
INTRODUCTION

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It is now well established that interest in traditional, complementary and alternative medicine (TCAM) is rising rapidly throughout the world. Policy-makers, consumers and professional organisations have been calling variously for greater evidence, integration of TCAM and modern medical services; public sector support for TCAM services; and comprehensive national policy for what has been a consumer-led trend in most countries. Some countries, notably China, India and a number of other Asian nations, have been working actively to build the TCAM sector for the combined motives of perpetuating tradition and promoting cost-effectiveness in health services. In addition, there has been a dawning awareness of the significant export potential of traditional medicines in a burgeoning global marketplace for herbal medicines. This economic incentive has strengthened the drive for increased levels of production and quality control.

At the same time as consumer demand is rising and policy-makers are beginning to respond with moves to formalise TCAM within national policy, it is widely recognised that the indigenous sources of medical knowledge are disappearing and that there is a substantial inter-generational loss of traditional medical knowledge, especially within the oral traditions of the world (Posey, 2000). In these traditions, health knowledge extends to an appreciation of both the material and non-material properties of plants, animals and minerals. Their classificatory systems range in scope from the

cosmological to the particular in addressing the physiological makeup of individuals and the specific categories of *materia medica* needed to enhance health and well-being. Mental, social, emotional, spiritual, physical and ecological factors are all taken into account. In establishing policy, these fundamental theoretical underpinnings of traditional health systems may either be respected and perpetuated, or converted into a biomedical expression and agenda. These approaches result in very different prospects for traditional medical knowledge and its continuity as a cultural health care resource.

With such a wide spectrum of approaches to TCAM at national and local levels, and the growing trend towards global and regional analysis of utilisation patterns and formalisation, there is now a clear need for a set of public health and policy perspectives to provide models and reference points for planners, policy-makers, programme developers and practitioners.

A broad policy overview and study of trends in utilisation and regulatory and policy development can be found in the World Health Organisation's Global Atlas of Traditional, Complementary and Alternative Medicine (Bodeker *et al.*, 2005). Based around a set of standardised core indicators, the WHO Global Atlas on TCAM provides information on the context, levels of use, structure and processes of TCAM at national, regional and global levels.

The Atlas, coordinated and edited by teams at Oxford University and the London School of Hygiene and Tropical Medicine, draws on data gathered by regional teams from Africa, the Americas, the Eastern Mediterranean, Europe, the Western Pacific, and South and South-East Asia. It comprises a map volume and a text volume. Through global and regional maps and tables, the former provides a visual representation of topics such as the popularity of herbal/traditional medicine, Ayurveda, Siddha, Unani, traditional Chinese medicine, homeopathy, acupuncture, chiropractic, osteopathy, bone-setting, spiritual therapies, and others; national legislation and traditional medicine policy; public financing; legal recognition of traditional medicine practitioners by their area of therapy; education and professional regulation; conventional health care practitioners who are entitled to provide various traditional, complementary and alternative therapies; and many other aspects. The text volume expands and supplements the map

volume through detailed accounts of the development of traditional, complementary and alternative medicine in 23 countries across the world, as well as overviews of their status in each of the six WHO Regions.

Through these two volumes, a global picture of the development of traditional, complementary and alternative medicine becomes evident, revealing people's belief in and dependence on different traditional health systems around the world.

In the context of producing this first attempt at generating a systematic global overview of TCAM, what became apparent was that there is less data available on TCAM than the coordinating or regional teams would have wished, thus making mapping and policy analysis a more approximate exercise than was considered ideal. What this data collection exercise did reveal, however, is the wide spectrum of stages of policy development across regions, and among countries within regions. Interestingly, the global trend has shifted from being led by consumers and advocacy groups of practitioners, to a situation in most countries where governments are now working towards establishing a full regulatory context for the practice and use of TCAM. At one end of the spectrum, there are countries that formally promote and finance TCAM development, while at the other end, there are countries where the process of national recognition and regulation has not yet begun. For the countries in between, the picture is one of emerging policy, legislation and investment, with varying degrees of autonomy for the different TCAM professions. What is little known, other than in a very few industrialised countries, is the full extent of TCAM use by the public. At a global level, the often-cited 1983 estimate by Bannerman *et al.* that 'over 80% of the world's population relies on traditional medicine for its primary health care needs' has neither been updated, nor analysed in detail. In particular, little research has been conducted on the differing patterns of TCAM utilisation according to disease, income, gender, geography and culture.

Our work on the WHO Global Atlas on TCAM led to the realisation that, in addition to gaps in comparative policy studies of this sector, there was also a dearth of public health models for countries to draw on in planning health services and in integrating TCAM — either fully or selectively — into national health care.

Accordingly, drawing in part on data from the WHO Global Atlas, with permission of WHO Kobe, the sponsor of this project, we have assembled a set of policy-related chapters that analyse trends across a set of key policy issues such as regulation, education, safety, and finance within the TCAM sector.

We extend our appreciation and recognition to all who participated in the massive global data collection exercise and who are listed by name in the WHO Global Atlas. It is this data that has been analysed and commented on in the first four chapters of this volume.

At the same time, we were also aware that there exist important public health models, policy examples, NGO programmes and other TCAM innovations which highlight more fundamental principles of health planning, service development and public health outcomes. Accordingly, this volume brings together a sample of these. These include a model for self-sufficiency in family medicines through the production of home herbal gardens and data on significant public health benefits that have resulted; and an approach to harnessing the indigenous health knowledge and provider networks in refugee communities as a means of providing basic health needs and mental health through the use of locally available and culturally familiar strategies in an environment where most links with heritage and home have been shattered. Priority diseases such as malaria and HIV/AIDS are also considered from the perspective of TCAM as are common ailments such as skin conditions. Finally, resource rights issues are addressed through discussions of sustainability in medical plant use and in the intellectual property issues associated with the development of traditional medical knowledge for commercial purposes.

It is an intentionally eclectic and broad-based set of perspectives, designed to illustrate the wide range of work being done in this field. It is simply a beginning. Future work will inevitably build on, differentiate and diverge from these perspectives to create new directions, analytic frameworks and frames of reference for service development and integrated health care delivery in TCAM.

