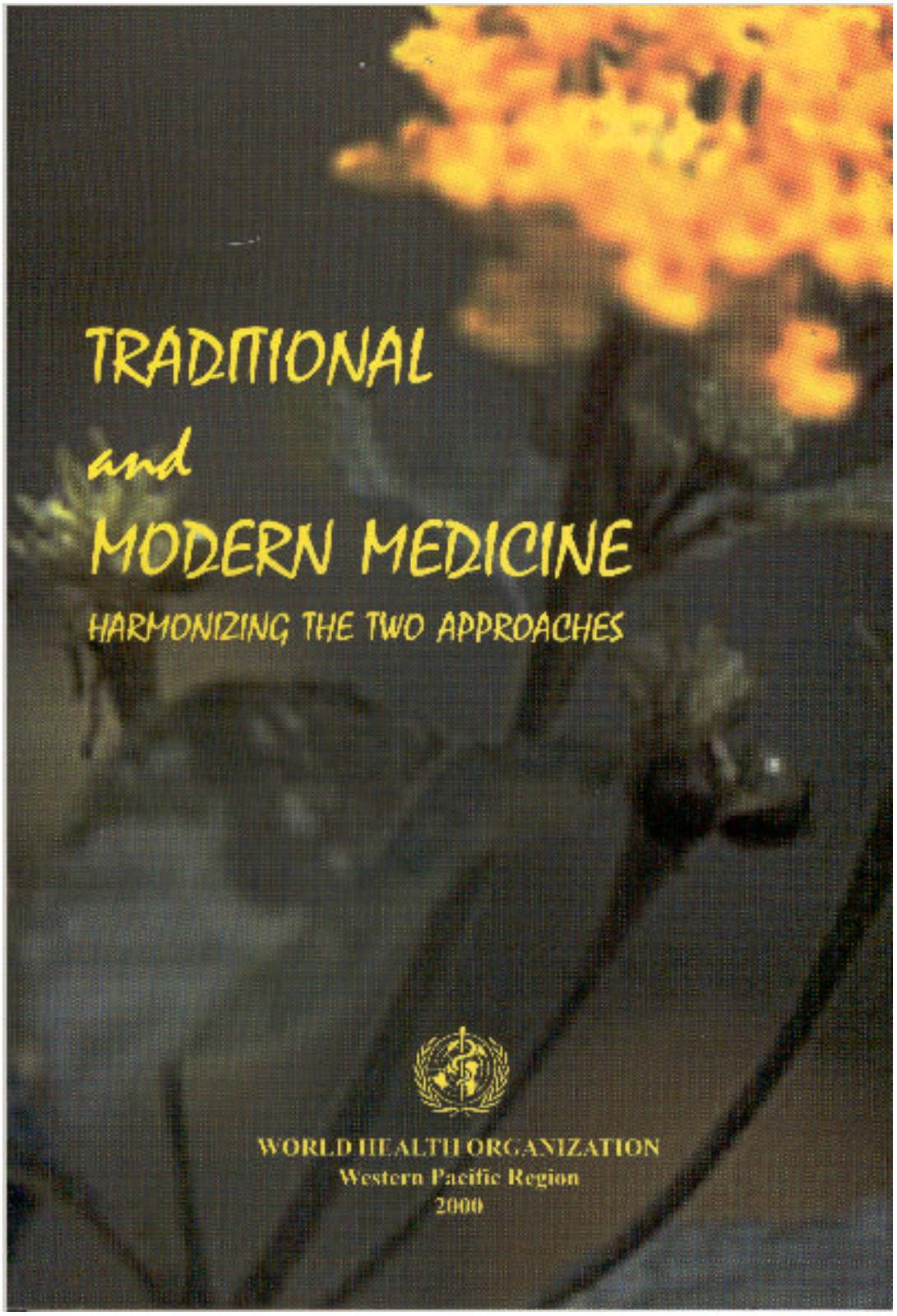
TRADITIONAL
and
MODERN MEDICINE
HARMONIZING THE TWO APPROACHES
WORLD HEALTH ORGANIZATION
Western Pacific Region
2000

TRADITIONAL AND MODERN MEDICINE

HARMONIZING THE TWO APPROACHES

A Report of the Consultation Meeting
on Traditional and Modern Medicine:
Harmonizing the Two Approaches,
22-26 November 1999, Beijing, China

WORLD HEALTH ORGANIZATION
Western Pacific Region
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SUMMARY

The major aims of the meeting held in Beijing China, from 22 to 26 November 1999 were to evaluate the contemporary role of traditional medicine in maintaining health, to develop a scientific approach to policy–making in traditional medicine, and, ultimately, to assess how traditional medicine can be harmonized with modern medicine. The meeting also provided a forum for identifying research requirements in traditional medicine.

The meeting was attended by 24 temporary advisers, three consultants, one secretariat staff from the WHO Regional Office for the Western Pacific, and 19 observers.

Participants presented review papers on past research, barriers to the acceptance of traditional medicine, research methodology and evidence–based medicine. Participants were divided into sub–groups to deal with acupuncture, herbal medicine and socio–economic aspects relevant to harmonization.

In the course of these discussions, the meeting concluded that there were challenges to the harmonization of traditional and modern medicine. Better access to information, facilitating appropriate clinical trials, improving rigour in clinical trials, improving education and collaboration of practitioners and researchers, and respecting traditional practices in research, were all identified as important steps towards achieving harmonization.

The group concluded that WHO should continue to encourage governments to adopt policies to promote rational and safe use of traditional medicine. WHO and its Member States should support the harmonization and appropriate integration of traditional medicine with modern medicine.

The group believed that evidence–based research could be an essential step towards the harmonization. In addition to detailed recommendations on steps for harmonizing the two approaches, the meeting also provided the following recommendations:

(1) WHO should continue to encourage governments to adopt policies to promote rational and safe use of traditional medicine.

(2) WHO and its Member States should support the harmonization and appropriate integration of traditional medicine with modern medicine.

(3) Findings of well–designed and well–performed research should be disseminated as widely as possible. This should include the preparation and dissemination in English and native languages of rigorous systematic reviews based on the research literature from various countries.

(4) WHO should develop appropriate mechanisms to improve dissemination of information on research activities. It should assist in updating the available databases on traditional medicine, preparing a document illustrative of the evidence–based approach to clinical research in traditional medicine, and forming networks.

(5) WHO should continue to co-ordinate critical data analysis on traditional remedies.

(6) Relevant governments and professional agencies should ensure appropriate adverse event reporting and recording mechanisms are in place.

(7) WHO should support training in research methodologies as well as in traditional medicine.

(8) WHO and its Member States should advocate, support and encourage conducting of high quality research.

(9) Research that establishes the value of traditional medicine in promoting health and wellness beyond treating diseases should be encouraged.

(10) Clinical trials of widely used and established traditional remedies should be encouraged and undertaken prior to obtaining the results of extensive 'pre–clinical' basic research.

1. INTRODUCTION

Traditional medicine is the ancient and culture–bound medical practice which existed in human societies before the application of modern science to health. The practice of traditional medicine varies widely, in keeping with the societal and cultural heritage of different countries. Every human community responds to the challenge of maintaining health and treating diseases by developing a medical system. Thus, traditional medicine has been practised to some degree in all cultures.

After the introduction of modern medicine into the Region, traditional medicine was usually rejected by the formal medical service system. Recently, however, attitudes towards traditional medicine have changed. Traditional medicine is now widely used in the Region and practised side by side with modern medicine in most countries. Many traditional remedies and therapies have transcended their original culture and become "complementary/alternative" medicine in other countries.

