CHAPTER TWO

2 Challenges

TM/CAM has many positive features including: diversity and flexibility; accessibility and affordability in many parts of the world; broad acceptance among many populations in developing countries; increasing popularity in developed countries; comparatively low cost; low level of technological input; and growing economic importance. These can all be seen as opportunities to be maximized.

But other features of this type of health care can be regarded as challenges to be overcome. They include: the varying degree with which it is recognized by governments; the lack of sound scientific evidence concerning the efficacy of many of its therapies; difficulties relating to the protection of indigenous TM knowledge; and problems in ensuring its proper use.

WHO's broad range of TM/CAM expertise means that it is well placed to help tackle many of these challenges. Indeed, WHO Member States are increasingly and repeatedly requesting more assistance and guidance on TM/CAM issues — as expressed, for example, during WHO Regional Committee meetings, at the International Conferences of Drug Regulatory Authorities (ICDRAs) and at international government forums.

In 2000, the WHO Regional Committee for Africa, attended by 25 ministers of health, requested support for: creation of an enabling environment for TM; development of guidelines for formulating and evaluating national policies on TM; and development of mechanisms for improving the economic and regulatory environments for local production of traditional medicines.[2] Similar requests were also made by WHO's Regional Office for South-East Asia (SEARO) in 1999[47] and by the Government Forum on Traditional Medicine in China in 2000, and by the 9th ICDRA meeting in 1999.

Some challenges are common to regions. For example, the Chinese and Indian Governments are concerned with how best to use TM to strengthen primary health care in remote areas. In Africa, many countries are seeking means of making best use of local TM resources and how to make TM an integrated component of minimal health care packages. For European WHO Member States, safety and quality, licensing of providers and standards of training, methodologies, and priorities for research, have rapidly become issues of great importance.

2.1 What needs to be done?

The most important issues to be tackled are outlined in Table 6 and fall into four categories:

- national policy and regulatory frameworks
- safety, efficacy and quality
- access
- rational use.

Table 6

TM/CAM challenges fall into four categories

National policy and regulatory frameworks	• Lack of official recognition of TM/CAM and TM/CAM providers • TM/CAM not integrated into national health care systems • Lack of regulatory and legal mechanisms • Equitable distribution of benefits of indigenous TM knowledge and products • Inadequate allocation of resources for TM/CAM development and capacity building
Safety, efficacy and quality	• Lack of research methodology • Inadequate evidence-base for TM/CAM therapies and products • Lack of international and national standards for ensuring safety, efficacy and quality control of TM/CAM therapies and products • Lack of adequate regulation and registration of herbal medicines • Lack of registration of TM/CAM providers • Inadequate support for research
Access	• Lack of data measuring access levels and affordability • Need to identify safe and effective therapies and products • Lack of official recognition of role of TM/CAM providers • Lack of cooperation between TM/CAM providers and allopathic practitioners • Unsustainable use of medicinal plant resources
Rational use	• Lack of training for TM/CAM providers and on TM/CAM for allopathic practitioners • Lack of communication between TM/CAM and allopathic practitioners, and between allopathic practitioners and consumers • Lack of information for public on rational use of TM/CAM

2.2 National policies and legal framework

Although TM/CAM is widely used in the prevention, diagnosis, treatment and management of disease, very few countries have developed a national TM/CAM policy.

"Without critical assessment of what should be integrated and what should not, we risk developing a health care system that costs more, is less safe, and fails to address the management of chronic disease in a publicly responsible manner."[32]

Yet such policies are needed in order to define the role of TM/CAM in national health care delivery systems and how it can contribute to health sector reform. They can also ensure that the necessary regulatory and legal mechanisms are in place for promoting and maintaining good practice, that access to TM/CAM is equitable, and that the authenticity, safety and efficacy of any therapies used are assured. Without such policies, TM/CAM is practised without government oversight and without patient/consumer protection.

TM/CAM policies should therefore cover a range of issues, including: legislation and regulation for herbal products and practice of therapies; education, training and licensing of providers; research and development; and allocation of financial and other resources (Table 7.) In brief, sound TM/CAM policies can increase the types of safe and effective health care available to patients and consumers. To date, only 25 of WHO's 191 Member States have developed a national TM/CAM policy.