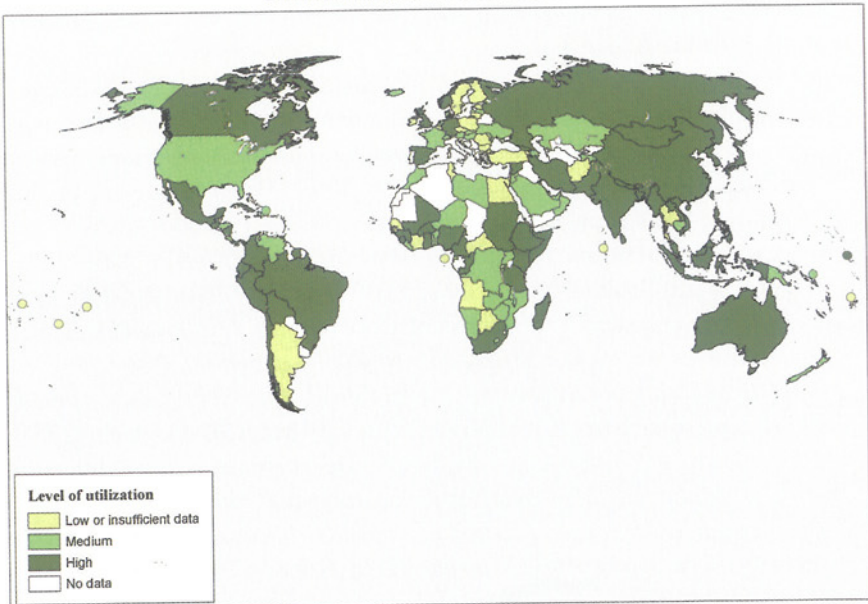
We would like to thank all of the contributors to the book, to WHO Kobe for allowing the use of data from the WHO Global Atlas in the first four chapters, and all who generated this data in the production of the WHO Global Atlas. We also recognise the work of many NGOs and community

groups who are pioneering important public health initiatives at the local level in combating major diseases and common ailments through the use of TCAM.

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D1: Utilization of herbal / traditional medicine



Widespread global use of herbal/traditional medicine. [Source: WHO Global Atlas of Traditional, Complementary & Alternative Medicine (TCAM) (Bodeker *et al.*, 2005).]

**POLICY AND PUBLIC HEALTH
PERSPECTIVES ON TRADITIONAL,
COMPLEMENTARY AND ALTERNATIVE
MEDICINE: AN OVERVIEW**

Gerard Bodeker, Fredi Kronenberg and Gemma Burford

1.1. Introduction

The growth of public interest in, and use of, traditional, complementary and alternative medicine (TCAM) has been well documented. In a number of industrialised countries, almost half of the population now regularly uses some form of TCAM, while the figures for Canada and Germany are 70% and 71–75% respectively (Table 1.1). Considerable use of TCAM also exists in many developing countries: 40% in China and Colombia, 71% in Chile, and up to 80% in some African countries (Kasilo *et al.*, 2005). In this book, the term ‘traditional medicine’ is used when there is a need to refer exclusively to the indigenous health traditions of the world, in their original settings, while ‘complementary and alternative medicine’ (CAM) refers to health care approaches outside the biomedical mainstream in industrialised countries. More often, ‘TCAM’ is used to encompass both of the above.

The WHO Global Atlas on Traditional, Complementary and Alternative Medicine, a large international collaborative effort to document current

Table 1.1. Utilisation of TCAM in Industrialised Countries.

Country	Utilisation (% of Population)	Reference
Australia	48	MacLennan <i>et al.</i> , 1996
Canada	70	Health Canada, 2001
Denmark	33	Dansk Institut for Klinisk Epidemiologi, 1995
France	49	Fisher & Ward, 1994
Germany	71	Melchart <i>et al.</i> , 1995
	75	Marstedt & Moebus, 2002
United Kingdom	47	Thomas <i>et al.</i> , 2001
United States	62%/36%*	Barnes <i>et al.</i> , 2004

*Note: 62% when definition included prayer specifically for health reasons; 36% when prayer was excluded.

trends in utilisation, sectoral growth and policy in TCAM, highlights the trend of high TCAM use around the world and the accompanying policy and research response (Bodeker *et al.*, 2005). Popular use of TCAM and increasing consumer demand has been accompanied by a growth in research and associated literature, with an increase in an evidence-based approach over the past decade (Barnes *et al.*, 1999). Research and policy developments to date have, however, largely addressed clinical, regulatory and supply-oriented issues, to the general neglect of wider public health dimensions. Typically, research has focused on efficacy, mechanisms of action and safety of complementary and traditional therapies.

In certain developing countries, where there is long-term practice of TCAM both within and outside the dominant health care system, interest has been building over the past decade or more for a policy framework for TCAM within national health care systems, and some guidelines have been developed (Nelson, 1998; Bodeker, 2001a). However, in industrialised countries, regulation of CAM practitioners, establishment of standards of practice, guidelines for licensing and self-regulation, while occurring within a small number of the licensed professions (massage; acupuncture; chiropractic), have only recently been considered on a broader national scale (House of Lords Select Committee on Science and Technology, 2000; White House Commission on Complementary and Alternative Medicine Policy, 2002). Education and training efforts in these countries have largely

focused on medical students and conventional health care practitioners (Bhattacharya, 2001; Marcus, 2001; Berman, 2001).

1.1.1. *Cultural and Spiritual Origins*

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

A fundamental concept found in many systems is that of balance — the balance between mind and body, between different dimensions of individual bodily functioning and need, between individual and community, individual/community and environment, and individual and the universe. The breaking of this interconnectedness of life is a fundamental source of *dis-ease*, which can progress to stages of illness and epidemic. Treatments, therefore, are designed not only to address the locus of the disease, but also to restore a state of systemic balance to the individual and his or her inner and outer environment (Bodeker, 2000). They often involve other members of the family or community, and may be associated with specific places, such as ancestral shrines (Neumann & Bodeker, this volume) or sacred groves (Lebbie & Guries, 1995).

