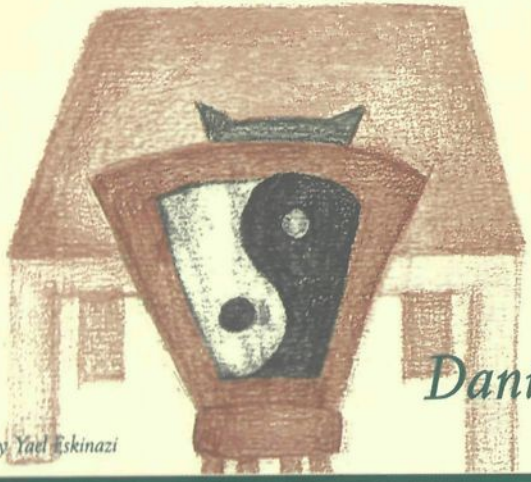
What Will Influence the Future of Alternative Medicine?

A WORLD PERSPECTIVE



editor

Daniel Eskinazi

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Foreword

The papers published in this monograph were presented at a symposium that took place in Seoul, South Korea, on October 22, 1999. I organized this part of the symposium at the request of Dr. Kwang-Yul Cha, MD, of CHA General Hospital, Pochon CHA University, Dr. Cha had approached the Richard and Hinda Rosenthal Center for Complementary and Alternative Medicine (RHRC), where I was a visiting faculty, in the hope of collaborating on projects of common interest. In this context, Dr. Cha generously agreed to underwrite the workshop I was organizing in Seoul as chair of the International Collaboration for Information on Complementary and Traditional Medicine. Further, Dr. Cha had the excellent idea to suggest this symposium because a number of international experts in alternative medicine already were to be present at the workshop.

I proposed to focus this part of the symposium on factors that shape the field of alternative medicine because I feel that it is a most important topic, and one that is frequently neglected. Most meetings on alternative medicine focus on the science of alternative medicine and not on the context within which this science is conducted. This is somewhat unfortunate, as science is not conducted in a vacuum, and the ultimate impact of any discussions and studies in that field will continue to be less than optimal if all the factors that are indeed playing a role in making "alternative" medicine "alternative" are not taken into account.

I would like to express my deep appreciation to Dr. Kwang-Yul Cha, both for his generous support, and also for his foresight and his wonderful hospitality while we were in Korea. I would also like to thank the team of organizers he appointed in Seoul. They not only helped us with the logistical arrangements for the symposium, but they also organized the presentation of a series of papers discussing the practice of Korean traditional medicine. These papers

were not immediately relevant to the topic of the present monograph (and therefore are not included here), but they certainly contributed to the success of the overall symposium. I worked very closely with our Korean colleagues, and their help was invaluable. I would like in particular to thank Dr. Lee Kyung-Ah, PhD, and Dr. Lee Youngjin, MD, for their tireless efforts in dealing with the endless issues that predictably came up while preparing this joint symposium halfway around the world. I would also like to thank Mr. Sung-Dae Suh, and other staff members of the CHA Hospital too numerous to mention here, for their attentive dedication while we were in Seoul. On the American side, I would like to acknowledge the help of Dr. Janet Mindes of the RHRC and her considerable input in collecting and editing the papers presented here.

Daniel Eskinazi, DDS, PhD, LAc
New York, April 2, 2001

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Factors that will Shape the Future of Alternative Medicine: An Overview

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1. Introduction

In the United States and worldwide, use of "complementary and alternative medicine" is increasing, and has resulted in major non-reimbursed medical or health-related consumer expenditures. Although the term "complementary and alternative medicine" ("CAM") has been largely adopted by the American academic community, there are also several possible other terms, such as alternative medicine (AM), integrative, unconventional, soft, parallel, etc. We feel that none of them is satisfactory. We will arbitrarily use the term AM throughout, as we imply that many of these practices as they exist in the US today are derived from traditional systems from other cultures. We will also use the word "traditional" to refer to age-old cultural practices, and "conventional" to refer to practices of Western biomedicine.

In this paper, I will propose a new definition of "alternative medicine". I will discuss how this definition predicts that factors other than the scientific either stimulate or impede progress in defining and investigating alternative and traditional medicine. I will also suggest that the proposed definition further implies programmatic directions that are often not being considered.

2. Background: Alternative Medicine in the United States

The current interest in AM in the US stems from the growing use of these practices by Americans.[1-5] In the US, private insurance companies largely cover healthcare costs, and subscribers' medical expenses are reimbursed in varying degree by health insurance, depending on their plans' policies. Reimbursement usually covers the accepted standard of care. Therefore, AM is, by definition, not covered by these plans, and must be paid out of the pocket. Non-reimbursed costs associated with use of AM in the US seem to have increased considerably, from US$14 billion in 1990 to US$21 billion in 1998,[1,2] a figure considerably higher than that of all non-reimbursed conventional healthcare expenses. This confirms a trend of increasing use of AM that was already suspected as early as the 1980s. Reflecting this interest of the American public in alternative medical care, the American Congress, in October 1991, instructed the National Institutes of Health (NIH), the premier medical research institution in the nation, to create an office to "investigate and validate unconventional medical practices." In 1993, that office was renamed "Office of Alternative Medicine (OAM)", and in October 1998, it was elevated to the rank of an NIH Center, the National Center for Complementary and Alternative Medicine (NCCAM).

3. Current Definition of Alternative Medicine

Despite the worldwide increasing use of and attention paid to AM,[6-8] no accepted definition of this term has been established thus far. The importance of definitions has been underestimated in that they define the scope of AM for the lay and professional public, and bias the mindset for approaching this varied and complex field. I also contend here that the "*why AM*" is essential to defining "*what is AM*". *Why* is there a field of AM in our ever-shrinking world, when the once-distant cultures that gave birth to most AM are now familiar to most? Why also, is there AM if science is dispassionate

as it claims to be in theory, and open to examining any worthwhile phenomena, instead of dismissing them at the outset? Shouldn't one expect that the best possible therapies would be available to patients regardless of what these therapies are or where they come from? Why have entire age-old systems of health been ignored by biomedical science?

Existing definitions of AM are unsatisfactory, in part because they fail to address the fundamental issue of *why* they are "alternative", and because they fail to take into account diverse fundamental characteristics of AM, which should be part of any definition. For example, many healthcare practices are labeled "alternative" because it is felt that there is a lack of relevant, good quality scientific research to substantiate claims of efficacy.[9,10] However, issues beyond the scientific appear to be involved, if one considers that it required congressional intervention for the US National Institutes of Health (NIH) to earmark 0.02% (US$2 million) of its US$10.7 billion 1992 budget to evaluate practices used by more than 35% of the American population.[11,12]

Some of the current definitions are pragmatic, and consist of ad hoc lists of disparate practices deemed alternative: entire complex traditional healthcare systems (e.g. Chinese (TCM), East Indian (Ayurveda) and Native American[5,13]); their components practiced as distinct complementary entities (e.g. herbal medicine, acupuncture, dietary principles and spiritual practices); and also a wide variety of difficult-to-categorize discrete modalities and products. Furthermore, among the proponents of practices such as hypnosis, osteopathy and chiropractic (taught in the US by degree-granting institutions for more than a century), there is little consensus as to whether these modalities are alternative or mainstream.

The few attempts at conceptual definitions identify AM as what is not conventional, e.g. what is not covered by insurance, or is not taught in medical schools.[1] These definitions also have drawbacks, as reference criteria are changing rapidly and are not consistent worldwide (nor even across the US). Health insurance coverage for alternative practices varies widely among countries, and regionally

within many countries. For example, homeopathic medicines have been reimbursed by the French national healthcare insurance for decades, while in other countries they are not. In Germany, medical doctors can prescribe herbal medicines like pharmaceutical drugs, while in France botanical medicine is not covered. In the US, great regional variation exists in the pattern of reimbursement for alternative forms of care, and most are not yet covered. In some countries (e.g. France), only physicians can legally practice any kind of medicine (including osteopathy, acupuncture and homeopathy), while in other countries (e.g. Great Britain and Germany) these same disciplines can be practiced by individuals who are not conventional physicians. Within the US, some 75 or so medical schools offer courses in AM. Most of these courses are elective, a few are now compulsory, and their curriculum varies widely.[14,15]

4. Proposed Definition of Alternative Medicine

To provide a rational definition of AM, it is clearly necessary to identify common traits of these very disparate practices. Most of what falls under the scope of AM has its origins in traditional systems of health. It is apparent that some kind of spirituality, often directly related to the dominant religion or philosophical system of the originating culture, is an integral part of most traditional systems of health.[5,13,16–19] In contrast, for biomedicine, spiritual aspects are often deemed peripheral to health promotion. This tacitly understood position of biomedicine is congruent with the observation that spirituality or holistic philosophies are among the major reasons for the growth of AM in the West.[3]

Based on a number of observations, we have proposed that AM may well be defined as a broad set of healthcare practices (i.e. already available to the public) that are not readily integrated into the dominant healthcare model because they pose challenges to diverse societal beliefs and practices (cultural, economic, scientific, medical and educational).[19]

Theoretically, this definition could apply to any healthcare practice imported into any foreign country. As expected, it applies well to traditional systems of health imported into the West. However, less predictably, it also applies to the categorization of these systems practiced in countries that have adopted Western values. For example, traditional Chinese medicine (TCM) would be expected to be part of the mainstream in countries where there is a substantial Chinese population. Yet in Singapore, for example, whose population is close to 80% Chinese, TCM is "alternative". This is because in Singapore, which has adopted Western values and lifestyles, TCM poses challenges at all the levels mentioned above, except the cultural one.

As a possible counter example, Ayurveda could theoretically be considered alternative by TCM practitioners and *vice versa*. However, both healthcare systems are based on the concept of "energy" (Qi in TCM, Prana in Ayurveda). In addition, both systems are holistic, and the respective multifaceted treatments include re-establishing a balance, dietary considerations, exercise, and use of medicinal plants. Therefore, the fundamental differences between the two systems may be small enough that the "challenges" presented by one system to the other are only mild or virtually non-existent.

5. Factors Posing Challenges to Integration of Alternative Medicine

Based on our definition, it is precisely *because* practices have some traits that make them "alternative" that they have not been studied, are not used in hospitals or taught in medical schools, and are not reimbursed by healthcare insurance companies, and not *vice versa*, as is implied in the current definitions of AM. As asserted above, the requirements of *science* are not the only reason why AM is deemed "alternative". As implied in the proposed definition, a number of other factors have played a role, either to keep these practices out of mainstream healthcare or, on the contrary, to draw attention to them, and encourage considering them as potential therapeutic

options. Below, we discuss briefly factors influencing understanding and integration of AM.

5.1 *Cultural Factors*

5.1.1 Philosophy/ideology (holism/materialism)

Philosophical considerations are often disregarded or their importance minimized in what are considered hard-core sciences, including biomedicine. It is believed that science is indeed "objective", and therefore, independent from the scientists' possible *a priori* biases and beliefs. On the other hand, other systems of health are considered unscientific and unreliable, in part because of their relatively obvious connections with a dominant philosophy or religion.

As discussed previously,[19] traditional healthcare systems represent philosophical approaches to managing health and disease that differ substantially from those of Western biomedicine.[5,13,16–18] The question of what is *common* to these traditional systems has been generally overlooked. It is apparent that "spirituality" is an integral part of each. As this trait is often directly related to the dominant religion or philosophical system of the originating culture, it is taken for granted within the context of healthcare. For example, the ancient Chinese healthcare system was influenced by several spiritual schools, in particular Taoism.[16] Ayurveda, a traditional medical system of India, reflects the traditional Hindu world view.[17] Similarly, Tibetan physicians practice Buddhist meditation as an integral part of their medical training.[18]

In many traditional medical systems, the primary explanation for biological phenomena is based on the existence of a "vital force", an elusive entity designated *Qi* in China, "*Ki*" in Korea and Japan, *prana* in India, *vital force* in Western traditions (e.g. homeopathy). The terms "energy" and "energy medicine" are also used with increasing frequency. However, given the scientific definition of "energy", this designation is misleading, as nothing is known of the nature of this hypothetical entity.

The characteristics common to traditional systems of health ("vital force", spirituality, and holism) also seem to distinguish them from biomedicine. Biomedicine is founded in part on materialism (in contrast to the "vital force" explanation). Materialism in this context refers to the theory that "physical matter is the only or fundamental reality, and that all beings and processes and phenomena are manifestations or results of matter."[20]

As it has not been scientifically demonstrated that "physical matter is the only reality," materialism, therefore, is akin to a religion, i.e. "a system of beliefs held to with ardor and faith."[20] Western "allopathic" medicine would, therefore, have the same fundamental quality as traditional systems of health – it reflects the dominant philosophical belief system of the society in which it developed.

5.1.2 Impact on medical systems

Common to many traditional cultures' philosophy is the belief that a vital force is the underlying entity behind all life and that there is a unity underlying all diversity, implying holism (or wholism), that nothing can be considered in isolation.[16–20] In the realm of health, these principles lead to considering the person as an invisible whole, rather than as dissected anatomic parts. Thus, diagnoses and treatments are based primarily on concepts of organ functions, though not necessarily directly correlated to the actual organ entities or their anatomic locations. In addition, it is believed that health maintenance depends on a proper interaction with the environment. Hence, therapeutic interventions include stimuli (e.g. sound, color and taste) for any of the five senses, as these allow the individual to interrelate with his/her environment. Similarly, means of communication with the "invisible" environment (e.g. meditation and prayers) form an important part of the therapeutic approach.[16–19]

Conversely, consistent with the philosophical theory of "Materialism", biomedicine considers biological entities more or less as equal to the sum of their anatomical parts (a view opposite to

holism), and endeavors to elucidate molecular, physiological and pathological mechanisms believed to form the basis of biological processes. "Allopathic" medical treatment often logically consists of interventions chosen to interfere with identified pathological molecular processes. While biomedicine does not necessarily reject religion or spirituality, it does not routinely integrate these aspects into diagnosis and treatment (unlike traditional systems).

I believe that it is often relatively simple underlying philosophical beliefs that shape the development of a society and all the subsystems (legal and educational, etc.) within that society. In this context, it will not be surprising that philosophical underpinnings are reflected in the various factors that affect healthcare, sociological, economic and scientific/medical. The following grouping is arbitrary because, ultimately, all factors could be grouped under "philosophical" or "cultural", as these considerations are, in our view, those that underlie the development of society. We have nevertheless arbitrarily defined three categories. A group of "sociological factors" more or less correspond to the basic structure and function of society (political and regulatory factors, competition and administrative structures). "Economic factors" have been segregated because in most cultures these considerations are the major driving force for societies' priorities, and because they increasingly influence other values, such as ethics and education, that once were more central in guiding individuals' lives. Finally, "scientific/medical factors" were also grouped separately, because they present a set of issues that are of particular relevance to the evaluation of AM.

5.2 *Sociological Factors*

5.2.1 Politics/regulation

The interaction of politics and healthcare is extensive, complex, and inevitable because healthcare is such a fundamental aspect of national economies, and because individual and population health status must be addressed.

In the US, for example, political interventions, as suggested above, have played a significant role in AM's recent development. In October 1991, the US Congress directed the NIH to create an Office of Unconventional Medical Practices.[12] This was met with a less-than-enthusiastic response from the government agency,[21,22] but simultaneously, with high public expectations.[23] The public and congress have consistently put pressure on the OAM (now the NCCAM) to fulfill its mandate, while the NIH has been reluctant to progress too fast in a field that it does not consider "scientific".

In most countries, politics are similarly involved at some level of the development of alternative or traditional medicine. For example, in the Peoples' Republic of China, the Chinese Administration of Traditional Chinese Medicine is under the authority of the Chinese Ministry of Health. The Chinese government has been active in guiding the modernization of technological and scientific approaches to TCM. This has brought much better standards to the quality control of TCM botanical medicine preparations so that they can enter the international market and compete effectively with other botanical medicine preparations, in particular those from Europe.

On the other hand, in Singapore, where scientific biomedicine is the standard of care, the government has only recently expressed interest in acupuncture, and only in the context of scientifically documenting that therapy's effectiveness prior to allowing its official use. This process also drew attention to the fact that TCM was being used by approximately half the population and practiced by a significant number of practitioners, while there were no regulations, neither for practitioner qualification, nor to ensure quality of the products.

Regulatory issues are a subset of political issues, as regulations are a product of government agencies.[24] In the US, the Food and Drug Administration (FDA) oversees products and devices used in the practice of medicine. For complex political and legal reasons too long to detail here, botanical medicines and dietary supplements have become essentially unregulated.[25] They need not meet quality-control standards, and no significant information may currently be

provided on the packaging of these products, which may put the public at risk.

It is difficult to apply to alternative medical products the same regulations as those applied to biomedical products and devices, in particular to those used in traditional practices from other cultures. The lack of appropriate US regulations for alternative medical products reflects this difficulty. There are several reasons for this. For example, many traditional practices follow different diagnostic classifications than biomedicine. In addition, the complex substances (e.g. botanical, animal products) they use cannot easily meet the criteria established for essentially pure drugs, or even for conventional biologics. However recently, the FDA has begun addressing the issues posed by AM product evaluation. In particular, FDA representatives actively participated in the organization of two conferences that addressed the special considerations of acupuncture[26,27] and of botanical medicines.[28]

5.2.2 Cooperation or competition

Cultural factors are deeply ingrained and sometimes difficult to identify, as they have become second nature to the people who have been born to that culture. They give rise to a wide-ranging set of societal characteristics, such as relative degree of cooperation and competition among their members. Of particular interest are traits that many alternative medicine enthusiasts criticize in their society, but espouse somewhat unconsciously or unwillingly.

For example, values of competition, of scientific principles, of economic gain, etc. are actively espoused by at least a segment of the AM proponents in the US. Perhaps one of the most detrimental results is the insularity of those who have conducted research in this field. This insularity is another hindrance to the development of better understanding of alternative practices. It may be understood at least in two ways, insularity amongst disciplines and amongst countries.

Within a given environment, the isolation between disciplines (for example, between acupuncturists and homeopaths) may limit the perspective of similar conceptual or practical issues among disciplines. Even within the same general disciplines, varying schools may lock themselves into sectarian isolation. For example, homeopaths have long been divided into Unicists and Pluralists. These schools can be more or less dominant, but usually co-exist within the same countries. The Unicist School claims that only the constitutional remedy (i.e. the remedy that can correct individual's susceptibility to disease) can be effective for a particular patient. In contrast, the Pluralist School insists that various remedies can be prescribed according to individual symptoms, similarly to the use of conventional pharmaceutical drugs. Little has been done to resolve this dispute that affects both practice and research.