Attention should also be paid to intellectual property issues if the country concerned has a wealth of indigenous TM knowledge and/or natural resources that are used in TM/CAM products. Some groups recommend protecting TM under existing or new forms of intellectual property rights. Others object to this suggestion for ethical or economic reasons. Nevertheless, "biopiracy" – the unauthorized appropriation of TM knowledge and materials – is largely condemned. Clearly, when drafting national TM/CAM policies, the objectives and implications of intellectual property right protection should be thoroughly considered.[48]

Table 7

Key elements to include in a national policy on TM/CAM

- Definition of TM/CAM.
- Definition of 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 of proper use of TM/CAM.
- Provision for capacity building of TM/CAM human resources, including allocation of financial resources.
- Provision for coverage by state health insurance.
- Consideration of intellectual property issues.

Indeed, great caution generally should be exercised when developing TM/CAM policies. Careful assessment has first to be made of the use and practice of TM/CAM in the relevant country and the most appropriate means of using TM/CAM to help meet its health care goals. National policies should benefit patients using TM/CAM therapies. They fail to provide this benefit if they are: unable to ensure the safety, efficacy and quality of TM/CAM products and practices; unduly restrict the practice of TM/CAM; lead to higher health care costs; unjustifiably hinder patient treatment options; or reduce the ability of allopathic medicine practitioners to cross-refer patients.

2.3 Safety, efficacy, quality

Allopathic medicine is based on Western culture. Practitioners therefore emphasize its scientific approach, and contend that it is both value-free and unmarked by cultural values. TM/CAM therapies have developed rather differently, having been very much influenced by the culture and historical conditions within which they first evolved. Their common basis is an holistic approach to life, equilibrium between the mind, body and their environment, and an emphasis on health rather than on disease. Generally, the practitioner focuses on the overall condition of the individual patient, rather than on the particular ailment or diseases from which he or she is suffering.

> "The quantity and quality of the safety and efficacy data on traditional medicine 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 a lack of adequate or accepted research methodology for evaluating traditional medicine. It should also be noted that there are published and unpublished data on research in traditional medicine in various countries, but further research in safety and efficacy should be promoted, and the quality of the research... improved."[49]

This more complex approach to health care makes TM/CAM very attractive to many. But it also makes evaluation highly difficult since so many factors must be taken into account. And since TM/CAM practices have

developed within different cultures in different regions, there has been no parallel development of standards and methods — either national or international — for undertaking evaluation. Moreover, CAM providers may come from a cultural and philosophical background that differs radically from that surrounding the original development of a therapy. This can lead to problems of interpretation and application. Understandably, therefore, allopathic medicine practitioners in some countries have been reluctant to refer patients to CAM providers. (This in turn has made health insurance schemes unwilling to reimburse CAM treatments, effectively reducing patients' choice of health care.)

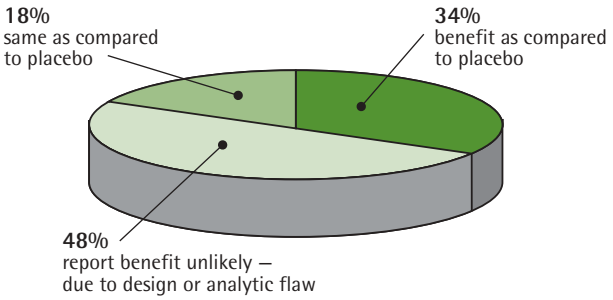
Evaluation of TM/CAM products, such as herbal medicines, is especially difficult. Accuracy of plant identification is essential, as is isolation of active ingredients. The latter is complex, though, because medicinal plant properties are influenced by the time of plant collection and area of plant origin (including environmental conditions). At the same time, a single medicinal plant can contain hundreds of natural constituents. Establishing which constituent is responsible for what effect can therefore be prohibitively expensive. Yet given the worldwide popularity of herbal medicines, a widely applicable, appropriate and effective means of evaluating herbal medicines with limited resources is urgently needed.

Research, research methodology and cost-effectiveness

It is perhaps not surprising that reviews have shown that clinical trials have been few, small and inadequately controlled. The Cochrane Complementary Field (see Chapter 4) found that articles indexed as "alternative medicine" formed only 0.4% of the total number of MEDLINE-listed articles for the period 1966–1996. (However, the annual total was steadily increasing during this period and the growing proportion of reports of randomized clinical trials (RCTs) suggested a trend towards an evidence-based medicine approach.) Only some of the RCTs reported included costs (incurred for the therapy in question, and including cost of consultation, materials used, etc.). In fact, very few reliable and full economic analyses of TM/CAM have been made.