There is an emerging trend for certain elements of traditional health care to be removed from their original context and subsequently incorporated into formal health systems, or developed as part of a parallel ‘complementary and alternative medicine’ (CAM) sector. This is not a new process—the CAM disciplines of chiropractic and osteopathy both evolved from earlier traditions of bone setting (Hemmila *et al.*, 2002) — but it appears to be on the increase. In several industrialised countries, for example, acupuncture is offered in clinical settings as a pain relief technique, with no reference to the theories of energy (*qi*) flow that underlie its use in Traditional Chinese Medicine. In Belgium, 74% of acupuncture treatments are given

by conventional allopathic physicians (Monckton *et al.*, 1999), while in Iceland, nurses and physiotherapists can be licensed to provide acupuncture after an 18-month training course (Veal, 2001).

In establishing policies, it is important that the fundamental theoretical underpinnings of traditional health systems be respected and perpetuated, in order to ensure their continuity in an intact form. It is also important to acknowledge that the social contexts of traditional health care often differ from those of the allopathic (modern, biomedical or 'Western') health sector, particularly with regard to family involvement and the economics of treatment.

1.1.2. *World Health Organization Policy*

The WHO Traditional Medicines Strategy 2002–2005 focused on four areas identified as requiring action, in order to maximise the potential of TCAM to play a role in public health: namely policy; safety, efficacy and quality; access; and rational use. Within these areas, WHO 2002–2005 identified respective challenges for action:

National policy and regulation

- Lack of official recognition of TCAM and TCAM providers
- Lack of regulatory and legal mechanisms
- TCAM not integrated into national health care systems
- Equitable distribution of benefits in indigenous knowledge and products
- Inadequate allocation of resources for TCAM development and capacity building

Safety, efficacy and quality

- Inadequate evidence base for TCAM therapies and products
- Lack of international and national standards for ensuring safety, efficacy and quality control
- Lack of adequate regulation of herbal medicines
- Lack of registration of TCAM providers
- Inadequate support of research
- Lack of research methodology

Access

- Lack of data measuring access levels and affordability
- Lack of official recognition of role of TCAM providers
- Need to identify safe and effective practices
- Lack of cooperation between TCAM providers and allopathic practitioners
- Unsustainable use of medicinal plant resources

Rational Use

- Lack of training for TCAM providers
- Lack of training for allopathic practitioners on TCAM
- Lack of communication between TCAM and allopathic practitioners, and between allopathic practitioners and consumers
- Lack of information for the public on rational use of TCAM

Considerable progress has been made in the development of national policies. At the launch of the Strategy in 2002, only 25 of WHO's 191 Member States had a national policy on TCAM (WHO, 2002), but the recent Global Atlas on Traditional, Complementary and Alternative Medicine commissioned by the WHO Centre for Health Development shows that there are now 66 out of a total of 213 Member States with TCAM policies (Bodeker *et al.*, 2005). A further 43 Member States have at least some specific legislation relating to TCAM, even in the absence of an official national policy, while 20 Member States are currently in the process of developing policies and/or legislation.

In the absence of baseline data, the extent to which the Strategy's other objectives have been achieved is unclear. The development of the WHO Global Atlas on TCAM has highlighted the urgent need for systematic policy-related research, utilisation studies and public outcomes research at the regional, national and international levels. The standardisation of data collection initiatives would allow for international and inter-regional comparisons, as well as the monitoring of progress, and the development of a systematic framework for such research would provide a firm foundation for future WHO Strategies.

1.2. Contexts for Integration and Evaluation: Shaping Questions and Establishing Priorities for Action

1.2.1. Health Service Utilisation and Evaluation

As noted above, the public of many countries is using health care services that are outside the purview and understanding of the dominant medical system. Complementary and traditional medical services are often used alongside conventional medical treatment, but many patients avoid disclosing their use of TCAM to their conventional health care providers: some recent studies have found the rate of non-disclosure to be as high as 77%. The main reasons for non-disclosure were concern about negative responses by medical practitioners; a belief that the practitioners did not need to know about their TCAM use; and the fact that the practitioners did not ask (Robinson & McGrail, 2004).

Thus, a vast, informal, and until recently, 'silent' health care sector exists in all countries, and no comprehensive picture of this exists as yet in any country. Most estimates of the extent of TCAM use have not been population-based, particularly in African countries, where estimates of use range from very low to very high (Bodeker, 2001b). Even in the few countries — mostly industrialised — where population-level TCAM utilisation studies have been conducted, methodological differences make comparisons extremely difficult. Some surveys specify visits to TCAM providers only, others focus on self-medication with TCAM products, and others include both. Lists of eligible therapies are provided in some surveys, whereas in others, the respondents themselves are left to define what constitutes TCAM. The interview technique (questionnaire, telephone or face-to-face) may affect the findings. Even the period of recall varies from one survey to another: some studies are concerned with TCAM utilisation in the past year, or a shorter period such as the past three months, while others relate to lifetime use (WHO Centre for Health Development, 2001).

In particular, what is lacking is a detailed understanding of the differing patterns of use according to disease, income, gender, age, geography and culture. Other research questions include: What are the emerging trends of TCAM use? What is the quality of services being offered to the public? What models exist for partnering the best of TCAM along with the best of conventional medicine to provide effective and affordable health care?

1.2.2. Social and Cultural Dimensions

Social, cultural and political values, as well as socio-economic factors, influence TCAM use in industrialised societies (Astin, 1998; Ong *et al.*, 2002; Eskinazi & Mindes, 2001; Eskinazi, 2001). Predictors of TCAM use in the United States, in a 1998 survey, included commitment to environmentalism, commitment to feminism, and interest in spirituality and personal growth psychology. Members of such groups tend to perceive TCAM as more congruent with their values, worldview and beliefs than the dominant health care system (Astin, 1998).