Insularity amongst countries translates into vastly differing rules and regulations governing practice (credentialling) and availability of products that are used in AM. These concerns overlap with some of those described under regulatory issues. In addition, the same type of isolation seen among various schools is compounded by differences in languages and cultural loyalties. For example, there are many different schools of acupuncture, and each makes different claims as to its methods and mechanisms. Thus, one Chinese school insists that needles should be inserted deeply, and twirled until the patient reports the "de Qi" sensation, an indication that the needle has stimulated the point. One Japanese school, in contrast, teaches that needles should be inserted only barely below the skin. This not only has clinical implications, but is also relevant to research. For example, in attempts to establish "placebo" baselines in clinical studies, proponents of that Chinese school have used shallow insertions as "negative" controls, which would equate Japanese acupuncture to a practice of placebo acupuncture. Improved dialog among the various schools could help to resolve differences, reducing the confusion that has been detrimental to progress in the field.

Another example of impediments to important progress is the isolation that exists among various forms of "energy medicine", often

originating in various countries. These therapies are also relatively isolated from each other, and even when they are practiced in the same countries, there has been little effort to identify common traits between them. Practitioners of Qigong, Therapeutic Touch, Johrei, Reiki, etc. although engaged in very similar practices, do not seem to have joined forces yet to understand how to optimize practice and research. For example, TT practitioners state that they need to feel the "human energy field" to be able to manipulate it and be effective. Practitioners of other very similar practices assume that therapeutic efficacy is essentially independent of the practitioner's ability to feel the "field". Are the practitioners dealing with differing health-promoting entities? Are they equally effective (or ineffective) in helping patients?

5.2.3 Administrative structures

We will focus here only on some administrative/bureaucratic aspects. In the case of AM, their impact is felt in a number of areas. To cite only one, AM does not fit well with the current structure of medically related institutions. For example, funding agencies supporting biomedical research are often structured according to disease categories. In the US, the major funding agency, i.e. the NIH is divided into a number of institutes that are often related to types of diseases or dysfunction (Allergy and Infectious Diseases, Cancer, Deafness and Communication Disorders, Diabetes and Digestive and Kidney Diseases, etc.). Topics related to AM do not fit well into such categorizations. This leads to either easier rejection of funding applications or to a mandatory restructuring of applications to fit the funding structure.

For example, the OAM was an administrative structure with no funding authority, like any other such structure within the NIH. This implied that any research grant pragmatically relevant to the OAM could only be funded by one of the institutes or centers. As a consequence, topics had to be tailored primarily to the programmatic

responsibility of the institutes rather than to the topics of interest to AM. Similarly, other grants that were perhaps less relevant to AM per se, had difficulty finding a home because they were multidisciplinary in nature and, while of cross-cutting interest to the NIH, they were not of interest to any specific institute or center.

5.3 *Economic Factors*

In most countries, the economic potential of growing AM markets has meant that much business and research interest in AM to date has been focused on specific techniques and products that can be marketed. On the other hand, the "healthcare industry", or even academia, have rarely paid attention to conceptual and philosophical principles on which the use of those products and techniques are based. This trend is even reflected in government-sponsored research.

In countries like Peru, the government's interest in traditional medicine began mostly in the context of providing affordable healthcare for indigenous populations, for example, in the Amazon basin, where most people are too poor to afford costly Western medicine and too remote to have access to it. However, in these countries also, the new interest in specific products (e.g. "cat's claw", "camu-camu" and "sangre de grado") by the herbal medicine industry is beginning to create incentives other than those of affordable and accessible healthcare for the indigenous populations. These new economic incentives may be counter-productive: they may endanger both the survival of the plant species, and consequently, the health of the indigenous populations, because they encourage an economically needy population to over-harvest (perhaps to extinction) plants on which they may need to rely for their own health.

In China, the government has launched a program implementing timetables for development of new TCM "products". Government and academic representatives have visited the US to indicate their eagerness to collaborate and to follow "proper methodology" (double-blind randomized clinical trials, RCT). Recently, at such a meeting,

it was recognized that traditional Chinese "medicine" should be distinguished from TCM "products".

In the US, the "healthcare industry", as the major players themselves define it, is one of the most lucrative American enterprises. As documented in several recent reports,[1-5] a large proportion of the American population uses AM and, therefore, constitutes a considerable potential market in the US. Consequently, alternative practices and products that had been shunned by the traditional healthcare industry are becoming an increasingly promoted feature of American healthcare packages, from healthcare maintenance organizations (HMO) to hospitals, including academically affiliated ones. The fact that the NCCAM is beginning to sponsor a few large clinical trials (e.g. St John's wort for the treatment of depression and glucosamine for the treatment of arthritis), also stresses an emphasis on products and disease rather than on conceptual and philosophical approaches to maintaining health.

In 1999, two major "first of their kind" conferences were held, co-sponsored by academic medical center (AM) units and private "integrative medicine" entities, to educate not so much professionals and researchers, but mostly hospital, HMO, and insurance executives and administrators about how to integrate AM practices and products into their institutions and services.[29,30] It is laudable that a wider community will become informed, but will the adoption of "complementary care", as it is sometimes called, truly lead to changes in the practice of medicine?

The large and rapidly growing market for AM has created the potential for substantial financial gain, but realizing a quick "pay-off" may also yield research of poor quality, and perpetuate research only aimed at narrowly evaluating products' effectiveness. While it is important to conduct such research, this may also lead to botanical medicine being used in the same manner as conventional drugs, as "magic bullets" for the treatment of specific medical conditions. In addition, because whole plants themselves are difficult to patent, there is strong financial incentive to attempt to identify active ingredients only, or at least standardized and relatively purified ones.

There are many reasons to explore options other than "magic bullet" drugs, one of which is the escalating, critical problem with drug interactions.[31–33] In the West in particular, more people take more "magic bullets" than ever before, in part because many older people have chronic ills requiring many medications. We must understand other routes to maintaining and restoring health with diminished reliance on polypharmacy.

5.4 *Scientific and Medical Factors*

Science is not a field of study but a *method of observation* that must be tailored to the object (or phenomenon) being studied. Thus, scientists must tailor the means of observation (the scientific method) to the subject, *not* have a standard method of observation and try to fit the object of study within the method that may deform (sometimes beyond recognition) the subject being studied. In this context, any phenomenon, if felt to be of importance, may be studied scientifically. Many factors can determine whether an area is worthy of study — for example, scientific significance of potential findings for scientists and the public, or strength of evidence to date. However, in many countries the scope of studies is limited by the fact that scientific investigations are guided by available support, which does not necessarily correspond to the intrinsic worth of the topics, but rather to other factors such as economic interest or technological limitations.

In general, there are many methodological approaches to the study of alternative or traditional medicine, and there is no restriction as to which one can be used. However, one must be very careful about the interpretation and extrapolation of results. For example, a number of double-blind studies have been conducted on acupuncture for nausea, using a single point, "Pericardium 6" (P6).[34] This series of generally well-designed studies has indicated that the stimulation by a needle of a traditional acupoint (P6) can decrease a centrally controlled symptom (nausea), and that this effect is specific since

needling of another point is not effective. Thus, these results give credence to the basic premise of acupuncture. However, in our opinion, this series of studies does not evaluate the effectiveness of acupuncture, as in most instances, acupuncturists would not needle a single point, regardless of other accompanying signs and symptoms.

While science claims to be dispassionate, many scientists have become polarized around the issue of AM. For decades, Western academia has excluded research and practice in areas identified with AM, and has shunned those who dared defy the status quo. This opposition has contributed substantially to the paucity of data in this area. For example, in the US, established academics have been discredited and have had difficulties when attempting to do AM research, [35,36] and at times, explicit threats were made by mainstream medicine to individuals and institutions that would associate with alternative practitioners,[37] or who would do research in areas identified as alternative.[38,39] Consequently, most AM research has been conducted outside of academia by individuals with limited research training and resources, and their investigations are often methodologically inadequate.[9,10] Conversely, those AM studies deemed methodologically sound may lack comparability and replicability. For example, lack of funding and differences among individual investigators' resources and personal research interests have limited replication of hundreds of studies in acupuncture and homeopathy.[26]

In summary, we strongly believe that the scientific method *can* and *must* be applied to the study of traditional medicine, but that the blind application of methodologies designed for other purposes and circumstances is poor science.

6. Implications for a Program in Alternative Medicine

Based on the above, to be successful, a program in AM needs to be multifaceted and address at least the major factors that will impact on the integration of AM into conventional healthcare.

I have presented, and I hope clarified, factors that impact in different ways on alternative and traditional medicine as compared to biomedicine. According to this outline, I believe that a program should address the following:

- A commonality exists among various traditional systems of health, all of which describe a spiritual and "energy" basis for biological mechanisms. *The physical and biological effects of non-molecular interactions should be investigated.*
- Alternative and traditional therapies are very heterogeneous, and include a variety of different health systems, some of which may be as complex as biomedicine itself. *The health benefits and economic impact of improved access to indigenous medicine by whole populations should be examined and evaluated.*
- Many traditional medical treatments are holistic and multifaceted. *To evaluate the potential benefits of such holistic systems on patients, outcome studies should be carefully designed in which the practitioners will have no other constraints than to recruit suitable patients and accurately record the treatment.*
- Each health system reflects the beliefs and philosophical systems of the culture from which it evolved. These considerations should be included in teaching curricula from early pre-school age to professional level education to counter-balance the notion that science, in particular medicine, is objective. *Ultimately, it should be understood that each healthcare approach should be evaluated on its demonstrated merit, not on a priori beliefs.*
- Much of the healthcare system is driven by profit. *We must develop models of coverage that are based on factors other than consumption of medical goods.*

We believe that such programs, if clearly and decisively coordinated, could have a profound impact on worldwide healthcare because the various facets of such programs touch upon the essence of the differences between traditional systems of health and biomedicine, not only from a medical, but also from a cultural and value-based standpoint.

7. Conclusions

In the US and throughout the world, many non-scientific factors contribute to defining AM scope and the context for its evaluation. Therefore, to reach optimal integration, it is critical to take into account those many factors. For example, it is important to improve academic freedom for investigators to explore the variety of traditional medical systems, even if the principles they study seem to be difficult to reconcile with conventional biomedicine, at present. There is a welcome change in this direction since the NIH funded several academic centers dedicated to AM assessment at major US institutions.[40] We feel that, as another important factor in the development of AM , the alternative community should refrain from uncritical and premature enthusiasm for experimental results and theoretical implications that have not yet been thoroughly evaluated. While building theoretical models is intrinsic to the development of science, it is important to accumulate sufficient information and knowledge on the observed phenomena, based on solidly confirmed observations, instead of prematurely proposing hypothetical mechanisms.

The effort to take advantage of both alternative or traditional healthcare and mainstream Western medicine should be seen as a great opportunity, provided that the conceptual framework of systems is also taken into account along with the techniques and products used by these systems. Internationally, we have the opportunity to research, understand and mobilize a wider range of therapies to individualize clinical approaches, a trend seen by some as intrinsically and medically worthwhile. Such diversity of potential therapies and practices could result in more effective healthcare approaches, tailored to local or personal constraints as well as preferences, and to improved functioning of the medical, economic, political and social infrastructures as they impact on healthcare.

In this time of great scientific and medical opportunity and change, considerable economic promise exists in the growing markets derived from the increased use of alternative as well as high-tech medicine.

We hope that beyond a focus on developing profitable AM products, there will also be an abiding interest in improving world healthcare. Improvement in healthcare should include an attempt to understand and address the underlying issues that have prompted the public to seek AM practices, based on a clearer conceptualization of the nature and role of those therapies currently deemed alternative. All non-scientific and scientific factors that are shaping this unusually heterogeneous and potentially fruitful field must be taken into account for a thoughtful evaluation to yield more than incremental progress. More rapid and thoroughgoing progress in integrating medicine could yield multiple benefits of greatly improved healthcare worldwide, which in turn would support national as well as global economic and social progress, at the same time exploring important and exciting new areas of research.

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On The Development of Traditional Chinese Medicine in 21st Century China

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1. The Unprecedented Opportunities for the Development of Traditional Chinese Medicine in the 21st Century

1.1 *The Change of the Disease Spectrum and Medical Mode*

As the living conditions and environment of human beings change, more and more psychosomatic diseases, multiple factors diseases and non-infectious diseases, will replace infectious diseases to become the main human diseases. In accordance with this, the medical mode is changing from biomedicine into a bio-psycho-social medicine. People will demand much more from medicine.

Since they are largely caused by complicated social and psychological factors, psychosomatic diseases are uniquely expressed in each individual. Western medicine, which has been based on the mass treatment model, first with public health measures, then with vaccines and pharmaceuticals, is not fully adequate to address this change of the disease spectrum, and is increasingly transforming its treatment mode into an individually tailored mode. In contrast to Western medicine, the development of traditional Chinese medicine is based on its unique theory, syndrome differentiation treatment. It has always focused on individual diagnosis and treatment. In Western medicine (biomedicine), the diagnostic endpoint(s) is suitable for all the patients with the same disease. For example, an abnormally high blood sugar level is a critical diagnostic criterion for all the patients with diabetes, while in TCM, there is no such diagnostic endpoint for all the patients with the same disease of Western

medicine. Instead, the TCM doctor's diagnosis is individualized because the patient has his own manifestation different from the others, although they may receive the same biomedical diagnosis. For example, one patient with diabetes may be diagnosed as suffering from kidney deficiency according to his clinical manifestation observed by a TCM doctor, whereas another patient with diabetes diagnosed as with Qi deficiency alone or with both Qi and kidney deficiencies. Owing to differences among the individual clinical manifestations, the TCM basic diagnosis though similar (kidney deficiency), varies in treatments depending on the characteristic clinical features of individual patients. With Western medicine, however, similar therapy is always associated with similar diagnosis. Therefore, TCM will have great vitality in the 21st century.

The concept of health is changing due to the gradual increase of living standards worldwide. People no longer are content to be disease-free, but now need and want to be stronger and to have a higher quality of life. Today, people demand preventive medicine and health promotion, not just treatment of illness and medical emergencies. In this regard, TCM pays more attention to health promotion than Western medicine. While Western medicine emphasizes treatment aimed at pathogenic factors, TCM stresses the body's self-regulation. While Western medicine focuses more on disease itself than on people, TCM emphasizes the people rather than the disease. The latter is much more adapted to people's contemporary medical needs.

Recently, evidence-based medicine has appeared in the medical field, requiring that assessments of clinical efficacy be based on scientific evidence. The therapeutic effects of drugs and therapies need to be evaluated by sufficient reliable evidence. According to this principle, evidence-based medicine has led to re-evaluation of much of Western treatment methods. TCM, however, has always been an experimental medicine since ancient time. All the therapies of TCM are summarized and built up from clinical practice. It is typically a medicine based on evidence, which is in complete agreement with this developing trend in medicine.

1.2 *Increasing Demand for Natural Medicinal Products*

Chemical (standard pharmaceutical) drugs are facing more and more serious problems, including side-effects (e.g., depression of bone marrow, damage of digestive system and so on, induced by anticancer chemotherapy); drug resistance (e.g., bacteria resistant to antibiotics, cancer cells resistant to chemotherapy); drug-induced diseases (e.g., thalidomide events in the 1960s); ineffective against some intractable diseases (e.g., osteoporosis, virus infections such as hepatitis and AIDS); and so on. The development of new chemical drugs becomes more and more difficult. The success rate of producing new chemical drugs from chemical compounds reportedly decreased from 1/900 to 1/10 000, and the research and development time and cost are increasing all the time. The average research cost of a new chemical drug is currently estimated at US$300–500 million, and the average research development period is ten years. However, the lifespan of a new chemical drug has also become much shorter in recent years, and is now on average about three to five years. All these factors have forced people to turn their focus to the broad class of natural medicinal products, which have advantages such as less toxicity and fewer side-effects, have the capability to be developed in a shorter period of time, at lower cost, etc. The Chinese *materia medica*, a very large group of natural medicinal products, in particular, has some excellent therapeutic remedies for diseases for which many standard Western pharmaceutical drugs have little or no effectiveness.

Today, there are about 170 companies and 40 research institutions engaged in the research and development of natural medicinal products throughout the world. International patent applications for natural medicinal products are increasing rapidly. According to the statistics, there were 15 000 patent applications for natural medicinal products in 1978, and 30 000 in 1985, a doubling in seven years. The period from 1990 to 1995 is considered to be the growth period of international research and development of Chinese *materia medica*, while that from 1996 to 2000 is the boom period of it. At the same time, the international demand for natural medicinal products is

increasing. Since 1990, consumption of traditional Chinese medicinal products in Japan has been rising by 15% every year, and the total sales were ¥250 billion in 1993. The annual rate of increase in use of natural medicinal products in the US is greater than 20%. The total sales of natural medicinal products in the European Economic Community in 1993 were US$2.2 billion. On the world market, the total sales of medicinal plants are currently around US$27 billion, 30% of the total sales in the world medicine market.

1.3 *Traditional Chinese Medicine and Pharmacology are Gaining in Recognition*

TCM and pharmacology have been gradually gaining international recognition since the 1970s. Acupuncture was first noticed in the US mostly due to the then President Nixon's China trip. From 1976 to 1978, the World Health Organization (WHO) placed traditional medicine on its agenda three times, and prepared and disseminated two documents about traditional medicine training and traditional medicine research. The Office of Traditional Medicine Planning was founded, and 27 WHO Traditional Medicine Collaborating Centers were established. Up to now, institutions related to TCM and pharmacology have been founded in 124 countries. There are more than 9000 foreign students getting formal TCM training in China every year. In France, there are about 2800 Chinese medical clinics, and 45 Chinese medicine associations with 12 000 members. The consumption of Chinese *materia medica* is 43 million kilograms each year in France. In Britain, there are special agencies of examination and registration for TCM practitioners. In London alone, there are more than 600 TCM clinics. Most states in the US have legalized acupuncture. The US National Institutes of Health (NIH) created the Office of Alternative Medicine (OAM) in 1992, which is now called (as of 1998) the National Center of Complementary and Alternative Medicine (NCCAM). In 1994, the US Food and Drug Administration (FDA) published the Dietary Supplement Health and Education Act.

All the factors and trends mentioned above provide excellent conditions for the development of TCM in the coming century.

2. Analysis on the Developing Trend of Traditional Chinese Medicine and Pharmacology in the 21st Century

2.1 *Anticipated Change in the Disease Spectrum Treated by TCM*

Accompanying the change of the disease spectrum of humans, that treated by TCM will also be changed. In fact, every change of disease spectrum treated by TCM in history was accompanied by academic progress in TCM. For example, in the Han Dynasty, based on the theory of Neijing (The Yellow Emperor's Internal Classic), and the disease epidemic situation, Dr. Zhang Zhongjing put forward a new febrile disease spectrum, which led to great progress in TCM. Since then, whenever TCM theory schools (whether it was Four Eminent Physicians in the Jin and Yuan Dynasties, or Sect of Epidemic Febrile Disease) encountered a new disease spectrum, there always followed an obvious improvement in the theoretic system and clinical practice of TCM. Today, the disease spectrum is changing again, worldwide. The development of TCM in the coming century will face the adjustment of the disease spectrum it treats, as well. The new disease spectrum will conform to the trend of increasingly prevalent psychosomatic diseases. A new system will be put forward, and the relevant diagnostic and treatment system will be set up, which will necessarily bring a leap forward in development of TCM.

