo or vs. other treatments. Statistically significant results, however, are not necessarily clinically significant as well.

On the other hand, the need for large samples to ensure statistical significance, poses considerable problems, for example, when dealing with rare diseases.

6. *Tendency to disregard important variables, not provided for by the study design, but affecting the relevant outcome*

Much of medical knowledge originates from serendipic observations that are not included in the original design of the study. In most clinical trials, patient-related variables affect results much more than

the treatment (or placebo) for which patients have been randomized, but this emerging data tends to be ignored or underemphasized.

b) Four intrinsic limits

1. *The design of clinical trials may influence results significantly, in spite of the use of a control group*

The design of a randomized clinical trial may significantly influence the probability for an action to turn out more or less effective than a placebo. The argument is that clinical trials are not neutral by their nature, and using a control group does not ensure that all biases, intrinsic to the design of any study, are overcome.

2. *The results of clinical trials are generally referred to patient groups and ignore individual variability*

Considering, for example, a typical clinical trial with 60% of patients responding positively to drug A, 20% to drug B, and 20% to both, we would conclude that drug A is the most effective “for all” patients, rather than “for most patients”.

In the drug manuals of many hospitals (drafted according to economic and statistical criteria), this is also the principle for choice of the “best” drug to keep in store “for all” patients, without considering that a different drug is certainly the best for many of them.

3. *No standard exists for interpretation of side effects, and this is a cause for biases in the interpretation of the results of any clinical trial.*
4. *The intrinsic requirements of clinical trials inevitably warp the placebo effect, because patients need to be aware that they will not necessarily receive the “best” treatment.*

ii) Three additional limits

1. *Patients participating to a clinical trial generally account for 0.001% of patients that will receive treatment.*
2. *Exclusion criteria imply that the patient population participating to the*

study may not be representative of the universe of patients suffering from the disease concerned or, anyway, that will receive treatment.

3. *Very high cost of this kind of studies.*

The authors, therefore, review the intrinsic problems of the measurement tools so far considered as unapproachable, within the field of research methodology.

An Innovative Idea: Patient Self-Report Questionnaires

The authors review a tool proposed by one of the most critical and constructive experts in RCTs (Pincus T. 1997) and used for about a decade for the management of a public outpatient clinic for rheumatic patients: the patient self-report questionnaires. This tool consists of a computer-based collection of self-report questionnaires, may be used to assess the efficacy of conventional, complementary, or integrated medical treatments alike, and is fit for evaluation of the efficacy of any treatment performed on the human being as a whole.

The use of these tools is undoubtedly an interesting option for performance of studies in homeopathy, because they combine several issues, including the possibility to collect long-term data with respect to chronic diseases, flexible use, the opportunity to set up work team networks, if necessary, and to collect a huge amount of secondary data supporting primary research, that may represent a starting point for new assumptions and trends of research.

Patient Self-Report Questionnaires

- 1 - *Assumption*: the assumption is that the interventions proposed and performed by healthcare providers are effective and not harmful if related to the treated condition.
- 2 - *Protocol*: consists in standardized data collection through a questionnaire filled out by the patient. Such questionnaire may also provide for collection of laboratory data, X-ray reports, other physiological parameters, and any additional questionnaires.
- 3 - *Data collection method*: the method consists in handing out the

questionnaires in sequence to each patient reporting the problem under study; this ensures non-selection of patients.

- 4 - *Result*: should be defined at the beginning of the observation period and may concern traditional indicators, like death, blood pressure, reduced arthral swelling, as well as bio-psychosocial indicators, including functional changes, pain, depression, impotence, optimism, care, or stress.
- 5 - *Analysis techniques*: depend on the database type, but sometimes a computer is not required. The need for such tool depends on the type of questionnaire used, i.e. by the number of data it contains, and this concerns the problem that is under study.

Conclusions

The authors believe that homeopathy, if analyzed as a daily practice without biases, is a very complex therapeutic approach, overlapped to the wide and complex basic clinical methodology. The study of this sophisticated integrated therapeutic system poses several important methodological challenges to classical clinical research. Thus, while on one hand a biased and strongly ideological approach, placing homeopathy beyond any possibility for scientific examination, is certainly to be rejected, it is not fair, on the other, to accept a position pretending to assess an abstract kind of homeopathy that has hardly anything in common with clinical homeopathy, by now in use for several hundreds of years. In this respect, we think we may support the W.H.O. recommendation, aimed at promoting a thorough analysis of traditional methods, however respecting their peculiarities and characteristics. On the other hand, an analysis of tools for evaluation of therapeutic effects, criticized by several references in literature that do not support any special field of medicine or, more generally, of scientific methodology, leads to conclude that there is probably no ultimate tool for examination and that the best path to follow is almost certainly the identification of several examination tools, taking into account both subjective and objective data, sometimes to be used in combination.

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DISCUSSION

Discussion of Fifth Session Policy of CAM

Chairman: Dr. Adrian White

Rapporteur: Dr. Abdullah Ibin Muhammad Al-Bedah

Dr. Ali Haeri, Iran: It is quite obvious from the speeches of the eminent speakers, which is I enjoyed very much, especially the one addressed by Dr. Fonnebo, and Dr. White. It is quite obvious that we are heading to an incredible size of work to verify and then justify our practice in CAM. What I would suggest that to have more practical approach is that we categorize and classify what we want to practice in CAM. That we classify into A,B,C, D and so on. Then we screen what modalities already exist and therapeutic approaches already exist in the traditional or alternative medicine. Have those which are absolutely safe been practiced for hundreds of years with no problem, with no adverse effects, nobody is scared to utilize it. By this, you will screen out about 50% of what you have already in your hands, provided it will follow certain quality measures and guidelines of WHO and other organizations for the production, method of a practice and so on. And then, we go from simple to complex. When we reach certain instances, like for example, I would never ever advise now to use a traditional approach to cure very acute meningitis. Unless, there is some body to prove to me through standard evidence based approach that there is, for example in India and China, I have done the miracle, in 24 hours and the problem is finished. This is what I mean that we reach bit more complicated and more complex and then so on, where we need to compare, we may reach a situation. We have to compare the CAM with the conventional approach and then the cost effectiveness may come there to be discussed and so on. For example, I just give an example. If somebody comes to me and says I have this berry that the CAM can cure hypertension then I compare it in a classical clinical study. Then according to the classification I am suggesting I have to do comparative studies to see and then I have to take in consideration many other issues. What I am saying is size of the work too incredible to tackle, in order to have west assured

practices. So, in order to have more practical and speed up approach, we need to have a task force or group of expertise, may be coordinated by WHO and these respectable organizations that we are under their coverage we are sitting in their conference and then try to classify these drugs according to certain standards and screen out those absolutely safe and have no problem. This is my comment.

Dr. Adrian White: I think you are addressing a very important issue. Because, lot of the research I have done on Traditional and Complementary Medicine, has been done, as if it was a new treatment to introduce in the market. And, that is a very important point. We have discussed this point somewhere, where we worked in a health research. I think you are making that a free treatment market where people halt and feel where they want to go. We have people going to Alternative or Traditional Medicine. If we want to approach those traditional modalities research wise, it might be a problem to have a research. Just as you say if you have something going on for hundreds of years in a culture, you should start what you are exactly saying. And I am not sure that they are perfect, because we have some experience where we try to go into areas and look at safety. We found more problems than we thought. If you cross that kind of point, that is safety, the next it directs to treat this condition in this study then in another study. And, if there is no other alternative treatment, there is no need to go for the research. It is a very important aspect, it should be seriously discussed when considering Traditional Medicine research.

Participant: This is a preliminary issue. What is a most important is the clinical manifestation. Clinical manifestation of the disease and your treatment strategy or therapeutic strategy, that's a different matter. On the analytical and holistic that it is too preliminary to this rather important issue. We have to be careful in clinical manifestation of the disease, whether diagnosing it, or treating. - Thank you!

Dr. Adrian White: Dr. Gindy, please.

Dr. A. R. El-Gindy: Thank you Mr. Chairman! When we were planning to convene this meeting, we were sure that the issue of safety will be a very important issue. But before that our organization had organized an important meeting with WHO and we invited many who

are working in the field of Traditional Medicine. We came to the conclusion that we can classify the plants into three main categories. The first one is that one where it was being used for a long time and so we should not have most sophisticated studies for this plant. But the only thing is to make chronic toxicity study for 6 weeks on two types of animals. The second category was those, which are published, in the original books or literatures. This should be subjected somewhat more elaborated study. The third one, which are unknown, this should be treated as an allopathic medicine and should follow the same procedure.

At the same time, we are talking about active ingredients; we are not talking the plant as it is. So, now the idea is developed and now we shall give the patients the whole plant, so what we shall do? Shall we make the whole study on the plant or as our friends here always insisted that we have to extract and identify the active ingredients to study? The two approaches are completely different. - Thank you!

Participant: I think a clinical trial has been designed for active ingredients. Because, investments on medication's clinical trial was a must. Now, with health or food, which is a gift from God for human being without discrimination, shall we continue to do the same clinical trial, pre-clinical or post-clinical or shall we modify the clinical trial to be suitable for the plant as a whole? As you see, if we measure the safety by separation of active ingredients, this is unfair. You know the sorts of foods, it is composed of certain chloride, if you separate the two components, it becomes very toxic. So, the plant if we take it as a whole I think, we need to modify the clinical trial to be suitable for whole plant. That has been in UK, Italy and we have a long experience for that.

Dr. Adrian White: Thank you very much!

Prof. Emilio Minelli: I completely agree with you, because the question you are raising is how do we have the proper research method to the research question asked. If you want to study the effect of the single substance, you identify that you have isolated. But if you want to study the effect of the plant, you make sure that you give the same plant to everyone. If you say, you want the effect of the plant

and then you isolate one of the substances and research on that; then giving answer to different questions and this is just like what was mentioned in homeopathy. If you want the effect of going to a homeopath, you don't do a procedure to control the homoeopathic remedy. But this is common for all fields of research. We have to harmonize research questions with the research method that we are using. So these are the issues that are very important. The research questions the method how to be harmonized?

Dr. Ahmed Daij: I am a Pharmacologist from Ministry of Health, Kuwait. Let us take to tobacco leaves, which contain more than 600 active ingredients. It will be very difficult to make clinical trials in the herbal medicine. But I think with the chronic patient, we have the problem of hesitation. He was in Modern Medicine, take modern chemicals and then in order to improve his health, he is going on alternative or unconventional medicine. The most important thing is the hesitation inside himself. It is important to concentrate on drug and drug interaction between the modern drugs along the herbal medicine. - Thank you!

Prof. Anwar Hasan Gilani: I am a Professor of Pharmacology at Aga Khan University. I fully agree with some of the questions raised here, which are extremely difficult to compare the clinical trial conducted for whole plants compared to the active ingredients. There are several reasons and one reason, which has not been mentioned here, perhaps, I pointed out in some of the traditional systems. For example, in Greeko-Arab Unani System, they also consider the individualized treatment. Treatment option is obviously different for different patients. And this particular consideration is not taken into account when we talk about the clinical trial in the orthodox medicine of the pure compounds. When we are talking about the safety of particular herbal product, it is important that under what circumstances that particular product is given. So, it is important when we are comparing the safety or the efficacy under which circumstances the product has been used and who used that product.

Dr. Adrian White: Thank you very much! Dr. Hall, please.

Dr. Howard Hall: Let me say that I am a western research scientist,

but there are serious limitations. First, you can't prove that these drugs don't work, you can't prove the thesis. The only thing you can scientifically say, we fail to find some results. - Thank you very much!

Participant: I want to make a last comment on safety issue on Traditional Medicine. There is one thing one has to realize and think about. If some thing has been used for hundreds of years and people think it has a good effect, it is almost impossible to realize what are the potential adverse effects. Because, it is all universally used for such a long time and what is happening, as adverse effects are not realized affecting adversely the population who uses it. This is an important thing just to keep in mind.

Dr. Abdulla Al-Bedah.: Many questions have been raised and no answers in this short session. But I recommend for those who are interested to go for yesterday's presentation of Dr. Chang from Korea. He showed the photocopies of many of WHO publications and reports.

Sixth Session
Saturday, 13 October 2002
Clinical Evaluation of CAM

Chairman : Prof. Gerard Bodeker
Rapporteur : Dr. Narimah Awin

Speakers:

- 1 - Mr. Paul McCarthy (Ireland)*
- 2 - Dr. Karin Kraft (Germany)*
- Dr. Hu Hai-Yan (Switzerland)*

**THE USE OF CLINICAL TRIALS
AS A MEASUREMENT OF
EFFICACY IN TRADITIONAL
CHINESE MEDICINE**

Mr. Paul McCarthy

(Ireland)

THE USE OF CLINICAL TRIALS AS A MEASUREMENT OF EFFICACY IN TRADITIONAL CHINESE MEDICINE

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Abstract

The use of clinical trials as a measurement of efficacy lies at the heart of the debate between Orthodox and Traditional Chinese Medicine (TCM). Many medical doctors have voiced serious concerns about the safety of herbal medicine and argue that without clinical trials, the efficacy and safety of TCM cannot be demonstrated. The double-blind randomised controlled clinical trial is the 'gold standard' for the measurement of efficacy of orthodox drugs. Yet despite this, orthodox drugs are not without significant dangers. In addition, while clinical trials are designed to test the efficacy of treatment in a relatively unbiased way, they have many limitations. They are based on a view of the world that adopts narrow descriptions of disease and treatment, and which does not always recognise the patient as a person. Furthermore, in standardising the treatment, the clinical trial may remove from it elements which are an essential part of it. The gold standard for measurement of the efficacy of single drugs may not be the best research tool to measure the efficacy of TCM where many herbs may be used in an herbal prescription and each disease episode and every patient is treated as being different from any other. A change in research perspectives, with more flexible clinical trials that account for TCM's holistic nature, is required in order to evaluate its efficacy.

Introduction

Last year the Irish Medicine Board (IMB) decided to classify the herb *Hypericum Perforatum* (St John's Wort), *Gingko Biloba*, and

many other herbs, in the same category as prescription only drugs. This action raised many old questions regarding freedom of choice, protection of the public, efficacy, quality control and the competence of a medical doctor or herbal practitioner to prescribe herbs. The IMB claims that any products, which claim to cure, alleviate, or prevent diseases will be considered to be medical products. In addition any herbal products which imply a claim by using such phrases as -heals, treats, helps with, calms, alleviates, or prevents disease is by definition a medical product and should undergo the same rigorous clinical research trials as any orthodox synthetic drug.⁽¹⁾ As these valuable herbs do not have Irish product licenses and very few doctors in Ireland have formal training in herbal medicine this ruling effectively amounts to a ban.⁽²⁾ This is not in the interests of the public who are being driven to buy herbs on the Internet or from Northern Ireland where they remain on sale over the counter. The indignation felt by a large section of the Irish public, and protests from herbal practitioners about the effective banning of St John's Wort resulted in thousands of letters of protest to the Government. In response the Irish Government established, within the IMB, a Scientific Committee on Herbal Medicinal Products that is considering practical ways to allow herbs to be marketed in Ireland.

Traditional Chinese Medicine (TCM)

Over the past few years there has been an increase in the number of reports in both medical journals and, national newspapers regarding the safety and efficacy of herbal remedies. Practitioners of herbal medicine would argue that the issue of safety and efficacy of Chinese herbs should not be considered in isolation from the principles and practice of Traditional Chinese Medicine. Traditional Chinese Medicine (TCM) has developed through extensive observation and clinical testing over the last 3000 years as a system of medical theory and practice. This is different from, but no less valid than, Western medicine. It has its own consistent theoretical concepts, philosophy of health and disease, theory of disease aetiology, system of disease classification and a coherent diagnostic and treatment framework.

Disease is seldom thought as being the sole result of a single causative agent. Rather it is seen as due to a pattern of influences leading to disease and imbalance. Everything in one's internal and external environment can contribute to the development of a pattern of disharmony or disease. Treatment is therefore aimed at restoring the balance or harmony of the whole person psychological, social, physical and spiritual. This perspective has many correlations with modern quantum physics, systems theory, complexity theory, and ecology.^(3,4) This TCM perspective also mirrors the World Health Organization (1947) definition of health as 'a state of complete physical, mental and social well being'.⁽⁵⁾

Measurement of Efficacy

Measurement of efficacy is one of the issues that lie at the heart of the debate between orthodox drugs and herbal medicine. Many doctors reject user surveys and anecdotal information regarding TCM.^(6,7,8,9) They argue that success is more to do with 'magical thinking' or the placebo effect.^(7,10,11,12,13)

Serious concerns have also been voiced about the possible harm of herbal medicine and claims have been made that without clinical trials, the efficacy and safety of herbal medicine cannot be demonstrated. Despite clinical trials, however, orthodox medicine is not without significant dangers. For example, according to one study by Lazarou et al. (1998) published in the JAMA, two million serious adverse drug reactions occur each year in the USA.⁽¹⁴⁾

In addition, while clinical trials are designed to test efficacy of treatment in a relatively unbiased way, they have many limitations. They are based on a view of the world which adopts relatively narrow descriptions of illness and treatment, and which does not always acknowledge the patient as a whole person. Furthermore, in standardising the treatment, the clinical trial may remove from it elements which are an essential part of it. The therapeutic relationship, for example, which lies at the core of every clinical practice, is completely ignored. This is despite the fact that considerable variability has been reported among doctors regarding different aspects of their practice.

For example, Anderson et al. (1983) reported that doctors differ in their diagnosis of asthma.⁽¹⁵⁾ Marteau et al. (1984) reported that doctors differ in their treatment of diabetes.⁽¹⁶⁾ Bennette et al. (2002) reported that doctors vary in their treatment of heart disease.⁽¹⁷⁾ Mapes (1980) claimed that they also differ in terms of their prescribing behaviour with between 15% and 90% receiving drugs.⁽¹⁸⁾ These differences cannot be simply explained in terms of difference in knowledge and experience. The variability is explained by different health belief systems, variations in perceptions of the incidence and seriousness of various diseases,⁽¹⁹⁾ the doctor's mood,⁽²⁰⁾ and to the whole process involved in communication between the doctor and patient as this interaction takes place in the context of these beliefs.⁽²¹⁾ Medical education now emphasises the importance and value of the doctor-patient relationship and studies show significantly different outcomes depending on how it is managed.⁽²²⁾ There is much in the research literature on the value of communication skills as determinants of outcome and related psychological research suggesting that it is the doctor's qualities of personal presence (rather than any particular therapeutic techniques) that determines outcomes of the therapeutic interaction.^(21,23)

Is the type of clinical trial that is used for measurement of the efficacy of single drugs the best research tool to measure the efficacy of TCM where many herbs are used in an herbal prescription and each disease episode and every patient is treated as being different from any other?

Double-blind, randomised controlled clinical trials

The classical way to test efficacy in conventional medicine is clinical trials. Ideally, the experiment follows certain criteria. It must: compare the effect of treatment with the effect of no treatment; ensure that people are randomly selected into each group; control for placebo effect; identify a clearly diagnosed illness and a standardised treatment; provide for a noticeable change; use measures that are precise, valid and reliable. The most common version of clinical trials, which satisfy these rules, is the double-blind, randomised controlled clinical trial

(RCCT), where neither patient nor the therapist giving the treatment knows who is receiving the actual treatment.

The search for a scientific basis to conventional medicine has led to the double blind randomised controlled trial as the ‘gold standard’ for the evaluation of therapeutic interventions yet conventional medicine still relies to a large extent on individual experience, opinion and invalidated treatment.⁽¹¹⁾ For example, there are approximately 30,000 biomedical journals in the world,⁽²⁴⁾ yet, according to David Eddy, professor of health policy and management at Duke University, North Carolina, only about 15% of medical interventions are supported by solid medical evidence.⁽²⁵⁾ This is because only 1% of the articles in medical journals are scientifically sound and partly because many treatments have never been assessed at all.⁽²⁶⁾

Limitations of RCCT

1) Reality is poorly reflected in the controlled clinical trial setting.

The systematic and controlled setting used in experiments is a poor model of the complex and dynamic real world of the clinical practice. Selecting and controlling variables means the exclusion of others that are influential and may involve disregarding some of those that are selected and controlled. Consequently the resulting findings have little relevance to understanding the real world where all the variables may be at work.^(23,27,28) In addition, with less easily diagnosed conditions, treatment does not necessarily follow diagnosis in a strict chronological sequence. Also, there are usually a variety of causes in illness, not just one, and many people have diseases which may defy classification.⁽²⁹⁾

2) Conventional classification of the diseases (such as the International Classification of Diseases) may not adequately describe the signs, symptoms and syndromes of illnesses that are more likely to be seen in a TCM practice.

For example, myalgic encephalomyelitis / chronic fatigue syndrome and irritable bowel syndrome, are not associated with any consistent,

measurable physiological abnormality. Moreover in TCM there is a completely different system of disease aetiology, diagnosis, classification and treatment framework.

A TCM diagnosis of Liver Qi Stagnation, for example, is one of the most common of the Liver patterns. This single pattern may present with symptoms commonly seen in patients with migraine, irritable bowel syndrome, Pre-menstrual tension, dysmenorrhoea, irritability, hypochondriac pain and depression.⁽³⁰⁾

3) Measurements of change in clinical trials may not be adequate indications of a successful outcome from the patient's perspective.

The measures of change in clinical drug trials (e.g. changes in hormone and neurotransmitter levels) may not be adequate indications of a successful outcome from the patient's point of view. Since 1947 reliance on laboratory tests has increased while diagnosis from clinical signs and symptoms has declined significantly. Similarly, the frequency with which the emotional, psychological, occupational or social status of health are subjects has been reported has diminished with time.⁽³¹⁾ Most operational measures of health are poor relations of concepts such as quality of life,⁽²⁹⁾ and bear little relationship to a TCM definition of health as a state of physical, mental-emotional, social and spiritual well-being.⁽³⁰⁾

For example, a study published in the Lancet in 1986, on the efficacy of acupuncture in the treatment of chronic obstructive pulmonary disease showed that the subjective reporting of breathlessness in patients with this condition was significantly improved although objective indices of lung function (such as thoracic gas volume and expiratory flow rates) remained unchanged. This paper was the first to be published in the Lancet where traditional Chinese diagnosis has been respected.⁽³²⁾

Many other clinical trials demonstrated this greater subjective perception of symptom relief by patients whilst there was only mild to moderate improvement in the 'objective' assessment indices.^(33,34,35,36,37)

4) In standardising the treatment, the clinical trial may remove from the treatment elements, which are an essential part of it.

The double-blind randomised controlled trials give us a statistical probability of the effect of treatment on a group of people. This probability is derived from a comparison of treated patients with control subjects. These groups are constructed on the basis of common shared criteria that should be as few, simple, objective and reproducible as possible if results are to be generally applied. In other words, there is a price to pay for the objectivity of these trials. Gain in objectivity is achieved by simplification and at the cost of completeness and wholeness. The whole philosophy of the trial is to exclude individual differences and concentrate on group similarities. Indeed, the exclusion should ideally apply to every aspect of the therapeutic encounter except the specific intervention under assessment.^(23,27,28)

In contrast, the TCM model is more dependent upon integration of a wide range of data, and a therapeutic decision is seldom based on one or two factors alone. The fundamental reason for this is that no symptom or sign provides a single objective reading that acts as a basis for diagnostic conclusion. In the TCM model any piece of information (symptom or sign) gathered from the patient can only be interpreted subjectively in relation to other symptoms and signs.⁽³⁸⁾ In other words, any one observation on the patient may hold several meanings dependent upon other observations made of the patient.

For example, a bright red tongue may be meaningfully interpreted as an excess heat (yang) patient constitution if there is also a thick yellow tongue coating and a strong pulse, or as a deficiency syndrome (yin xu) if the coat is absent and the pulse is thin. The meaning of the red tongue is most clearly stated by observing other data.⁽³⁹⁾

The double-blind, randomised controlled trial aspires to a world where effective medicine is so simple that the therapeutic relationship between the doctor and patient and patient's individuality are rendered unimportant compared with the objective probabilities established by rigorous evaluation. From the patient's perspective the deficiencies of the clinical trial approach is even more obvious since, more often than not, there is a genuine discrepancy between illness as actually

experienced by the patient and as it is conceptualised in the reductionist biomedical mode. When patients tell their doctor their symptoms and medical history, they find that elements that they deem important are either ignored completely in favour of more objective physical signs and laboratory results, or at best filtered for those few discriminatory symptoms that have been subjected to group Trials.^(23,27,28)

In contrast the practice of TCM is based on the evaluation of individualistic factors, so that no two patients are treated exactly the same. Of course, this requires time for full assessment on the part of the TCM practitioner rather than a seven-minute consultation by an overburdened general practitioner or an intervention by a hospital consultant who may put technology first and all too often ignore the patient as a person.

5) In TCM single herbal products are rarely used alone and each disease episode and every patient is treated as being different from any other.

TCM uses very complex herbal prescriptions tailored to the individual patient during particular stage of the disease process and the prescriptions may act over a long period, which may preclude single drug studies. As these TCM prescriptions are directed at promoting the body to heal itself, the time-scale for experiments needs to be sufficiently long. Many of these traditional prescriptions have been safely and successfully used by millions of people over thousands of years.⁽³⁰⁾

One of the first clinical trials on Chinese herbal medicine that adhered to the traditional diagnostic and treatment process while using a double-blind randomised control trial protocol was carried out on irritable bowel syndrome (IBS) by a group of researchers in Australia led by Alan Bensoussan during 1996-7. Patients were recruited from two teaching hospitals and five private practices of gastroenterologists. They received Chinese herbal medicine in three herbal clinics. Patients were randomly selected to one of three treatment groups: placebo⁽³⁵⁾, as standard Chinese herbal formulation⁽⁴³⁾ or individualised Chinese

herbal formulations⁽³⁸⁾. Patients received 5 capsules 3 times a day for 16 weeks and were evaluated regularly by a traditional Chinese herbalist and by a gastroenterologist. Patients, gastroenterologist and herbalists were all blinded to treatment group. The study demonstrated that Chinese herbal medicine is effective in the management of symptoms related to IBS. In follow up assessment 14 weeks after completion of the treatment, only the patients who received individualized herbal formulas maintained improvement.⁽⁴⁰⁾

6) Clinical trials can be dehumanising.

Although the vast majority of studies are subjected to ethical scrutiny, this does not always guarantee the protection of individuals participating in clinical trials. In double-blind randomised controlled trials, there may be substantial ignorance on the part of the person being treated. The premise that there needs to be a high degree of objectivity on the part of the experimenter can lead to patients being treated as objects and their personal power being reduced to an object. This is a frequent complaint by patients participating on clinical trials.^(41,42,43,44,45)

7) Safety: The use of clinical trials does not guarantee protection against adverse reactions.

In 1990 the General Accounting Office in the US reported that over half the drugs approved as "safe" by the FDA between 1976 and 1985 caused such serious side effects as to require relabelling or withdrawal of the drug from the market. These side effects were described as "common" and resulted in hospitalisation, permanent disability or death.⁽²⁸⁾ A more research study to estimate the incidence of serious and fatal adverse drug reactions (ADRs) in hospitalised patients published in the Journal of the American Medical Association in 1998 states that properly researched, regulated, prescribed and properly used drugs are the fourth most common cause of death in the USA. This is over 100,000 deaths per year. The study also reported that over 2 million serious adverse drug reactions (defined as requiring hospitalisation or causing permanent disability) occur each year in the USA.⁽¹⁴⁾ 46 people die every day from Aspirin alone in the USA.

Reilly (2001) states that in Britain last year 2,500 people died from bleeding due to non-steroidal-anti-inflammatory drugs.⁽⁶⁰⁾ A report by Professor Breckenridge of Liverpool University claims that up to 20,000 deaths a year in Britain may be linked to ADRs, that ADRs may be implicated in 5% of all hospital admissions and that they may occur in as many as one in five hospital in-patients. Among patients taking five or more drugs, there is a 50% chance of an adverse reaction.⁽⁶¹⁾

In contrast, Maciocia (1999) points out that the WHO monitoring centre in Uppsala, Sweden, issued a summary of reports on adverse reactions to herbs worldwide over a 20-year period. The total number of adverse reactions reported is 8984, a relatively low figure considering that it covers the whole world and extends over a period of 20 years. Combinations of herbs seem to cause fewer adverse reactions than single herbs. The reported adverse reactions in the all-herbal combinations, are only 368, this is only 4% of the total reports of adverse reactions.⁽⁶¹⁾ These WHO figures should be treated with caution as systems for reporting adverse herb reactions are not in place in many parts of the world.

However, a more recent study by Prof. Ernst (2002), who surveyed the medical literature over a five year period between 1992-96 for reports concerning adverse effects of herbal medicines found a total of 35 fatalities and less than 200 other adverse effects involving herbal remedies. This works out an average of 7 fatalities and less than 40 adverse events per year ascribable to the use of herbal medicines.

8) The use of clinical trials does not guarantee bias-free research.

Sackette (1979) points out 56 known potential sources of bias in clinical research. Bias can creep into experiments at every stage of research, from reviewing the literature, through design, sampling, and analysis to interpretation, presentation, and publication of findings.⁽⁴⁶⁾ Klein et al (1994) demonstrated that the clinical trial might be compromised by poor physician compliance with trial protocol.^(47,48) Other studies showed bias in selection and allocation.^(49,50,51) Numerous studies have shown that the value of the clinical trial may be

undermined by negligence, dishonesty, fraud and other kinds of wrongdoing usually for purposes of academic or economic gain.^(52,53,54,55,56) In addition, Sapiro et al (1989) reported that the regulatory bodies such as the FDA never audit the vast majority of drug trials and penalties for unethical or fraudulent behaviour are lenient to nonexistent.⁽⁵⁵⁾ Pliefer et al (1990) have shown that fraudulent conclusions from clinical trials, later retracted, continue to live on and influence future clinical conclusions.⁽⁵⁷⁾

Researchers may have political bias and subvert the scientific process in order to discredit complementary medicine.⁽⁵⁸⁾ Bias can even effect what papers eventually get published. For example, a study of 398 experts who review papers for publications, found that they were prejudiced against complementary medicine. This was a randomized, controlled double-blind study using two versions of a fictional report on obesity. These reports were identical except for the nature of the intervention (an orthodox drug as against a homeopathic remedy). One of the two versions and an assessment form were sent to each of the 398 experts. They were asked to rate the reports significance and publication potential. The findings revealed that the expert peer reviewers were three times as likely to favour an orthodox version over the unconventional version of the report.⁽⁵⁹⁾

The Future

The dominant research model of disease today is biomedical, and its strictest manifestation leaves little room within its framework for the social, psychological, behavioural and ecological dimensions to illness. It leaves little or no room for complementary and alternative medicine systems. There are profound differences in the philosophical perspective of the proponents and opponents of clinical trials. These differences reflect the many different views of reality.

No one view of reality is more correct than any other. The premise that any one method of evaluation is right leads to scientific stagnation. No single method of evaluation should be expected to assess the effectiveness of all treatments. Indeed Austin Bradford Hill, the father of the controlled clinical trial, stated at the end of his life that:

"Given the right attitude of mind there is more than one way in which we can study therapeutic efficacy. Any belief that the controlled trial is the only way would mean, not that the pendulum has swung too far, but that it had come right off the hook"⁽²⁸⁾

If there is to be greater integration between TCM and orthodox practitioners in terms of measurement of efficacy, there will need to be a paradigm shift which, facilitates research that understands and respects the holistic nature of TCM. We need to be cognizant of the many biases that currently limit the efficacy of the double blind randomised controlled trial. Lewith (1998) claims that research in complementary therapies does not in many cases require placebo controls, standardised treatment or objective outcome measurements.⁽⁵⁸⁾

We need more flexible clinical trials where the therapeutic relationship, which is at the very heart of every type of clinical practice, is not removed from the trial no matter how impersonal we may wish to be. There is a need for more research using single case designs that looks at changes within individual patients over time.⁽⁶²⁾ Research of a collaborative kind between therapist and patient, rather than research by the therapist on the patient is required.⁽⁶³⁾ The philosopher John Heron recommends the use of a "participatory method of cooperative inquiry" where both researchers and subjects engage in democratic dialogue as co-researchers to design, manage and draw conclusions from the research.⁽²³⁾ The separation of the disease from the person loses those very qualities that we need to understand. Diseases may be treated as aggregates and submitted to statistical analysis, but it is the individual persons in whom these diseases are located and who confront us in our clinics. Consideration must be given to the fact that symptoms are located within individuals who perceive their symptoms differently.

TCM needs to develop its own research methodologies that take into account its own unique philosophical perspective of health and disease. The treatment method must be decided by the TCM practitioner based on traditional diagnosis therefore the number of treatments (acupuncture points or herbal formulas) should not be

controlled. The practitioner should be allowed to give advice regarding relevant nutritional, physical, psychosocial, occupational factors that may aid in the treatment strategy. The clinical trial by Bensoussan et al (1996) on traditional Chinese herbal medicine for irritable bowel syndrome is an innovative effort that respects the integrity of a TCM paradigm yet simultaneously manages to adopt the methodological safeguards demanded by scientific research. Birch (1998) claims that research into the efficacy of TCM may require a more multidisciplinary approach involving the skills of philosophers, clinical researchers, basic science researchers, linguists, sinologists and TCM practitioners at various times during the research process.⁽⁶⁴⁾

If research methodology is applied, simply as a formula, without becoming as familiar as possible with the subject matter under study, then no significant findings emerge. To do this relinquishes both responsibility in science and real discovery. Science is not methodology; methodology serves science. Tukey's (1979) wise comments about quantitative measures can also apply to the development of new more integrative and holistic research methods:

"When the right thing can only be measured poorly, it tends to cause the wrong thing to be measured only because it can be measured well. And it is often much worse to have good measurement of the wrong thing - especially when, as it is often the case, the wrong thing will IN FACT be used as an indicator of the right thing -than to have poor measurement of the right thing".⁽⁶⁵⁾

TCM practitioners agree with the Irish Medicine Board that TCM needs to be able to prove its efficacy. However, the type of clinical trial that is used for measurement of the efficacy of single drugs is not the best research tool to measure the efficacy of TCM where many herbs are used in an herbal prescription and each disease episode and every patient is treated as being different from any other. We need to develop new research models so that, in future, we may have a good measure of the right thing.

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WHAT IS "TRADITIONAL USE" EVIDENCE?

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WHAT IS "TRADITIONAL USE" EVIDENCE?

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Abstract

With regard to the proof of efficacy, the levels of evidence for traditional medicinal products and for medicinal products of well-established use are rather different. Evidence of the efficacy and safety relies basically on drug monographs, expert opinions and historical sources, but for medicinal products of well-established use additionally bibliographic data and increasingly also product-specific clinical trials are available which means that the latter are becoming more acceptable by evidence-based medicine. The "traditional use" evidence on the other hand results from a process of trial and error in pre-scientific medicine, which often covered centuries, and compilation of data, experiences and applications, especially in medicinal herbal drugs and their preparations. The process of licensing also means that applications must be transformed into modern indications. Thereby precious traditional experiences and useful information can be lost irreversibly, and - as the indications include prevention of health problems and adjuvant use in so-called minor indications, interest in further scientific evaluation may fade. On the other hand, many symptoms and diseases patients suffer from, cannot be explained and/or treated by modern scientific medicine. There the traditional medicinal products may bear a healing potential that should not be lost.

Key words: well-established use, evidence-based medicine, traditional use evidence, herbal medicinal drugs, herbal medicinal products

Introduction

The process of product licensing in the European Union relies on the product-specific evidences of quality, safety and efficacy. However, for herbal medicinal products rather often product-specific randomised

clinical trials do not exist. In the directive 2001/83/EG therefore additionally other sources of evidence such as post-marketing studies and epidemiological studies with similar products (bibliographic application) are allowed as a valid proof of safety and efficacy. This is called “well-established use”, which means evidence level I-III(IV) in terms of evidence-based medicine (table 1). Precise definitions of traditional medicinal drugs and products and especially of the “traditional use evidence” are still not clear. The following article presents some criteria which may alleviate the evaluation of traditional use evidence with focus on the peculiarities of herbal medicine.

Tab. 1: Levels of evidence (adapted from (3))

Level of evidence	Methods
Ia	- meta-analysis, several randomised controlled clinical trials
Ib	- at least one randomised clinical trial
IIa	- at least one non-randomised clinical trial with a well-designed protocol
IIb	- quasi-experimental descriptive clinical trials with a well-designed protocol
III	- case-control studies, cohort studies with a well-designed protocol
IV	- not evidence-based expert opinion, monograph, consensus conference etc.

Due to the recent intense scientific effort the evidence level of several medicinal herbal drugs/products could be upgraded. For example, the retarded preparation of peppermint oil for treatment of irritable bowel syndrome has reached level Ib, St John’s wort (*hyperici herba*) even has reached level Ia (12,13). Many other drugs such as lesser galangal root (*Galangae rhizoma*), which is used for treatment of dyspeptic syndrome, or herb of white dead nettle (*Lamii albi herba*), which is applied for respiratory problems, remained at evidence level IV (1). These statements seem to be very clear at first, but if one goes into details, several problems e.g. with diagnosis, indication, dose, preparation, way of application and efficacy show up.

These problems will be analysed by using examples. Garlic (*Allium sativum*) which is a very popular herbal medicinal drug all over the world can be used for illustrating the problem of indication. In ancient times, the Egyptians, Babylonians, Phoenicians, Vikings, Greek, Romans, Chinese and Indians used garlic for intestinal problems, invermination, flatulence, respiratory infections, skin diseases, wounds and problems in the ageing process. In a booklet for health workers in South East Asia from 1990 the WHO states that oral application of garlic as a paste or juice is useful in abdominal gas formation, in painful menstruation and in abdominal pain, and externally oil with juice can be used for pain of the ears (14).

The traditionally recognised health benefits of garlic have been confirmed by >3000 publications from all over the world. In consequence, the level of evidence meanwhile has increased to I for the indications hyperlipidemia (adjuvant use), and prevention of age-dependent arteriosclerosis (7). In the ESCOP monograph from 1997, several positive randomised clinical trials with the indications: prophylaxis of atherosclerosis, treatment of elevated blood lipid levels insufficiently influenced by diet, improvement of the circulation in peripheral arterial vascular disease, upper respiratory tract infections and catarrhal conditions have been performed, which means that the requirements for well-established use with regard to these indications are met (6). For the other indications, randomised clinical studies are not available, therefore garlic only reaches evidence level IV. A drug therefore can reach different levels of evidence dependent on the indication.

Further problems are dose and preparation. In the German drug monograph 4 g of intact garlic or equivalent preparations are recommended. This dose has not been substantiated scientifically e.g. by a dose-efficacy curve, but is derived from expert experience (10). The preparations (and medicinal herbal products) include dehydrated powder from raw or dried bulbs or cloves, distillates, extracts and oil macerates. They show enormous phytochemical differences, and thereby the effects are quite different. Oil macerates for example have no lipid-lowering effect (2), whereas freshly sliced garlic cloves, when

applied directly to wounds, inhibit the spread of infections (5). In the ESCOP drug monograph, the equivalent of 6-10 mg alliin per day the average content of one clove of garlic or of 0.5 — 1.0 g of dried garlic powder or other preparations is recommended for prevention of atherosclerosis, while in upper respiratory tract infections 2-4g of dried bulb or 2-4 ml of tincture (1:5, 45% ethanol) should be applied three times daily (6). Still product-specific dose-efficacy curves for the indications accepted for well-established use do not exist.

So far only the preparations for oral application with a daily dose covering the recommendations of the monograph come up to well-established use, provided that the efficacy for the indication has been proven by randomised clinical trials. With regard to the different preparations and their corresponding medicinal herbal products it is sometimes difficult to decide, whether a definite product meets all requirements for the well-established use status. It seems plausible on the other hand, that for “minor” indications also a lower grade of evidence may be sufficient. This point of view can be extended to all medicinal herbal drugs.

This example also leads to the idea that within traditional use evidence several levels could be defined all of them being the result of mainly direct observations. To be applicable, they should be substantiated, documented, repeatable and suitable for communication. Also the variability of the observation should be described (15).

The problems of efficacy, especially in traditional medicinal drugs

The effects of a drug can be tested by many pharmacological, including human models, but efficacy only can be proven in patients. This should also be true for traditionally used drugs. As the term efficacy covers improvement, healing or prevention of a disease or improving the stage of consciousness and avoiding complications, the concrete evaluation is rather often difficult. In the modern clinical trials efficacy is measured preferably by so-called hard endpoints such as mortality or hospitalisation. In many chronic diseases these endpoints are not applicable or they are even severely biased as a

consequence of standardisation. This even more applies to prevention or rehabilitation of diseases. Therefore efficacy should rather be defined as the summary of the concrete pretension in the healing process.

In clinical trials preferably clear and measurable effects of a drug in a well-defined disease are analysed, monocausal relations are preferred. This concept is easy to perform, but also it restricts the spectrum of diseases mainly to those of acute medicine and to acute events in chronically ill patients. In many acute diseases and events, clinical trials with evidence level I-III are available, and the safety is well documented. It is characteristic for the majority of these clinical trials that they are sponsored by institutions or providers with financial interests who are obliged to control the quality and efficacy of their products due to legal obligations. Therapeutic progress in this field therefore is more or less the result of primarily financial interests. Physicians and other therapists more and more are becoming qualified distributors who are obliged to keep up with new developments for diagnosis and treatment, to revise them critically, which often raises big problems, and to fit them into the concept of their treatment. The latter is often done by generation or adaptation of a guideline. The abundant number of already existing guidelines, which are often contradictory, illustrates the problems of this process. In these guidelines, which usually are constructed from easily available publications, therapeutic options of evidence level IV are seldom mentioned.

In internal medicine - with the exception of acute diseases or diseases which can be classified easily - in surgery, psychotherapy, psychiatry, neurology, prevention, rehabilitation and the metaphylaxis of chronic diseases, clinical trials meeting the criteria of evidence-based medicine are difficult to perform. Treatment therefore relies predominantly on experience and observations documented by monographs, textbooks, expert opinions, consensus conferences and historical sources. Actually, this means nothing else than evidence level IV. The quality of treatment often depends from the physician or other therapists. Research is mainly sponsored by governmental institutions, health organisations, foundations and other independent institutions

and, of course, by the producers of medicinal technical devices. Often the results of this research are not even mentioned in medicinal guidelines.

Traditional use evidence of medicinal herbal drugs and products clearly is evidence level IV. These drugs are not very interesting from a financial point of view, and they are used for minor indications or in self-medication, therefore a lower grade of evidence is acceptable. These are also the main reasons why randomised clinical trials have not been performed. Clinical trials with minor indications are often difficult to perform for statistical and other reasons. As a logical consequence, the majority of these drugs and medicinal products presumably forever will remain in category IV. The now uprising conflict between the traditional use and their drug status, which makes them subject to legal controls which apply to all medicinal products, could lead to the loss of the drug status, at least in Europe, and thereby to the disappearance of valuable traditional knowledge and experience.

Items which could be used to determine the level of traditional use

1) The type of documentation

The type of documentation of traditional use is very important: In general, monographs (in which the actual knowledge is compiled) are superior to results of consensus conferences, recommendations in textbooks, expert opinions or -least confidential- historical sources. A drug monograph should only be considered to be part of evidence level IV, if it is not based on adequate clinical trials. A good consistency of the historical and the present day use indicates a high level of traditional use evidence.

2) The geographical distribution of the use (indication)

The geographical distribution of the use (indication) of a herbal medicinal drug can be a further item to determine its traditional use evidence. If the use is documented world-wide, this means a higher classification than a use within a continent, in several countries, in one

country or - the lowest grade - only regionally. Of course, the geographic availability of the drug has to be considered in addition. Clove (*caryophylli flos*) is traditionally used in south-east Asia, but also in Europe for stimulation of digestive function, strengthening of the mucosa of the oropharynx (3), and for treatment of cough and toothache (20). The wide distribution of this drug since centuries is also a practical one: The weight is low, the stability is high.

3) Temporal aspects

Temporal aspects also can be used for classification of the traditional use evidence. The health promoting effects of onion (*allii cepae bulbus*) for example are known already since the Old Egyptian times, while the use of Siberian ginseng (*Eleutherococci senticosi rhizoma*) is documented in a German textbook for the first time in 1975 (3). Of course, the temporal aspect of the traditional use of a drug is by no means sufficient for the classification, as the knowledge of the healing potential of drugs derived from non-European plants is very often much older, at least in the respective countries of their origin. Therefore the historical research of the use of a herbal medicinal drug should not be limited to only European documents.

4) The quality of sources and the consistency of descriptions

The type of historical and present documentation also is important. For millennia, copying of manuscripts has been the only possibility besides the oral tradition to preserve precious knowledge. In Europe, famous ancient books were copied literally in the early and medieval Christian monasteries, thereby preserving knowledge from the antiquity. A documentation of a herbal medicinal drug and its indications in many independent sources seems to be superior to only few independent documents, even less valuable are many documents which rely on few sources or even only on one document such as a lay textbook. Documents in which sources are not given, should be looked at with suspicion.

There are rather often problems with regard to the consistency in the description, the name or the species of a medicinal plant or a

medicinal herbal drug. This can be due to various reasons such as a wrong translation from a foreign language or a dialect, or false copying from old manuscripts. A possible classification with respect to traditional use evidence may be a persistence with regard to description, name and/or species for at least three decades, minor or major alterations or a complete change in the decades or centuries before. Changes in the recent three decades may result to a loss of the traditional status.

5) Application form and dose

Traditional herbal drugs are often applied in a traditional application form such as tea, tincture, juice or syrup. In modern application forms defined extracts or even special extracts are marketed in e.g. tablets or capsules. Only a stable form of application since at least 3 decades, perhaps with minor alterations seems to be compatible with traditional use. For example in nearly all monographs of the commission E only the dose used for preparation of tea is given, and a use thrice daily is recommended. For other preparations usually only the hint is given: "For other preparations use equivalent doses". This leads to the next problem: Nearly all recommended doses are not supported by dose-finding studies. The single dose (2g/150 ml water) is a decision resulting from taste and practicability of preparing the tea, also there is no rationale for applying a tea thrice daily. This explains the deviation from the dose recommendations of the monograph in some medicinal herbal drugs with established use efficacy. Also there are only a few studies concerning doses for children.

6) Indications

The indications for the traditional use of a medicinal herbal drug can be very stable, but also they may have been changed considerably during the course of time. A drug may be used for the same indication since ancient times, since a millennium, since centuries or decades, or only since some years. Indications may have been adapted according to the scientific proceedings or even completely changed, if an indication had become irrational. For example, in the *Materia medica*, caraway tee has been recommended to improve digestion, and even

today it is used for the same reason (1). This of course is a good indication of a high level of traditional use evidence.

7) Stability in the use of a medicinal plant or drug

A medicinal plant can be used completely or only partially, this may change over the course of time. For example in ancient China the fruit of the ginkgo tree (*Ginkgo biloba*) was used in bronchial asthma. Since some decades the extract from ginkgo leaves is used, but also with a complete change of the indications. They now are vertigo, tinnitus, intermittant claudication, and dementia (1,9).

Preliminary proposal of an evaluation scheme for traditional use efficacy

The 7 items from above could be the base of a scheme for the evaluation of traditional use efficacy. Each item can be looked at in the same way: No change for at least 3 decades, minor or major alterations or a complete change in the decades or centuries before. This scheme is applicable for herbal medicinal drugs and their preparations likewise. Still it must be discussed which items are more important for the position of the drug or its preparation within traditional use efficacy.

It cannot be concealed that this scheme may raise some problems for certain herbal medicinal products. For example, in response to the requirements of the changes of the German drug law, the number of constituents of herbal medicinal products often was reduced in the last ten years. Therefore the rules for the claim to be traditional may be different even between herbal medicinal drugs and their products.

This leads us to a very special problem: Traditional use in herbal drug combinations or the respective medicinal products altogether seems to be a special and very complicated issue. The most important question is whether a combination of herbal drugs can be looked at as a whole or as a composition of several herbal drugs. Both points of view have their respective advantages and disadvantages. The view of a herbal drug combination as a whole seems to be less complicated, as all items listed above can be applied in the same way provided that the components have not been changed at all since a certain range of

time. In the European Commissions “Directive on Traditional Medicinal Products” this range is proposed to be three decades (4). Presumably this holds true for only few herbal medicinal products, as many were changed according to legal obligations or in order to improve the products according to modern scientific knowledge. It would be more than unfair to blame the products for these changes.