Figure 11

Good evidence of efficacy exists for some herbal medicines — but too often evaluation is inadequate



% of randomized clinical trials (RCTs) showing benefit of herbal medicines (based on 50 RCTs with 10 herbal medicines for 18 therapeutic indications)

Source: based on data in Herbal Medicines: an Evidence-based Look. Therapeutics Letter, *Issue 25, June–July 1998.*

The failure to support research in this area over recent years has resulted in a lack of data and development of methodology for evaluating the safety, efficacy and quality of TM/CAM. Yet there are indications that at least some commonly used alternative therapies — for instance, some herbal medicines, manipulative therapies and behavioural stress-reduction techniques, such as transcendental meditation — can provide effective management for chronic disease (Box 2). Box 3 indicates some of the more detailed cost-effective analysis that is beginning to be undertaken. More firm evidence along these lines would be of enormous assistance in presenting arguments for greater recognition and application of TM/CAM. Indeed, it will be a prerequisite if access to TM/CAM is to be promoted and extended, and rational use of this type of health care ensured.

Box 2

PROMISING POTENTIAL

Herbal medicines and acupuncture are the most widely-used TM/CAM therapies. Reports of investigations of their clinical efficacy have been published in prestigious international scientific journals. The efficacy of acupuncture in relieving pain[10] and nausea,[50] for instance, has been conclusively demonstrated and is now acknowledged worldwide.

For herbal medicines, some of the best-known evidence for efficacy of a herbal product, besides that for *Artemisia annua* for the treatment of malaria, concerns St John's wort for the management of mild to moderate depression. Patients usually experience fewer side-effects than when treated with antidepressants, such as amitriptyline. Such findings have inspired research worldwide to establish the efficacy of other extensively-used TM/CAM. In laboratory settings, plant extracts have been shown to have a variety of pharmacological effects, including anti-inflammatory, vasodilatory, antimicrobial, anticonvulsant, sedative and antipyretic effects.[10] However, almost no randomized-controlled studies have been carried out to investigate the practice and treatment delivery of herbal practitioners in their everyday work. This also applies to most other TM/CAM therapies.

Regarding non-medication therapies, the 1999 *British Medical Journal* series on CAM commented that randomized controlled trials have provided good evidence that both hypnosis and relaxation techniques can reduce anxiety, and prevent panic disorders and insomnia. Randomized trials have also shown hypnosis to be of value in treating asthma and irritable bowel syndrome, yoga to be of benefit in asthma, and tai ji in helping elderly people to reduce their fear of falls.[10]

Box 3

STUDYING CAM COST-EFFECTIVENESS IN PERU

A study undertaken by Peru's National Programme in Complementary Medicine and the Pan American Health Organization compared CAM practices to allopathic medicine practices, as used in clinics and hospitals operating within the Peruvian Social Security System.

The relative effectiveness of CAM was evaluated in terms of:

- observed clinical efficacy
- user/patient satisfaction
- reduction of future medical risk associated with a lifestyle change.

Treatments were compared for selected pathologies, of the same degree of severity, as registered in case histories and/or clinical evaluations.

A total of 339 patients — 170 being treated with CAM and 169 with allopathic medicine — were followed for one year. Treatments for the following pathologies were analysed: moderate osteoarthritis; back pain; anxiety-based neuroses; light or intermittent asthma; peptic acid disease; tension migraine headache; exogenous obesity; and peripheral facial analysis.

The conclusions (95% significance) can be summarized as follows:

1. The overall average of direct costs using CAM was less than that incurred using conventional therapy. (To evaluate the direct costs of both systems, costs actually incurred during treatment of each one of the selected pathologies were calculated and compared.)
2. For each of the criteria evaluated — clinical efficacy, user satisfaction and future risk reduction — CAM's efficacy was higher than that of conventional treatments, including:
   - fewer side-effects
   - higher correlation between patient perception of efficacy and clinical observation of efficacy
   - higher recognition among patients of the role played by medical systems in solving health problems.
3. The overall cost-effectiveness of CAM was 53–63% higher than that of conventional treatments for the selected pathologies.