2.2 *Anticipated Breakthrough in the TCM Theoretic System*

The theoretic system of TCM is established on the basis of Chinese classical philosophy. Many of its theories such as Yin-Yang and Five Elements are philosophical ones. During the long history of thousands of years, the theoretic system of TCM has gradually been developed, but it is still being perfected. There are some problems that need

to be solved. To take the Theory of Five Elements as an example, some of the explanations of the theory seem far-fetched. In modern society, the integration between the theory of TCM and modern science is not good enough. A lot of theories of TCM are neither to be explained by modern science, nor to be understood easily by people. It is much more difficult for western culture to accept these TCM theories and ideas. Of course, this is due to the difference between the two cultural traditions. However, there is no denying that one of the reasons is that TCM has not been explained well in modern scientific terms. Therefore, new ideas must be brought forth to TCM theory, in addition to carrying on and researching the old theory. This is the most important issue in the current and future development of TCM. The major mission of TCM in the next century is combining with modern science and technology to form the modern TCM academic-theoretic system.

2.3 *Anticipated Breakthrough in Diagnostic and Treatment*

In the past thousands of years, TCM diagnostic technique has been mainly based on four methods, including inspection, auscultation and olfaction, interrogation, pulse feeling and palpation. There are some advantages, as well as disadvantages in this diagnostic system. The most serious problem for research, and even for theoretical and clinical change, is that these classical diagnostic methods cannot be quantified. TCM has been satisfied with examining the body externally to know the disease inside the body for thousands of years. However, at the present age of advanced science it would be very helpful for the development of TCM if the diagnostic methods become more objective and quantifiable by means of modern science and technology. Otherwise, it will require that a student of TCM take more than ten years, or even decades, to master the diagnostic system for a practitioner of TCM, which will slow down the developing course of TCM. Up to now, many research projects address the improvement of TCM diagnostic methods by using modern science

and techniques, and great progress has been made. In China, we believe that many diagnostic and treatment breakthroughs in TCM will be made in the coming 21st century.

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A Cultural Perspective — Factors that Guide the Choice Between Local Health Traditions and Modern Medicine in India

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1. Introduction

Indian medical traditions exist in two social streams — the folk stream and the classical stream. The folk stream, known as local health traditions in the Indian context, is particularly alive in the villages of India. The classical stream consists of codified and organized knowledge with sophisticated theoretical foundations, expressed in several regional manuscripts and covering all branches of medicine and surgery. The classical stream comprises the Ayurveda, Siddha, Unani and Tibetan systems of medicine. Ayurveda (Ayuh means life and Veda means science) — the science of life — has an unbroken history of evolution for over 3000 years. Its medical texts have been written over a long period, from 1500 BC to 1900 AD. The written tradition has been faithfully documented and preserved in over 100 000 manuscripts. Siddha (the term siddha means achievement), is one of the oldest systems of medicine in India. Siddha specializes in the use of mercury and sulfur, and other metals, minerals, plant and animal parts. The principles and doctrines of this system, both fundamental and applied, are similar to those of Ayurveda. The difference between these two systems is more linguistic than doctrinal. The Unani system of medicine, an Islamic medicine with ancient origins in Greece, has a long and impressive history in India. It was introduced into India around the 11th century by the Arabs and

Persians. Tibetan medicine in India is, in a sense, a regional manifestation of Ayurveda in the trans-Himalayan regions and in parts of the northeast.[1]

Only after the colonial period, i.e. after 1948, when official public health policies adopted modern medicine to maintain or restore Indian populations' health (out of the colonial period's influential effect), did the use of local traditions and of traditional systems of health (TSH) begin to fade. Any system of medicine, be it modern (biomedicine), or traditional (Ayurveda, Siddha, Unani, Tibetan medicine or homeopathy), arguably has its own strengths and limitations. However, those parameters have not been systematically assessed for TSH, and the current status and use of these TSH is predominantly the result of political factors. In the current context, there are several factors that influence the choice of Indians towards using either modern medicine and/or local health traditions.

The use of biomedicine is generally widespread in urban areas across the country, but has been also introduced in rural areas through government-established primary healthcare centers. In rural areas however, people still depend on the traditional physician in their locality for health problems ranging from primary healthcare to chronic health problems. These traditional practices of healing are eroding because the younger generation is more attracted towards the Western socio-cultural style of living. Hence, they are not learning the traditional healing art from the older generations.

2. Political Factors

Ayurveda is recognized by the Indian government, and there are medical institutions in the government sector that teach it. Currently, there are more than 122 undergraduate colleges and more than 24 postgraduate institutions. Since it is recognized by the government, there is an established procedure for reimbursement.[3]

There is no official policy for "folk" traditional health practices. The official stance is that the government does not have sufficient

information about their conceptual or clinical characteristics to pass official policies. Hence, there is no facility of reimbursement for the treatment/medication by the local health traditions.[3]

It is correct that traditional Indian folk practices are very diverse, and very rich, in terms of both indigenous knowledge and bioresources. There are more than a million practitioners who serve as carriers of Indian health traditions. Although this is a remarkably large number, these folk healthcare practices do not receive any funding, neither from the government nor from any other organization. Continued availability of these practices is entirely contingent on the support and use by the community. However, community funds are only sufficient to ensure bare survival of traditional medicine practices, but not for their creative development.[3]

The classical Indian systems of medicine (ISM), although they are officially recognized, receive only 3% of the country's total health budget. It would not be incorrect to view this as sub-critical investment. By sub-critical, we mean that although there is some investment, it is not sufficient for education and research. The political management is evidently responsible for neglecting ISM, perhaps because it does not realize the richness of the ISM. This official attitude can be due in part to international trends and pressures that could also influence the Indian government's public health policies. Some influences that shape these policies include:

- WHO and giant multinational pharmaceutical companies strongly influence (due to political administration) national health policies, in India and elsewhere, especially in the developing world. These entities are dominated by Western medicine (again, due to political administration), and the WHA (World Health Assembly) has no representation of TSM from any part of the world.
- At the World Health Assembly (1996), WHO was unable to go through with a strong resolution on rational drug use, even though several countries' delegations were in favor of it (because

the US delegation threatened to withdraw its contribution to WHO).
- Major international educational and research centers in medicine are dominated by Western medicine. The Nobel Prize is awarded for achievements in Western biomedicine.
- Developing countries are being forced to change their national policies (due to influence of political administration), which formerly protected the rights of their citizens, to policies which favor transnational corporations (TNCs) and the interests of northern developed countries.[1]

In any event, the investment in traditional health is insufficient to stimulate quality teaching, research in the literature, clinical research and health services to meet the needs of society. In particular, investment insufficient to support ideal teaching of traditional health knowledge currently is eroding TSH. There was a time when the transmission of knowledge was through the "Guru-shishya parampara", where there is individual attention provided to the students. Ayurvedic education was not an exception. Nalanda, Takshashila and Banaras were the seats of learning, and to every guru were attached several shishyas. They were all given individual attention and teaching was very rigorous.[2] Today however, the teachers cannot give individual attention, as the ratio of students to teachers in each class is high.[3]

3. Research Disorientation

Research designs for ISMs in post-independence India have been based on the wrong assumption that the scientific validity of these systems can be only assessed through modern allopathic medical parameters. Despite the differences in their theoretical foundation (Table 1), clinical and drug research has attempted to assess ISMs along the lines of modern medical systems.[2]

Table 1 The Theories and Principles of Indian and Western Systems of Medicine.

	Indian	Western
1	Based on nyaya, vaisesika, sankhya, yoga, mimamsa and vedanta schools.	Based on positivist schools of west, Aristotelian logic and concepts of physics and chemistry.
2	The foundational world view is the panca mahabhuta theory.	The foundational world view is atomistic theory.
3	Biological phenomena are explained on the basis of dosha, dhatu and mala siddhanta.	Biological phenomena are explained on the basis of biochemistry and pharmacology.
4	Its key concepts are functional i.e. agni and aama.	Its key concepts are structural and molecular interactions.
5	Drug action is explained on the basis of rasa, guna, virya and vipaka siddhanta.	Drug action is explained on the basis of chemical composition.
6	Lays equal stress on promotion, prevention as well as cure.	Focuses on curative health.
7	Measurement and quantification are individualized and are of secondary importance.	Measurement and quantification are standardized and are of primary importance.

4. The Best of Ayurveda Cannot be Offered to Public Service

Given the high economic status of Western medicine in India, its medical theories, technology and scientific methods, the majority of indigenous medical practitioners could not, but be influenced by its powerful presence. This has initiated many debates concerning the proper interpretation and validation of indigenous knowledge systems.[1]

There is decline and confusion in understanding the traditional (TSH) medical theory and practice. This does not imply any "inherent" weakness in the indigenous knowledge systems as such, but rather a general weakness or cultural confusion in the Indian nation, arising

perhaps from the contemporary status of Indian culture being at a vulnerable stage of its evolution, again, with respect to the impact of Western influence.[1] Therefore, the best understanding and training in TSM cannot currently be practiced as in the past, or offered to public service.

5. Educational Factors

In India, no formal primary (6 to 11 years of age), secondary (12 to 15 years of age) and higher secondary (16 to 17 years of age) schools teach indigenous knowledge. For the first 12 years of education, the contents of any curriculum in grade school and high school, be it science, mathematics, architecture, social sciences, political sciences, performing arts, philosophy, psychology, etc. are all based on the Western knowledge system.[3] After that, those who want to learn any traditional Indian concepts, from systems such as Ayurveda, Siddha or Unani, have to make major adjustments to study and understand these topics within a span of approximately five and a half years. It is not easy for anyone who has been educated in the Western system for 12 years to understand the traditional Indian philosophy and worldview in such a short time.[3] The natural tendency is for students to look at Ayurveda, Siddha, Unani, etc. through the eyes of Western science. As a result, the impression is that traditional systems of health do not offer the same level of scientific standards as Western biomedicine. This educational gap also influences the choice between TSH and biomedicine.

6. Scientific Paradigm

There is a scientific debate on the efficacy of traditional health practices. If a traditional physician says that he/she has cured a disease, then the Western scientists would like to have further details as per the modern Western medical system too. The traditional physician (ISM) will have clinical data as per the theories of Ayurveda

or Siddha, etc. but they are not trained or equipped to gather the kind of data (e.g. MRI, tumor specific antigen, etc.) to satisfy the Western scientific community of the effectiveness of the traditional treatment. In addition, the patient treated successfully by traditional medicine does not go back to the Western doctor (who had diagnosed the ailment, and had then, due to failure, given up attempting to treating it, leaving the patient to turn to the traditional physician).

The problem, however, is that the requirements for scientific proof are not emanating from the traditional practitioners, but from Western-trained doctors and scientists in India and in the West. It would appear that if the Western scientific community is serious about this, then perhaps they should provide funds and expertise to carry out suitably designed research projects. The Indian government, as stated above, is only allocating 3% of the total country's health budget to activities devoted to TSH. There is no funding for comparative medical research. Lack of researched information on TSH based on Western medical parameters is a factor that influences diminished choice of medical treatment in the "middle social classes", who prefer the proofs of safety and effectiveness based on Western medical parameters, before trying TSH remedies.

Ayurveda originated in the Indian sub-continent, whereas Western medicine is of European origin. Thus, the foundational difference becomes evident here. Foundational differences are reflected in the formulation of theories pertaining to the causation of the disease, pharmacology and drug action, dietetics and nutrition, physiology and diagnostics. The differences in the theories and the principles between India and Western systems of medicine are given in Table 1.[1]

Additionally, there are differences in testing the products of TSH and modern Western medicine. There is a consensus that most of the manufacturers of herbal preparations, if relying purely on classical, well prepared Ayurvedic prescriptions, do not need to give modern clinical data to demonstrate that their products are safe and effective as they are time-tested preparations. Only for the new herbal preparations, even if based on Ayurvedic concepts, should testing

for safety, efficacy and effectiveness be performed. Even if the classical medicines are well prepared, questions will arise about the standardization and agricultural sources of the plant materials used as per the classical Ayurvedic literature; about accidental contamination, etc.

Currently, standardization of Ayurvedic drugs is not implemented,[1] and there are no standard methods for testing the pure classical products of TSH. Hence, drugs of poor quality have also found a place in the market. The patented herbal medicines based on Ayurveda, should therefore produce clinical and research evidence of their safety and effectiveness, using modern Western medical parameters. As manufacturers of herbal preparations (e.g. Ayurvedic) are also very eager to find new markets for their products in the West, they now share some of the responsibility to improve research and production.[3]

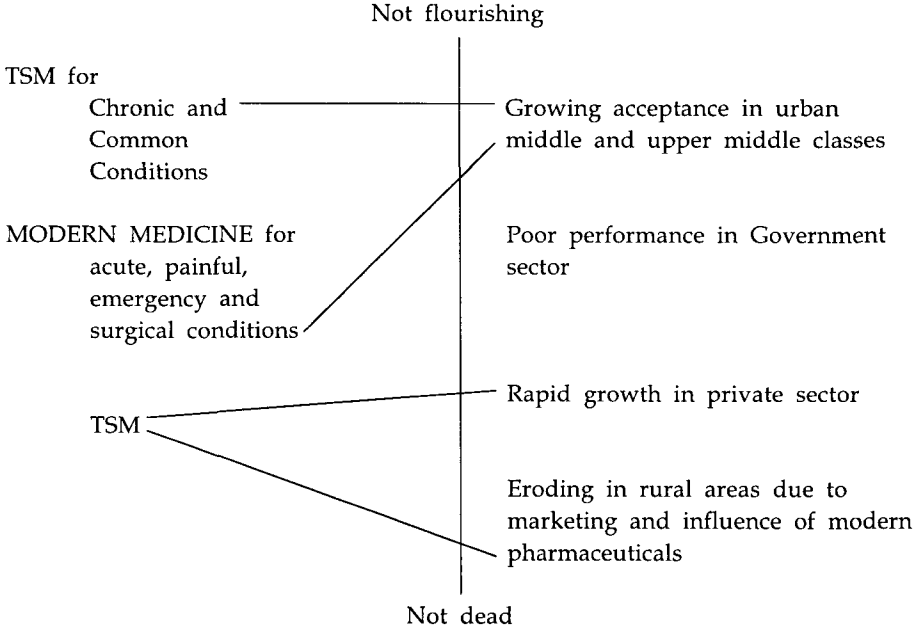
7. Socio-Cultural Factors Affecting the Community

7.1 *Economic Factors*

India is a developing country and individual financial status varies considerably, especially between urban and rural areas. Likewise, the preference for the medical system, whether biomedicine, traditional systems of health or local health traditions, varies from rural to urban areas.[3] People in the urban areas are turning towards codified traditional systems of medicine, although it is becoming as expensive as Western medicine. The cost of herbal medicine is increasing because of high demand for the bulk plants/plant parts, and the supply is diminished. As a result, the cost of the bulk plants/plant parts has increased in the marketplace.[3] In the rural areas, people living on daily, subsistence wages look for the most economical remedies, which in some cases may be LHT, and in some cases may be those of modern medicine.[3]

7.2 *Perception of Efficacy of Health Systems*

People in rural as well as urban areas prefer to use Western medicine for severe conditions and for emergencies. For common ailments like indigestion, fever, cough, diarrhea, etc. (devoid of complications), people in rural areas use local herbal remedies.[3] However, while local health traditions have been eroding due to the powerful influence of modern pharmaceuticals, it now appears that, in urban areas, an increasing number of people are becoming aware of the side-effects of modern pharmaceuticals. Many are once again turning to medicinal herbs (TSH), which they now often view as more likely to bring about a cure, especially for chronic ailments, rather than just masking symptoms.[3] The socio-cultural picture denoting the status of the TSH in the country can be depicted as shown in the diagram below.



8. Conclusion

There are multiple factors that influence choice among Indians between local health traditions and Western medicine. They are essentially political, economic and cultural rather than medical.

9. Recommendations

1. National guidelines for standardization of TSH drugs for efficacy and safety are required.
2. National policy for documentation and revitalization of reliable LHTs is necessary.
3. National education policy review is required for primary, secondary, higher secondary and TSH medical practitioners for public service.
4. Increase of funds in the field of literature and clinical research is required for the establishment of the best TSH understanding and training for public service.
5. Establish a bridge between the logical study of TSH in India, and modern Western medicine.

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A Cultural Perspective: Conceptual Similarities and Differences Between Traditional Chinese Medicine and Traditional Japanese Medicine

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Abstract

Initiated because of the great interest in complementary and alternative medicine (CAM) in the United States, the concept of CAM is spreading around the world. Japan has had a long history of using "traditional" medicine, which is currently being re-categorized as CAM due to the fascination with this new concept. Many Japanese traditional practitioners do not welcome this new categorization. It is not easy to define CAM, but it can be said that Japanese traditional medicine fits its implied definition in that it complements modern (or bio-) medicine in providing certain healing techniques lacking in modern medicine. Nevertheless, as modern medicine co-exists with traditional medicine in Japan, both ancient and modern medicine can be said to complement each other: consumers use and experience them both, relative to their individuals' own cultural contexts and medical preferences. In this paper, we review the social characteristics of the culture that shaped traditional Japanese medicine. Traditional Japanese medicine has been used for 1500 years and includes Kampo (herbal medicine), acupuncture and shiatsu (a special massage technique). We also compare today' s Japanese traditional medicine and the traditional

Chinese medicine (TCM) from which it evolved. We also discuss current public awareness and behavioral study of Japanese traditional medicine in urban Japan. Finally, we point to cultural and philosophical factors that play a role in the new categorization of traditional Japanese medicine as a "complementary and alternative" medicine.

1. Introduction

Eisenberg previously evaluated and reported the use of CAM in the US in two articles published in 1993 and 1998.[1,2] These studies revealed that the frequency of CAM use is far higher than previously thought and that the economic impact is considerable. Reflecting this level of use, a National Center for Complementary and Alternative Medicine (NCCAM) was established in the US, at the National Institutes of Health (NIH) in October 1998.

The categorization of traditional systems of health as CAM is due to the considerable progress of modern medicine (biomedicine), which has become prominent in the world. However, in many countries with a rich history and culture going back several thousands of years, there have been well-established traditional systems of health that have been utilized for a long time. There are many instances where these traditional systems are also being used in conjunction with biomedicine, hence their classification as CAM. However, for the professionals of these traditional systems and for their users, the terminology of "CAM" is unnecessary and perhaps inappropriate as it places their system in a subordinate position relative to biomedicine. Going beyond the issue of terminology, we should earnestly focus on the fact that CAM, which includes mostly traditional systems of health, has been utilized by billions of people throughout the ages.

The Japanese people have had a long history of using traditional medicine, Kampo, acupuncture and massage shiatsu for 1500 years. We describe below, the culture and history that fostered the origin of Japanese traditional medicine and how it has survived over the

centuries. We compare today' s Japanese traditional medicine and TCM through data documenting medical status in Japan. We also discuss the public awareness and behavioral study of traditional Japanese medicine in urban Japan.

