A Public Health Agenda for Traditional, Complementary, and Alternative Medicine

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Traditional medicine (a term used here to denote the indigenous health traditions of the world) and complementary and alternative medicine (T/CAM) have, in the past 10 years, claimed an increasing share of the public's awareness and the agenda of medical researchers. Studies have documented that about half the population of many industrialized countries now use T/CAM, and the proportion is as high as 80% in many developing countries.

Most research has focused on clinical and experimental medicine (safety, efficacy, and mechanism of action) and regulatory issues, to the general neglect of public health dimensions. Public health research must consider social, cultural, political, and economic contexts to maximize the contribution of T/CAM to health care systems globally.

THE GROWTH OF PUBLIC

interest in and use of traditional medicine and complementary and alternative medicine (T/CAM) has been well documented. Almost half the population in many industrialized countries now regularly use some form of T/CAM (United States, 42%¹; Australia, $48\%^{2}$: France, $49\%^{3}$: Canada. 70%⁴), and considerable use exists in many developing countries (China, 40%; Chile, 71%; Colombia, 40%; up to 80% in African countries^{5,6}). Popular use of T/CAM has been accompanied by a growth in research and associated literature, with an increase in an evidence-based approach over the past decade.⁷ In developing countries, where T/CAM has long been practiced both within and outside the dominant health care system, interest has been building over the past decade for a policy framework for T/CAM within national health care systems, and some guidelines have been created.^{8,9}

The term "traditional medicine" is used here to denote the indigenous health traditions of the world; "complementary and alternative medicine" primarily refers to methods outside the biomedical mainstream, particularly in industrialized countries; and "conventional medicine" refers to "biomedicine" or modern medicine.

While much of the momentum in the research and policy arenas has been driven by consumer demand or continued customary and traditional use, research and policy developments to date have tended to address 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. Educational and training efforts, particularly in industrialized countries, have involved medical students and conventional health care practitioners.¹⁰⁻¹² Regulation of practitioners and guidelines for licensing and establishment of standards of practice and self-regulation have only recently been considered in industrialized countries.^{13,14} Only 25 of the 191 World Health Organization (WHO) member states have national policies on T/CAM. The newest WHO policy on T/CAM focuses attention on regulation as well as safety and efficacy issues.⁶

A concerted effort by public health professionals to develop a comprehensive view of the field, to generate a targeted public health research agenda, and to set policy priorities is now needed to address the public health dimensions of the use of T/CAM. While it is not our intent to provide such an agenda, which will likely vary from country to country, we hope that this article may stimulate the development of a more comprehensive approach by research groups and funders.

WHO TRADITIONAL MEDICINES STRATEGY

The newly published (May 16, 2002) WHO Traditional Medicines Strategy 2002–2005 focuses on 4 areas that will require action if the potential role of T/CAM in public health is to be maximized. These areas are policy; safety, efficacy, and quality; access; and rational use. Within each of these areas, WHO identifies challenges for action.

National policy and regulation

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

Safety, efficacy, and quality

- Inadequate evidence base for T/CAM 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 T/CAM 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 T/CAM providers
- Need to identify safe and effective practices
- Lack of cooperation between T/CAM providers and allopathic practitioners
- Unsustainable use of medicinal plant resources

Rational use

- Lack of training for T/CAM providers
- Lack of T/CAM training for allopathic practitioners
- Lack of communication between T/CAM and allopathic practitioners and between allopathic practitioners and consumers
- Lack of information for the public on rational use of T/CAM.

These are tasks that have been repeatedly identified by numerous groups. If WHO can now stimulate action by bringing attention, and perhaps funding, to some of these goals, that would be a significant step forward.

CONTEXTS FOR CONSIDERATION AND EVALUATION OF T/CAM

The above-mentioned activities should be considered within social, cultural, and economic contexts to help shape questions and establish priorities for action.

Health Service Utilization and Evaluation

As noted above, the public in 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 (and in addition to) conventional medical treatments.



Thus, a vast informal and until recently silent health care sector exists in all countries, and no comprehensive picture of this sector exists as yet in any country.¹⁵ Most estimates of extent of traditional health care use have not been population-based, particularly in African countries, where estimates of use range from very low to very high.¹⁵

Research questions include the following: What are the trends and demographics of T/CAM use? What is the quality of services being offered to the public? What

A pharmacist stands in front of medicine cabinets displaying herbal extracts.



Right: An herbal medicine stall in the market of Antananarivo, Madagascar.

Below: Artemisia annua drying before being processed into a new antimalarial derived by the Chinese method of preparation. The plant is known in Chinese as *qing hao su* and is used traditionally as a febrifuge.



models exist for partnering the best of T/CAM with conventional medicine to provide effective and affordable health care?