Ethnic minorities in industrialised countries often continue to use the traditional medicine from their culture alongside, or even in place of, conventional medicine (Ma, 1999; Kronenberg *et al.*, 2002; Factor-Litvak *et al.*, 2001; Reiff *et al.*, 2003). This can apply even in settings where conventional health care is provided free of charge, but traditional health care services must be paid out of pocket, as in the case of Chinese communities in the United Kingdom (Ong *et al.*, 2001; Green *et al.*, 2002). As in developing countries, the affordability, availability and cultural familiarity of traditional medicine, together with family influence (Vissandjee *et al.*, 1997), contribute to the continued use of traditional medical providers and medicines in 'ethnic enclaves'. Ethnic minority patients may be reluctant to seek treatment via the conventional system, or may fail to return for follow-up, due to linguistic barriers and the corresponding absence of shared concepts about health and illness. This is particularly true in the case of patients with mental health problems (Green *et al.*, 2002).

In both ethnic enclaves in industrialised countries and in developing countries, the 'disease' perspective of conventional biomedicine, with its emphasis on quantifiable physical data and on the individual patient, often excludes other dimensions of meaning — psychological, moral and social — that are relevant to patients and their families. Thus, a patient may be told after a physical examination and tests that 'nothing is wrong' physically, but continue to feel unwell or unhappy (Helman, 1994: 137–138). 'Soul loss' may not be recognised as a possible cause of illness, yet may lead to serious problems (O'Connor, 1995). In these situations, a culturally familiar TCAM practitioner, or 'vernacular specialist', can often provide a way of addressing the experience of illness, rather than the physical presence of disease, within the context of the patient's family or wider community.

Policy and research questions in this arena include: In industrialised societies, can ethnic preferences for traditional medicine be built into conventional health service design, to create greater consumer-friendliness in services? What combination of TCAM and conventional services will enhance the health of ethnic minorities? In developing countries, where the number of traditional health practitioners can be hundreds of times greater than that of modern medical practitioners (WHO, 2002), can this vast informal sector be brought into a partnership for addressing national health care goals in an improved model of health care, ensuring that important primary care services are delivered to all those who need them? How can attention to cultural aspects of health and health care be a bridge rather than a barrier to increased health service utilisation and improved levels of health in developing societies?

1.2.3. *Economic Factors*

In most countries, patients are paying out-of-pocket, sometimes on a large scale, for TCAM services still largely not covered by insurance. Of 213 WHO Member States surveyed for the recent Global Atlas (Bodeker *et al.*, 2005), only 58 (27%) are known to have any form of public financing for TCAM, whether full or partial. Reimbursement of TCAM costs by public health insurance is often restricted to specific therapies, or to certain categories of practitioners, and only in a few countries — such as China, Korea and Viet Nam — are traditional treatments and products fully covered by public health insurance. Dedicated public-sector hospitals for TCAM (not necessarily all therapies) are found only in China, Viet Nam, Pakistan, Cuba and the United Kingdom, although individual therapies are offered in public-sector general hospitals in a number of other countries (Bodeker *et al.*, 2005), and in Britain there is a growing trend for the National Health Service to pay for the services of complementary providers (House of Lords Select Committee on Science and Technology, 2000).

Adequate government funding is a prerequisite for effective traditional health care services. Under-investment risks perpetuating poor standards of practice and products, and also contributes to maintaining old stereotypes of inferior services and knowledge in traditional medicine.

In rural areas of many developing countries, self-medication with herbal remedies or dietary therapies is the first-line approach to treating common

diseases, with traditional healers consulted only after home remedies have failed. Increasing regulation and professionalisation of traditional medicine in these countries may result in rising costs, with the risk that the poor may eventually be deprived of services that have historically been their first and last resort for health care. Even if the cost of treatment does not rise in real terms, formalisation processes that disallow flexible methods of payment—such as instalments, and payments in kind—may compromise affordability.

As growing TCAM markets lead to new economic possibilities, research and business interests may shift from providing affordable health care to developing products that can be marketed. The commercial production of botanical medicines can further complicate issues of availability and affordability. As an example, *Artemisia annua* grown in Tanzania is exported to Europe for processing into anti-malarial drugs, with dihydroartemisinin as the active ingredient; the finished products are re-imported to Tanzania and sold for US\$6–7 per dose, far beyond the reach of most people who need them. A feasibility study conducted by Tanzania's National Institute of Medical Research recommended the commercial production of dihydroartemisinin products within the country, at a cost of around \$2 per dose. The WHO Regional Director for Africa has already announced technical support for the programme, including the provision of pure dihydroartemisinin as a reference standard (WHO/AFRO, 2003). An alternative approach could be to fund research into appropriate methodologies for sustainable cultivation and processing of *A. annua* at the local level, with a focus on maximising safety and efficacy while minimising costs. The utilisation of a whole-plant product such as herbal tea, rather than a pharmaceutical with a single 'active' ingredient, may also reduce the potential for the development of parasite resistance (Willcox *et al.*, 2004).

Questions relevant to the economics of TCAM include: Is the public getting value for its money? What modalities are safest and most cost-effective for managing the conditions that are the largest burden on national health budgets? Do TCAM modalities contribute to cost savings through preventing illness, and if so, how can they be expanded? Why are people paying out-of-pocket, as in the UK, for complementary health care services when they have free conventional health services available, or in the US when they may have insurance coverage for conventional approaches? What impact does insurance coverage of TCAM have on use? What are sound models of health financing for CAM and traditional medical services? In the

developing world, how might international funders such as the World Bank, WHO, the Gates and Rockefeller Foundations, the Global Fund and others evaluate and potentially include traditional medicine within the treatment spectrum for priority diseases in public health programmes that they are supporting?

1.2.4. *Priority Disease Management*

TCAM is being used by the public in the management of chronic conditions that are costly to society, including pain and arthritis, and for more life-threatening diseases such as heart disease, cancer and HIV-related illness (Wootton & Sparber, 2001a; Wootton & Sparber, 2001b; Lengacher *et al.*, 2002; Bodeker *et al.*, 2001). In poorer countries, the search for effective and affordable treatments for such epidemics as malaria and opportunistic infections associated with AIDS is driving renewed interest in traditional medicine (Bodeker *et al.*, 2005; UNAIDS, 2002), although herbal medicines are not always the first treatment choice (WHO, 2002). Yet, adequate data do not exist on current patterns of use and effectiveness of the various treatments being used alone and in combination. Additional information is needed on health concerns of the elderly, women, and children. Increasingly, patients are expecting health professionals to guide them in making differential treatment decisions, based on either formal evidence or clinical experience as to whether TCAM or conventional approaches work better, alone, or together.