The view, that a herbal medicinal drug combination product is a combination of herbal drugs, which one by the other must be examined, whether and how traditional they are, according to the items proposed above, raises many problems such as which of the components is(are) the most important one(s) or which determine(s) the traditional use evidence. Is it the so-called main component or the component which may be the most effective one - this may be interesting for example in a bitter - or that one with the longest traditional use? Can possibly the problem be solved by creating an index? There are still many problems to be dealt with.

Problems of diagnosis and indication

Traditional use of herbal medicinal drugs does not only mean that they are used traditionally, but also the purpose of the use of a herbal medicinal drug may be a “traditional” one. Due to the intense activities in medical research earlier and more precise diagnosis, and hopefully, a more efficient treatment of many diseases seems to be possible. This progress also caused an increasing problem, which can be paraphrased with a discrepancy between diagnosis and indication. Patients do not care for this theoretical problem, as they primarily want to be released from symptoms and, if possible, to be cured. The physicians, who are obliged to work on a scientific base as far as possible, prefer to derive the adequate treatment from a precise diagnosis. Diagnosis means the nosological-systematic denomination of a disease. From the practical point of view it is the sum of findings from objective diagnostic measures. Indication on the other hand is by far more patient-orientated and means the reason(s) for applying adequate medical treatment, which after assessing possible advantages and risks and under paying attention to possible contraindications is

useful for the patient. Presently mainstream medicine is dominated by treatment of diagnoses, not by treatment of symptoms, and this trend presumably will be stable. Diagnosis-orientated medicine can result in a reduced compliance, as patients often refuse treatment without suffering from symptoms, and high costs, because many diseases can and should be treated already in a symptom-free stage.

The present problem of the acceptance of the medicinal herbal drugs by the mainstream medicine is an excellent example for the discrepancy between diagnosis and indication. Most herbal drugs are applied in more or less traditional indications as for example dyspeptic syndrome or diarrhea, only some drugs are used in patients with a rather defined diagnosis. A good example is butterburr (*Petasitidis rhizoma*), which is applied as an adjuvant to treat acute colic of the lower urinary passages and is traditionally used in dyspepsia, to induce sweating, and externally, for moist wounds (1, 11). In recent clinical trials it has been shown to be helpful in migraine. Migraine is an example for a symptomatic disease with a long tradition, which in present times has been much more precisely defined, but still has the old label. Many new diagnoses have been established which have completely replaced older ones such as dropsy, some diagnoses even have been abandoned completely in modern medicine such as the constitutional ones, which are based on the imagination of a dysbalance of the energy of life.

Symptoms of course do not care for background philosophies of medicinal systems, and patients want remedies for relieve independently from a precise diagnosis. Therefore it is deplorable that indications are rather seldom subject of recommendations and systematic reviews in evidence-based medicine. Also the health insurances increasingly prefer standardised diagnostic procedures which hopefully result in precise preferably ICD-10 based diagnosis. This could raise difficulties for research and treatment with herbal medicinal drugs, especially for traditionally used ones. For example, the dried fruit of bilberry (*myrtilli fructus*) is used undoubtedly with regard to its efficacy for acute diarrhea and mild oral and pharyngeal mucositis (indications) due to various diseases (diagnoses) especially in children

(10). Medicinal herbal products with bilberry are not available on the German market. If planning a clinical trial with this drug, one has to decide whether the indication(s) or a disease causing the symptoms should be tested. Sponsoring presumably will be hardly available. If choosing one of the indications it may be difficult to publish the results in a peer-reviewed paper. The only possible way to preserve this well-tolerated herbal medicinal drug for the future may be self-medication and its excellent traditional use efficacy.

Traditional use evidence - tasks for the future

Traditional use evidence can be defined with regard to several points of view: The medicinal herbal drug/product itself, the modern or traditional diagnosis, the indication (symptom- or disease-oriented) and the medicinal system (traditional or modern allopathic). In order to prevent the loss of precious knowledge, collecting material by using all sources available is the first step to be done. This is a national, but also an international task which includes in a second step comparisons of subspecies, and pharmaceutical, pharmacological and clinical aspects. In a third step evaluation of drug potential by pharmacological tests may follow and clinical trials. Especially the developing countries will become important partners as they have a basic interest in traditional medicine due to their difficult financial situations. Further tasks and their tradition are the careful conversion of traditional indications to modern ones and the testing of new indications for herbal medicinal drugs in clinical trials. Last but not least, therapists and patients must be informed precisely and independently to improve the level of self-medication.

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GANODERMA LUCIDUM: THE MUSHROOM AND ITS SPORE

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1. Introduction

Ganoderma lucidum (GL) is a fungus of Basidionmycetes. Known as Lingzhi in Chinese or Reishi in Japanese, it is a mushroom of the Polyporaceae family. It was known in China over 4000 years ago and was considered as the “elixir of life” and reserved only for emperors (Seng Nongs Herbal Classic (220-265 A.D.)). This annual mushroom is extremely rare among the plants of this family. There are 6 different types (differentiated by color: red, purple, blue, yellow, black, white) recorded in Chinese pharmacopoeia. They are actually one species under different conditions. *Ganoderma lucidum* mushroom grows on trunks or fallen logs of broad-leaf trees. Only in recent days it is possible to cultivate it on the bed logs of oaks.

The spore of *Ganoderma lucidum* (GLS) is called basidiospore, i.e. the seed of *Ganoderma lucidum*. Mature spore is several microns, brown and egg-shaped with double layer wall, visible only with a high power microscope. Collecting the spores is very difficult under natural conditions. Only 1 Kg of spores can be collected from 1000 Kg of *Ganoderma lucidum*, hence its preciousness.

2. China has a long history of GL application

China first found the effectiveness of GL and used it to treat diseases. Earliest recognition and application of GL dates back to around 2000 B.C. “Shen Nongs Herbal Classic”, the oldest Chinese pharmacopoeia written in West Han Dynasty (206 B.C.), has already a detailed description of GL: its division into different types according to their colors as well as its benefits as a medicinal plant. In traditional Chinese medicine (TCM), a medicinal element of animal, vegetal or mineral origin can be divided into three categories. Among the 365

species, GL is ranked No.1 among the first "superior" category. The characteristic of this category is that there are no side effects observed even after taking for a long time. On the contrary, consistent uptake can reduce body weight and prolong life span. In Song Dynasty, about 800 AC, Li Fang, described in "Taiping Reading for His Majesty" that GL grows on organic litters and, after taking it people felt refreshed and energetic.

In the ancient days, only the fruiting body of the mushroom was used and the spores of GL were discarded. However, increasing attention has been paid recently on the spores. Different pharmacological studies have been carried out. Promising results show that spores are more effective and have higher clinical values.

3. Modern research on bioactive components:

Although the medicinal value of GL has been proved since ancient times, it is important to explore its virtues and mechanism underlying this function via modern science and research. Biochemical studies have identified 103 components from GL entity and its spores. The main effective compounds are as follows:

- * Polysaccharides: *Ganoderma lucidum* contains 4 kinds of polysaccharides (BN3C1~BN3C4): glucose, arabinose, xylose, galactose, fructose, etc. Polysaccharides have the functions of destroying tumor, immunomodulation, lowering blood sugar, lowering blood-lipid and have anti-aging effects.⁽¹⁾
- * Triterpenes: GL/GLS contain triterpenes such as Ganoderma acid A, B, C, D, F, H, K, M, R, S and Y. Ganoderma acid has strong pharmacological effects with acesodyne, tranquilizing, inhibiting the release of histamine, detoxification, protecting the liver and destroying tumor cells.^(2,3)
- * Adenosine: GL adenosine derivative is highly effective in lowering blood viscosity, inhibiting aggregation of platelet, enhancing 2,3-DPG in hemoglobin, improving oxygen supply in blood and blood circulation.

Other effective components include organic germanium, aminoacids, mannitol, lactone, taurine, polypeptides, etc.

The spores have similar components as the fruiting body, whereas the percentage of polysaccharide, adenosine, amino acid, vitamin and trace elements are higher than GL. For example, water-soluble polysaccharide in spore is 11.9% compared to 2.9% in GL. Ether extraction from the spore is 16.1%, compared to only 3.4% with GL. Due to its higher concentration of the effective components, the spore is deemed to have stronger pharmacodynamic effects than GL.

4. Toxicity

Toxicity tests are conducted on mice, rabbits and dogs. With an application dose 320 fold of the clinical dosage for 10-20 days, there is no negative side effect to the animals appetite, weight, liver and kidney function, and blood pressure. There is also no pathological effect to the important organs such as heart, lung, liver and kidney.^(4,5)

5. Pharmacological studies:

Different experiments have been made to measure the effect of GL and GLS in vivo on several physiological systems, such as immune system, cardiovascular system, central nervous system etc. GL and GLS show comparable functions as follows:

- i) Immunity system: Ganoderma has pronounced effects on the immune system. It enhances cellular and humoral immunity, augments macrophages and regulates T and B lymphocytes. It also stimulates the production of IgG, IgM in the body, strengthens reticuloendothelial system and adrenocortical functions, and increases the production of leukocytes.
- ii) Antineoplastic and anti-radiation effects: GL and GLS induce the production of interferon and the activity of killer cells as well as macrophagocytes; promote anti-tumor action on mice. When it is used to treat leukemia together with chemotherapy, it can improve the tolerance of the latter treatment and increase remission rate and survival rate. For treating primary liver carcinoma, GL/GLS induce tumor regression, mitigate the pains, increase appetite, and prevent the occurrence or recurrence of digestive tract cancer.^(5,6)

- iii) Liver-protective and detoxifying effect: GL/GLS can inhibit the rising of propylene aldehyde and GPT induced by CCl₄; promoting liver regeneration and catalase activity.^(7,8)
- iv) Cardiovascular system function: GL/GLS improve coronary blood flow, microcirculation and cordial action; reduce oxygen consumption of myocardium, reduce blood lipoids and thus decrease the risk of atherogenesis.⁽⁹⁾
- v) Respiratory system: GL/GLS can help to stop cough, eliminate sputum, and relieve asthma.
- vi) Nervous system: Ganoderma can strengthen hypoxia tolerance; has sedative, analgesic and soporific actions. Protect biological, emotional and environmental stresses.

6. Anti-carcinoma mechanism of GLS

The anti-cancer agents in Ganoderma are the polysaccharides and Germanium, and they insert their actions via direct and indirect ways. With abundant polysaccharide, polypeptide and organic germanium, GLS can directly destroy the telomerase of tumor cells and thus kill the tumor cells. The indirect action against tumor cells is via strengthening the immune system of the individual, namely inducing the production of immunoglobulin, alexin interleukin-2 (IL-2) and tumor necro factors, increasing lymphocytes (T and B), promoting macrophage linked with phagocytosis to eliminate cancerous cells. Furthermore, the organic germanium is able to seize electrons from tumor cells, restraining their potential of eventual development, and minimize metastasis (up to 83.9%). GLS helps to prevent sudden death of cancer patients due to thrombus because it is capable of inhibiting the formation of thrombus,

GLS is often used as a supplement of anti-cancer therapies. It can reduce the toxic and side effects and mitigate pains during chemotherapy and radiotherapy, increase appetite and improve quality of life during such treatment.

The anti-tumor effect of Ganoderma lucidum is mediated by cytokines released from activated macrophages and T lymphocytes.^(10,11,12,13)

7. Clinical application of GL

Clinical reports and case studies from China and other countries prove that GL preparations are very effective for many diseases.

- i) Due to its anti-tumor efficacy, GL is used in combination with chemotherapy and radiotherapy to supplement cancer treatment. It can also improve the physiological condition of a patient in a late phase of cancer for eventual operation, chemotherapy or radiotherapy.⁽¹⁴⁾
- ii) GL is effective to treat leukopenia. A test has been done on 52 patients in a hospital in Fujian Province. The number of WBC of all of them was less than 4000/mm³ before the treatment, after using GL for 10-20 days, part of the patients has WBC increased to 1028/mm³ in average. Total effective rate was 82.4%
- iii) Treatment of coronary heart disease. A test on 105 cases with GL chips in Shanghai showed that the effective rate was 62.5% for angina pectoris and 56.2% for arrhythmia.
- iv) Treatment of acute and chronic hepatitis. Hunan Provincial Peoples Hospital used GL syrup for acute and chronic hepatitis in 50 cases. 6 patients (12%) were cured; 38% of patients improved. The total effective rate was 98%.
- v) GL is also effective for neurosis, chronic bronchitis in clinical application. Beijing Chronic Bronchitis Co-operative Society used GL for chronic bronchitis in 646 cases with a total effective rate of 79%.

8. GL as a dietary supplement

Besides all the medicinal claims of Ganoderma, this mushroom has been known for its spiritual potency in Asia. The ancient Chinese text "Seng Nongs Herbal Classic" states its potential for enhancing vital energy, stabilizing mental condition and preventing memory loss linked with aging. It is also commonly used for nervousness, insomnia, and dizziness and being considered as one of the most potent natural mood elevators known to man.

Continuous ingesting of GL can maintain homeostasis of human

being, preserve youth and vitality, clean toxins and ensure recovery of health. Results show an improvement of general well being, enhancement of stamina and longevity.⁽¹⁵⁾

9. Conclusion

As recorded in “Shen Nongs Herbal Classic”, written in Han Dynasty 2000 years ago, GL is classified as a medicinal herb of superior category: no side effects, effective for different diseases and mostly responsible for maintaining and restoring the body balance. These claims have been proved by modern pharmaceutical research in China, Japan, South Korea, Malaysia and now in the United States, and have been proven to exert significant effects, mitigating the pain, fortifying the bodys immune system and prolonging life. Nowadays it is better to employ preventive measures against cancer, and doctors from prestigious medical research institutions recommend the administration of GL for its preventive function as well as a means of treatment.

As a medicinal mushroom, GL/GLS offer both dietary and therapeutic benefits. Being a natural medicine, Ganoderma is likely to become a staple in the natural medicine of tomorrow, as they were in the past.

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DISCUSSION

Discussion of Sixth Session Clinical Evaluation of CAM

Chairman: Prof. Gerard Bodeker

Rapporteur: Dr. Narimah Awin

Participant: Thank you very much Mr. Chairman! I have a question to Dr. Karin Kraft. I really did not clearly understand what is meant by if I could not find the diagnosis in IDC10? Can you explain? Is there a new disease or what is it?

Dr. Karin Kraft: It is not a new disease, of course, but a way of Chinese System and you won't find the details also of course. Somehow, it is a very strict system to know and we have to rebuild it once again which indicates so far from being optimal that is what I mean.

Prof. Gerard Bodeker: Your next question to Dr. McCarthy please.

Dr. Moo Chang: I would like to make one suggestion to the Dr. McCarthy's presentation. Theory for some individualized treatment, I think, it is made by Alan D'souza of Australia. In relation with individualization, I like to report another Chinese in other principles for selecting human subject. There is another plan on the human subject. Usually the human being is grouped into 4 types such as High priority group, Low-priority group, Low-young priority group, and High impriority group. There is a parameter to identify how you can group the four type of the priority of human subject. So, when you select the basis of such kind of another parameter, may be you can get a pair of clinical result, because of human subject just like a,b,c, .. A-type, B-type. So according to the oriental medical perspect, the human subject is divided to 4 groups. I think you have to consider the human subject when you are entering the clinical trials.

Prof. Gerard Bodeker: Yes another question, please.

Ms. Malti Sinha: I have a comment than a question with regard to Mr. McCarthy's lecture on drugs and digestion. I would like to endorse what Mr. McCarthy says "effectiveness of a drug diminishes if it is standardized". In fact, in ayurvedic system, sometimes, there are

drugs with about 48 ingredients. The doctor or the Vaid, the Ayurvedic, might consider the 48 or 45 ingredients are unnecessary or even 20 ingredients are unnecessary. And their dosage also differ from case to case. So, this is one side effect. To get the maximum effect, the jurists say this is the best way of treatment. But then this will apply only in cases where the doctor himself prepares the medicine for the patient. But now we are dealing with drug manufacturers who are making huge quantities and selling all over the world. For their drug, standardization is definitely necessary to avert any problem, to ensure that it is safe, efficacious etc. - Thank you!

Prof. Gerard Bodeker: Thank you for the comment. Next comment, please.

Participant: Thank you Mr. Chairman! I have, may be two or three comments. First of all, listening to some of these traditions, we start questioning the methodology. To me, we have to be very careful, if we would like to promote Traditional Medicine, and then start questioning the methodology as well as the scientific approach of dealing with the issues. This is little bit serious. If this bias is in clinical trials, so this is wrong, those who are doing the clinical trials. Otherwise, we could end up by asking that we need to develop a new methodology and we stop. So, we are going to have some dilemma for trying to convince people with efficacy and usefulness of our medicine. This is an important issue to take into consideration.

The second comment is that, as far as I understood from the basis of the Unani and Islamic Medicine that we have to start our treatment first by food without using the medicine. The next step, if we are not successful using food, we have to use the single medicine. This is an important principle, if we are doing real to base our diagnosis and treatment on the principle. When you go to Avicenna's book, if you want to use more than one drug, it is very restrictive rule. There are 1, 2, 3 up to 12 products. You can only use more than one medicine or plant or intervention. So, I don't know exactly where is the basis in the science, on the principle of Traditional Medicine that we used 20, 30, 40 ingredients in one product. I couldn't find the basis for this. For the Mushrooms, I would not challenge the claims. It is nice that

anything that will do everything like this. So, it is nice to have this as a food or something that is to use regularly, no harm, no side effects. So it is no problem that everyone would use it everyday, so that would feel healthy, powerful. This kind of, it would like to prove. I need to sit with you hundreds of years to convince me, this kind of single food treatment all this types of disease. - Thank you.

Prof. Gerard Bodeker: Thank you for your comments. Yes response, please.

Participant: I agree that all the Chinese remedies are like cocktail. You have different substance. According to theory that has been studied, has been used, it is not really studied of thousands of years. They found this convergence of substance and give a broader effect. If you just choose one of them, may be they are effective. So you can separate effective active components like we are doing with modern, pharmaceutical search. But if you separate it one by one, I cannot guarantee its efficacy as of the whole.

Prof. Gerard Bodeker: Dr. McCarthy would like to respond.

Dr. McCarthy: I don't think we should be afraid to challenge some traditional methodologies. Spiritually, we are looking on more holistic systems than you rather than trying to get the system to set a methodology, should be working to get methodology first what you are explaining. - Thank you!

Dr. Narimah Awin: Thank you Mr. Chairman! The session 6 is a wonderful session. Major issue that rose by many participants is that of evidence which is of course, so relevant today, with almost all countries are moving very actively towards evidence based medicine. Of course, Mr. McCarthy revisited. The randomized control trial and he particularly, specifically applied these principles to traditional Chinese medicine. But, I am sure these principles applied to other forms of CAM. He used Traditional or Complementary Medicine as an example, and he repeated the wisdom of, no single evaluation can be done for all aspects of effectiveness of efficacy. We should aim right measurement for the right thing. Because he did not see that, but it is better to wrongly measure the right thing than to rightly measure the wrong thing.

I respect second speaker Dr. Karin Kraft, who very eloquently deliberated further on this very issue on the theme of evidence. She enlightened us on traditional use evidence in which she has elaborated various ways. We can enhance the validity of this traditional use, if you don't mind, the respectability of traditional use in evidence in traditional and complementary medicine.

And finally, the third speaker Dr. Hu gave very interesting facts of this incredible Lucy-Mushroom. - Thank you very much Mr. Chairman!

Prof. Gerard Bodeker: Thank you the audience. It is a good session.

Seventh Session
Saturday, 13 October 2002
Safety, Quality and Regulation

Chairman : Dr. Haytham Al-Khayat

Rapporteur : Prof. Anwar-ul-Hassan Gilani

Speakers:

1 - Prof. Ikhlas A. Khan (U.S.A.)

2 - Prof. Konstantin Keller (Germany)

3 - Dr. Abdullah Ibin Muhammad Al Bedah (K.S.A.)

**ISSUES OF QUALITY, SAFETY
AND EFFICACY IN THE SCIENTIFIC
INTEGRATION OF HERBAL
MEDICINE INTO MODERN MEDICAL
PRACTICES AND MARKETING
BOTANICAL DRUGS IN USA**

Prof. Ikhlas A. Khan and Harry H.S. Fong
(U.S.A)

ISSUES OF QUALITY, SAFETY AND EFFICACY IN THE SCIENTIFIC INTEGRATION OF HERBAL MEDICINE INTO MODERN MEDICAL PRACTICES AND MARKETING BOTANICAL DRUGS IN USA

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Abstract

The scientific integration of herbal medicine into modern medical practices must take into account the interrelated issues of quality, safety and efficacy. Quality is the paramount issue since it can affect the efficacy and/or safety of the herbal products being used. Current product quality ranges from very high to very low due to intrinsic, extrinsic and regulatory factors. Product quality improvement may be achieved by implementing control measures from the point of medicinal plant procurement, whether by field collection from the wild or by cultivation, under good agricultural practices (GAP) and the manufacture of the finished botanical products under good manufacturing practices (GMP), plus post-marketing quality assurance surveillance. Voluntary implementation of such measures, dictated by market forces, will be spotty. Only regulatory requirements can impose such measures on the source material producers and finished product manufacturers. Thus, all nations contemplating the integration of herbal medicine into their conventional healthcare systems should adopt and harmonize regulations on the quality of raw and finished herbal products. Once the quality of a product can be established, the pharmacological and clinical studies must be obtained. Currently, the

lack of pharmacological and clinical data on the majority of herbal medicinal products is a major impediment to the integration of herbal medicines into conventional medical practices. For a valid science based integration, pharmacological and especially, clinical studies, must be conducted on those plants lacking such data. Adverse events, including drug-herb interaction must also be monitored in order to promote a safe integration of efficacious herbal medicine into conventional medical practices.

Introduction

Nature has provided cultures with treatments for disease since the beginning of time. These treatments, which were developed hundreds of generations ago and then passed on to today's generation, have become known as traditional medicines (TRM). Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs and experiences indigenous to these different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.⁽¹⁾ According to a World Health Organization (WHO) estimate, as high as 80% of the population in developing countries depend on traditional and herbal medicines as their primary source of health care.⁽²⁾ Over the past decade, there has been an increased global interest in traditional systems of medicine and herbal medicinal products. In part, this surge has been due to the rare or non-existent access to modern medicine in developing countries as well as the acceptance of herbal medicines by large populations of people in affluent nations. In developed countries, non-conventional medical modalities, also designated as complementary and alternative medicine (CAM), are often used concomitantly with conventional medicine. The popularity of CAM in the USA is reflected in a survey, which showed its use increased from 34% in 1990 to 42% of adults in 1997.⁽³⁾ The same survey showed that American consumers spent \$27 billion on alternative treatments, and an estimated \$5.1 billion on herbal medicines in 1997.⁽³⁾ In the same year, the global market for herbal products was estimated to be approximately \$20 billion.^(4,5)

A new modality known as integrated or integrative medicine developed due to the increasing concomitant use of conventional medicine and non-conventional medicine in developing and developed nations. Integrated medicine has been defined as practicing medicine in a way that selectively incorporates elements of CAM into comprehensive treatment plans along side orthodox methods of diagnosis and treatment. This may be accomplished by either incorporating CAM into the general health service systems as two recognizable medical practices, or by integrating the two, CAM and modern medicine, into a new, single branch of healthcare.^(6,7) Integrated medicine as described by the first example in the previous sentence presently exist in a number of countries, but the second option remains a theoretical concept. In either instance, integrated medical practices can only be accomplished through scientific research, which must take into account the interrelated issues of quality, efficacy and safety.

Quality

A current impediment to the integration of herbal medicines into modern medical practices is the quality of these products. One of the most difficult challenges for a company in the herbal industry is being able to consistently formulate a product, which will deliver the promised physiological effect. Currently, companies standardize a product for a determined percentage of a marker compound(s) thought to be responsible for the products medicinal benefits.⁽⁸⁾ Unfortunately, many studies have shown the content of these marker compounds in a product range from very high to non-existent, even within different batch numbers of the same product. A recent study on selected commercial ginseng products prepared from *Panax ginseng*, *Panax quinquefolius* and *Eleutherococcus senticosus* marketed as botanical supplements in North America in the 1995-1998 period showed that the ginsenoside contents of 232 *Panax ginseng* and 81 *Panax quinquefolius* products ranged from 0.00 to 13.54% and 0.009 - 8.00%, respectively, and that *ca.* 26% of these products did not meet label claims.^(9,10) The eleutherosides B and E content of eleuthero root powder and other formulated extract products also showed large

variation.^(9,10) Studies on the quality of St. John's Wort (*Hypericum perforatum*) products showed hypericin content ranging from 22-140% of label claim, when analyzed using an official spectrophotometric procedure,⁽¹¹⁾ and from 47-165% employing an HPLC method.⁽¹²⁾ Similarly, silymarin was detected at 58-116% of labeled claim.⁽¹³⁾ Aside from the variation in the chemical content of herbal medicine, there can also be pharmaceutical quality differences in these products. In a dissolution and bioequivalent study of nine silymarin products, three yielded 100, 50, and 0% of silymarin after one hour under official dissolution study conditions.⁽¹³⁾ A bioequivalency study of three of these products showed that the bioavailability of one product was 2-fold greater than the other two preparations.⁽¹³⁾ The quality of these preparations are primarily affected by several factors. A number of influences which greatly affect botanical quality have been analyzed to date: species differences, organ specificity, diurnal and seasonal variation, environment, field collection and cultivation methods, contamination, substitution, adulteration, and processing and manufacturing practices.⁽¹⁴⁻¹⁸⁾ Only by addressing all of these issues will it be possible to manufacture a reproducible high quality product, which will achieve the promised physiological affect.

The first step towards product quality involves analysis of the herb itself. Botanicals are derived from dynamic living organisms, each of which is capable of being slightly different in its physical and chemical characters due to genetic influence. St. John's Wort, *Hypericum perforatum*, is one case where genetic influence has affected the concentration of hypericin in different populations. The narrow leafed populations exhibited a greater concentration of hypericin than the broader leafed variety.^(19,20) The location of the population has also been shown to affect chemical concentration such as in the steroidal saponins in *Tribulus terrestris* from Bulgaria, India and China,⁽²¹⁾ in the lactones in *Piper methysticum* from Hawaii, Tonga, Fiji and Samoa⁽²²⁾ and in the aristolochic acid I concentration in *Asarum canadense* from the Eastern and Western states of the US.⁽²³⁾ Genetic influences have also been studied by comparing wild and domesticated populations. In general, both qualitative and quantitative variations of

phytochemicals are greater in wild than in domesticated populations of the same species. This variation in phytochemicals was shown in various plant studies such as on artemisinin, the antimalarial agent, in *Artemisia annua*^(14,24); on michellamine B, a compound with *in vitro* anti-HIV activity, in *Ancistrocladus korupensis*⁽¹⁴⁾; and on the essential oil composition of *Ocimum basilicum*⁽¹⁴⁾, and the podophyllotoxin content in *Podophyllum peltatum*.⁽²⁵⁾ Also, the secondary chemical constituents of medicinal plants differ from species to species within a genus as demonstrated by the presence of structurally different alkylamides in the roots of *Echinacea angustifolia* and *E. purpurea*, and by their total absence in *E. pallida*^(26,27) and the saponins in *Astragalus membranaceus*, *A. oleifolius* and *A. melanophrurius*.⁽²⁸⁾ Thus, to insure chemical uniformity, it is necessary that the starting plant material for the manufacture of botanicals be accurately identified and authenticated by their scientific names (Latin binomial) in the form of a voucher specimen. The need for the scientific name is important because a common name is inadequate as it often refers to more than one species. Such as in the case of *Ephedra*, Ma Huang is considered the common name for *E. sinica*, *E. equisetina* or *E. intermedia*. Even when plants may not have the same common name, problems still arise when common names are similar. This can lead to accidental substitution of a safe species by a toxic species. An example would be the nontoxic *Sinomenium acutum* (Boui) versus the toxic *Aristolochia fangchi* (Kou-boui).⁽²⁹⁾ Chemical fingerprinting of species within a genus is one possible method for the authentication of plant material. Recently, a HPLC method was reported which could distinguish between 90 species of *Passiflora*.⁽³⁰⁾

Another factor involves plant organ specificity in which the site of biosynthesis and the site of accumulation and storage are normally different. Chemical biosynthesis usually takes place in the leaves, and then the chemical is transported through the stems to the roots for storage. Although accumulation and storage can also take place in the leaves, it is to a much lower extent, and storage is very infrequently in the stems. An example of site-specific accumulation, as well as species specificity, is that of the compounds considered responsible for the

immunostimulant effect of *Echinacea* species. These compounds encompass five groups of chemicals: caffeic acid derivatives, alkylamides, polyacetylenes (ketodialkenes and ketodialkynes), glycoproteins and polysaccharides. As indicated above, alkylamides are found in the roots of *Echinacea angustifolia* and *E. purpurea*, but they are structurally different; and are totally absent in *E. pallida* roots. Polyacetylenes, on the other hand, are present abundantly in the roots of *E. pallida*, but absent in *E. angustifolia* and *E. purpurea* roots. While the glycoproteins and polysaccharides are present in the fresh juices and aerial parts of all three species, they occur only in minute quantities in the roots.^(26,27)

Diurnal and seasonal variations are other factors affecting chemical accumulation in both wild and cultivated plants. Depending on the plant, the accumulation of chemical constituents can occur at any time during the various stages of their growth. In the majority of cases, maximum chemical accumulation occurs at the time of flowering, followed by a decline beginning at the fruiting stage. The time of harvest for field collection can thus influence the quality of the final herbal product. Samples of *Ginkgo biloba* leaves were collected over a year to determine the concentration versus harvest time. The concentrations of ginkgolides A, B and C and bilobalide was lowest in the spring and gradually increased to a maximum level in late summer or early fall. The concentration then decreased gradually until the leaves had fallen from the tree.⁽³¹⁾ A seasonal factor was also exhibited in the concentration of sesquiterpene lactones in the leaves of *Magnolia grandiflora*.⁽³²⁾

Besides these factors, there are many other factors affecting the quality of medicinal plants, whether it is environmental or manufacturer factors. Various studies have established that environmental factors such as soil, light, water, temperature and nutrients affect phytochemical accumulation in plants, as exemplified by alkaloid concentrations of 1.3 and 0.3%, respectively, in *Atropa belladonna* grown in the Caucasus and those cultivated in Sweden⁽¹⁶⁾; essential oil content in shade-grown (1.09%) and normal light-grown (1.43%) *Mentha piperita* plants⁽¹⁷⁾; and by the silymarin content being highest

in the fruits of plants grown under 60% water/field capacity (1.39%) and nitrogen level of 100 (1.46%) and 150 kg (1.42%) per feddan.⁽³³⁾ Manufacturer factors deal with collection of the plants from the wild, as well as in commercial cultivation, harvest, post-harvest processing, shipping and storage, where by each of these factors can influence the physical appearance and chemical quality of the botanical source materials. A number of studies of products purchased from the market have shown a difference in chemical concentration: the parthenolide content in feverfew (*Tanacetum parthenium*) products from 0.00% to 0.36%,⁽³⁴⁾ the hydrastine and berberine content in goldenseal (*Hydrastis canadensis*) products from 0.00% to 2.51% and 0.00% to 4.35% respectively,⁽³⁵⁾ the macaenes and macamides content in maca (*Lepidium meyenii*) products,⁽³⁶⁾ the flavanoid, naphthodianthrone and hyperforin content in St. John's Wort (*Hypericum perforatum*) products,⁽³⁷⁾ the nepetalactone content in *Nepeta cataria* products,⁽³⁸⁾ the oxindole alkaloid content in cats claw (*Unicaria tomentosa*) products,⁽³⁹⁾ the boswellic acids content in *Boswellia serrata* products,⁽⁴⁰⁾ the marker compound content in golden root (*Rhodiola rosea*) products⁽⁴¹⁾ and the triterpene glycosides content in black cohosh (*Cimicifuga racemosa*) products.⁽⁴²⁾ During processing of the material there is a possibility of contamination by microbial and chemical agents (pesticides, herbicides, heavy metals), as well as by insect, animal, animal parts and animal excreta during any of the stages of source plant material production can lead to lower quality and/or unsafe materials.⁽¹⁵⁻¹⁸⁾ Collection of plants for the use in botanical can also affect quality. Plants collected in the wild may include non-targeted species either by accidental substitution or by intentional adulteration. In one case, the substitution of *Periploca sepium* for eleuthero (*Eleutherococcus senticosus*) has been widely documented, and is regarded as responsible for the "hairy baby" case involving maternal/neonatal androgenization.⁽⁴³⁾ More recently, plantain (*Plantago ovata*) was found to be contaminated by *Digitalis lanata* at the supplier end.⁽⁴⁴⁾ Other examples of adulteration/substitution of botanicals include *Coptis japonica*, *Xanthorhiza simplicissim*, *Mahonia aquifolium*, *Chelidonium majus* and *Berberis vulgaris* for *Hydrastis canadensis*

(Goldenseal). Each of the substitutes contains berberine, but only goldenseal contains berberine and hydrastine.^(45,46)

Other plant species are not the only possible adulterants, spiking of a product with synthetic constituents is another quality concern. Evidence of synthetic adulteration has been a concern in herbal mixtures that are multi-component Chinese herbal remedies. Chemical analysis of some arthritis remedies have led to the finding that synthetic anti-inflammatory drugs such as phenylbutazone, indomethacin and/or corticoid steroids have been added.⁽⁴⁷⁾ In a recent study of chemical adulteration of traditional medicine in Taiwan, 23.7 % (618 of 2,609) of samples collected by eight major hospitals were found to contain one or more synthetic therapeutic agents, including caffeine, acetaminophen, indomethacin, hydrochlorothiazide, prednisolone, ethoxybenzamide, phenylbutazone, betamethasone, theophylline, dexamethasone, diazepam, buccetin, chlorpheniramine maleate, prednisone, oxyphenbutazone, diclofenac sodium, ibuprofen, cortisone, ketoprofen, phenobarbital, hydrocortisone acetate, niflumic acid, triamcinolone, diethylpropion, mefenamic acid, piroxicam and salicylamide.⁽⁴⁸⁾ The most frequent adulterants were caffeine (213), acetaminophen (167), indomethacin (152), hydrochlorothiazide (127), prednisone (91), and chlorzoxazone (87 cases). Currently, *Ephedra* is easily adulterated with synthetic ephedrine alkaloids, namely ephedrine HCL. There is even the possibility of adulteration with methamphetamine, a simple conversion product from ephedrine.⁽⁴⁹⁾ Most recently, the product, PC-SPES, an herbal mixture of eight herbs that had been used for the treatment of prostate cancer,⁽⁵⁰⁾ was found to be contaminated with diethylstilbesterol (DES) and warfarin, which prompted the FDA to ban its sale in the USA.⁽⁵¹⁾

Heavy metal contamination is another quality concern. The contamination can occur at the cultivation, post-harvest treatment or product manufacturing stages. Lead and thallium contamination has been reported in multi-component herbal mixtures. Besides the unintentional in-process adulteration, it is well established that Ayurvedic and TCM sometimes employ complex mixtures of plant, animal and mineral substances, including heavy metals. It is not uncommon to

find appreciable quantities of heavy metals such as lead, mercury, cadmium, arsenic and gold in certain formulations. Cases of lead, thallium, mercury, arsenic, gold, and cadmium poisoning from the consumption of such products have been documented.^(47,52) One study detected chromium, nickel, lead, arsenic and organoleptic pesticides in Echinacea, Passion flower, Valerian and St. John's Wort products sold on the market.⁽⁵³⁾

As shown in the previous examples, quality of a botanical product can be affected at many different points in the manufacturing process, but much of the manufacturing procedures are determined by the governmental regulation in the country the products are produced, some more strict than others.⁽⁵⁴⁾ In the European community herbal medicines are regulated as medicine and subject to mandated standards, whereas in the U.S.A, they are most frequently marketed as dietary supplements under the Dietary Supplement Health and Education Act (DSHEA) of 1994 which allows botanical products to be marketed as dietary supplements. Although controlled by the FDA, they are not regulated under the same conditions as pharmaceuticals. Dietary supplements are considered food, thus must be proven dangerous before the FDA may remove them from the market. Unfortunately, this provides little assurance of identity, quality or purity. National policies exist in most of Asia and Southeast Asia. In some countries, these products are totally unregulated. Consequently, product quality may differ from country to country, and within the same country, from product brand to product brand, and even from lot to lot within the same brand.

For effective integration of herbal medicine into modern therapeutic practices, the quality of botanicals must be assured by control measures taken from the point of medicinal plant procurement, whether by field collection from the wild or cultivation, under good agricultural practices (GAP),⁽⁵⁵⁾ as the quality of the finished botanical products is obviously directly related to the quality of the raw materials. Whether field collected or produced by cultivation, authentication of plant species by a taxonomic botanist is paramount to insure that the correct source material is acquired. It is essential that the

plant materials are identified by their binomial Latin names, and a description of the macroscopic, microscopic and organoleptic (sensory) characters be provided along with herbarium specimens, drawings or photographs^(14,56-59). In the field collection of medicinal plants, care must be exercised to avoid the acquisition of non-targeted species, and to free the targeted source material of undesirable plant parts, soil, rock, insects, animals, animal excreta and other contaminants. Post collection treatments should mirror those accorded cultivated plant materials. Due to their genetic and chemical content variations, the site and date should be recorded for each collection. As stated earlier, cultivated herbs have been shown to be more uniform in their genetic make-up than the wild crafted plant material. Since the production of raw materials by cultivation should normally lead to more uniform botanical products due to greater genetic uniformity, cultivations of these botanicals would aid in product uniformity as well. The production of quality raw materials can only be assured by employing good agricultural practices (GAP) such as those carried out in the commercial cultivation of *Ginkgo biloba*⁽⁶⁰⁾ and of *Echinacea* species.⁽⁶¹⁾ Once harvested, the source materials must then be processed to produce the finished products under good manufacturing practices (GMP). General guidelines for the GMP production of botanical products have been published by the World Health Organization (WHO).⁽⁶²⁾ The GMP procedures outlined by the WHO address procedures at the raw material production end, such as the botanical taxonomic identification; the processing and manufacturing stages, and the macroscopic, microscopic, organoleptic analysis and analytical procedures end. These procedures are similar to those employed for the manufacture of conventional drugs to assure quality and purity by appropriate protocols.^(58,59) Once the quality has been addressed at the product manufacturing level, the post-marketing quality assurance surveillance must then be carried out by regulatory agencies. By meeting guidelines at each of the steps will it be possible to ensure the marketing of quality products for use in integrative medicine.

Safety

Once the uniformity of products in the botanical industry has been achieved, much of the safety issues will have been addressed, but this still does not mean the product is 100% safe. A uniform product will allow for the evaluation of its safety, whether taken over a short or long period of time. Generally, herbal medicines are considered safe when properly used at normal therapeutic doses. In the USA, botanical products are sold without the benefit of human studies to determine any possible adverse events. It is not until after a product has been on the market will the issue of its safety become a concern, and only when a high number of serious adverse events, such as poisoning, have been reported will the USA FDA initiate evaluative actions. Primarily, adverse events of most botanicals consist of mild and infrequent gastrointestinal or dermatological reactions.⁽⁶³⁾ A study monitoring the adverse events of thousands of users of ginkgo, St. John's Wort, and kava showed that less than 3% of patients encountered mild side effects.⁽¹³⁾ However, recent controversial reports of hepatotoxicity due to the ingestion of kava has prompted the regulatory agencies in Europe, Australia and the US to either remove the products from the market or attach an advisory claim to the product label.⁽⁶⁴⁾ Many experts have analyzed the adverse event reports and have concluded the evidence does not support hepatotoxicity due to kava consumption.⁽⁶⁴⁾ *Digitalis* species, *Rauwolfia serpentina*, *Atropa belladonna*, *Strychnos nox vomica*, among others, are toxic plants that are useful therapeutic agents that can be employed safely when administered in proper doses. On the other hand, there are medicinal plants that persistently evoke moderate to severe reactions, and should not be employed in any medical therapy. Plants including species of *Senecio*, *Crotalaria*, and *Symphytum*, which contain pyrrolizidine alkaloids having an unsaturated 1,2-double bond in the pyrrolizidine ring should be avoided due to the hepatotoxic effect of these compounds. On the other hand, *Echinacea* species that contain non-hepatotoxic saturated pyrrolizidine alkaloids are safe for consumption.⁽⁶⁵⁾ *Aristolochia* species is another example of plants containing toxic chemical constituents that should not be used medically. Aris-

tolochic acid I, found in all species of *Aristolochia* investigated to-date, has been identified as a potent carcinogen and nephrotoxin.^(23,66-68) Renal failures, nephritis, and urinary tract neoplasm have been associated with use of Chinese and Kampo herbal medicine preparations.^(29,68-70)

In recent years, it has become increasingly apparent that even therapeutically safe herbs can manifest toxic effects as a result of herb-drug interaction when administered concomitantly with synthetic pharmaceutical agents. For example, St. John's Wort (*Hypericum perforatum*), an effective botanical used in the management of mild to moderate depression, has been found to increase the effects of MAO inhibitors or serotonin re-uptake inhibitors; reduce the blood levels, hence the pharmacological effects, of anticonvulsants (carbamazepine, phenobarbitone), anticoagulants (warfarin, phenprocoumaon), oral contraceptives, theophylline, digoxin, cyclosporin, HIV reverse transcriptase inhibitors (nevirapine, efavirenz), and protease inhibitors (indibavir); increases photosensitivity with other such drugs; and prolongs narcotic induced sleeping time.⁽⁷¹⁻⁷⁸⁾ Herbal-drug interactions must be considered when evaluating herbal preparations for integration into modern medical practices.

Where safety information are lacking on any medicinal plants being contemplated for integrative medical use, relevant research must be performed prior to its employment. The WHO has established guidelines for such studies.⁽⁷⁹⁾ Adverse events, including drug-herb interaction must also be monitored in order to promote a safe integration of efficacious herbal medicine into conventional medical practices.

Efficacy

After ascertaining a products quality and safety, its efficacy should then be determined. It has been estimated that currently more than 1,500 herbal products are available in the USA market alone with little or no scientific documentation of either their safety or efficacy.⁽⁸⁰⁾ For a valid scientific based integration, pharmacological and clinical studies, especially, must be conducted on those plants lacking such

data. Current clinical studies on herbal medicine have been carried out under a variety of conditions, including single case, open, blind, double blind, randomized and cross over studies. Ideally, all clinical studies should be conducted by the double blind, randomized, cross over method. However, this may not be feasible for a variety of reasons. Nevertheless, the most suitable method for a given herbal medicine should be used to assess its efficacy to validate its usefulness as an integrated therapeutic agent. In recent years, the effectiveness of a number of herbal medicines have been clinically validated, including *Allium sativum* (garlic bulb), *Andrographis paniculata* (andrographis), *Cassia senna* (senna leaf, senna fruit), *Centella asiatica* (Centellae herb, Gotu Kola or Brahmi), *Cimicifuga racemosa* (black cohosh root), *Curcuma longa* (curcuma rhizome), *Echinacea augustifolia* and *E. pallida* (Echinacea root), *Echinacea purpurea* (Echinacea herb), *Ginkgo biloba* (ginkgo leaf), *Hypericum perforatum* (St. John's Wort), *Panax ginseng* (ginseng root), *Piper methysticum* (kava kava), *Plantago* species (plantago seed, plantago husk), *Rauwolfia serpentina* (rauwolfia root), *Rhamnus frangula* (frangula bark), *Rhamnus purshiana* (cascara), *Rheum officinale*, *R. palmatum* (rhubarb root), *Serenoa repens* (saw palmetto), *Silybum marianum* (milk thistle), *Valeriana officinalis* (valerian root), *Zingiberis officinale* (ginger root), among others.^(81,82) Such clinical validations represent a most important step in the scientific integration of herbal preparations into modern therapy. Unfortunately, these represent but a minuscule amount of such evidence based studies available to the clinician for use in integrative medicine. In order to answer the questions of "does it work?", "how does it work?", "is it safe?", "will it interact with conventional pharmaceuticals?", *in vivo* pharmacological and clinical studies must be accorded to as many botanical products as possible. Such studies have been the subjects of much discussion,⁽⁸³⁻⁸⁶⁾ and the WHO has published a number of guidelines for pharmacological and clinical evaluation of herbal and traditional medicine.^(1,79,80,87)

In clinical studies, be they open, single blind, double blind, randomized and cross over, the clinician must be aware that standards of quality for botanical products do not exist in many countries,

including the USA. Therefore, it is important that the issues of quality are addressed before a full evaluation of a product can be accurately undertaken.⁽⁸⁶⁾ Uniformity of a product must be established in order to obtain reliable results from the clinical studies. Otherwise, the data being published will be invalid and/or misleading.

Conclusion

There is a current movement for the scientific integration of herbal medicine into modern medical practices. Associated with this integrative herbal medicine are the interrelated issues of quality, safety and efficacy. The present lack of uniform quality in herbal products is an impediment, as both safety (toxicity) and efficacy will vary from product to product and from batch to batch. Fortunately, quality control methods do exist for the GAP and GMP production of botanical products, and there is a growing awareness and acceptance by the herbal product industry of the absolute need for standardization of botanical extracts to ensure batch-to-batch consistency. There are also available a number of research guidelines on the chemical, biological and clinical research on herbal medicine from the WHO. When safety and efficacy are established through valid scientific and clinical research, the integration of herbal medicine into orthodox medical practices will be fully accepted.

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**REGULATORY SITUATION OF
HERBAL MEDICINAL PRODUCTS
IN THE EUROPEAN UNION**

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REGULATORY SITUATION OF HERBAL MEDICINAL PRODUCTS IN THE EUROPEAN UNION

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For centuries, herbal medicinal products have been part of our cultural heritage. Take for example the ceilings of St. Michael's (Cathedral) in Bamberg, Bavaria, where nearly 400 medicinal herbs were painted by an unknown artist in 1614 AD. This deep rooted tradition may explain why herbal medicinal products continue to be widely used in Germany. In a recent study more than 70% of the German population declared that they used natural medicines, and for most of them herbal medicinal products were the first choice in the treatment of minor diseases or disorders.⁽¹⁾ With 39% of the total European market, the German market holds the biggest share by value, followed by France (29%), Italy (7%), Poland (6%) and the United Kingdom (6%).

It is important to stress that in Germany and in some other European Union countries, herbal medicines are not automatically "alternative" or "complementary" medicines but are fully integrated into conventional therapies, especially by general practitioners. The share in the prescribed herbal medicines market is 73% in France, 43% in the United Kingdom and 38% in Germany. Herbal medicinal products are found among the top 200 of the 2000 most prescribed medicines that were reimbursed by state-supported health insurances in the year 2000.⁽²⁾ As an example, a product composed of saccharomyces yeast used for the symptomatic treatment of diarrhoea ranks 51 with 1.5 million prescriptions, whereas the most popular brand antidiarrhoeal, with loperamide is placed at 145 with 851 000 prescriptions. By value, the most important herbals are ginkgo leaves, hypericum, ivy (*Hedera helix*), mistletoe, hawthorn, saw palmetto and horse chestnut. These data show that herbal medicines are rightly classified as medicinal products because they are used as such.

European pharmaceutical law classifies herbal products as "regular" medicinal products if they are presented for treating or preventing disease or if they may be administered with a view to restoring, correcting or modifying physiological functions.⁽³⁾ Several decisions of the European Court of Justice confirm this status. There are examples where a herbal preparation, such as peppermint tea, could be either food or medicine, depending on the claim presented with the product. In other cases, such as for senna extract, a product has to be declared a medicine independent of the labeled claim by virtue of its pharmacological action: in this case that of a stimulant laxative.

One other reason to classify herbal products as "full" medicinal products are risks that may be associated with their use. Some herbal medicines may present risks even when properly used. Such risks are mostly mild and can be avoided by appropriate labelling, e.g. allergic reactions in sensitive persons. However, in some cases the withdrawal of products from the market has been necessary because serious risks were identified, e.g. aristolochia preparations causing cancer and nephrotoxicity.