Modern medicine developed very quickly and made major contributions to disease control in the past century. Interestingly, despite a rapid growth in knowledge and techniques in modern medicine, the end of the last century also saw a dramatically increased interest in traditional medicine. The increasing public demand for its use has led to considerable interest among policy–makers, health administrators and medical doctors on the possibilities of bringing traditional and modern medicine together.

The practice of traditional medicine is mainly based on conventional use and personal experience. The value of traditional medicine (as well as many modern medical treatments) has not been fully tested by using modern scientific means. Extensive accounts of use and experiences from generation to generation provide some

evidence of the effectiveness of traditional medicine. However, scientific research is needed to provide additional evidence of its safety and effectiveness.

To evaluate the role of traditional medicine in maintaining health, to develop a scientific approach to policy–making in traditional medicine, and, ultimately, to focus on how traditional medicine can be harmonized with modern medicine, WHO Regional Office for the Western Pacific organized the consultation meeting on how to harmonize the two approaches, from 22 to 26 November 1999 in Beijing, People's Republic of China.

1.1 Objectives of the meeting

The objectives of the meeting were to:

(1) review the outcome of recent scientific research on traditional medicine and to confirm its value in maintaining health;

(2) identify the scientific basis for evaluating the efficacy of traditional medicine;

(3) discuss how to promote a dialogue of understanding between traditional and modern medicine;

(4) identify research requirements and research priorities for better understanding of the value of traditional medicine in the Region; and

(5) propose sound research methodologies for objective (4).

1.2 Participants

The consultation group on the harmonization of traditional and modern medicine was composed of 24 temporary advisers, 3 consultants, 1 secretariat staff from the WHO Regional Office for the Western Pacific and 19 observers. The list of participants is attached as Annex 1.

1.3 Organization

Professor Il Moo Chang and Professor Cao Xiaoding were elected as Chairman and Vice–Chairperson of the Consultation Group. Drs Charles Vincent, K.C. Tang, and Leonila Dans were the Rapporteurs.

2. PROCEEDINGS

2.1 Opening ceremony

Dr Shigeru Omi, WHO Regional Director for the Western Pacific, opened the meeting with the emphasis on WHO's commitment to foster a better understanding of traditional medicine. He reported on the high usage rate of traditional medicine in the Region and the increasing interest in traditional medicine from Member States during recent years. He indicated that WHO supported the efforts to bring traditional medicine into mainstream general health service. However, WHO could only endorse therapies supported by solid scientific evidence. Dr Omi reminded the participants that they were facing many threats to human health and the outcomes of the meeting would lay the foundation for traditional and modern medicine to work together to meet ever increasing challenges of the new century.

Dr Zhu Qing–shen, Vice–Minister of Health and Director–General of State Administration of Traditional Chinese Medicine (SATCM), of People's Republic of China, welcomed the attendees and described the important role traditional medicine plays in maintaining the health of the people of China.

Dr Margaret Chan, Director of Health of Hong Kong, China; Dr P.Y. Lam, Deputy Director of Health and several staff from Department of Health, Hong Kong, China; a delegate from Georgia; Professor Zheng Shou–Zhan, President of Beijing University of Traditional Medicine, and some senior staff from the State Administration of Traditional Chinese Medicine also attended the opening ceremony.

Dr S. Omi's speech is attached as Annex 2.

2.2 Purpose of the meeting, procedures and outcomes

Dr Chen Ken, Medical Officer of Traditional Medicine, WHO Regional Office for the Western Pacific and responsible officer for the meeting, gave a brief introduction to the objectives, process, and proposed methods of work of the workshop.

The purpose of this meeting was to:

- review previous scientific research on traditional medicine;
- discuss appropriate evidence for better acceptance of traditional medicine; and
- identify research requirements, research priorities and appropriate research methods which could be adopted for creating additional evidence on the usefulness of traditional medicine.

It is expected that the conclusions and recommendations of the consultation meeting will be followed up by WHO and its Member States to ensure the proper use of traditional medicine by harmonizing traditional and modern medicine.

2.3 Presentations

Papers on specific themes relevant to the conference were prepared by the consultants, temporary advisers and the secretariat and were distributed among all participants. The consultation group agreed to receive verbal summaries of these papers during the plenary session. Twenty verbal presentations were made by the authors of the papers and the topics included:

- WHO's involvement in traditional medicine;
- acupuncture – research on its mechanisms;
- acupuncture – clinical trials and clinical effectiveness;
- medicinal plants and herbal medicines – experimental research;

- quality of medicinal plants;
- clinical trials in herbal medicine;
- evidence–based health care practice;
- issues of evidence in traditional medicine;
- Growth of traditional medicine; and
- Clinical research methodologies.

These papers and presentations provided background material for subsequent discussions by sub–groups.

2.4 Group activities

The consultation group was divided into five sub–groups with each group focusing on one of the following: clinical research in acupuncture, clinical research in herbalism, basic science research in acupuncture, basic science research in herbalism, and socio–economic factors involved in harmonizing traditional and modern medicine. Following two days of small group discussions, the two sub–groups discussing herbal research were merged into one, and the two sub–groups discussing acupuncture research were merged into one on the final day of group discussions.

2.5 Plenary sessions

After lengthy periods of discussion, the groups reported to the consultation group. Interactions between groups continued until final recommendations were agreed upon.

2.6 Closing session

On behalf of all participants, Dr Acuin acknowledged the effort and support of the WHO Regional Office for the Western Pacific in holding the Consultation Meeting, and thanked the Chinese Government for hosting the meeting in Beijing.

Dr Il–Moo Chang, chairman of the meeting, thanked all temporary advisers, three short term consultants and the observers for their active participation and continued efforts in achieving the tasks assigned to the meeting. Dr Chang congratulated the group for the success of the meeting.

Due to another commitment, Dr S. Omi, WHO Regional Director for the Western Pacific was not able to attend the closing session. However, Dr Omi gave his response to recommendations of the meeting by a fax message. Dr Omi indicated the importance of identifying priorities for the future. He agreed that there was a need to collate what was happening in research on traditional medicine as well as a need to focus on research that would establish the value of traditional medicine for treating diseases and promoting health and wellness.

Dr Chen Ken thanked all participants for their contribution to render the meeting a successful, fruitful and productive one, and thanked WHO for its support of the traditional medicine programme. He expressed his thanks to the Chinese Government, the Ministry of Health and the State Administration of Traditional Chinese Medicine for their support of the meeting. He thanked the Chairman, the Vice–Chairperson, the chairmen of the group discussions and the Rapporteurs, the consultants and the colleagues from WHO as well as from the Institute of Chinese Materia Medica, a WHO collaborating centre for traditional medicine, for their support.

3. TRADITIONAL MEDICINE

3.1 Background and characteristics

Traditional medicine is the ancient and culture–bound medical practice which existed before the application of modern science to health. The practice of traditional medicine varies widely, in keeping with the societal and cultural heritage of different countries. Every human community has responded to the challenge of maintaining health and treating diseases by developing a medical system. Thus, traditional medicine has been practised to some degree in all cultures.

A workshop on development of national policy on traditional medicine organized by WHO Regional Office for the Western Pacific in October 1999 defined traditional medicine as the sum total of knowledge, skills and practices of holistic healthcare, which is recognized and accepted by the community for its role in the maintenance of health and the treatment of diseases. Traditional medicine, based on the theory, beliefs and experiences indigenous to different cultures, was developed and handed down from generation to generation[1].