Social and Cultural Dimensions

Social, cultural, and political values, as well as socioeconomic factors, influence T/CAM use in industrialized societies.^{16–19} Eth-

nic minorities in industrialized countries often continue to use their cultures' traditional medicine alongside, or even in place of, conventional medicine.^{20–22} Some cannot afford to pay for conventional biomedical services and find traditional medicines and practitioners affordable and accessible. Those who have insurance may have access to hospital procedures covered by their policies but may not be able to afford the out-of-pocket expenses for less invasive T/CAM services. In developing countries (and in ethnic enclaves in industrialized countries), the affordability, availability, and cultural familiarity of traditional medicine, as well as family influence, contribute to the continued use of traditional medical providers and medicines.²³ Yet important primary care services may not be available.

Policy and research questions in this arena include the following: In industrialized societies, can ethnic preferences for traditional medicine be built into conventional health service design to

create greater consumer friendliness? What combination of T/CAM 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 the number of modern medical practitioners,⁶ can this vast informal sector be brought into a partnership for addressing national health care goals in an improved model of health care? How can attention to cultural aspects of health and health care be a bridge rather than a barrier to increased health service utilization and improved levels of health in developing societies?

Economic Factors

In most countries, the public is paying out of pocket, sometimes on a large scale, for T/CAM services that are still, for the most part, not covered by health insurance. In a few countries, such as China, Korea, and Vietnam, insurance fully covers TM treatment and products.⁶ In most countries, however, insurance coverage for T/CAM is only partial (the United Kingdom, Japan, Germany, Australia, the United States) or nonexistent (e.g., most African countries; see also "Sustainability and Integration" in this article). In Great Britain there is a growing trend for the National Health Service to pay for the services of complementary providers.²⁴ Additionally, as growing T/CAM markets lead to new economic possibilities, research and business interests may shift from providing affordable health care to developing products that can be marketed.

Questions in this area include the following: Is the public getting value for its money? What modalities are safest and most cost-effective for managing the conditions that impose the largest burden on national health budgets? Do T/CAM modalities contribute cost savings by preventing illness? Why are people paying out of pocket for complementary medical services when they have free conventional health services available, as in Great Britain, or when they may have insurance coverage for conventional approaches, as in the United States? What impact does insurance coverage for T/CAM 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 programs that they support?

Priority Disease Management

T/CAM is being used by the public in the management of

chronic conditions that are costly to society, such as chronic pain and arthritis, and more lifethreatening diseases, such as heart disease, cancer, and HIVrelated illness.^{25–27} In poorer countries, the search for effective and affordable treatments for epidemic diseases such as malaria and opportunistic infections associated with AIDS is driving renewed interest in traditional medicine, although herbal medicines are not always the first treatment choice.⁶ Yet we do not have adequate data 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. And increasingly, patients are expecting health professionals to guide them, on the basis of either formal evidence or clinical experience, in making decisions about whether T/CAM or conventional approaches work better, or whether they might best be used together.

A POLICY FRAMEWORK

There are other important issues for consideration in the setting of national and international public health research priorities. One framework has been set forth by the Council on Health Research for Development, an international nongovernmental organization 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 T/CAM field as much as any other area of health care.²⁸ While there are other frameworks for policy development, the one developed by the

Council serves as a catalyst to thought and discussion.

EQUITY

In industrialized societies, use of complementary medicine has been found to be associated with higher income and higher education.^{1,16,17} Yet for ethnic minorities in those same societies, traditional medicine may at times be the first-line treatment for the poor and those who do not speak the language of the dominant society. Inadequate and expensive conventional medical services are

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factors in such reliance on traditional medicine. "Complementary" medicine in these situations is not complementary, since basic conventional medical care may not be accessible to these people; thus there is a danger of facilitating a "separate but unequal care system."¹⁴

In industrialized countries, members of the dominant culture who have lower incomes and educational levels tend not to use complementary medicine. This may be because they have less disposable income and less exposure to information about complementary therapies.¹⁷ The availability of broader choices in health care services in these countries is increasingly concentrated among the educated and well-to-do. Equity issues concern

both the availability of conventional medicine and the affordability of 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 rely mostly on traditional medicine or who have little or no medical care.

ETHICS

Clinical Research

While there are international guidelines for standards of clinical research,²⁹ research in traditional and complementary therapies 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.³⁰

Ethical dilemmas can present themselves. In studies to evaluate tropical plants used to prevent and treat malaria,³¹ research ethics may require that standard conventional treatment be given to all subjects, so the traditional remedy can be evaluated only in conjunction with conventional treatment. Unless alternative models can be developed, the full therapeutic potential of traditional medical treatments that are claimed to be effective may never be known through clinical research.