2. Origin and Tradition of Chinese Medicine

Ancient Chinese medicine developed around 3000 years ago and reached a coherent codified form approximately 2000 years ago with the compilation of medical manuscripts and drug books which are still in use today. In the development of Chinese medicine, it was traditional and characteristic for the ancient authorities — well-known doctors, researchers and philosophers — to inherit their predecessor' s writings, test their techniques, and in turn, add their own experience and knowledge thus transmitting to posterity.

For example, the original text of the oldest Chinese *materia medica*, the *Materia Medica of Shen Nong* (神農本草經), compiled in 200AD, has not been preserved. Instead, its contents are known through six *materia medicas* that were compiled later. The latest, the *Materia Medica of Li Zi Zhen* (本草綱目) was formed in 1590 with the text of *Materia Medica of Shen Nong*. Thus, Chinese physicians examined and used drugs for more than 1000 years to confirm their usage and therapeutic effects, and they added their own clinical observations to the original information before transmitting it for posterity. Currently, the Chinese *Materia Medica* (中藥大辭典) contains information on approximately 5000 crude drugs. It reflects ancient traditional knowledge as well modern scientific chemical and pharmacological information.

3. Transmission of Chinese Medicine to Japan

In the 5th century AD, the Yamato Imperial Court, the first government of Japan, eagerly sought to adopt the medical system from the Kingdoms of Kudara, Silla and Kokuryo in the Korean Peninsula. Historical records indicate that famous Korean physicians

visited Japan and met with the Japanese Emperors. In the next century, as Buddhism was spreading to Japan, diplomatic relations between this country and its neighbors in the Korean Peninsula strengthened, and medical books were imported into Japan along with Buddhist images and sacred books.

In those days, the people in countries of the Korean peninsula were practicing and using the Chinese medicine of the Latter Han dynasty (後漢) (AD 25–220). The books of Chinese medicine that were introduced into Japan from the Korean Peninsula were manuscripts of Chinese medicine written in classical Chinese. By the 7th century AD, official diplomatic relations between China and Japan were established, and the Yamato Imperial Court of Japan sent messengers to the Chinese courts of the Sui dynasty (隋) (AD 589–618), and the Tang dynasty (唐) (AD 618–906), to borrow models from the Chinese political and social systems to rule their own country.

The healthcare system of the Yamato Imperial Court was established and adopted the Tang medical system. Healthcare education to train and certify medical doctors, acupuncturists and masseurs was derived from that in effect during the Tang dynasty, and the textbooks used by the medical professions in the Yamato period were those utilized in China during the Tang dynasty. Crude drugs came along with the medical books. Some of the crude drugs were deposited at the Shosoin Repository in the Todaiji temple, along with information concerning Buddhism culture in the middle of the 8th century. Scientific analysis has indicated that some of these drugs likely came from countries in Tropical Asia and the Middle East. This gives us valuable information concerning the international trade of those days, as well as on the medicinal use of these imported plants.

Although Chinese medicine was imported into Japan and integrated into the Japanese medical system as mentioned above, it was only reserved to the nobility and others close to power. The common people had not yet started to use Chinese medicine at that time.

4. Development of Traditional Japanese Medicine as Kampo

Since the first introduction of Chinese medicine in the 6th century AD, the latest medicine was always eagerly taken into Japan from China, and was immediately accepted and used virtually without any modifications. But it was not until the Edo period in Japan (1603–1867) that Chinese medicine was modified to become a unique Japanese version of Chinese medicine, called "Kampo", which means "Chinese way" in Japanese. Kampo was traditional Japanese medicine, which included herbal medicine, acupuncture and shiatsu in the Edo and next periods. But recently, Kampo generally means just herbal medicine.

During the 11th century AD, during the so-called Song dynasty (宋) period in China (AD 960–1279), printing technology was developed by leaps and bounds, and many manuscripts were published, in particular a large number of medical books. The official trade between Song dynasty China and Japan led many of them to find their way into Japan. Medical manuscripts of the Jin period (金) (between the Song and Yuan dynasties, c. AD 1115–1260), and the Yuan (元), or Mongol, dynasty (1260–1368) led to increased influence of the theories of TCM, which were brought into Japan by the trade of that time. The trade between Ming dynasty China (明) (AD 1368–1644) and Japan continued to flourish, and so medical knowledge was continuously exchanged.

The large quantity of medical knowledge that had been introduced from China was accumulated steadily in Japan, and it was during the Edo period that Kampo flourished and became a unique Japanese brand of Chinese medicine. This consolidation of uniquely Japanese medical principles and practices occurred in part as a consequence of the distinct cultural and social characteristics of the feudal Edo period under the Tokugawa Shogunate, with respect to the principle of reduction, which led physicians to respect practices more than theories. Political and philosophical attitudes were largely changed to be practical and rational against the Neo-Confucian doctrines, and developed the reductionistic approach, which was very characteristic

of Japanese thinking. Thus, the influence of Chinese theories waned somewhat, and native Japanese practices were developed and strengthened.

The Tokugawa government enforced a policy of national isolationism, and diplomatic relations were only maintained with the Netherlands, China and Korea via trade continued only through the port of Nagasaki. The uniqueness of native Japanese culture matured in the Edo period, which was in part fostered by technological advances and use of the printing press that became widespread in Japan during that period. As a result, many Chinese medical manuscripts were translated into Japanese, explanatory notes were added, and they were published and widely circulated in Japan.

Kampo medicine became widespread in Japan, clinical studies were done frequently, and many superior and famous researchers and doctors were produced. The Koho-ha (古方派) School (the classical school) focused on a concise and practical medicine and used *Shang han lun* (傷寒論) as a single classical medical book. As the book was very practical and rational without complicated theories of disease causation and preventive medicine, they wanted to de-emphasize the concept of Yin and Yang, and of the Five Elements Theory of the *Su wen* (素問). The Koho-ha School received excellent clinical evaluations, and many doctors at that time approved their approach. They are still influential and play a significant role in traditional Japanese medicine today. The Secchu-ha (折衷派) School (the "Compromise" School) integrated the Chinese medical concepts of the Jin and Yuan dynasties (金元醫學), and the surgical techniques of Dutch medicine, with the concepts of the Koho-ha School. The Koshou-ha (考證派) School (the Historical Investigation School) compiled and organized an enormous number of classic medical manuscripts, and to this school can be attributed the highest contribution to the educational basis of Kampo.

Special doctors of acupuncture became popular in the Azuchimomoyama period (AD 1573-1602, just before the establishment of the Tokugawa Shogunate), and in the Edo period,

and they formed influential schools of acupuncture. The efficacy of their treatments, which they dispensed to all, from the common people to the successive Tokugawa Shoguns, or generals, gave them fame and a high reputation in Kampo medicine.

A renowned blind acupuncturist of Waichi Sugiyama (1556–1635) invented the Kanshin-ho (管鍼法), the needling method using a guide tube, a special method of using a tube for inserting an acupuncture needle. This method enabled the practitioner to reduce the pain due to needle insertion, and to treat a patient with a number of acupuncture needles in a short time. This was the origin of the Japanese style of acupuncture today.

As discussed above, in the Edo period, the influence of the cultural characteristics of practical and rational, and technical ideas of the Japanese people gradually modified the medicine that had been introduced from China for more than a thousand years. It was developed as Kampo, which came to be used by most of the Japanese people, and was supported by the Japanese medical system of the period.

5. Repression of Traditional Medicine in Japan

In the Meiji era (1868–1912) following the Edo period, Kampo that had formed the mainstay of Japanese medical care during the Edo period was suppressed by the new government which adopted western values and way of life to enhance the wealth and the military strength of Japan. In 1895, the Japanese parliament, the Diet, announced that only those who learned Western medicine would be qualified to treat patients.

Japan competed with the international military powers at that time, and gradually strengthened its army. In the armed forces, Western medicine rapidly supplanted traditional medicine, because of its superior performance in surgery, which would be the most useful on battlefields. Although Western medicine became the standard of official medical care, Kampo survived in national medical

care as specialized medications, acupuncture treatments and shiatsu massage treatment. Drugs used in Kampo treatments were called Kampo-yaku (Kampo drugs), and were supplied by pharmacies and drugstores. Specially trained individuals (acupuncturists and shiatsu practitioners) continued to administer acupuncture and shiatsu in their private offices. During the Edo period, blind acupuncturists and shiatsu practitioners contributed to the development of their disciplines, following in the footsteps of Waichi Sugiyama. Under the repression in the Meiji period, Kampo was practically divided into three categories of herbal medicine, acupuncture and shiatsu. It is a main reason why Kampo means just medication of Kampo-yaku (herbal medicine) today.

During World War II, the Japanese people experienced restrictions of food and medical supplies. In these hard times, they remembered Kampo medicine, because they could easily obtain materials of Kampo drugs and moxa (an herb used for acupuncture) locally. Notably, an Oriental medicine department responsible for teaching Kampo medicine was established in a university to train practitioners to meet the general population' s needs.

Thus, from the Meiji era to World War II, Kampo medicine was officially suppressed, but the Japanese population sought out and used Kampo medicine, thereby disregarding the government' s official policy. Paralleling this trend, Kampo practitioners, pharmacists and acupuncturists kept up the skill they had received from predecessors in their Kampo medical family line.

6. Revival of Traditional Japanese Medicine

Just after the War, under the control of the General Headquarters (GHQ), the Japanese government changed laws and policies and turned towards building a new nation. Although there were no major changes in the healthcare system, the American General Douglas MacArthur of the GHQ issued a ruling prohibiting acupuncture in 1947, because this practice was considered to be barbaric and

unhygienic, and lacking in conclusive scientific evidence. However, the ruling was reversed following the immediate objection formulated by the acupuncture professional organizations (including the associations of blind acupuncturists), and this opened the way to the scientific study of efficacy and safety of acupuncture.

In 1961, when Japan had been reconstructed and its economy had greatly strengthened, universal care was created by the governmental health insurance. In 1967, health insurance began to cover acupuncture treatments for five diseases, if recommended by physicians and delivered by acupuncturists. The same year, health insurance began reimbursing four formulations of Kampo drugs prescribed by doctors (147 formulations in 1987).

The production of Kampo drugs increased, paralleling the Japanese economy' s remarkable growth, and so did the medical insurance coverage of Kampo drugs (Figure 1). This phenomenon indicates that many physicians who were not trained in Kampo medicine prescribed Kampo drugs abundantly, like administering vitamins and supplements, as part of the Kampo medicine boom among the Japanese people. The ratio of production amount of Kampo to total medical drugs was 2% in 1984, and it increased to 3% in 1992. The production of Kampo drugs began decreasing after 1992, after a side-effect of *Xiao-chai-hu-tang* (小柴胡湯), *Forsula bupleuri minor*, was reported in Japan.

As mentioned above, Kampo, which was on the verge of extinction at certain times in the past, is now part of the Japanese healthcare again. A well-known Kampo specialist, Dr. Yasuo Otsuka, proposed reasons for the rise of Kampo' s popularity:

(1) Reaction to the serious side-effects of modern medicine.
(2) Modern medical doctors being too specialized.
(3) Relationship between patients and western-style physicians is impersonal.
(4) The patterns of illness has changed in recent years (chronic illnesses, for which western medicine is not so effective, have increased).

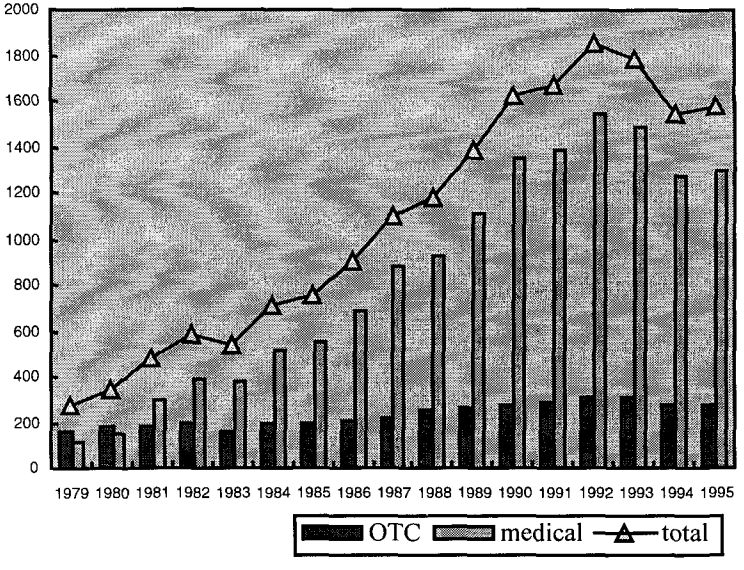

Figure 1 Changes in the Amount of Money Spent on Kampo Drug Production.

7. Appearance of TCM in China

The People' s Republic of China was founded in 1949. During World War II, Western medicine was used in the medical care system, under the influence of the then dominant Japanese army. In 1956, the new government led by Mao Zedong suggested that Chinese medicine should be utilized as the standard of medical care.

There were various schools of Chinese medicine at that time in China. The schools of Chinese medicine were integrated to establish an educational system of Chinese medicine. A new medical theory and approach was built up involving the integration of those schools and named as traditional Chinese medicine ("TCM"). National universities for TCM were established subsequently all over the country. Medications with crude drugs, acupuncture, massage manipulation, Qigong and dietary treatments are taught currently at those universities in China.

8. Today's Traditional Japanese Medicine and TCM

As mentioned above, the theory of TCM was unified somewhat forcibly in China. But in Japan, a unification theory of traditional Japanese medicine has not been established.

In Kampo (medication of Kampo drugs), a theory on the basis of *Shang han lun* of the Koho-ha school that gained power in the Edo period is still the mainstream in traditional Japanese medicine. Abdominal diagnosis by palpation is more commonly performed than pulse diagnosis, but Japanese practitioners generally tend to check by symptoms and name of disease, then choose a most suitable formulation of Kampo drugs (隨證療法). Less than 200 formulations are commonly used without any addition of crude drugs. Kampo extract (extract of herbal medicine) is more popular than Kampo decoction now. On the other hand, in China, pulse diagnosis is generally conducted where Chinese practitioners choose some crude drugs and concoct a special formulation for a patient (弁證療法).

In acupuncture treatment, the meridian treatment theory of taking in Yin-Yang and the Five Elements Theory was established in the Showa era (1926–1989). This treatment method, uses pulse diagnosis to gain insight into the state of viscera and meridians and the condition is addressed by regulating the circulation of meridians with acupuncture stimulation. An acupuncture treatment is then applied to various illnesses and pain syndromes.

A medical theory for the treatment of febrile diseases, called *Wen bing xue* (温病學), was established in TCM but not in Japanese Kampo. This fact is reflected in the following examples. For treatment of the flu or a cold, *Ge-gen-tang* (葛根湯), *Forsula puerariae*, is used frequently in Japan, but in China, *Yin-qiao-san* (銀翹散), *Pulvis forsythiae et lonicera*, is generally preferred. *Ge-gen-tang* is the prescription used frequently by doctors at the Koho-ha School of the Edo period. Its source is the *Shang han lun*, which is a sacred book of the school originally brought from China. On the other hand, *Yin-qiao-san* is a new Chinese prescription developed from an original idea of the *Wen bing xue* theory. *Wen bing xue* is a theory that was completed in the

latter period of the Qing (清) dynasty (AD 1636–1912) in China, while Japan was in the early Meiji era, just after the disturbance of the late Tokugawa period. The *Wen bing xue* theory was not accepted in Japan because of the rapid Japanese adoption in the late 19th century of Western medicine, in conformity with the policies of the new Meiji government, in particular to modernize and end cultural isolation.

Another difference between Kampo and TCM can be seen in the dosages of drugs. Generally, dosages of Japanese Kampo drugs are equivalent to about one-quarter to one-third of Chinese ones. It is related to the regulation of the production authorization of Kampo drugs by the Japanese government, and to the difference in quality and type of crude drugs as raw materials.

9. Traditional Medical Workers in Japan and China

Japanese traditional medical workers who are practitioners of Kampo are classified into doctors, pharmacists, acupuncturists and shiatsu practitioners.

A qualification of medical doctor is given to the person who has mastered six years of tertiary education on Western medicine and passed the national examination. The rule of the qualification is almost the same as that of the Meiji era. Students in medical schools are not required to take lessons in Kampo. There are several universities where Kampo is taken in as an elective subject, and some of the universities have set up a Kampo medical examination and treatment section at their hospitals (in six universities). At such universities, students get a chance to learn Kampo as residents at bedside.

Pharmacists receive four years of tertiary education on Western medicine; Kampo is not a required subject but an elective one. There are very few opportunities for pharmacists to receive an occupational education of Kampo. But there are some pharmacists who have successfully mastered Kampo. They entertain consultations from patients, and very often offer Kampo drugs to them.

Qualifications of acupuncture and massage shiatsu are given to the candidate who successfully completes a three-year course in an acupuncture vocational school (26 schools) or an acupuncture university (one university). A visually handicapped person can be educated on acupuncture and massage shiatsu in a school for the blind, receiving full qualifications after passing the national examination. In acupuncture vocational schools, Kampo (general idea, diagnosis and clinical), TCM (just general idea), anatomy and pathology of Western medicine are taught as essential subjects.

The number of medical workers — doctors, pharmacists, acupuncturists and massage shiatsu practitioners — are about 211 498, 95 642, 125 971 and 94 150, respectively. However, the precise number of medical workers specializing in Kampo cannot be determined, as the data counting number of Kampo experts (doctors and pharmacists) is not available.

On the other hand, according to the 1989 data on Chinese medical workers, there are a total of 1718 000 doctors in China, 370 000 of which are TCM doctors.

10. Use and Experience with Traditional Japanese Medicine in Tokyo

The Tokyo Metropolitan Government conducted a survey to investigate the public' s awareness and behavior with regards to the use of traditional Japanese medicine in 1989. Data were collected from 2293 residents in Tokyo. It was found that the number of persons who had taken Kampo drugs was 1115 (48.6%). The reasons for taking Kampo drugs were obtained from the respondents by choosing more than one answer. The most commonly given reasons were: absence of side-effects (38.7%), effective against chronic disease (27.3%), and uneasiness in health (27.0%). In terms of effectiveness of Kampo drugs, 25.8% felt that the drugs were very effective, and 45.8% replied that they were effective.

On the other hand, patients who underwent acupuncture treatments in Tokyo were 682 out of 2293 persons (29.7%). In evaluation of acupuncture effectiveness, 39.6% replied that the treatments were very effective, and 35.3% said they were effective.

11. Conclusion

A characteristic of Japanese traditional medicine is that of having been developed by the introduction of Chinese traditional medicine into Japanese unique culture and historical background. The Kampo, which was Japanese traditional medicine established in the Edo period, is still the mainstream of Japanese traditional medicine, and characteristic of today' s Japanese traditional medicine. Table 1 shows the summary of difference between TCM and Japanese traditional medicine.