In some countries, remedies used by traditional medicine have re–emerged. Such techniques are usually known as "alternative" or "complementary" medicine, which as a form of medicine has evolved recently as a reaction to high technology medicine[2].

A traditional medicine practitioner is a person who is recognized by the community where he or she lives as someone competent to provide health care by using plant, animal and mineral substances and other methods based on social, cultural and religious practices. Traditional medicine practitioners are also recognized as experts on community attitudes and beliefs related to physical, mental and social

well–being and the causes of disease and disability. Traditional medicine practitioners include traditional healers, traditional birth attendants, herbalists and bone–setters.

There are many traditional systems of medicine. However, many traditional systems of medicine have some common characteristics.

- Traditional medicine is based on a belief that health is a state of balance between several opposing aspects in the human body. Illness occurs when an individual falls out of balance, physically or mentally. The "causes" of imbalance could be change of weather, intake of certain food; external factors, such as magical or supernatural powers; mental stimulation and societal reasons. Traditional medicine tries to restore the balance using different therapies.
- Traditional medicine is based on the needs of individuals. Different people may receive different treatments even if they suffer from the same disease. Traditional medicine is based on a belief that each individual has his or her own constitution and social circumstances which result in different reactions to "causes of disease" and treatment.
- Traditional medicine applies a holistic approach. It considers a person in his or her totality within an ecological context and usually will not only look after the sick part of the body. Besides giving treatment, traditional practitioners usually provide advice on lifestyles and healthy behaviour.
- Traditional medicine precedes modern medicine. Most traditional remedies have not been evaluated by sound scientific methods. This means that, at this stage, traditional medicine is not easily understood by modern medicine. However, traditional remedies have been "field–tested" by tens of thousands of people for hundreds of years.

- Traditional medicine covers a wide scope and its practices vary widely from country to country. In the Region, the main therapeutic techniques are medicinal plants and acupuncture.

3.2 Changes in trends of usage

Traditional medicine exists in most countries and areas in the Western Pacific Region and makes a significant contribution to the health of the people of the Region. Interest in traditional medicine has increased over the last decade and seems likely to continue. People now are more prepared to look for alternative approaches to maintain their health.

There are no solid data on the extent of usage of traditional medicine in the Region. However, data from several countries and areas in the Region show that around 40% to 60% of the population of these countries and areas use traditional medicine. For example, traditional medicine accounts for around 40% of all health care delivered in China and in Hong Kong, approximately 60% of the population has consulted traditional medicine practitioners at one time or another.[3]

The use of traditional/complementary medicine in industrialized countries has increased significantly. Studies conducted in the US show that complementary therapy usage increased from 34% in 1990 to 42% in 1997.[4] In Australia, research has indicated that 48.5% of the population used at least one non–medically prescribed alternative medicine in 1993. The estimated national expenditure on alternative medicines and alternative practitioners is close to A$1 000 million per annum, of which A$621 million is spent on alternative medicines.[5] An Australian government report in 1996 estimated that there were at least 2.8 million traditional Chinese medicine consultations in 1996, representing an annual turnover of A$84 million within the health economy. This growth was also reflected in a four–fold increase in the importation of Chinese herbal medicines since 1992.[6]

Clearly, traditional medicine is widely used by the public, and in some countries its use has increased dramatically. Increased demands from public lead to increased interest and involvement of

the academic and scientific community. Concurrently, more and more governments from countries and areas within the Region have shown their interest and willingness to promote the proper use of traditional medicine.

3.3 Consumers, government and other stakeholders

Based on the growing interest in traditional medicine shown by consumers, scientists and regulators, three important challenges present themselves.

- The public and the users of traditional medicine request safe, quality–controlled and effective remedies.
- Medical scientists request more scientifically sound evidence before comfortably accepting many traditional medicine practices. Many health professionals have doubts about the usefulness of traditional medicine. In many cases, they require more scientifically–based evidence if they are to trust its safety and effectiveness. Meanwhile, the involvement of the academic and scientific community provides the opportunity to create more evidence by means of modern science.
- Governments need to establish and update mechanisms for the regulation of traditional medicine and its practitioners and, in doing so, require more scientifically–based evidence to support decision–making. As traditional systems of medicine become better documented, and more scientifically credible, usage is only likely to increase further.

Consumers, of course, have many different reasons for using traditional medicine, and may not require the same level of evidence of practice that is espoused by medical scientists. Consumers may have confidence in, for example, oriental herbal medicine because of its existence in public hospitals and medical infrastructure in China, Republic of Korea, and Japan, instituted by centuries of use, scholarly writings and a formal tertiary education system. Consumers may also be prepared to try an herbal formula that has been used and documented in classical medical literature for many

centuries and may be less convinced by a clinical trial of a new drug – having been applied only to a well–defined sample group. Consumers' awareness of these factors may generate more confidence in terms of 'evidence behind practice' than any single methodologically rigorous clinical trial. However, to the scientist it's the latter, and not the former, that represents the stronger evidence.

4. TRADITIONAL MEDICINE AND MODERN MEDICINE

Traditional and modern systems of medicine were developed by different philosophies in different cultural backgrounds. They look at health, diseases and causes of diseases in different ways. These differences bring different approaches to health and diseases. However, both systems deal with the same subject – human being. The old and modern arts of healing should exist together.

4.1 Integration of traditional medicine with modern medicine

The integration of traditional medicine with modern medicine may have three different meanings.

First, it may mean incorporation of traditional medicine into the general health service system. The government recognizes the practice of traditional medicine and the use of traditional medicine is incorporated into the mainstream of health service system. In the Region, traditional medicine has been an integral part of formal health service system in several countries, albeit in different forms.

Second, it may mean integration of the practice of traditional medicine with that of modern medicine. In fact, many medical doctors who have adequate knowledge of traditional medicine have tried to incorporate remedies used by traditional medicine into their daily work. In some places, traditional and modern medicine are practised side by side. Studies have also shown that many patients use both traditional and modern medicine.

Third, it may mean the integration of traditional and modern medicine as two branches of medical science. Although traditional and modern medicines have developed in different cultural contexts and are at different stages of scientific development, they have many similarities. Efforts have been made to synthesize the two branches, in order to form a new branch of medical science, incorporating elements of both. However, at this stage this would appear to be a difficult task.

4.2 The need for harmonization of traditional and modern medicine

Increased cross–cultural communication has resulted in the exposure of many indigenous forms of traditional medicine to new, more modern, medical environments. Various responses may and have occurred to the presence of differing approaches to health care. These range from complete rejection of TM by modern medical practitioners and of modern medicine by TM practitioners, to a parallel existence with little communication over patient care, or to ultimately forced understanding, subsuming and integration of one model by the other. None of these approaches is ideal precisely because none confers adequate respect on the practices of the other. This results in a weak utilization and exploration of the benefits presented by each model.

Harmonization of traditional and modern medicine emphasizes the importance of respectful co–existence. Within the model of harmonization, there is the requirement to develop and hold a good understanding of the other approaches to health care. Modern medicine practitioners and researchers are required to achieve adequate education and awareness of the practice, principles and context of traditional medicine. Similarly, TM practitioners need to be significantly more aware of the nature of practice and strengths of modern medical approaches. The purpose of this broader education base is not simply to yield a better understanding of differing practices, but primarily to promote the best care for patients by intelligently selecting the most facilitating route to health and wellness.