There are many other dimensions of public health significance that have yet to receive serious and dedicated research attention, funding, or policy consideration. What is called for now is the generation of public health agendas to guide the development of this field. While such agendas will, of course, vary from country to country, a framework is offered here as a contribution towards the development of a more comprehensive approach by policy makers, research groups and funders.

1.3. A Policy Framework

Important issues for setting national and international public health research priorities have been outlined by the Council on Health Research for

Development (COHRED), an international NGO established to ‘promote, facilitate, support and evaluate the Essential National Health Research strategy’. This includes underlying values and operating principles that are sufficiently general to fit the TCAM field as much as any other area of health care (Bodeker *et al.*, 2001). These are: equity; ethics; sustainability; knowledge generation; knowledge management/utilisation; capacity building; and the development of an appropriate research environment. While there are other frameworks for policy development, COHRED’s serves as a catalyst for thought and discussion.

1.3.1. Equity

Equity issues concern both availability of conventional medicine for those who have access only to traditional medicine, and inability to afford the more researched and increasingly expensive CAM treatments. An equity perspective in developing country health care systems would ensure access to affordable, high quality services for those who currently most rely on traditional medicine or have little or no medical care.

In industrialised societies, complementary medicine use has been found to be associated with higher income and education (Astin, 1998; Eisenberg *et al.*, 1998; Ong *et al.*, 2002). Members of the dominant culture who have lower incomes and educational levels tend not to use complementary medicine: this may be due to less disposable income, and less exposure to information about complementary therapies. Availability of broader choices in health care services in these countries is increasingly becoming an elite service for the educated and well-to-do.

Conversely, traditional medicine use by ethnic minorities in those same societies is substantive at times may be the first line treatment for the poor and for those not speaking the language of the dominant society (Kronenberg *et al.*, in press). Inadequate and expensive conventional medical services are factors in such reliance on traditional medicine. ‘Complementary’ medicine in these situations is not complementary; rather, since basic conventional medical care may not be accessible, a danger exists of facilitating a ‘separate but unequal health care system’ (White House Commission on CAM Policy, 2002).

1.3.2. *Ethics*

1.3.2.1. Clinical research

While there are international guidelines for standards of clinical research (Levine & Gorvitz, 2000; Willcox *et al.*, Chapter 16 of this volume), research in TCAM may differ from clinical evaluation of conventional drugs. WHO guidelines for evaluation of herbal medicines consider that for traditional medicines with an established history of use, it is ethical to proceed from basic animal toxicity studies directly to Phase 3 clinical trials (Chaudhury *et al.*, this volume).

Ethical dilemmas can present themselves. In studies to evaluate tropical plants used to prevent and treat malaria, research ethics may require that standard conventional treatment be given to all subjects, so the traditional remedy can only be evaluated in conjunction with conventional treatment (Willcox & Bodeker, Chapter 10 of this volume). Unless alternative models can be developed, the full therapeutic potential of traditional medical treatments may never be known through clinical research.

1.3.2.2. Intellectual Property Rights (IPR)

Exploitation of traditional medical knowledge for drug development without the consent of customary knowledge holders is not acceptable under international law (UN Convention on Biological Diversity, 1993). State parties are required to ‘respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles ... and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices’. Contracting parties should ‘encourage and develop models of co-operation for the development and use of technologies, including traditional and indigenous technologies’.

Until recently, the Convention on Biological Diversity (CBD) competed for influence with the more powerful Trade Related Aspects of Intellectual Property Systems (TRIPS) of the World Trade Organisation (WTO). TRIPS makes no reference to the protection of traditional knowledge. Nor does TRIPS acknowledge or distinguish between indigenous, community-based knowledge and that of industry. In November 2001, the declaration of the

Fourth Ministerial Conference in Doha, Qatar, mandated a review of TRIPS provisions and called for a harmonisation between the CBD and TRIPS. The WTO has begun the process to harmonise TRIPS and the CBD, with particular attention to ensuring adequate protection for indigenous intellectual and cultural property rights (World Trade Organization, 2002).

Researchers evaluating traditional medicines need to recognise that under international law, the customary owner — and often the country of origin — holds rights over the knowledge being evaluated. This has implications for patenting. If a patent is sought by a non-indigenous group, prior informed consent and just benefit sharing with customary owners must be established. A challenge here is how to determine who represents a community, and what represents full consent. These issues are explored in more depth by Bodeker (Chapter 17 of this volume).

1.3.3. *Sustainability*

A number of factors need to be addressed if new policies and practices are to become entrenched and endure. Among the most important are regulation of practice and practitioners, and the provision of adequate financing mechanisms.

1.3.3.1. Regulation

In order to achieve incorporation of TCAM into national health care programmes and systems, it is necessary to distinguish qualified practitioners from those without such qualifications, and to differentiate safe TCAM products from potentially hazardous ones (Shia *et al.*, Chapter 4 of this volume). Issues relating to pharmacovigilance (the monitoring of adverse drug reactions, and appropriate responses to ensure the safety of the public) are explored in detail by Barnes (Chapter 5 of this volume) with reference to herbal medicines in the United Kingdom within the broader context of emerging EU-wide legislation.

Some countries have already taken steps to achieve regulation of practitioners. In the United Kingdom, the House of Lords Select Committee on Science and Technology (2000) recommended that self-regulation should be a cornerstone for the formalisation of the complementary professions. Osteopaths and chiropractors have been registered as official health

professions in the UK through an Act of Parliament, and the basis for maintenance of professional standards is that of self-regulation. The same principle is being applied to medical herbalists and acupuncturists, both of which professions are on track for registration (Walker & Budd, 2002; McIntyre, 2004). Self-regulation of certain TCAM professions is also emerging in Belgium (Eeckloo, 2001), Norway (Langworthy & Birkelid, 2001) and the Russian Federation (Goryunov, 2003, personal communication).