Table 1 Differences Between TCM and Japanese Traditional Medicine: A Synopsis

	China	Japan
Practitioners	TCM doctor /pharmacist /acupuncturist /manipulator	medical doctor /pharmacist /acupuncturist /shiatsu practitioner
Education	TCM university	university/vocational school
Concept	philosophical/abstract	practical/rational
Theory	TCM (*Su wen*)	Kampo (*Shang han lun*)
Diagnosis	pulse	abdominal palpation
Prescription	special formulation	suitable formulation
Dose of a prescription	45–200 g	15–50 g
Acupuncture	twirl needling	guide tube needling

The characteristic of traditional Japanese medicine is to eliminate a complicated, philosophical and abstract theory of traditional Chinese medicine, and to adopt the reductionistic approach with a practical and rational theory. This is based on the Japanese cultural tradition as well as the Japanese medical care system — another important factor affecting the characteristic. For health insurance coverage of Kampo drugs and acupuncture treatment, medical doctors need to diagnose and prescribe using the criteria of modern medicine. The reimbursement of Kampo drugs and acupuncture treatments are 147 formulations and five diseases, respectively.

Another characteristic is that of traditional Japanese medicine practitioners, consisting of some medical doctors, pharmacists, acupuncturists and shiatsu practitioners, practising independently. For traditional Japanese medicine, the theory of each treatment method is not unified like for TCM. Therefore, practitioners of traditional Japanese medicine cannot cooperate theoretically, and very seldom diagnose and treat as a team.

Traditional Japanese medicine faced the crisis of continuation historically, but conquered it by dividing the technique practically into herbal treatment, acupuncture and shiatsu resulting in a lack of conceptual unity in traditional Japanese medicine.

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Some Political Aspects of Non-Conventional Medical Practices in Europe

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The unification of Europe implies the free movement of European citizens within the European Union (EU), and thus the increasing need for greater harmonization of laws and regulations concerning medical practices and medicaments. At present, only medically trained practitioners are entitled to diagnose and prescribe. The paramedical professionals' role is to carry out medical acts prescribed by the medical professionals.

The health authorities of each country are sovereign in determining the conditions of medical practice, fixing the contents of the corresponding training, and conferring diplomas and licenses to practice within that country. Because of the lack of European, and often of national regulation, the frame of reference for these activities still remains national legislation concerning medical practice in general.

For non-conventional medicine, a large disparity exists among the countries of the EU. No European regulation has been adopted, but a resolution of the parliamentary assembly has been passed for identifying each unconventional discipline, and for implementing a study establishing its safety and efficacy.[1]

At present, no specific European regulation (homeopathy excluded) exists on products used in non-conventional disciplines (herbs in Traditional Chinese Medicine, for instance). So, these medicaments still depend on the general rules, with only some national tolerance in their adaptation.

The resistance to bringing official recognition and regulation to the non-conventional medical disciplines, at national as well as European levels, is said to be related to an insufficiency of scientific validation (i.e. animal experimentation, clinical validation and social evaluation).

I. General Considerations

Some general considerations allow us to understand the diverse positions of health authorities or of populations of the different EU countries towards non-conventional medicines and their practice.[2,3]

As there is only one and the same patient, only one medicine can exist, and therefore only one diagnosis. The methods of diagnosis and therapeutics may change because they follow the concepts used for examination and therapeutic choice.

Only the medical professions (medical doctors, dentists, veterinary surgeons and midwives) are entitled to diagnose, and to prescribe, or otherwise initiate, a course of therapy in the statutory and specific field of their practice.[4,5]

The role of paramedical professions (nurses, optometrists, physiotherapists, speech-therapists, audiologists, dental-technicians, podiatrists, radiographers, electroradiology assistants, dietitians and laboratory assistants) is to apply a special therapeutic or care method, or execute a medical investigation upon medical prescription as far as their competence permits it. They are authorized practitioners, but are not entitled to diagnose or to prescribe, because they are not trained to do so.

Legislation and regulations define competencies of each specialty, set up adequate training and its ensuing evaluation. These training and evaluation procedures comply with national or European community regulations and directives concerning public health, and they insure patient safety.

To distinguish between teaching and practice is essential. Only a practice diploma, issued and recognized by the health authorities

of each country allows medical practice. An economist, a reporter or a medical doctor may follow a curriculum of "humanitarian medicine", but only the latter is entitled to practice medicine.[6]

Each country is sovereign with respect to conferring titles and authorization to practice, for all medical and paramedical professions, in other words, for all healthcare practitioners.

Relevant regulations determine the limits of competency and the responsibility of each practitioner.[7] Thus, an MD is fully responsible for his diagnostic and therapeutic acts. He is entitled to prescribe and to treat within the broad field of his competencies. The European ethics code (Art. 11, January 7, 1988) specifies that he is not authorized "to claim *a competence which he does not hold*". Thus, a dentist is entitled to prescribe and treat everything relevant to the dental area and tissues, but he has no competence to treat a leg pain, or constipation.

2. Training and Titles

The contents of medical training must develop competency for diagnosis and therapeutics to allow one to practice in the field of the said competency.

The theoretical teaching and the practice training leading to a practice diploma depend on the health authorities of each country. Obviously, equivalence or the mutual recognition of diplomas can only exist, across national lines, for the highest level of training.[1]

3. Conditions and Licence to Practice

Aside from the mutual recognition of diplomas, the national health authorities regulate the conditions for practicing (exclusive or not; in a recognized establishment; or private practice, etc.), and issue practice licenses. Licenses may also be subject to non-medical requirements, such as knowledge of the national language, for instance.

4. Terminology Applied to Non-Conventional Medicines

The terms are numerous, and often confusing: natural medicine, soft medicine, alternative medicine, complementary medicine, traditional medicine, energy medicine, and so on.[8]

The European parliament (A 4-0075/97) has chosen the general term of non-conventional medicine to cover all the medical disciplines that do not enter in European conventional medical curriculum. Other terms are still being used, but are sometimes confusing.[a]

For example, sometimes the conventional modern medicine is also called "traditional", which is confusing since ancient traditional medical practices (Chinese, Indian, African, Korean, etc.) are also called traditional.

Some other terms are too restrictive. Thus it is implied that complementary medicine is added to conventional methods, whereas an alternative medicine replaces a conventional one. However, the same method may be complementary or alternative according to the conditions. For example, acupuncture sometimes may be used either as an alternative or as a complementary approach to a modern medical treatment. But food supplements obviously are part of complementary treatment methods.

5. Correspondence with Conventional Discriplines

It is necessary to distinguish between the methods without any correspondence to the conventional disciplines, and those that may be attached to one of these. Thus, traditional phytotherapy is a part of the *materia medica*, and legally cannot be detached from it, even though the principles ruling its utilization are not conceptually the

[a]In the explanatory statement: *"by non-conventional medicine, we mean... medical disciplines or practices such as anthroposophy, homeopathy, Chinese medicine or naturopathy which are full blown medical systems based on theoretical and/or philosophical concepts and view illness as being less the result of the action of external agent than the imbalance of the organism itself."*

same (e.g., Chinese, Indian, African and Mesoamerican). Similarly, preparation of traditional drugs depends on the same regulation as any other medicament.[b]

Acupuncture has no equivalence among the conventional therapeutic methods, but its mechanisms bring it nearer to reflex therapies, transcutaneous electrical nerve stimulation (TENS), for example. Nevertheless, the choice of stimulation sites follows very different logic than other methods. Thus, the distinctions among the methods are not always perfectly clear.

6. Definition of Non-Conventional Methods

The definition of each medical method is essential, to locate and identify it within the public health field, and within medical practice. For instance, acupuncture is a diagnostic and therapeutic act; thus acupuncture is a medical act, even if there are no specific regulations currently governing its practice.

Similarly, homeopathic prescriptions are relevant to medical practice. For example, a dentist is entitled to prescribe, and therefore can prescribe homeopathic drugs within the limits of his competence. Conversely, a paramedical health practitioner is not entitled to prescribe, which also applies to homeopathic medicaments (as well as conventional ones).

Homeopathic drugs have been proposed as food supplements (and are currently freely available without prescription in Quebec). However, most consider that homeopathic drugs are medicaments, and therefore, should be prescribed by a medically trained individual.

According to the resolution of the European Parliament (A4-0075/97), each non-conventional medicine must be individually defined and researched (e.g. chiropractic, osteopathy, acupuncture,

[b]But in the resolution (A4-0075/97) we find: *"Whereas it is important to ensure that patients have the broadest possible choice of therapy'... (paragraph C). "The European Pharmacopeia should include the full range of pharmaceutical and herbal products used in non-conventional medicine"... (paragraph M).*

naturopathy, homeopathy, phytotherapy and shiatsu massage). In fact, some forms of legal recognition exist in certain EU member-states, and most important, some of these disciplines possess organizational structures at the European level (common basic training, ethical code, etc.).

7. Practice of Non-Conventional Medical Disciplines

A fuzziness exists in much national legislation about non-conventional medical disciplines. As a result, many controversies concerning these practices arise.[3,8] Nevertheless, due to the lack of legal dispositions or regulations, the general regulations of medical practice are used as reference.

As for other disciplines (clinical biology), some European countries authorize (specific laws) or tolerate (i.e. implicitly, through lack of official texts) the practice of acupuncture by non-MDs: UK, Germany [Heilpraktikers: by official exam since 1976], Switzerland and Sweden.[8,9]

In many European countries, the legislation governing non-conventional therapies is that of medical practice, in general; but often the legislation is incomplete, or in progress, explaining changes that have occurred in the recent past. For instance, in Denmark, acupuncture practice by non-MD was not illegal; however, since 1981, acupuncture has been considered as a surgical procedure because there is breach of the skin, so only MDs may carry out this medical act.[9] Even in countries where the law seems clear (e.g., Belgium and France), the scope of acupuncture practice is not clearly defined for midwives and dentists. And finally, some countries do not take into account one or another of these methods, or dismiss all of them. The European official position shows the difficulties involved in coordinating the various points of view of the member-states.[2,3,6]

Acupuncture, as for all other non-conventional disciplines, is not included in the European list of recognized medical specialties. Therefore, guidelines regarding acupuncture practice are to be derived

from Article 8 of the Directive 75/362: *"Each member-state may require, from the nationals of the other member-states wishing to get a medical specialist diploma not listed in the Directive, that they meet the training requirements specified by its own regulations". "If each member-state is entitled to regulate the access or practice conditions for a specific professional activity, and therefore make it official, this does not constrain the other member-states to modify their own regulations or internal legislation to authorize the practice of this activity on their territory."* In no case can this regulation be discriminatory; that is, it must be impartially applied to nationals of this member-state, and to nationals of any other member-state (Art. 48, 52 and 59, EC treaty).

Two judgments confirm this position:

(1) *"Because of the lack of homogeneity in the European community as regards activities depending on medical practice, Article 52 of the EC treaty is not opposed that a member state should reserve a paramedical activity to medical doctors only."* (Court of Justice of the European Community; judgment of October 3, 1990; case of Bouchara).

(2) The Tribunal Correctionnel (county court) of Mons, Belgium (judgment of June 26, 1987) stipulates: *"For want of regulations, indeed Directives, concerning a possible harmonization of requirements for acupuncture practice within the European community, each country is free to regulate this practice as it sees fit,"* according to Article 52 of the EC treaty.

A recent European update of December 1993 (Directive 93/16; April 5, 1993) aims at facilitating the free circulation of MDs, and the mutual recognition of their diplomas (OJCE, 07/07/93).

Meanwhile, in the explanatory statement of the resolution (A4-0075/97) we find: *"In view of this lack of regulations, the [European] Parliament has no choice but to call on the [European] Commission to take the steps necessary to achieve coordination of the conditions for the exercise of the medical and allied professions," to use the wording of Article 5 7(3) of the Treaty. This does not mean that conditions for practicing non-conventional medicine should be*

standardized, but that all practitioners should be guaranteed the right of establishment, by providing them with the wherewithal to exercise their Profession, while fully respecting the principle of subsidiarity. In order to achieve this, it is essential that the status of non-conventional practitioners be legalized and harmonized, that conditions be established as regards training, that the appropriate medical products be included in the European Pharmacopoeia, and that social security bodies cover the reimbursement of non-conventional healthcare and medical products."

8. Conditions of Non-Conventional Therapeutics in Medical Practice in General

From a European public health viewpoint, the use of these non-conventional medical practices differs very much across countries.[6] For example, 30 years ago, 50% of the French population used acupuncture or homeopathy, or both. On the other hand, the use of other non-conventional methods was very low. Conversely, the use of medicinal herbs (phytotherapy) was common in Germany, and chiropractic flourished in Anglo-Saxon countries.[10–12] Public health authorities could no longer ignore this *de facto* state. They are now engaged in evaluating issues of professional recognition and the control of these practices.

At the present time, these practices may depend on:

- Current standards of general medical practice (medical and/or paramedical professions).
- Specific official recognition concerning the non-conventional method, its practice and/or its coverage by the healthcare system.
- An ongoing procedure for specific recognition.
- An official tolerance.
- A voluntary lack of acknowledgement pending validation, national or European policies, etc.

9. Reimbursement of Medical, Act, Procedure or Medicament

The coverage of the cost of a medical act, procedure or medicament must be distinguished from an official recognition of the method; nevertheless it may be considered as a favorable factor.

The reimbursement of the act or the medicament by the social security system (government healthcare insurance), or by a supplementary insurance, or a private insurance company, etc. may vary considerably, from total, to partial, to nil.

For instance, acupuncture reimbursement:

- may be specific (France).
- may be considered as any other medical act (Belgium and Ireland).
- may be considered if the act is practiced by an MD, but not by a non-MD (Germany).
- may be considered if it is medically prescribed (Spain).
- may not be covered by social security but might be reimbursed by a supplementary insurance, or private insurance.
- may not be covered.

10. Validation

The resistance to granting recognition to these non-conventional medical disciplines is generally said to be due to a lack of scientific validation. Although some neural, biochemical, morphologic, immunological or biomechanical mechanisms are well explored, clinical validation is only beginning for most non-conventional disciplines.

Clinical validation always rests on experiments to demonstrate the validity of a defined and limited aspect of a therapy. We must strongly emphasize that research without a good methodology is a waste of time and money, and of no use for the validation of the non-conventional medical method. Worse, a bad methodology raises a substantial risk that a non-conventional medical method could be discredited.

Any research must begin by with a written protocol, accurate and complete, including bibliography of relevant published works, and following current standards of biological and medical research, even if an adaptation of the methodology is necessary. To make non-conventional medical methods progress, "names and words" alone are not useful, but rather, solid scientific data must be obtained addressing the three aspects of any medical topic:

- mechanism of action.
- clinical efficacy (effectiveness).
- usefulness for public health.

It is necessary that everyone worldwide work in the same direction, and even better, in coordination, for example, without any competition among Chinese, Japanese, Korean, Tibetan or Vietnamese acupuncture, or between modern and traditional ways. But any research needs significant funding. For non-drug methods (i.e., massage, acupuncture, chiropractic and physical medicine), only national or international public health institutions, or patronage may provide the appropriate funding.

11. Conclusion

Ignoring the considerable use of non-conventional medicine by the public, counterproductive competition between practitioners or proponents of conventional and non-conventional medicine are negative attitudes that are detrimental to both, because these two ways of practicing medicine are complementary rather than competitive.

The only correct, scientific and constructive attitude is: (1) to consider only one medicine gathering together all the disciplines beneficial to public health; (2) to consider the future of medicine and therefore design the best training curriculum for health practitioners at all the levels; (3) to work so that narrow-minded competitive quarrels can be resolved with minimal adverse impact

for all concerned; and (4) to expend the best effort for the medical systems to bring everybody the best possible care, taking into account the actual possibilities of each country, including geographical, climatic, economic and cultural conditions.

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81/1057/CEE	(L385/25-26) (31-12-81)	Completes Directives (75:362; 77/452; 78/866) (78/026/CEE)
82/76/CEE	(L43/21-25) (15-2-82)	Modifies directives (75/362 and 75/363)
89/594/CEE	(L341/19-29) (23-11-89)	Modifies directives (75/362; 77/452; 78/8-66; 78/1026; 80/154; and 75/363; 78/1027; 80/155)
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Harmonization of Traditional Oriental (Chinese) Medicine and Modern Medicine – A Step Forward with the TradiMed Database 2000

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1. Retrospective on Traditional Medicine and Western Medicine

When the human race appeared on the face of the earth, disease-causing bacteria, germs and viruses were already in existence and caused great suffering and death. Treatment for illness, however primitive, must also have been in evidence, though there is a lack of material proof of this. To look for the origin of such treatment, we must study records after the invention of written communication, as humanity formed into social groups and historical records appeared.

From around 2500 BC to 1500 BC, Egyptian papyri and Chinese manuscripts provide accounts of credible treatments for a variety of ailments, and it is safe to assume that this is the earliest verifiable known use of traditional medicines.[1,2] During this time period, there were distinct ethnic groupings worldwide, with different cultures, who developed their own therapies with natural-herbal materials available. These remedies became systematized and were passed down through generations.

As many civilizations rose and fell, there was a great deal of interchange among different peoples worldwide. Increases in trade

also brought on the exchange of ideas including ideas concerning medical treatment for various ailments, and there is evidence of this throughout the world. Typical examples are India's traditional Ayurveda and Chinese herbal medicine. A substantial number of Indian herbal remedies were imported into China, as were Persian remedies via the ancient "Silk Road", the trade route from the Mediterranean cultures to China by way of many other Asian countries, including India.[3] In much the same way today, some herbal remedies of Latin America,[4] and from Africa are now encroaching into Western medicine as part of a more organic approach to the treatment of illness and disease, ephedrine and quinine are examples of modern drugs derived from traditional herbal remedies.[5,6]

Worldwide, there are several common traits in the development of traditional medicines, consistent with the advancement of society. Firstly, religious and shamanistic treatments among more primitive groups of humans had a big influence on the development of traditional medicines,[7] some of which remains to this day. Secondly, there was a tendency for traditional medicine systems to take advantage of the adaptability of the human body to changes in the environment to stimulate self-healing.[8] This was highly visible in Western medicine during Hippocrates time, around 460 BC.[2] However, from the Renaissance period onwards through the Industrial revolution, Western medicine diverged from its oriental cousins, and as its religious aspects became more and more irrelevant, it became a more structured scientific subject looking at single therapy for each specific disease. The discoveries of X-rays and the microscope, and the subsequent development of vaccines and identification of disease-causing organisms, all within the last 100 to 200 years, made great leaps forward for the art of medicine. Western medicine has made tremendous steps in eradicating diseases, especially among infants, but while progressing towards its current manifestation, it did lose the more holistic, whole body approach, something that it is slowly regaining today.[9]

On the other hand, traditional Oriental medicine, widely practiced in China, Korea, Japan and other Asian countries continued its

development using a more conceptualized approach, and now following detailed analysis, the value of herbal medicines and acupuncture/moxibustion has been realized and their efficacy proved clinically.[10,11] A decade ago, the World Health Organization (WHO) recognized traditional medicine as an invaluable adjunct to Western treatment methods in a special program to integrate the two for the benefit of humans.[12] Many traditional herbs are now purified and produced like their Western counterparts.[13] As aforementioned, for example, morphine, reserpine, artemisine and shizandrin are cases of the merging of Western medicine and traditional medicine to develop effective treatments for pervasive diseases. The merging of the diverse medical traditions and disciplines has been widely carried out in China under the name of "Integrative Medicine" for about the past two decades, and currently similar treatments are practiced in Korea and Japan as well.[10,14,15]

In the West, the importance of traditional medicine, especially Oriental medicine is rapidly being realized and its use expanding, with many acupuncture centers in France, the UK, Germany and other countries.[16,17] In the United States, the National Center for Complementary and Alternative Medicine (NCCAM) within the framework of the National Institutes of Health (NIH) has been set up in 1998, an administrative upgrade of the Office of Alternative Medicine (OAM) that was created in 1992. Studies in acupuncture therapy and herbal remedies have been supported by the Center as extramural research activities.[9,18]

2. The Characteristics of Traditional Oriental (Chinese) Medicine

TOM (TCM) practices can be characterized as using two major therapies as follows:

- *Acupuncture:* Apply acupuncture needles at the various meridian points that are hypothetical points of physiological significance within TCM, but which are without experimental verification in

terms of human anatomy as understood in the West. However, significant clinical effects have been frequently noted.