Surveys and other sources of evidence indicate that traditional medical practices are frequently utilized in the management of chronic diseases.[7] It is particularly for this category of illness that TM has developed a reputation. It is also in this area of treatment that modern medicine is considered the weaker. An approach to harmonizing activities between modern and traditional medicine will promote a clearer understanding of the strengths and weaknesses of each, and encourage the provision of the best therapeutic option for patients. The alternative to this is poor health care practice and bad medicine, most especially as the quantifiable scientific evidence of effective TM practices mounts.

Collecting evidence based on research is, therefore, regarded an essential step, although, of course, much more is involved in harmonization.

5. EVIDENCE AND TRADITIONAL MEDICINE

5.1 Acquisition of traditional medical knowledge

"In order to evaluate the efficacy of ginseng, find two people and let one eat ginseng and run, and the other run without eating ginseng. The one that did not eat ginseng will develop shortness of breath sooner." Bencao Tujing, *Atlas of Materia Medica*, 1061AD.

Traditional medicine practitioners have developed unique methods of diagnosis and treatment that are specific to their particular cultures. Some of these approaches based on complex theoretical frameworks can be traced back as far as 3 500 years.

Although there is evidence from the Song dynasty in China that comparative trials were used to illustrate treatment effects, they were not applied in a rigorous systematic manner to advance the state of knowledge. For the most part, it was assumed that knowledge of traditional medicine was reinforced through clinical experience and transferred either verbally or by cataloguing accumulated experience in reference texts.

Clinical experience is an excellent way to learn about medicine. However, development of new medical knowledge relies on treatment safety, costs, and systematic research. Given today's interest in traditional and complementary medicine, information on safety, efficacy and costs is being requested by patients, governments, traditional practitioners and practitioners of modern medicine.

5.2. Evidence–based health care practice

The practice of evidence–based medicine (EBM) involves "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."[8] When it was originally proposed in 1992, EBM was defined as a new paradigm for medical practice: "Evidence–based medicine de–emphasizes intuition, unsystematic clinical experience and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research."[9]

Although evidence–based medicine emphasizes the use of the randomized controlled trial (RCT) for the evaluation of therapeutic effectiveness whenever possible, the practice of EBM does not rely exclusively on the randomized controlled trial. Evidence to support clinical practice can come from any number of systematic research designs; however, these different types of research designs do not all lead to the same *level of evidence*. The rules of EBM privilege certain kinds of evidence as having more weight. The latest levels of evidence provided by the Cochrane collaboration include:

Level I. Strong evidence from at least one systematic review of well–designed RCTs.

Level II. Strong evidence from at least one RCT.

Level III. Well–designed trials without randomization.

Level IV. Non–experimental evidence.

Level V. Expert opinion.

Level VI. Someone told me.

There are several other ways to level the evidence proposed by different institutions.

EBM is the use of best evidence integrated with individual clinical expertise in making a medical decision. One can not stand without the other. Without the clinical expertise, external evidence might not be applied appropriately to individual patients. Without the use of evidence, clinical expertise alone might be biased and

out–of–date. In clinical guideline development process, actual recommendations come from different levels of evidence. Strong recommendations come from strong evidence (i.e. from well–designed randomized controlled trials). However, in most situations when there is a lack of good evidence, the panel usually considers other factors such as cost, availability of health personnel, laboratory and medical interventions, practical considerations, target population, etc. to decide on the best recommendations. Therefore, the role of traditional medicine in areas where western medicine is not readily available or affordable has to be emphasized. Even if there might be a lack of good evidence (and this is also true of western medicine), use of traditional medicine interventions might still be part of most clinical practice guideline recommendations.

The following methodology is proposed for creating evidence based recommendations (EBRs). This framework provides a series of validated steps to ensure the development and acceptance of objective, users–friendly, evidence–based recommendations for clinical practise.

The six–steps to EBR development are described below.[10]

Step 1: Project definition and team formation:

- specification of questions to be addressed and selection of team,
- focused questions on the management of a specific disease or condition;

Step 2: Perform a formal literature search:

- electronic search, where possible,
- retrieval of local publications, including translation of primary sources by persons trained in traditional medicine and clinical epidemiology;

Step 3: Create systematic overviews:

- evaluation of literature discovered, based on objective criteria;

Step 4: Estimate expected benefits, harms and costs:

- evaluation of important sources of information from observational and historical databases which may reveal important information with respect to toxicity, costs and culturally–based patient preferences;

Step 5: Judge relative value of expected benefits, harms and costs:

- relative importance of benefits and harms to the patient and payer; and

Step 6: Develop EBRs based on levels of evidence.

Evidence–based medicine is not a methodological research framework; it is a *research transfer framework* . Although evidence–based medicine de–emphasizes the sharing of unsystematic clinical experience, it does not invalidate clinical experience as a method of gaining knowledge. Using the EBM framework, however, a clinician can transfer his or her knowledge to other practitioners; the knowledge must be presented in a transparent fashion so that the recipient can appraise the knowledge to determine the level of evidence it represents.

6. EVIDENCE OF PRACTICE IN TRADITIONAL MEDICINE

These notes reflect consensus views developed in groups in response to papers submitted to the meeting. The groups consisted of representatives from various Member States with backgrounds in both traditional medicine and modern medicine.

6.1 Basic science research in acupuncture

The group recognized that although acupuncture research initially concentrated on analgesia and neurological models, recently it had broadened to other areas of physiological systems including endocrine, immunological and metabolic.

Two perspectives could be discerned in the research:

- traditional theory and clinical evidence is used to provide the basis for modern experiments in neurophysiology, and
- basic scientists are attempting to describe traditional ideas of meridians, point location, etc. in scientific terms.

The principal areas of this research were described in papers by Professors Cao Xiaoding, Kyuya Kogure and Liu Jungling. The group recognized, however, that much of the important original scientific work on acupuncture was not yet available in English.

Most of the research work on mechanisms of action was carried out on acute pain management, and it was not clear whether this was relevant to effects of acupuncture on chronic pain, which may have different underlying mechanisms, nor whether similar

mechanisms could be applied to other therapeutic applications of acupuncture. The issue underscored the importance of integrating clinical science and basic research in future acupuncture studies.

6.2 Clinical research on acupuncture

The starting point of the group's discussion centred on the awareness of the enormous historical and cultural significance of traditional acupuncture, as well as the importance of clinical experience and observation in this area. However, the focus of discussion was on the modern methods of treatment evaluation.

A number of English language reports of clinical trials are available.[11,12] In the last few years, activities of the Cochrane Centre for Systematic Reviews have been extended to include reviews of complementary/traditional medicine. Reviews of the clinical trial literature on acupuncture for low back pain, asthma, nausea and vomiting and smoking cessation are also available. Reviews are in progress for the acupuncture treatment of chronic headache.

The findings from all these reviews are similar, in that clinical trials have been too few, too small, and inadequately controlled. There have been doubts about the adequacy of treatment, problems with the definition of placebos and a variety of other methodological problems. Overall, methodological details have been lacking in many study reports. While progress has been made in defining an appropriate methodology for acupuncture evaluation, this has not yet translated into trials of a high standard that can provide definitive results. Hence, the results from most reviews are fundamentally inconclusive. Clearly, if research is to be continued, much larger trials of considerably better quality need to be conducted. Most of research literature remains in Chinese, and, therefore, not easily accessible to those carrying out the systematic reviews. Conversely, the English language studies and reviews are not easily accessed within China.

The conclusions reached from the clinical trial perspective contrast strongly with those reached by clinicians and researchers working from within a traditional medicine framework. From within traditional medicine, the result of literally hundreds of years of clinical

experience, and thousands of case series suggest that acupuncture can be effective for a wide range of clinical conditions.