New Zealand has registered more than 600 Maori traditional healers who provide services within the wider health care system. While the government reimburses their services under health insurance, criteria for registration and oversight of professional practice are the responsibility of Maori traditional health practitioner associations (Scrimgeour, 1996).

In the United States, chiropractors are licensed in all 50 states, and acupuncturists are licensed in 41 states. The National Council for Certification of Acupuncture and Oriental Medicine holds a national exam for Traditional Chinese Herbal Medicine. The Botanical Medicine Academy and the American Herbalists Guild are developing a voluntary national examination in the US for practitioners of Western herbal medicine (Abascal & Yarnell, 2001). The United States conferred greater national attention to the policy arena with the establishment in 2000 of the White House Commission on Complementary and Alternative Medicine Policy, whose mandate was to provide 'legislative and administrative recommendations for assuring that public policy maximised the benefits to Americans of Complementary and Alternative Medicine'.

Asia has seen the most progress in incorporating traditional health systems into national health policy. In China, this began in 1951 with the establishment of a Traditional Chinese Medicine Division within the Ministry of Public Health, upgraded to a Department in 1954. In 1988, the State Council established the State Administration of Traditional Chinese Medicine as an independent administrative body in its own right, with eight major departments. The current Chinese regulatory framework not only promotes integration with modern medicine, but also regards TCAM as a major source of international trade and foreign exchange earnings. The Government's commitment to 'develop modern medicine and Traditional Chinese Medicine' has been written into the National Constitution, and the two are regarded as being of equal importance (Baoyan, 2005).

Integration of TCAM into national health care services also began in the 1950s in Viet Nam, where regulated TCAM provision is now available in the Government sector — including institutes of traditional medicine, hospitals of traditional medicine, and departments of traditional medicine in general hospitals, town and village centres — as well as the non-governmental sector. There are several dedicated agencies for TCAM, regulation of practice and products, research, formal training coursework and associations of practitioners. The official national policy on TCAM was formulated in 2003 (Hien & Truong, 2005).

In India, formal recognition for Indian systems of medicine came with the Indian Medicine Central Council Act of 1970, which established regulatory councils for education and practice. The first steps towards mainstreaming traditional health care systems in national health services were taken in 1983, with the recognition of their potential contribution towards achieving the goal of ‘Health for All’. This ultimately led to the establishment of an independent Department headed by a Secretary in the Government of India and, in 2002, to the development of a specific national policy on Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH). In addition to facilitating the integration of these health care systems into national health programmes, the policy also emphasises affordability, safety, efficacy, and the sustainable use of raw materials — particularly those of plant origin (Lavekar & Sharma, 2005).

1.3.3.2. Financing/Insurance Coverage

Out-of-pocket is the most important means of financing TCAM treatments worldwide, and the *only* available financing mechanism in a large number of developing countries, where neither public funding nor private insurance covers these treatments (Burford *et al.*, Chapter 2 of this volume). Even in industrialised countries, insurance coverage for CAM services is relatively new and incomplete, so out-of-pocket spending is considerable. Americans have been found to spend more on CAM than on all US hospitalisations (Eisenberg *et al.*, 1993; Astin, 1998), while Australians spend more on CAM than on all prescription drugs (MacLennan *et al.*, 1996). In Canada, the total out-of-pocket expenditure on CAM was estimated at US\$2.4 billion in 1997 (Health Canada, 2001), while in the United Kingdom it was

estimated at £1.47 billion per annum in 2003, with the inclusion of over-the-counter products (Ong & Banks, 2003).

The effect of user fees on health care utilisation and health outcomes was a subject of debate in the 1990s, centred on the ability and willingness of households to pay out-of-pocket for health care. Research indicates that willingness to pay is not always synonymous with ability to pay: the poor may sacrifice other basic needs such as food and education in order to pay for health care, often with serious consequences (Bodeker, 2002).

Public health insurance is an important funding mechanism for TCAM services in a number of countries of the European Region, with 22 European countries offering full or partial reimbursement for selected TCAM therapies (Burford *et al.*, Chapter 2 of this volume) as well as a few other industrialised countries. Some major American medical insurers confer some benefits for limited complementary medical services, primarily through employer-sponsored health plans (Pelletier & Astin, 2002). In the year 2000, 70% of employee-sponsored programmes covered chiropractic; 17% covered acupuncture, 12% covered massage, and the numbers dwindled from there for other CAM services (White House Commission on CAM Policy, 2002). In the United Kingdom in 1995, 40% of GP practices provided access to CAM, with 10% of the cost being met by the National Health Service (Thomas *et al.*, 2001). In Australia, since the introduction of a Medicare rebate for acupuncture in 1984, use of acupuncture by medical practitioners has increased greatly. Claims rose from 655,000 in the financial year 1984–85 to 960,000 in 1996–97, and Medicare reimbursements to doctors for acupuncture rose from \$7.7 million to \$17.7 million (Easthope *et al.*, 1998).

In the few developing countries where insurance exists, those who can afford the insurance payments will tend to be beneficiaries of a more regulated and safe traditional medicine practice, while the poor continue to purchase unregulated drugs from unlicensed vendors. This creates the skewing of services towards the more affluent that is found with complementary medicine use in industrialised societies, in contrast to the customary role of traditional medicine serving as the first and last resort for health care for the poorer members of society. There is also a risk that improved regulation and training may have the unwanted ‘side effect’ of destroying the flexibility and community-centred focus inherent in many traditional health systems,

which permits the poorest clients to pay by instalments or make a gift in kind to the practitioner. Careful planning by policy-makers is required to ensure that, in becoming 'modernised' and 'professionalised', traditional health care services do not lose the advantages that currently make them an attractive option for millions around the world (Burford *et al.*, Chapter 2 of this volume).

In the case of ethnic minorities in industrialised societies, health insurance coverage can lead to a substantial increase in the use of traditional medical services (Pourat *et al.*, 1999). Again, there is creation of an elite programme through the requirement of insurance coverage, with the poor being less likely to have access to their traditional health care services.