Source: EsSalud & Pan American Health Organization, 2000.[51]

Ensuring safety and quality at national level

Low levels of research activity have also slowed development of national standards for ensuring the safety and quality of TM/CAM therapies and products. In particular, lack of technical guidance and information has hindered development of regulation and registration for herbal medicines. This in turn has slowed development of, for example, national surveillance systems for monitoring and evaluating adverse events. The fact that only 3% of 771 cases of counterfeit drugs reported to WHO by April 1997 involved herbal medicines might be a reflection of this low level of monitoring, rather than an indication that adverse effects from herbal medicines are few.[52]

Table 8

Key needs in ensuring the safety, efficacy and quality of TM/CAM

At national level:

- National regulation and registration of herbal medicines.
- Safety monitoring for herbal medicines and other TM/CAM.
- 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.

Determining research needs

The 6th report from the Committee on Science and Technology to the House of Lords cites a number of problems relating to CAM research in the United Kingdom. They can be taken as applying to research problems in the field in general. The Committee found a poor research infrastructure and concluded that research is often of poor quality because research ethics are not well understood, sound methodology is lacking, resources are in short supply and researchers are unwilling to evaluate evidence. A summary of key needs in ensuring the safety, efficacy and quality of TM/CAM is given in Table 8.

Some priority areas for research are outlined in Table 9.

Table 9

Priority areas for research

- Effects of each individual therapy: efficacy, safety and cost-effectiveness.
- Research into mechanisms of action of individual therapies, including patterns of response to treatment.
- Research into TM/CAM genre itself, including social research into motivation of patients seeking TM/CAM and usage patterns of TM/CAM.
- Research into new research strategies which are sensitive to the TM/CAM paradigm.
- Research into efficacy of diagnostic methods used.
- Research into implementation and effects of TM/CAM in specific health care settings.

Source: House of Lords, 2000.[16]

2.4 Access

Statistics demonstrate overwhelmingly that it is the world's poorest countries who are most in need of inexpensive, effective treatments for communicable diseases. Of the 10.5 million children who died in 1999, 99% came from developing countries. Over 50% of children's deaths in developing countries are due to just five infectious diseases. Similarly, 99% of the two million tuberculosis deaths each year occur in developing countries, and 80% of the current 30 million people living with HIV/AIDS live in sub-Saharan Africa.[53]

At the same time, access to modern essential chemical drugs is lowest where people are suffering

most from communicable diseases. The reasons are well known and include inadequate financing and poor health care delivery. In developing countries, however, TM can be comparatively inexpensive. Additionally, TM practitioners may be widely trusted and respected providers of health care, albeit not necessarily officially recognized.

If access to TM is to be increased to help improve health status in developing countries, however, several problems must be tackled (Table 10). Firstly, reliable standard indicators to accurately measure levels of access — both financial and geographic — to TM must be developed. Qualitative research to help identify constraints to extending access should also be undertaken.

Table 10

Key needs in increasing availability and affordability of TM/CAM

At national and global levels:

- Identification of safest and most effective TM/CAM therapies and products (including: evidence that the therapy is effective; evidence that the therapy is safe; evidence that the therapy is cost-effective).
- Research into safe and effective TM/CAM treatment for diseases that represent the greatest burden, particularly for poorer populations.
- Recognition of role of TM practitioners in providing health care in developing countries.
- Optimized and upgraded skills of TM practitioners in developing countries.
- Indigenous TM knowledge protected and preserved.
- Sustainable cultivation of medicinal plants.

Secondly, the safest and most effective TM therapies must be identified, to provide a sound basis for efforts to promote TM. The focus should be on treatments for diseases that represent the greatest burden for poor populations. This means focusing on the development of antimalarials, and HIV/AIDS treatment and prevention.

Evidently, increasing access to safe and effective TM should not mean displacing programmes to increase access to allopathic medicine. Rather opportunities to improve cooperation between TM practitioners and allopathic medicine practitioners, should be created, to enable patients to draw upon both TM and allopathic therapies to best meet their needs. This is of course the case everywhere (and applies also to CAM). But it is particularly relevant in areas with poor access to allopathic medicine. Fortunately, in these areas, TM practitioners tend to be well established and well respected. Working with these practitioners can facilitate effective dissemination of important health messages to communities, as well as promotion of safe TM practices.