- *Herbal Remedies:* A single herb or multiple herbs combined according to traditional theory (actually a hypothesis), called Polypharmacy in TCM. They are administered in the various forms of pharmaceutical preparation like decoction, pill, powder, fluid extract, ointment, etc. Nearly 100,000 prescription titles were developed and reported in China using around 2000 herbs, and also including some minerals and animal substances.[18]
- *Others:* Moxibustion,[a] Qi gong[b] and massage are also used now.[20] There have been surgical procedures performed according to ancient medical classics in China. However, two major forms of therapy in traditional Oriental medicine remain, acupuncture, medicinal and herbal.

3. Understanding the Wisdom of Traditional Oriental (Chinese) Herbal Therapy

All treatments practiced by TOM (TCM) doctors are based on the great hypothesis called Yin and Yang and Five Elements. This hypothesis represents the Chinese view of nature and the cosmos. The essence of the hypothesis in relation to traditional medicine is that Yin Yang and Five Elements are used to interpret the phenomena of human physiology and disease, in the context of the Chinese belief that man is an integral part of nature. Being born, growing up and dying within nature, they believed that man was governed by it. This hypothesis took deep roots in the regional culture, and was manifested in all aspects of life, language and the writing of alphabets

[a]Moxibustion: It refers to the method by which diseases are treated by burning, fumigating or ironing with moxa wool (usually powder of dried Argyi wormwood leaves placed in a cone).

[b]Qui gong: An exercising therapy to promote a flow of internal vital air(qui), and massage therapy is one kind of it.

in Chinese, and thus also influenced other areas in Asia, including Korea and Japan.[1] For instance, the word Ki (Qui) was used to describe various states of human life and cultural activities; Ki (Qui) in terms of human physiology represents some entity of vital force; some say it is a type of state of mental and mind control ability that can be achieved through focus and or practice.[20] Virtually all human life and social activities within the region of Asian culture are influenced by such hypotheses of Yin and Yang, and the Five Elements. So when Western scientists like to access to the knowledge of TOM (TCM), they should understand such hypotheses and cultural background as well as learn the Chinese alphabets so as to read the ancient medical classics. I think it will require inordinate time and efforts for Western scientists before they access TOM (TCM). In this respect, we should develop a tool for bridging TOM (TCM) herbal remedies and Western counterparts. In other words, we have to overcome several stumbling blocks that have been great barriers for Western scientists attempting to understand the essence of TOM (TCM) herbal remedies.

In Korea, we have made great efforts to provide such bridging tools to integrate and make TOM (TCM) herbal remedies conceptually accessible to Western science and scientists by building the Traditional Oriental Medicine Database (TradiMed 2000) since 1992.[21] The TradiMed 2000 database represents a significant step towards worldwide understanding of TOM (TCM) therapies by providing several new kinds of information as follows:

- Conversion of TOM (TCM) diagnosis and classification of diseases into modern ones. Our survey on medical classics indicates that nearly 4000 diseases were well described up to the 17th century. Even detailed classical descriptions of symptoms of particular illnesses helped us very much to accurately interpret and classify the diseases in modern terms.
- There are reports that there exist altogether nearly 100 000 prescription titles of a single herb, and also of polypharmacy type remedies. All of the titles are described in Chinese characters. It

is very difficult to understand the meanings of the titles unless one has considerable knowledge of Chinese literature. So we developed a code system for prescription titles under the guidance of several institutions in China, Japan and Korea. In this regard, the WHO regional office of the Western Pacific gave us much additional advice and guidance.[22]

I think the above accomplishment will be a significant step towards the understanding and access to the information on TOM (TCM) herbal remedies. Other information contained in the contents of TradiMed 2000 and summarized in the following.

4. Contents of TradiMed 2000

The Natural Products Research Institute, Seoul National University, has developed a unique database, "TradiMed©" DB, derived from the knowledge of traditional oriental (Chinese) medicine. This information research work has been supported as a national project by the Ministry of Science and Technology from 1992 to 1997, and by the Ministry of Health and Welfare later on. The first version of TradiMed was launched as a CD-ROM title in 1996, and the second one has just been published this year under the title of TradiMed 2000.

The contents of TradiMed 2000 can be characterized as a sort of treatise: a great deal of information on traditional Chinese herbal remedies integrated with knowledge of modern medical and natural products science. The database offers six major categories of information on traditional Chinese herbal therapy as follows:

(1) *Herbal prescriptions*, including those made of a single herb, or of combinations of several herbs (polypharmacy). A total of 12 634 prescriptions was collected from 11 traditional Korean classics and seven Chinese medical classics, and described. In addition,

herbal formulae, dosages, reports of efficacy, target meridian organs in acupuncture, and other references can be found.

(2) *Botanical and taxonomical information* on herbal materials and original plants, including full-color photo images. A total of 1225 photos of medicinal plants that were carefully identified by botanists, labeled with their Latin names, are described.

(3) *Chemical information* on constituents with analytical spectral data, including diagrams of chemical structure. A total of 11 586 natural constituents as ingredients of Chinese herbs were put into a chemical database, and their analytical data such as ultra-violet, infra-red, nuclear magnetic resonance, and mass spectra were described, together with references. These will offer much help in identifying active ingredients, as well as establishing quality control of herbal materials. One can cross-check whether the same ingredients are available in other herbs.

(4) *A dictionary of disease classification* by traditional and modern medical terms, including detailed description of symptoms. A total of 4080 diseases/symptoms were converted into Western classification in English.

(5) *Processing methods of herbal materials* by unique and traditional ways in order to remove possible toxic constituents; usually these processes eliminate unwanted, toxic substances from herbs.

(6) *Clinical case studies* by integrated treatments with TOM and modern medical practices. A total of 844 case studies using TOM (TCM) together with Western treatments have been conducted in China during the past two decades, and are described. These case studies will provide some ideas for Western scientists to understand the effectiveness of such integration therapies.

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An Information Perspective: The Role of the British Library in Supporting Complementary and Alternative Medicine in Britain

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The British Library is the national library for the United Kingdom. Our mission statement asserts that we aim to be the world's leading resource for scholarship, research and innovation. The move to our new custom-built, multimillion pound building in London has allowed us to become a library on two sites, which has eased access to our collection both in the Humanities and the Sciences. The British Library is one of the five copyright libraries for the UK, which means that we obtain all material published in the UK that is sent to us by the publishers. On top of this, we spend a large proportion of our budget buying materials in a huge variety of languages and topics. We also have a major document delivery operation at our other site in Yorkshire, which also purchases material for both loan and copying purposes. It has been estimated that over a year, the British Library uses eight miles of shelving and takes in over 8000 items per day.[1]

In the UK, the whole area of complementary and alternative medicine (CAM) is a minefield. The rise of "evidence-based medicine" (EBM) in Canada[2] has been fervently supported by the UK government.[3] The first unit in the UK was the Centre for Evidence-Based Medicine at Oxford University set up and run by David Sackett, this has been followed in the complementary medicine area by the Centre for Complementary Medicine Studies at the University of

Exeter which has been set up along similar lines. The Research Council for Complementary Medicine has also adopted an EBM approach, and has been working closely with the Cochrane Collaboration to apply the techniques of EBM to complementary medicine.[4] However, the concept of EBM applied to CAM has produced many problems which include the difficulty of applying "randomized control techniques" to complementary modalities or techniques such as acupuncture and shiatsu massage.[5] EBM has also been supported by the "Western scientific Mafia" who continue to denigrate CAM as not being "scientifically based" and certainly not "evidence-based".[6] However, a recent article by Feinstein and Horwitz has, whilst supporting the idea of evidence-based practice, pointed out the limits of the EBM approach to treatment.[7]

In the early 1990s the British Medical Association (BMA), which represents the majority of the medical profession in the UK, gave its blessing to the whole area of complementary medicine through the publication of their report on complementary medicine that supported the concept of complementary practice as an adjunct to standard medical practice.[8] The BMA failed to respond to demands for further, more public, support from CAM practitioners, for two reasons: lack of resources, and it not being the BMA's core business.[9]

However, there has been a recent move by the British Medical Journal (BMJ), the official publication of the BMA, to publish a series written by two general practitioners based at the Research Council for Complementary Medicine, on complementary medicine. The editor of the BMJ insists that this series will be "evidence-based". One of the UK newspapers perhaps correctly pointed out, that the BMA have bowed to one of the greatest social trends of the 1990s, and that the therapeutic benefit of lengthy consultations by complementary medicine practitioners may be the reason why people are turning to alternative forms of treatment.[10]

EBM has led to an interesting problem within the British Library. The UK medical library community, which serves the National Health Service and the higher education sector, has wholeheartedly embraced

EBM as it has led to a "raison d'etre" for medical librarians, with an increasing role in the provision of literature searches and their critical appraisal.[11]

The British Library has not responded to this movement as it feels, rightly or wrongly, that there are problems with librarians appraising literature without the requisite specialized medical knowledge, and that this will eventually lead to insurance and litigation problems. The response to this problem from the British Library has been to make the Cochrane Database available in the Reading Rooms for readers to use on their own with only tuition on the database given by staff. It should be realized however that usage of the Cochrane database in the British Library reading rooms is tiny compared to usage of Medline or EMBASE as search tools.

Even with this unprecedented push towards EBM and its questionable applicability to complementary medicine, the British Library continues to support complementary and alternative medical practice in the UK and internationally through the provision of library and information services, its AMED database (see below) and its unsurpassed collections.

1. Health Care Information Service

The services offered by the British Library to the healthcare arena are many. The Health Care Information Service (HCIS) aims to act as a focus for users, from the healthcare professional through to the patient. Due to the production of the AMED database, the HCIS is particularly eager to promote itself as *the* information service in complementary and alternative medicine.

Since 1966, the British Library has been the Medlars Centre for the UK. This means that the British Library has a special relationship with the National Library of Medicine (NLM) in Bethesda, MD, USA, and carries out indexing work for them for their Medline database. This is a significant source of income for the HCIS section, and the British Library as a whole. This money and expertise allows us to

run spin-off activities such as training courses and other indexing consultancy work. We currently have two contracts with outside bodies worth over £100 000.

2. Allied and Complementary Medicine Database (AMED)

In 1985, the HCIS, which was then called the Medical Information Service, carried out a survey of MEDLINE to find out which areas were not adequately covered by this major medical bibliography.[12] We discovered that complementary medicine and the paramedical disciplines such as physiotherapy and occupational therapy were particularly badly covered, so a decision was made to start a specific database to cover these subjects.[13] Although this was not supported by the British Library management at the time, the section persisted with production of the database and is now showing increased income from this product. The coverage of alternative medicine by both MEDLINE and EMBASE has increased over the last few years but their inadequacy in answering some natural product questions has been recently pointed out in the literature,[14] although the article failed to survey both the AMED and the NAPRALERT database.

The original database produced by the British Library was entitled Allied and Alternative Medicine database, as that was the accepted term for the discipline at the time and the term used in MESH, the thesaurus for the MEDLINE database. We have recently changed the title to Allied and Complementary Medicine database, due to the work done in the early 1990s by the British Medical Association in defining CAM. We developed the MEDLINE thesaurus in the areas specifically covered by our new database, and indexed journals that we had in the British Library collection in Yorkshire. In the early 1990s, we decided to make the database available through a number of online hosts including Dialog and Datastar. Since then the database has grown to over 100 000 references on complementary medicine and the paramedical disciplines and we are now indexing over 400 journals.[15] In the last year, the database has been made available

on CD-ROM with the help of SilverPlatter and we are currently awaiting new CD-ROM and Web versions of AMED from OVID Technologies Inc. and from EBSCO Publications, both electronic information providers. We continue to publish the print version of *Complementary Medicine Index,* which sells well as does the thesaurus and list of journals indexed for AMED although a simple version is available on our Website.[16]

The growth in the concept of EBM in the UK has led to requests by the Research Council for Complementary Medicine for the term "Randomised Controlled Trial" to be included on AMED. This however, has led to technical problems, with the need to add extra fields to the database and then rebuild the whole. Adding extra fields leads to extra expenses in staff time and those costs are then, in turn, passed on to the CD-ROM producer who has to follow suit.

In the next year, we plan to add the literature of speech and language therapy and to start adding conference proceedings and patents in the area of complementary and alternative medicine, which we believe, will make AMED more useful to the researcher.

3. Document Supply

The British Library is a major international supplier of documents from both serial and monographic material. The British Library's Document Supply Centre is based in Boston Spa in Yorkshire, and is basically a copying factory. In 1998, we supplied over 4.5 million articles worldwide. This operation has recently been improved by the use of *Inside,* which is our current awareness database. We take 21 000 of the most requested titles, and the title pages are keyed into a Web-accessible database. This database can be searched by keyword in title and the references retrieved can then be requested from the Document Supply Centre. The database is particularly good in science, technology and medicine and covers most of the complementary and alternative medical journals. Although not indexed in depth like AMED, it is particularly up to date, with

references from weekly journals being added within two days. Free 30-day trials of this service are available.[17]

Most document supply transactions are carried out through the intermediary of the library at present, although with the introduction of "Inside" we are increasingly looking to the end user to request material directly.

Negotiations have just been concluded with the NLM in the USA, which allows librarians in the US to request materials from the British Library using the DOCLINE and LOANSOME DOC programs. This service was launched in October 1999.

4. Publications

The British Library publishes many works across the spectrum of humanities and sciences, drawing on its amazing collections. In the healthcare area, we publish "*How to Find Information*" guides;[18] one on CAM is scheduled. We are just putting the finishing touches to a "*Directory of Organisations in Allied and Complementary Health Care in the UK and Europe*," which will be published in November.[19] It is hoped that this publication will sell well, but we will also be looking to put a cut-down version on our Website. In the humanities area, we are awaiting publication of a book on the "*Mediaeval Herbal*."[20]

5. Reading Rooms

The opening of our multimillion pound building at St. Pancras in London, has finally allowed us to bring together the science and humanities collections. Readers can now get a pass and consult historical materials alongside current research. Due to the work of the HCIS, we are beginning to collect more complementary medical material and we have access to the comprehensive historical collections of the Humanities section which includes many books and manuscripts on traditional medicine. The Document Supply

Collection at Boston Spa, which can be consulted in the Reading Rooms in London within 24 hours, subscribes to over 260 000 serial titles and holds over three million monographs. We are currently working on a guide to the collections specifically for complementary medical practitioners.

Also on site, we have the Business and Patents Information Services. The Business Information Service can answer inquiries about companies, equipment and market research.[21] The collection of market research reports is second to none, and provides a large amount of health-related information. The Patents collection is the largest in the world with over 40 million patents. These include patents on health devices and equipment, and any complementary medical treatments that can be patented. They are a useful source of information, as holders of potential patents must have carried out a comprehensive literature search before submission. This is published with the patent and is a useful source of information. The Patents Information Service also advises on intellectual property rights and trademarks.

6. Search Services

HCIS provides both a free and a priced search service. We carry out basic reference searches which take less than 15 minutes for free, whilst we also offer a priced service for longer, more involved searches. A priced search usually covers a number of databases and is therefore more comprehensive. Most of the searches we carry out are for small to medium businesses.

7. Conclusion

Although there are still concerns about complementary medicine from mainstream UK medical practitioners exacerbated by EBM, greater numbers of patients are using complementary medicine and more and more general practitioners are offering complementary clinics.

It is also noticeable that university medical schools are beginning to include a complementary medicine course as part of their curricula.[22]

In this area, the British Library offers a comprehensive range of information services for the complementary medical practitioner but especially for the researcher at whom our services are mainly targeted. Although the British Library and specifically HCIS has yet to be comprehensively marketed to the complementary practitioner and researcher, this will be taking place in the next couple of months in a joint campaign with Optology, the UK supplier of our AMED CD-ROM.

Both the new Reading Rooms and the Document Supply Centre in Yorkshire can supply materials on a wide range of topics that include materials which would be of interest to these practitioners. HCIS is striving to become *the* information service for CAM in the UK through the production of its AMED database, and will continue to support the complementary medicine movement in the UK.

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World Health and International Collaboration in Traditional Medicine and Medicinal Plant Research

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Abstract

Over the past decade, traditional and botanical medicines have become topics of increasing global importance, with both medical and economic consequences. In developing countries, up to 80% of the population depend on traditional systems of medicine and botanicals as their primary source of healthcare. In Europe and the United States, approximately 30 to 50% of the population use herbal medicines on a regular basis. For example, in the European Community (EC), herbal medicinal products retain an important share of the pharmaceutical market, with annual sales in the range of US$7 billion. In the US, the sale of herbal medicines has dramatically increased from US$200 million in 1988, to over US$5.1 billion in 1997.

In recognition of the global importance of traditional medicine and plant-based medicines, the World Health Organization's Traditional Medicine Programme (TRM) has been responsible for promoting research and development of traditional and botanical medicines, when shown to be safe and effective. The Program does so through a worldwide network of 25 collaborating centers, of which the College of Pharmacy at the University of Illinois

(UIC) is one of only two such centers in the US. The collaborating centers are the technical backbone of TRM, and provide basic information and scientific input to TRM as a result of specific research expertise. This information is then put at the disposal of the global healthcare system, thereby improving healthcare and decreasing the costs associated with healthcare research.

As part of its collaboration with TRM, UIC is responsible for the education and training of students and scholars from around the world in the field of medicinal plant research (pharmacognosy). Since 1995, UIC has been involved in drafting a series of books for TRM entitled the *"WHO Monographs on Selected Medicinal Plants,"* Volumes I, II and III. The books contain scientific reviews of the quality, safety and efficacy of medicinal plants from around the world. In addition, UIC provides scientific information on medicinal plant to developing countries for free by way of the NAPRALERT database, thereby decreasing the costs of establishing research and education programs. All 25 collaborating centers work together with the TRM to promote the safe and effective use of traditional medicines, thereby positively impacting the healthcare of approximately four billion people worldwide. Thus, organized international collaboration in traditional medicine offers many benefits to both the world health and the global economy. In the future, traditional medicine and medicinal plant research will depend on the development of strong nationally sponsored programs, and the application of modern scientific methods to the assessment of safety and efficacy, with WHO-TRM acting as an international catalyst for such programs.