Evaluating health insurance records can be an effective way of estimating whether there are cost savings from using traditional or complementary health care. A retrospective study of Quebec health insurance enrollees compared a group of 1418 Transcendental Meditation (TM) practitioners with 1418 non-meditators. The yearly rate of increase in payments in both groups was not significantly different before learning meditation. After learning, the annual change in mean payments was a decline of 1–2% for the TM group, and an increase of up to 12% for non-meditators. The estimated cost saving was as much as \$300 million per year (Herron & Hillis, 2000).

Cost-benefit research could assess outcomes when traditional or complementary approaches are compared, or combined, with conventional care. This would assist health authorities in making informed choices about the selection of treatments and services to be incorporated into integrated health care programmes.

1.3.4. *Knowledge Generation*

The initiative taken by the United States Congress a decade ago to establish at the National Institutes of Health an Office of Alternative Medicine (now the National Center for Complementary and Alternative Medicine, NCCAM) has led to a focused programme of clinical and basic science research, now seen internationally as a model for how to proceed in conventional scientific research in TCAM (Bodeker & Kronenberg, 2002). NCCAM's mandate is to support rigorous research into efficacy and safety, and thereby establish the evidence base needed for integration of TCAM

into standard medical care (Brixey *et al.*, 2005). A public health agenda is now required, in addition to the focus on experimental and clinical research. While some progress has already been made towards this goal in the United States, with the establishment of a Committee on the Use of Complementary and Alternative Medicine by the American Public under the Institute of Medicine (IOM, a non-profit non-governmental organisation) to explore scientific, policy and practice questions arising from the significant and increasing use of CAM within the country (Institute of Medicine, 2005), efforts must be increased, both within the US and globally. Public health professionals themselves need to be involved in defining the public health dimensions of traditional and complementary medicine.

Adequate funding is of central importance. In the US, funding was initially provided by private donors whose contributions resulted in programmes at academic medical centres (Kronenberg, 2001a). The advent of NCCAM at the NIH substantially legitimised CAM research, and has been followed by funding initiatives from national and international foundations. The biomedical community's response has escalated research momentum. This wave has yet to reach public health research. In the absence of a significant voice from the public health research community, funders have remained focused on issues of safety, efficacy and the mechanisms of action of complementary and traditional medicine. Priority should now be assigned to strengthening the public health research agenda if knowledge generation is to keep abreast of consumer demand for cost-effective services, and government and insurer demands for policy information.

In addition, mainstream research funds should encourage a component of research into traditional ways of treating specific conditions, and the contribution of TCAM therapies to disease prevention and general health maintenance. While research into prevention is long-term, methodologically difficult and often expensive, the potential benefits could be substantial (Herron & Hillis, 2000). Other important areas of research include the extent to which therapeutic outcomes are based on belief, attitude and expectations; the contribution of TCAM therapies to the spiritual dimensions used in assessing an individual's quality of life; and the effects of combining therapies, as when traditional Chinese medicine and allopathic medicine are used simultaneously in treating a condition.

1.3.5. *Knowledge Management and Utilisation*

In order to ensure sound standards of practice based on recognised levels of training and the use of TCAM therapies that are safe and effective, information generation and dissemination is needed across a wide range of professional and commercial areas. Comprehensive information resources will be fundamental to the evolution of research and policy activities, but developing them will be challenging to accomplish. Material currently accessible online is limited in scope. Much of it consists of commercial sites containing information related to products being marketed. Only a small number of bibliographic databases (e.g. MEDLINE from the US, and the British Library's AMED) allow free access to information, albeit from a limited sample of journals. Full papers are available free of charge only in rare cases; more usually, the abstract or even just the citation is given. Most relevant scientific databases are accessible on a fee-paying basis. Each database is compiled in a unique format and style. Data structure, indexing methods and terminology used for data retrieval are also vary widely. Much of the material is not available in English (Kronenberg, 2001b).

A freely available, comprehensive, web-based resource on complementary and traditional medicine could provide accurate and authoritative information on safety and efficacy, legal and regulatory policies, research resources, education and training programmes, trade statistics, intellectual property guidelines, among other content. It would also allow for rapid, global updating of information in a field of growing significance worldwide. Initiatives have been proposed to make significant investments of time, but would need substantive funding to establish this — e.g. by the Commonwealth countries (Reuters, 2001) and others (Noller *et al.*, 2001; Kronenberg, 2001a).

1.3.6. *Capacity Building*

What constitutes capacity in public health with respect to complementary and traditional medicine, and how should capacity be strengthened? Strengthening is needed in safety, efficacy, standardisation, current utilisation, cost-effectiveness, customer satisfaction, priority diseases (communicable and degenerative), disease prevention, and the maintenance of overall well-being.

Investment in professionals will result in leaders who will contribute to implementing public health responses to the growth in complementary and traditional medicine. Schools of public health can contribute by offering training for students in areas of TCAM, encouraging masters and doctoral research projects, and providing continuing education programmes. Wherever biomedical health care providers, such as physicians, nurses, pharmacists and midwives, are permitted to offer TCAM therapies, they must receive adequate training in the fundamentals of the relevant TCAM modalities as well as in conventional medicine. A matter of some concern is the number of countries in which physicians and/or allied health professionals are legally entitled to provide TCAM treatments with only limited training, or without receiving any specific training in these health care approaches (Bodeker *et al.*, Chapter 3 of this volume).

Expanded capacity would include greater understanding of the potential for benefit, risks, and the costs of these health care approaches. It would include systems for harnessing potential contributions to meeting major public health challenges — both in terms of practitioners as a resource for disseminating health information, and through tested modalities offering potential cost-effective choices.