If access to TM is to be increased sustainably, the natural resource base upon which it often depends must be sustained. Raw materials for herbal medicines, for instance, are often collected from wild plant populations. Over-harvesting due to intensified local use or to meet export demand is a growing problem. In Eastern and Southern Africa, the sustainability of wild stocks of the African potato *(Hypoxis hemerocallidea* — formerly *H. rooperi)* is threatened because widespread publicity about the use of the plant in treatment of HIV/AIDS has boosted demand for it.[31] Since the vast majority of plant genetic resources and other forms of biodiversity are found in or originate from developing countries with least capacity to protect them, such problems are in urgent need of resolution.

Unresolved intellectual property issues are another access problem. While research into TM is essential to ensuring access to safe and effective treatments, the knowledge of indigenous TM practices and products gained by researchers can be a source of substantial benefits to companies and research institutes. Increasingly, it appears that knowledge of TM is being appropriated, adapted and patented by scientists and industry, with little or no compensation to its original custodians, and without their informed consent.[17]

2.5 Rational use

In many countries, considerably more activity is required regarding: qualification and licensing of providers; proper use of products of assured quality; good communication between TM/CAM providers, allopathic medicine practitioners and patients; and provision of scientific information and guidance for the public.

Table 11

Key needs in promoting sound use of TM/CAM by providers and consumers

At national level:

- Training guidelines for most commonly used TM/CAM therapies.
- Strengthened and increased organization of TM/CAM providers.
- Strengthened cooperation between TM/CAM medicine providers and allopathic medicine practitioners.
- Reliable information for consumers on proper use of TM/CAM therapies and products.
- Improved communication between allopathic medicine practitioners and their patients concerning latter's use of TM/CAM.

Education and training

Challenges in this area are at least twofold (Table 11). Firstly, ensuring that the qualifications and training of TM/CAM providers are adequate. Secondly, using training to ensure that TM/CAM providers and allopathic medicine practitioners understand and appreciate the complementarity of the types of health care they offer. The first involves establishing, where possible, examination and licensing systems for TM/CAM, and legislation – so that only those who are qualified can practice TM/CAM or sell TM/CAM products. The second requires modifying training programmes for TM/CAM providers to include basic elements of primary health care and public health, and ensuring that pharmacy, medical and public health degrees include a component on TM/CAM.

Proper use of products of assured quality

Proper use of products of assured quality can also do much to reduce risks associated with TM/CAM products such as herbal medicines. However, regulation and registration of herbal medicines are not well developed in most countries. Products may be contaminated or vary tremendously in content, quality and safety. Garlic, for example, often claimed to have cholesterol-lowering effects, may fail to produce such effects if processed in certain ways.[54] At the same time, standards to control labelling of and publicity for herbal medicines are few. Moreover, many are sold as over-the-counter or dietary supplements, with little advice offered on their appropriate use. Consumers may then be unaware of potential side-effects, and how and when herbal medicines can be taken safely. Reversing this situation will necessitate much more stringent control of TM/CAM products and greater efforts to educate the public in this area.

Information and communication

Use of TM/CAM is increasing rapidly. But appreciation of its risks and how to avoid those risks has not kept pace. As a result, consumers may not understand why they should seek treatment only from suitably qualified and trained providers, or why they should exercise caution when using TM/CAM products. It is not commonly understood, for example, that side-effects following reactions between herbal medicines and chemical drugs can occur. On its own, for example, ginseng has few serious adverse

effects. But if combined with warfarin, its antiplatelet activity risks causing overanti-coagulation.[55] Similarly, use of St John's wort as an antidepressant has been shown to compare favourably with a standard antidepressant, imipramine. But if St John's wort is taken by subjects who are also taking indinavir, an HIV protease inhibitor, levels of indinavir in the blood are reduced below the level required to block HIV multiplication.[56,57]

Without knowledge of the possibility of such interactions, patients may fail to inform their allopathic doctors about the TM/CAM products they are using, while allopathic doctors may fail to ask. In the USA, for both 1990 and 1997, less than 40% of CAM therapies used were disclosed to a physician.[13] At the same time, allopathic doctors, nurses and pharmacists, all of whom may be used as information sources by the general public, may not be informed about CAM and therefore unable to answer patients' queries about CAM treatment options.

Information, education and communication strategies could overcome some of these problems, and raise awareness of the potential benefits of TM/CAM.