An increasing problem is the potential interaction of herbal medicinal products with conventional medicines and the most prominent example here is hypericum. Such risks have to be carefully assessed, balanced against potential benefits and clearly labelled for consumers and health professionals in order to protect public health. Such an approach can only be enforced if herbal medicines are subject to pharmaceutical legislation.

An additional aspect that makes herbal products a very special group is the particular character of the quality requirements. Herbal products are, even if they contain only one herb, very complex biological mixtures and in most cases it will not be possible to identify a certain chemical constituent responsible for the efficacy of the product in question. Consistent production parameters and process validation become increasingly important to achieve reproducible efficacy. Because of their complexity, strict quality control is a prerequisite for safety. There are plenty of examples where insufficient

quality control has led to toxic effects, such as by contaminations with heavy metals or adulteration with toxic plants.

Since many herbal products rely on traditional use, only very few new clinical studies are available. Industry is not motivated to perform such studies, since the results cannot be patented and protection of intellectual property is practically absent. Clinical trials with herbal medicinal products pose specific difficulties. For essential oils, blinded studies are not feasible because of their strong smell and taste. Recent studies with hypericum in major depression demonstrate that in studies with an active comparator, sertraline in the case of hypericum, the comparator has been unblinded due to side effects.⁽⁴⁾ This makes the interpretation of results very difficult. Finally, anyone who has been involved in the design of clinical trials will agree that trials in those therapeutic areas that are particularly important for herbal medicines (i.e. symptomatic treatment of minor conditions in an over-the-counter (OTC) environment) are most difficult to plan and perform.

Regulatory action

The WHO acknowledged these specific challenges at the Eighth International Conference of Drug Regulatory Authorities (ICDRA), in Bahrain in 1996. WHO member states were encouraged to establish groups of experts for herbal medicines in their own countries and regions and to update national legislation in order to allow registration of herbal medicinal products. This was reconfirmed at the Ninth ICDRA in Berlin in 1999.

In 1996, the European Parliament requested facilitated systems for marketing of herbal medicinal products; and in 1997 a specific Herbal Medicinal Products Working Party was created at the European Medicines Evaluation Agency (EMA) in London. A permanent working party of the European Committee of Proprietary Medicinal Products at the EMA is now composed of delegates from all Member States of the European Union, experts and observers from future new Member States, the European Commission, the European Parliament and the European Pharmacopoeia. The main thrust of the group is to facilitate mutual recognition of marketing authorizations within the

European Union by preparing guidance for documentation and assessment of quality, safety and efficacy of herbal medicines. In addition to these tasks the group may give advice on pharmacovigilance actions and on future legislation. All documents prepared by the group are available from the EMEA homepage (www.emea.eu.int). The work of the group is complemented by the European Pharmacopoeia that has established two working parties to prepare general and specific monographs on herbal drugs. These monographs are fully integrated into the official European Pharmacopoeia.

Quality assurance

Quality assurance and control of herbal medicinal products has to start at a very early stage, i.e. at collection or agricultural production of a medicinal herb. A specific guideline addressing this aspect was published recently. Two other documents defining criteria on how to test quality and how to set appropriate specifications are available as well. One important part of both guidelines is the glossary that explains how the term "herbal medicinal product" is defined in the European Union. It should be understood that isolated constituents such as digoxin, taxol, menthol are not classified as herbal drug preparations.

Safety and efficacy

The most controversial topic relates to assessment of the safety and efficacy of herbal medicines. The European Union facilitates the registration of well-established and traditional herbal medicinal products by permitting different types of applications for marketing authorization.

Herbal medicines may be authorized on the basis of new pre-clinical tests and new clinical trials. This type of full dossier application is mandatory for any new product, including herbals. The same type of dossier is required if a completely new indication is requested for a product that has already been marketed for a different use.

However, if the product has "well-established medicinal use with

recognized efficacy and an acceptable level of safety" an applicant may substitute new tests and trials by reference to bibliographic data.

The concept is based on the idea that a long-term use in humans will probably have resulted in sufficient and even more reliable experience than animal experiments could ever provide. Factors that have to be taken into account are the time and extent of use, the amount and quality of bibliographic information and the consistency of that information. A minimum time frame of ten years of medicinal use within the EU is requested.

The European Herbal Medicinal Products Working Group clarified the extent of pre-clinical data that are required for a bibliographic application for a herbal medicinal product: new studies should concentrate on effects that are difficult,- or even impossible -to detect clinically. This would include data on mutagenicity / genotoxicity, toxicity on reproduction and carcinogenicity. If sufficient experience in humans can be extracted from the literature, tests such as single dose toxicity, repeated dose toxicity, immunotoxicity and local tolerance are not required. Due to the complex composition of herbal medicinal products, pharmacokinetic studies are not required unless there are safety concerns.

A specific guideline addresses the assessment of efficacy. The strategy is to follow the concept of evidence-based medicine and to require evidence that will relate to the type of claim, e.g. treatment of symptoms, cure of disease, prophylaxis of disease, etc. and seriousness of diseases. For the treatment of symptoms in minor disorders, a lower level of evidence will be acceptable if the experience with a particular herbal medicinal product is well documented and plausible on the basis of pharmacological data. However, such an approach can only be accepted if the product does not present any risk to the consumer / patient. For more serious conditions, or if the product may present any direct risk, a higher level of evidence must be provided and the therapeutic alternatives have to be carefully considered.

The concept is in line with WHO guidelines⁽⁵⁾ published in 2001, and similar approaches in other countries, such as Australia. On the basis of this concept, agreement has been reached for a number of

herbal drugs, and so-called core data have been published. These core data give a summary of the herbal product characteristics, including indications, contra-indications, side effects, warnings, etc. An example would be isphagula husks, where different levels of evidence support three different indications.

Despite the fact that these two types of marketing authorization will be appropriate for a great number of herbal medicinal products, especially those covered by monographs published by the WHO⁽⁶⁾ or the European Scientific Cooperative on Phytopharmaceuticals, ESCOP⁽⁷⁾ 8, it is evident that there will be traditional herbal medicinal products that do not dispose of sufficient bibliographic evidence. As an example, the hop plant has been used as a mild sedative for centuries but experimental or clinical data are virtually absent. The question was raised whether such products should be classified as food or whether a third level should be introduced under pharmaceutical law.

The European Union has decided to introduce a new category of traditional medicines into pharmaceutical legislation and a proposed Directive is about to be discussed by the European Parliament.⁽⁸⁾ The benefit of this regulation will be that traditional medicines are classified, labelled and controlled as medicines. This will include strict quality control, compliance with good manufacturing practice (GMP), control of safety and application of all rules and regulations related to pharmacovigilance.

Herbal medicinal products that have been used for at least 30 years, with a minimum of 15 years in the European Union, will be eligible for registration as a traditional medicinal product. In respect of quality-related data such registration will be identical to full marketing authorization. The applicant has to submit bibliographic evidence that the product is safe. For the documentation of efficacy, the applicant must produce expert evidence of the traditional use that makes the claim of efficacy plausible - even though scientific evidence is not available. A new committee will be set up to publish European lists of traditional herbal substances and monographs on traditional and well-established herbal medicinal products. These lists and mono-

graphs will serve as the basis of any marketing authorization within the EU unless new evidence is submitted.

This threefold requirement for more complete evidence for new products and for treatment options in serious diseases, lesser evidence for minor claims, and allowing a "traditionally used" label for really traditional herbal medicinal products, will guarantee protection of consumers from fraudulent and unsafe herbal medicines while allowing access to well-founded and safe treatment options.

In summary, the European experience is that herbal medicines are rightly classified as medicinal products because they are used in the same way as any other medicine, they may have risks that must be identified, assessed and labelled as with any other medicine; they have clear pharmacological effects and need, probably more than many chemically defined pure substances, strict quality control and adherence to GMP.

To do this, specific experience and expertise is needed coupled with fair assessment of long-term experience; while marketing authorization procedures have to be adapted to this special group of medicines.

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**REGULATIONS AND LEGISLATIONS
OF THE COMPLEMENTARY &
ALTERNATIVE MEDICINE IN GULF
STATES... GENERAL LOOK**

Abdulla Ibin Muhammad Al-Bedah

(K.S.A.)

REGULATIONS AND LEGISLATIONS OF THE COMPLEMENTARY & ALTERNATIVE MEDI- CINE IN GULF STATES... GENERAL LOOK

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The Gulf area knew the modern medicine at the end of the second quarter of the previous century, and at the time where the oil has been discovered in this area, when the modern medicine completed its bases in the western community. In the second half of the previous century the modern medicine in the Gulf area showed great progress and stood as a competitor to the modern medicine in the western community, this has led to the elimination of the traditional medicine for a long time. When the Complementary & Alternative Medicine taken up in the last years particularly in the western communities it has been transmitted to the Gulf communities. In this time the traditional medical practices returned back to the Gulf area, some of these practices came from the east, some came from the west and some came from the desert and the shores of the Arab peninsula. These traditional medical practices have been confronted by people who support and prefer the modern medicine, this lead to the importance of finding regulations and legislations to organize the practice of the CAM as the same as what has been applied in the field of the modern medicine.

The Gulf States began to issue many regulations by using the experinece of the western and eastern countries that has wide experience in the field of the CAM, and by using the efforts of the World Health Organization in this matter. Some of the Gulf states became pioneers in the field of the CAM and its applications and issued regulations that considered to be a model to follow.

This paper will tackle the efforts of the Gulf states in this issue and will show the history of the regulations that was issued or renewed due to the efforts of the practitioners or the training or the trade of the materials that are used in the CAM especially the herbal medicine and food supplements.

Note: Full text of this paper is not available in English. However, it is available in Arabic.

DISCUSSION

Discussion of Seventh Session Safety, Quality and Regulations

Chairman: Dr. M. Haitham Al-Khayat

Rapporteur: Prof. Anwar-ul-Hassan Gilani

Participant: In the name of God, the most merciful, beneficent! In the light of lecture of Dr. Mansour Al-Said, Dean of the Faculty of Pharmacy in the University of King Saud, Riyadh, and in the light of remarks voiced by some speakers, it was recommendations of a symposium, the necessity for governance to concentrate on the Ministry of Health help in preparing laboratories in order to take care of medicinal herbs. And consolidation specialties given to drugs that are totally manufactured. Countries cannot all alone, however, try to carry out such tasks without consolidation from financial support or bodies and institutions.

Participant: I just want to mention that after attending almost 48 hours sessions, I feel very much embarrassed that I cannot get integrated with the terminology of integration of TM with the CAM. I feel like having two bottles, one of it with orange juice and another bottle with aspirin and we mix up both together. I feel that both of them got infected. There will be an interaction between TM and Modern Medicine. So, I do suggest as a pediatrician that if possible we could put one of recommendations concerning the Children. First of all, I would like to call the TM actually primary medicine and then the Modern Medicine, the secondary medicine according the chronological sequences.

If we look about the primary health care of the child, I believe that the primary medicine will be very much compatible in the primary health care. I do suggest again that, for the children specifically, I do prefer primary use of the TM, if it does not work, I will shift to secondary medicine. -Thank you!

Dr. M. H. Al-Khayat: Thank you! I am happy that we started to put some recommendations. This is good sign that we have now two recommendations. I wonder if Dr. Assiri will make third one.

Dr. Assiri: I want to ask Dr. Konstantin about, what do you mean by quality of water? This is the first. The second, the pre-clinical investigation for the safety. How can we apply the herb for the animal? Is it active ingredient or as a whole plant?

Dr. Konstantin Keller: May I give a reply to the first question. We have guideline on the quality of water use in the pharmaceutical preparations. And this guideline establishes for example for chemical substances if you want to prepare a solution or whatever. We have to use purified water according to the pharmacopoeia.

Second question is very clear. We would like seeing data for the herbal preparation or the extract. So, we are very strict in this issue.

Participant: Very sad story behind guidelines form the ministry to have guidelines for alternative medicine, acupuncture, chiropractic and herbal treatment. There were people from university, pharmacology, medicine and I was the Rapporteur of Faculty of Medicines for 6 months at the very beginning. I found there was a desire to stifle whole. I contacted several bodies from Kuwait, WHO. I went to China twice and contacted USA. So, many like to see rules and legislation. The WHO has consultation meeting in order to see how best we could organize the training courses in acupuncture. We got to make distinctions between those who were doctors and non-doctors, to 100 hours as minimum. So, I made a comparison between acupuncture, herbal therapy treatment. It was asked that we would have one general practitioner and not a specialist in acupuncture. And 200 hours minimum training was recommended by the WHO.

Here is one recommendation, I submit in Arabic. Because I have shown it in presentation in Arabic. We have heard yesterday and today and we have heard about evaluation, legislation concerning alternative herb, drugs specially the herbal medicine in EMRO region and the European Union and in Asia.

Dr. Bedah has so nice evaluation concerning herbs. My recommendation is following: We want evaluations and legislations for the Arab-Gulf region concerning some practices, not concerning some herbs. And I review some titles without fewer explanations. Among these practices, some are good and some are really frightening. 1. Cauteriza-

tion 2. Hejjama with the knife 3. Shibara, practitioners who do not resort to x-ray and practice osteopathy. We need legislations concerning practices, especially in our countries. - Thank you!

Dr. Mohd. El-Dawy: I am Dr. El-Dawy from Egypt. The point I am raising is related to regulatory aspects of herbal medicine. Dr. Khan started with the fact that in US, for example, they have under the dietary supplement health educational act, then the US Pharmacopoeia. Last March, they started a programme, which is called “Dietary Supplement”.

The applicant company would like to market its product, it pays for the expenses related, something that is very much related in the prescription tobacco, it is called as “Tobacco use and its act”. Purposely, that you pay for the expenses of the review in order to get a fast track decision and this may involve a conflict of interest and now this is prescription. Then we come to the dietary supplement verification programme for the herbal medicine, the same thing is applying. Actually, in a certain system this might be concluded that the role of integrity between the regulatory authority and academic society efforts is being breached by this type of programme. The reason I am advising this point is that where we investigate to try to formulate regulations, we should be able to do what others are doing and try to adopt what suits our need and not to adopt what’s being conducted to avoid them.

Dr. M. H. Al-Khayat: Thank you Dr. El-Dawy!

Dr. Ikhlas Khan: Just a little bit clarification required here. FDA would like very much to control it. But that is mandated from the congress. So FDA can’t do that, even though they want. So, FDA notes the law, but it is not ignored. But the public demanded it, congress acted on it, and that’s the way law is written. There is a list of saved plan material that has been used in the food, there is a list, we call it “GROSS”, generally regarded as safe, and is listed there. If this product has not been in the GROSS list then you have to give the document. You mentioned about USP program of verification. I know this program has no binding whatsoever with FDA. As I told you, I am very concerned because pharmacognosists are not there on the

standard issues. Because we don't teach them. Now, there are a lot of companies, they don't know where to get the certificate of analysis, what does it mean. So USP thought they could create a verification program, where they can go and identify the companies, make sure the good GMP. But it does not mean that if they do it they have not been in a fast track. The only thing is GMP compliance. - Thank you!

Dr. M. H. Al-Khayat: Yes, Hazleton, please.

Ms. Nancy Hazleton: I would like to talk just on Dr. Khan's comment that the US pharmacopoeia is a private agency. It is not affiliated with the government of US. So, what they do is strictly on the private side. -Thank you!

Participant: This is to Dr. Konstantin Keller. I would like to ask you about what you mentioned something about peppermint. So, what are the active ingredients in peppermint?

Dr. Konstantin Keller: I think it differs with what you are using. The difference of which kind of preparation, are you using in the peppermint. Are you using from peppermint leaves, or peppermint oils or distilled oil, I think menthol. If you are using peppermint teas, such thing would not play a major role. It depends on how it is prepared, what is the dosage, what is the way of preparation and so on. I just clarified this issue.

May I just make a comment on previous speaker? I appreciate very much the suggestion that there should be a discussion on harmonization on the requirements of practitioners, legislation for practitioners. I think this is very important. It is difficult to discuss such legislation, if the criteria are not let down. My impression of today's discussion and yesterday's discussion was, that we are using many terms common in Islamic Medicine, Homoeopathy, Chinese Medicine etc. But my impression, is that everybody is thinking about something totally different.

So, It is very important that before establishing legislation, each society of TM, Islamic Medicine establishes clear cut area of diagnosis and treatment. So, it is very difficult to make such legislation.

Dr. M. H. Al-Khayat: This is another recommendation. Yes last question, please.

Participant: Thank you Mr. Chairman! My name is Dr. Ghaya Saad from Kuwait, In charge of Drug Quality Control in the Ministry of Health. I would like to thank all the panelists and the participants. I would like to make one addition in just a few words. I would like to come back to the Kuwaiti experience by Dr. Abdullah Al-Bedah. There is always modernization and always something new. But there are rules and regulations to veterinary drugs, to the medical devices, to the special food. There are laboratories equipped with very latest equipments. As for the rest, of course, it will depend on the case by case or situation. We have listened so far to 12 panelists and tomorrow we have 12 other panelists who will make presentations. There are so many branches and numerous sub branches. We could have proposals so that we would have an importance given and then the whole thing that developed, but modern medicines need to be regulated to, because there are malpractices that are harming alternative medicine. So there must be some rules and regulations and it seems to me many professors have underlined the necessity for regulations. Such regulations can only take place when, World Health Organization for instance would adopt alternative medicine as a branch, scientific branch in medicine putting rules and regulations for Alternative medicine and an organization should be for the product, for the factory and for all aspects concerning Alternative Medicine.

Second thing is the price dimension here. We put the regulation in the price, but there is a difficulty from the consumer to accept. So, we should have basic regulations first and then price regulation so as to have competition between Alternative and Modern Medicine. - Thank you!

Dr. M. H. Al-Khayat: Yes, please.

Participant: Thank you Mr. Chairman! I am working as a Journalist. Alternative Medicine to me is comparable to in India. But this manifestation will face challenges on part of Modern Medicine. This is a phenomenon we need with resistance and opposition on part of physicians, who control the situation. I made recommendation that patient will not go to see an Alternative physician. We in the Gulf,

when we are sick we go to US, to find best possible treatment. Unless the modern doctors are convinced with Alternative Medicine, it will not be a long way. So, the best way to convince doctors on Alternative Medicine. It should be taught in institutes as a subject. It should be simple topic, so the doctor may be convinced of the importance and concept of Alternative Medicine. We will not be able to face the resistance of modern physicians. It should be taught as a necessary subject such as History of Medicine or History of Pharmacy. After that, modern physicians can advocate Alternative Medicine, which alternatively serve to each and every one. I thank you for your proposal, which we added to other proposals. It is necessary for us to gain a new draft to advocate Alternative Medicine. We should agree first to assess definitions and regulations. It should be regulated, the public should be convinced.

In all countries, family assumes responsibility for healing in most cases and critical cases go to the physicians. I would like to thank you all once again!

Dr. M. H. Al-Khayat: Yes, please.

Participant: I would like to add one point. The relation between Modern and Alternative Medicine, in fact, we have a repeated problem in recognition of Modern Medicine. The problem that we face even in modern books. They put Alternative Medicine and the unapproved medicine. At the beginning of the century curing tumors, it was not recognized by Modern Medicine, 100% used Alternative Medicine, it was not recognized, while it has proved proficient efficacy, it has been moved to Traditional Medicine and to Modern Medicine. It is hegemony about the Modern Medicine over Traditional Medicine. If you can prove certain validity of any practice of Traditional Medicine, then Modern Medicine will accept it as a part of it. We should find the solution to that so that we may draw the line between definition of Traditional Medicine and Modern Medicine. And that Modern Medicine may not put the practices of Traditional Medicine and put it under its umbrella.

Dr. M. H. Al-Khayat: Thank you for your patience and contribution. I hope that everybody has seen revised programme for tomorrow. See you tomorrow - Insha-Allah!

Eighth Session

Saturday, 14 October 2002

National Policies

Chairman : Dr. Abdul Aziz Saleh

Rapporteur : Dr. Peter J. Graaf

Speakers:

1 - Dr. Alan Dumoff (U.S.A.)

2 - Mrs. Malti S. Sinha (India)

3 - Dr. Suresh Kumar Agarwal (India)

**NATIONAL POLICIES AND
REGULATIONS ON INTEGRATION -
THE UNITED STATES EXPERIENCE**

Dr. Alan Dumoff

(U.S.A.)

NATIONAL POLICIES AND REGULATIONS ON INTEGRATION - THE UNITED STATES EXPERIENCE

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Introduction

Given the extent to which conventional medicine is professionally entrenched in medical, legal, and policy institutions in the United States, the rapid development toward a system more inclusive of complementary and alternative medicine (CAM) over the past few decades has been quite remarkable. This increasing presence has been fueled primarily by public demand, an insistence by consumers that has resulted in increased direct access to CAM practitioners and a flurry of activity by professionals and patients seeking to either incorporate or reject these approaches. The resulting public policy debate in the United States has been quite active.

There have enormous inroads in the acceptance of CAM, and direct access to CAM practitioners has dramatically increased. Many legitimate practices continue to face legal obstacles, however, while some questionable practitioners practice openly. The research, education, training, credentialing, and other critical underpinnings of accepting legitimate CAM practices are slowly but certainly moving forward. The collaborative delivery of care, however, in which patients have the benefit of partnerships that bring the best of conventional and CAM approaches within an integrated setting, is developing very slowly. CAM services and integrated settings face numerous business, regulatory, and professional obstacles. The lack of progress in professional collaboration and development of clinical models that blend various conventional and CAM practices shifts the burden to regulators to create guidelines for acceptable practice.

This paper will provide a sense of the landscape of CAM/integrative policy and practice in the United States, describe a number of key policy initiatives that have recently been completed, and discuss the underlying issues, barriers and professional responsibilities involved in creating a more fully developed collaborative care system.

Background

Decisions affecting the role of CAM within the larger health system in the U.S. occur within a large number of venues. Various agencies within the federal government control the sale of drugs and medical devices and oversee health claims made for botanicals and dietary supplements. The federal government also impacts health delivery through its control over public funds for the care of the elderly, setting standards that are widely followed within the private insurance industry that pays for most care in the U.S. A number of national private associations play a key regulatory role, overseeing the quality of care delivery by accrediting hospitals, health systems and schools and credentialing professionals. The policies and standards set by the large hospital systems that deliver care, and the managed care organizations and insurers that pay for care, all have a direct impact on the direction of health care policy. The economic strength in these organizations give them great weight when lobbying and negotiating for favorable governmental policy.

State governments directly oversee the health care professions, resulting in considerable variation state by state in what practitioners can do. Naturopathy and homeopathy, for example, are widely practiced in some states and illegal in others. This is by design, as the states are seen as individual policy “laboratories,” allowing for experimentation with various regulatory approaches as well as to allow for regulation sensitive to local differences.

The Current Landscape

CAM use has made significant inroads both in institutional development and consumer use. In the 1970’s and early 1980’s, there was very little interest, acceptance, or access to CAM approaches other

than chiropractic. The burgeoning dietary supplement industry, along with a growing interest in mind-body approaches and efforts by the acupuncture and other communities to build their own professional infrastructure, began a rather dramatic evolution. A brief survey of the current status of CAM makes the dramatic progress over the past few decades quite clear:

CAM Use

- * Estimates of CAM use by consumers have reached 33% to 66%, a figure that varies depending upon the definition of CAM used in the survey. When narrowed to those that actually see a CAM practitioner, rather than using self-prescribed remedies, the figure is probably about 11-15%. The financial interests at stake are significant; a widely quoted figure from a Harvard-based survey found that U.S. citizens spent more of their out-of-pocket (non-insurance covered) dollars on CAM services and products than on visits to medical physicians.
- * Of the nearly 6,000 hospitals in the U.S., about 25% are developing integrative programs, with surveys finding that 11-13% already offer some form of CAM. Hospitals with some CAM offering rises to 32% when focusing on hospitals with over 500 beds. It should be understood that this figure includes those offering only modest services, and could simply be, for example, an acupuncturist operating in an outpatient physical therapy setting.

Medical Acceptance

- * While few physicians yet deliver CAM care, estimates of those who have referred to a CAM practitioner or practice have now reached percentages as high as 60%.
- * While CAM was initially defined as those services not taught in medical schools, over 80 of 117 U.S. medical schools now offer some elective courses in CAM or include CAM topics in required courses. As these new physicians replace retiring physicians, a real increase in CAM practices by medical physicians is expected.

- * The National Institutes of Health (NIH), a public-private partnership at the hub of medical research in the U.S., contains the National Center of Complementary and Alternative Medicine (NCCAM)(web site at <http://nccam.nih.gov/>), which provides professional and consumer information, technical and funding support for clinical studies, designs methodologies appropriate to CAM trials, and has funded 12 centers at major medical institutions to act as principle sites for clinical trials. Each of these centers addresses a different group of illnesses: addictions, aging and women's health, arthritis, botanicals, cancer, cardiovascular diseases, cardiovascular disease and aging in African Americans, chiropractic, craniofacial disorders, neurological disorders, neuro-degenerative diseases, and pediatrics. The Center, which began as an Office in 1993 was elevated to a full Center status in 1998. NCCAM has been controversial, because it is widely seen as an endorsement by the U.S. Congress that CAM is a field worth serious study and whose treatments should be included in the health system where proven.
- * NIH held a consensus conference on acupuncture in 1997, finding acupuncture useful in the treatment of nausea caused by chemotherapeutic agents, surgical anesthesia or pregnancy, post-operative, post-dental, myofascial and lower back pain, as well as recognizing positive clinical reports for the treatment of asthma, carpal tunnel syndrome, drug addiction, fibromyalgia, headache, menstrual cramps, stroke rehabilitation and osteoarthritis.

The Legal Climate

- * The CAM professions have made significant inroads in their right to practice. Of the 51 jurisdictions in the U.S. (50 state plus the District of Columbia) chiropractors are licensed or otherwise able to practice in all jurisdictions, acupuncturists in 39, naturopaths in 12, nutritionists in 41, massage therapists in 31. These professions are all thriving, with numerous practitioners available in most areas of the country. Unlicensed practitioners practice openly in many states, offering herbal, homeopathic, or other

“holistic” consultations. They are generally allowed to practice as long as they limit their services to educational consultations rather than diagnosing and treating disease.

- * In response to the chilling effect medical board sanctions have had on physicians practicing CAM, 14 states have passed legislation protecting medical physicians from board discipline that is based upon the use of CAM approaches within their practice.
- * Herbs, botanicals, and other dietary supplements such as vitamins and minerals are widely available, and while most health claims are not allowed, there is a free flow of information about the use of these products.
- * Tracking and paying for CAM services has been difficult, in part because the codes used to identify services do not include most CAM services, and mistaken coding can bring charges of fraud. A CAM coding system may be adopted that could improve the recognition and tracking of CAM services as well as reducing legal risk.

Funding for CAM Services

- * Funding for research and development of CAM services were so low they were once described as “homeopathic.” They are now at levels that might be considered “physiologic;” they still reflect a limited priority but have reached levels where study results are impacting practice.
- * A significant portion of health care is paid for by employers who self-insure. Employers, who have a vested interest in keeping their workforce healthy, have the highest participation in CAM, with nearly 60% offering CAM services, a figure that jumps to over 75% if chiropractic is included.

While these developments have provided a much wider range of health care choices for U.S. citizens, the full flowering of CAM as a viable, integrated part of health care delivery has in many ways been stymied:

- * With narrow exceptions for chiropractic and very limited reimbur-

sement for acupuncture and nutritional consultation, efforts to gain insurance reimbursement for CAM therapies, either by Medicare or private insurance companies, have been largely unsuccessful. Some discount programs are available where practitioners absorb the cost of providing a discount in order to market their services through health plans, but few plans actually provide coverage for CAM services. Since most consumers rely upon health insurance to cover their care, and can receive conventional medical services at little cost, this sharply influences choices and channels consumers to conventional medicine.

- * Unresolved differences in philosophy of science, conflicts over the appropriate methodology for studying CAM practices, and financial pressures upon professions to protect their self interest have stalled integration from flowering within individual professions, too often channeling efforts instead into a contest over competing professional viewpoints.
- * Clinical centers where patients can access the best of conventional and CAM approaches with coordinated assessment and treatment planning have had a very difficult time surviving, and most have not survived due to difficult business and legal realities, primarily due to a lack of insurance reimbursement. While some hospitals offer vital programs that integrate a wide range of CAM with conventional services, they are few in number and many have ceased operations.
- * In the too-few settings where physicians and CAM practitioners do make an effort to work side-by-side, professional and legal pressures place the medical physicians in a supervisory role, making real collaboration difficult.

Controversial Areas: A Closer Look

The policy struggles alluded to in this brief listing have been immense and ongoing. A closer examination of two areas will serve to give a flavor of the policy dynamic within this ongoing debate: the regulation of herbs and botanicals and the discipline of physicians that offer CAM practices:

The Regulation of Herbs and Botanicals

Much of the international debate about integrative medicine has focused on the regulation of herbal products, and while much of the CAM debate in the U.S. has focused upon the right to practice various professions in the face of pressure imposed by professional medicine, the regulation of botanicals and herbs has also been an active and continuing area of debate. The U.S. Food and Drug Administration (USFDA) is the principal federal agency with authority over the regulation of herbs, botanicals, and other dietary supplements such as minerals and vitamins. While the USFDA serves under authority delegated by the U.S. Congress, it has considerable autonomy to create policy direction unless specifically countermanded by Congress. There has been considerable tension between these two bodies, as Congress has consistently supported the public's desire to have relatively unrestricted access to these products while the USFDA focus is upon barring unfounded claims, reflecting a view that products should only be available where efficacy is demonstrated in controlled trials. The last three decades have seen numerous cycles in which USFDA regulations restricting access to nutraceuticals - natural products sold for a health benefit - have been overturned by Congress.

The primary struggle over the marketing of nutraceuticals is a struggle about the freedom to speak, a right generally considered sacrosanct under the U.S. Constitution. Speech about health and the health impacts of products must be balanced against the need to protect consumers from false claims. In an evolving cycle, USFDA has restricted the sale of nutraceuticals, the restrictions are attacked with little success in court, and Congress then acts to curtail the broad restrictions USFDA had imposed. At the center of this controversy is the legal position in which professional medicine preempts any claim for a product that is not pre-approved by USFDA to “diagnose, cure, mitigate, treat, or prevent disease.”

The tension over dietary supplements arises from different views of the role of government in regulating the choices available to its citizens. Some see consumers as having a fundamental right to make health choices, and able to do so when well-informed. The role of

government in this view is to allow a broad spectrum of information that meets minimal standards of accuracy, a viewpoint that holds it is better to err on the side of allowing access to supplements rather than withholding products that might be helpful. Others believe that the scientific community has a responsibility to protect consumers, and that products should be evaluated for safety and effectiveness before they are available to consumers. This view holds that the primary interest is in preventing the marketing of unsafe or fraudulent products, and that it is better to err on the side of ensuring that harmful products do not reach the market. This latter standard is globally held to apply to drugs, but its application to more benign products such as vitamins has caused considerable controversy within the U.S. and internationally. This controversy mirrors similar professional struggles over the extent to which professional medicine should be able to control direct patient access to a wide array of CAM practitioners and practices.

To some extent, the lines drawn are ultimately personal, even when established by legal process. A good example of this is a ruling upon a USFDA regulation that was contested in the early 1970's. USFDA decided that vitamins over a certain potency - the so-called mega-vitamins - were drugs and subject to the very burdensome preapproval requirements of new drugs. When challenged in court, the judge ruled in support of USFDA, but he was appalled at the way USFDA's regulations would have affected the Vitamin C supplement he took personally. The opinion therefore contains a footnote that exempts Vitamin C from the Court's ruling. Supplements do frequently cause such reactions when we are impacted personally; unfortunately, such recognitions does not always consistently translate into the rule of law.

The public was incensed by the impact the USFDA's stance had on their access to vitamins and minerals. Congress was inundated with over one million letters resulting in the passage of a law in 1976 that barred the USFDAs attempt to classify vitamins as drugs.

The battle was rejoined in the late 1980's, this time over what health claims could be made for nutraceuticals. USFDA wanted to regulate products as a drug if a they were marketed with a health

claim. Numerous herbs and botanicals are offered in the United States for every manner of health condition, a practice that under food and drug law converts them into a drug, a legal classification that requires pre-approval based upon three phases of clinical testing that can run as high as US\$500 million. Congress believed that dietary supplements require special attention given their long history of safe use, growing recognition by health scientists of their important role in health, and widespread use. The legislature therefore wanted to find a less restrictive alternative that would better fit these products. The resulting compromise was the Nutritional Labeling and Education Act (NLEA), passed in 1990. The NLEA allowed health claims to be approved by the USFDA without requiring the completion of the drug approval process if the manufacturer showed there was “significant scientific agreement” supporting the proposed health claim. This standard was an effort to create an intermediate threshold that would not be insurmountable for supplements, yet would limit the radical and unregulated claims being made for some health foods and supplements. Under NLEA, the USFDA has thus far approved a few dietary supplement claims, such as linking calcium with osteoporosis and folate with neural tube defects. It has approved a number of health claims for foods: sodium and hypertension, dietary fat and cancer, dietary saturated fat and cholesterol and risk of coronary heart disease, fiber-containing grain products, fruits, and vegetables and cancer, fruits and vegetables and cancer, dietary sugar alcohol and dental caries, and soluble fiber from whole oats and risk of coronary heart disease. But most of the health claims that are regularly made for botanicals and other dietary supplements are not approved by the USFDA.

The NLEA did not resolve the issue, however, due to the controversy over the meaning of “significant scientific agreement,” and the rejection of numerous claims the industry believed were sensible. The Dietary Supplement Health and Education Act of 1994 (DSHEA) was enacted to create a different compromise about what health statements may be made for dietary supplements.

The DSHEA compromise allows a claim based on the impact a

product has on the structure/function of the body while still preventing disease claims. An example of this distinction is that calcium could not be marketed to “prevent or relieve osteoporosis,” or to impliedly treat osteoporosis with a claim that a product “prevents bone fragility in post-menopausal women.” This product could, however, be marketed with the statement “helps build healthy bones.” Disease and structure/function claims clearly overlap; where a statement includes a disease claim, it cannot be made under the DSHEA.

Nevertheless, thousands of herbs, botanicals, and other dietary supplements are widely sold with health care claims that are, at best, questionable. USFDA occasionally makes some enforcement effort, but it simply does not have the resources to counter a very active, U.S.\$26 billion dollar industry. As a result, consumers have considerable access, and at the same time little protection, from a wide range of health information that mixes the reliable and the fraudulent. The professional debate about whether the market should be open or restricted is one that places corporate interests in promoting dietary supplements against the corporate interests of pharmaceutical houses and medical physicians whose financial interests may be served by limiting such sales. These financial interests cloud legitimate concerns from both sides of the debate.

International Regulation of Nutraceutical and U.S. Concern Over GATT

Particularly given the extensive effort that has gone into maintaining access to nutraceuticals within the U.S., the impacts of the decisions of the Committee on Nutrition and Foods for Special Dietary Use of the Codex Alimentarius Commission (CCNFSDU) are generating some concern within the United States. The Codex, entered into under the General Agreement on Tariffs and Trade (GATT), takes a radically more restrictive approach to approvals for nutraceutical sales than current U.S. law. To the extent that the United States is required, as a signatory on the Codex under GATT, to harmonize its internal regulation of dietary supplements, the U.S. might have to adopt more restrictive marketing requirements originating in Germany

and other members of the EU. Some attorneys in the U.S. believe this could create real difficulty for access to these products, but USFDA takes the position that internal sales will not be affected and that the end result of the Codex/GATT requirements will not affect the marketing of these products in the U.S.

German law sets numerous limitations, such as restricting sales of vitamins exceeding potency limits to pharmacies and requiring an approved monograph before herbal remedies may be sold. There is concern that the Codex could preempt national law and require such restrictions, including approval of all new dietary supplements. This issue has not yet become a primary issue within the United States, but should the availability of products be curtailed in the future due to these international treaties, it will most certainly become a major issue. Historically, access to dietary supplements has generated more public comment before the U.S. Congress than almost any other issue.

The other side of this coin is that a more tightly regulated herbal pharmacy appears, in the German experience, to encourage medical physicians to more actively prescribe herbal compounds. The greater assurance of safety and efficacy in a preapproved herbal registry would likely have a similar, though less robust impact, among Western physicians. Most herbs at this point are self-prescribed, and pharmacists and others are attempting to compile information about drug-herb interactions and other needed data to assist consumers and physicians. The climate in the U.S. is clearly one in which broad availability and consumer access will remain a keystone for herbal and supplement policy.

A Note About U.S. and International Topics of Interest

Regulating nutraceuticals is an area in which both U.S. and international attention have focused. Some issues that have been at the forefront of international attention have not had the same emphasis in the United States. Questions, for example, about the proper balance between protecting intellectual property rights and the need for free flowing information have been more directly discussed by the international community. This has been an active area of discussion in the

U.S. regarding genetic patents and other areas within conventional medicine, but has not been part of the conversation with regard to CAM products or services. While business interests are central in the U.S., the free flow of information is paramount, largely unrestricted, and an enormous amount of information is available to consumers. Businesses maintain their primacy through economic power, more than controlling intellectual property rights.

Some within the United States have been sensitive to other issues that have been the focus of WHO activities, such as the need to preserve traditional medical knowledge and indigenous natural resources. The U.S. environmental movement seeks to protect biodiversity for medicinal as well as other purposes, but within the CAM community this awareness has been quite limited to practitioners practicing Tibetan Medicine and other traditional methods who are more sensitive to these issues.

Conversely, it appears that many of the concerns that are the focus of U.S. development, such as payment for services and licensure, are less of an interest globally due to differences in the payment systems and to a longer tradition of diverse systems of healing.

State Medical Board Regulation of Physicians Practicing CAM

Medical physicians in the U.S. work under licenses issued by state medical boards which govern minimal standards of care and discipline physicians delivering substandard care. Physicians incorporating CAM care or working closely with CAM practitioners have on occasion been sanctioned, with some licenses to practice suspended or revoked, by boards that believe this nonstandard care is substandard. This risk undercuts physician willingness to deliver innovative care or participate in collaborative CAM efforts, and makes it particularly difficult for health systems and hospitals to become involved in aspects of CAM delivery. Practices like acupuncture and massage are separately licensed, and while these practices still meet some skepticism, they are rarely the subject of any state board concern. Medical practices like vitamin IV therapies, prescription of herbs, botanicals or mega-doses

of vitamins, chelation therapy, energy medicine, homeopathy, immunoenhancing and other alternative cancer therapies, among other practices, have been widely criticized and in some cases subjected to investigation and sanction.

While most CAM physicians practice without disciplinary problems, many state boards have adopted policies that define these CAM practices as “unscientific” and are treated as dangerous. State medical boards all belong to a private national body, The Federation of State Medical Boards, Inc. (FSMB) which has issued policies urged by small factions within medicine dedicated to destroying the adoption of any CAM methods, even more accepted ones such as acupuncture.

The anti-CAM activities of state medical boards caused such concern that fourteen states adopted legislation that expressly forbids the boards from disciplining physicians for using CAM practices. Similar legislation is pending in several other states. These laws offer limited protection, as Boards may still investigate and bring charges against physicians without making the CAM practice the *per se* basis for the charges. Nonetheless, these laws make it clear that these state legislatures wish patients to have access to CAM services.

In a rather dramatic turn of events, FSMB recently reevaluated its position in consultation with a number of well-known CAM physicians and input from national associations advocating for health freedom. As a result of these efforts, and a willingness on the part of FSMB to reconsider some of the myths about CAM practice, a new set of Guidelines has emerged that are far more open to CAM practice. One of the critical components of state legislation protecting practice are findings that “a licensed physician shall not be found guilty of unprofessional conduct for failure to practice medicine in an acceptable manner solely on the basis of utilizing CAM.” Amazingly, the FSMB position has matured from defining CAM practices as “deceptive” to adopting this very language in its policy. The FSMB acknowledges that “... standards [of medicine] allow a wide degree of latitude in physicians exercise of their professional judgment and do not preclude the use of any methods that are reasonably likely to benefit patients without undue risk.” The FSMB also acknowledged that

assessing the evidence in support of either conventional medicine and CAM should be done on a “level playing field,” using appropriate, equitable measures of safety and effectiveness.

As a policy shift, the value in this change is dramatic. The change in FSMB policy just occurred this year, and changes in medical board attitudes to CAM will likely take some years of continuing growth. Whether parity of evaluation of treatments can ever be achieved in practice is an open question whose resolution will be based upon a complex mix of politics and differing scientific perception. A true level playing field will require that methodologies used to assess CAM services are appropriate to the claims under review. Too frequently research methods reduce interventions to a single active agent, an approach inherently incapable of determining the effectiveness of the multi-agent, systemic interventions that mark many CAM approaches.

Public Policy Development Efforts

A number of public policy initiatives have recently been completed that offer suggested next steps in the evolution of integrated health care. The extent to which these initiatives will be implemented is at the moment not clear; the public policy energy is at the moment elsewhere, though continuing, steady development continues. Efforts are currently focused upon building consensus, which is needed before these recommendations can begin to impact practice. Much of these recommendations are calls for greater resources to be committed to research, education and training, and other quality controls that underlie an infrastructure that is accountable and allows for proper access to CAM practitioners.

White House Commission on Complementary and Alternative Medicine Policy

President Clinton designated a White House Commission on Complementary and Alternative Medicine Policy (“WHCCAMP”) in early 2000, which issued its final report in March of 2002. The Commission, which was chaired by James Gordon, M.D., a presenter

at this conference, issued numerous recommendations in the areas of research methodology and coordination, education and training of health practitioners, public education and dissemination of credible information, ensuring the safety of CAM products, improving access to CAM services, ensuring accountability of CAM practitioners, coverage and reimbursement of CAM practices, the role of CAM in furthering the United State's health goals, and coordinating federal CAM activities. These recommendations do not constitute a formal policy adopted by the United States - there is no such formal policy - but are recommendations to the government about how CAM can be better integrated within the larger health care system.

The Commission's recommendations suggest a phased approach to CAM integration, looking first to the building blocks that need to be in place before a deeper role for CAM can take root within the larger health care system. While not delineating the relative value of specific CAM modalities, the Commission's recommendations set forth a spectrum of approaches that would allow reasonably accepted therapies to move forward through increased training and other development, while greater research and accountability mechanisms would help provide safety across the board but especially for questionable therapies.

Achieving this balance proved difficult, and underlying the WHCCAMP considerations were central differences in how to weigh the safety and effectiveness of CAM services and products, and the extent to which such standards have been met. Reflecting the debates in most forums worldwide, some on the Commission felt that rigorous testing had not yet demonstrated sufficient value for many CAM services to warrant increased resources and access to practice. The majority of the Commission took the position that CAM's history justifies its growing role, and that it is clearly part of the U.S. care system so that accountability, infrastructure, research and education should be improved. The Commission report has generated considerably controversy, including reactions by factions strongly opposed to CAM who have invested considerable energy publishing attacks belittling the Commission.

In order for the Commission's recommendations to have an impact, it may be necessary to establish one of its first recommendations - an office to coordinate CAM policy within the Department of Health and Human Services. Little movement is occurring in this direction, but a national office could eventually be created that would provide a platform for further development of national CAM policy.

National Policy Dialogue and the Design Principles for Healthcare Renewal Project

A collaborative effort at generating national policy recommendations achieved a consensus report by creating an active dialogue among major medical and CAM educational institutions and professional associations and public policy groups. These intensive meetings led to a consensus document entitled the "National Policy Dialogue to Advance Integrated Health Care: Finding Common Ground." This report focuses on recommendations for research and education, the regulation of CAM products and services, access to CAM insurance benefits, public and community health, and on those populations that are undeserved or have special needs. A sister group to the National Policy Dialogue is developing principles for a health system that truly adopts an integrative approach. The National Design Principles For Healthcare Renewal Project has developed ten draft principles to inform and weigh policy and program developments within health care systems and providers as well as within the national debate.

The WHCCAMP, National Policy Dialogue, Design Principles group, and other efforts all address the same core issues that confound the development of a care system that patients seek - a safe, intelligent, unbiased, caring system that makes available the best methods of diagnosis and treatment, no matter their source. They share a view that the field is maturing, and needs now to grow beyond bias and marketing hype and explore appropriate clinical research, practitioner education, and methods of accountability that can accomplish this vision.

Exploring Core Issues

Efforts to establish a clear-headed national policy agenda must come to grips with a number of interwoven core issues. Addressing these is complicated by the extent to which the professional self-interests of the professions and product manufacturers color the national policy discussion. Though rarely articulated in this way, much of the public policy debate about CAM in the United States begins with the very definition of “integrative medicine” or more generically, “integrative healthcare.” The most prevalent definition is based on a vision in which patients have access to a wide range of separate medical and CAM services coordinated, if at all, by the patient. Another view sees professional medicine incorporating CAM services within its own activities, a vision in which CAM practitioners would function as ancillary providers coordinated within a view of health and illness dominated by the medical profession. While this vision could provide oversight and coordination, it would likely result in a real loss of the values that traditional/CAM approaches contribute to patient care. A more full vision of integrative healthcare may be one in which medical physicians and CAM practitioners work side-by-side to coordinate care and to develop a larger understanding of health and illness than currently exists in any one view. This view may create the most sustainable system, but is clearly the most difficult to develop.

U.S. policy has evolved to include considerable access to many CAM therapies and products, though extensive efforts to adequately fund research and pay for treatment, educate doctors and patients, and further develop infrastructure such as credentialing bodies and state licensure remain. After an initial flurry of conferences and political activity, much of the current focus has settled into the work of increasing research and educational opportunities by establishing collaborative efforts between academic institutions, professional associations, and other stakeholders. This phase of development includes beginning efforts to gather better outcome and research data, needed to inform better decisions about future efforts and upon which payment decisions can be based.

Policy development is marked by strong opposition from segments of the medical community, and considerable differences within the CAM community itself. Debates about these unresolved policy issues and tensions repeatedly raise the same core questions, which include:

- *What requirements of proof should apply to traditional/CAM methods and products?* Some maintain, and U.S. law provides in the instance of botanicals and devices, that longstanding use of a product implies sufficient assurance of safety for marketing with limited claims. Others believe that CAM services need to be held to rigorous standards, such as proof by randomized controlled trials, that have presumably been met by allopathic medicine.
- *To what extent should hospitals and clinics integrate medicine and CAM as aspects within a larger whole of care delivery?* Some view CAM as an intrinsically separate system that should avoid the intensely regulated approach taken with professional medicine, while others hope the U.S. health care system will evolve into an integrated system that weaves the best of allopathic and CAM methods within the fabric of a unified health system.
- *What role will allopathic/professional medicine play within a larger health care system?* To the extent that the health system continues to evolve greater levels of integration, it becomes more important to understand and position the role that allopathic medicine will play. Some are concerned that professional medicine is moving to develop “Integrated Medicine” as a professional specialty within the guild of professional medicine, a move that could place the emerging CAM professions in a subordinate position to medical physicians. Others believe that it is only through the cooperation and oversight of physicians friendly to CAM that such integration will in fact take place.
- *To what extent should an informed public have access to CAM practitioners without governmental oversight?* Regulators desire some demonstrations of proof before accepting controversial therapies as valid, but the methods of demonstrating value are themselves part of the controversy. Some believe that the benefit of the doubt should resolve in favor of access in the absence of demonstrated

harm, while others believe the tools developed by scientific medicine are critical and that only techniques demonstrated under these standards should be available.

- *What is the proper role of governmental oversight?* Federal and state regulators have considerable power over what treatments and products may be offered. Some think that the most appropriate role is for these agencies to make sure that the public is informed, an educational role that would offer guidance but leave the public free to weigh and choose. Others believe that government should be even more aggressive in regulating care delivery and rooting out what is perceived as health care fraud.
- *What is the proper role of business in matters of science?* Perhaps more than any other country, decisions in the United States are influenced by corporations with enormous profit interests in health care delivery. Some believe that the financial interests of the pharmaceutical and insurance interests oppress traditional methods in favor of patented medicines or treatments accepted by institutional medicine, while others have faith that this marketplace remains the best means of developing new therapies.