An often-quoted statistic is that only 10% of the funding for health care research and development is spent on 90% of the world's health problems (Global Forum for Health Research, 2004). Traditional health care systems can make a significant contribution to the fight against priority diseases affecting the developing world, including HIV/AIDS, malaria and tuberculosis, and against the unacceptably high levels of maternal and perinatal mortality that currently exist in many countries (Bodeker *et al.*, Chapter 3 of this volume). There are notable examples in Africa of traditional health practitioners being involved in HIV prevention programmes. Each trained practitioner is able to deliver a prevention message to around 1000 people in less than a year (Green, 1997). Emerging research is focusing on the role that traditional herbal medicines might play in alleviating the symptoms of HIV/AIDS, for those unable to afford or obtain even subsidised anti-retroviral drugs (Liu, Chapter 12 of this volume; Bodeker *et al.*, Chapter 11 of this volume; Bodeker *et al.*, 2000). Similarly, in the field of malaria, an international research collaboration coordinated

by the Global Initiative for Traditional Systems of Health is addressing both prevention — through traditional methods for repelling and controlling mosquitoes — and treatment (Willcox & Bodeker, Chapter 10 of this volume; Bodeker & Willcox, 2000, Willcox *et al.*, 2001; Willcox *et al.*, 2004).

Despite the growing number of small and medium-sized initiatives to involve traditional health care providers in the management of priority health problems, their potential has been almost entirely overlooked in the large-scale international programmes for combating these problems, such as those funded by the World Bank, Gates Foundation, Global Fund and other major donors. If these large global programmes are to achieve their goals, however, there is also a need for them to consider factors such as cultural familiarity and acceptability, affordability, accessibility, and the potential for local production in order to generate long-term sustainability after the withdrawal of funding. Effective capacity building can raise awareness of such issues and help traditional health care systems, which offer all of these advantages, to find a place across disease categories in the respective agendas of large funders.

1.3.7. *Research Environment*

Further development of TCAM services is predicated on a broad base of quality research. The NIH/NCCAM experience in the US has shown that when funds are available and priorities are set, TCAM research will grow exponentially. As noted in Section 1.3.4 above, the need now is to expand beyond just basic, clinical and experimental research to a fully articulated programme of public health research.

Donors, policy-makers, patients, and health care providers worldwide have all called for evidence of what constitutes the ‘best’ treatments. The randomised controlled clinical trial (RCT) is considered by the biomedical establishment to be the core of biomedical evidence, but considerable preliminary work is essential, particularly in areas of traditional systems of medicine, before one can even design the appropriate RCT. Respecting the basic concepts and principles of traditional health care systems,

while developing trials according to rigorous clinical pharmacological principles, is an important challenge. The question of how 'gold standard' RCT methodology can be adapted to meet the needs of these systems, or other scientific methodologies used, is already being addressed, both within the Indian context and in Traditional Chinese Medicine (Chaudhury *et al.*, Chapter 15 of this volume). It should also be recognised that while providing valuable information, RCTs have limitations that can be addressed by social science and public health research methodologies. RCTs are inadequate for measuring infrequent adverse outcomes, such as rare side-effects of drugs, and there are also limitations in adequately evaluating the long-term consequences of therapy, such as toxicity from chronic, low-level exposure to medications. Ethnographic, epidemiological, observational, survey and cohort methodologies can contribute, and fall within the public health domain (Margolin, 1999).

Unmet health needs of ethnic minorities, women, children, the poor, the elderly and those with special medical conditions must be considered in the establishment of a public health research framework and priorities for action. Also needing attention are diseases for which current conventional treatment regimens are unsatisfactory, e.g. many cancers and chronic debilitating conditions, for which the public are turning to TCAM.

Prevention of disease is a cornerstone of many traditional and complementary health systems, with diet and nutrition as well as traditional forms of exercise (e.g. yoga, Tai Chi) and stress reduction being used in combination to promote balanced health (Schneider *et al.*, 2002). While research into illness prevention is long-term, methodologically difficult and often expensive, the potential benefits could be substantial (Herron & Hillis, 2000).

Belief and attitude have an influence on treatment outcomes in all therapeutic settings, western and other traditions. A 'placebo' or 'meaning response' effect is an important component of many therapies. The extent to which therapeutic outcomes are based on expectancy is an important area of study.

WHO's Quality of Life Assessment includes spiritual dimensions in assessing an individual's quality of life. Here, 'spiritual' relates to the sense of meaning regarding the self or extending beyond the self. The spiritual dimension of life and well-being is central to many traditional and complementary health systems. In Britain, 12% of those who use CAM providers

use the services of ‘spiritual healers’ (Ong *et al.*, 2002). This trend, its origins and outcomes are important areas of research.

Comparative evaluation of complementary and conventional medicine approaches to treating specific health conditions is needed. This may include study of cross-cultural healing practices to identify common treatments and/or to combine evidence for a specific herb or treatment regimen. Comparative studies could assess feasibility, cost-effectiveness, and environmental impact as well as specific biomedical outcomes.

Combinations of therapies should also be studied. For example modern medicine and traditional systems (such as Ayurveda in India and Traditional Chinese medicine) are often used simultaneously in the treatment of certain diseases in Asian countries. Caution should be exercised to identify and address cultural biases in the assumptions, methodologies and concepts when conducting comparative research.

A range of methodologies, then, can and should be employed in evaluating traditional and complementary therapies. These should be applied in a manner that is sensitive to the theoretical, clinical, and cultural assumptions of the modality/systems being evaluated in order to ensure that the research design adequately measures what one thinks is being studied (Chaudhury *et al.*, Chapter 15 of this volume).

New directions must be forged by researchers who are able to transcend limitations in research orthodoxy in the interests of providing sound information to the public on what constitutes good health care.

1.4. Conclusion

As governments, the World Health Organization, and other international bodies begin to address the complexities of establishing regulatory and policy guidelines for ensuring the safety and quality of complementary and traditional health services, a broad public health capacity is called for. As discussed here, this should evolve with an awareness of social, cultural and political dimensions, and should address values (equity, ethics), sustainability (regulation, financing, knowledge generation, knowledge management, capacity building) and the research environment.

Such a broad-based strategy is required if complementary and traditional medicine is to shift from the marginal status it holds in most countries,

to having a significant role in national health care. Political will as well as scientific will and data are needed to support such an agenda. Ultimately, nothing would be considered complementary or alternative, orthodox or conventional. Rather, all possible contributions to health would be evaluated for their promise, and harnessed for the good of the public's health.

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