Intellectual Property Rights

Exploitation of traditional medical knowledge for drug development without the consent of customary knowledge holders is not acceptable under international law. State parties are required to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles . . . and promote involvement of the holders of such knowledge and practices 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."32

Until recently, the Convention on Biological Diversity competed for influence with the more powerful Trade Related Aspects of **Intellectual Property Systems** (TRIPS) of the World Trade Organization. TRIPS makes no reference to the protection of traditional knowledge, nor does it acknowledge or distinguish between indigenous, communitybased knowledge and that of industry. In early 2002, the World Trade Organization began a process to harmonize TRIPS and the Convention on Biological Diversity to ensure adequate protection for indigenous intellectual and cultural property rights.33

Researchers evaluating traditional medicines need to recognize that under international law, the customary owner, and often that owner's country of origin, holds rights over the knowledge being evaluated. This has implications for patenting. If a patent is sought by a nonindigenous group, prior informed consent and just benefit sharing with customary owners must be established. The challenge here is how to determine who represents a community and what represents full consent.

SUSTAINABILITY AND INTEGRATION

A number of factors need to be addressed if new policies and practices are to become entrenched and endure.

Regulation of Practice and **Practitioners**

To achieve incorporation of T/CAM into national health care programs and systems, one must distinguish qualified practitioners and practices. Some countries have taken steps to achieve this. The House of Lords Committee on Complementary Medicine in Great Britain recommended that self-regulation be a cornerstone for the formalization of the complementary professions.13 In Great Britain, osteopaths and chiropractors have been registered as official health professionals through an act of Parliament, and the basis for maintenance of professional standards is self-regulation. The same principle is being applied to medical herbalists and acupuncturists, both of which are on track for registration in Great Britain.

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.³⁴

Asia has seen the most progress in incorporating traditional health systems into national health policy. In some Asian countries, such as China, this has been achieved through national policy.³⁵ In others (e.g., India and South Korea), change has come about as a result of

To achieve incorporation of T/CAM into national health care programs and systems, one must distinguish qualified practitioners and practices.



Left to Right: Man undergoing cupping, a traditional Chinese remedy; sports massage; insertion of acupuncture needles into a patient's back.

politicization of the traditional medicine agenda.

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 for US practitioners of Western herbal medicine.³⁶ The United States recently conferred greater national attention on the policy arena with the establishment in 2000 of the White House Commission on Complementary and Alternative Medicine Policy. The commission's mandate was to provide "legislative and administrative recommendations for assuring that public policy maximized the benefits to Americans of Complementary and Alternative Medicine."

Financing and Insurance Coverage

In industrialized 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 hospitalizations.^{16,37} Australians spend more on CAM than on all prescription drugs.² Some major American medical insurers confer some benefits for limited complementary medical services, primarily through employersponsored health plans.³⁸ In 2000, 70% of employee-sponsored programs covered chiropractic, 17% covered acupuncture, 12% covered massage, and

the numbers dwindled from there for other CAM services.¹⁴

The effect of user fees on health care utilization and health outcomes was a subject of debate in the 1990s, a debate centered on the ability and willingness of households to pay out of pocket for health care. Research indicates that the poor may sacrifice other basic needs to pay for health care, often with serious consequences.³⁹ When funds are allocated to the traditional medicine sector in resource-poor countries, resentment can arise in underfunded sections of the conventional medical sector.

In developing countries, those who can afford insurance will be beneficiaries of a more regulated and safe traditional medicine practice, while the poor may be purchasing unregulated drugs from unlicensed vendors. This

leads to T/CAM utilization by those who can afford to pay for insurance, thus creating the skewing of services toward the more affluent that is found with complementary medicine use in industrialized societies. This is in contrast to the customary role of traditional medicine, that is, the first and last resort for health care for the poorer members of society.

In the case of ethnic minorities in industrialized societies, health



Row of eyedroppers in an herbal tonic cafe.

insurance coverage can lead to a substantial increase in the use of traditional medical services. Again, there is the creation of an elite who can afford traditional medicine because they have insurance coverage, while the poor are less likely to have access to their traditional health care services.

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 1984/1985 to 960 000 in 1996/1997, and Medicare reimbursements to doctors for acupuncture rose from \$7.7 million to \$17.7 million.⁴⁰

Evaluating health insurance records can be an effective way of estimating whether there is a 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 nonmeditators. The yearly rate of increase in payments in both groups was not significantly different before the TM group learned meditation; after learning, the annual change in mean payments was a decline of 1% to 2% for the TM group and an increase of up to 12% for nonmeditators. The estimated cost saving was as much as \$300 million per year.41

Cost-benefit research could assess outcomes when traditional or complementary approaches are compared 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 programs.