The Responsibility of the Professions in Researching and Developing Integrative Care

To some extent, the difficult national policy choices that must be faced are a result of professional failings, failings both to rise above the bias of self-interest and to recognize and honestly address the limitations in information about the effectiveness of both medical and CAM interventions. Were the various professions able to accommodate a broad view of health and disease and work toward the joint coordination of diverse care, or at the very least respect the value of the various traditions, less regulatory activity would be required. Were outcomes clearly tracked so that the connection between practice and results were better understood, rather than merely the subject of competing opinions, policy choices would be clearer. That the professions instead struggle over turf and interpret uncertain information about the quality of health care interventions in a manner that only

favors their interest requires that decisions be shifted to legislators and regulators to make choices instead.

Environmental regulation is necessary, by way of example, because industry is unwilling to conform with environmentally safe practices and the economics of the marketplace are not self-correcting; polluters do not bear the costs of their pollution as a natural consequence of their activities. This combination of unwillingness and economic disconnection shifts the burden to regulators to artificially require polluters to bear costs. The resulting public policy debate requires a convoluted, value-laden and costly argument about the economic and social values resulting from pollution.

While little noted, the situation within integrative medicine is similar. The economic disconnection is very real, as payments for health care services in the U.S. are based on acceptance within established medicine, a layer of professional opinion that replaces actual outcome data. Countries with more socialist health care systems face this disconnect as well, due to the artificial nature of payments designed by bureaucracies rather than determined in the marketplace.

An ideal system would see professional cooperation in a grand, healing adventure. Human health is a complex system that can be viewed from many perspectives, a small sampling of which includes molecular, genetic, biochemical, mechanical, energetic, and structural views. Were each profession to see its viewpoint in the larger context, and embrace the other health care professions as brothers in a common pursuit, much of the struggle to regulate integrative health care would be resolved at its source, rather than being called on to mediate a false dispute.

While this disconnect from the natural consequences of our endeavors may not seem apparent in a field where doctors follow their patients response to treatment, the disconnect is nonetheless real and impairs the ability to simply follow natural consequences without undue, artificial regulation. During the last several years, for example, a steady stream of studies undercutting well-accepted, presumably evidence-based practices have made headlines, finding that they may in fact be no better than placebo or potentially dangerous, such as

selective serotonin reuptake inhibitor (SSRI) antidepressants, hormone replacement therapy, or arthroscopic knee surgery for osteoarthritis. The top three SSRI medications account for US\$5.4 billion dollars in annual expenditures in the U.S., with over 64 million annual prescriptions. There are over 600,000 arthroscopic knee surgeries performed, at a total cost of approximately \$6,000 each (although it must be recognized that this figure is exaggerated as only some of these surgeries were for osteoarthritis.) Over 37% of postmenopausal women in the U.S. use HRT. This information followed studies the year before that reported that the “appropriate” use of pharmaceuticals was estimated to fatally injure 108,000 U.S. patients per year, with significant injuries estimated in excess of 2 million, a figure that does not include medical mistakes.

These questionable and dangerous treatments together affect huge portions of the population and billions in medical spending. Yet these treatments will continue to be prescribed and insurance payments made for these conventional treatments, in part because physicians are not trained in alternative methods. And the mythology that medical treatments are generally proven safe and effective, while CAM interventions are not, will continue to have some strength.

Differences of opinion about demonstrations of effectiveness arise in large part from differences about experimental design. A widely held view by CAM practitioners is that uneven standards are applied to proof, which arises where the mechanisms of action are unfamiliar. Conventional medicine tends to place higher expectations of proof on CAM by following the old maxim of the skeptic that “extraordinary claims require extraordinary proof.” The converse of this maxim is that therapies that fall within the expected paradigm are often uncritically accepted. Medical acceptance is based as often on belief and history as on real empirical evidence. The presumption that medical science uses interventions of proven effectiveness is to some extent a myth, one that persists even in the face of continual evidence to the contrary.

In many instances, criticisms of CAM’s research base are quite well-founded, as CAM practitioners have been reluctant to see their

methods tested. This reluctance is at times due to a mistrust based on experience, in which clinical trials of CAM interventions have been designed to fail, or in which conclusions drawn go far beyond what may be drawn from an experimental design given the difference nature of CAM services. CAM practitioners often simply fail to critically evaluate their own therapies, holding that conformity with their beliefs about health is sufficient. This makes honest appraisals of the outcomes of their work difficult and undercuts the development of integration. The CAM community must take a greater role, for its part, in designing and conducting acceptable studies.

The professions are beginning to work together to design clinical research methodologies that actually address the questions posed by integrative care. Too often, entrenched differences in philosophy of science are used as a sword to attack traditions based upon different views of knowledge. Perceptions of proof are to some extent in the eye of the beholder despite claims of objectivity, and the value seen in CAM services is shifting as CAM professional associations gain a stronger voice. From the distance of those who design policy, it is apparent that findings from clinical studies are very much a matter of interpretation, and therefore of perception. Perception is a reflection of professional development. The continuing development can be expected to alter the terms of the discussion.

A Few Thoughts About Solutions

While national regulatory responses are vital, the real heart of integration lies within the professions themselves. When the dust settles and public policy solutions have been found that resolve debate and create a more inclusive health care system, true integration will only occur if clinical models are developed that allow sensible multidisciplinary clinical decision making in the face of different theoretical views of health.

Legislative solutions continue to be sought in the U.S. The Access to Medical Treatment Act (AMTA) serves as a good example.

Proponents of health care freedom have been attempting since 1996 to enact legislation which would establish a basic right for patients to receive treatment, even if not approved by the USFDA, if not demonstrably dangerous and offered by a licensed health care practitioner. The bill would require informed consent, would offer certain protections to practitioners using CAM approaches, and would create an adverse reporting databank to which practitioners would be required to report difficulties so that dangerous therapies could be tracked. This is conceived of as informal clinical trials that would involve practitioner's offices across the nation, and is an effort to combine access with accountability. Versions of this bill would change the import restrictions on approved drugs or devices from other countries. The bill has been slowly gathering steam and may at some point become law.

In a regulatory environment that bears some hostility toward CAM, integrative health care requires protections such as found in AMTA. Much of the work that brought about the progress of the past few decades, however, was the development within the professions that created credible and accountable health care services. Many of the CAM professions have extensive professional support networks, including national credentialing bodies, certification programs, state licensure, accredited core and continuing education training programs, recognized bodies of research and considerable legislative activity aimed at preserving, even if in a limited fashion, patients rights of access. This remains the most vital area for development.

Ultimately, multi-disciplinary interaction is the goal of integration, which places open channels of communication as the most vital aspect. In the U.S. a greater level of collegial conversation is finally well underway. A good example of a primary meeting ground for physicians and researchers from both the conventional and CAM worlds has been the Center for Mind-Body Medicine's "Comprehensive Cancer Care Conference," which has for three years worked to bring the CAM medical world into "productive dialogue with the American

cancer establishment.” These are working conferences, cosponsored by the National Cancer Institute (NCI) and NIH’s National Center for Complementary and Alternative Medicine (NCCAM), which allow for intense, multidisciplinary discussion.

International conferences such as this Seminar on the Integration of Traditional (CAM) and Modern Medicine, are a wonderful opportunity for national and international sharing and are vital aspects of this effort.

**THE STATUS OF TRADITIONAL
MEDICAL SYSTEMS IN INDIA AND
GOVERNMENT'S POLICY
TOWARDS HEALTH CARE
ADMINISTRATIVE SETUP IN INDIA**

Mrs. Malti S. Sinha

(India)

THE STATUS OF TRADITIONAL MEDICAL SYSTEMS IN INDIA AND GOVERNMENT'S POLICY TOWARDS HEALTH CARE ADMINISTRATIVE SETUP IN INDIA

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India has a Federal structure with a Union Government and Provincial/State Government. The Union Government is directly concerned with, laying down standards of medical education, Enforcement of Drug Laws, Prevention and Control of certain diseases, Reproductive and Child Health programs and the State Governments implement health care through; Network of primary, secondary and tertiary institutions, Establish medical institutions for teaching and training and Regulate Drug industry

Indian Systems of Medicine & Homoeopathy (ISM&H) are looked after by an independent Department in the Ministry of Health & Family Welfare, Government of India, headed by a Secretary to the Government of India since 1995. Under this the following Systems of Medicine and therapies are recognized by the Government of India:

- * Ayurveda
- * Homoeopathy
- * Siddha
- * Unani
- * Yoga and Naturopathy

Thrust Areas of the Department are Improvement and upgradation of standards of education in ISM&H, Standardization of drugs, Research and development, Enhancing the availability of Raw Materials i.e. Medicinal Plants which constitute 90% of the ingredients of the drugs in ISM&H, Information education and communication and

Involvement of ISM&H in the National Health care delivery system and National Health & Family Welfare Programmes

The Infrastructure of ISM&H is wide, there are 6,88,802, Registered Practitioners, 412 ISM&H colleges and Admission capacity per annum is 18295.

NO. OF HOSPITALS, DISPENSARIES ALONG WITH BED STRENGTH UNDER ISM & H

S. No.	System	No. of Hospitals	No. of Beds	No. of Dispensaries
1.	Ayurveda	2955	43973	14721
2.	Unani	312	5128	958
3.	Siddha	237	1986	352
4.	Homoeopathy	307	13694	1411
5.	Yoga	007	200	65
6.	Naturopathy	022	757	56.
	<u>Total</u>	<u>3840</u>	<u>65738</u>	<u>23563</u>

System wise infrastructure for Indian systems of Medicine and Homeopathy

Systems	<u>Medical Under graduate</u>	<u>Colleges Post graduate</u>	Registered Practitioners	Licensed Manufacturing Units
Ayurveda	196	53	430890	8386
Unani	039	05	43108	453
Siddha	05	02	17097	384
Homoeopathy	166	17	1,97,253	609
Yoga & Naturopathy	06		455	
<u>Total</u>	<u>412</u>	<u>77</u>	<u>6,88,802</u>	<u>9,832</u>
Admission Capacity	18295	991		

Statutory Regulatory Bodies established by the Government for ISM&H

- * Central Council of Indian Medicine (For Ayurveda, Siddha & Unani)
- * Central Council of Homoeopathy (For Homoeopathy)
- * Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945
- * Separate Drug Technical Advisory Board under Drugs & Cosmetics Act, 1940 for Indian Systems of Medicine to advise Government on all aspects related to quality control and drug standardization

Apex Level Pharmacopoeial testing facilities for Indian systems of Medicine & Homoeopathy

- Pharmacopoeial Laboratory for Indian Medicine (For evolving Pharmacopoeial standards of Ayurveda, Siddha and Unani drugs)
- Homoeopathic Pharmacopoeia Laboratory (For evolving Pharmacopoeial Standards for Homoeopathic drugs)

These Laboratories are also Appellate Laboratories for Drug Testing and Quality Control

- 16 State Laboratories have been upgraded
- Private laboratories are being recognised as Public Test Laboratories
- Good Manufacturing Practices have been notified.

Pharmacopoeia Committees for Indian Systems of Medicine & Homeopathy

Pharmacopoeia Committees notified by Central Government for laying down Pharmacopoeial Standards

- * Ayurveda Pharmacopoeia Committee
- * Siddha Pharmacopoeia Committee
- * Unani Pharmacopoeia Committee
- * Homoeopathic Pharmacopoeia Committee

Drug Standardization & Quality Control

- * Production of drugs and Quality Control are regulated under Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945
- * Act was amended in 1982 to include Ayurveda, Siddha and Unani Medicine
- * Good Manufacturing Practices (GMP) for Ayurvedic, Unani and Siddha drugs have been notified on 23rd June, 2000
- * 35 apex level laboratories/scientific institutions have been notified for evolving pharmacopoeial standards
- * Enabling provision has been made to recognise private drug testing laboratory
- * Ayurvedic Pharmacopoeia Committee approves the Formulary and Pharmacopoeial standards
- * 258 Pharmacopoeial standards and Formulary containing 634 drugs have been published
- * Completion of Pharmacopoeial standards has been accorded high priority and the work is targeted for completion by 2003
- * Pharmacopoeial Laboratory For Indian Medicine prepares Pharmacopoeial standards and also acts as an appellate laboratory

To act as model institutes in respective systems, to produce graduates and post-graduates of high quality, conduct Research and to provide quality medical care, the following National Institutes have been set up by the Government of India.

- * National Institute of Ayurveda, Jaipur
- * National Institute of Unani Medicine, Bangalore
- * National Institute of Homoeopathy, Calcutta
- * National Institute of Naturopathy, Pune
- * Morarji Desai National Institute of Yoga, New Delhi
- * National Institute of Siddha, Chennai
- * Rashtriya Ayurveda Vidyapeeth, New Delhi

- * Institute of Post-graduate Teaching & Research, Gujarat Ayurved University, Jamnagar

CENTRAL COUNCIL OF INDIAN MEDICINES

The Central Council of Indian Medicines was established under the Indian Medicines Central Council Act, 1970 (For Ayurveda, Siddha and Unani)

The Central Council of Indian Medicines is constituted out of: -

- Persons elected by the Practitioners of Ayurveda, Siddha and Unani enrolled on the State Medical Register.
- Persons elected by the faculty of Ayurveda, Siddha and Unani of each University.
- Persons nominated by the Central Government having special knowledge and practical experience in respect of Indian Medicines.
- There are about 132 Members of the Central Council representing Ayurveda, Siddha & Unani Systems

And its office bearers are: -

- President
- Vice President (One each for Ayurveda, Siddha and Unani)
- Registrar/ Secretary

The Council has the following Committees:

- A Committee for Ayurveda
- A Committee for Siddha
- A Committee for Unani
- Education Committee (one each for Ayurveda, Siddha, & Unani)
- Registration Committee
- Regulation Committee

Duration of Under-graduate & Post-graduate Courses

- Bachelor of Medicine & Surgery in Ayurveda, Unani and Siddha is of 5½ years duration including one year internship.
- Duration of Post-graduate teaching is three years.

MEDICAL QUALIFICATIONS

The Medical Qualification granted by the University, Board and other Medical Institutions are recognized by the Central Government, after consulting the Central Council, by notification in the Official Gazette.

Rights of Registered Medical Practitioners

Hold Office in Government non-Government sector as Vaidya, Siddha, Hakim or Physician or related posts of Indian System of Medicine & Homoeopathy, Shall practice ISM in any State, Shall be entitled to sign or authenticate a medical or fitness certificate or any other certificate required by law to be signed or authenticated by a duly qualified medical practitioner, Shall be entitled to give evidence at any inquest or any court of law as an expert under section-45 of the Indian Evidence Act — 1872 or any matters related to ISM.

Regulation of Education

The Central Council may prescribe minimum standards of education in Indian Medicine, required for granting recognised medical qualifications by the Universities, Boards or Medical Institutions in India

The Central Council makes regulations with the previous sanction of the Central Government for regulating and maintaining minimum standards of undergraduate and post-graduate education. It enforces compliance by periodical visits and inspections of the medical institutions. The Central Council has made and enforced Minimum Standards of Education.

The Central Register of Indian Medicine

The Central Council shall cause to be maintained in the prescribed manner, a register of practitioners in separate parts for each of the systems of Indian Medicine to be known as the Central Register of Indian Medicine which shall contain the names of all persons who are for the time being enrolled on any State Register of Indian Medicine and who possess any of the recognized medical qualifications.

Professional Conduct is Governed by “Practitioners of Indian Medicines (Standards of Professional Conduct, Etiquette & Code of Ethics) Regulation, 1982

MAINSTREAMING AND INTEGRATION IN HEALTH CARE DELIVERY SYSTEM

- * Government has taken a policy decision to mainstream and integrate ISM&H Systems in Health Care Delivery and National Programmes
- * In order to acquaint students of Allopathic systems with concepts and principles of other systems of medicine, an exposure on Ayurveda, Unani and Homoeopathy systems of medicine is being introduced in the course content of Allopathic Course (15 hour module containing lectures and lessons has been proposed)
- * Decision to include Ayurveda and Unani Medicines in the National Programme of Reproductive and Child Health (RCH) has been taken.
- * Speciality Clinics of Ayurveda, Unani & Homoeopathy are being run in selected Govt. hospitals of modern medicine.
- * KSHAR SUTRA an extremely efficacious Ayurvedic procedure for Ano-rectal disorders and PANCH KARMA (Five procedures) for Arthritis, Paralysis, heart related disease, obesity, insomnia and a number of other indications are being encouraged.

RESEARCH COUNCILS SET UP BY THE DEPARTMENT

There are four Research Councils engaged in Intra-Mural research with units in different parts of the country

	Institutions/Units
- Central Council for Research in Ayurveda & Siddha	36
- Central Council for Research in Homoeopathy	52
- Central Council for Research in Unani Medicine	25

- Central Council for Research
in Yoga & Naturopathy

RESEARCH COUNCILS

Objectives

They initiate, aid, guide, develop and coordinate scientific research both fundamental and applied relating to each system of medicine.

The Research Councils are engaged in the following areas of Health Care Research and Development.

- Clinical Research
- Drug Research including standardization
- Survey and Cultivation of Medicinal Plants
- Tribal health Research
- Literary Research
- Family Welfare Research

The Research Councils have patented drugs for Malaria, Epilepsy, Psoriasis, Contraception, Rheumatoid arthritis, Leucoderma, Eczema, Filaria, Bronchial Asthma, Sinusitis, infective Hepatitis

- CCRAS 18 Drugs
- CCRUM 7 Drugs

EXTRA-MURAL RESEARCH

Extra-Mural Research is undertaken by scientific institutions/Laboratories like

- * Banaras Hindu University
- * Gujarat Ayurved University
- * Council for Scientific & Industrial Research
- * Department of Bio-technology
- * Department of Science & Technology
- * Indian Council for Medical Research (ICMR)
- * Modern Medical Institutions

TRADITIONAL KNOWLEDGE DIGITAL LIBRARY

- * Traditional Knowledge Digital Library (TKDL) is being established covering 35,000 formulations described in 14 Ayurvedic texts. The library would be available in English, Hindi, Spanish, French, German and Japanese in patent compatible form easily accessible to the patent examination. This will help prevent claims by others for patenting.
- * More formulations will be covered in the second phase
- * TKDL for Unani and Siddha will be taken up after December, 2002.
- * Folk medicines/lores are also being documented and published.

ESTABLISHMENT OF THE MEDICINAL PLANTS BOARD

- * Government has setup a Medicinal Plants Board under the Chairmanship of Union Minister of Health & Family Welfare on 24th Nov. 2000 to co-ordinate all activities relating to conservation, cultivation, marketing and augmenting supply of medicinal plants both for domestic consumption and export of medicinal plants.
- * 24 States/UTs have set up state level Medicinal Plants Board. Other states are in the process of setting up of Medicinal Plants Board

GLOBAL SCENARIO OF ALTERNATE MEDICINE MARKET

- * According to the WHO, the global market for medicinal herbs and herbal products is estimated to touch US\$ 5 trillion by 2050.
- * Percentage of population using Traditional Medicine at least once:

Australia	48%	Canada	50%
USA	42%	Belgium	40%
France	75%	UK	90%
- * 46% of Swiss doctors use complementary, alternative medicine mainly Homoeopathy and Acupuncture

- * 40% of General practitioners in UK offer access to complementary or alternative medicine
- * In USA the use of traditional medicine by doctors increased from 34% in 1990 to 42% in 1997
- * In Africa more than 80% of population uses traditional medicine.
- * In several African countries more than 60% of children with high fever are treated at home with traditional medicine. They are interested in low cost options based on Indian medicine.
- * In Japan 60-70% of Medical doctors prescribe Pompon medicine.
- * In Malaysia, Malay, Chinese and Indian Medicine is extensively used.
- * In China, traditional medicine accounts for more than 40% of the drugs provided by the health care system.
- * 71% of population in Chile and 40% of population in Columbia accept traditional and complementary medicine.

INTERNATIONAL RECOGNITION/COLLABORATION

- * The Govt. of India has entered into an Memorandum of Understanding with Government of Russia on collaboration in the field of Ayurvedic Teaching, Treatment and Research.
- * *Panch Karma* and *Kshar Sutra* are in the process of being recognised in Russia.
- * WHO held consultation on *Panch Karma* to finalize guidelines
- * Hungary has recognized Ayurveda-40 drugs
- * Select committees on Complementary and Alternative Medicine set up by the House of Lords of the UK Parliament has placed single drug in category 1. Govt. of U.K. has accepted the recommendation
- * The Government of South Africa have expressed their interest in buying Indian Drugs. They are also proposing to start Under Graduate and Post Graduate Course in Ayurveda.
- * A delegation of 15 students from National Institute of Health,

USA will visit India to discuss application and collaboration in Indian medicine research.

- * Medical schools in USA have expressed desire to introduce course module in Ayurveda measuring thereby that Ayurveda is a Scientific medical system for students of modern medicine for exposure.
- * Module on Ayurveda have been designed and sent to USA.
- * Gujarat Ayurveda University, Jamnagar (Gujarat) has entered into Memorandum of Understanding for collaboration in the field of Education and Research with the following institutions:
 - 1 - Institution of Traditional Oriental Medicine, Japan.
 - 2 - Australian Academy of Natural Medicine, Australia.
 - 3 - European Institute for Scientific Research on Ayurveda, Netherlands
 - 4 - The Ayurveda Health Group, Argentina
 - 5 - Instituto Italiano De Ayurveda, Italy
 - 6 - California College of Ayurveda, USA
 - 7 - Department de Medicina Ayurveda Universidad Abierta Interamericana, Argentina

MANY OTHER COLLABORATIONS ARE UNDER PROCESS FOR APPROVAL

- * Students from Japan, Russia, The Netherlands, France and Sri Lanka are studying in the Bachelor of Ayurvedic Medicine & Surgery course at Gujarat Ayurveda University.
- * Professionals from USA, Poland, Germany, Brazil, Switzerland and Ukraine are attending three-month introductory course
- * The Benaras Hindu University, Varanasi is conducting a nine-month course in Ayurveda for foreign doctors

INTERNATIONAL CO-OPERATION

- * The Benaras Hindu University is also conducting M.D. (Ayurveda) for doctors having M.B.B.S. Qualification

- * Mauritius has recognized Ayurveda
- * South Africa has accepted Ayurveda as a Medical System and registered all Ayurvedic doctors. Process of allowing import of Ayurvedic Drugs has begun. They are going to register Ayurvedic Products for import to South Africa.
- * A Faculty of Ayurveda is being set up in Nelson Mandela School of Medicine
- * South Africa has decided to start BAMS and PG course in Ayurveda. They have sought our assistance for starting the course.
- * Proposals were received for introducing short term training Course in history & concept of Ayurveda for the American Medical Students (Allopathy). Course Capsule prepared and sent.
- * Hungary has recognised Ayurveda and about 40 Ayurvedic drugs are also being sold there. Hungary has sought assistance to start Ayurvedic teaching in 3 Universities
- * UK has upgraded Ayurveda to Category I for single formulation.
- * U.K. is introducing a herbal medicine course to be regulated by an Act of Parliament. Ayurveda component in the course will span over 1600 Hrs.
- * Deputy Minister of Health, Government of Russian Federation is likely to visit India.
- * 15 scientists from USA are likely to visit India in April, 2003 to have one to one dialogue for understanding collaborative research in specified areas.
- * US Medical students are proposing to visit India for exposure in Ayurvedic hospitals.
- * Modalities for similar visit by Russian students are being finalised. Government of India will support the visit financially.
- * Department of ISM&H arranged a presentation-cum-exhibition in Geneva in May 2001 and 2002 about the strengths of Ayurveda and Yoga etc.
- * Department of ISM&H has participated and/or sent representa-

tive for various Seminars & Trade Fairs in countries such as Germany, South Africa, Brazil, USA, Portugal and Japan.

ISM&H AND WHO

A Cell for Ayurveda has been set up in WHO South-East Asia Office of World Health Organisation w.e.f 12.4.2001. Ayurvedic expert has been engaged to advise WHO on traditional medicine.

FOREIGN DELEGATIONS VISITED INDIA FOR ISM&H

- * Delegations from Myanmar, South Africa, Holland, Brazil, Russia, and Thailand visited India and held discussion on traditional medicine during 2000-2001.

FOR MORE INFORMATION VISIT US AT

Department's Website URL:

- * <http://indianmedicine.nic.in>

And also the Research Councils Websites URL:

- * Ayurveda: <http://www.ccras.org>
- * Homoeopathy: <http://www.ccrhindia.org>
- * Unani: <http://www.unanimedicine.org>

**REGISTRATION AND LEGISLATION
OF TRADITIONAL MEDICINES AND
PRACTITIONERS IN INDIA**

Dr. Suresh Kumar Agarwal

(India)

REGISTRATION AND LEGISLATION OF TRADITIONAL MEDICINES AND PRACTITIONERS IN INDIA

Suresh Kumar Agarwal

Indian Board of Alternative Medicines,
Calcutta, India

Complementary and Alternative Medicine (CAM) as it is called outside India and Traditional Medicine as it is referred to by the WHO is rapidly growing worldwide. People are becoming more concerned about the adverse effects of chemical drugs and the escalating costs of conventional health care. Longer life expectancy and life style related problems have brought with them an increased risk of the development of chronic, debilitating diseases such as heart disease, cancer, diabetes and mental disorders. Although new treatment and technologies for dealing with them are plentiful, nonetheless more and more patients are now looking for simpler, gentler therapies for improving the quality of life and avoiding iatrogenic problems.

India possesses an unmatched heritage represented by the ancient systems of medicine which are a treasure house of knowledge for both preventive and curative health care. The positive feature of Indian Systems of Medicine include their diversity and flexibility, accessibility and affordability throughout the country, a broad acceptance by a major section of the general public, comparatively low cost, a low level of technological input and growing economic value. These opportunities are still maximizing in all its aspects.

India is one of those unique countries in the world where traditional medicines found their use in well-developed systems of medicine. India is the only country in the world where various systems of traditional medicine such as Ayurveda, Unani, Siddha, Yoga and Naturopathy are recognized by separate Acts of Parliament and are given direct government patronage and supervision in the field of

legitimate practice with full authority and powers as those enjoyed by registered medical practitioners of allopathy system of medicine.

The upsurge in traditional medical practices and the increasing use of traditional medicines, however, have also led to an increase in the number of unscrupulous practitioners. Thus, in order to standardize and maintain the uniformity in the educational standards, quality control, standardization of drugs, improvement of raw materials, time bound research and building awareness about the efficacy of these systems, the Government of India has established a Department of Indian Systems of Medicine and Homoeopathy (ISM & H) under the Ministry of Health & Family Welfare. This Department has at its disposal various statutory bodies to regularize and legalise the practice of traditional medicines such as Ayurveda, Unani, Siddha, Yoga, Naturopathy and Homoeopathy.

Two statutory regulatory bodies namely the Central Council of Indian Medicine (established in 1970) and the Central Council of Homoeopathy (established in 1973) by respective Acts of Parliament of the Government of India are responsible for the following objectives:

- 1 - To prescribe minimum standards of education in Indian Systems of Medicine viz. Ayurveda, Siddha, Unani Tibb and Homoeopathy.
- 2 - To advise the Central Government in matters relating to the recognition and withdrawal of recognition of medical qualifications in Indian Medicine and Homoeopathy.
- 3 - To maintain the Central Register of Indian Medicine and Homoeopathy and revise the Register from time to time.
- 4 - To prescribe standards of professional conduct, etiquette and code of ethics to be observed by the practitioners.

The CCIM and CCH have laid down and are maintaining uniform standards of academic curriculum and syllabi for under graduate and post graduate education in ayurveda, siddha, unani and homeopathy. These councils are responsible for the regulation of legitimate practice under the provisions of their respective Acts. The councils have also

prescribed the Standards of Professional Conduct, Etiquette and Code of Ethics for practitioners of ISM&H. The councils are also responsible for consideration of the issue of inclusion of medical qualifications granted by the universities and make necessary recommendations to the central govt.

In all the recognized systems of medicine, an educational course of 5 ½ years is prescribed with an internship of 6 to 12 months leading to the award of a Graduation Degree. Even post graduate courses of 2 to 3 years duration are also available in various fields of traditional medicine. Almost all the universities in India have graduate and post graduate courses in the Indian systems of medicine and Homoeopathy. All the medical colleges of ISM&H are attached compulsorily with the hospitals and clinics for the benefit of the students.

There are State Medical Councils in almost all the states of the Indian Union under the guidance of the Central Councils in these fields of medicine to register and legalise the practice of traditional systems of medicine and homoeopathy. Doctors qualified in these systems of medicine are given equal opportunity in the government services as well. These doctors can hold office as physician in government or in any institution maintained by a local or other authority. They are also entitled to sign or authenticate a medical or fitness certificate or any other certificate required by any law to be signed or authenticated by a duly qualified medical practitioner and can give evidence at any inquest or in any court of law as an expert under Section 45 of the Indian Evidence Act, 1872 (1 of 1872) on any matter relating to Indian medicine.

In the last five years 75 colleges of Ayurveda and 40 colleges of Homoeopathy have been added. Large portions of the syllabus covers modern medicine which enables the practitioners to use modern diagnostic tools and advise timely referrals. In some of the states, there is a joint common entrance exam for admission into various medical courses including the course in Allopathy.

In the recently published National Policy of the ISM&H, it has been suggested that the under graduate syllabus of Ayurveda (BAMS), Unani (BUMS) and Homoeopathy (BHMS), the irrelevant material

would be eliminated from the syllabus and emerging areas of interest would be covered so that ISM&H can play a significant role. The widest possible consultation is being facilitated to enable the best education and practices being taught to the young students based upon the strength of the systems, consumer preferences and the outcome of research & development. The quantum of modern medical component in under graduate courses would not exceed 25% of the syllabus and would be taught mostly to cover the pre-clinical and para-clinical subjects so that graduates are encouraged to utilize basic modern medical knowledge for diagnostics and not for treatments. While reorienting the syllabus, the preventive health aspects of ISM would be given due emphasis. Schemes are being undertaken to provide basic vocational training for housewives, dais, nurses and midwives regarding general knowledge about Indian System Medicines remedies including identification of plants, their common usage and preparation of effective home remedies.

Hence, a national policy of redesigning, restructuring and reform of the methodology in the field of education in ISM&H has been framed for systematic reorientation of both teaching and syllabus. ISM&H graduates are supposed to receive the knowledge, training and skills that promote professional and skilled service. The admission criteria, syllabus and orientation of the new graduate has been suggested to be a useful practitioner and not a duplicate of the modern medicine practitioner.

The ISM&H Department has prepared a capsule containing basic concepts and fundamentals of ISM&H for incorporation in the MBBS curriculum. This has been forwarded to the Medical Council of India for appropriate further action.

India has been a seat of ancient learning in traditional medicine. The ISM&H policy enjoins Indian Missions abroad to play an active role in propagating ISM. While export of practitioners to answer an unmet need for holistic health care would be encouraged, the objective is also to see that the fair name of ISM is not tarnished through short cut courses which can only lead to poor quality practitioners. A uniform syllabus is being developed for institutions abroad. Countries

seeking the services of Ayurvedic practitioners would be encouraged to look for the proper registration certificate issued by the CCIM whose authenticity would be monitored by Indian Missions abroad.

The ISM&H teachers are also exposed to current developments and ideas as to how ISM&H can complement modern therapeutics.

Registered ISM&H practitioners can play a complementary role which includes dealing in preventive care such as immunization, sanitation, family welfare activities, RCH activities, supervision of TB therapy, screening of cases for cataract blindness, attending to malaria cases within the drug regime of the malaria programme etc. This responsibility would be given to ISM&H practitioners with training where necessary. It has been suggested in the national policy on ISM & H that the ISM & H practitioners would inter-alia be permitted to employ modern medicine for

- 1 - Primary health care measures including preventive health measures which should be spelt out by each state.
- 2 - To assist in reaching the goals of the Population Policy as assigned.
- 3 - Prescription of OTC drugs and essential drugs like pain killers while primarily using ISM treatment.
- 4 - Diagnostics to be undertaken by patients with suitable referrals to an allopathic facility.
- 5 - For dispensation of drugs for Malaria, TB, Leprosy, screening cases of cataract blindness as assigned specifically by the States.
- 6 - For immunization activities.
- 7 - For undertaking surveillance and notification of public health problems, outbreaks and epidemics, as assigned by State Governments.

The introduction of reorientation training is being planned on a compulsory basis for physicians and teachers of ISM&H system with a requirement that each physician undergoes at least one such training in a period of 5 years with renewal of registration being linked thereto.

In view of the increasing demand to establish ISM courses in foreign countries and for more foreigners to join ISM courses in India, the government is planning to establish centers of excellence for ISM.

Apex research bodies such as the Central Council for Research in Ayurveda & Siddha, the Central Council for Research in Unani Medicine, the Central Council for Research in Naturopathy & Yoga and the Central Council for Research in Homoeopathy have all been established by respective acts of the Parliament of India. Institutes of national importance such as the National Institute of Ayurveda, the National Institute of Naturopathy and the National Institute of Homoeopathy have already been established as model educational institutes, of national importance, for education and training. A National Institute for Siddha is to be established by 2006, A National Institute for Unani Medicine by 2004 and a National Centre for Yoga by 2003. Pharmacoepeial committees and laboratories are also working towards the modernization and standardization of these systems of medicine.

The Central Government Health Scheme which was introduced in 1954 with only allopathic dispensaries has introduced traditional systems of medicine such as Ayurveda in 1964, Homoeopathy since 1967 - 68, Unani in 1974 - 75 and Siddha in 1980 - 81.

Presently there are more than 3000 government hospitals with over 60,000 beds in the field of traditional medicine and homoeopathy and about 23,000 dispensaries functioning in various parts of the country. More than 6,25,000 practitioners are recognized with the above mentioned government councils of which there are 430,000 practitioners of Ayurveda, 42,500 of Unani, 17,000 of Siddha, 500 naturopathy practitioners and 200,000 practitioners of Homoeopathy. There are about 400 under graduate colleges with an admission capacity in excess of 17,000 thousand per year. There are 200 colleges of Ayurveda, 40 of Unani, 2 for Siddha and 170 for Homoeopathy. In addition, there are also 70 graduate colleges with a student capacity of about 1000.

Specialised clinics in Ayurveda, Unani and Homoeopathy have been established to facilitate treatment in the OPD of the two central

government hospitals namely Safdarjung Hospital and Dr. Ram Manohar Lohia Hospital since 14th January 1998. These clinics are being run on an experimental basis by three research councils i.e. CCRAS, CCRH and CCRUM.

Unfortunately, inspite of its widespread use and accessibility, the government of India has allocated only 2% of the total health budget of the nation to ISM &H while 98% is devoted to western modern medicine. The Department of ISM & H has suggested to raise the budget to the extent of at least 4% for the better development of these systems of medicine.

In addition to these systems of medicine mentioned here, Acupuncture is also widely used. Two states of the Indian union - West Bengal and Chhattisgarh - have established a regulatory body to control the education and practice of this system. Besides Acupuncture, Acupresure, Magnet therapy, Electro Homoeopathy, Bach Flower Remedies, Reiki, Pranic Healing etc. are also practiced though the Government has not established any controlling body to supervise these systems. However, numerous non-government organizations are promoting the education, research and practice of these systems and there are over 200,000 practitioners of these systems of healing. The rights of these practitioners are protected by Article 19 (1) g of the Constitution of India and have been upheld by various High Courts in India.

DISCUSSION

Discussion of Eighth Session National Policies

Chairman: Dr. Abdul Aziz Saleh

Rapporteur: Dr. Peter J. Graaff

Dr. Ali Haeri: Thank you very much Mr. Chairman! I appreciate and congratulate the Indian delegates for a very extensive system, well displayed and very well authenticative. The most important part in medicine is diagnosis. Have you run the quality assurance system to make sure that 25% of the information required to cover the differential diagnosis, but not to decide for conventional treatment rather to be oriental or herbal medicine whatever, the different systems you called? Now, after you diagnose rightly whether you use herbal medicine or synthetic medicine, it is something else we have to argue about it. That's my main concern. How did you check, or evaluate or quality assured that 25% informational knowledge on basic medical issues for diagnosis and recognition of symptoms and signs?

Dr. S.K. Agarwal: This 25% principle is not in terms of definite classes only. This is on the basic medical education. At present, we have 65% basic medical education in the field of Traditional Medicine. So, practitioners are passing out from these courses, they are more going to practice Modern Medicine than Traditional Medicine. So, we are giving more emphasis on the education of Traditional Medicine. It has to be there, it will be there. There is no question of compromise.

Prof. A. A. Ansari: Mr. Chairman, I have some information regarding Indian systems of diagnosis. Actually, full emphasis is given to diagnose the diseases according to the system, because Ayurveda, Unani has a very elaborate systematic systems and diagnostic systems in diagnosing various diseases. We are teaching in colleges all the modern diagnostic methods since beginning. All investigation on blood, x-ray and latest testing methods are available. In each and every hospital, all the modern diagnosis facilities are available. So, we take the aid, but give the main emphasis on our own fundamentals, fundamentals of our system of our diagnosis. We give priority to

dimension and take it and handle from these modern scientific methods.

Dr. Abdul Aziz Saleh: Thank you! Yes, please.

Participant: Thank you Mr. Chairman! In fact, the two last speakers made a very distinct case study of the systems in India. I say systems, according to them there are 6 parallel systems. One of them is the allopathic, the others should be considered as the sub-systems of Traditional Medicine. There is a beginning for a case study of integration, where you start by recognition then you go further to coordination, which is going to do then the integration, they will be whole collaborated within this system. So, I think they have a way, the way of integration, but now at least they have the sub-systems recognized. The second comment is on the researches for cancer in each parts of the Traditional Medicine systems, I found a research, because I found that in many cases, resources are so bias, so the most of the work will be determining and defending the heritage, within the system. I am sure that the writers of the Arabic text of Ibn Sina, if they come-back, they will write a new edition of the book based on research updating new findings, exclusion, combination of drugs and so on. So, I would like to get some feed back from that. - Thank you!

Prof. A.A. Ansari: We have the Central Council for Research in Ayurveda, Siddha, Unani and Homoeopathic. For the Central Council for Research in Ayurveda, we have the governing body, the scientists of other systems of medicine, especially the conventional medicine, allopathic systems of medicine. And each council has a Scientific Advisory Committee. Scientific Advisory Committee not only has the CAM physician, Ayurvedic, Unani physician also but there are Pharmacologists, modern pharmacologists, modern elaborative doctors to assess the scientific findings, simultaneously with the Ayurveda and with Hakims, and after a long discussion and consultations findings are finalized. This is the first term.

Second term is that at the time of study for the research, we give all emphasis and all latest type researches single plan trial, double-plan trial and at that stage also we have a strong collaboration with the medical institutions, which are available in most parts of India. For

example, in Delhi, All India Institute of Medical Sciences (AIIMS). So in all, we have strong, continuous collaboration with the doctors and physicians and professors of All India Institute of Medical Sciences (AIIMS). In our councils, Scientific Advisory Committee, is aware and conscious about the safe hand to our people. We are not only love to, or blind love to, our systems, because we have the systems for thousands of years, which are very good. In spite of that we are trying at our level best to authenticate these systems on the all latest available test of whatever the screening you can do. - Thank you!

Dr. Abdul Aziz Saleh: Thank you! Yes, please.

Dr. A.A. Bedah: It is wondering presentation from the last three speakers. 3 or 6 systems in Indian sub-continent. If you consider Pakistan, Bangladesh, Sri Lanka and Maldives, I don't talk here about Chinese Medicine. Putting in mind, I read a recent research said, acupuncture originated in Sri Lanka thousand years ago. But Sri Lankans are not that clever like Chinese. Chinese taking it thousand years ago and developed and marketed it. So, there is somewhere in the future to consider Chinese Medical Tradition part of this 6 systems to make as 7.

Dr. Abdul Aziz Saleh: Thank you very much for this question. When I was listening to the presentation, I was thinking how the Chinese medicine practitioners are thinking? They may be also in the position talking about Ayurvedic practitioners the way that we are talking about allopathic medicine. But let us listen to this thing.

Ms. Malti S. Sinha: As my colleague from India had said that several other medical systems, which are not actual systems, are being practiced. But we have not recognized them. There is no strong lobby for recognition of such at least since last 8 months I have been in this department. I have not received any request from any of these systems to grant them recognition and treat them as a system. It has not happened. But in the future, we never know, what will happen. There is an upsurge of demand. May be, we will be adding more to the system. - Thank you!

Dr. Abdul Aziz Saleh: Yes, please.

Dr. S.K.Agarwal: In India, we have several states. In the state of West Bengal, from where I hail from, and this is Calcutta, in the State of West Bengal. West Bengal is the only state in our country (India), which has recognized the Acupuncture system of medicine in 1998. There has been separate act for that, separate colleges for that, institutions for learning and practitioners are enrolled in the state register of acupuncture. So, this is the only state in India, which has acupuncture also as a system of medicine. Other states may follow this soon. - Thank you!

Dr. Abdul Aziz Saleh: Next, Dr. Ezzeddin.

Dr. Ezzeddin Ibrahim: Morality of medical systems in India, most of which are recognized by the government. I have the questions. How do people choose from these systems? On Geographical Grounds, Religious Grounds, Governmental Guidance, Cultural Grounds, or what? That is the first question.

The second question: There is an impression on the side of the Gulf people, specially the elderly to go to India for many reasons including medical reasons. Are they guided when they arrive, to which system they should go? - Thank you very much!

Ms. Malti S. Sinha: Yes, there are cultural voices; I will not disagree with that. But in the long run, the patients come for treatment after they have heard about the patient, after they have realized the kind of treatment they are offered, the kind of cures they have been able to get. Only then they go to a doctor. It is true that in Kerala region of our country people would go most for Ayurvedic treatment and for panchkarma treatment and other things. But it is not to rule out the Unani aspects there. So, it is not safe for one system to exclude the other. It is just depending upon the personal choice of the patient, and also the order of the doctor who treats basically of that. We go to all kinds of doctors, Muslim doctors, Hindu doctors, and various kinds of doctors, who practice different kinds of medicine. So, that is the way in India. - Thank you!

Dr. Abdul Aziz Saleh: Yes, thank you! Next!

Dr. Mohd. El-Dawy: I want to comment on the excellent presenta-

tions this morning session. I would like to raise a point on that was touched upon during the presentation from the legal point of view by Mr. Alan Dumoff and the presentation of Mrs. Malti Sinha regarding the protection of traditional knowledge. And, I was learning to enlist with the trained, on traditional knowledge digital library and what we trained about patenting and protection of the traditional knowledge. In this area, Dr. Al-Awadi at the beginning of the conference said that there would be a task-force, to look into what to do regarding different aspects of the subject matters of this very important symposium. If we get to this point of intellectual property, it is most unfortunate that there are lots of avenues that are offered by different organizations even so as to try to look into the intellectual property protection and rights and also to look into intellectual property responsibilities. Because we cannot say only about intellectual property rights from one point of view, we should also talk about intellectual property responsibilities towards the community in general. It is in the best interest of developing countries to look into the responsibilities of intellectual property and we get this scientific matter of traditional knowledge. It is most unfortunate that we usually go to meetings, which are held by multinational organizations like WTO and WIPO. I would very much appreciate if Mrs. Sinha would elaborate a little bit how to go about that, because we can learn about other countries comments on that.

Dr. Abdul Aziz Saleh: Thank you Dr. El-Dawy for your comment!

Ms. Malti S. Sinha: I have understood from you that how we should share the knowledge. We will be advising the international forum about the need of equitable sharing of benefits of the custodians of the knowledge. And a system of compensating such knowledge is introduced. That is one point. And the TRIPS has provided its signatory countries the freedom to choose intellectual property on protectional plant varieties and patent or free generate system or combination. Free generate system will be set up to provide gross root innovators of plants based knowledge and incentives to disclose knowledge. In fact, I can tell you, I can share with you about one particular Jeevani was found amongst the tribal in the village in

remote Karnataka hills, in the Nilgiri hills. And, there if you took the grass, you feel very energetic. Now, this was tested in one of our government of India laboratories in Kerala and it was patented. Most of the money goes to the community of that Nilgiri area and the government of India institutions keep a small amount. So, that is the benefit we are sharing, we are talking about.

Dr. Abdul Aziz Saleh: Thank you! And the last question from Dr. Saad.

Dr. Saad Abdual Al-Aal, Cairo, Egypt: I have a remark and I have a question. The remark, I would have preferred with the title of this session to be not National Policies, but trans-national policies. We are talking about one issue which goes all over the countries and I believe that will be much more efficient. The question is to the Indian representative in this hall. Have you got an experience about using such a TM in children? How far have you tried for TM in children? And, if possible, we could in the future, try to integrate our TM in Egypt, Pharaonic. Do you think that it will be possible in the future that we exchange such message? - Thank you!

Ms. Malti S. Sinha: Now, whether we have used in children. As a child, I have to tell you myself. I had chicken-pox when I was 5 years old. I was bathed in hot neem water. It has anti-septic values. And, this is what modern scientists have approved. When 9 yeras old, I had acne on my forehead. And, I applied all kinds of creams. Then one homoeopathy doctor suggested Thuja1000. I was amazed, the next morning nothing on my forehead. It was just like magic. So, there are two systems. The neem one is the Ayurvedic system and homoeopathy was the other, which cured my forehead of all acne. In daily diet, we eat everyday turmeric, which was being patented in U.S. This is part of a diet in every curry we make, and there is a reason behind it, because it has anti-septic values. When we cook a fish, we first wash it in marine salt and turmeric to get rid of all the bacteria before we cook it. This has become a part of our life. It has medicinal property. When we cook a food, it is a very hygienic because we use “Haldi” (Turmeric).

On the spices that we use in our foodstuff, also have the medicinal

significance. We are using Garlic. I think 5000 years ago our forefathers knew what is good for us and they put it down as a recipe for a diet and that diet continued over the centuries and we accepted that as a food, but not as a medicine any more.

What you are saying about children, of course, they in daily diet, my own children, have a lot Ayurvedic medicines, when they were young. We were very scared of antibiotics to be given to them. Thank God, we didn't give it to them, because it has so many side effects. All the research that is undertaken by the modern system, it goes on for 20 years and after that they will say it is bad. Here is 5000 years of practice, nothing has been proven to be toxic.

Dr. Abdul Aziz Saleh: Thank you very much! I ask Mr. Peter Graaff to say few words about the conclusion of this session.

Mr. Peter Graaff: As a Rapporteur, I have listened carefully. It made easier and I am saying that the presentations were clear. Allow me to pop-up basically by quoting a few things that Mrs. Sinha said. First of all, in terms of, at the end of your presentation, I think you beautifully concentrated over the valuable information you provided. And afterwards we stress again in terms of the strength of your system, bio-diversity, the strong traditional knowledge base, the human resources, but as somebody coming from an Arab part of the world, I was also particularly impressed with the extremely strong system, from system to system and the links to the systems that you are putting in place. So, the different cultural backgrounds can understood the way together in India. That is one thing. I think that your precious presentation is extremely useful.

Dr. Abdul Aziz Saleh: I would like to thank all the speakers of this session for the very interesting and very lightly discussion relished from Drs. Alan Dumoff, Malti S. Sinha, Suresh Kumar Agarwal.

Ninth Session

Saturday, 14 October 2002

Country Experience

Chairman : Prof. Konstantin Keller

Rapporteur : Prof. Mohammed Younis Haggag

Speakers:

1 - Ms. Nancy A. Hazleton (U.S.A.)

2 - Hakim Abdul Hannan (Pakistan)

3 - Prof. Mansour S. Al-Said (K.S.A.)

**EXPANDING GLOBAL HORIZONS
OF HEALTH CARE: AN OVERVIEW
OF THE NATIONAL CENTER
FOR COMPLEMENTARY AND
ALTERNATIVE MEDICINE**

Ms. Nancy A. Hazleton

(U.S.A.)

EXPANDING GLOBAL HORIZONS OF HEALTH CARE: AN OVERVIEW OF THE NA- TIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Nancy A. Hazleton

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In 1993, The United States Congress formally established the Office of Alternative Medicine (OAM) at the National Institutes of Health. In 1998, Congress expanded the status, mandate, and authority of the Office by enacting legislation to create The National Center for Complementary and Alternative Medicine. (NCCAM). NCCAM is charged to “conduct basic and applied research (intramural and extramural), research training, and disseminate health information and other programs with respect to identifying, investigating, and validating CAM treatments, diagnostic and prevention modalities, disciplines and systems.” Congress has expressed growing support for NCCAM’s mission by providing progressive budget increases for the Center. Succinctly, NCCAM is dedicated to exploring complementary and alternative healing programs in the context of rigorous science, training, researchers and disseminating authoritative information to the public.