The modern clinical trial and the traditional medicine perspectives can be usefully encompassed with the evidence–based medicine framework described above. There is a need to acknowledge the evidence base within traditional medicine, while also recognizing the importance of clarifying the extent and limitations of traditional practice through methodologically sound research. However, the design of studies needs to incorporate traditional medicine perspectives, including differences in diagnostic approaches that guide treatment.

6.3. Basic science research in herbal medicine

A wealth of information exists in the literature regarding plants and plant formulas used in traditional medicine. The Western Pacific Region is a particularly rich source of such information. Historical data has also been the starting point for basic science research that has led to the discovery of active components. Using highly advanced research techniques a number of compounds have been discovered over the years and successfully brought into clinical use.

The collection of data on herbal use is an ongoing process. In China, over 100 000 herbal preparations have been recorded that are still in clinical use. Researchers in Fiji, Malaysia, Samoa and Tonga have recently published monographs on medicinal plants with information on taxonomy, traditional use, chemical constituents, etc. Also, an extensive Korean database exists of over 12 000 prescription titles with respective formulas, 12 000 natural constituents with drawings of chemical structure and analytical data, photo images of standard herbal materials and original medicinal whole plants with taxonomical verification and a dictionary of disease classification in terms of TCM and modern medicine. All participants voiced the need for a comprehensive regional database that would allow easy access and exchange of information.

Quality control of herbal products will have a significant impact on the overall effectiveness of herbal medicines. To this end, China has introduced new legislation requiring approval for new raw

materials and traditional herbal formulas to be classified as drugs. New drug approvals require documentation of identification, cultivation, physical and chemical characteristics, pharmacology, standards of clinical use, stability, and preparation methods along with three reference samples. To date over 1000 new drug applications have been approved. Recent legislation in Malaysia requiring the registration of herbal products has lead to the licensing of 4778 (28.9%) out of 16 518 products. Many (71.1%) failed to satisfy strict regulatory requirements as to their quality, safety and efficacy.[13] Research activities currently include evaluation of active herbal constituents for efficacy, bioavailability and toxicity. In Japan, 80% of practising physicians have experience using herbal formulas. Japan now produces 210 Kampo herbal formulas according to strict quality controls, 147 of which are covered by health insurance. It was the consensus of the group that quality control measures should continue to be promoted.

Phytochemical and pre–clinical research are the areas of research in which the active components of herbal remedies are isolated, their structures identified and biological activities analyzed for mechanisms of action, toxicity, etc. Recently in the Republic of Korea, acubin was isolated from *Plantago asiatica*, a traditional medicinal plant that has been used for hepatitis B. Derivatives synthesized from the lead compound, higenamine, isolated from *Aconitum tuber*, have shown activity as an anti–platelet aggregating agent. Extensive research has been performed in Japan on about 30 Kampo formulas on a pre–clinical or basic science level. One example of this research is the work on the immunostimulating activity of Juzen–Taiho–To (JTT). JTT consists of ten different component herbs. It has been shown to influence the immune system by enhancing the T–cell dependent antibody response, phagocytosis, anti–complementary activity and mitogenic activity against spleen B cells in mice. The biological activity was identified to originate from three different types of polysaccharides having different activities. These three different types of polysaccharides were separated into 22 unique active pectic polysaccharides. Although JTT consists of ten component herbs, the corresponding carbohydrate–lignan complex fractions from each component herb did not demonstrate immunity enhancing activity. However, when

at least five certain herbs were combined, the activity was observed. The series of experiments strongly suggests the presence of a synergistic effect in this Kampo preparation. Examples of other areas of Kampo medicine that are currently being investigated include the anti–dementia actions on the nervous system, treatment of liver diseases, allergic reactions, anti–influenza, anti–atherosclerosis activity, suppression of chronic inflammatory airway disease and anti–pyretic activity.

6.4 Clinical research in herbal medicine

The range and number of human clinical trials of traditional herbal medicines performed in China, Republic of Korea, Japan and other countries are extensive. For the purposes of this summary a sub–group of participants reviewed and graded a limited number of studies submitted to the group by participants to provide a snapshot of research activity in this area. The focus of activity of this group was on oriental herbal medicine.

The following six major aspects of clinical trial design were utilized to objectively evaluate the studies at hand:

- the use of explicit, objective entry criteria;
- appropriate use of a control group;
- random allocation of patients to control and intervention groups;
- appropriate levels of blinding;
- complete follow–up and reporting on all patients recruited into the trial; and
- the selection of unambiguous and clinically meaningful, patient–based end points.

Two additional criteria were considered important by the group if traditional medicine were to be assessed appropriately:

- the use of a traditional diagnostic framework in guiding treatment; and
- tailoring the treatment to trial subjects where possible.

These clinical trial criteria were used to grade clinical trials according to the strength of evidence they represent. The trials reviewed are summarized below and presented in Table 1. The quality of evidence represented by each trial was rated according to the guidelines in section 5.2.

Summary of studies

Gastroenterology

One well–performed randomized controlled trial has been recently published in English on irritable bowel syndrome. This trial was considered to represent level II evidence.

Hepatology

A randomized, prospective unblinded Japanese study of a traditional herbal formula demonstrated reduced cumulative incidence of hepatocellular carcinoma and increased survival of patients with cirrhosis. This trial was considered to represent level II evidence.

A retrospective study also demonstrated that long–term administration of a licorice root derivative was effective in reducing the cumulative incidence of liver cancer in chronic hepatitis C patients. This trial was considered to represent level IV evidence.

Reproductive endocrinology

An unblinded, randomized controlled comparison of herbal medicine with conventional medicine in polycystic ovary disease demonstrated positive outcomes along a number of parameters although there were concerns about methodological standards. This trial was considered to represent level II evidence.

A small randomized controlled trial on intrauterine growth retardation demonstrated a positive outcome on birth weight and placental villi but exhibited similar methodological problems. This trial was considered to represent level II evidence.

Dermatology

Two studies of traditional herbal medicine demonstrated effectiveness over placebo in both children and adults with refractory atopic eczema. Both studies were deemed level II evidence.

Psychiatry

A randomized, placebo–controlled blinded trial demonstrated the benefit of a traditional herbal formula in the treatment of vascular dementia. Although there were some limitations in design this study was credible overall. The trial was considered to represent level II evidence (see Table 1).

Reviews

In addition, one systematic review and one meta–analysis were available for discussion.

Acute ischaemic or hemorrhagic stroke

A review and meta–analysis performed on 15 clinical trials of a State approved traditional Chinese herbal medicine, conducted between 1992–1996, revealed variable methodological quality (unpublished). Only one of the clinical trials reported single blind procedure, none double blind. All claimed a positive outcome. However, the review identified significant problems with the trial methodology.