1. Introduction

Over the past decade, there has been a renewed global interest in traditional systems of medicine and medicinal plants. The dramatic resurgence in the use of herbal medicines has a significant impact on both world health, and the global economy.[1] In terms of world health, herbal medicines play a central role in traditional medicine and the healthcare systems of large portions of the world's

population.[2] According to the World Health Organization (WHO), up to 80% of the population in developing countries depend on traditional and botanical medicines as their primary source of healthcare.[3] Considering that the world's population is now estimated at six billion, and that two-thirds live in developing countries, then approximately three billion people depend on traditional and herbal medicine. Further confounding factors include the fact that the burden of disease resides heavily in developing nations, where epidemics of malaria, hookworm, sleeping sickness, schistosomiasis and AIDS abound. In addition, the four billion people in developing countries use only 21% of all pharmaceutical drugs produced annually, while the two billion people in industrialized countries use approximately 79%.[4] The reasons for such disparity are varied, and range from ecological factors, cultural and philosophical differences, to matters of simple economics.

2. Cultural Considerations

According to WHO, traditional systems of medicine are specific medical systems that have been practiced worldwide for hundreds or thousands of years.[3,5] Traditional medical systems are deeply rooted in both the culture and philosophy of these societies,[3] and are well accepted and patronized by local communities. China, for example, has a long history in the practice of traditional medicine. Traditional Chinese medicine (TCM), which is an intrinsic part of the Chinese culture, has served the health needs of the Chinese population for almost 5000 years.[6,7] It has achieved considerable success in providing healthcare to its entire population, over 1000 million people. Traditional treatments like herbal medicines, acupuncture, acupressure and massage, account for approximately 40–80% of all healthcare delivered in China.[8] This system of medicine has its own unique methods of diagnosis, and incorporates over 7000 species of medicinal plants into clinical practice (Medicinal Plants in China 1989).[9] The TCM physician can choose from over 500 common classical

prescriptions containing combinations of five to 15 or more medicinal plants.[8] Today, the use of Chinese medicines has increased around the world, although only a small percentage of these medicinal plants have ever been thoroughly scientifically investigated. In cases where randomized controlled clinical trials exist, the results of these investigations are generally published in local Chinese scientific journals, and most are printed in Mandarin. As a consequence, much of this information is not included in most abstracting services in the US, making these data inaccessible to Western physicians.[10] Similar situations exist in other developing countries such as Africa, Brazil, India, Mexico, and Thailand where traditional medicine serves as the primary source of healthcare for 50 to 80% of the general population.[3,11]

3. Economic Considerations

Global financial resources continue to diminish in the social sectors, specifically in the healthcare sector, while the demand and cost for health services has steadily escalated.[5] This is especially problematic for many developing countries where diseases such as malaria, schistosomiasis and AIDS are epidemic, and where financial resources for healthcare are extremely limited. It is estimated that as many as 700 million people (projected to rise to 1.5 billion by 2030) live in the 42 so-called Highly Indebted Poor Countries (HIPCs),[4] where a combination of extreme poverty and financial insolvency makes the availability of modern prescription drugs unattainable. Life expectancy in HIPCs averages approximately 51 years as opposed to 76 years in the US.[4] In these, and other developing countries, the use of traditional healers and herbal medicines is not alternative, but a life and death necessity. Adding to the economic impediments, there are also availability constraints for prescription medicines in developing countries. When the financial resources are available to buy prescription drugs, many pharmaceuticals are simply unobtainable or of substandard quality, making herbal medicines

the mainstay of pharmacotherapy. Therefore, it is an undeniable fact that traditional and herbal medicines play a vital role in healthcare in developing countries, often bridging the gap between availability and the demand for modern medicine.

Traditional medicines are commonly used to respond to healthcare needs, not only in developing countries, but also in affluent nations, where the use of medicinal plants and acupuncture are now accepted medical practices. Herbal medicines are recognized as an alternative or complementary therapy in many modern healthcare systems, and in some countries such as Canada, Germany, Switzerland, and the US, patients can be reimbursed by the social security or healthcare system. In the European Community, herbal medicinal products play an important role, and retain a large share of the pharmaceutical market, with annual sales in the range of US$7 billion.[12] In fact, herbal medicines have been popular in Europe for over 50 years. To sell herbal medicines in Europe, manufacturers must obtain a "marketing authorization" from the drug regulatory authorities.[13] Procurement of marketing approval requires the submission of a formal dossier providing scientific proof of safety and efficacy for each herbal product.[13] As a consequence, many clinical trials involving herbal medicinal products were performed and published in European medical literature, and are published in the native French, German, Italian or Spanish languages. While these data provide important insight into the safety and efficacy of herbal medicines, due to language barriers this information is also often inaccessible to other cultures.

Probably the most extreme example of a philosophical change in attitude toward traditional and herbal medicines has occurred in the US, where traditional and herbal medicines fall under the category of complementary alternative and therapy. American consumers are now spending and average of US$21 billion annually on alternative treatments, and an estimated US$5.1 billion on herbal medicines.[14] Strong consumer interest in botanicals has focused both research and research spending on the evaluation of quality, safety and efficacy

of these products. However, the use of plant-based medicines in the US is not really a new phenomenon. Approximately 25% of all prescription drugs are plant-based.[15] This represents a great deal of money, as the prescription drug market is estimated at more than US$220 billion in Europe and the US alone. Furthermore, ten plants have been approved by the Food and Drug Administration for inclusion into over-the-counter drug products, and represent a large percentage of the OTC market, that has been estimated at $25 billion annually in the US, alone. Moreover, the global sales of herbal medicines have been conservatively estimated at US$25 billion. Analysis of these numbers suggests that at least US$75 million dollars is spent annually on plant-based medicines, thereby having a tremendous impact on the global economy.

4. Health Considerations

In recognition of the importance and potential benefits of traditional medicine to world health, WHO established the Traditional Medicine Programme (TRM) in 1976. The program, which is housed in Geneva, Switzerland, is the only one of its kind and serves to promote and develop the safe and effective use of traditional medicine throughout the world through scientific research, clinical investigations, education and training, as well as information exchange. The policy of the TRM is based on a number of resolutions adopted by the World Health Assembly and the regional committees. TRM policies highlight the fact that: (1) much of the world's population depends on traditional medicine and medicinal plants for primary healthcare; (2) that traditional medicine practitioners are a potential important resource for the delivery of healthcare; and (3) medicinal plants are of great importance to the health of individuals and communities.[5] Moreover, the Declaration of Alma-Ata, drafted during the International Conference on Primary Health Care convened by WHO and UNICEF in Alma-Ata, USSR in 1978, provided for the incorporation of proven traditional medicines into national drug policies and regulatory

measures.[5] As a consequence, WHO urged its member states to initiate comprehensive programs for the identification, evaluation, preparation, cultivation and conservation of medicinal plants used in traditional medicine. WHO also encouraged assurance of quality control of drugs derived from medicinal plants by the implementation of modern techniques, and by applying suitable standards and good manufacturing practices (GMP).[2]

5. WHO-TRM Collaborating Centres

To facilitate the enactment of these policies, WHO-TRM established a number of WHO collaborating centers for traditional medicine throughout the world. The WHO collaborating centers are the technical backbone of the program. They form a worldwide network in the different areas of WHO's work, which provide the secretariat and member states with basic technical and scientific input, resulting from the research and expertise at the collaborating centers, which is put at the disposal of the global healthcare system. Currently, there are 25 collaborating centers worldwide, and they assist WHO-TRM in five main areas: (1) national program development; (2) health systems and operational research; (3) clinical and scientific investigations; (4) education and training; and (5) the exchange of scientific information.

In 1981, the College of Pharmacy at the University of Illinois (UIC) was designated a WHO Collaborating Center for Traditional Medicine. Most of the major activities of the center have been with the Program for Collaborative Research in the Pharmaceutical Sciences (PCRPS) within the college. As part of our collaborative arrangement with WHO, we have three terms of reference, or functions that we perform for WHO-TRM. The PCRPS provides education and research training in the field of medicinal plant research to students from developing countries at the Masters and Doctor of Philosophy level. We also host short training sessions (six months to two years) for postdoctoral fellows and scholars from around the world. Our second

term of reference is to provide consultative and technical support to WHO-TRM by participating in workshops on herbal medicines, and by the production of a series of technical guidelines on herbal medicines. For example, our collaborating center and the Natural Products Research Institute in Seoul, Korea actively participated in the preparation of the *"WHO Guidelines for the Assessment of Herbal Medicines,"* which was adopted for general use by WHO in 1991. Since 1995, our collaborating center has been responsible for the drafting of the *"WHO Monographs on Selected Medicinal Plants,"* Volumes I and II, and we will be starting Volume III later this year.[16] The purpose of the WHO monographs is to provide accurate scientific information on the safety, efficacy and quality control/quality assurance of widely used medicinal plants, to facilitate the harmonization of common uses of herbal medicines throughout the world. The proper use of herbal medicines has a two-fold benefit in that it will not only promote health, but also protect consumer safety. In addition to the perceived medical benefits, there is a potential for the establishment of industry and international trade in developing countries. New industry and trade will bring employment to these countries, and thereby promote a better standard of living.

The monographs are also intended to serve as examples to assist and encourage the WHO member states in the development of their own medicinal plant monographs. The monographs were drafted based on a systematic review of the world scientific literature from 1975 to 1995, including various pharmacopoeias; monographs such as the German Commission E Monographs; information from MEDLINE, NAPRALERT, and TOXLINE, reference texts, and peer-reviewed scientific journals. Volume I of the monographs contains 28 technical monographs, and provides details of quality, safety and efficacy for 39 species of plants, including aloe, aloe vera gel, astragalus, chamomile, echinacea, ephedra, garlic, ginkgo, ginseng, senna and valerian. Volume I of the WHO Monographs is now in print and available through WHO publications in Geneva. The draft of the *"WHO Monographs of Selected Medicinal Plants,"* Volume II has

now been completed, and is in the editorial phase. The second volume includes 32 monographs, including black cohosh, dong quai, *Eleutherococcus*, evening primrose, feverfew, hawthorn, kava, saw palmetto, St. John's wort and stinging nettle among others. Publication is expected early in 2000. The drafting of Volume III is scheduled to begin in November 1999.

Inasmuch as WHO-TRM acts as a clearing-house for the dissemination of information on traditional medicines, the third term of reference for the UIC collaborating center is to provide medicinal plant information to developing countries for free. Our collaborating center does so via the NAPRALERT database, the world's largest relational database that is housed at UIC.

6. Application of NAPRALERT to Medicinal Plant Research

NAPRALERT, an acronym for **NA**tural **PR**oducts **ALERT**, is the largest relational database of world scientific literature on the ethnobotanical uses, pharmacology, pharmacokinetics, toxicology and chemistry of medicinal plants. The database was initiated by Dr. Norman Farnsworth in 1975, and is housed within the Program for Collaborative Research in the Pharmaceutical Sciences, at the College of Pharmacy, UIC. NAPRALERT was designed expressly to facilitate traditional medicine and medicinal plant research by allowing for systematic analysis of the world literature of medicinal plants. NAPRALERT is a relational database, and is presently managed under Ingres, a legacy SQL-based commercial product, on a Sun SPARCstation 5 at 170 MHz. NAPRALERT contains data extracted from over 150 000 scientific articles collected from almost every country throughout the world. Many articles, published in foreign languages, have been translated into English, and are in either the form of an abstract or the entirely translated article. Approximately 700 international journals are perused on a monthly basis by PhD level scientists for inclusion of pertinent articles into the database. Data from over 600 articles are added monthly to the database, which

appears to be sufficient to cover the world literature of botanical research.

From its very inception, the NAPRALERT database has been part of a global network of scientific collaborators, due to the intrinsic international nature of medicinal plant research. Most of the important medicinal plants come from tropical areas of the world, particularly developing countries such as Africa, Brazil, China, Costa Rica, India, Mexico and Thailand. Thus, the countries with the bulk of the botanical resources do not generally have the financial capability to develop them. However, application of modern scientific methods to the cultivation, selection, standardization, and clinical trials of botanicals, is essential for the integration of safe and effective traditional medicines into modern medical practice. Hence, research and development of botanical medicines, or the isolation and characterization of new drugs from natural sources, can play a vital role in the improvement of the overall economic and medical health of developing countries. Furthermore, results from scientific investigations published in developing countries also benefit scientists and healthcare providers in the US, and other industrialized countries.

7. Information in NAPRALERT

Generally speaking, the NAPRALERT database stores five finds of records: ethnomedical (folkloric uses), organism (plant description), activity (pharmacology activity), chemical (chemical constituents) and bibliographical data. The database terms each of these data sets as a separate entity and each may have as many fields as needed to describe it. The bibliographic data describes the literature source, and is very critical to the data structure as it provides the primary key that ties the other data sets together. The bibliographic information is stored in two tables and each record contains all information concerning the publication that was the original source of data. This record is usually not queried directly, but is accessed in response to all queries to provide a reference to the original citation. We have

developed a referencing system to standardize all botanical nomenclature and yet retain the author's nomenclature as well as a single standard nomenclature. This is to instill consistency so that a given plant will always be referred to by one name. We do this by determining a correct scientific name (Latin binomial) for each plant species and the possible synonyms of a plant Latin binomial, using the best taxonomic literature available to us (and two Ph.D. level taxonomists). However, we still retain the author's original nomenclature in case disagreements with the synonymy arise. We also maintain lists of common names for each plant species.

The ethnomedical records contain information on the folkloric or ethnomedical uses of the plant species, while the biological activity records contain information on the pharmacology of the plant or plant extract or isolated chemical constituents. It is important to note that there are no pre-conceived limits to the types of ethnomedical or biological activity records that can be coded. All activities are uniquely coded through a system of "major pharmacological activities/specific pharmacological activities." All of the data is tied together via the worktype table that indicates what type of work is described in each article. For example, experiment type (*in vitro*, *in vivo*, clinical trials, biosynthetic studies), isolation and identification methods (HPLC, IR, UV, NMR, etc.). Simply speaking, the data structure assumes that the bibliographic records (cited literature) contains information that describe plants (organism data) and their chemical constituents (compound data) that have specific biological activities (pharmacological activity) and/or ethnomedical uses. Access to NAPRALERT is currently restricted to online service via the Internet, and through some offline requests. Our international WHO collaborators send email messages to a one-headed, first-in, first-out (FIFO) queue and eventually receive plain-text email replies with data in a report format. The online requests are currently restricted to the types of data analysis that can be performed, due to the limited types of "canned" queries available to the end user. Furthermore, due to the present limitation of plain text report formats, our collaborators cannot manipulate the data from these reports. Over

the next year, NAPRALERT will be converted to a more interactive form that will be available online through the Internet.

Developing countries use the scientific information extracted from NAPRALERT to facilitate the assessment of quality, safety and efficacy of their own indigenous medicinal plants, to establish education and research programs, and to facilitate the initiation of new drug discovery programs from natural products. This service not only enhances the probability of the success of these programs, but also saves time, effort and the limited financial resources of these countries. Thus, the international exchange of scientific information plays a vital role in the advancement of traditional medicine.

8. Future Directions

As our past experiences have demonstrated, international collaboration is an important aspect of traditional medicine and medicinal plant research. By working together, all countries involved have benefited. However, much research remains to be done. While it has been estimated that between 35 000 to 70 000 plants or plant products have been used globally as medicines, only a small fraction of these plants have ever been thoroughly investigated on a scientific level. Thus, the large number of plant species that have not been investigated represent a potential rich resource for the world to explore. In addition, while medicinal plant research is now receiving a lot of attention, there are other aspects of traditional and complementary medicine that need attention as well. For example, there are numerous methodological issues that have not been addressed, such as – the future of traditional medicine – and medicinal plant research will rely heavily on international collaborative efforts. However, strong national support for these programs is also needed. Research and development of traditional medicines, supported at the national level, will be essential for capacity building in developing countries. Strong national support for these activities is strategic to the overall development of new drugs from

local medicinal plants, and for the promotion of safe and effective traditional medicines. The initiation of medicinal plant research programs will require a serious commitment in terms of effort and money; however, failure to do so will ultimately be more costly.

Establishing quality, safety and efficacy for plant-based medicines will be another goal for future research. By the application of advanced scientific techniques to the cultivation, selection, manufacture and clinical trials of herbal medicines, developing countries can transform traditional medicines into a modern medical industry. In doing so, medicinal plants or plant extracts that are shown to be safe and efficacious could be added to the national lists of drugs for use in primary healthcare, and may replace some expensive pharmaceutical products, thus reducing overall healthcare expenditures. Global acceptance of the safety and efficacy of these products will lead to the development of industry and the improvement of living conditions, all of which will have an impact on world health.

The development of medicinal plant screening programs can already be greatly facilitated by sophisticated searching techniques and data analysis of the scientific literature in NAPRALERT. The ability to produce lists of plants with a high priority for screening will maximize the potential to discover new therapeutic agents, as well as determine the mechanism of action and safety of known medicinal plants. It will also prevent duplication of research efforts, and reduce the time and money required to produce safe and effective crude extracts or new natural drug entities.

Previous obstacles to traditional medicine and medicinal plant research in the US, such as low priority status and lack of federal funding for such projects, are gradually beginning to disappear. This year alone, the federal government has approved substantial funding for botanical research, and will be establishing two NIH-funded botanical centers within the US. In the next few years, if funding for scientific research continues to increase, and the safety and efficacy of specific herbal medicines can be established, they should be recognized as such and integrated into our medical armamentarium.

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Academic and Funding Perspective in Developing Alternative Medicine Research in the US: Experience of the Rosenthal Center for Complementary and Alternative Medicine

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Abstract

Complementary and alternative medicine (CAM) has entered the American consciousness. For many years it was considered fringe and in the realm of the unscientific. Now, given the results of national surveys that indicate that more than 40% of the American public are using some form of alternative medicine, and that they are paying for it themselves,[1] medical centers and funding agencies around the country are realizing that CAM is not just a passing fad. There is a substantial and steadily increasing cadre of researchers and clinicians studying alternative medicine practices and providing clinical services to their patients.

Initiating the first such research and clinical programs at academic medical centers, for the most part resulted from the efforts of individuals at each institution and a small group of private funders. The National Institutes of Health (NIH), the premier national governmental funder of biomedical research, now hosts a National Center for Complementary and Alternative Medicine (NCCAM). This institution has played a significant role in spurring the development of CAM research around the United States.

Yet obstacles to research progress still exist. New approaches need to be found to facilitate the funding and conduct of complementary and alternative medicine research.