NCCAM presently supports a broad portfolio of research, research training and educational grants and contracts across the major CAM domains, 1)alternative medical systems; 2)mind-body interventions; 3)biologically based therapies; 4)manipulative and body-based methods; and 5)energy therapies.. In addition, the Center conducts outreach activities, including the dissemination of information through the NCCAM Clearinghouse, which responds to public inquires for information on CAM treatments and modalities and the NCCAM Web site (<http://nccam.nih.gov>), which received close to half a million hits a month. Programs to expand basic and clinical research, train investiga-

tors to conduct CAM research, disseminate information, and facilitate integration of CAM and conventional healthcare delivery are essential in moving the CAM field forward.

NCCAM created the Office of International Health Research (OIHR) in February 2001 to provide global leadership in complementary, alternative and traditional medicine research. In June, 2002, a strategic plan was developed to serve as a guide for OIHR activities.

OIHR MISSION

OIHR will identify promising international CAM practices, encourage their rigorous scientific assessment, and promote the development of effective CAM applications by facilitating international scientific collaborations. Also, OIHR will educate and train CAM researchers and disseminate authoritative information to the public and professionals.

OIHR VISION

OIHR will advance international collaborative research on complementary and alternative healing practices leading to improvements in domestic and international health while fostering integration of safe and effective practices.

In pursuing these aims, OIHR is mindful of the need to partner NCCAM resources and the utility of leveraging existing international research and research training plans and programs across the National Institutes of Health, US governmental agencies, private organizations and with multilateral and bilateral international partners. The Office recognizes the importance of ensuring mutual cultural sensitivity among participants in international research ventures and is committed to the following guiding principles:

- * OIHR will conduct research on traditional and indigenous health practices at sites where the most promising opportunities for CAM research can be identified, working in coordination with international organizations and respecting the heritage and practices of indigenous peoples.

- * OIHR will align international programs with existing NIH-funded and other international research programs to ensure the availability of supporting research expertise and the necessary infrastructure to ensure long-term sustainability.

OIHR GOALS

The OIHR strategic plan has formulated goals and initiatives that are congruent with each of the four strategic areas in the NCCAM Strategic Plan. Specific projects that operationalize OIHR goals are developed in an annual work plan that reflects research opportunities and resources available. This ensures that OIHR remains on the cutting edge of traditional, complementary and alternative medicine research in the international arena.

Goal 1: To Foster International Research

"International research" includes grant applications submitted by applicants in other countries as well as those originating in domestic institutions with significant foreign involvement. Foreign research applications to NCCAM often come from practitioners who are not familiar with the NIH peer-review system and who may not have had prior research training. They may also lack institutional support and research resources in their home countries. In order to better assist our international partners, OIHR proposes approaches and funding mechanisms designed to:

- * Facilitate the acquisition of research skills by foreign investigators through formal training and/or collaboration with experienced, NIH-funded investigators;
- * Train members of the prospective international research community in grant writing and grants management;
- * Assist international institutional leadership in its role in promoting CAM research;
- * Improve the existing international CAM research infrastructure and resources; OIHR has recently received concept approval for a research model development program that will fund up to 3 meritorious, peer-reviewed projects. The goal of this program is

to develop a viable and sustainable network of international research institutions that can successfully compete for NCCAM funding; and

- * Provide opportunities for the promotion of scientific exchange, technology transfer, and discussion/resolution of issues related to intellectual property rights.

To maximize support and opportunities for international CAM research, OIHR will partner with other public and private funding agencies. We will also continue to co-fund meritorious proposals submitted to other NIH Institutes and Centers, and build on existing research programs in promising international sites.

Objectives

- * Encourage the development of international sites of CAM research excellence by fostering U.S. and foreign research partnerships for the conduct of collaborative CAM research projects at promising foreign venues.
- * Sponsor and partner with other agencies in supporting CAM-related research in areas of the world that possess unique CAM resources (such as medicinal plants or animal products), while respecting the sustainability of native resources.

It should be noted that, regarding natural products, many practitioners of Complementary and Alternative Medicine (CAM) believe that the polypharmacy of complex natural products has advantages over single-ingredient drugs by providing greater therapeutic benefit and less overall toxicity. In pursuit of its mission, the NCCAM supports research to determine safety, efficacy, and mechanisms of action of complex natural products. The NCCAM will support research characterizing single constituents extracted from complex natural products if the purpose is to identify and standardize whole products, compare the actions of single constituents with the complex product, or identify the mechanisms of action for the whole product. However, the NCCAM will not accept applications to isolate the active constituents of complex natural products for the express purpose of developing these constituents as discrete drugs. I.e., drug discovery.

Funding support for applications to develop active constituents as drugs may be available from other Institutes and Centers at NIH.

- * Promote studies of whole systems of CAM in their countries of origin, working with relevant government agencies, native teachers, practitioners, and patients. NCCAM has sponsored a program announcement to support developmental studies to establish the methodological feasibility and strengthen the scientific rationale for proceeding to full-scale randomized controlled trials on the use of traditional, indigenous systems of medicine as practiced in the United States. These studies, which should emphasize the development of appropriate study designs to investigate safety and efficacy, have the potential to identify and address difficult methodological and design issues particular to complex medical interventions, as well as to allow for the development of contextually and culturally sensitive research more closely mirroring practice in the United States. This model is being refined for potential use in the international arena.
- * Facilitate productive working relationships between international research partners through programs focused on bioethics concerns and intellectual property rights.

Goal 2: To Promote International Research Training

OIHR vigorously supports diverse models of international research training, including classroom courses, workshops, distance learning and other modalities as appropriate. Training will also be used as a strategy in programs to promote international research collaborations. Priority areas for CAM international research training will be: basic and clinical research methodologies; grant writing skills; grants management skills; and the ethical conduct of research. Such training is essential to the conduct of rigorous research, as well as the learning processes leading to successful NCCAM grant applications.

Objectives

- * Sponsor workshops at international sites dedicated to training on research methodology and grant writing. In 2001, the Office co-

sponsored with the National University Hospital and Johns Hopkins University Singapore one workshop and will be presenting another one at the end of October that is co-sponsored by the Government of the Semi Autonomous Region of Hong Kong.

- * Support NIH-wide efforts to improve the quality of international ethics training, and support advanced training of professionals who could assume leadership in ethics review of research studies. The Office currently supports four universities that offer training in ethics and biomedicine through one US-based university and three foreign universities in the Philippines, Bangladesh and Canada in collaboration with the NIH Fogarty International Center.
- * Partner with other organizations to develop in CAM research training programs. These programs are designed to support extramural research training in the United States for international scientists with doctoral degrees. An international fellowship program is currently being developed and we expect to announce it in the next few months.
- * Continue to develop new and exploit existing NIH research training award programs and supplemental funding tailored to international CAM students, teachers, researchers, and practitioners. OIHR currently co-funds a data center under the International Clinical, Operational and Health Service Research and Training Award, which supports evidence-based, hypothesis-driven interventions and research on major global health problems that are developed cooperatively by foreign and US-based institutions.

Goal 3: To Expand Outreach and Dissemination of International Research Information

The establishment of OIHR in itself is concrete evidence of NCCAM's recognition of the importance of reaching out to the international and domestic community for the exchange of ideas, personnel, and resources to facilitate CAM international research. The Office uses multimedia, the Internet through the NCCAM website, as

well as personal representation at international and domestic venues to communicate information on NCCAM and OIHR policies, plans, and projects to a global network of interested parties and agencies as well as to the public at large.

Objectives

- * Represent OIHR and NCCAM at international meetings to exhibit and/or exchange information and provide details on NCCAM programs.
- * Develop and distribute culturally sensitive informational materials to promote understanding and participation in OIHR/NCCAM programs.
- * Develop a user-friendly OIHR homepage for incorporation into the NCCAM Web site.
- * Collaborate with other NIH components, WHO, and relevant private and public agencies in communication and outreach concerning CAM international research and research training efforts and joint ventures.

Goal 4: To Facilitate Integration Using Global Models

OIHR participation in international meetings is a means of learning about different CAM models in use around the world and their level of success in achieving integration of CAM therapies and modalities in conventional medicine. OIHR uses these occasions to disseminate reliable research information to participants and network with other attendees with the goal of enhancing the NCCAM research portfolio with international research activities. Visits to local research institutions and funding agencies also allow a better understanding of local research priorities and available resources to support rigorous research. The knowledge gained from these activities contributes to more effective program planning at OIHR and can suggest new ways of health care research and delivery as well as the discovery of new data that can enhance global health.

Objectives

- * Encourage integration of CAM teaching in domestic medical schools through the exchange of international faculty in U.S. institutions.
- * Promote international meetings and workshops where conventional practitioners can learn about validated CAM therapies from native experts.
- * Identify and develop strategies to overcome barriers to the integration of safe and effective CAM practices through basic, applied and clinical research.

EVALUATING OIHR PLANS AND PROGRAMS

OIHR will develop a process for the periodic evaluation of both short- and long-term outcomes of OIHR initiatives. Intermediate indicators and endpoints will be defined qualitatively and quantitatively. For example, an intermediate indicator might be the number and type of publications/presentations accomplished during the period of NCCAM support. The final endpoint will be the number and success rate of awardees competing for exploratory/developmental grants. Secondary endpoints could include, but are not limited to, awardee-initiated CAM activities at the home institution (e.g., seminar series, journal club, visiting speakers), creation of distinct academic units dedicated to CAM research, and endowment of programs or lecturers. These data will allow timely evaluation of OIHR programs and their success in accomplishing OIHR goals.

SUMMARY

In summary, the National Center for Complementary and Alternative Medicine and the Office of International Health Research look forward to working closely with international partners in advancing world-class quality research in traditional, complementary and alternative medicine with the ultimate goal of improving health for all.

Thank you.

**STATUS OF TRADITIONAL
MEDICINE IN PAKISTAN AND ITS
ACADEMIC AND SCIENTIFIC VALUE**

Hakim Abdul Hannan

(Pakistan)

STATUS OF TRADITIONAL MEDICINE IN PAKISTAN AND ITS ACADEMIC AND SCIENTIFIC VALUE

Hakim Abdul Hannan and Usman Ghani Khan

Faculty of Eastern Medicine,
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The Pakistan constitution provides that both the Central and the Provincial Governments can bring laws and frame policies on education or in simpler words the subject education is the responsibility of both the respective Provincial Governments as well as Government of Pakistan. Therefore almost every Province has its own Secondary Education Board and is responsible for establishing Province Universities and maintaining them under the Central Government as a co-coordinator and helps in determining a uniform standard of education in the country.

The Pakistan education system is based upon 12 years of schooling (5+5+2) that includes primary and secondary education. Secondary Schools are affiliated with Central or Provinces boards for conduct of examination. All the Pakistan universities and other institutions of higher education recognize the various 5+5+2 qualifications from different Provinces as well as all Central Boards. Though Class 12th is the entry-level qualification for pursuing higher education in any field, passing it in itself does not guarantee admission to a particular course. Here at this very juncture our education has bitterly failed to provide the wider selection of the subject for pursuing the under graduate and graduate level education in the higher Colleges or Universities. The basic division after 12th grade for science subject is to partition into Pre-medical and Pre-Engineering is wrong. Because students entering the medical education or engineering education had limited choice. With advancement taking place in the medical and engineering disciplines the core curriculum of math and biology together is

required. If a student has not learnt the biology and where as he would like to become an engineer, and this engineer in turn is going to design an instruments, medical equipment or building a bridge, or making environment friendly project he is supposed to be working for biological beings (human, animal and plants). In the absence of his knowledge of biology he will certainly fall in the doldrums. Otherwise a biology student in his careers will often require the maths and stats. Preclinical and clinical years of orientation and practice in medicine will demand the knowledge of maths and stats for the better performance. So stand the medical student without having mathematical back ground at the ravages of society and a less competitive social meileu in the committee of nations.

Bachelor's degrees in medical science both for allopathic and Unani take five years of duration after 12th class (Premedical). Diploma course in Unani Medicine is also available at the Colleges of Unani Medicine and the duration of their study is of 4 years after the matriculation (10th class). Those interested in pursuing further studies in Unani medicine a graduate student only may either directly register themselves for Ph.D. or do a pre-doctoral program - Master of Philosophy (M.Phil) which is either completely research based or may also include some course work. It takes lesser time to complete Ph.D. in Unani Medicine for those doing it after M.Phil. Government of Pakistan is primarily responsible for framing major policies relating to higher education in medical sciences in the country. It is Government of Pakistan entity, is responsible for coordination, determination and maintenance of standards, and release of central grants to the universities through University Grants Commission.

A statutory body with the aim of maintaining uniform standards of Unani medical education in the country at undergraduate and post-graduate levels is yet to be established under the proposed Unani Medical Council Act/Ordinance. It is mandatory for a Unani doctor/Physician/Hakim to register himself with the Council after gathering necessary medical qualifications. Another important function of the Council is to establish reciprocity with foreign countries in the matter of mutual recognition of medical qualifications. The Council also

maintains Pakistan Medical Register containing information about all medical practitioners in the county.

It is responsible for laying down and maintaining uniform standards of education in the fields of Unani and regulating practice in these systems. The Council in future will prescribe the curriculum and syllabus for under-graduate & post-graduate education in these systems and amend them from time to time as per requirements. It also advises the Central Government in matters relating to recognition of medical qualifications of Unani Medicine. The proposed Council will also maintain a Central Register of Unani Medicine containing details of practitioners of this system.

APPLICATIONS IN UNANI MEDICINE

The Department of UNANI does not exist in the Ministry of Health so as to develop and propagate Unani education, research and its multifarious applications. Some of the key areas to be addressed are indicated below:

- * Improvement and upgradation of standards of education in Unani Medicine.
- * Standardization of drugs
- * Enhancing the availability of raw materials i.e. medicinal plants, minerals and materials of animal origin etc.
- * Information education and communication
- * Involvement of Unani in the national health care delivery system, national health and family welfare programs, beside tertiary medical care.

Research Councils

There is no single Unani Research Council except a section of Traditional Medicine under the National Institute for Health, Islamabad under the Ministry of Health. It is an urgent need to establish the following councils:

- 1 - Central Council for Research in Unani at Islamabad.

- 2 - Provincial Institute for Central Council for Research in Unani Medicine in all the provinces of Pakistan.

These Research Councils having units in all parts of the country should be engaged in the following areas of Research and Development:

- 1 - Health Care Research
- 2 - Drug Research
- 3 - Drug Standardization
- 4 - Medico Botanical Survey /Agriculture related medicinal crop production.
- 5 - Rural Health Research
- 6 - Cultivation of Medicinal plants
- 7 - Clinical and Preclinical research on Qarabadhini and Non-Qarabadhini medicine.
- 8 - Primary Health Care integration and Research.

Standardization of Drugs

The standardization of drugs and quality control is important factors in the treatment of UNANI. The pharmacopoeia committee under NIH, Islamabad was activated to expedite preparation of standards for Unani drugs. This has led to significant progress where in under NIH, Islamabad essential lists of Unani Medicine as well as Comprehensive list of Muffradat (Simples) and Murrakabat (Compound) has already been finalized. Voluntary scheme for certification of quality should be encouraged.

Focussed Research

Another important area of concern is the need to undertake much more focussed research. Unani systems have a particular strength to cater for preventive and curative health and clinical research into therapeutic claims is being taken up in institutions like Shifa-ul-Mulk Memorial Hospital at Hamdard University as well as some private hospitals. The phase II trials should also be conducted into the efficacy of herbal drugs, long accepted in Unani and proved to have efficacy.

A number of time-tested drugs of herbal, animal or mineral origin should be introduced under program of collaborative efforts with modern hospitals.

Strengthening of Province Drug Testing Laboratories and Unani Medicine

The UNANI should receive funding to handle plant-based material. These days people are most worried about presence of microbial contamination, heavy metal contents and non-permissible chemical substance. To overcome this, the Ministry of Health under the NIH, Islamabad is bringing forward a quality marking scheme which will be open to manufacturers to join on a voluntary basis, whereby certification should be available from NIH about the content of the formulations.

Establishment of Traditional Knowledge Digital Library

A Traditional Knowledge Digital Library on medicinal plants should be established at Hamdard University so to acquire and expose the therapeutic uses of plants. This should be done with a view to documenting information, preserving knowledge, which is the public domain, and making it capable of being retrieved. This will help decide whether the claim is a novelty or an invention.

Setting Up of Medicinal Plant Board

It should be planned to set up a National Medicinal Plant Board. The Board would provide focussed attention to the medicinal plants sector to enhance availability of quality raw materials for the manufacture of drugs for indigenous consumption and export. It will also ensure concerted efforts under single co-ordination agency covering all aspects relating to cultivation, marketing, conservation and sustained availability of Medicinal plants.

Maintaining Standards of Education

The regulatory bodies, under the Ministry of Health, should be, whose main functions is to lay down the minimum standards of education and to register the practitioners of the respective systems. This body also lay down the code of conduct and ethics for the physician.

- * In order to establish institutes of excellence and provide a model for others to follow, the Faculty of Eastern Medicine at Hamdard University be declared as center of excellence in Unani education and research.

Unani Education and University Grants Commission

As the degree in Eastern/Unani medicine has been approved by the Ministry of Health for the registration of Unani practice, it becomes imperative for University Grants Commission encourage and evaluate the learning, teaching, evaluation of curriculum and degree equivalence of Unani medicine at the national level.

Pharmacopoeia Laboratory of Unani Medicine

National Institute is providing the technical back up to the Pharmacopoeia Committees for Health, Islamabad, and The Faculty of Eastern Medicine, Hamdard University, namely the Pharmacopoeia Laboratory (HPL) both located and established at Islamabad and Karachi by the Ministry of Health.

Establishment of National Unani Hospital

The National Unani Hospital should be set up in Karachi and let the Shifaul Mulk Memorial Hospital of The Faculty of Eastern Medicine at Hamdard University Karachi be declared as National Unani Hospital. The very concept that this hospital as National Unani Hospital which will have teaching and research facilities.

Convergence and Integrations

A view has been taken that all systems and all agencies should converge on health programs. This paves way for integration of UNANI with modern medicines in health care delivery system and national programs as far as practicable depending upon the strength of each system. It has also been announced that in the new health policy UNANI would be given appropriate place.

Establishment of Educational Facilities and Regulation of Practice:

A high power body should be established by The Director General health to study the question of establishing standards in respect of

education and regulation of practice. The Committee formulated a model syllabus for the integrated course of 5 years duration, including one year of internship. It recommended the establishment of faculties for Unani in Universities, and the upgrading of existing colleges to the degree level by providing indoor hospital facilities.

Educational Facilities.

The National Tibbi Council was established accordingly in 1967 to regulate educational standards and professional practice between Unani and practitioners. The Council has formulated a standard syllabus for the Diploma, but at that time there was no undergraduate (and post-graduate teaching available in Pakistan)

Table 1
Number of Colleges of Traditional Systems of Medicine at Diploma level and Allopathic Medical Colleges at Degree level

Provinces	UNANI		AYURVEDIC		HOMEOPATHY		ALLOPATHIC	
	No. of Colleges	Admission Capacity	No. of Colleges	Admission Capacity	No. of Colleges	Admission Capacity	No. of Colleges	Admission Capacity
Punjab	14	430	Nil	Nil	23	2100	14	3155
Sindh	10	325	Nil	Nil	34	3210	13	4160
NWFP	4	425	Nil	Nil	7	324	5	2105
Baluchistan	1	58	NIL	Nil	3	123	1	150

Table 2
Traditional Medical Education, Traditional Medical Practitioners and Traditional Hospital and Dispensaries in India.

System	Medical Education Under graduate	Medical Education Post-Graduate	Medical Practitioners	Hospitals and Dispensaries
Unani	39	5	42445	3004/2308
Ayurvedic	198	53	427504	All inclusive
Siddha	2	2	16599	All inclusive
Homeopathy	166	17	194147	All inclusive

Only there is one Faculty of Eastern Medicine at Hamdard University and One College at Bahawalpur affiliated with the University having degree program in the whole of Pakistan. The post-graduate admission capacity for Unani is 50 seats at present available only at The Faculty of Eastern Medicine, Hamdard University that is basically responsible for evolving and demonstrating high standards of teaching, training and research.

Manpower Position

Table 3 gives the approximate estimates of the number of practitioners of the Unani Systems of Medicine in Pakistan, registered with the Council. The registered practitioners belong to one category, namely those who have acquired a diploma from College. The degree level registration has recently been initiated after the promulgation of Ayurvedic, Unani and homeopathic practitioners amendment act 2002.

Table 3
Number of Registered Practitioners of Unani System Medicine,
Census, 1985.

Province	No. of Practitioners	Population
Punjab	14000	44,253,000
Sindh	8000	18,000,000
NWFP	3800	9,000,000
Baluchistan	1600	04,000,000

In general, a definite decline in the number of these professionals is discernible. Even Unani, the most widespread in Pakistan has declined or not kept pace with population growth in several Provinces

Table 4
Comparative Statement of Unani/Chinese System of Medicine
in Pakistan and Neighboring Countries.

Pakistan	India	Sri-Lanka	Bangladesh	China
Diploma Fazil Tibb wa Jar- ahat (FTJ)	Nil	Nil	Nil	Nil
Duration of Stu- dies 4 years	Nil	Nil	Nil	Nil
Eligibility of Ad- mission Matric	Nil	Nil	Nil	Nil
Bachelor of East- ern Medicine and Surgery	Bachelor of Unani Medicine and Sur- gery	Bachelor of Unani Medicine and Sur- gery	Bachelor of Unani Medicine and Sur- gery	Bachelor of Tra- ditional Medicine and Surgery
Eligibility of Ad- mission F.Sc.(Pre-medical) 12 year education	F.Sc.(Pre-medical) 12 year education	F.Sc.(Pre-medical) 12 year education	F.Sc.(Pre-medical) 12 year education	12 year education
Duration of Stu- dies 5 Years	Duration of Stu- dies 5 Years	Duration of Stu- dies 5 Years	Duration of Stu- dies 5 Years	Duration of Stu- dies 5 Years

Primary Health Care and Indigenous Practitioners.

As can be mentioned in this section, soon after Independence, policy recommendations favored the incorporation of indigenous practitioners into the national health services and the development of an integrated medical care system. However, this was never implemented. In the early 1970s international concern was voiced in the World Health Assembly debates, that the existing health services in developing countries were not meeting the requirement of the majority. The two important developments for the promotion of national health services were the adoption of the primary health care approach, and the setting of the main social target for Governments, of Health for all by 2000 AD. Although Punjab took the lead in this respect and instituted the Unani Physicians into the hospital settings for integra-

tion of Traditional Medicine into Primary health care program. But all the other provinces did not follow the lead. The search for new programs and strategies focussed on developing community participation through a variety of locally acceptable people like practitioners of Unani Medicine having Bachelors degree is inducted for the adoption of WHO strategy.

Table 5
Medical Care Facilities under different Systems of Medicine.
NUMBER OF HOSPITALS & DISPENSARIES (Public)

Management Status	Unani Hospitals/Dispensaries	Ayurvedic Hospitals/Dispensaries	Homeopathy Hospitals/Dispensaries
Punjab	24/233	Nil/Nil	50/215
Sindh	--/85	Nil/Nil	50/415
NWFP	--/50	Nil/Nil	20/115
Baluchistan	--/30	Nil/Nil	3/26

Table 6
Required Projection Facilities under the Unani System of Medicine in Pakistan

Sr. No.	Facilities	Unani Medicine Numerical
1	Hospitals	185
2	Beds	3500
3	Dispensaries	975
4	Regular Practitioners in Govt./Public	4000
5	Colleges (degree)	30
6	Admission Capacity students	1800
7	University	10
8	M.Phil. /Ph.D. Program Capacity students	60
9	Research Councils	5

A proposal by Hamdard to incorporate Pakistan traditional Unani medicine into the new National Policy Plan is to accept at the National Workshop Integration of traditional medicine into Primary Health should be to recommend and stress the importance of strengthening the quality of rural health care in Pakistan. Exploring, encouraging, and improving the use of traditional plant-based medicines, on which a large proportion of Pakistani population still depends for effective, low-cost health care, could achieve these. Pakistanis of all ages rely on herbal medicines for primary health care. We are contributing to the final policy plan of action and We-The manufacturers-Educators assure that all our efforts is to focus attention on the importance of these traditional remedies.

During the recent meeting of Pakistan Association for Eastern Medicine with Unani/Herbal manufacturers Association we have selected recommendations for inclusion in the National Health Policy Plan. Our recommendations are as follows:

- * Unani/Herbal traditional medicines provide low-cost remedies for rural health care; therefore, the traditional medicine should be explored, encouraged and developed into primary, secondary and tertiary health care program.
- * Government and non-governmental organizations should help to create and support education and use of traditional medicines at the priority basis.
- * The Government of Pakistan should promote and support research and development at the university level in order to modernize techniques for producing effective natural health care products.
- * The Faculty of Eastern Medicine, Hamdard University be declared as WHO center for collaborative research on traditional medicine and that Shifa-ul-Mulk Memorial Hospital under the Faculty of Eastern Medicine, Hamdard University as the center of excellence for primary health care.
- * An international symposium on traditional medicine at Hamdard University be organized with the collaborative efforts of National

Institute for Health, Islamabad and Faculty of Eastern Medicine, Hamdard University under the auspices of World Health Organization (WHO) where in deliberations affirming the importance of traditional medicine and endorsing its integration in the health-care systems.

- * The National workshops on traditional medicine practices and utilization are further channeled so as to facilitate and promote innovative research strategies for traditional medicine through the coordination of interdisciplinary and collaborative research.
- * The recommendations made by National Institute for Health, Islamabad, Faculty of Eastern Medicine, Hamdard University, Pakistan Association for Eastern Medicine and Herbal Manufacturing Association of Pakistan aimed at strengthening the practice of traditional, complementary or alternative medicines be given priority for the implementation, harmonization and integration of traditional medicine into health care delivery systems.
- * The support in the development of guidelines for the protection of intellectual cultural property rights of holders of traditional health knowledge; support the development of appropriate frameworks, and provide guidelines and methodologies for research and evaluation to ensure the quality, safety, efficacy, cost-effectiveness, utilization, and best practices.
- * We feel very strongly that now it is a high time that Clinical Practice Guidelines be also adopted in your workshop details to create an impact on primary care provider. Clinical or practice guidelines are quality improving strategies. This means that Evidence-based Medicine be defined and practiced that bring together the best external evidence and other knowledge necessary for decision-making about a specific health problem.

Good clinical guidelines have three properties.

- * First, these be defined practice questions and explicitly identify all their decision options and outcomes.
- * Second, these should identify, appraise and summarize, in ways that are most relevant to decision-makers, the best evidence about

prevention, diagnosis, prognosis, therapy, harm, and cost-effectiveness.

- * Third, these should explicitly identify the decision points at which this valid evidence needs to be integrated with individual clinical experience in deciding on a course of action.
- * Thus, it will help you make your own decision in the best interest of your patient. If these are the part and parcel of your practices, then comes the evolution of Evidence Based Medicine for the implementation requires changes in your behavior be applied in your practice.

Evidence Based Medicine

- * Good guidelines come from evidence-based medicine (EBM), which is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.

The five steps of EBM are:

- * Convert clinical information needs into answerable questions;
- * Track down the best evidence with which to answer them;
- * Critically appraise that evidence for its validity (closeness to the truth) and usefulness (clinical applicability);
- * Apply the results of this appraisal in clinical practice;
- * Evaluate your clinical performance.

EBM can address each of the five clinical objectives of:

Achieving diagnoses;

Estimating a prognosis;

Deciding on the best therapy;

Determining harm; providing care of the highest quality.

After these thought-provoking ideas I come the conclusion that the recommendation that we are forwarding should be taken very seriously by the higher authorities. Definitely integration of traditional medicine into primary health care program is of paramount importance and we

are lacking behind in this respect even from many of the developing countries. I am sure recommendations on Unani education in Pakistan will pave a new chapter will certainly needs to be adopted for the better promise of tomorrow and health for all.

Benefits to introducing Unani Education

- * Enthusiasm for knowledge
- * Staying ahead in knowledge
- * Tight coupling of complimentary skill set
- * Higher learning order
- * Expansion of research and development
- * To cover health care for all

**EXPERIENCE OF SAUDI ARABIA
IN THE LEGISLATION OF
HERBAL MEDICINE**

Prof. Mansour S. Al-Said

(K.S.A.)

EXPERIENCE OF SAUDI ARABIA IN THE LEGISLATION OF HERBAL MEDICINE

Mansour S. Al-Said

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King Saud University, Riyadh, Saudi Arabia

Brief Historical Overview

Early humans recognized their dependence on nature in both health and illness. Led by instinct, taste, and experience, primitive men and women treated illness by using plants, animal parts, and minerals that were not part of their usual diet.

The invention of writing was a focus around which herbal knowledge could accumulate and grow. The first written records detailing the use of herbs in the treatment of illness are the Mesopotamian clay tablet writings and the Egyptian papyrus. The Ebers papyrus, the most important of the preserved Egyptian manuscripts, was written around 1500 B.C. and includes much earlier information.

The Arabs preserved and built on the body of knowledge of the Greco-Roman period as they learned of new remedies from remote places. They even introduced to the West the Chinese technique of chemically preparing minerals.

The principal storehouse of the Muslim materia medica is the text of Jami of Ibn Baitar (died 1248 A.D.), which lists more than 2,000 substances, including many plant products. Since last few decades a global back to nature trend has boost the use of herbal derived medicines, Saudi Arabia and the Gulf countries are not the exceptions.

Kingdom of Saudi Arabia being a sacred and blessed land for Muslims from all over the world is a transit land for them. These pilgrims not only come for the purpose of pilgrimage, they also bring with them number of samples of herbal remedies either for trade or for their personal use. Moreover, the local population of these

countries has a strong belief in using herbal medicine, which is part of their culture and heritage.

The government of Saudi Arabia is not unaware of this situation, the concerned authorities have laid down certain legislations in order to market the herbal products.

Why Regulatory Issues?

The increased use of plant medicines has potential for improving public health and lowering healthcare costs. Phytomedicines, if combined with the preventive model of medical practice, could be among the most cost-effective, practical ways to shift the focus of modern healthcare from disease treatment to prevention. But the regulatory policy prevents in most of the countries from taking advantage of these phytomedicines for two reasons. The first is the exorbitant expense involved in investigating each chemical compound in a given plant extract before it can be tested for clinical usefulness. Hence there is an urgent need to rework current research guidelines to allow the whole plant material or combination mixture (an herbal remedy containing more than one plant) to be evaluated instead of requiring separate evaluations of each chemical component of the therapeutic ingredients.

The second reason is that regulatory requirements for proof of safety and efficacy constitute an economic disincentive for private industry to conduct additional scientific studies. Relaxing regulatory requirements for efficacy for herbal products might make it economically feasible for more private companies to pursue research into issues of safety and quality control. Even with such regulatory change some public funding of research is needed to confirm the remedies' validity. Public funds are needed because private industry has no incentive to develop an herbal product that might displace a patented drug from an approved treatment regime.

The Regulation for Registration

The Kingdom of Saudi Arabia has realized the importance of the fact related to herbal medicines and public health. In order to regulate

the process of importation, sale and distribution of herbal products in the Kingdom, a Royal Decree was issued through the Shora Council on 20-10-1356H bearing # 7/4/57. According to this Decree the Ministry of Health - Directorate of Medical and Pharmaceutical Licences, issued certificates for those working or willing to work in the field of crude drugs and herbal medicine.

Again in 18/3/1398H (1978 G) a new regulation was issued by the Ministry of Health according to the point 37 of Pharmacy, Drugs and Medical Preparations Protocol. In 23/11/1406H (1985 G), the Ministry of Health stopped giving new licences for any herbal shops who are selling, at the same time spices and condiments. A high committee from the Ministries of Health, Commerce and Municipal and Rural Affairs was established to discuss and regulate these issues.

In 17/06/1409 H (1988 G), the new protocol named “Regulation for registrations of herbal preparations, health and supplementary food, cosmetics and antiseptics that have medical claims” was issued by the General Directorate of Medical and Pharmaceutical Licences - Ministry of Health. The application form contains 29 points, including full information about the agent, the manufacturer and the preparation. Up to-date more than 417 products (herbal, health or disinfectant) with medical claims have been registered.

I believe that these regulations must be revised as needed to incorporate improvements and to reflect developments in work being carried out at national and international levels.

GCC Outlook

Every Gulf country used to have its own regulation for the registration of a plant-based medicinal product. This year 1422 H (2001G) a “unified directory for the registration of herbal products” was issued by the Executive Board of the Health Ministers council of the G.C.C. states. Despite this directory, I still believe that forming a central high committee from all G.C.C. states devoted only to phytomedicines is a necessity.

Acknowledgement

I would like to thank Dr. Sabah Al-Rayas the General Director of the General Directorate of Medical and Pharmaceutical Licences - Ministry of Health, Saudi Arabia for the useful information.



DISCUSSION

Discussion of Ninth Session Country Experience

Chairman: Prof. Konstantin Keller

Rapporteur: Prof. Mohammed Younis Haggag

Dr. Ali Haeri: Thank you Mr. Chairman! Specially, the last and very nice comment of Prof. Mansour and I would like to refer Ms. Hazleton's. Because you have entered now, the phase of doctor and philosophy and on the regulatory issues. With definition that Ms. Hazleton made for Alternative and Complementary, I would think that it is better to move it in two phases. With the complementary, we are ensured that you are putting the practice together with already qualified, certified, international standard accepted medical doctors, psychologically accepted by the professional community and by the public. But when we talk about alternative, which I think it means exactly the replacement, further placement. I would be very much curious to make sure that what I want to replace that plays the same role. I would not call the mind-body as alternative, because it is utilizing the same basis and knowledge. It is a new transmission and control of immunity. So, it is complementary to what we already have. But talking about alternative, for example, the acute appendicitis with a magic herbal extract that demolishes the requirement, the need for soldier that I will call that alternative. But this needs to be very well controlled. That's my comment.

Ms. Nancy Hazleton: I want to respond to your comment about acute appendicitis in alternative and operation for western medicine, for western medicine is good. And, I think, that western medicine has enormous success in terms of surgery, in terms of trauma. So, however, the limitations are in terms of chronic conditions, such as, for instance Cancer, Diabetes and also in the psychological and psychiatric conditions in western medicine.

Prof. Konstantin Keller: There was one request, please Dr. Khan could you introduce yourself.

Prof. Ikhlas Khan: I am Prof. Ikhlas Khan from Mississippi. I was

amazed to seeing the regulations in Kingdom of Saudi Arabia. How they really are regulating it and that tells you about the people who are dealing with the real issue and science behind it. So, I really commend on that. We should have very comprehensive system of license. How long does it take? Who care for all this inspections? And, is there any indigenous industry in Arab countries; is there a movement of the industries evolving in that region to produce their home product “Islamic Traditional Medicine or Local Medicine”?

Prof. Mansour Al-Said: No, not really. I think most of companies in our region, are concentrating on drugs, not on herbs. Because, they still believe that drugs are the best way to get money for them. While really, if they think right, the future is for herbs. And, with regard to the part of question for analysis, this is made, as I said, mainly by the Central Lab of Ministry of Health. We have one lab for analysis, at least in our city.

Participant: If you file such an application for registration how long does a company has to wait until it can market product?

Participant: It depends on how much it is complicated. If it is simple one, it will not take long time, especially when plants are well known. But for the rare plants it needs a long time and you have to develop a technique to do this. This is a major problem. Some times, we have to think how to analyze it? It is complicated. I cannot say that it will take short time.

Dr. A. R. El-Gindy: I want to thank all panelists for their excellent presentations. While we were preparing this programme, we placed USA as representing the advanced countries and Pakistan as being one country of the region, and K.S.A. to represent the Gulf Region. So, geographically speaking, we have covered the broad picture. Prof. Mansour mentioned that when the Islamic Medicine re-emerged, we started to register medicinal plants. We can control this subject to some degree. When we started putting the rules and regulations, we started to see what was already existing in the Mediterranean Region and we did not have any regulation for registering medicinal plants. But in order to do it in a proper way, we organized two meetings. One of them was to see how best we cope with the establishment and

drawing up of regulations. We received, quite appreciably, the K.S.A telling us what were the characteristics of certain plants. When we gave the whole idea for the project, we received green light from all ministries of health, so unified document would be the basis for registration. This was done in Kuwait when there was a ministerial decree giving the full details of so many aspects of the issue as presented by Prof. Mansour, and the Islamic Medicine Center contributed to drawing up of this unified document. But we still have the cooperation between the Islamic Medicine Center and the Organization for Control of Medicinal Practices. When we made a proposal we said that these plants should be devoid of any chemicals or insecticides, chemical or contamination, this was made clear. But we were surprised to see that some of these medicines were a mixture of medicinal herbs plus some food. And, this is why we have a committee established which called the “Uncategorized materials belong to neither medicinal herbs nor food products as such”. So, we wanted to collect the opinion in order to include them in the debate. Dr. Ikhlas has asked very important question. These companies, when we register their medicines, we examine their products and review everything that was produced by the factories whether through analysis or through medicinal claims. If these are claims, we make sure that the claims are substantiated and that the ingredients are existing in pharmacopoeia. But if we come across something new for the very first time for an ingredient then we ask for the details and get cooperation from the Center of Registration. Another question is how long it takes to register? Perhaps, the Center of Control with the assistance of the Islamic Medical Center make sure by the chemical, phytochemical, and microbiological studies that there is nothing harmful, perhaps, in one month everything is over and it can be marketed. But, the Center of Control follows-up once the product is marketed and they get the samples of these products periodically, they are being analyzed and reanalyzed. What is important here is that the herbalists are being controlled, and we are making sure that all plants entering Kuwait go through the control centre, just to make sure that they are valid.

Prof. Konstantin Keller: This is the additional information from Kuwait. Next request, please.

Dr. Sadiq Abdel Aal: I would like to just send a question to Madam Nancy. I am going to grasp one of the sentences that you talked about globalized collaborations about this traditional medicine. Based on the golden rule that I have learned a lot since long time ago. The golden rule is who owns the gold, makes the rule. I believe that your institute should, in the future, create such dialogue of civilizations through these traditional medicines. I believe that we should address this genuine dialogue. The children who are 50% of almost of our total population, in the all counties almost. If we could support this trans-national traditional pediatrics, how we could write down together the guidelines or encyclopedia of traditional pediatrics in all our civilizations from Pakistan to India, from Iran to the Arab countries? Shall we get together to write down such traditional pediatrics? I believe it will enhance this dialogue through the child health. If I defer with you about the terminology of CAM, I called it as PAM, which stands for “Primary Authentic Medicine” and you call it the CAM. This should not interfere that we should work together and get together for this peaceful purpose, I mean this traditional pediatrics. - Thank you!

Ms. Nancy Hazleton: Thank you very much! Unfortunately, that is true, upto some extent, about gold and the money. I agree with that and I understand that I am happy that I have some money to work with. You don't have a lot of money to get together and to build the bridges. I think your idea about pediatric manual, that documents the pediatric traditional health practices in the Gulf region is an excellent one. I hope that you will contact me to explore the ways of working together and also working with the IOMS. - Thank you!

Prof. Konstantin Keller: Thank you for your interesting explanation. And next, please.

Dr. Mohd. El-Dawy: I have three questions for each speaker. Mrs. Hazleton, you pointed during your presentation regarding the Office of International Health Exchange. You said you are exploring the possibility for one, what you tell is “I should” seems to long sustainable research. I will very much appreciate if you could elaborate that and give an example in the area of CAM.

For Hakim Hannan, I would much appreciate if you would inform us about the efforts that are made regarding protection of traditional knowledge with reference to bio-diversity in Pakistan?

For Prof. Al-Said, I will comment on your approach of thinking globally, planning visually and implementing locally. This is a very good approach actually. Talking about implementation, with particular reference to approval inspection. Are these apply to regular pharmaceuticals and not to herbals. This is just a point of clarification. Are there re-approval inspection of manufacturing of CAM products with emphasis on herbal products?

Prof. Konstantin Keller: Thank you! Very brief reply to that, yes Ms. Nancy, please.

Ms. Nancy Hazleton: Ok. We have one guarantee in the Peoples Republic of China that the Beijing Medical University has been funded for over 20 years. That is one example of long-term sustainable research. As far as our office, it is created in February 2001, we don't have a long-term track. I came to work in humanitarian system.

Prof. Konstantin Keller: Thank you! The comment about a colleague from Pakistan.

Hakeem Hannan: No reply

Prof. Mansour Al-Said: Regarding to the unified directory from El-Dawy. It is mainly for herbal medicines. We collect the information before we start to work on that directory. We have collected from 26 countries all over the globe and then we see, it was amazing for me and my colleague to find the big difference between countries even inside Europe for example. There is big difference between Romania and UK in the legislation of herbal medicine. We asked South Africa, India, China and go everywhere and will collect the information. There we will find what is suitable for our region and then we will apply according to local needs.

Prof. Konstantin Keller: Thank you very much. We have to conclude this session now, because we are very late. This is time for break and prayer.

Tenth Session

Saturday, 14 October 2002

Country Experience

Chairman : Prof. Ahmed Fouad Basha

Rapporteur : Prof. Ikhlas A. Khan

Speakers:

1 - Prof. Mohammed Younis Haggag (Egypt)

2 - Dr. M. Mosaddegh (Iran)

3 - Prof. Anwar-ul Hassan Gilani (Pakistan)

**HOW THE TRADITIONAL MEDICINE
IS SUPPORTIVE IN CONVENTIONAL
MEDICINE? HERBAL MEDICINE
AND EXPERIENCE OF EGYPT FOR
HERBAL LEGISLATION**

Prof. Mohammed Younis Haggag

(Egypt)

HOW THE TRADITIONAL MEDICINE IS SUPPORTIVE IN CONVENTIONAL MEDICINE? HERBAL MEDICINE AND EXPERIENCE OF EGYPT FOR HERBAL LEGISLATION

Mohammed Y. Haggag

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Traditional medicine is prevailing in numerous countries including almost all the developing countries.

According to published data and recent statistics, over 80% of world population rely on traditional medicine.

Even in the highly developed countries, herbal medicine shares to a varying extent in their health care systems. About 25% of prescriptions in western conventional medicine contain and/or are based on constituents of herbal origin.

WHO, East Mediterranean Regional Office is doing much efforts to encourage member states incorporating herbal medicine at primary health care levels. Several intercountry workshops were held to prepare primary basic lists of medicinal plants. The medicinal plants were chosen according to their safety, efficacy, health needs of the community, availability, assurance of continuous supply and cost of treatment. These lists were prepared so as to be considered by countries when preparing their own lists of medicinal plants for use at different levels of health care. However, WHO suggested member states to establish "National Expert Committees" (NEC); the main task of these NEC are:

- * To formulate the national list of herbal medicine and develop official monograph including national standards and specifications of this list.
- * Develop guidelines on registration requirements of herbal medicine.

- * Advice the national licensing system to regulate the profession of traditional medicine.
- * Advice on means of reporting adverse reaction on use of herbal medicine.
- * Advice on means of integrating traditional medicine in national health care system.

In Egypt, traditional medicine up till now is sharing to a minor degree in the health care systems. Recommendations of WHO have not yet been adopted and no NEC has been established.

Of course traditional medicine including herbal medicine cannot be an alternative to conventional medicine; but it can be used as supportive to it. It can be used whenever found sufficiently effective beside being safe and cheap.

The minor use of herbal medicine is attributed to many factors may be the most important one from my point of view is the lack of recent curricula of faculties of medicines in Egypt of courses pertaining to this topic. The graduated physicians therefore lack the knowledge of herbal medicine and hence do not describe any to their patients. Moreover, many physicians are not convinced with efficacy of herbal medicines, regarding them as food supplements only.

Herbal medicine constitutes the main branch of traditional medicine allover the world. They can be incorporated in health care systems for treatment of many diseases; e.g. diseases of the GIT such as diarrhea, constipation, as demulcents, laxatives, purgatives, astringents, as well as, flavoring agents, antispasmodics, carminatives, anthelmintics,...

Diseases of respiratory tract infections such as anticough, antiasthma, expectorants,....

Urinary tract troubles as diuretics, antispasmodics, urinary disinfectants, to remove urinary calculi,....

Externally, herbal medicines are applied as emollients, antiseptics, anti-rheumatic, anti-inflammatory, antileucodermic,...

Egypt had a very old history in using traditional, mainly herbal medicine in treatment of different illness.

According to writing in papyrus scrolls and on temple walls, Ancient Egyptians adopted the system of specialization in their health care system and were pioneer in this respect. They had the surgeon, the dentist, the gynecologist as well as the herbalist. The herbalist was a specialized priest known as "*Sennow*". The herbalist priest was helped by a herbalist son, called "*Aurma*" who was prepared to be the future herbalist priest.

Preparation of medicaments was carried out in a special room affiliated to the temple, called "*Esst*". This room was used for storing drugs as well and can be considered as their drug store or pharmacy.

The writing left showed that Ancient Egyptians were aware of the usefulness of many plants and used some of them for the same purposes as they are used to-day.

Certain Ancient Egyptian prescriptions contained magic while others included about 400 materials. Some of these materials were of animal origin as blood, meat, horn, milk, eggs, urine and excreta.

The other group included materials from vegetable origin such as *Acacia, Aloes, Gums, Myrrh, Poppy, Pomegranate, Colocynth, Linseed, Squill, Coriander, Cumin, Palms, Onions, Garlic, Anise, Grapes, Melons, Castor,....*

They used different plant organs such as *roots, rhizomes, stems, flowers, leaves, fruits, seeds as well as oils and gums.*

They used mineral stones as *alabaster, antimony, sulphur, salt and lead salts.*

They prepared their medicaments in different forms including powders, pills, suppositories, creams, lotions, pastes and ointments. The papyrus "*Ebers*" included about 800 prescriptions using plants for curing a variety of diseases.

Nature remained the main if not the only source of remedy for a long time. The scientific revolution in the last century, however, was accompanied by a great progress in chemistry which enabled the synthesis of numerous compounds. Many of these compounds were used medicinally. These synthetic compounds had the advantage of being accessible any time and in quantities according to needs. Their

use was favored by an increasing demand for drugs to face the increase of population and spread of health care together with condensed propaganda from producing companies. The concomitant use of herbal medicine became minimized.

Unfortunately, the serious side effects and adverse reactions that appeared after use of some synthetic drugs lead health institutes throughout the world to revise their health regimes and drugs they use. A call for more safe drugs appeared and the motto "back to nature" spread every where.

Nowadays there is an increasing confidence among consumers of the ability of herbal medicine to cure both major and minor diseases. The public is becoming increasingly aware of the benefits of alternative medicine as opposed to chemical drugs.

Egypt is not far away from what is happening in the whole world. We have in Egypt a call to make use of our own resources of medicinal plants. This call is encouraged by the fear of problems expected to happen on adopting the GATT and TRIPS agreements in the near future. There was, then a need to re-evaluate our resources of medicinal plants. Astonishing results showed a marked variation in the availability of many medicinal plants. According to a recent report, the number of wild plants forming the Egyptian flora are about 2095; Among this number, 850 species (about 40.5%) are considered very rare; 567 species (27%) are regarded "rare; the remaining 678 species (32%) are believed to be common or very common. The decrease in number and amounts of many medicinal plant species are attributed to many factors such as land reclamation, extinction, urbanization, conversion of wetlands and steppe for agriculture and extension of building on expense of many rural areas.

Although the soil, climate and other environmental conditions favor the cultivation of many medicinal plants in Egypt, yet there is no a national plan for cultivation of medicinal plants in Egypt. Only small areas in scattered places are cultivated with some medicinal plants. This may be due to the fact that Cultivation of medicinal plants requires a special skill, beside the problem of selling and marketing these products after collection. In addition, some pharma-

ceutical companies in Egypt prefer importing their needs of medicinal plants from abroad rather than encouraging the local ones, claiming that they can better guarantee their permanent need, qualitatively and quantitatively from the imported one. May be the newly reclaimed areas in Egypt, such as Toshki area becomes very suitable regions for cultivation of medicinal plants of good quality, away from pollution and ensures a steady supply that will encourage the pharmaceutical firms to deal with them.