KNOWLEDGE GENERATION

The initiative taken by the US Congress a decade ago to establish an Office of Alternative Medicine (now the National Center for Complementary and Alternative Medicine [NCCAM]) at the National Institutes of Health has led to a focused program of clinical and basic science research, now seen internationally as a model for how to proceed in conventional scientific research in T/CAM. A public health agenda is needed in addition to the focus on experimental research. Public health professionals need to define the public health dimensions of traditional and complementary medicine.

Adequate funding is of central importance. In the United States, funding was initially provided by private donors whose contributions resulted in programs at academic medical centers.42 The advent of NCCAM substantially legitimized CAM research and has been followed by funding initiatives from national and international foundations. The biomedical community's response has escalated research. 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 will need to be assigned to public health if knowledge generation is to keep abreast of consumer demand for cost-effective services and government and insurer demands for policy information.

KNOWLEDGE MANAGEMENT AND UTILIZATION

To ensure sound standards of practice based on recognized levels of training and the use of T/CAM therapies that are safe and effective, information and its dissemination are 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 a

challenge. Material currently accessible online is limited in scope, and much of it consists of information related to commercial products being marketed. Only a small number of bibliographic databases (e.g., MED-LINE in the United States and the British Library's AMED) allow free access to information, albeit from a limited sample of journals. Most relevant scientific databases are accessible on a fee basis. Each database is compiled in a unique format and style. Data structure, indexing methods, and terminology used for data retrieval also vary widely. Much of the material is not available in English.43

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 programs, trade statistics, intellectual property guidelines, and other areas. It would also allow for rapid, global updating of information in a field of growing significance worldwide. Initiatives exist to make significant investments of time and money to establish this.43-45

CAPACITY BUILDING

What constitutes capacity in public health with respect to T/CAM and how should capacity be strengthened? Strengthening is needed in safety, efficacy, standardization, current utilization, cost-effectiveness, customer satisfaction, priority diseases (communicable and degenerative), disease prevention, and 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 T/CAM, encouraging masters and doctoral research projects and continuing education programs.

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 in terms of tested modalities offering potential cost-effective choices.

RESEARCH ENVIRONMENT

Further development of T/CAM services is predicated on a broad base of quality research. The NCCAM experience in the United States has shown that when funds are available and priorities are set, CAM research will grow exponentially. The need now is to expand beyond basic clinical and experimental research to a fully articulated program of public health research.

The international community has called for evidence of what constitutes best treatments. The core of biomedical evidence is the randomized controlled clinical trial (RCT). 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 infrequent adverse effects of drugs. There are also limitations in adequately evaluating



the long-term consequences of therapy, such as toxicity from long-term, low-level exposure to medications. Considerable preliminary work is essential, particularly in areas of traditional systems of medicine, before one can even design the appropriate RCT. Ethnographic, epidemiological, observational, survey, and cohort methodologies can make a contribution, and they fall within the public health domain.⁴⁶

Unmet needs of ethnic minorities, women, children, the poor, the elderly, and persons 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, for example, many cancers and chronic debilitating conditions, for which many people are turning to complementary medicine.

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.⁴⁷ While research into prevention is longterm, methodologically difficult, and often expensive, the potential befits could be substantial.⁴¹

Belief and attitude have an influence on treatment outcomes in all therapeutic settings, in 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. 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 Great Britain, 12% of those who use complementary medicine providers use the services of spiri-

tual healers.¹⁷ This trend and its origins and outcomes are important areas of research.

Comparative evaluations of complementary and conventional medicine approaches to treating specific health conditions are needed. This may include study of cross-cultural healing practices to identify common treatments 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 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 or system being evaluated in order to ensure that the research design adequately measures what one thinks is being studied.

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.

CONCLUSION

As governments 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 agenda is called for. This agenda 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 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 intent as well as scientific intent 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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This article was accepted July 2, 2002.

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Both authors contributed to the writing and editing of the article.

Acknowledgments

This work was funded in part by the NIH National Center for Complementary and Alternative Medicine (grant P50-AT00090) and by Global Initiative for Traditional Systems of Health.

Thanks to Christine Wade, Janet Mindes, and Corrine Axelrod for their helpful comments on the manuscript and to Eric Shaw for helping with research and with putting the manuscript together.

This material was originally presented in part by Dr Bodeker as an invited lecture, titled "Use of Traditional and Complementary Medicine: Relevance for Public Health," at the Rosenthal Center for Complementary and Alternative Medicine, Columbia University, New York, NY, February 20, 2002.

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