Acute respiratory infections

A systematic review of clinical trials of Chinese herbal medicines in acute respiratory infections concluded that the inadequate methods of most studies made it difficult to interpret the results with confidence.[14]

Table 1: Summative table of human clinical trials reviewed

Disease	Reference characte-ristics	Trial	Results	Level of evidence
Hepatocellular carcinoma	*Cancer*, 1995, 76(5):743-749	Randomized, unblinded, controlled	Reduced cumula-tive incidence of hepatocellular carcinoma, increased survival	II
Hepatocellular carcinoma	*Cancer*, 1997, 79(8):1494-1500	Retrospective, historical controls	Reduced cumula-tive incidence of hepatocellular carcinoma	IV
Eczema	*Lancet*, 1992, 340:13-17	Double–blind, crossover, placebo–controlled, adults	Reduced skin damage	II
Eczema	*British Journal of Dermatology* 1992, 126:179-84	Double–blind, crossover, placebo–controlled, children	Reduced skin damage	II
Vascular dementia	*Journal of Traditional Medicine*, 1994, 11:246-255	Double–blind, randomized, placebo–controlled, multi–centre	Improvement in global ratings, psychiatric symptoms, and activities of daily living	II
Irritable bowel syndrome	*JAMA*, 1998, 280 (18):1585-89	Double–blind, randomized, placebo–controlled, follow–ups	Positive improvement in bowel symptom measures	II

Conclusions

Overall, the herbal trial reports represent some good preliminary evidence of the efficacy of herbal medicine in a number of clinical disorders including, but not limited to, those reported above. There is further evidence in numerous other clinical areas. The process of

acquiring quantifiable clinical trial evidence on traditional oriental herbal medicine is clearly underway.

However, whilst some good quality research has been reported, there is a relative paucity of good clinical trials and systematic reviews of the practice of traditional (oriental) herbal medicine, and most remain published in non–English journals. Whilst the outcomes of the trials largely support the efficacy of herbal medicine, many are compromised by methodological flaws. The clinical trials published in English are few. There is a significant volume of clinical trials in the Chinese herbal literature, although methodological problems have been a major concern which weaken the credibility of the outcomes.

7. HARMONIZING TRADITIONAL AND MODERN MEDICINE:

CONCLUSIONS AND RECOMMENDATIONS

The meeting participants recognized that a large proportion of the population in the Region use traditional medicine as a primary means of care. Traditional medicine will continue to exist as a separated medical system for some time. It was noted that many users of traditional remedies also use modern medicine at the same time. Many medical doctors apply both traditional and modern medicine. Harmonization of traditional and modern medicine will, therefore, ensure that the two approaches work effectively side by side properly.

7.1 Towards harmonization of traditional and modern medicine

By the end of the conference, the consultation group identified a number of issues that were important in the harmonization of traditional and modern medicine. The group recommended several steps which would contribute to the goal of harmonizing the two systems of medicine.

7.1.1 Promoting an evidence–based approach

An evidence–based approach is important in harmonizing traditional and modern medicine and minimizing bias. There is a need to acknowledge the evidence base within traditional medicine; traditional medicine should recognize the importance to clarify the

extent and limitations of traditional practice through methodologically sound research. Importantly, the consultation group did not see any major problems with applying the principles of evidence–based medicine (including the randomized controlled trial) to TM research and practice. This is a process that will only assist in increasing the credibility of TM practices. To this end, researchers should endeavor to utilize rigorous features in clinical trial design as described in sections 5 and 6. All suitable and appropriate study designs should be encouraged for the purpose of acquiring useful information on the efficacy and safety of traditional practices and medicines. This would include drawing on study designs such as case series, retrospective studies, cohort and case–control studies, and involvement of traditional healers in documentation of treatment outcomes.

Research should establish the value of traditional medicine in not only treating disease, but also in promoting health and wellness. This could include research on the use of combinations of therapy (for example, acupuncture with dietary changes and/or herbal medicine).

The concept of an holistic approach to treating patients is important and paramount in traditional medicine. Hence, outcome measures in clinical trials need to be relevant to the whole health of patients. A strong emphasis was placed on the need to develop and validate the reliable, clinically meaningful, multi–dimensional outcome measures that related to quality of life.

Whenever possible, researchers should endeavor to utilize rigorous features in clinical trial design, including;

- the use of explicit, objective entry criteria;
- appropriate use of a control group;
- random allocation of patients to control and intervention groups;
- appropriate levels of blinding;
- complete follow–up and reporting on all patients recruited into the trial; and

- the selection of unambiguous and clinically meaningful, patient–based end points.

A more conducive environment for research on traditional medicine needs to be set up. This includes looking into the legal status and training practitioners, education of researchers, funding and utilization of research findings.

In undertaking clinical research, the Declaration of Helsinki and other guidelines relevant to ethical issues in health research should be followed.

7.1.2 Encouraging a mutual respect

Lack of adequate education by modern medical practitioners in the TM approaches to diagnosis and treatment, and the lack of adequate education in designing methodologically sound research by traditional medicine practitioners represent significant barriers to the harmonization of traditional and modern medicine. In the past, non–TM trained researchers conducted poor quality clinical research due to the inappropriate application of TM techniques. Similarly, poor quality research resulted from TM practitioners failing to recognize the well–established importance of rigorous approaches to performing clinical trials. Improved relevant education is required on both sides.

While performing rigorous research on TM, it must be emphasized that TM principles of practice should be strictly adhered to. It is important that traditional medical theory is not ignored in the context of a good trial design. In some cases, whilst a modern medical diagnosis may be required for the purposes of screening and including patients for a clinical trial, the trial should be designed to permit a traditional diagnostic and therapeutic approach to practice. Practice is particularly individualized in TM and a research design that moves too far from TM practice would no longer achieve its purpose in evaluating TM. The importance of collaboration between TM practitioners and clinical researchers is apparent. Trialists and researchers need to develop expertise in both traditional medicine and research methodology, and they need to ensure that research methodologies are appropriate to the practice of traditional

medicine. Furthermore, developing interpretations of traditional medicine in terms of modern medical theory is also important. This can provide credibility to the traditional medical diagnostic and theoretical concepts without undermining its practice base.

Harmonization through mutual respect of practices will occur if a wide range of well–performed clinical trials proceed. Barriers to the performance of worthy clinical trials should be minimized. For example, it has been proposed that since herbal medicines are available in the public arena and the government has not sought to restrict their usage, a clinical evaluation of the products should be encouraged. For the purpose of a clinical trial, safety evaluation beyond the recorded history of use of the medicinal agents should not generally be required. In fact, the clinical trial itself provides safety information. Regulation and restriction, if required, should occur as a matter of public risk minimization measure, not to obstruct evaluation of publicly available products. This will provide an evaluation of effectiveness and assist the government not only to define a regulatory position, but also to clarify the potential role of the therapeutic agents concerned. This issue is of relevance to clinical researchers, government regulators and institutional ethics committees.

7.1.3 Disseminating information

Poor dissemination of research literature related to the practice of TM presents a major barrier to researchers worldwide. Some high quality basic science and clinical research on many forms of traditional medicine exist only in Japanese, Korean or Chinese language journals and are relatively inaccessible. Hence, there remains a need to translate, collate and disseminate the relevant research findings of the last two decades. In addition, TM researchers need to reach a broad readership and raise the level of awareness. WHO, researchers, professional associations, research institutes and other agencies should consider mechanisms to improve communication and information sharing. These include further networking, newsletters, expert meetings, conferences and other mechanisms.

Due to the vast array of TM practices, geographical separation and cultural diversity, communication, even in the same tongue, presents a barrier to harmonization. The development of a "modern" language for TM may lead to better understanding of its theory and practice by the public, policy–makers and the medical society. A common language will contribute to further cooperation amongst researchers.

The general public will also benefit from information on the safety and effectiveness of traditional medicine and the outcome of scientific research explained in simple language easily understood.

7.1.4 Research on herbal medicine

The basic science areas of herbal medicine provides a means of assuring the quality and safety of herbal remedies. It may also lead to the discovery of clinically important drugs.