The application of herbal medicine was accompanied by a fear of its irrational use. This was attributed to such reasons, as for examples, some dealers of herbal medicines are not experts and are seeking mainly for profits; their advertisements, to some time ago, were full of exaggerations regarding the ability of herbal medicines to cure nearly all sorts of ailments without having any side effect. Besides, some herbalists may describe wrong herbs in a non-specified doses, having no scientific backgrounds may lead to serious health problems.

The fears of irrational use of herbal medicine may be overcome through their:

- Regulation and registration.
- Quality control.
- Following up their use and evaluating their adverse reactions.
- Rational use.

To rationalize the use of herbal medicine in Egypt, the government started putting some regulations regarding their use to ensure their safety and efficacy, beside putting restrictions on advertisements and announcements on herbal medicine in all public journals.

Now in Egypt we have some pharmaceutical companies specialized in producing drugs based on medicinal plants or their constituents. The drugs they produce fulfill all the required parameters of efficacy and safety and pass all quality control tests.

For a herbal medicine to be registered as a normal drug, it should fulfill all the necessary requirements for a normal drug. The matter of efficacy, safety and quality is a must. A committee in ministry of health consisting of specialists in different branches of medicine

(unfortunately not including a pharmacognosist) should revise the file and suggest the necessary tests and processes to be followed. However, the quality control procedures for herbal medicines are lengthy and requires much skill and efforts as compared to quality control of simple organic compounds.

The first step in carrying out quality control of a herbal medicine is assuring its quality through botanical identification including Latin binomial name and synonyms, vernacular names and part of plant used.

For assuring safety and efficacy, medicinal herbs are categorized into 2 groups:

- * First group includes those herbs with well-documented history of medicinal use. Literature reports are evaluated using reference books, review articles and all accessible literature through database researches. The research may extend to collect information on closely related species for chemotaxonomic correlation. In vitro biochemical or cellular safety data should be viewed as indication of potential toxicity. In vivo data from animal studies are considered more indicative of toxicity.
- * Second group includes medicinal herbs which do not have a long history of use or which have not been previously investigated, These plants need more detailed study including clinical ones. Additional toxicity study should be performed in vitro.

It is noteworthy that the absence of any reported or documented side effects is not an absolute assurance of safety of herbal medicine. Some simple tests are advised to be carried such as immunotoxicity, genotoxicity, carcinogenicity and reproductive toxicity.

The registration processes may take a long time, especially if the drug is new. Therefore many manufactures of herbal medicines prefer registering their products as food supplements in Food Institute.

Nowadays vast researches are carried out on medicinal plants to isolate, characterize and evaluate their constituents including even the minor ones. The studies include assessing their pharmacological,

biological (antiviral, antitumour, anti-belharzial, immunomodulator, anti-inflammatory, analgesic,) microbiological...values.

For Better use of herbal medicine in the future, different research institutes in Egypt are now carrying much research on medicinal plants.

Our target in our Pharmacognosy department lab. in studying medicinal plants, beside studying their active constituents, and confirming their efficacy and quality, is to establish their safety. This is done through carrying out toxicity studies (both acute and chronic) and finding out the most effective dose, form of use and contra-indications if any. We call always for the co-operation of scientists of different specialties e.g Pharmacognosists, Biochemists, Microbiologists, Pharmacologists, Histopathologists and all concerned specialization. Some clinical studies have already been carried out on certain medicinal plants with collaboration of faculty of medicine, Ain Shams University; promising results were obtained.

For sure, future will witness more awareness of the value of herbal medicine and it will occupy the position it deserves as supportive to conventional medicine.

**IRANIAN TRADITIONAL MEDICINE,
PAST AND PRESENT**

Dr. M. Mosaddegh

(Iran)

IRANIAN TRADITIONAL MEDICINE, PAST AND PRESENT

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SUMMARY

The medical scientists worldwide have not been sufficing to modern medical ways for treating patients for the past few decades. The view of human being of his surroundings in the 1960s and 1970s prompted him to re-assess the nature around him and his inter-actions with nature. This re-assessment caused him to realize that the technological trend he was pursuing had caused great damage to him and the nature and the damage was rising. Thus, he concluded in the course of the re-assessment that he must endeavor to preserve the earth and the nature. Hence, scientists were obliged to center their research in every field on preservation of nature. The idea spread to scientists of the medical community who reviewed treatment methods of illnesses and pains, both medically and medicinally. They concluded that they had to make an essential return to nature to treat illnesses of human beings. By recognizing complementary medicine, they paved the way for finding new treatment methods conforming to preservation of nature.

Scientists of the medical community thus endeavored to examine the medical knowledge of different nations to find a proper status for traditional medicine in the Primary Health Care (PHC) and Health Care System (HCS). By defining that status, the integration of traditional and modern medicines will gain sense and meaning.

Traditional medicine dates back more than 3000 years in Iran. Iranians were the first people to establish the first empire (The Persian Empire) in the world. They also established the university called Gondi Shapoor. With arrival of Islam in Iran and the great motive of Muslims to gain knowledge, medical knowledge in particular, Gondi

Shapoor University served as a link between the Islamic medicine and medical science in other communities. Medical knowledge of Iranians and the countless pieces of advice in Islam for learning, prompted Muslim scientists, such as Avicenna and Razes, to theorize medical knowledge in Iran. Works of those scientists were translated into different languages. Some of these books such as Canon in Medicine written by Avicenna were used in European scientific centers for more than 600 years.

Although the Iranian traditional medicine was influenced by modern medicine, being an integral part of culture of the Iranian people; it continued to prevail despite great pressure from modern medicine. Fortunately, scientists working at universities as well as state officials have been paying attention to it in the past two decades. The Iranian traditional medicine is currently endeavoring to gain a proper place within the PHC and HCS system.

INTRODUCTION

Improvement of "quality of life" is gaining more and more significance, recently. Such an improvement, which will give social welfare a shot in the arm, will be a non-starter without education and health care. We seem to have been provided with a fair opportunity to build a world where all humanity enjoys individual, social and environmental support. However many people around the world do not have access to health care and other basic services in physical, psychological, social and economic welfare. There have been great advances as far as medicine is concerned.

Huge death tolls sparked by out break of diseases are non-existent nowadays. Many diseases are now a thing of the past. Life spans are increasing by the day, thanks to medical and other scientific advances. Death rate among children under five has registered a drastic fall. There has been a tangible decrease in the number of deaths among expecting mothers. Deficiency still exists despite all this progress and success. Human need for prevention, control and treatment of diseases paved the way for advances in medicine. To meet ever-increasing needs we had to turn to modern technology in both treatment methods and

drug therapy. This had such acute side effects that sometimes jeopardized human's long and intermediate term health.

Turning to synthetic drugs has become one big problem of modern medicine. Technology-based therapies have also given rise to new diseases. This sets the stage for man to pay increasing attention to traditional and complementary medicine. In recent years many articles have appeared in journals and books focusing on these issues. Failure of the modern medicine to treat chronic diseases such as arthritis and cardio-vascular diseases etc., changes in health criteria, medical prospects offered by complementary medicine and a growth in people's tendency to remain healthy are the reasons behind revival of the complementary medicine. In traditional medicine physician creativity and efficiency are more tangible for both patient and doctor. Psychological findings reveal this can play a surprising role in treatment. In modern medicine technology replaces physician proficiency. This makes physician proficiency intangible. Technology reduces to a minimum the relationship between patients and doctor, which is instrumental in treatment. Driven by technology advances, the modern medicine separates physiological, psychological, social, preventative and curative aspects. Maybe an increasing overspecialization under modern medicine is to blame for this problem. Thus traditional medicine, which views these different aspects altogether focusing on bio-psycho-social therapies and makes use of natural products and herbal medicines in particular, is on the rise.

Supporting the traditional medicine, studying its treatment, techniques and tools and promoting the modern medicine, that is to give a more prominent role to physician proficiency, to rebuild patient-physician relationship and to simultaneously turn to bio-social therapies - can cut costs of leading a healthy life. That all countries and scientific forums are paying undivided attention to traditional medicine bears testimony to this accomplished fact.

Iran's Traditional Medicine (ITM) has its roots in pre-Islamic Iranian medicine and Greek, Indian and Egyptian medicine. Over long years the ITM secured a firm foothold not only in Iran but also in the

vast part of Europe and India sub-continent proving crucial in promotion of medicine as a whole.

In other words, the ITM could be likened to an alloy made up of Indian, Chinese, Macepotemian, Egyptian, Greek and particularly Aryan metals which turned into an all new matter with Post-Islamic medicine serving as a catalyst. It retained its original features yet had new distinctive attributes.

HISTORY OF IRAN'S TRADITIONAL MEDICINE (ITM)

Medicine has always played a significant role in Iranian culture and civilization, one of the oldest and strongest in the world. Archeological finds at the site of the "Torched City" in Sistan-Baluchestan province speak of a surgical operation on the skull of a 13-year-old girl suffering from hydrocephalus some 4850 years ago. Iran, which straddled east and west, came to be known as the Middle Empire. The term "Iran" derives from "Aryan" and has a history stretching over 7000 years. Medicine, physicians and hospitals have been of great account in Iran since Median, Achaemenian, Parthian and Sassanid dynasties. Under Achaemenians the most important medical reference was Avesta, a collection of sacred Zoroastrian writings. Other sacred books dealt with medicine as well. Zoroastrians believed *Thrita* was the first physician in Iran. Mazdaism led by *Zoroaster* would teach people practical and scientific treatment of diseases.

Another Iranian faith was Ecbatana founded by *Senapour Ahum Setut* a student of *Zoroaster*, 100 years after the emergence of Mazdaism. *Senapour* and 100 of his students would treat patients. Medical science reached its peak in ancient Iran with the establishment of Gondi Shapoor University by *Shapoor the First* (241-271 AD). He founded the university after overwhelming Roman Emperor *Valerianus*. In the sixth century (AD) *Khosrow Anooshirvan* (531-579 AD), a Sassanid monarch, contributed to the education center a lot. In 489 (AD) the world-class faculty in Edessea city close to Syria was shut down. That prompted Christians, Nestorian scientists in particular, to flood the palace of the Sassanid monarch. The university of Athens

closed down in 529 (AD). That led to migration of Neo-Platonic philosophers in Athens and Alexandria to Iran. They rose to prominence in Gondi Shapoor University where they later taught various courses. *Khosrow Anooshirvan* invited all famous scientists teaching at Gondi Shapoor to forge an assembly which can be identified as the first medical science academy in the world. Courses were offered in Pahlavi language in Gondi Shapoor. Among the most prominent scientists who taught at the university was *Bakhtishoo* whose children, grandchildren and great-grandchildren followed his line-practicing medicine for 6 generations (259 years), and the *Masooyas* (780-857 AD) who were originally Nestorian. In later centuries with the dawn of Islam, Gondi Shapoor proved instrumental in promoting Islamic Science, which shortly swept the world. This opened a new chapter in the medicine practiced in Iran and other Islamic countries. Iranian sciences absorbed Islamic concepts when Islam found its way into Iran.

In the early years of the Abbasid dynasty, *Ibn-e Moghaffa* (724-759 AD) translated medical texts from Pahlavi to Arabic. Abbasid statesmen would urge translator to translate scientific books from foreign languages, Sanskrit in particular, to Arabic. This paved the way for formation of an independent Islamic offshoot in medicine. At this stage Arabic became the official language of many Islamic countries. Many Iranian Muslim scientists would now write in Arabic. *Ali-ibn-e Rabn Tabari* wrote the first Islamic-era medical book "Ferdous-ul-hekmah" in 236 A. H. Tabari is also credited with teaching an ingenious- *Mohammad Ibn Zakariya Razi* (Razes)- who later rose to prominence.

Razes (865-925 AD) was the most famous clinical physician in Iran and Islamic nations. His works completed by those of Avicenna were instrumental in history of medicine. In the late 800s and early 900s *Razes* penned his first book. He wrote over 56 books, says *Biruni* (972-1048 AD). The most important of them was "Al-hawi" a comprehensive medical encyclopedia. By own account, he spent over 15 years to complete "Al-hawi". This affected his sight and led to muscular dystrophy. "When physician is a no-show" also known as

"Poor people's medicine", includes simple instructions for treatment of diseases. Poor people could use it not to pay visit fees. Just like all other books written at that era, Razes' books were all in Arabic. *Ali-ibn-e Abbas Majussi Ahvazi* (930-994 AD) a physician who exclusively looked after *King Azod-od-dowleh Dailamy* was a famous physician who authored "Kamel-os- sana'at fi-tebb" a.k.a. "Tebbol maleki".

Avicenna was a prominent physician of the late 900s and early 1000s who systematized medicine in Islamic Iran. All his books and papers on medicine except for "Nabz" (Pulse), "Anatomy" and "Judiyeh" were in Arabic. His "Canon in medicine" gave medicine a shot in the arm. It was used for centuries as a major medical reference in the world, particularly in Europe.

Major advances were made in pharmacy and pharmacology by the ninth century. "Qarabadin" (Pharmacopoeia) by *Shapoor ibn-e Sahl Jondi Shapoori* was an indication of such advances. Drug stores and hospitals would use the book, which was in Arabic for centuries. Another major work on pharmacology was "Al-abnieh an-el hadaye- qul-advieh" by *Abu Mansoor Mowaffaq ibn-e Heravi* (11th century) written in Farsi.

From the 1000s to 1200s several famous physicians emerged who wrote in Farsi. They tried to give Farsi a shot in the arm by writing their books in Farsi and by coining new medical terms in Farsi. Among the most prominent of them were *Mushref-ul Zaman Mohammed Ilaqi*, a student of *Bahmanyar* who was in turn a student of *Avicenna* and *Ali ibn-e Abbissadeq Neyshaboori* (995-1077 AD) a.k.a. Second Hypocrite and author of "Sharh-e Fosol Boqrat" (Commentary of hypocrites books).

Seyed Ismaeel Jorjani (1045-1137 AD) was a prominent physician who revived medicine in an era dominated by stagnation. "Zakhireh kharazmshahi" which appeared in Farsi was part and parcel of Iran's Traditional Medicine. He penned other books on medicine in Farsi, too. In later centuries there was a tendency to write in Farsi, many books appeared in Arabic though. Avicenna's "Canon in medicine" was still dominant during the 1200s and 1300s AD. All medicine texts were either abstractions of "Canon in medicine" or interpretation of

what it said. Among the most prominent physicians of this era were *Qotb-eddin Shirazi*, *Najib-ul-din Samarqandi*, *Sadid-ul-din Kazerooni*, *Jamal-ul-din Mohammd ibn Afsavaei* and *Burhaneddin Nafis ibn Evaz Kermani*.

"Ma-la-yasol Tabib Jahlo" by *Yousef ibn Ismaeel Khoei* was a book on materia and medica in Arabic. One of the Farsi books on materia and medica in this era was "Ekhtiyarate - Badi'ee" by *Ali-ibn Hussein Ansari* (1329-1404 AD). In the 1500s AD physicians shifted to a new style: brief and in-depth writing. So books written in this century were not reference books anymore. Prominent physicians of the 1400s included *Mohammad Sabzevari*, author of "Qavanin ul-alaj", in Farsi and *Faqih Shirazi* author of "Tashrih-ul-abdan" and "Kefayeh mojahe-diyeh" in two volumes, the first of which dealt with theoretical medicine and the second with practical medicine. *Sultan Ali Gonabadi* is the author of "Dastoor-ul-alaj" and *Yousef-ibn Mohammad Yousef Tabib Heravi* wrote a couple of poetry collections on medicine in Farsi. He also penned "Hefz-ul seha". *Hakim Alaeddin Tabrizi* is another author who wrote "Kamel alaei" which put medical terms in alphabetical order.

On the list of physicians in the 1600s and early 1700s are *Kamal-ul-din Gilani* author of "Jame-ul-Javame" in psychology, *Mohammed Mo'men Hosseini Tonekaboni Deylami* a.k.a. *Hakim Mo'men* author of "Tohfat-ul-mo'menin" on simple and combined medicine, *Mohammad Hashem ibn Mohammad Taher Tehrani* author of "Mesbah-ul-khazayen" and "Meftah-ul-dafayen". The latter appeared in Farsi. Superstition led Iran's Traditional Medicine into decline in the 1700s AD. No prominent figure rose to revive Avicenna's methods or introduce a new version of traditional medicine.

Modern medicine gradually offset traditional medicine. With the establishment of Dar-ul-fonoon, which was a polytechnique college patterned after European schools, European physicians were invited over to teach in this center. That was how Iranian physicians learned about western medicine and wrote books on the modern medicine practiced in the west. Among Dar-ul-fonoon's physicians were *Bolak*, an Austrian, *Schlimher*, a Dutch, *Tolojan* a French and Iranian

Abulhassankhani. That was how Iranian medicine set foot on a modern path, and what once was synonymous with Iran's history became a thing of the past. However there were physicians who tried to stand up to modern western medicine by writing books, among them *Mirza Babay-e-Shirazi (Malek-ul-Atebba)* who authored "Jouhariyeh".

Modern medicine secured a firm foothold offsetting the spread of Iran's traditional medicine. However since traditional medicine was an integral part of Iran's culture, it never faded.

BASIS OF ITM

ITM was originated from the following basis:

- * The medicine practiced in Ancient Iran.
- * The medicine of Iran Plateau which was mainly based on Zoroastrian teachings and "Avesta".
- * Oriental medicine - highly likely to have originated from Indo-chinese philosophies and faiths - which made its way to Iran via the Indian subcontinent and central Asia.
- * Mesopotamian medicine which found its way to Iran in the west and southwest over a long period of time.
- * Egyptian medicine, which was interjected to the ITM, thanks to expansionism of the Achaemenian dynasty (Darius is said to have captured as far west as Africa. Some even say he was the first who built the Suez canal).
- * Greek medicine which first made it onto ITM stage after Alexander's invasion and then through the Islamic civilization and its westward expansion.
- * Folk medicine which was purely based on experience of people over centuries.
- * Islamic medicine, which emerged on ITM stage, thanks to expansion of Islamic civilization and left an in-depth positive effect.

ENDURANCE OF ITM

The traditional medicine of Iran gradually started to fade out with the beginning of eighteenth century. The arrival of modern medicine in Iran, combined with little support lent by the officialdom to the traditional medicine and moreover establishment of medical and pharmacy schools, on the western style, were among the main causes that brushed aside the traditional medicine from the focus of scientific attention to the wayside. Though it was never completely disappeared from the life of the folks at large.

Modern medicine was gaining evermore momentum and thereby extending its influence simultaneous with sending of students abroad and training others domestically at the newly founded medical and pharmacy schools. Swift treatment, new drugs presentation, advanced diagnostic and therapeutic devices were other reasons that encouraged the people, particularly the educated elites to seek remedy for their ailments through modern medicine.

In the face of all these pressures from the modern medicine, by employing different inroads the traditional medicine could manage to resist and avoid complete fall out. These elements of endurance include:

- * Popular belief of the Iranians on traditional medicine
- * Efforts undertaken by a small number of traditional practitioners
- * Continued existence of "Attaris" or medicinal herbs shops, who met demands of the public for medicinal herbs
- * Inability of the modern medicine in curing certain diseases, particularly chronic ailments
- * Advent of the Islamic Revolution that aroused sentiment and interest of the people in turning to their own national capabilities and knowledge
- * Inclusion of courses on medicinal herbs in the syllabus and as selected dissertation topic in pharmacy schools in Iran

CURRENT SITUATION OF TRADITIONAL MEDICINE IN IRAN

Today the traditional medicine in Iran faces with the problem of legality. The practice has yet to be lawfully recognized by the government. Due to this egalitarian little effort has been made in the education of traditional medicine and establishment of traditional medicine school or department. Perhaps a reason could be that the officials at Ministry of Health and Medical Education have modern and western style education. Hence their view of medicine is rooted in the modern medical discipline and are probably a little worried about the presence of traditional practice as part of the country's medical and health system, therefore act conservatively toward its revival and development. There is no independent department within the Ministry of Health and Medical Education for the protection, development and legislation of traditional medicine. Quite recently, though, a number of gatherings have been organized by the Ministry on the role of traditional medicine, following the new perception emerged universally with respect to complementary medicine. It should be said that no practical measures have been undertaken up to now. Nonetheless, as a result of enthusiasm manifested by the people over the last two decade in taking medicinal herbs, noticeable progress has been visible in this area so much so that new herbal medicines enter the Iranian drug market every year. Consequently what can be discussed here is the status and position of medicinal herbs in Iran.

REGULATIONS AND LEGISLATION FOR HERBAL MEDICINE PRODUCTS IN IRAN

Iran's age-old culture and civilization have created a suitable ground for use of herbal remedies.

The great number of its ecosystems and its special climate has set the stage for the growth of over 8000 plant species. Many of these plants are native to Iran and have medical properties as well as economical value. That is why many botanists call Iran's flora "green gold".

Nowadays there are two different ways of using herbal remedies in therapeutics.

Traditional Method

Use of herbal extractions in Iran's Traditional Medicine dates back to thousands of years ago. Some instructions on how to practice herbal medicine exist in writing. Herbalists use their own and traditional experience to prepare herbal medicines and dispense them.

Modern Method

Production of herbal medicines based on modern methods started in 1981 under the supervision of the Ministry of Health. The Drug Administration Agency has drawn up certain rules for production and supply of herbal medicines.

Herbal Medicine Bureau and its Duties

An upsurge in the number of herbal medicine products since 1981 has led to establishment of the "Herbal Medicine Bureau" to supervise the production of herbal medicines. Among other things it handles, are the following.

- 1 - Issuing license for establishment of companies which produce herbal products
- 2 - Issuing license for production and packaging of herbal medicines
- 3 - Issuing license for production of herbal extractions and essence
- 4 - Supervising production and GMP conditions at herbal medicine plants
- 5 - Initial reviewing of applications for production of herbal medicine and raising the applications later at the National Experts Committee of Herbal Medicine.

National Experts Committee of Herbal Medicine

The need for scientific studies and use of expert's experience in pharmacology, pharmacognosy, pharmacy, etc and the close cooperation between the Ministry of Health and research centers as well as

universities led to the establishment of the National Expert Committee of Herbal Medicine in 1996.

Among the responsibilities of the committee are:

- 1 - Drawing up national strategies for production, application and expansion of herbal medicines

Under the committee's strategies herbal medicines fall into three different categories.

- a - Herbal medicines, which are being formulated in Iran for the first time.
 - b - Herbal medicines, which are prepared according to traditional medicine sources.
 - c - Herbal medicines, which are internationally recognized.
- 2 - Drawing up regulations for production of scientific and standard herbal medicines
 - 3 - Processing the applications for production of herbal medicines
 - 4 - Cataloging the herbal medicines used in the ITM.
 - 5 - Drawing up executive Acts for production of herbal products

In this respect the committee has passed the following Acts, which are to be complied with by the manufacturers as of the date of legislation.

- a - The Act on establishment of medicinal plants production units and packaging process.
 - b - The Act on production of herbal medicines.
 - c - The Act on production of herbal extracts.
 - d - The Act on production of essential oils and aromatic waters from plants.
 - e - The Act on production and packaging of medicinal plants.
 - f - The Act on production of herbal teas.
- 6 - Reviewing the list of official herbal medicines, with paying attention to reports on their side effects and interactions.
 - 7 - Establishing contacts with universities and scientific research centers.

Legal procedure to issue license for herbal medicine products

- 1 - Registering the application of applicants.
- 2 - Initial reviewing by "Herbal Medicine Bureau" experts. If the documents are complete, the application goes to the National Expert Committee of Herbal Medicine.
- 3 - Analysis of the drug at the food & drug central laboratory of the Ministry of Health and Medical Education.
- 4 - Reviewing the case and making decision on whether the medicine should be added to the list of official national herbal medicines. If the committee agrees to put the new product on the official list, the following stages are gone through.
- 5 - Making a decision on price by the price-setting commission.
- 6 - Final approval by a commission in charge of production and imports of biological products.
- 7 - Issuing production license.
- 8 - Taking sample from early products and comparing it with the original medicine.
- 9 - Post-marketing surveillance.

IRAN'S POTENTIAL OF HERBAL MEDICINES PRODUCTION

Geographical location and climatic condition variety as well as abundance of medicinal herbs species have provided Iran with very high potential for the manufacturing of medicinal herb products.

Currently fifteen companies, equipped suitably, are producing medicinal herbs in Iran and eight chemical drug manufacturers have set up production lines for medicinal herbs in the recent years. So far 91 brands of medicinal herbs have been approved by the National Expert Committee of Herbal Medicine at the Ministry of Health and Medical Education and are being produced and marketed through pharmacy shops all over the country. Majority of these medications is sold without prescription over-the-counter (OTC) and only a few need to be prescribed.

Medicinal herbs account for less than 10% of the Iranian drugs market, but this figure is increasing annually. About 100,000 jobs are provided by the industry. The figure excludes the traditional producers of herbal extracts on whom no reliable statistics is available. The manufacturers are now looking beyond the domestic market and are exporting their products abroad in the form of unprocessed products, flavors, powder or extracts. Iran is a major exporter of tragacanth, saffron, sweetroot, cumin seed and some other medicinal herbs. This amount of activity only taps 10% of the country's potential in medicinal herb production, which is expected to grow in not very far future. The address of herbal medicine manufacturers is available at the "Herbal Medicine Bureau" in the Ministry of Health and Medical Education.

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**PROSPECTS OF TRADITIONAL
MEDICINE IN PAKISTAN**

Prof. Anwar-ul-Hassan Gilani

(Pakistan)

PROSPECTS OF TRADITIONAL MEDICINE IN PAKISTAN

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Historical aspects

According to WHO more than three-quarters of the world population relies upon traditional remedies (mainly herbs) for the health care of its people. In fact, herbs/plants are the oldest friends of mankind. They not only provided food and shelter but also served the humanity to cure different ailments. The herbal medicine also sometime called as, traditional or natural medicine existed in one way or another in different cultures/civilizations, such as Egyptians, Western, Chinese, Kampo (Japan) and Greco-Arab (practiced and named as “Unani/Tibb” in south Asia).

Historians from all around the world have produced evidence to show that apparently all primitive peoples used herbs-often in a sophisticated way. Quinine from Cinchona bark was used to treat the symptoms of malaria long before the disease was identified and the raw ingredients of a common or garden aspirin tablet have been a popular painkiller for far longer than we have had access to tablet-making machinery.

By the middle of the nineteenth century at least 80 per cent of all medicines were derived from herbs. Then came the revolution inspired by the development of the pharmaceutical industry and synthetic drugs dominated, though herbal medicine has never been out of scene. Even today if you walk into any pharmacy in the West, you will find at least 25 % plant-derived drugs. Indeed today many pharmacological classes of drugs include a natural product prototype. Morphine, digoxin, quinine, quinidine, atropine, reserpine, physostigmine, pilocar-

pine, vincristine, vinblastine, taxol, warfarin and artimesinin are a few examples of what medicinal plants have given us in the past. Most of these plant-derived drugs were originally discovered through the study of traditional cures and folk knowledge of indigenous people.

Revival of Interest in Natural Medicine

There is revival of interest in natural medicine at a global level, the revival which has been so dramatic that sales of herbal products in USA are now worth staggering over 20 billions dollars a year. There are several specific reasons for this revival in the fortunes of herbalism-

- First, there is a massive 'back-to-nature' movement in the Western World - inspired at least in part by the fact that a growing number of people are aware of and frightened of the side-effects associated with chemical drugs.
- Second, there are many medical disorders, such as, arthritis, diabetes, hypertension, asthma etc., for which there is no complete cure despite remarkable advancement in science and treatment in orthodox medicine requires the life-long use of expensive drugs mainly for the symptomatic relief.
- Third, there is a widespread feeling abroad that the individual should retain responsibility, for his/her own health. It is easier to retain responsibility if you are not taking pills, which have been prescribed for you by someone else.
- Fourth, those who promote and sell herbal remedies have managed somehow to convince their potential customers that herbal remedies are entirely safe.
- Fifth, there is recognition of traditional medical systems, particularly of Asian origin, and the identification of medicinal plants from indigenous pharmacopoeias that have shown to have significant healing power, either in the natural state or as the source of new pharmaceuticals.

Whatever the reasons may be for the rise in popularity of herbal medicine, the fact, is that there are today millions of people who use herbal products regularly and the number is growing every day.

Compared to the other Alternate practices, such as acupuncture, homeopathy, hypnotherapy, chiropractic, yoga, etc., Herbal Medicine is the most widely used system and closest to the Modern Medicine, in terms of application to a wide variety of diseases and the way it treats disease. It has maximum contribution in modern medicine (Gilani et al., 1992).

East is already well known for its adherence to herbal medicine and China and India are two leading countries in this regard. There are over 50 Teaching and/or Research Institutions of Traditional System of Medicine in India. In a recent survey done on patients attending out-patient department of Internal medicine at a modern hospital in India, over 76 % were found to had used one or more of the unconventional therapies in the past one year (Malhotra et al., 2001).

Even in the western world, popularity of the Herbal Medicine is increasing at a rapid pace. Almost every Industrialized country now has "State funded Teaching and/or Research Institutions of Traditional Medicine. A large Center of Complimentary and Alternate Medicine has been established recently at the NIH, USA with heavy funding (Jones, 1998). Germany is the most advanced country in the West in the use of herbal remedies. Over 70 % of German Physicians either prescribe herbs or refer their patients to the traditional practitioners (Harrison, 1998). Germany shares about 40 % of the total European market of OTC herbal drugs.

Traditional Medicine in Pakistan

The traditional system of medicine in Pakistan owe its origin in antiquity, therefore, usually it is referred to as *Unani* system of medicine (Unani meaning Greek). *Tibb* and *Hikmat*, the two words are also popularly known for the traditional system of medicine in Pakistan and other Arabic speaking countries. Actually these two words are of Arabic origin, *Tibb* means medicine, *Hikmat* meaning the doctrine of medicine. In addition to the exclusive use of herbs in treating the disease, unique herbo-mineral preparations, locally known as "Kushta(s)" are also used in Pakistan (Aziz et al., 2002), where a

specific herb is treated with a specific mineral through special manner, which results in highly potent and efficacious "dosage form"

The origin of Greek medicine can be traced back to *Aesculapius*, *Hippocrates*, *Dioscorides* and many more who enormously contributed to the many virtues of herbal medicines. Greek medicine found its votaries among Arabs who developed the traditional medicine manifold; the prominent among them are *Rhazes*, *Avicenna*, *Al-Idrisi*, *Ibn Al-Baitar*, *Ali Ibn Rabban*, *Ibn Al-Nafis*, and others. The Arabs preserved and gave impetus to the art of learning and practice of traditional medicine. This system of medicine flourished for centuries in Middle East, Southeast and Central Asia. It is for this reason; this system of medicine has been referred to as either Arabic medicine, or Greco-Arabic medicine. With the spread of Islam from the Arab peninsula to the areas as far as Spain on one side, and on the other side through Iran, Indo-Pakistan, Afghanistan, Central Asian regions, Malaya and up to Indonesia, the Greco-Arab complexion of traditional medical system in the largest context has also been designated to as *Islamic System of Medicine*. After the creation of Pakistan, the prevalent traditional system of medicine was also cited as *Eastern or Oriental system of medicine* to distinguish with the system of medicines in vogue in the west i.e. allopathy and homeopathy (Germany being the home town for homeopathy).

No deliberation on the science of medicine can be complete without a reference to the most famous book of medicine, *al-Qanun fi al-Tibb*, known as "Canon" in the west written by famous Arab physician, scientist and philosopher, Ibn Sina (981-1037 C.E.), known as, Avicenna in the west. This book is an immense encyclopedia of medicine and remained supreme for six centuries because of its systematic approach, formal perfection as well as intrinsic value. British Pharmacology Society (BPS) recently decided to publish regularly in its Bulletin the postage stamps that portray famous physicians. Interestingly, the old famous stamp on herbal medicine

issued by Pakistan Post with an image of Ibn Sina, occupied first place in this series (BPS Bulletin Spring Issue, 2001).

The Greco-Arab system of herbal medicine practiced in Pakistan is, in fact based on the philosophy that believed in the individualized treatment considering the genetic variations amongst the individuals. These physicians of early history divided the human race into four groups. One could hardly imagine at that times that human population will be again divided into 4 groups known today based on 4 different blood groups. According to this philosophy of individualized treatment, different treatment options suit to different individuals, which is similar to the concept of Pharmacogenetics in modern medicine. A world-renowned expert on Pharmacogenetics stated at the European meeting of Pharmacologists last year that if the modern physicians would have considered pharmacogenetic differences at the time of prescribing, with drawl of some useful drugs from the market could have been easily avoided (Benitez, 2001). Thus the old concept that there is no safe medicine, rather the safe physician or the safe use is getting strength. In fact, the concept of side effects and the individualized treatment is perhaps more effectively elaborated in the Greco-Arab system (Tibb), where even herbal products, like ispaghula (which is considered probably the safest by the modern physicians) is not necessarily free from side effects, rather known to rarely cause numbness, even paralysis or impotence (unless combined with honey) if used regularly in cold weather. There is hardly qualified herbalist who would recommend indiscriminate use of a rather safer medicine, like Ispahula.

Ispaghula Brings Traditional and Modern Medicine Closer

There is enormous contribution of traditional practices in the conventional/modern medicine however practitioners of the two systems still keep distance. Most physicians of the conventional medicine believe that only pure compounds are acceptable in modern medicine without realizing that the modern medicine accepts even the herbal

drugs in natural form, once scientifically validated. For example, psyllium husk or ispaghula (seed husk of *Plantago ovata*) is a crude plant material but extensively used by practitioners of modern medicine, as its efficacy in chronic constipation has been proven (Gilani et al., 1998). Herbalists on the other hand are reluctant to use the pure compounds, even isolated from plants, as they believe, that the plant-derived pure compound loses its identity and no more natural or represent the herb in natural form, rather are like any synthetic chemical. They believe that the herbs in natural form contain multiple components and act in synergy or neutralize the side effects. This may be true but needs to be scientifically validated.

We recently found that ispaghula, which has been traditionally, used both in constipation and diarrhoea (two opposite disease states of the gut) has scientific explanation. It was interesting to see that in addition to the known fiber content, it contains both gut stimulatory and inhibitory chemicals, which become more effective in the constipated and hyperactive gut respectively (Gilani et al., 1998a). Studies on possible mechanism revealed that the stimulatory component is partially cholinergic and the inhibitory is mediated through blockade of calcium channels, known to be useful motility disorders. This is a unique combination, as the relaxant component seen at higher doses, does not allow the stimulatory response to reach beyond certain limit, which would otherwise be harmful. Interestingly, ispaghula has also been used traditionally in amoebic dysentery and we provided 1st evidence that it also contains chemical(s) with anti-amoebic activity, concentrated in the organic fraction (Zaman et al., 2002). In fact, no patented medicine can be claimed to be better than ispaghula particularly for chronic constipation and south Asia is the largest exporter in the world. Ispaghula is also considered effective remedy to lower cholesterol (MacMahon and Carless, 1998) and also to treat irritable bowel syndrome (Prior and Whorwell, 1987), a GI disorder, where use of both spasmogenic and spasmolytics is recommended depending upon accompanying constipation or diarrhoea. Similarly, a

unique combination of spasmogenic and sapsasmolytic activities is also present in some other plants such as ginger, a popular prokinetic remedy (Gilani et al., 2001) with spasmogenic component being more effective in stomach and spasmolytic in small intestine.

Current Status of Traditional Medicine in Pakistan

Pakistan has a rich heritage of herbal wealth and the prevalent Greco-Arab system of medicine (Tibb) has the deep roots in the culture. According to an old survey conducted about two decades ago, there are 45,000 traditional healers of whom about three-quarters are practicing in the rural areas (Govt. of Pakistan, 1980; Fendal, 1982), though this number has not been significantly increased particularly if considered growth in population, despite the fact, well over 80 % of the country's population relies upon traditional healers for their healthcare needs. There is increasing trend of Homeopathy and Acupuncture, though quality of training is again questionable.

There are around 5,000 species of wild plants in Pakistan. According to National Institute of Health (NIH) about 400 plants species are used in traditional medicine. Tibbi Pharmacopoeia of traditional drugs lists around 900 single drugs and about 500 compound preparations based on medicinal plants. There are over 20 large herbal manufacturing companies in Pakistan, produce Unani/Tibbi medicines on commercial scale, though the non-organized small herbal manufacturers run into hundreds. Some of the herbal products are being exported and the annual turnover of some large herbal manufacturers is comparable to some multinationals.

Pakistan is amongst the eight leading countries that export medicinal plants. According to Export Promotion Bureau, Pakistan exported 8,500 tones of medicinal plants in 1999. The leading medicinal plants for export purpose include, *Acacia arabica*, *Carum copticum*, *Cuminum cyminum*, *Ephedra* species, *Foeniculum vulgare*, *Papaver somniferum*, *Rheum emodi*, *Ricinus communis* and *Valeriana wallichii*. However, technology is not fully in place to export the "processed form" of herbal products and hence Pakistan could earn

only US \$ 6 million from export compared to what was spent on import of herbal products (\$ 31 million).

Unfortunately, little advancement has occurred at the Government level to promote the use of traditional medicine in Pakistan. There is hardly any State-funded Institution in the country, which provides training or involved actively in research on traditional medicine, which resulted in wider distance amongst two systems of medicine. Despite the fact, south Asia is the largest exporter of ispaghula (widely used herbal product both in traditional and modern medicine at a global level), our modern physicians learned to use ispaghula when fully established in the West.

Prospects of Traditional Medicine in Pakistan

Interestingly, things are now changing and the modern physicians are now beginning to accept some of the herbal remedies partly due to the revival of interest at a global level and because the new chemical drugs becoming out of the reach of a large population. The use of Acupuncture and homeopathy is also on the rise. One of the most advanced tertiary care hospitals in the country has recently started a clinic on hypnotherapy for the irritable bowel syndrome and also the pain management clinic, which is mainly based on the non-drug measures. There is increasing trend to carry out research on herbal medicine, and our Natural Products Pharmacology Unit now enjoys international recognition.

A degree program on Herbal Medicine has been initiated at state-funded University. Following the recent imposition of general sales tax (GST) on medicine, the Government was bound to respond to the reaction of the poor public. Newer drugs to be registered are extremely expensive, and the price control over modern medicine will be beyond the control of the Government after the implementation of WTO treaty in the years to come, particularly when the economy of the country is influenced by the foreign loans. Hence, the Government is now seriously thinking to promote the use of indigenous resources and there is serious discussion going on in the Ministry of Health to regularize the herbal products for the purpose of assuring quality and

safety. This will build the patient's trust as well as promotion of integration of traditional and modern medicine, which is the need of the time to meet the challenge of growing poverty and health problems. Based on the high demand of herbal products at a global level, the Government is now quite conscious in developing technology, as the export value of finished products is at least 30 times higher than the value of the raw materials.

Thus, the prospects of traditional medicine are bright in Pakistan. The ispaghula, the indigenous product of south Asia has already played a vital role to bring traditional and modern medicine closer and this seminar can play very effective role for the promotion of integration of traditional and modern medicine.

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CRUDE DRUGS EXPORTED FROM PAKISTAN

Name of Plant	Part Used	Total Quantity (Kgs)	Value (Rupees)
<i>Acacia arabica</i>	Gum	8,57,075	3,123,000
<i>Carum copticum</i>	Fruits	9,900	34,00
<i>Cuminum cyminum</i>	Fruits	6,87,950	5,440,000
<i>Ephedra</i> sp.	Twigs	64,950	288,000
<i>Foeniculum vulgare</i>	Fruits	3,16,650	3,965,000
<i>Papaver somniaferum</i>	Seeds	7,31,200	1,976,000
<i>Rheum emodi</i>	Roots	1,43,000	224,861
<i>Ricinus communis</i>	Seeds	6,937,00	26,316,000
<i>Valeriana wallichii</i>	Rhizomes	346,320	4,002,162

DISCUSSION

Discussion of Tenth Session Country Experience

Chairman: Prof. Ahmed Fouad Basha.

Rapporteur: Prof. Ikhlas A. Khan

Prof. Anis A. Ansari: Prof. Haggag said that Egyptian Flora has about 2095 plants and 678 species. So my suggestion is that all these plants should be documented here, they should be botanically identified. Because, due to intense globalization, there is a rapid exchange and some times, a country does not know that this plant has gone to another country and they are taking advantage of its use and patented. The mother country, in which this plant grows, has to fight and spend a lot of money for depatentization as India suffered a very setback in this direction. So, traditional knowledge data bank, means a data library, should be introduced here also. It will be in the interest of the developing of herbal medicine here.

My second suggestion is that if you want to develop any herbal system or herbal medicine, it is necessary to develop the herbal banks of your country. For that, you might exercise the experience as we have in India, which established a Medicinal Plants Board. National Medicinal Plant Board is a multi-visit approach, it identifies the plants, which are necessary for the use of public, how much plants grow in various zones of the country. They are enlisted first and then the cultivation practices are to be transferred to the agriculture people so they can earn money from cultivation of the plants also, in the fresh, right and genuine plants will be available to the manufacturer as we have mentioned here that many manufacturing companies are also producing these plants.

Prof. Md. Younis Haggag: I would like to answer your question about the Egyptian Flora. We have already established here in Egypt a Bank and we are planning to restore such plants, trying to cultivate these plants. But plants are just beginning. We are trying to restore our resources in this bank and try to cultivate. There is new plan to

make use newly reclaimed areas, away from pollution. This is very suitable area for cultivation.

As for the second part of your question to make use of traditional healers, may be, we here in Egypt have another system. We are dealing with folk treatments, which are known as “ATTAREEN”. They work in special shops, they gain their knowledge from old people. We miss some healing from the rural areas and special knowledge about the special plants that grow around them. There are some traditional healers; we can benefit from their knowledge. Up-till-now, there is no bridge between the official treatment and those working in the shop. There is no official recognition for traditional treatment in Egypt. There is a gap. May be in Egypt, we rely mainly on Modern/Conventional Medicine, except of course, in the most remote rural areas where we depend on the traditional healers.

Prof. Ahmed Foudad Basha: Yes Prof. Ansari, your second question, please.

Prof. Anis A. Ansari: My second question to Dr. Mosaddegh. I am very happy that Iran has such a rich cultural heritage for developing the Unani System of Medicine. You can say as traditional, but I will say Unani. Because there is significant contribution of Iranian physicians for the development of the Unani System of Medicine. As Dr. Mosaddegh, I have already said that a lot of good work like Firdouse Al-Hikmat, Al-Hadi Fitibb, Al-Qanun Fitibb has been written by the Iranian Physicians. There are a lot of scholars, who have contributed not only in the form of books, but also in practical experiences in this system. Najmudin Sirazi, Ismail Dajani have let it all in India. Also various Iranian physicians came and contributed a lot. There is a lot of medicinal plants, which grow which we use in our Unani system. My suggestion is to revise the system in Iran. There are a lot of chances to revise this system.

Dr. Mosaddegh: I agree with you. In regard with medicinal plants, we got nearly 8000 species. Unfortunately there are some problems. One of the main problems is that most officials, who are working in the Ministry of Health are educated mostly in Europe and America. And they are very conservative about putting the Traditional Medicine

in health systems. We are struggling and we could not persuade them yet that Traditional Medicine can play a significant role in our health systems.

Prof. Ahmed Foudad Basha: Any other questions please, or any comment. Thank you very much, we are going to have one-hour break for lunch. Thank you!

Eleventh Session Saturday, 14 October 2002 Ethical Issues

Chairman : Prof. Andrew T. Weil

Rapporteur : Prof. Ali Abdul Monem Mustafa

Speakers:

1 - Dr. Narimah Awin (Malaysia)

2 - Dr. Aly Bayoumi Hammad (Egypt)

3 - Prof. John H. Bryant (U.S.A.)

**ETHICAL ISSUES OF TRADITIONAL
AND COMPLEMENTARY
MEDICINE (T/CM) AND
REGISTRATION REQUIREMENTS
FOR PRACTITIONERS
THE MALAYSIAN EXPERIENCE**

Dr. Narimah Awin
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ETHICAL ISSUES OF TRADITIONAL AND COMPLEMENTARY MEDICINE (T/CM) AND REGISTRATION REQUIREMENTS FOR PRAC- TITIONERS - THE MALAYSIAN EXPERIENCE

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Abstract

There are many imperatives for the Malaysian government to seriously look at the potential and role of T/CM in the country. The Ministry of Health Malaysia, as the custodian of health care in the country, recognises historical and cultural perspective and the growing popularity of T/CM. The Malaysian government also recognises the economic potential of a growing herbal industry, especially in view of the rich biodiversity of the Malaysian rain forests. The Ministry of Health Malaysia therefore has made a policy to form a partnership with those involved in T/CM, generally the practitioners. This partnership, while not amounting to the full integration of T/CM into the mainstream modern (allopathic) medicine, is an extremely important linkage because it provides for the discussion of common issues and mutual interest. Essentially the policy is one of an inclusive approach rather than integrative, and therefore there is a parallel system of practice. However, full integration is something to be pursued as the system matures. Indeed, integration is mentioned in the policy statement of the National Policy on T/CM

The perspective of the Ministry of Health on TCM is best reflected in the foundation of this partnership. This foundation has two pillars; while optimising the potential of TCM as a value-adding input in health, at the same time we need to ensure the protection of the consumers in terms of safety. The ethical implications of these are obvious. Practitioners of T/CM must be encouraged to have an ethical

set of standards and code. Like the modern doctors their practice must rest on the two basic ethical principles of non-maleficence and beneficence. Then there is also the relevance of the other principles of autonomy, respect and justice, including distributive justice

The Ministry of Health operationalises the partnership by identifying four areas of concern: (a) practice of T/CM including registration, (b) training of practitioners, (c) products (safety and quality) and (d) research

The partnership is effected through five “umbrella” bodies of T/CM practitioners, based on the cultural and ethnic profile of Malaysian T/CM (Malay, Chinese, Indian, Complementary, Homeopathy) and these bodies are encouraged to do self-regulation. While the processes and standards are being identified for registration, accreditation and credentialing, the Ministry of Health, universities and other sources of expertise are assisting these bodies in these processes before they are fully capable of self-regulation.

1. INTRODUCTION

Medicine has undergone very dramatic evolutionary phases, and newer paradigms are continually being adopted for the betterment of human health. With three thousand years of history, traditional medicine has played a key role in this evolutionary process. However the advent of modern or allopathic medicine has to some extent overshadowed this role, although it is used by a very large section of all communities all over the world. Thus the current resurge in interest and commitment to traditional medicine (and now extended to alternative and complementary medicine) and the development of more and more integrated medicine system, is a positive step in reforming health care systems. With the scientific basis of traditional and complementary medicine being generally less vigorous than modern medicine, such a keen level of interest, however encouraging it may be, is in danger of compromising safety and quality standards. Thus the issue of ethics (and of course other forms of regulations) and the registration requirements (of both products and practitioners) are very

central matters that must be considered in the development of integrated medicine.

2. APPROACH OF PAPER

For this paper, the term used is *Traditional/Complementary Medicine* or T/CM for short, as is being used in the Malaysian policy at the moment. In view of the very wide scope of T/CM, even if limited to the Malaysian scenario, this paper attempts to describe only the very salient points. A background is provided to cover (a) the formalization and acceptance level of T/CM, (b) regulatory mechanisms of medical practice in general. This is followed by a section on the principles of medical ethics, and how these may be applied to T/CM. The next section then describes the major responses of the Malaysian health sector to these issues, followed by a brief section on the registration processes.