There is a need to change the order in which basic science research is performed in the discovery of new drugs in the practice of traditional herbal medicine. Historically, basic science research in herbal medicine begins with the selection of plants based on widespread use and folklore. This is followed by intensive laboratory work leading to the development of bioassays, isolation techniques and characterization of active constituents, determination of the mechanism of action and a battery of toxicology testing. Promising agents are then moved into clinical trials. Although many extremely useful drugs have been discovered using this method, the vast majority of plants that undergo this method of evaluation do not yield clinically useful drugs. Applying two new strategies that embrace the principles of evidence–based medicine may dramatically increase this success rate.

The first strategy is to categorize plants and traditional medicine formulas according to an Evidence Rated Research Scale. By utilizing this style of categorizing plants and herbal formulas, researchers will have a common language in which to assess the body of knowledge available for each plant or formula.

Evidence Rated Research Scale consists of the following:

1. Single plant or herbal formula that has extensive positive clinical efficacy, proven safety, known mechanism of action, structurally identified active compounds and strict quality control which fully supports its use in the general population

2. Single plant or herbal formula that has extensive pre–clinical in vitro and/or in vivo positive research results along with basic science research on safety, mechanism of action, structurally identified active compounds and strict quality control which supports its use in the general population but has not been clinically verified.

3. Single plant or herbal formula used and broadly accepted as efficacious based on a long history of use that has been tested for quality control and safety. Clinical efficacy has not been verified by randomized controlled trials.

4. Single plant or herbal formula used and broadly accepted as efficacious based on a widespread and long history of use. Clinical efficacy has not been verified by randomized controlled trials.

5. Single plant or herbal formula used locally or only rarely found in the literature.

The second strategy involves shifting the initial focus of TM herbal research from that of basic science to clinical outcomes. According to this approach, high quality clinical trials would initially be performed using plants or herbal formula believed to be efficacious. Those TM herbal remedies confirmed to be effective would then undergo rigorous scientific investigation. By applying a Post–clinical Basic Science Research Approach, the basic research scientists will conduct their investigations starting with clinically proven effective material which may enhance and expedite the discovery new clinically effective agents and research tools. The format of the Post–clinical Basic Science Research Approach is as follows:

(1) Each interested regional country identifies and prioritizes diseases that warrant research.

(2) Single plants or herbal formulas used to treat those diseases might then be chosen for a variety of reasons (most notably, clinical experience) although preference might also be given to plants appearing high on the Evidence Rated Research Scale.

(3) Safety and toxicity studies should be carried out (unless already documented). A long history of human use is acceptable evidence of basic safety under this scheme.

(4) High quality, evidence–based clinical trials should then be designed and performed.

(5) Plants or formulas that are shown to be positive in clinical trials will then undergo rigorous basic science research including:

- isolation and structure elucidation of the active compound(s);
- dosage, bioavailability and advanced safety studies;
- pharmacokinetics and mechanism of action identification;
- activity enhancing chemical modification studies;
- other types biological activity studies; and
- quality control studies to standardize phytopharmacological equivalents.[15]

Thus, by combining the knowledge and use of traditional medicine to obtain clinically useful evidence in which to focus the resources of modern medicine's basic science research, the health of the people utilizing both systems may be improved.

During the process of evaluating traditional herbal remedies, the responsibility of TM practitioners will be to facilitate the appropriate evaluation of effectiveness, while other medical research techniques provide the capacity and approaches to determine how the therapeutic agents work. This order of activity differs from

conventional synthetic or semi–synthetic pharmaceutical research for new therapeutic chemical constituents, where the latter has had no marketplace exposure or history of human usage in therapy. This is an important distinction: TM therapeutics have a long history of human usage and previously accepted marketplace exposure. This distinction should motivate traditional medicine practitioners and relevant industry sectors to collaborate to raise adequate funding and to develop and fulfill meaningful research plans.

An awareness of the principles of TM practice is important in basic science research. The synergism of activity of the herbs demonstrated by the Japanese studies reported in section 6.3, where individual herbs failed to show activity demonstrated by the whole formula, highlights the importance of adopting traditional approaches to the utilization of traditional medicines. Attention in research should be paid to the synergistic behaviour of whole formulations in contrast to actions and safety of single bioactive agents.

In accordance with the UN Convention on Biologic Diversity held in Rio de Janeiro in 1992, researchers in the development of herbal remedies must recognize the importance of the conservation of diverse plant species.

7.1.5 Research on acupuncture

There is a need to standardize animal models in basic acupuncture research by considering standardized models from other fields. The animal models used in acupuncture research need to be understandable, reproducible, and exchangeable. Animal research must correlate as closely as possible to clinical reality.

Acupuncture researchers need to document the morphological and physiological connection to internal organs through the use of technologically advanced modalities such as functional magnetic resonance imagine (MRI) and positron emission tomography (PET) scans. This could lead to better understanding of the importance of acupoints and meridians, including the awareness of micro–anatomy, connective tissue and metabolic aspects. In view of the costs associated with these technologies, it was suggested that ways to

co–ordinate and facilitate the use of these resources must be promoted by governmental bodies.

Acupuncture research presents some unique methodological challenges that can cause problems with respect to the maintenance of blinding and thus may open trials of acupuncture to bias. The acupuncture researcher must consider the appropriate selection of sham procedures in order to address these issues. Some points to consider include:

- Sham needling presents difficulties related to choice of position, stimulation, duration and technique. Patient expectations and experience with acupuncture can result in failures in blinding.
- Mock TENS is difficult to undertake because the patient can perceive the active stimulation.
- Minimal acupuncture may have a mild effect and can be distinguished from true acupuncture by the subject.
- Placebo acupuncture, with a retractable blunt needle, demonstrates promise but has not yet been adequately evaluated in clinical trials.
- Alternative treatment, such as physiotherapy, may give indication of effectiveness over 'standard care'.

Researchers need to be very explicit when describing experimental trials so that all the steps of design and procedures are fully explained in order to allow other researchers to repeat the same experiment and grade the level of evidence.

7.1.6 Other perspectives on acceptance

Traditional medicine is rooted in respective cultures and traditions, so there are many issues and perspectives that need to be examined aside from the basic science and clinical aspects. Like all other systems of health care, the development of traditional medicine is not solely driven by science but equally by policy, and economic and socio–behavioral factors. These factors can act as a bridge between research and action.

Research on traditional medicine beyond the basic science and clinical perspective should be conducted. Other scientists such as social scientists, health economists and epidemiologists need to be part of multi–disciplinary teams conducting research in traditional medicine.

There is a need to understand the health and health care seeking behaviour of the users and non–users in the following areas:

- pathways to seeking care – issues such as delay of seeking care, concomitant use, doctor shopping and switching from one medical system to another;
- patterns of use – issues such as user characteristics, medical conditions for which traditional medicine are sought, extent and frequency of use, payments, factors associated with use and non–use and effects of education and policy on use and non–use;
- provider behaviour – issues such as provider characteristics, prescribing behaviour and referrals; and
- policy studies – cost analysis and issues such as effects of education and policy on patterns of use.

Research in the context of the above will provide useful evidence to policy–makers in dealing with traditional medicine.

Business involvement in TM is a global concern. It is possible that profit motivation could override safety, efficacy and health concerns. Issues of professionalism, ethics and marketing are important areas for future research. Some examples include:

- impact of TM on health care expenditures (e.g. insurance coverage);
- investment in product development by business/ commercial sector (their concerns, marketing behaviour, and interest in private investment in TM)

Governments should actively promote the rational use of traditional medicine that have been scientifically validated. To do so, they need a national policy for approving those drugs and techniques that are safe and effective for specified clinical indications.