3. BACKGROUND

3.1. Levels and process of formalization of T/CM

Countries of the world may be seen to fall into any of the four categories or levels of T/CM based on the acceptance by the community, and the acceptance and recognition by the practitioners of modern medicine and official health authority of the country. These stages or levels of formalization of T/CM and the accompanying response of the modern or allopathic medical practitioner are:

- a) **Exclusive** - there is no relationship at all between T/CM and modern medicine, and indeed the modern medical fraternity does not recognize the role of T/CM; with perhaps antagonism or competition between the two systems. Here, the modern medical practitioner has a **monopolistic** (which may be antagonistic) view of medicine
- b) **Tolerant** - T/CM is practiced alongside modern medicine but with no formal recognition, and the two are directed by their own separate policies and rules. With this tolerant attitude, the modern doctor is willing to co-exist in the dual and separate systems

- c) **Inclusive** - there is a more formal recognition by the health authorities, and the two systems exist side-by-side. With recognition from the authorities, the two systems run *parallel* to each other
- d) **Integrated** - this is the highest level, which exist in countries like China, India and Vietnam, where T/CM has not been overshadowed by modern medicine, and the two practices are really integrated into a *single* health system

Malaysia has made significant steps in recent years in terms of recognizing T/CM and is moving from the tolerant to the inclusive level of formalization. The two systems run parallel and the consumer has the freedom to choose his/her preference. Indeed, in a large segment of the Malaysian population, the health service user accesses both systems for the same condition, thus broadening the choices of possible interventions. This of course has serious implications on issues such as drug interaction.

3.2. Regulating medical practice

One of the strengths of a “profession” such as medicine is the regulatory requirements for its practice. So important is health and medical care to an individual, that the person taking charge of and responsibility for it must be of adequate competence. There are several approaches and vehicles for regulating practice, and ethics is only one of them. The strongest form of regulation is legislation. In many countries, there are laws specific to T/CM. In Malaysia, the T/CM law is still being developed (See Section 4.5. below), and currently, legal provisions related to T/CM are through relevant sections of relevant laws. It cannot be denied that while legislation is required in many aspects of medical practice, it is often peer and societal sanctions through codes of ethics and of practice that are more effective. Thus the importance of ethical standards, and this is more so in situations where the legal provisions are either not in place or not adequate.

Besides legislations and ethical codes of practice/conduct, medicine rests upon strong policies and guidelines, which are also forms of regulation. There is for example a strong impetus in many countries,

including Malaysia, for evidence-based medicine in modern (allopathic) medicine. It is generally true that by and large, T/CM including use of herbal products is based on less rigorous and established scientific evidence as allopathic medicine is.

4. MEDICAL ETHICS - APPLICATION TO T/CM

The question of ethics begins with the concept of rights. Health is a human right, and this concept has at least three dimensions. The first dimension is that the right is a *fundamental* one, enshrined in instruments such as the International Declaration of Human Rights, and therefore cannot be compromised under any circumstance. The second dimension is that health is both an *entitlement* and a *freedom*. Therefore, an individual is entitled to health, which includes adequate health care, and has the freedom to choose (of course with accurate and adequate information) what health care he needs. Thirdly, health as a human right requires protection, and this may be either be a *legal* right or a moral right. Hence, the right may be protected by legal, or in the case of a *moral* right, by *ethical* instruments. Ethics is central in the practice of modern medicine as espoused as long ago as the time of Hippocrates.

Ethics is a set of philosophical beliefs and practices concerned with the distinction between right and wrong, with moral values, and of course with rights. Medical ethics is founded upon the four basic principles of *autonomy*, *non-maleficence*, *beneficence* and *justice*. These are relevant to, and must be encouraged for not only modern medical practice, but also for T/CM practice.:

- a) **Respect for autonomy** means concern about human dignity and freedom, the fundamental rights of the individual. This does include other ethical concerns such as confidentiality and privacy. In the overall system, this principle ensures the choice of the public to use whatever system of health care including T/CM. For the T/CM practitioner, there should be no constraint for practitioners of T/CM to follow this simple principle, and to ensure issues of privacy and confidentiality of their patients.
- b) **Nonmaleficence** is the principle of not harming, derived from the

ancient medical maxim, *primum non nocere*, “first do no harm”, especially relevant in situations where there is possible harm, hazard or danger to the patient from the treatment. This is a very relevant point in health, because the very reason of consulting a “medicine man” is to get better. If it is not possible to make the patient get better, the least one should ensure that no harm is done. Even if the patient does get better, side effects of treatment must be minimized. The areas of concern in T/CM are several, especially in use of modalities including herbal therapy with inadequate scientific evidence on safety.

- c) **Beneficence** is the principle of doing good, with interventions that benefit the patient. This principle is perhaps most relevant to the seeker of treatment; he wants to get better, and assumes that whatever is done is for his good. If nonmaleficence requires evidence of safety, then beneficence requires evidence of efficacy, and this is perhaps the weakest area in T/CM. Of course, it has to be recognized that “evidence” can be in different forms and at different levels, with the most rigorous being the “gold standard” of the randomized clinical trial (RCT). In public health, this principle of beneficence is extended from the individual to the population, as the concept of “common good”, doing what is good for the biggest number of people. In this context, T/CM offers opportunities for a broader common good, as it widens the range of health care providers, allowing more people to have access to some form of health care.
- d) **Justice** in the ethical sense means natural justice and distributive justice (fairness, equity, impartiality); and again is mostly invoked in public health especially in policy making and health programme service development. Thus it would be unjust to deprive people of health care that can be made available to them at a price that they can afford.

The implications of these principles on T/CM as briefly outlined above may appear daunting to practitioners of T/CM especially in terms of ensuring that the practice “does no harm” and “does good”. Thus there have been arguments for setting different standards for the

two systems of medicine, such as for T/CM products. In Malaysia, the registration of herbal products does not yet need proof of efficacy, it only needs proof of safety and quality. However, as far as possible and practicable, under no circumstance should standards be compromised. This principle and policy is a good opportunity for the encouragement of T/CM, because it builds confidence of the public, and at the same time, allows T/CM to be at the same level as modern medicine. The search for evidence, and the exclusion of unsafe products will not only broaden and expand the compendium of and choices for medical treatment, but is an opportunity for the growth of national economies.

5. THE MALAYSIAN RESPONSE

Against this background, the Malaysian government and its partners in T/CM have begun since about 6 years ago serious efforts towards integrating T/CM into mainstream medical care. The various aspects of these efforts are described briefly in the following sections.

5.1. The philosophy and rationale

The Malaysian approach is based on the very obvious and simple philosophy based on two major realities. Firstly, whether it is officially recognized or not, T/CM is used to a large extent by a large proportion of the population. Secondly, while we need to promote this popular system which also has vast economic potential for the country, we also must remember that the consumers need to be protected. Although the main issue for protection is the safety issue, the consumers also need to be protected against fraud and economic misdeeds. These two realities underscore the need for regulation of some forms. In addition to these two realities, there are other compelling reasons for regulating T/CM, and these include the increasing volume of imports into the country of various preparations, with a possibility of exploitation and the country being used as a “dumping ground”.

5.2. Laws related to T/CM in Malaysia

Public protection is best served by regulations by an authority or authorities. There is as yet no legislation in Malaysia specific for T/CM, and efforts have begun to draft the T/CM Act. In the meantime, practice of T/CM is governed by relevant provisions of relevant acts. Allopathic medicine is largely regulated by the Medical Act 1971. Under Part V(General) of this Act, section 33 subsection 1 details out the offences as

Any person not registered or exempted from registration under this Act who:-

- (a) willfully and falsely pretends to be registered under this Act or to be qualified to practice medicine or surgery; or*
- (b) willfully and falsely takes or uses the name or title of physician, doctor of medicine, licentiate in medicine and surgery, bachelor of medicine, surgeon, general practitioner or apothecary; or*
- (c) willfully and falsely takes or uses any name, title, addition or description implying that he is registered under this Act, or that he is recognised by law as a physician or surgeon or licentiate etc; or*
- (d) willfully and falsely takes or uses any name, title, addition or description, or uses any instrument, calculated to induce any person to believe that he is qualified to practice medicine or surgery according to modern scientific methods; or*
- (e) practices medicine or surgery; or*
- (f) uses the term “clinic” or “dispensary” or “hospital” or the equivalent of any of these terms in any other language in the signboard over his place of practice of medicine or surgery as a person registered under this Act; or*
- (g) uses the symbol designed by the Council for the use of registered medical practitioners only; shall be guilty of an offence under this Act*

However, a broad general exemption for T/CM is provided under Subsection 1 Section 34 (Malay, Chinese, Indian or other native methods of therapeutics) of this act, which reads

Subject to the provisions of subsection 2() and regulations made under this Act, 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 practice 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*

Note: (*) Subsection 2 of this section restricts the treatment of the eye to allopathic practitioners.

In addition to the Medical Act 1971, the Poisons Act restricts the use of certain medicines to allopathic doctors. In recent past, it has become necessary to enforce the Medicine Sale and Advertisement Act in the light of several illegal and unethical promotional activities of T/CM practitioners, especially in the form of unfounded and exaggerated claims for the cure of certain diseases. The newly introduced Private Health facilities and Services Act passed in 1998 will also have provisions that can be used for T/CM.

The T/CM Act

The Ministry of Health is in the process of formulating the T/CM Act, but it is still in the very early stages of discussion. The Act is envisaged to have four main parts —

Part 1 Setting up of the T/CM Council and registration

Part 2 Enforcement of practices and control of products and services

Part 3 Controls on training and research

Part 4 General provisions

5.3. The National Policy on T/CM

While legislations as above including the forthcoming T/CM Act provide much of the essence to ensure the interest of the public are protected, there are other instruments not amounting to laws, and codes of ethics that regulate or at least provide some directions to the practice of medicine of any form. Towards this end, the Ministry of Health Malaysia had developed in 2001, a National Policy on T/CM.

Besides the general policy statement, the document also has definitions (of traditional medicine, complementary medicine and T/CM, taken from several sources - see Appendix 1), the vision and mission of the policy, the general objectives and specific objectives, and the strategies to meet these objectives. The specific objectives are presented under the four areas of concern. See section 5. 4

The policy statement reflects the formalization level (co-existence, parallel system) and recognizes not only the health but also the economic and social benefits of T/CM, and it reads as:

Traditional / complementary medicine (T/CM) shall be an important component of the healthcare system. It will co-exist with modern medicine and contribute towards enhancing the health and quality of life of all Malaysians. The government will facilitate the development of T/CM in the country and ensure the quality, safe practices and products of T/CM. It will support the identification of its health, economic and social benefits

There are two general objectives of this policy:

- (i) *To ensure that safe, quality T/CM practices and products are made available to the public at large, and*
- (ii) *To facilitate the integration of T/CM into the national health care system*

Following these general objectives are detailed specific objectives related to the four areas of concern, products, practice, training and research

5.4. The organization, approach and the linkages

The approach to ensure linkage and coordination is described below - under the umbrella bodies, the four areas of concern and the coordinating mechanism.

(a) The umbrella bodies

Reflecting the multi-ethnic composition of the Malaysian population, traditional medicine is practiced along the three major ethnic groups. Thus there are the clear disciplines of Malay, Chinese and Indian medicine, which are based on a very long history of use, and

which a very compendium of methods and preparations. The aborigine population living in the relatively interior parts of the country and having deep knowledge of the Malaysian forests with their flora and fauna, also has its own traditional medicinal practice. But they are a small and self-contained community. In addition to these traditional forms of medicine, alternative or complementary medicine too is widely used in Malaysia. For the purposes of approaching the issues and making linkages two groups of complementary or alternative medicine have been identified - homeopathy and complementary (consisting of a variety of systems such as chiropractic, aromatherapy, etc.) Thus there are five discrete groups, and each of them has established a pro-tem committee referred to as the “umbrella body”; and these five are therefore:

- a) Malay traditional
- b) Chinese traditional
- c) Indian traditional
- d) Homeopathy
- e) Complementary

It is to be noted that some forms of practice may be under more than one of these groups. The clearest example of this is acupuncture, which, although identified as mainly Chinese, is also practiced by other therapists.

(b) The areas of concern (scope)

As used in the objectives of the policy, there are four areas of concern that direct the activities of T/CM in Malaysia. These are practice, training and education, raw materials and products, and research. These common grounds are to be applied to all the 5 groups above. As expected, the five groups are at varying levels and degrees of capability for these areas of concern. For example, the training for Indian and Chinese traditional medicine are more established than for Malay medicine. Practices too differ in terms of scope, premises and requirements and recognition of practitioners. Raw and finished products is an important area for all practices, and the issues of

efficacy and safety may be at differing levels among them. Research is largely based on the products used in whatever system or group of T/CM.

(c) The coordinating mechanism/Committees

In the approach of the Malaysian healthcare system to bringing T/CM on board, efforts have been put in place to coordinate all the activities. To effect this, a National Steering Committee has been set up with the Ministry of Health as the secretariat and coordinator. Membership includes all related government agencies including universities, as well as the representatives of the 5 umbrella bodies. There is under this a National Technical Committee, with technical experts as members. Under this, there are 4 Working Groups, one for each of the 4 areas of concern. The coordinating body for each of these four groups is:

- 1 - Practice - Family Health Dev. Division, Ministry of Health
- 2 - Products - National Pharmaceuticals Control Bureau, Min of Health
- 3 - Training and education - National University of Malaysia
- 4 - Research - Institute for Medical Research, Ministry of Health

When the T/CM is ready, assuming the current draft is accepted, there will be a National T/CM Council to be headed by the Director General of Health, and will oversee the national Steering Committee.

6. REGISTRATION PROCESSES

The issue of registration applies to all 4 areas of concern - products, practice, training and to a lesser extent, research.

6.1. Products

Currently, T/CM products refer to those under the Control of Drugs and Cosmetics Regulations 1984. The Ministry of Health began registration of herbal and other traditional medicinal products in 1992, and up to the end of 2001, almost 10,000 (9,894) such products have been registered. Almost the same number (9,104) products that applied for registration were rejected. There are 142 registered and licensed

manufacturing premises for T/CM products throughout the country. The registration of herbal products requirements is less stringent than for modern pharmaceutical products. As mentioned earlier, proof is required for safety of the product and the quality during the whole manufacturing process, but is not yet required for efficacy. Evidence of Good manufacturing Guidelines is required. With the Muslim as the majority of the nation's population, the issue of "halal/ haram" is to be addressed as well

6.2. Practice

There is no system of registration and credentialing yet in place, but efforts are being made with each umbrella body to look out for practitioners of their respective group and inviting them to be "registered" which is currently only a form of listing of members. The awareness of this is through announcements and advertisements. This process of "listing of members" took about two years (1999 to 2001).

The Ministry of Health has officially appointed the 5 umbrella bodies to conduct administrative registration, and they are required to develop the Guidelines for Registration and a Code of Conduct for their members. This effectively allows to (i) begin administrative registration of members, (ii) self-regulation using the Code of Conduct and (iii) deregister members if the situation warrants it. Thus far the umbrella bodies have identified 3 categories of membership (i) therapists (ii) healers and (iii) advance practitioners

Besides the practitioners themselves, the registration of practice shall also include that of the premise, which will need either a license separate from services, or a single license (the decision is not yet finalized)

A major setback is the fact that these umbrella bodies do not have any legislative authority to register and regulate their members, and therefore non-compliance is not accompanied by any meaningful punitive action. The involvement of the Ministry of Health in the form of administrative assistance, regular discussions and joint activities, to some extent lend some credence and clout to these bodies. The

promulgation of the T/CM Act is a significant step towards better governance including registration procedures.

6.3. Training

This too is still in the very early preparatory phases. Efforts have begun on the identification of the training curriculum for each of the 5 systems of T/CM as in the umbrella bodies. It is the aim of the Ministry of Health to ultimately allow practitioners who have the desired qualifications to practise. Until such time, the umbrella bodies will accredit the practitioners. Currently, practitioners are assessed on the training they have undergone and their experience. Of the 5 groups, the Chinese, Indian and Homeopathy practitioners have some form of curriculum, which is being reviewed by the Ministry of Health and Ministry of Education with the intention of formalizing and later on accrediting them. The recommended curriculum should at least consist of a minimum standard of knowledge and skills for practice, and to also include the ability to conduct practical research to ensure safe and efficacious practice.

6.4. Research

Research is the basis for product development, and for ensuring safety and efficacy of products. Operational research can provide valuable information on various operational aspects. Research in essence provides evidence. Although the regulation for research is less urgent than the other 3 areas of concern, there may be areas for regulating research, such as the qualifications of the researchers and the licensing of the research institutions.

7. CONCLUSION

Traditional and complementary medicine as an entity in society plays a significant role in its healthcare; and its existence can neither be denied nor ignored. While efforts are actively being taken to promote T/CM in Malaysia, there is a clear need to ensure safety to the consumers, and in this, the issues related to regulations and registration are pertinent. A legal mechanism is the most ensuring

instrument, if properly enforced. In Malaysia, there is as yet no law specific to T/CM, and efforts are being made to formulate such an Act.

While some aspects of T/CM, like in modern medicine, can and should be controlled by legal provisions, some aspects are more easily or more effectively enforced by non-legal instruments, such as ethics. The principles of medical ethics can be applied to T/CM. Besides the legal and ethical mechanisms, there are other regulating mechanism, such as policies and administrative procedures.

APPENDIX 1: DEFINITIONS OF TERMS ACCORDING TO THE NATIONAL POLICY ON TRADITIONAL/COMPELEMEN-TARY MEDICINE

- Traditional medicine is the sum total of knowledge, skills and practices on holistic health care, which is recognized and accepted by the community for its role in the maintenance of health and the treatment of disease. Traditional medicine is based on theory, beliefs and experiences that are indigenous to the different cultures, and that is developed and handed down from generation to generation

(Source: WHO/WPRO Report on Workshop on Development of National Policy on Traditional Medicine, Beijing, Oct 1999)

- Complementary medicine, in practice, refers to a wide range of health interventions originating from the different cultures across thousands of years of history

(Source: Scottish Department of Health, Complementary Medicine and National Health Services, Nov 1996)

- Traditional and Complementary medicine practised together, is other than the practice of medicine or surgery by registered medical practitioners, as defined by the Medical Act 1971.

(Source: Malaysian Medical Council, Ministry of Health Malaysia)

**COMPLEMENTARY MEDICINE;
MEDICAL ETHICS**

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COMPLEMENTARY MEDICINE; MEDICAL ETHICS

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Several general questions arise when considering Complementary or Alternative forms of medical therapy:

- 1 - Do the different forms of Alternative Medicine Therapy work?
- 2 - Are the methods of Complementary Medicine safe & effective?
- 3 - At what point must retail pharmacists ethically decline to sell non-proven medications of TM Therapies?
- 4 - Should health care plans pay for Complementary Therapies?
- 5 - On what basis should a Physician refer his patient to TM practitioner?
- 6 - How is informed consent related to Complementary Medicine?
- 7 - What commitments should the TM Practitioner respect?

1. Do the different forms of Alternative Medicine Therapy work?

Allopathic practitioners emphasize the scientific approach of allopathic medicine, and contend that it is free of cultural value. TM therapies have developed rather differently, having been very much influenced by the culture & historical conditions within which they first evolved. Their common basis is a holistic approach of life, equilibrium between the mind, body and their environment, and an emphasis on health rather than on disease. Generally, the provider focuses on the overall condition of the individual patient, rather than on the particular ailment or disease from which the patient is suffering. This more complex approach to health care makes TM very attractive to many. But it also makes scientific evaluation highly difficult since so many factors must be taken into account.

Even evaluating TM products such as herbal medicines, can prove

very difficult. This is because several factors, such as when and where the raw materials were collected, and the accuracy of plant identification influence herbal medicine quality.

The need to believe in complementary medicine is further supported by the high-technology, high-cost and impersonal nature of standard medical practice that failed to deal with people suffering from a chronic illness in a humane way.

2. Are the methods of Complementary Medicine safe & effective?

The quantity & quality of the safety and efficacy data on TM are far from sufficient to meet the criteria needed to support its use worldwide. The reasons for the lack of research data are due not only to health care policies, but also to lack of adequate or accepted research methodology for evaluating TM.

The checklist for evaluation of safety, efficacy & quality of TM therapies should:

- * Establish registration and licensing of providers.
- * Establish national regulation and registration of herbal medicines.
- * Establish safety monitoring of herbal medicines and other TM therapies.
- * Provide selective support for clinical research into use of TM for treating country's common health problems.
- * Develop national standards, and technical guidelines and methodology for evaluating safety, efficacy and quality of TM.
- * Develop national pharmacopoeia and monographs of medicinal plants.

3. At what point must retail pharmacists ethically decline to sell non-proven medications of TM Therapies?

This debate continues within the pharmaceutical profession, although the issue may be moot as the giant pharmacy chains find increased profits in selling these items.

4. Should health care plans pay for Complementary Therapies?

This matter is a subject of controversy. A group of issue claim that the society should not be burdened by paying for treatments that may

be neither safe nor effective. This is countered by asking whether individuals should have a right to have their health care plans supply the types of therapy they desire.

5. On what basis should a Physician refer his patient to TM practitioner?

The physician’s decision to refer a patient to TM practitioner is often confounded by the physician’s scant knowledge (and negative preconceptions) of alternative therapies, the sheer number and bewildering variety practices that fall under the complementary heading (no one can be familiar with them all), and the shortage of evidence for the efficacy of many complementary treatments.

This situation is certain to be improving over the next few years, given the quantity of research now being done on the efficacy of complementary medicine.

6. How is informed consent related to Complementary Medicine?

The principle of informed consent requires that the patient be adequately informed of therapeutic options and the benefits and risks associated with each. Historically, physicians have simply ignored alternative treatments when presenting options, or have summarily dismissed them as quackery.

Given the current level of public interest in complementary treatments, any treatments that might be of benefit should be presented to the patient, and any that involve significant risk identified as dangers. But in those situations where the physician does not feel he has adequate knowledge of a complementary option, at most, a particular alternative method might be mentioned as a possible adjunct, and the patient given the responsibility of investigating options and obtaining sufficient knowledge for a sound decision.

7. What commitments should the TM Practitioner respect?

Commitment to the Patient:

He should:

- * Respect the rights, dignity, and person of each patient.
- * Render to each patient the highest quality of care and make

timely referrals to other complementary medicine providers or health care professionals as may be appropriate.

- * Avoid treating patients when the practitioner judgment or competence is impaired by untreated chemical dependency or physical or mental incapacity reasonably believed to be hazardous to the safety of the patient.
- * Accept and treat all those seeking TM services in a nondiscriminatory manner.
- * Keep accurate records of history and treatment and respect the confidentiality of those records or any other personal information imparted by the patient in accordance with law.
- * Keep the patient informed by explaining treatments and outcomes and avoid making promises with regard to outcomes that will create inappropriate expectations.

Commitment to the Profession:

He should:

- * Continue to work to raise the standards of the profession.
- * Use appropriate professional mechanisms to report ethical and professional practice violations.
- * Maintain the highest standard of ethical and professional practice to the benefit of patients and the profession.

Commitment to the Public:

He should:

- * Provide accurate information regarding education, training, experience, professional affiliations, and certification status.
- * Refrain from making public statements on the efficacy of Oriental medicine that are not supported by the generally accepted experience of the profession.
- * Respect the integrity of other forms of health care and other medical traditions and seek to develop collaborative relationships to achieve the highest quality of care for individual patients.

**EQUITY AS AN ETHICAL ISSUE
IN TRADITIONAL MEDICINE**

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EQUITY AS AN ETHICAL ISSUE IN TRADITIONAL MEDICINE

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Introduction:

It is increasingly apparent that there is an international movement toward integration of traditional and complementary/alternative medicine --TM(CAM)** -- and modern or conventional medicine. WHO and many governments and NGOs are supporting this transition toward greater respect for traditional medicine, with concrete steps for strengthening country capacities, including developing countries, for their uses of traditional medicine. Special attention is being given to research and development processes for ensuring safety and efficacy in their uses.

It is important to note the attention given to this area by WHO and the US Government.

- * **WHO Policy Perspectives on Medicines.** Traditional Medicine - Growing Needs and Potential. Traditional Medicine Strategy 2002-2005.
- * **U.S. Government:**
- * National Center for Complementary and Alternative Medicine, at the National Institutes of Health, now the leading Federal agency for scientific research on CAM.
- * White House Commission on Complementary and Alternative

** (The meanings of TM(CAM) as we understand them are described in the Annex. Here, we will use the term traditional medicine (TM), unless there are specific reasons for using the other terms.)

Medicines, Established by Executive Order in March, 2000, with its Final Report in March 2002.

Our assignment is to discuss equity as an ethical issue in traditional medicine, particularly in the context of this integrative process.

It is important that we turn our attention to the breadth of issues that should be taken into account as we look for what is equitable in the uses of traditional medicine. It needs to be appreciated that there is great complexity in the interactions of traditional and conventional medicine as fields of study and applications go forward. Consideration of the place of equity cannot be singled out from this complexity but remains an integral part of it. We will proceed along five pathways:

- One is to consider those aspects of traditional medicine that stand as a challenge to equity in its provision and outcome. Of course, equity does not sit by itself in health and health care, but is linked with a series of other ethical principles and concepts, and we will review them.
- A second pathway relates to applying research methodologies in determining the safety and efficacy of interventions in traditional medicine. The scientific and ethical processes for ensuring safety and efficacy represent a major area of importance, and also of potential conflict between conventional and traditional medicines, and equity is heavily dependent on these factors.
- A third has to do with traditional medicine as a part of health system development and how it relates to other aspects of health care and social development. Inequities are to a large extent addressed through appropriately developed policies and operations of the health care system and other approaches to health development. Here we will consider two relevant factors.
- * Primary health care, long a key component of health system development, particularly for developing countries, now gaining new approaches and support of its vitality and relevance to traditional medicine.
- * Increasing recognition of the growing burden of chronic conditions and their needs for health care that goes beyond the usual

care provided by conventional medicine. Here is an opportunity for traditional medicine to be integrated with conventional medicine.

- A fourth pathway relates to tools and methodologies for health system development. We focus on three of these.
 - * The Global Health Equity Initiative, which brings fresh approaches to ensuring equity, particularly for poor populations.
 - * WHO's own process for Strengthening Health System Performance which can be linked with its current effort to bring new dimensions to PHC.
 - * Benchmarks of Fairness for Health Care Reform, which seeks to ensure fairness at the level of policies and their implementation in health care and other approaches to enhancing health.
- Finally, it needs to be appreciated that these various efforts that would bring traditional medicine into integrative relationships with conventional medicine cannot be seen as isolated efforts unrelated to one another. There must be a convergence of interests and actions that yields a true integration of the various relevant factors.

I. Equity and its Applications to Traditional Medicines

Considerations of equity in relation to traditional medicine could open some opportunities for comparison with the role of equity in conventional medicine.

First, let us consider equity in the familiar context of conventional medicine.

For understanding this concept, we turn to the book: *Challenging Inequities in Health - From Ethics to Action* (1). What is meant by equity in health?

- * Inequalities in health describe the differences in health between groups independent of any assessment of their fairness.
- * Inequities refer to a subset of inequalities that are deemed unfair.
- * The unfairness qualification invokes assessments of whether the inequalities are avoidable as well as more complex ideas of distributive justice as applied to health.

A further notion of importance is that of equity in health outcomes. This reflects the premise that disparities in health outcomes are the most important dimensions of health equity. Other dimensions, such as equity in access to health care, although important, need to be understood in relation to their impact on health status. Indeed, health has many determinants beyond those of health care.

A common goal of health services is to ensure equitable distribution of services, with priority to those most in need, with emphasis on care according to need and a special concern for health outcomes.

Now, let us consider how these concepts might apply to traditional medicine.

Where traditional medicine is congruent with conventional medicine, the application is clear enough - safe and efficacious interventions are applied according to need, with special concern for those who are worse off.

Now, as we shift over to those aspects of traditional medicines that are less like conventional medicine, such as alternative medicines, we can ask how they relate to the overall concept of equity?

We begin, as before, by identifying those in need of care (not only health care), and consider what kinds of response will make them better off for the care they receive?

We should include consideration of the principles of biomedical ethics (2):

- * Autonomy - are the patient or community exercising their right of choice as to the kind of care they wish to receive?
- * Beneficence - will the care they receive be to their benefit?
- * Non-maleficence - will it be safe and do them no harm?
- * Justice - here is a further expression of equity - even if they are deprived, will they receive the care they need?

These principles work in tandem with equity, and they remain a valid sequence of questions to ask.

Another issue relevant to equity that will become apparent is that interventions involving traditional medicine will often involve relating

to patients and communities in ways that have strong social, cultural, spiritual and psychological components, which are directly relevant to the needs of those patients. Here, then, may be examples of equity that can be expressed in terms of benefits responsive to need that rival the above mentioned importance of health outcomes. Health outcomes, remain important, to be sure, but the more immediate psychosocial benefits need to be fully appreciated.

There are other ethical issues that should be seen in concert with equity in relation to traditional medicine. Here we will mention them briefly, and discuss them more fully below:

- * Social determinants of health, a field of concern that leads us beyond the effects of health care to other parameters of causation of ill health.
- * Fairness, an expression of justice. This will be considered in relation to Benchmarks of Fairness, discussed later.

II. Assessing the Safety and Efficacy of Traditional Medicine

As we move toward those aspects of traditional medicine which do not have familiar impacts on health, and where there is uncertainty with respect to safety and efficacy, their role with respect to equity becomes uncertain as well.

An important aspect of traditional medicine has to do with the varieties of traditional medicine that are at work. Here, are major types of complementary and alternative medicine (from the National Center for Complementary and Alternative Medicine NCCAM, (3)) — 5 categories:

- * Alternative medical systems - homeopathic, naturopathic, traditional Chinese medicines, Ayurveda.
- * Mind-Body Interventions - designed to enhance the minds capacity to affect bodily function and symptoms, patient support groups, cognitive behavioral therapy, meditation, prayer, mental healing, therapies using creative outlets such as art, music, dance
- * Biologically-based therapies - use of substances found in nature, such as herbs, foods, vitamins, and the use of other so-called

“natural” but as yet scientifically unproven therapies (for example, using shark cartilage to treat cancer).

- * Manipulative and Body-Based Methods - chiropractic and osteopathic manipulation and massage.
- * Energy Therapies —
- * Biofield therapies - some forms of energy therapy manipulate biofields by applying pressure and/or manipulating the body by placing hands in, or through, these fields. Examples: gi gong, Reiki, therapeutic touch.
- * Bioelectronic-based therapies - unconventional use of electromagnetic fields, such as pulsed fields, magnetic fields, alternating current or direct current fields.

WHO has a comparable listing of traditional, alternative and complementary medicines (4).

This listing the various types of traditional medicine raises important issues relating to efficacy and safety and therefore to ethics and equity.

There are well established methodologies for examining and ensuring the safety and efficacy of conventional medicines and for doing so in ways that are consistent with ethical guidelines. The Helsinki Declaration (5) and the CIOMS International Ethical Guidelines for Research Involving Human Subjects (6) are prominent examples. There are lessons from the history of these guidelines that can be helpful in thinking about research using traditional medicines. Both the Helsinki Declaration and the CIOMS Guidelines have been carried through extensive revisions in recent years due to changing perspectives on ethics and research. Those changes have involved substantial debates based on differing and evolving moral values. The debates have taken place within the familiar moral territory of science-based medicine. To move onward to products and interventions that are more difficult to associate with science-based processes will undoubtedly involve even more extensive ethical questioning, such as the nature of human benefit from traditional medicine products, and the extent of risk or harm that might result.

While there is much that can be done through the applications to traditional medicine of the scientific methodologies used with conventional medicine, there are many examples of traditional medicines that lie beyond current applications of such methodologies. Examples of those traditional medicines would include:

- * mind-body interventions -- cognitive behavioral therapy, meditation, prayer, mental healing
- * biofield therapies - applying hands to parts of the body - gi gong, Reiki, therapeutic touch
- * Bioelectronic based therapies - unconventional use of electromagnetic fields

To assess the efficacy and safety of some of these traditional medicines will call for innovative thinking with respect to scientific methodologies. It is important that those aspects of traditional medicines that fall outside the purview of scientific methodologies not be discarded simply for that reason. It remains possible that traditional medicines could have positive effects that lie outside the current boundaries of evidence-based functions.

Further, it needs to be appreciated that many aspects of traditional medicine are not intended to cure disease but to serve other functions, such as disease prevention, to bring greater comfort in the presence of disease, and to prevent advances of damaging diseases. The notion of psychosocial support for persons with disease or threatened by disease becomes of great importance. This is an area where conventional medicine has given some, but limited attention. It is to be appreciated that equity is seen here in terms of responding to needs with care explicitly according to those needs.

White House Commission on CAM Policy - Ten Guiding Principles

Based on its mission and responsibilities, the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) issued ten guiding principles to shape the formulation of their recommendations. This listing is quite sensitive in its appreciation of the various dimensions of traditional medicine.

- 1 - A wholeness orientation in health care delivery.
- 2 - Evidence of safety and efficacy.
- 3 - The healing capacity of the person.
- 4 - Respect for individuality.
- 5 - The right to choose treatment.
- 6 - An emphasis on health promotion and self-care.
- 7 - Partners as essential to integrated health care.
- 8 - Education as a fundamental health service.
- 9 - Dissemination of comprehensive and timely information.
- 10 - Integral public involvement.

These Guiding Principles indicate the new and expanding dimensions that are being brought to traditional medicine. It can also be said that these principles are directly supportive of equity, for it is through their elaboration and implementation that needs are both identified and responded to.

Pluralism in Research Approaches and Quality in Research Methodology

At this point, it is useful to turn to further work of the White House Commission. One of the participants in the WHCCAMP has been Dan Callahan, ethicist and a leader of the Hastings Center for Biomedical Ethics. He chaired a working group on *Pluralism in Research Approaches and Quality in Research Methodology*, which may be seen to be at the points of intersection of both CAM and conventional medicine. A brief report of that group, taken from the Report of the WHCCAMP follows (3):

“Various research approaches pertinent to CAM contribute to developing evidence of safety and clinical efficacy, understanding basic mechanisms of action underlying practices and products, and evaluating general effectiveness in the health care system. Among these approaches are basic research, randomized controlled clinical trials, non-randomized studies, empirical observation, case studies, evaluation of practice-based data, and practice-based outcomes research. Also included are epidemiological and surveillance studies, behavioral and quality-of-life studies, qualitative research, systematic reviews and

meta-analyses, cost-effectiveness and cost-benefit studies, population and utilization studies, studies on health care delivery, and health care demonstration projects on various aspects of CAM use and services. To be methodologically sound, CAM studies must have a clear question (hypothesis), a sound study design, a qualified and appropriately constituted research team, objective and verifiable data, carefully defined outcome measures, and balanced conclusions that meet acceptable standards of evidence. The randomized controlled clinical trial is recognized as the gold standard for examining many clinical questions. Because of the complexity and uniqueness of illness and CAM approaches to illness, it may be necessary to adapt clinical trial methodology, in a flexible step-wise fashion, to the unique characteristics of CAM questions and systems of care, while complying with protections for human subjects and institutional review board (IRB) guidelines. Questions of standardization and non-standardization, individualization and generalization, blinding, randomization, the placebo effect, compound mixtures, and many other research methodology challenges need to be resolved within the context of the study question and design and the overall research strategy.

“It is important to note that investigators in conventional clinical research have also adapted methodology and design to meet the needs of a study. Scientists have always followed their quests for knowledge by developing new ways to answer difficult questions, and pluralism in research design will allow scientists to develop innovative methods to examine complex CAM questions. Funding mechanisms that have promoted interdisciplinary exchange of ideas in addressing difficult research questions in conventional research may offer settings in which creative ways of approaching difficult CAM research questions can be developed. In addition, multidisciplinary conferences, workshops, and expert panels, such as the CAM cancer symptom management research panel convened in November 2001, provide effective forums for exploring ways to address CAM research-related issues and challenges. The results of meetings such as these are often published in peer-reviewed journals and can stimulate new research and public and private investment.”

Further, Callahan edited a book based on that work, entitled *The Role of Complementary and Alternative Medicine: Accommodating Pluralism*; Hastings Center Studies in Ethics Series which has been recently published (8). An interesting Book Review was reported in the *New England Journal of Medicine*, written by Barrie R. Cassileth of Memorial Sloan-Kettering Cancer Center (9). Cassileth comments on the extensive and increasing uses of CAM and the rapidly expanding numbers of CAM practitioners in the U.S. and other developed countries. He then observes that there is some research data and a great deal of speculation about what contributes to this substantive degree of interest in therapies often denounced by scientists and medical practitioners as unproved, nonsensical or inconsistent with a scientific understanding of human physiology and disease. But complementary and alternative medicine and its practitioners offer something that patients want and do not get from mainstream medicine, which is the basic issue addressed in this very interesting book. Callahan comments in the introduction to the book that the authors are “sympathetic to CAM, take it seriously, and yet are quite willing to subject it to criticism.” The authors represent a spectrum of fields from which the socio-cultural underpinnings and implications of CAM come to light - medicine, philosophy, culture and folklore, research methodology, and sociology.

An example of the contentious areas that can afflict CAM is in the potential place of placebo effects in studies of the effectiveness of CAM. The point is made in the book that the value of positive results of research on CAM is not impaired even if those results are discovered to be attributable to placebo effects alone. Placebo effects add to the benefits of conventional therapies as well, and the goal, it is stressed, is to benefit patients, regardless of the placebo contribution. Placebo benefits stem from patients belief in the value of treatment but also from spiritual, cultural, or emotional aspects of the therapy - aspects of health care that are desired by the majority of patients across studies.

The conclusion of several contributors is that the health care system must adopt a philosophy better attuned to the need of patients

for comprehensive care, a philosophy that can accommodate unusual beliefs and the desire for individualized attention and cultural sensitivity. The writer of the review was supportive of these perspectives in general terms but questioned the practicality of the process.

Overall, this work calls attention in clear terms to the immensity and the importance of the challenge involved in the integration of traditional medicine (CAM) and conventional medicine. At the heart of such interactions must be science-based research, on the one hand, and flexible, socio-cultural, spiritual, emotional sensitivities, on the other.

What is the place of equity in this complexity? That remains clear in terms of the need to define the needs of patients and populations, and to respond to those needs in ways that benefit them, in terms of both immediate needs and health outcomes. The importance of defining needs and relevant responses should not be packaged solely with conventional science-based research and conventional approaches to health care. In short, the quest for equity must be carefully linked with the process whereby traditional medicine and conventional medicine are brought together in mutually respectful, scientifically rigorous, socio-culturally sensitive ways.

Social Determinants of Health

Another area deserves mention that could have substantial positive interactions with traditional medicine - social determinants of health. Here we draw on the work of Dan Brock, Philosopher at Brown University, USA (10). There is increasing recognition of the limited impact of health care on health. For example, medical care is estimated to account for only about one fifth of life expectancy gains in the 20th century. As one moves up the socioeconomic scale, there is a consistent increase in life expectancy. However, it is not just where one stands in the socioeconomic hierarchy that affects health, but also the degree of socioeconomic inequality in the society. Higher societal income inequality adversely affects citizens health and life expectancy.

The first major, and still classic, study demonstrating this effect - the Whitehall study - found that as one went up each grade in the

British civil service there was a consistent increase in life expectancy, all in the absence of material deprivation at any grade. The differences in life expectancy were not small. Between the highest and the lowest grades, it was 4.4 years - greater than the effect on mortality of all coronary disease. In short, here were differences in life expectancy related to socioeconomic status but unrelated to poverty.

So there are at least two important social determinants at work:

- * Where one stands in the socioeconomic hierarchy affects one's health;
- * The degree of income inequality in a society affects the society's overall level of health and health inequality.

What are the mechanisms for these impacts? They are not fully understood. Because in developed countries it is one's relative rather than absolute income that is important, it appears to be the psychosocial rather than the material effects of income levels and inequality that are important. The social gradient of health is largely determined by relative deprivation. Socioeconomic status is correlated with the degree of social supports and participation in social networks outside the family, which have strong protective effects on health. More egalitarian societies exhibit stronger social cohesion and community life. In a variety of ways, the lower economic classes are subject to higher chronic psychosocial stress, which has a powerful effect on death and illness rates. Put generally, the quality of the social life in a society and the social capital of its members are two of the most powerful determinants of health, and they are very closely related to the particular socioeconomic position of individual members of a society. REVIEW

Now let us turn to the applications of these ideas to developing countries. We have seen the evidence that socioeconomic inequalities, with their psychosocial effects, contribute in significant ways to decreased life expectancy in developed countries, and this is seen in the absence of poverty.

Here we see a strong rationale for the very low rates of life expectancy in poor countries. The poor are at the bottom of the heap;

and the extent of income inequality is extreme. It is apparent then how the social determinants described for developed countries are at work in developing countries and to a much greater degree. The notions of a sense of a lack of self worth, of humiliation, of hopelessness - are rampant in developing countries, and clearly contribute in major ways to diminished life expectancies.

Is there a place here for traditional medicine? I would say - indeed there could be! The social cohesion that traditional medicine can contribute to communities, and the psychosocial support for individuals in need could make a distinct difference in their sense of their place in a family and community. It is of considerable interest that these areas of potential impact for traditional medicine are quite different from those of conventional medicine.

Now let us take one further step in probing at the possibilities of finding expressions of equity in the uses of traditional medicines in developing country settings. This could be seen as quite subtle in the health care context. Equity calls for care according to need. In the context of conventional medicine, care is generally in accord with patterns of disease and organ system involvement. Those with diabetes or hypertension receive care determined by those diagnoses, taking into account the stage of progression of those diseases. Thus, those with similar diseases will be treated similarly. And, of course, there will be concern for the person and her or his particular circumstances.

However, in addition to concern for the diagnosis of disease, traditional medicine will often focus quite carefully on the overall circumstances of mind, body and spirit of the patient, and apply relevant interventions accordingly. Thus, a number of people with similar patterns of disease might be treated quite differently, according to their psychosocial, spiritual and physical needs. Here, then, is an example of care being according to needs that are often overlooked in the context of conventional medicine.

This effort to reach into the shadows of uncertainties regarding traditional medicine is a necessary direction of action if there is to be meaningful integration of traditional and conventional medicine.

A Place for Epidemiology?

An important further question has to do with the place of epidemiology in this area of concern. Epidemiology, the science of patterns of disease and their causation, plays a critical role in the health sector. Social epidemiology focuses on social and economic factors that affect health and efforts to deal with threats to health. We can suggest, therefore, that there is a place for epidemiology to join in this effort to promote integration of traditional and conventional medicine. Epidemiological support of efforts to define the impacts of social determinants of ill health and other aspects of ill health that go beyond familiar patterns of disease and related discomforts, could be very helpful. Further, epidemiological analysis of the impacts of traditional medicines that are outside of the usual health care methods could be supportive of the integrative process.

III. Traditional medicine and health system and social development

Equity calls for consideration of a series of concepts relating to health care and determinants of health. We need to ask what aspects of modern or conventional medicine are to be the objects of the integrative process? Given our concern that people benefit from traditional medicine as it moves ahead in this integrative process, we must turn our attention to those aspects of conventional health care systems that can be supportive of traditional medicine and its approaches.

Here we will focus on a series of issues that guide us toward better understanding of the place of PHC -- past, present and future -- and how it relates to the larger health system context in which it functions, keeping in mind the global reach. Those issues will include the origins and evolution of PHC beginning with Alma-Ata.

A. The Place of PHC

For the moment, let us switch back to the formal origins of PHC -- Alma-Ata, 1978. There we put it this way: PHC is essential health care based on practical, scientifically sound and socially acceptable

methods and technology, made universally accessible to individuals and families in the community through their full participation, and at a cost the community and the country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. Alma-Ata 1978 (11).

A fine way to reflect on the origins of PHC and its subsequent pathways is to turn to the International Meeting to Celebrate 20 Years After Alma Ata, held in Almaty (same city, different name), Kazakhstan, November, 1998. That meeting included a number of the original participants (Halfdan Mahler, Jo Asvall, Carl Taylor, Jack Bryant, and more!), and the report of the meeting is a fine rendering of the recollections and prospects relating to PHC and Health for All (HFA) (12).

A consensus statement of the participants captures important insights and feelings.

We, the participants of the international meeting "Primary Health Care 21", reaffirm our belief in the values of equity, participation and intersectoral development which are expressed in the 1978 Declaration of Alma Ata. They are as valid today as they were twenty years ago. We also believe that the understanding and implementation of PHC needs to be revitalized in view of the changes taking place on the threshold of the 21st Century. The challenge will be to operationalize the values of Alma-Ata by developing, on the one hand, sustainable health systems for managing PHC and by establishing, on the other hand, complementary systems for governance that will ensure equity and intersectoral response to health needs of people, effectively uniting PHC and HFA.

The meeting gave rise to a Contextual Overview, which can be usefully summarized:

The insights into health problems and societal responses as seen in 1978 were strikingly accurate, and the proposed solutions have proven to be highly appropriate, namely:

- * The critical place that human values would play in the pursuit of HFA and PHC, such as equity, fairness and gender sensitivity;

- * The importance of having accurate information regarding the nature of the problems and the effectiveness of responses;
- * The importance of community participation as essential to health care that would improve the health and well being of those communities;
- * Weaknesses in health systems research and the needs for building research capacities, particularly for reaching toward the needs of the poor.

Not surprisingly, however, some problems of the time were less apparent and came more fully to light as the struggles to pursue HFA and PHC moved onward. As examples:

- * The limitations of governmental capacity to absorb and carry forward comprehensive approaches to health care;
- * The notions of health services being interactive with other sectors, moving onward to advanced concepts of intersectoral action, expressing a key characteristic of PHC as the centerpiece of health development;
- * Social and cultural parameters, often locally unique, involved in identifying and responding to health problems of particular societies;
- * The ways in which the challenge of incorporating PHC into health systems enlarged to encompass needs for health care reform in virtually every nation, whatever its level of development.

Turning to another dimension in this historic sequence of global change, there **were other problems in the health sector that were largely beyond the range of predictability**. As examples:

- * Emerging and re-emerging diseases, such as HIV/AIDS;
- * Dramatic advances in market orientation and information technologies have led to globalization of interactions across the world, benefiting some immensely but aggravating inequities for others;
- * The shift in political tensions between the larger powers to armed

conflicts at local levels with widespread civil disobedience emerging as threats to peace and human well-being;

- * In increasingly pluralistic societies, the call is for PHC to be designed to embrace the major components of life styles, environment and health care issues -- as through society-wide movements focused on settings-based programs such as schools, workplaces and cities.

Still another important advance relating to PHC is being undertaken by WHO. The initiating step is from WHO-HQ, entitled Primary Health Care Review -- An Issue-Raising Report: A Framework for Regional Workshops Regional Workshops (13). The contextual issues are summarized in the Director Generals statement to the Executive Board in January 2000:

“Primary Health Care is an important feature of the health system. Over the years, it has drawn attention to the needs of the many, and has been a powerful instrument for making governments and their partners recognize that the provision of health care cannot be left to the professionals alone. Our focus on the diseases of the poor and our work on health systems is consistent with the messages of Primary Health Care. But many countries face new economic, institutional and social challenges. Over the course of the next year we will be carrying out a review which will focus on the challenges to Primary Health Care in the changing context of international health.”

Along side PHC is another movement of growing importance -- the growing recognition of the increasing burden of chronic conditions in the populations of both developed and developing countries. Accordingly, health services must undergo major changes in order to bring relevant care to those so afflicted. We must ask how traditional medicine might relate to that process, and what are the implications for equity?

B. Innovative Care for Chronic Conditions

WHO has recently published a monograph - Innovative Care for Chronic Conditions: Building Blocks for Action, A Global Report (14) -- that calls attention to a problem of great seriousness. It is basically

that the management of chronic conditions - non-communicable diseases, long-term mental disorders, and certain communicable diseases, such as HIV/AIDS - is one of the greatest challenges facing health care systems throughout the world. Currently, chronic conditions are responsible for 60% of the global disease burden. They are increasing such that by the year 2020, developing countries can expect 80% of their disease burden to come from chronic problems.

In developing countries, most persons with chronic conditions seek care at the primary health care level, yet most primary health care is oriented toward acute and episodic care. An evolution of primary health care is imperative. To successfully manage chronic conditions, care must be more strongly oriented toward the care and support that can be provided by families and communities, and by the patients themselves. The WHO monograph is well structured in its recommendations and interest in supporting these directions of change.

There are eight essential elements for taking action. After reviewing these, we can consider where traditional medicine could serve in supportive roles:

* **Support a paradigm shift.**

Through innovation, health care systems can maximize their returns from scarce and seemingly non-existent resources by shifting their services to encompass care for chronic conditions.

* **Manage the political environment.**

Policy making and service planning inevitably occur in a political context. For transformation toward care of chronic conditions to be successful, it is crucial to initiate bidirectional information sharing and to build consensus and political commitment among stakeholders at each stage.