The adoption of such policy will help to overcome some of the legal barriers against the use of traditional medicine.

7.2 Operational recommendations

There are clear challenges to the harmonization of traditional and modern medicine. Better access to information, facilitating appropriate clinical trials, improving rigour in clinical trials, improving education and collaboration of practitioners and researchers, and respecting traditional practices in research are all important steps towards achieving harmonization.

It is recognized that the idea for harmonizing traditional and modern medicine will not occur immediately. To accumulate evidence based on research can be regarded as the first step. However, much more is involved in harmonization of traditional and modern medicine. The group also believes that a number of simple actions can be taken to initiate the efforts for harmonization. In addition to the suggestions and recommendations mentioned above, the group made the following operational recommendations to establish a framework to begin the process.

(1) WHO should continue to encourage governments to adopt policies to promote the rational and safe use of traditional medicine.

(2) WHO and its Member States should support the harmonization and appropriate integration of traditional medicine with modern medicine.

(3) WHO should collaborate with research institutes and researchers engaged in research on traditional medicine to disseminate their findings as widely as possible, including publication of their results in broadly circulated English language journals. Furthermore, professional associations, journals, research institutes and other agencies should endeavour to make available in English the reports of research studies presently available only in Chinese, Japanese and Korean literatures. This should include the preparation and dissemination in English and native languages such as

Chinese, reviews of research conducted in other countries. The successful dissemination of the outcomes of well–designed and well–performed research will assist traditional and modern medicine practitioners to make informed decisions about the most effective therapy for patients.

(4) Appropriate mechanisms to improve dissemination of and access to information resulting from research activities should be developed:

- WHO should assist in updating available databases on traditional medicines and utilization of those databases by researchers and other interested users;
- WHO should consider commissioning the preparation of a document which could be available in English and native languages, to illustrate the use of the evidence–based approach to research in traditional medicine; and
- WHO should undertake activities (forming networks, organizing meetings and conferences, and using electronic media) for information dissemination.

(5) WHO should continue to co–ordinate data analysis on important traditional remedies. Researchers who have expertise in trial evaluation and traditional medicine should be mobilized to evaluate research papers published in the last five to ten years according to the levels of EBM. This could then form the framework for a scientifically–evaluated traditional medicine.

(6) As part of acquiring clinical evidence, relevant governments or professional agencies should ensure that appropriate adverse event reporting and recording mechanisms are in place. Regular summary findings should be disseminated by the relevant government or professional agency to interested parties.

(7) WHO should support the training of people with knowledge of traditional medicine to acquire skills in research methodologies including clinical epidemiology. Furthermore, WHO should encourage and support the training of clinical trialists to acquire training in the theory and fundamentals of traditional medicine.

(8) WHO and its Member States should advocate, support and encourage the conducting of high quality research in traditional medicine, including clinical research, basic sciences, policy issues (legal and educational), and social, behavioural and economic issues. *Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicine* and *Guidelines for Clinical Research on Acupuncture*, prepared and published by WHO Regional Office for the Western Pacific, provide valuable guidance on principle and methodology for designing, conducting and evaluating basic scientific and clinical research in traditional medicine.

(9) WHO should encourage research to establish the value of traditional medicine in promoting health and wellness beyond treating diseases.

(10) WHO and its Member States should advocate that, provided adequate evidence of safety (such as history of human use) is available, clinical trials of widely used and established traditional remedies may be undertaken prior to obtaining the results of extensive 'pre–clinical' basic sciences research.

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ANNEX 2

**OPENING SPEECH BY DR SHIGERU OMI,
REGIONAL DIRECTOR,
WHO REGIONAL OFFICE FOR THE WESTERN PACIFIC,
AT THE CONSULTATION MEETING ON TRADITIONAL
AND MODERN MEDICINE:
HARMONIZING THE TWO APPROACHES,
22-26 NOVEMBER 1999, BEIJING, CHINA**

Honourable Vice Minister of Health, China, Dr Zhu Qing-Shen,

Honourable Director of Health of Hong Kong, China, Dr Margaret Chan,

Distinguished participants, Ladies and Gentlemen,

I am very pleased to welcome all of you to this Consultation Meeting on Traditional and Modern Medicine: Harmonizing the Two Approaches. On behalf of the World Health Organization, I would like to express my sincere appreciation to the Government of China for hosting this very important meeting in your beautiful capital.

WHO has had a traditional medicine programme for the last 20 years. It was developed in conjunction with the goal of health for all and the adoption of the primary health care approach. WHO recognizes that a large percentage of the population of the Western Pacific Region still uses traditional medicine to treat disease and maintain health. Figures show that around 50% of the population in some countries in the Region is using traditional medicine for different reasons. This is also the case elsewhere in the world. For example, studies show that use of traditional or complementary medicine in the U.S.A. has increased from 33.8% of the population in 1990 to 42.1% in 1997. It seems probable that interest in traditional medicine will continue to increase in the future.

We support Member States in their efforts to bring the proper use of traditional medicine into the mainstream of general health service systems. WHO's involvement in traditional medicine is focused on our joint efforts with Member States for national policy development, regulation of traditional medicine, use of traditional medicine in supporting primary health care, research and information exchange. WHO supports only a few specific remedies and techniques used by traditional medicine, such as use of artemisinin and acupuncture. For example, use of artemisinin in some countries as a first line anti-malaria drug is supported by WHO. In the case of acupuncture, in June 1997, a provisional list of 43 diseases and disorders that lend themselves to acupuncture treatment was drawn up by a WHO Interregional Seminar on Acupuncture, Moxibustion and Acupuncture Anaesthesia held in Beijing, China. However, the selection of those diseases and disorders was based on clinical experience and not necessarily on controlled clinical research.

A number of resolutions adopted by the World Health Assembly and the Regional Committee for the Western Pacific have urged Member States to undertake research on traditional medicine and to improve cooperation between traditional and modern medicine, especially as regards the use of scientifically proven, safe and effective traditional remedies. However, lack of scientifically-based evidence limits our involvement in supporting the use of specific traditional remedies.

We believe that we need to keep an open mind on traditional medicine. However, we would like to endorse a therapy with solid scientific evidence.

Long historical use of many forms of traditional medicine and experiences passed from generation to generation have demonstrated the effectiveness of traditional remedies. However, scientific research is needed to provide additional evidence of its safety and effectiveness. Scientific research will serve as the basis of our endorsement of the use of traditional remedies and techniques.

The major tasks of this consultation meeting are, first, to review the outcome of previous research on traditional medicine and, second, to identify research priorities and sound research methods. By identifying a research strategy, we will be able to focus on the

kinds of evidence we need in different areas of traditional medicine.

This meeting is very timely. We are about to welcome a new century and a new millennium. Looking back over this century, it is clear that modern medicine developed very quickly in the last 100 years. However, if we look back over the whole millennium, traditional medicine represented main stream of health care to deal with the health problems of human beings. Although modern medicine has enabled us to make great advances, particularly in disease control, many threats to human health remain. Some of these are new threats, such as lifestyle-related diseases including drug abuse and depression. I believe that traditional medicine has an important role to play in helping us to meet these challenges.

We have to prepare ourselves to meet the challenge of the next century. That is why the WHO Regional Office for the Western Pacific is holding this meeting. We expect that the outcome of this meeting will lay the foundation for traditional and modern medicine to work together to meet ever increasing challenge in the new millennium.

With these few words, I wish you a successful and fruitful meeting. Thank you.