* **Build integrated health care**

Health care must guard against fragmentation of services. The outcome of integrated services is improved health, less waste, less inefficiency and a less frustrating experience for patients.

* **Align sectoral policies for health**

In government, diverse authorities create policies and strategies that affect health. The policies of all sectors need to be analyzed and aligned to maximize health outcomes.

* **Use health care personnel more effectively**

Health care providers, public health personnel and those who support health care organizations need new team care models and evidence-based skills for managing chronic conditions. Advanced communication abilities, behavioral change techniques, patient education, and counseling skills are necessary in helping patients with chronic problems.

* **Center care on the patient and family**

Because the management of chronic conditions requires lifestyle and daily behavioral change, emphasis must be upon the patient's central role and responsibility in health care. At present, systems relegate the patient to the role of passive recipient of care, missing the opportunity to leverage what he or she can do to promote personal health.

* **Support patients in their communities**

Health care for patients with chronic conditions does not end or begin at the doorway of the clinic. It has to extend beyond clinic walls and permeate patients living and working environments. Patients and their families need services and support from their communities.

* **Emphasize prevention**

Most chronic conditions are preventable. Additionally, many of the complications of chronic conditions can be prevented. Prevention should be a component of every health care interaction.

It becomes immediately clear that traditional medicine can fit into a number of the above essential elements. Traditional medicine represents additional and underused resources for health care. It will fit well into the integrative process that is being called for, and it can

readily reach across sectors. Traditional medicine practitioners can be integrated with those of conventional medicine, and be a part of creating new health care models. With conventional medicine it can extend health care to patients, their families and communities. And preventive actions are among traditional medicines special strengths.

Thus, WHO's call for substantial changes in support of improved care for chronic conditions can be effectively linked with parallel efforts to strengthen traditional medicine and pursue a strategy of integration with conventional medicine.

We can add, in passing, that incorporating concepts related to equity can add further strengths to these processes.

IV. New Tools to Strengthen Health Systems

PHC is not the sole object in the search for effective health services that can be supportive of the inclusion of traditional medicine. There are other tools and methodologies that facilitate and support the functions of PHC and other levels of care. So we will consider some tools that are important and relevant.

- * One tool is WHO's own process of Strengthening Health System Performance, which can be linked with its current effort to bring new dimensions to PHC.
- * Another tool is the Global Health Equity Initiative, which brings fresh approaches to ensuring equity, particularly in poor populations.
- * Still another tool would be Benchmarks of Fairness for Health Care Reform, which seeks to ensure fairness at the level of policies and their implementation in health care and other approaches to enhancing health.

A. WHO's Framework for Assessing Health System Performance

Here we introduce WHO's Framework for Measuring Health System Performance. A fresh conceptualization of health, it is described in the Bulletin of the World Health Organization (15) and elaborated in WHO's World Health Report 2000 (16). It has generated considerable debate on its methodology for international comparisons

of health attainment. It also represents an encompassing perspective of the function of health systems at the national level.

World Health Report 2000 presents a conceptual description of the Framework, including the statistical base for national indices, along with detailed descriptions of health system realities. It provides defining goals of the health system including:

- * Improving health of the population, both the average level and the distribution of health.
- * Enhancing responsiveness of the health system to the expectations of the population -- the average level of responsiveness and its distribution.
- * Fairness in financing and financial risk protection for households.

Pursuing these goals gives rise to three critical concepts:

- * Quality -- the level of goal attainment for health and responsiveness.
- * Equity -- fair distributions of health, responsiveness and financial burdens.
- * Efficiency -- achieving the socially desired mix of the goals compared to available resources.

Stewardship is a key factor in defining strategic directions for the entire health system. It focuses on the changing role of the state in health system development, and includes the notion of good governance and policy making that serves the public interest

We see PHC, with its capacity to reach out to entire populations with basic services and participatory interactions as being foundational for the WHO Framework. Having said that, we also see ways in which traditional medicine could strengthen the framework, particularly through its integration with conventional medicine. As an example, the criterion of enhancing responsiveness of the health system to the expectations of the population would be an area of strength of traditional medicine. Contributions to quality, equity and efficiency could be there as well.

B. Challenging Inequities in Health

Given our concern for the place of equity in the applications of traditional medicine, it is useful to call attention to the Global Health Equity Initiative (GHEI). This is an excellent resource for considering the interactions of equity and traditional medicine. Motivated by a common concern regarding unacceptable differentials in health, what was a small initial international collaboration in 1996 evolved into the Global Health Equity Initiative (GHEI). This network links over 100 researchers from more than 15 countries who are unified by their interest in finding way to address inequities in health. The GHEI, funded by the Rockefeller Foundation and Swedish International Development Agency (SIDA), represents a concerted effort to ensure that health equity research is undertaken by researchers within countries most affected by inequities in health. An early phase of this work of the GHEI had five aims:

- * To articulate the concepts and values underlying equity in health.
- * To develop measures and tools for health research and policy to help analyze equity and inequity in health.
- * To encourage empirical research on health inequities within countries in the developing world.
- * To establish a scientific foundation for proactive advocacy, policies and programs.
- * To stimulate action to reduce inequities in health in all levels of society, by providing decision makers with knowledge and con-creted suggestions for change.

A key product of GHEI is this splendid book - *Challenging Inequities in Health - From Ethics to Action* (1). Other publications are to follow.

There are at least three main features that make the GHEI distinctive over and above the wide range of countries and the large number of international researchers involved:

- * The participants in the Initiative share common values and concerns about equity, an interest that drew many to the Initiative in the first place.

- * The country studies have been undertaken by study teams within each of the countries rather than by Northern “experts” parachuted in from the outside.
- * The participants in the Initiative, through a mutually supportive network, have been able to engage in an ongoing dialogue on the multiple complex dimensions of health equity analysis.

The concluding chapter of the book provides a policy-oriented overview of the whole process from ethics to action. Given the global nature of the Initiative, this incorporates an important section on how the international agencies could work together to challenge these unacceptable inequities in health.

C. Benchmarks of Fairness for Health Care Reform

In considering the place of traditional medicine in an integrated relationship with conventional medicine and the challenges of meeting the health needs of deprived populations, the notion of fairness has a central importance.

Norman Daniels, philosopher at Harvard University in Boston, has long been concerned with interactions of justice and health. His writings have included *Just Health Care*, *Am I My Parents Keeper?*, and *Seeking Fair Treatment*. In 1996, working with the Clinton Task Force on Health Care Reform, he and colleagues published *Benchmarks of Fairness for Health Care Reform*, 1996. (17).

Fairness is a many-sided concept, broader than the concept of equity, including:

- * Equity in health outcomes, in access to all forms of care, and in financing;
- * Fairness also includes efficiency in management and allocation, since when resources are constrained their inefficient use means that some needs will not be met that could have been;
- * For the public to have influence over health care, fairness must also include accountability;
- * Finally, fairness also includes appropriate forms of patient and provider autonomy.

While health care reform in the U.S. has (sadly) remained somewhat stagnant, the Benchmarks attracted the interest of a number of persons interested in justice and health in developing countries. Over the past two years, a cluster of colleagues from Asia, Africa and Latin America have been working toward adapting the Benchmarks to the realities and needs for reform in those countries. Those experiences are described in an article in the Bulletin of WHO, Benchmarks of fairness for health care reform: policy tool for developing countries (18).

The Benchmarks are seen as promoting change related to fairness at local and national levels through policy change. There are nine benchmarks.

- 1 - Intersectoral public health
- 2 - Financial barriers to equitable access
- 3 - Non-financial barriers to access
- 4 - Comprehensiveness of benefits and tiering
- 5 - Equitable financing
- 6 - Efficacy, efficiency and quality of health care
- 7 - Administrative efficiency
- 8 - Democratic accountability and empowerment
- 9 - Patient and provider autonomy

While this is not the place for detailed discussion of the Benchmarks, the point can be made that the intent is not to provide a blue print for health care reform calling for insistent action following a fixed pattern. Rather, the Benchmarks are seen as a tool for facilitating deliberation and reflection on reform options.

The following are abbreviated examples of emphases drawn from four of the Benchmarks.

1. Intersectoral public health

- * Basic education and health literacy
- * Information infrastructure for monitoring health status inequalities
- * Improvements in social determinants of health

3. Non-financial barriers to access

- * Reduction in geographical maldistribution
- * Reduction in gender and cultural discrimination

6. Efficacy, efficiency, quality of health care

- * Focus on Primary Health Care with community participation
- * Implementation of evidence-based practice

8. Democratic accountability and empowerment

- * Explicit procedures for resource allocation with transparency
- * Strengthening civil society and advocacy groups

Reflecting for a moment on some of the most serious aspects of poverty and despair, it is to be noted that the Benchmarks reach well beyond the health sector as such, calling for assessment of fairness across sectors and with respect to social determinants of health.

A further aspect of using the Benchmark includes scoring of reform options in terms of their fairness. Employing a scale of -5.0 to +5.0, reform options can be judged according to the fairness of their assessed intent or impacts. The scoring is applied to national, district and local levels, and it is important that the scoring be built upon evidence-based indicators.

Reflecting on the Benchmarks, it can be seen that traditional medicine could have a place in actions related to fairness in dealing with policy changes that could benefit deprived populations.

Plans are currently underway for applications of the Benchmarks to other countries in Latin America, Africa and Asia. These plans include the building of country and regional capacities to use the Benchmarks as a tool for facilitating health policies deliberation with the goal of enhancing fairness. A concern for the place of traditional medicine could be introduced into these considerations.

V. Concluding Reflections

There is no doubting the importance of seeking stronger interac-

tions and even integration of traditional medicines with modern or conventional medicine. At least three reasons are becoming apparent:

- * One is that the increasingly widespread use of traditional medicine calls for assessments of safety and efficacy of the interventions.
- * Another is that traditional medicines reach large numbers of people who cannot afford nor gain access to conventional medicines.
- * Still another is that traditional medicines respond to health needs that go beyond the responses of conventional medicine, to include such matters as mind, body and spirit. While these responses may be beyond what is scientifically evidence-based, there needs to be openness to the possibilities that these approaches are beneficial to human kind in ways that science has not yet been able to determine.

When we turn to the ethical content of traditional medicine, the applications of the principles of biomedical ethics apply fully as well to traditional medicine traditional medicine as to conventional medicines. The principles of autonomy, beneficence, non-maleficence and justice are relevant and supportive of traditional medicines. Equity has its place with traditional medicines as fully as it does with conventional medicines, possibly even more so, though with less rigorous methodologies to map its applications and outcomes.

Certainly, equity calls for care according to need, with special concern for those whose needs are greatest. Additionally, equity directs attention beyond access to care to health outcomes - are people better off in terms of health status?

Now we enter a somewhat shadowy arena, where science-based evidence may be only partially applicable or even absent. The evidence base for assessing the benefits of spiritual therapy, mental healing and meditation, is open to debate, and there are many other examples of traditional medicine that fall into this category of uncertainty.

There are other issues, such as social determinants of health, where science has defined critical aspects of the problem, but much remains to be done in better defining causative factors and healthful or

damaging outcomes. But, it is possible that traditional medicines have approaches to both causes and outcomes that are quite positive. Here is an example where both conventional and traditional medicines can usefully work together in combating one of the most serious problem areas of our world.

To reflect for a moment on the dynamics of integration of traditional medicine and conventional medicine -- each can gain from the other. Traditional medicine can absorb from conventional medicine an insistence on rigor in assessing efficacy and fairness. Conventional medicine can gain from traditional medicine a widening of its boundaries regarding what are acceptable factors in both interventions and benefits. Each can learn from the other and advance their perspectives on purpose and method in relation to the well-being of the people they serve.

Finally, it needs to be appreciated that these various efforts that would bring traditional medicine into integrative relationships with modern or conventional medicine cannot be seen as isolated efforts unrelated to other advances in the health sector. There are important initiatives underway, that have global importance, including WHO's efforts to advance the place of primary health care, and to grapple with the growing burdens of chronic conditions. There are new tools in this field -- including the Framework for Assessing Health System Performance, the Benchmarks of Fairness for Health Care Reform, and the Global Health Equity Initiative - that can advance health globally. But not if each functions in fragmented isolation from the others.

Step by step, an integrated system can emerge. Given this possibility -- at this time in our history of global health that is tinged with such inadequacy and uncertainty -- we believe it is reasonable to at least address the challenge of bringing these components together into some form of synergy and interdependence. Yes, it is time to generate an international determination to achieve a convergence of the best of current knowledge to shape the development of health systems and other approaches to improving the health of the worlds people. And it is reasonable to see the integration of traditional medicine and conventional medicine as a component of this global effort.

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ANNEX

Meanings of TM(CAM)

Here, our understanding of the meanings of these terms is as follows:

- * Traditional medicine (TM) includes diverse health practices, approaches, knowledge and beliefs incorporating plant, animal and/or mineral-based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to maintain well-being as well as to treat, diagnose or prevent illness. (4)
- * Complementary and alternative medicine (CAM) is increasingly used in parallel to allopathic medicine, particularly for treating and managing chronic disease (3). Some sources describe complementary and alternative medicines as different from one another: complementary medicine being used together with conventional medicine, as using aromatherapy to help lessen a patient's discomfort following surgery; alternative medicine being used in place of conventional medicine, such using a special diet to treat cancer instead of undergoing surgery, radiation or chemotherapy that has been recommended by a conventional doctor.
- * Here, we will use the term traditional medicine (TM), unless there are specific reasons for using the other terms.

DISCUSSION

Discussion of Eleventh Session

Ethical Issues

Chairman: Prof. Andrew T. Weil

Rapporteur: Prof. Ali Abdul Monem Mustafa

Prof. Andrew T. Weil: This is time for discussion. I would like to make a comment. One of the great problems facing the Aryurvedic Medicine Movement, I am involved in US, at the moment, generally we do not reimburse the insurance. So there is a tendency that the Ayurvedic Medicine is available only to those who are rich and it is also abnormal to see some of these Traditional Medicine Systems, other cultures coming to US. Being termed this way, Ayurveda, I think is a wonderful example. In India, Ayurveda is an affordable system that can be used by many people who don't have access to the allopathic medicine. In America, as it is becoming available, it is extremely expensive and available only to those who are very rich people, to go to Ayurvedic bars opened there.

Dr. Khalid Assiri: As a matter of fact, this last presentation let me to say that I have concluded two sorts of medicines based on ethics and non-ethics. Modern Medicine is based on; perhaps, non-ethical grounds in terms of equity. I will give you example with Malaria. Malaria costs so many lives, 300 million people can die under shadow of a tree, but because of Modern Medicine compelling not to resort to anything except active ingredients. These populations are deprived from medical therapy. There is something wrong ethically speaking, not in Alternative Medicine, but in Modern Medicine. Therefore, we have to correct it. We gave examples about AIDS for instance. AIDS strikes 14 million people. If we go back to ethics among populations, may be we can spare such populations. Lets take the conventional medicine doctors, these doctors compel patients to come to them first, but in the ethics of medicine, we start with nutrition, then with versato, then with compound versato and then we start with chemicals. So, where is ethics in that, if we compel all patients to go to Modern Medicine? Those cases that cannot be treated by Modern Medicine are treated by diets. So, it is not ethics against Alternative Medicine, but

an ethical problem against Modern Medicine. I would like to hear some comments about it.

Prof. Andrew T. Weil: Thank you for that comment. I feel that ethics training has to be integral part of all the institutions training physicians and at the every level of training. What is happening now, that I see in American schools some practice on ethics in first year and second year medical school and this is all forgotten as students go on to their researches. I think this needs to be built in every level. And when given special power as physicians are, I think there is with that responsibility and needs to be constant ethical training. You gave me this book “Islamic Code of Medical Ethics”. Traditional systems have a real developed code. I hope that talk rests on physicians training. Any one else would like to comment.

Dr. Narimah Awin: I think, we cannot deny the fact that there has been many failures of Modern Medicine.

- 1 - We have failed to find good technological intervention. Till today, we don't have vaccine.
- 2 - We have almost forgotten preventive care and looking at well-being in health and quality of life.
- 3 - There has been a forward professionalization and the clarification of the modern medical doctor and this was very eloquently illustrated by the Russian Writer Healing of Medicine “Healist”.
- 4 - We got failure because we have succeeded. We have so much succeeded in selling the lives of babies, then we have the ethical problems of how do we keep these babies free of mental retardation. We have met so much successes in lengthening of life, health of long life, so in keeping old people, we fail to keep them in a good quality of life. So, there are many reasons of failures due to the absence of ethics among modern practitioners of medicine.

So, the failure of Malaria Control, I would not say is a failure of ethics or modern medicine, it is a failure of us, Ministry of Health, Policy Makers of not assuring equity in health. But, I don't agree that failure in Malaria is due to the absence of ethics.

Dr. Assiri: The Malaria is an orphan disease. There are no investments on orphans. So, the companies took to give the medication. As you know some of the countries, the budget for each person per year is about US\$4/-, where is more equity, the cost is US\$60/-.

Dr. Narimah Awin: I think this is very accurate. As pharmaceutical companies are concerned, they have been totally unethical. These industries are unethical. We knew it from the beginning.

Dr. Saad Abdul Aal, Cairo: Thank you Mr. Chairman! I want to say just a word to my fellow colleague from Kingdom of Saudi Arabia talking about Malaria. I don't know if he knows that in 1995 WHO in Geneva offered a prize to a professor in Columbia called "Emanuel Patharoiu". He had invented a vaccine for Malaria in 1995. I was there as representative of my country. I have seen it with my own eyes. This inventor of vaccine had taken a big prize from WHO but since then unethically this innovation has been put into roads.

I want just to talk what I have concluded from all such discussions again as a Pediatrician. Let me tell you Traditional Medicine and Modern Medicine for me is like breast-feeding, naturally and artificially feeding with milk substitute. In breast-feeding, there is something so divine that mother can eat acceptable infectious foods, but milk comes out in a very natural and clean way. It reminds me a citation: to eat is human but to digest is divine. Now, with this Traditional Medicine, I believe that we have to consider this spiritual divine factor that we can take the plants with an acceptable elements of risk, but still it will be an immuno-enhancer for the poor and healthy people. I am concerned about the children. Healthy child, poor child is so compatible with the Traditional Medicine and then with Modern Medicine. We had a big debate about integration. Yes, I would use integration, but integration of Modern Medicine to the primary authentic medicine. We don't have enough time to have such a fight between Modern and Traditional Medicine.

Prof. Andrew T. Weil: That reminds me of, I saw recently in a medical publication that showed two doctors in white coats walking in front of big medical institution and one is saying to the other "What is mean, we are becoming the alternative". Yes, next please.

Participant: My question is to Dr.Awin. It is about training. When do you finish the training on CAM? Whom you send to get trained under Higher Education Ministry? Who checks on their skills? How the product is evaluated? Then those come out of these schools, how they are evaluated that they will maintain or keep enough skills to deal with patients?

Dr. Narimah Awain: Right now, we have the system where practitioners themselves are in need of colleges and schools that are accredited. That's why we are trying to help them coming with the system. The Homoeopath has already a school in Malaysia. And he was training for the last 12 years, he does not know the school was illegal. When I brought him in the National Accredited Council to advise him how to have accreditation to his school, he has never been registered in Ministry of Education. So, the physicians are coming from Beijing, China. They just practice, but there is no system. What I am trying to encourage is you to do among yourself sub-registration, sub-regulation and sub-sanction. You decide who can be registered, but because they are very new in the process, they become nervous, we have to keep them with much encouragement. So, the Ministry of Health, Ministry of Education, universities, nobody looks in that. But for the future, we may have modalities. Now, the modality is sub-regulation.

Participant: The reason I raised this issue, when we talk about ethical dimension, it is always focused on the practice. And the relation between the practitioner and the patient or whatever else the issue, but we neglect the ethical issues of educating those people. The institutions are ethically responsible to guarantee the quality and the skills of product. This is always ignored and we always think how to treat other people, that we are dealing with which people, who are dealers, who are the practitioners, they have to have an ethical self-critic sort of stand.

Prof. J. H. Bryant: Let me to comment briefly on medical national education in ethics. In Aga Khan University, we recognize the importance of this and university is said to do it. Then we realized afterward. Firstly, you teach the technical problem based in physiol-

ogy, biochemistry or whatever, then they begin to apply these ethical principles. They began to take new stands on different issues of patient care, hospitals etc. Thus, the university has ethical perspective.

Dr. A. R. Al-Awadi: The ethical issue, which Prof. Bryant is very broader. It is a big challenge in ethics. Until you know the rights as human being, you cannot be somewhere in ethical boundaries. I think we must be very careful to have a look on the ethical problem.

Prof. Andrew T. Weil: I want to thank all the panelists. This was a wonderful discussion.

Papers Submitted, But Not Presented in the Conference

1 - Policies and programmes of integration and mainstreaming of indigenous systems of medicine in india

by Prof. Anis Ahmad Ansari, India

2 - Preserving and protecting traditional medicinal knowledge

by Dr. Xiaorui Zhang, Switzerland

**POLICIES AND PROGRAMMES
OF INTEGRATION AND
MAINSTREAMING OF INDIGENOUS
SYSTEMS OF MEDICINE IN INDIA**

Prof. Anis Ahmad Ansari

(India)

POLICIES AND PROGRAMMES OF INTEGRATION AND MAINSTREAMING OF INDIGENOUS SYSTEMS OF MEDICINE IN INDIA

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Indian cultural heritage is enriched with the presence of well established indigenous system of medicine, like, Ayurveda, Unani, Siddha and drug less therapies like Yoga and Naturopathy, these were the only streams of Health Care in Pre-British India.

Ayurveda developed from the hymns of Atharvaveda (an ancient book of India wisdom and culture) having a positive concept of health maintained through the equilibrium of humours (body fluids). Unani system of medicine originated in Greece developed by Arabs and Iranian physicians and finally by the Indian physicians. Siddha is also the oldest system developed in southern part of India followed by Siddhars (saints) who understood the correlation between human body and mind during health and illness. Homoeopathy which developed in later part of 18th Century in Germany has also been accepted as a System of Medicine in health care. Yoga which is as old as Ayurveda, described various physical postures to prevent diseases and to cure illness, and also advocates Meditation which regularises emotional changes and prevent abnormal functions of vital organs of the body and stabilises relation with body and soul (God). Naturopathy is based on the application of simple laws of nature in eating, living habits, use of hydrotherapy, cold packs, mud packs, massage, etc.

In a post-independence India, the Government recognized the merit of each of the Indian System of Medicine, and was felt that the goal of the World Health Organization of Health for All cannot be achieved through the modern Allopathic System alone and there is need to involve the Ayurveda, Unani, Siddha and Homoeopathy practitioners in the national mainstream for achieving this goal. This recognition has paved the way for the organized development of all these systems of medicine, each on

the basis of its own individual philosophy, merit and strength. These systems use plant-based drugs though drugs of minerals and marine origin are also used. Due to Broad based policy support of our Govt. a good institutional frame work exists.

INSTITUTIONAL FRAMEWORK

Department of ISM&H: Created in 1995 under Ministry of Health and Family Welfare. The Secretary ISM&H is the Head and following Institutions are governed by the Secretary.

- i) Statutory Regulatory Councils.
- ii) Research Councils
- iii) National Institutes
- iv) Pharmacopoeial Laboratory of Indian Medicine (PLIM).
- v) Homoeopathic Pharmacopoeia Laboratory (HPL).
- vi) Manufacturing Units.
- vii) Medicinal Plant Board.

STATUTORY REGULATORY COUNCILS.

- viii) Central Council of Indian Medicine (CCIM)
- ix) Central Council of Homoeopathy (CCH)

These Councils prescribe course curricula evolve and maintain standard of education and maintain Central Registration of the Physicians of their systems.

EDUCATION FACILITIES AVAILABLE UNDER INDIAN SYSTEM OF MEDICINE & HOMOEOPATHY

Name of the system	Under Graduate College	Admission capacity	Post Graduate College	Admission capacity
* Ayurveda	173	6300	44	437
* Unani	24	1252	5	55
* Siddha	6	200	2	24
* Homoeopathy	118	5357	10	99
Total	321	13109	61	615

MEDICAL CARE, MEDICAL MANPOWER & MEDICAL FACILITIES AVAILABLE UNDER INDIAN SYSTEM OF MEDICINE & HOMOEOPATHY

Name of the system	Facilities		
	Hospital	Beds	Dispensaries
* Ayurveda	2189	33145	14252
* Unani	189	4157	966
* Siddha	204	1681	357
* Yoga	8	201	42
* Naturopathy	21	733	55
* Homoeopathy	243	9436	7037
Total	2854	49353	22735

REGISTERED PRACTITIONERS UNDER INDIAN SYSTEM OF MEDICINE & HOMOEOPATHY

System of Medicine	Institutionally Qualified	Total
> Ayurveda	270349	366812
> Unani Medicine	19685	40748
> Siddha	2577	12911
> Naturopathy	353	402
> Homoeopathy	106723	188527
Total	399687	609400

CENTRAL RESEARCH COUNCILS

- A - Central Council for Research in Ayurveda and Siddha (CCRAS)
- B - Central Council for Research in Unani Medicine (CCRUM)
- C - Central Council for Research in Homoeopathy (CCRH)
- D - Central Council for Research in Yoga and Naturopathy (CCRYN)

These Councils are engaged in conducting clinical research in healthcare, drug research covering survey and cultivation of medicinal plants, pharmacognosy, phyto-chemistry, pharmacology, toxicology, drug standardization, literary research for revival of the ancient, classical literature and research in ante-natal and post-natal care and the development of contraceptive drugs.

NATIONAL INSTITUTES

- * National Institute of Ayurveda, Jaipur
- * National Institute of Homoeopathy, Kolkata
- * National Institute of Unani Medicine, Bangalore (under establishment)
- * National Institute of Siddha, Chennai
- * National Institute of Naturopathy, Pune
- * Morarji Desai National Institute of Yoga, New Delhi
- * Rastriya Ayurveda Vidyapeeth, New Delhi
- * Institute of Postgraduate Teaching & Research, Jam Nagar.

DRUG REGULATION

- * Drug and Cosmetic Act 1940 amended 1982, 1986 and 1995.
- * Drug & Magic Remedies (Objectionable advertisement) Act. 1954 & 55.
- * Drug Technical Advisory Board for ASU
- * State Drug Licensing Authorities
- * Good Manufacturing Practices (G.M.P) enforced by an act of Parliament for Ayurveda and Unani manufacturing companies to ensure quality control of their products.
- * Ayurvedic, Unani and Siddha Pharmacopoeia Committees.

NATIONAL PHARMACOPOEIAS & FORMULARIES

Ayurveda	Pharmacopoeia	Volume -I	80 drugs
		Volume-II	78 drugs
		Volume-III	100 drugs
	Formularies	Volume-I	441
		Volume-II	202
Unani	Pharmacopoeia	Volume-I	45 drugs
	Formularies	Volume-I	441
		Volume-II	202
		Volume-III	103
Siddha	Formulary	Volume-1	248

MANUFACTURING UNITS

To meet the demand of drugs, there are about 10,000 Ayurveda, Unani, Siddha and Homoeopathy licensed pharmacies in India most of them are in Private Sector and some are in Central and State Government Sectors.

Licensed Pharmacies in India	
Ayurveda	8533
Unani	462
Siddha	385
Homoeopathy	613
Total	9992

ISM Industry - At a Glance		
* Rs.4200 crore Industry (Rs.3500 in Ayurveda)		
* 7000 manufacturers of Ayurvedic products		
- Large	> 50 cr	10
-Medium	5-50 cr	25
- Small	1-5 cr	965
- Very small	> 1 cr	6000

MAIN STREAMING IN HEALTH CARE

To cater health care of the people at Primary health care level all four systems are contributing significantly

All four systems have specific strengths to offer good treatment at secondary level Health Care. Ayurveda offers effective remedies for liver disorders, arthritis, skin diseases, cardio vascular problems; Unani has effective remedies for liver, skin, metabolic disorders, Arthritis, Bronchial Asthma etc. Homoeopathy has excellent remedies for blood related problems, venereal diseases, cataract and hair loss etc.

Central Government, to provide comprehensive medical care to their employees under the Central Government Health Scheme (C.G.H.S) allopathic dispensaries were opened in 1954, but after 10 years, on the demand of employees, 80 Ayurveda, Unani, Siddha and Homoeopathy dispensaries are opened till now in various big cities of the country.

1.	Ayurveda Hospital	1
2.	Ayurveda Dispensaries	5
3.	Ayurveda Units	26
4.	Homoeopathic Dispensaries	3
5.	Homoeopathic Units	31
6.	Unani Dispensary	1
7.	Unani Units	8
8.	Siddha Units	2
9.	Yoga Units	3
	Total	80

To meet the demand of the public and to promote the Indian Systems of medicine and Homoeopathy the Government of India opened speciality clinics of Ayurveda, Unani, and Homoeopathy at Central Government allopathic Hospital in New Delhi. The popularity of these clinics is increasing day by day. This is evident from the increasing number of the patients availing the facility in these clinics. The figures are as under:-

	1998-1999	1999-2000	2000-2001
RML Hospital (Unani)	52,145	60,618	58,453
Safdarjung Hospital (Ayurvedic)	20,488	23,389	18,136
Safdarjung Hospital (Homoeopathy)	23,618	26,085	24,960

It is an established fact that people in India have good faith in these time tested and cost effective remedies which are safe and effective in various common diseases caused by the modern lifestyle.

**PRESERVING AND PROTECTING
TRADITIONAL MEDICINAL
KNOWLEDGE**

Dr. Xiaorui Zhang

(Switzerland)

PRESERVING AND PROTECTING TRADITIONAL MEDICINAL KNOWLEDGE

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I. Definition of Traditional and Complementary/Alternative Medicine (TM/CAM)

Traditional medicine is defined by the WHO as including the diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness. In countries where the dominant health care system is based on modern Western medicine or where traditional medicine has not been incorporated into the national health care system, traditional medicine is often termed “complementary”, “alternative” or “non-conventional” medicine (CAM).

II. Current global situation of TM/CAM

Despite limited evidence of efficacy, traditional and complementary/alternative medicine is used for the full spectrum of diseases from self-limiting to life-threatening illnesses. Some herbal medicines and TM/CAM therapies have been investigated for their clinical efficacy and the reports of these investigations have been published in prestigious international scientific journals. The efficacy of acupuncture in relieving pain and nausea, for instance, has been conclusively demonstrated and is now acknowledged worldwide.

A Roll Back Malaria survey reported that in Ghana, Mali, Nigeria and Zambia, the first line of treatment for more than 60% of children with high fever is the use of herbal medicines at home. Surveys show that over three-quarters of AIDS patients in Africa, North America and Europe use traditional or complementary medicine for various

symptoms or conditions. Worldwide, TM/CAM is often used to treat chronic pain and to improve the quality of life of those suffering from incurable diseases. In Africa, up to 80%, and in India, 65% of the population depend on traditional medicine to help meet their health care needs. Traditional medicine and complementary/alternative medicine are also popular throughout Asia and the Americas. In many developed countries, certain complementary and alternative medicine therapies are popular; the percentage of the population that has used complementary and alternative medicine at least once is 48% in Australia, 70% in Canada, 70% in USA, 40% in Belgium and 75% in France.

In trying to explain the high use of TM/CAM in both developing and the developed world, it becomes clear that consumers often believe strongly in the efficacy of TM/CAM therapies. Surveys of consumers and patients who have used TM/CAM treatment in different countries showed that, in the Belgium, 77% of patients were satisfied with TM/CAM treatment. In a similar study in Denmark, 77% of TM/CAM patients considered themselves to be cured, while only 17% experienced no effect and 1% reported the worsening of symptoms. In a study in Viet Nam, TM/CAM therapies were considered to be 100% effective, but slower than Western medicine. In USA, 66% of women have confidence in the safety of herbal medicines and 37% of women assume some effectiveness of herbal medicine. The same survey even showed that 57% of doctors believe herbal medicines can provide some benefits. Additionally, scientific data also showed efficacy of some herbal medicines. A summary of a few of the randomised clinical trials of TM/CAM therapies showed benefits in 34% trials as compared to the placebo control groups.

The global and national market sales for herbal medicines show rapidly growth. According to the Secretariats of the Convention on Biological Diversity (CBD) report there was US\$60,000 million sales in the world herbal medicines market in 2000. In Japan, sales of herbal medicines totalled US\$1,000 million in 1991, US\$2,000 million in 1994, US\$2,200 million in 1996 and US\$2,400 million in 2000. In the United Kingdom, herbal sales totalled US\$92 million in 1994, US\$134 million

in 1998, US\$159 million in 2000 and it was expected to be US\$184 million in 2002. In United America, the sale of herbal medicines totalled US\$1600 million in 1994, US\$3,000 million in 1997, US\$4,400 million in 1999 and US\$5,400 million in 2000.

III. Integration of traditional medicine into national health care systems

Policy and regulation are crucial to defining the role of TM/CAM in national health care delivery systems, ensuring the creation of regulatory and legal mechanisms for promoting and maintaining good practice, and stimulating research and education efforts. Policies are also needed in order to respond to issues concerning protection of indigenous traditional medicine knowledge and protection of natural resources (such as medicinal plants) used in TM/CAM products. As of 2000, only 25 of WHO's 191 Member States have developed national TM/CAM policies and only 70 countries have established regulation on herbal medicine.

There are four main systems of national policy on Traditional, Complementary and Alternative Medicines: Integrative, Inclusive, Tolerant and Exclusive. According to the WHO strategy, integration means that traditional medicine has been officially recognized and they have been completely incorporated into all areas of the health care system, including national policy, regulation and registration of practitioners and remedies, practice in all levels and health insurance coverage, as well as research and education. Worldwide, only four countries have reached integration level: China, The Republic of Korea, the Democratic Peoples Republic of Korea and Viet Nam. While countries with exclusive systems in which there is no legal recognition or regulation of TM/CAM are decreasing in number, most countries adopt Inclusive or Tolerant systems for TM/CAM.

Two years ago, a survey on regulation of herbal medicines was conducted in 23 EMRO Member States and responses received from 13 countries. A review of the regulatory situation of herbal medicine in Member States in WHO EMRO showed that five of the 23 countries have a national policy on traditional medicine. There are eight countries that have regulation for herbal medicines, and in nine

countries herbal medicines are sold legally without registration/market authorization; in five countries, there are national research institutes of herbal medicine. In addition, five countries intend to establish national regulation for herbal medicine.

Kuwait is the first EMRO Member State to recognize the Islamic medicine in its constitution and set up the regulation of herbal medicines separate from that for conventional medicines. In 1984, Islamic medicine was recognized by the Constitution of the State of Kuwait. In the law, it described clearly that "An organization for 'Islamic Medicine' called 'The Islamic Organization for Medical Sciences' shall be established, having its own identity and independence, for which the State of Kuwait is the Residency. It might establish centres for research and study in or out of Kuwait and shall function according to its constitution that will be issued by an Amiree Decree. The law also states that "Ministers, each within his Jurisdiction, shall see to the implementation of this Decree, effective on date of its publication in the official gazette." In 1986, the law of herbal medicines was established. It supports the development of the safety and quality aspects of herbal medicine. The Islamic Medicine Centre was established in 1985.

In the United Arab Emirates, there is a long history in the use of traditional medicine, to which the government has paid attention to researching. His Highness Sheikh Zayed Bin Sultan Al Nahyan felt deeply that despite all the recent developments in the modern health care system available to the people of UAE, there is need for a Research Centre that deals exclusively with herbal and traditional therapy. The Zayed Complex for Herbal Research & Traditional Medicine (ZCHRTM) was established in 1996. The major mission of the Zayed Complex is to use traditional medicine therapies and herbal medicines in treating the common diseases; to produce new and known herbal medicines in different dosage forms through research and development; to collect, record and analyze the traditional medicine knowledge from traditional practitioners; to do laboratory research in testing the safety, efficacy and quality of traditionally used herbal medicines; to assess the quality control studies of the crude and

finished herbal products to be registered at United Arab Emirates. The Centre also supports the Department of Drug Control of Ministry of Health to develop the regulation for herbal products and also to test registered herbal medicines.

Iran has its long history of Iranian and Islamic traditional medicine and has rich resources of medicinal plants. According to the Government of Iran, it is estimated that there are more than 8 000 medicinal plants in the country. In seven provinces, the faculties of pharmacy are conducting research in medicinal plants. There are 30 pharmaceutical companies producing herbal medicines: 20 of these produce herbal products and 10 produce only tea bags or raw materials of herbs. Some of them produce both herbal products and chemical drugs.

In Jordan, the health authorities are taking action to ensure the safety and efficacy of traditional medicine. Currently the government of Jordan is focusing on the regulation of herbal medicines as a high priority and has drafted requirements for the registration of herbal medicines. In 1990 the Expert Committee was established and drafted requirements for registration of herbal medicine. In 1996, the committee formulated guidelines and rules for herbal medicines and preparations. Since 1999, the herbal medicines have to be approved by the herbal medicine committee. In recent years, the governments of Gulf countries are also very interesting to develop their national regulation of herbal medicines. The Secretariat of the Gulf Countries Committee is developing the guidelines for regulation of herbal medicines.

IV. Impact of globalisation on traditional medicine

Beyond the high level of use as primary forms of health care, traditional knowledge, particularly the traditional medicine knowledge (TMK) is beginning to be seen as having potential economic and trade value. Meanwhile, given the pace at which cultures, lifestyles and communities are changing, the need to preserve and protect traditional medicine knowledge has become increasingly evident. The issues surrounding the protection of traditional knowledge, including TMK, have become central to a number of international organizations and governing bodies, including the World Trade Organization (WTO), the

World Intellectual Property Organization (WIPO), the United Nations Conference on Trade and Development (UNCTAD), the Convention on the Treaty on Biodiversity (CBD) and the World Health Organization (WHO).

The issues surrounding the preservation and protection of indigenous traditional knowledge are complex, and involve numerous stakeholders, including communities, indigenous groups, political figures, national governments and international organization. The development of appropriate forms of protection of traditional knowledge, including intellectual property rights, has the potential to facilitate formal recognition of the value of TMK, stimulate evidence-based research in traditional medicine and to determine precisely the way to avoid unauthorized appropriation.

V. Protecting Traditional Medicine Knowledge

The need to establish adequate systems and mechanisms for the preservation of traditional medicine knowledge is clearly essential. However, there are also some risks associated with the development of legal protective systems like intellectual property rights in that these may limit rather than enhance access to TMK at the local level, conflicts may arise between individuals and communities over ownership and benefits may accrue only for individuals and not for communities. Furthermore, the processes involved in intellectual property rights are costly and complex; obtaining the patent right requires research to prove the function of innovation from the TMK as well as the funds to obtain legal counsel and maintain rights over time. The acquisition of IPRs also may prove very difficult in regions where traditional medicine has not been legally practised. Also, the popular use of TMK and traditional therapies entails that identifying the founders of therapies and medicinal plant uses are next to impossible, especially given the fact that popular use is often not bounded by national territories. Thus, a similar technique or medicinal substance may be used for similar illnesses across national, regional, and ethnic boundaries.

The protection of TMK under IPR raises many questions as to the

most appropriate legal framework for ensuring that TMK is protected and equity in access to TM/CAM is established and preserved. An important question is the extent to which TMK may be protected by existing or new IPR systems. There have been many proposals to develop *sui generis* systems of protection. Such proposals are often based on considerations of equity: if innovations in the formal system of innovation receive compensation through IPRS, holders of TMK should be similarly treated.

The main reasons that have been suggested for the protection of TMK are the need to preserve the knowledge against erosion, to prevent misappropriation and to promote self-determination. However, IPRs are not an end in itself; establishment of IPRs should be considered as a means to effectively reach well-defined goals. Besides intellectual property rights, other methods and regimes could be used for protection of traditional medicine knowledge such as developing national policy and regulation of traditional medicine, developing the national inventory of medicinal plants with their use, recording traditional medicine knowledge and setting up the *sui generis* (contractual and voluntary systems)

In recent years, the Member States in WHO Eastern Mediterranean region have taken alternative approaches to preserve and protect their traditional medicine knowledge for safe and effective use. Some states have taken steps to preserve and protect the traditional knowledge of their people. The establishment of research institutes in Iran and the UAE are examples of national efforts to protect and preserve traditional medicine and traditional medical knowledge. Also, the Iranian Ministry of Health has also developed a national inventory of medicinal plants and has published monographs on over 2500 plants among the 8000 traditional used plants whose uses have been recorded in Iran. The United Arab Emirates's Zayed Complex for Herbal Research and Traditional Medicine is an example of a member states commitment to the preservation and promotion of traditional medicine, as well as to the promotion of safe and effective traditional medicine into the national health care system.

VI. WHO Strategy for traditional medicine

Traditional Medicine has been widely involved in health care in both developing and developed countries. The WHO has recently developed its Strategy for Traditional Medicine, which is flexible enough to meet the needs of different regions and Member States, yet lays out clear objectives relating to national policy, safety and efficacy and the rational use of TM/CAM. This strategy was constructed to meet the numerous challenges and opportunities offered by the integration of traditional, complementary and alternative medical systems in national health care systems. There are four major objectives:

- **Policy:** Integrate Traditional and Complementary/Alternative Medicine (TM/CAM) with national health care systems, as appropriate, by developing and implementing national TM/CAM policies and programmes.
- **Safety, efficacy and quality:** Promote the safety, efficacy and quality of TM/CAM by expanding the knowledge base on TM/CAM and by providing guidance on regulatory and quality assurance standards.
- **Access:** Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations.
- **Rational use:** promote therapeutically-sound use of TM/CAM by providers and consumers.

Traditional medicine is human valuable heritage and will continue to play a role in health care in the 21st century. One of the first steps in ensuring the access of the world's population to effective, safe and high quality traditional, complementary and alternative medical systems is the preservation and protection of traditional medicine knowledge.

RECOMMENDATIONS

In the name of God The Compassionate, the Merciful

الحمد لله رب العالمين والصلاة والسلام على المبعوث رحمة للعالمين سيدنا محمد وعلى آله وصحبه وسائر الأنبياء والمرسلين.

Noting the Islamic Organization of Medical Sciences efforts to address important medical and health issues of special concern to the Islamic world; such efforts were demonstrated by the several seminars and conferences organized by the IOMS.

Recognizing that traditional/complementary/alternative medicine systems in the Islamic world and other developing countries have a heritage of community acceptance, that have played and continued to play an important part in preventive, promotive, and curative, aspects of health, particularly in the developing countries.

Noting that the primary health care in developing countries has not reached the bulk of population and that it is therefore important to make use of all available health resources including Traditional Medicine practices.

Recognizing the important contributions of Traditional Medicine to the provision of essential care, especially the populations with limited access to health care systems.

Acknowledging the wide use of CAM by a large number of population in the treatment of several illnesses by informed self medications and noting that the Islamic countries and other developing countries have a large number of CAM practitioners and almost untapped wealth of Medicinal Plants that are much of therapeutic active ingredients. However they may possibly show some toxicity when improperly used.

Since some Member States have achieved a number of successful experiences in integrating traditional/complementary/alternative medicine with modern medicine, the organization found this time appropriate to hold an international seminar in search of integration of the above mentioned medicines, especially since WHO and ISESCO had agreed to the idea.

This seminar was held, God willingly, from 6-9 Shaaban 1423; 12-

15 Teshreen Awal / October 2002 AC, under the patronage of Professor Dr Atef Ebeid, Prime Minister of Egypt.

A large number of high-ranking Faqihs, Medical Doctors, Pharmacists and Specialists in a number of complementary/alternative medicine branches and scholars in other human sciences participated in the seminar.

The opening session was held in the Kuwait Conference Hall, at the WHO Eastern Mediterranean Regional Office in Cairo. It commenced with verses from the holy Qoran recited by Dr Ahmed Neinaa followed by opening remarks by the Minister of Health and Population of Egypt delivered by Dr Mahmoud Abul Nasr, Under-Secretary of Health on his behalf, remarks by Dr Abdel Aziz Bin Othman Al Tweijry, Director of the Islamic Organization for Science Education and Culture, an address by Dr Hussein Al Gezairy, Regional Director, WHO Eastern Mediterranean Regional Office, as well as an address by Dr Abdel Rahman Al Awadi, President of the Islamic Organization of Medical Sciences.

Following that a presentation was made by Dr Ezzedin Ibrahim, Advisor of His Royal Highness President of the United Arab Emirates. It was "Integration of Complementary and Alternative Medicine with Mainstream Medicine: An Islamic and Cultural Point of View". The Opening session of the Seminar took place at the WHO Regional Office for the Eastern Mediterranean, and regular sessions continued to be held at Le Meridien Hotel.

The First session gave an overview of the Complementary and Alternative Medicine; the Second Session dealt with its basics; the third dealt with the spiritual dimension and its role in recovery; the Fourth Session concentrated on the integration between complementary/Alternative Medicine and Modern Medicine; the Fifth Session was dedicated to Traditional Medicine; the Sixth Session discussed the clinical evaluation of complementary/Alternative Medicine; the Seventh for safety, effectiveness, and stipulations already drawn in that field.

The issue of national policies was discussed during the third day. During the tenth session some countries elaborated their experience in Complementary and Alternative Medicine, whereas Ethics was dis-

cussed during the tenth session. The Seminar participants took part in a general discussion reaching a comprehensive overview and discussing some issues that needed more elaboration. The Seminar in its Closing Session, Tuesday afternoon, reached the following recommendations:

FIRST: Policy Issues

- 1) Urge Islamic Countries to recognize in principle TM/CAM as an allied medical system to Modern Medicine and take necessary legal and practical measures to accommodate experienced (alternative) practitioners of Alternative Medicine and make use of them to increase coverage by primary Health Care. This is in accordance of scientific and ethical measures of medical practitioners.
- 2) Urge Islamic countries to endorse and adopt WHO strategy on TM/CAM as a national framework for establishing and developing national programmes on Traditional Medicines.
- 3) Urge Islamic countries to take necessary measures to explore available capabilities, capacities and human as well as financial resources in this area. This may include kinds, numbers, qualifications of practitioners and the natural plant resources which are naturally abundant in those member states as well as pharmaceutical dosage form prepared from them. Also developing scientific criteria for proof of safety and efficacy and ensuring adherence to the GMP rules.
- 4) Urge Islamic countries to take necessary measures to protect and preserve national and legitimate rights to use traditional knowledge and various national resources and avoid any possible misuse of some articles of TRIPS agreement and protect the national wealth of Traditional Medicine from commercial exploitation.

SECOND: Practical Implementation issues

- 5) Invite TM/CAM practitioners in each country to establish professional organization with major objectives to ensure adherence of

all those who work in this field to scientific and ethical code of professional practice.

- 6) Invite Medical scholars and other health services schools to include in their teaching curricula, briefing courses on Traditional Medicine and its main systems and call upon Ministry of Education to include comprehensive information on Traditional Medicine in secondary schools courses. Medicines are administered to provide clear and correct information on Traditional Medicine including all types for public education.
- 7) TM/CAM systems should be developed to catch up with recent world development by publishing appropriate documents and organizing workshops, continued education courses to traditional practitioners.
- 8) Compile an inventory of medicinal plants used in the different countries, with standardized botanical nomenclature for the ones most widely used and encourage exchange of information and other experience between Traditional Medicine practitioners in various countries. This may also include exchange visits and organizing seminars and scientific meetings.
- 9) Encourage scientific research in the area of medical plants and other areas of Traditional Medicine to develop and promote this system.

THIRD: Organizing Organizations

- 10) Request the IOMS to take necessary steps to distribute all the valid scientific articles through publications, media and Internet as wide as possible.
- 11) Request IOMS to coordinate between all practitioners who work to realize integration between Traditional Medicine and modern medicine and ensure the continuous follow up on implementing the same recommendations.
- 12) Urge the three organizing organizations to revive the great Islamic heritage in the fields of medicine and explain, publish and translate it, as well as benefit from it in solidifying the concepts

of the holistic approach and health promotion through applying the Islamic lifestyles and raising interest in the spiritual dimensions of health.

- 13) Request the organizers to establish a task force to prepare guidelines to support government and practitioners to prepare appropriate legislation and regulations for professional practices, licensing, production, cultivation and other means relevant to Traditional Medicine.

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