1. Introduction

For more than 30 years, CAM in the US was primarily practiced by individuals operating outside of the medical mainstream. CAM, previously more commonly called holistic medicine was considered a "fringe" activity. Practitioners were generally without nationally recognized credentials, and the clientele were primarily individuals self-identified as "counterculture." Research was conducted in relative obscurity, with little outside funding, often at the investigator's own expense as a result of individual interests and passions. Sample sizes were small and it was often difficult to get results published.

However, today, an increasingly broad spectrum of mainstream Americans are using CAM. A recent survey indicates that as of 1997, more than 40% of Americans are using alternative therapies.[1] Results of another survey suggest that these therapies are used by people who are better educated, and "hold a philosophical orientation toward health that can be described as holistic (i.e. they believe in the importance of body, mind, and spirit in health)."[2]

Intensified public interest over the past decade has resulted in steady growth in alternative medicine programs in medical centers around the US (both research and clinical programs), with most of that growth coming in the past two to three years. 1993 was a watershed year for the development of CAM in the US; from being considered a "fringe" activity practiced largely by "counterculture" individuals, CAM rapidly became an area of interest to the medical mainstream. Four events contributed to the awakening of a broader public consciousness regarding CAM: (1) the establishment within the NIH of an Office of Alternative Medicine (OAM); (2) a public television series: "Healing and the Mind" (1/93); (3) publication in *The New England Journal of Medicine* of the results of a national survey

indicating that in 1990, about one-third of Americans used "unconventional" medical therapies;[3] (4) the establishment of The Richard and Hinda Rosenthal Center for Complementary and Alternative Medicine at Columbia University College of Physicians and Surgeons (10/93).

(1) The *NIH OAM* was established by a mandate from the US Congress; it was not initiated from within the NIH. That is, had it not been for an act of Congress, this office would not exist. Although officially initiated in 1991, its activities were not widely known to the public before 1993. The OAM began with a budget of just US$2 million and a mandate to investigate *all* of what was being defined as alternative and complementary medicine. This was a tall order, particularly with the "homeopathic budget" as the first director, Dr. Joe Jacobs called it. Seven years later, the budget (1999) is now US$50 million and growing.

The formation of the OAM within the NIH gave CAM research the federal government's stamp of approval, enhanced the credibility of those conducting such research, and provided some funding, minimal though it was, for the conduct of some small studies of complementary and alternative therapies. CAM research was thus legitimized and it became more acceptable for other organizations to begin to support it. The OAM was recently (1998) elevated to a "Center" – National Center for Complementary and Alternative Medicine (NCCAM), with the authority to award and administer its own monies that it did not have as an office.

(2) *"Healing and the Mind,"* a special public television series hosted by Bill Moyers, is estimated to have been viewed all, or in part, by 15 million people. This program, and an accompanying book,[4] brought to public attention a variety of topics associated with CAM practices or therapies such as traditional Chinese medicine (TCM), mindfulness meditation, and alternative approaches to healing for cancer patients. The work of a number of people, conventionally or unconventionally trained, was highlighted. For years they had quietly developed their "unconventional"

approaches to treating illness and maintaining health and well-being.

(3) A *national survey* of Americans' use of CAM conducted by researchers at Harvard University, found that use of "unconventional: medical therapies, that they defined as "not taught widely at US medical schools or generally available at US hospitals," was widespread. The survey, published in one of the most respected US medical journals (*The New England Journal of Medicine*, 1993), was a wake-up call to many American doctors, who had no idea that more visits were being made to CAM practitioners than to conventional primary care doctors, and that the public was paying for these therapies out of their own pockets.

(4) The launching of *The Richard and Hinda Rosenthal Center for Complementary and Alternative Medicine* at a premier US medical school, Columbia University College of Physicians and Surgeons, greatly strengthened the academic credibility of research in CAM. While a few other centers existed at the time, the establishment of the center at Columbia provided substantial legitimacy. Other institutions took notice, and many subsequently followed suit. Researchers and administrators from other medical centers called and visited to inquire about how they might start such a program, and over the next four years, more programs at academic medical centers were initiated. CAM programs received a further boost when the NIH OAM funded ten CAM specialty centers at academic institutions nationwide (1995), including one at Columbia University (see below).

2. Initiation of CAM Centers/Programs at Conventional Medical Centers

The development of alternative medicine programs at major academic medical centers can be seen to have gone through several growth phases, even since 1993. Although the phases are not sharply delineated, they can be identified, and are described below: a first

phase during which a few centers were funded by private funding sources; a second phase of growth spurred by NIH OAM funding, and a third (current) phase of much expanded growth at medical centers and hospitals around the country.

2.1 *First Phase: Privately Funded Programs at Academic Medical Centers*

The early officially sanctioned programs were established through the efforts of a few individual faculty members at each institution, primarily with support from private donors, and with little if any institutional funding.

Perhaps the earliest formal program at an academic medical center was the Lange Center for Complementary Medicine at the University of Maryland School of Medicine. This program, which may have been the first formal complementary medicine program at a US medical school, began in 1991 in the Department of Anesthesiology and is now the Complementary Medicine Program at the University of Maryland School of Medicine, within the Department of Family Medicine. Another early program at a mainstream medical school was the University of California, Los Angeles (UCLA), Center for East-West Medicine, established in 1993 in the Department of Medicine at the UCLA School of Medicine. The goal of the program is to integrate modern Western with traditional Chinese medicine (TCM). The Rosenthal Center for Complementary and Alternative Medicine Research was established in 1993. It was one of the first CAM research and education programs at a medical school in the US with a broadly defined research, education and training agenda. The Rosenthal Center resides in the Department of Rehabilitation Medicine, because this was the home department of its director. Given the national status of Columbia's Medical School, the impact of this center's existence was significant.

The program at the University of Maryland was started with funding from the Lange Foundation. The program at UCLA was

also initiated with private funding. The Rosenthal Center was launched with funding from the Richard and Hinda Rosenthal Foundation. This initial funding allowed for the launch of these centers, and gave the directors the platform from which to seek the more substantial funds necessary to develop research or clinical programs.

The founding directors for these early centers came from a variety of backgrounds. Dr. Brian Berman at the University of Maryland is a physician conventionally trained in the US. He did his residency in Europe, where he was exposed to complementary medicine, including homeopathy, herbal medicine, and many other therapies he did not learn about in medical school. He returned to the US to set up a program that included these other practices. Dr. Ka Kit Hui, of UCLA also a conventionally trained physician, had background in Eastern medical traditions and wanted to create a clinical program that integrated the best of Eastern and Western medicines. Dr. Fredi Kronenberg is a physiologist doing research in thermoregulatory and reproductive endocrinology. She learned about complementary medicine while in graduate school in California, where she took classes in a variety of CAM areas, and began practicing yoga and Aikido. She had also worked in environmental health and environmental conservation, and had exposure to Native American culture, and to TCM through a visit to China in 1990.

After the Rosenthal Center was established at Columbia University, a survey was conducted of Columbia's faculty and staff to see what interest and expertise in CAM already existed there. More than 400 people responded, who not only had interest (Table 1), but in many cases, relevant expertise as well (e.g. licensed acupuncturists, licensed massage therapists, yoga instructors, clinical researchers studying biofeedback and Tai Chi, basic researchers investigating green tea and the chemistry of natural products). This interest had been until then a closeted interest, and yet it existed in virtually every department in Medical School, the School of Nursing, School of Public Health, School of Oral and Dental Surgery, as well as in other academic departments such as the Department of Religion. Faculty interests

Table 1 Selected CAM Interests of Columbia University Faculty (n).

Alternative medicine (78)	Massage (14)
Biofeedback (50)	Nutrition (13)
Acupuncture (47)	Acupressure (11)
Hypnosis (38)	Vitamin therapy (11)
Herbal medicine (34)	Shiatsu (8)
Relaxation techniques (19)	Therapeutic touch (8)
Homeopathy (17)	Music therapy (6)
Imagery/visualization (11)	Light therapy (5)
Meditation (16)	Tai Chi (4)
Chinese medicine (15)	Ayurveda (3)

and knowledge of CAM ranged from the more familiar areas, such as acupuncture, massage, visualization, biofeedback, Shiatsu, Tai Chi and yoga, to the more esoteric and less known, including craniosacral therapy, Reiki, and aromatherapy.

It is likely that many if not most medical centers around the country have faculty and staff with these "side" or "secret" interests that were not previously shared with their colleagues. When The Rosenthal Center was initiated, with the encouragement and blessing of the Dean of the Medical School, people in a broad range of clinical and scientific areas began to talk openly about their interests in CAM, and were excited to find compatriots and potential research collaborators among their colleagues. Of course, not everyone shared this enthusiasm. Particularly during the Center's first year or two, there was criticism, often sharp, from some Columbia faculty and alumni who wondered why their medical school was wasting money on such things, and risking the shining image of this illustrious medical institution. Antagonistic letters were sent to the Dean by faculty and alumni who expressed concern that "impressionable" medical students were being exposed to material that they were in no position to evaluate. At one point picketing was threatened. Some of the outspoken critics were invited to participate in a dialogue with the medical students. Programs were developed with credible

faculty from within and outside of the university, gradually, the intensity of the opposition was reduced (although inevitably some still exists).

The initiation of CAM programs across the country in the 1990s broke down barriers and took CAM into the arena of the conventional medical culture.

2.2 *Second Phase: NIH-Funded CAM Specialty Research Centers at Academic Institutions Raise the Public Profile of CAM*

A major boost was given to the fledgling CAM programs in mainstream medical institutions by the OAM at the NIH. Early in its existence, the OAM decided to commit a significant portion of its meager budget to fund academically-based research centers. The OAM's director determined that it would be strategically and politically wise to fund a number of centers, each with a different specific research focus, geographically distributed around the country, at well-respected medical institutions. The specialized areas of the first ten centers were: asthma/allergy/immunology, cancer, pain (two centers), women's health, neurological conditions, addiction, HIV/AIDS, aging, and chronic illness (Table 2). Subsequently, in 1998, three new centers were funded: pediatrics, cardiovascular disease, and chiropractic. And, as of September 1999, additional centers were funded in the areas of neurological disorders, craniofacial disorders, and cardiovascular disease and aging in African Americans (Table 3). These centers raised the public profile of CAM and further extended scientific research in CAM.

The initial ten centers were provided relatively modest annual funding with the expectation that it be used to develop infrastructure and to seed pilot research. Centers were expected to raise other funds either from the government, private industry, or private foundations to support research projects. The center directors have spent considerable time and effort seeking funding for research and educational programs (e.g. from government, private foundations,

Table 2 NIH National Center for Complementary and Alternative Medicine (NCCAM).

The NCCAM-funded ten specialty centers of 1994–1995:	
Bastyr University	HIV/AIDS
Columbia University	Women's health
Harvard University	General medicine
Kessler Inst. For Rehabilitation	Neurological and stroke
Minneapolis Medical Research Ctr.	Addictions
Stanford University	Aging
U.C. Davis	Asthma and allergy
University of Maryland	Pain
University of Texas	Cancer
University of Virginia, Nursing	Pain

Table 3 NIH CAM Centers (Re)funded (1998–1999).

Columbia University	Aging and women's health
Maharishi University	Cardiovascular and aging in African Americans
Minneapolis Medical Research Ctr.	Addictions
Oregon Ctr. Health Research	Craniofacial disorders
Oregon Health Sciences Univ.	Neurological disorders
Palmer Center for Chiropractic	Chiropractic
University of Arizona	Pediatrics
University of Maryland	Arthritis
University of Michigan	Cardiovascular

individual private donors, and industry, including pharmaceutical, herbal and health insurance companies).

CAM research has also been increasingly funded by other NIH institutes. Some institutes were funding these areas before the OAM existed. The topics and approaches tended to be in areas that could be easily understood by Western scientists, primarily ones that fit into the standard biomedical research models. So, for example, the

National Cancer Institute (NCI) has funded projects on phytoestrogens (plant estrogenic substances) and cancer. The National Heart, Lung and Blood Institute (NHLBI) has funded studies of stress management for heart disease, and vitamins for cardiovascular disease. The National Institute on Aging (NIA) funded studies of Vitamin E and atherosclerosis prevention, and Tai Chi exercise for older adults. The National Institute of Mental Health (NIMH) funded studies on the therapeutic process in religious healing, on acupuncture for drug addiction, on "Communication and Experience in Navaho Healing," and most recently, on the herb St. John's wort, for the treatment of depression (with the OAM). Other studies that the NIH funded that some considered to be under the CAM umbrella are studies of melatonin, dehydroepiandrosterone (DHEA), studies of antioxidants, ginkgo for Alzheimer's disease, and studies of green tea for cancer prevention.

Up to now, the NCCAM focused little attention on traditional systems of medicine. Some pieces of the systems have been studied, such as acupuncture for arthritis and the use of herbal remedies, particularly Western herbs that are used singly. But little emphasis has been placed on studying whole systems as they have traditionally been practiced (e.g. traditional Chinese medicine, Ayurveda). However, this is changing; NCCAM is now actively encouraging research proposals in traditional medicine.

2.3 *Third Phase: Rapid Expansion of Programs at Academic Medical Centers, Independent Hospitals and Private Practices Around the Country*

New Programs: Research and clinical service provision in CAM has been increasing steadily and more rapidly each year. Interest is building, as medical centers and hospitals around the country are now developing alternative medicine programs. Clinical programs have been initiated at many places, including in New York, Columbia-Presbyterian Medical Center (Department of Complementary Medical

Services), Beth Israel Medical Center (Center for Health and Healing) and Memorial Sloan Kettering Hospital (Integrative Medicine Program); in California, UCLA Medical Center (The Cedars-Sinai Integrative Medicine Medical Group) and Stanford University (CAM clinic); in New Jersey, Hackensack Medical Center Jersey (Complementary Medicine Program); and many other hospitals around the country.

Particularly in the last year or two, the awareness and level of comfort with CAM among medical center faculty and administrators has increased. But institutional comfort exists primarily for CAM areas that are culturally and medically most accessible, and interpretable within a biomedical framework.

Media Coverage: During the four-year funding period for the initial NIH CAM centers, media coverage of CAM grew exponentially. Not only were activities of the centers covered in newspapers and other publications, but journalists sought out information on CAM from researchers, practitioners and patients, around the country and the world, and television news stories and special interest pieces abounded.

The media coverage continues unabated. What was at first curiosity and novelty coverage has become regular columns and systematic coverage in magazines and newspapers, new publications, and a steady stream of television programs. With increased media coverage, the consumer market is maturing. It knows the terminology, and knows somewhat better what it wants, and what it wants to know. People want medical services; they want treatments to be provided by practitioners they know and trust. But questions remain as to who or what to trust; which practitioners, and what information. The public wants to see research that "validates" the therapies that they are trying or would try if research data were presented to them.

Health Insurers: A number of health insurance companies and health maintenance organizations are beginning to cover CAM clinical services, and in some cases, to fund research to determine the

effectiveness and cost-effectiveness of CAM therapies. But there are so many different therapies and illnesses that are being treated that it is unrealistic, even given a significant increase in funding, to expect that in any reasonable time period the requisite studies can be completed to validate with rigorous biomedical methodologies, even a fraction of the therapies and multi-therapy approaches being used for the great variety of medical problems being treated. Therefore, other ways of evaluating the efficacy of these practices, particularly the long-used traditional systems of medicine, should be considered.

3. Research Issues and Challenges in Academic Medical Settings

There are a number of factors that impact on the conduct of CAM research at academic medical centers, particularly on clinical research. These factors include institutional review for human subjects and approval of protocols, funding, and research design issues.

3.1 *Clinical Research*

Institutional (Human Subjects) Review Boards (IRB): Academic institutions typically have review boards (human subjects committees) that are responsible for ensuring the safety and well-being of human subjects in clinical research studies. Their duties include assessing the potential risks of the intervention under investigation. Most Institutional Review Boards (IRBs) are relatively unfamiliar with CAM therapies. For example, Columbia University's IRB has not felt that it could take responsibility for CAM practices or medicines it knew little or nothing about, particularly therapies that might be delivered by practitioners of traditional medicine, who may not have any official license granted by a body accredited in the US, and whose qualifications are thus not easily evaluated. Some of our pilot studies have, therefore, been designed such that the treatment takes place off university premises so that the university assumes no legal liability

for what the traditional practitioners may do in the confines of their offices.

When a study involves herbal medicine, it is typically viewed as resembling work done with pharmaceutical drugs. However, IRB members generally know little or nothing about the specific herbs to be used and their safety. At Columbia, the IRB at first tied their approval of herbal protocols to prior FDA approval of the herbal agents being proposed for study. Thus, before we could begin a study of a Chinese herbal formula for the treatment of hot flashes in women, we were required by the IRB to submit an Investigational New Drug (IND) application. More recently, as applications to the IRB for herbal studies increase, approval is on a case-by-case basis and the requirements for the investigators depend on a number of factors, including whether the product is widely sold/available over the counter in the US, or whether the components are on the GRAS (Generally Recognized as Safe) list.

The Food and Drug Administration (FDA): The FDA remains relatively unfamiliar with herbs, and had not, until relatively recently, had experience reviewing herbal mixtures for clinical research. The FDA typically reviews studies evaluating pure, single compounds; they have had to be initiated into the world of complex mixtures, with complex chemistries.[5,6] With each successive herbal/botanical medicine application to the FDA, the way becomes easier for those who follow. However, the sophistication of the FDA has also increased over time, and the standards for information required of successive applicants have become more rigorous. Yet with botanicals, the FDA also reviews many applications on a case-by-case basis. They consider issues of historical use, or use by practitioners in the US (with documented patient records and follow-ups), which is of particular value when little direct experimental data exist. Requirements for animal toxicity data depend (as with pharmaceuticals) on type and stage of disease (for example, endstage cancer; no satisfactory Western treatment).

Collaborating with CAM practitioners: Despite the challenges, it is also rewarding to work with practitioners who may never before have been involved in clinical research. When doing this work, it is important to explain the purpose and details of study designs, and to have practitioners as involved as possible in the design phase of the research so the final design reflects their practice as accurately as possible, and they understand the values as well as the constraints of a particular methodology.

Another issue faced in performing CAM research is the need for clear definitions of things as basic as the definition of diseases/conditions to be investigated. Is what Western medicine calls disease "x" actually the same as the apparent counterpart in another culture? Are the diagnostic criteria the same in Western and traditional systems?

Access to Published Scientific Literature: For many alternative and complementary modalities, and especially traditional systems of medicine, results of research studies are often published in small journals, many located in other countries and not published in English. The data that exist in other countries are not easily accessible to researchers in the US. In addition, for particular modalities, or systems of medicine there may be no published research results. Without knowledge of what others have done, researchers may use their precious few resources to repeat work that has already been done, or not to have the advantage of being able to improve upon or extend what others have already done.

3.2 *Funding Issues*

Research in academia is primarily funded by grants obtained by individual investigators. Faculty members obtain funding from a variety of sources, including government agencies such as the NIH, the National Science Foundation, the Department of Defense, the Department of Energy, state and local government programs, private foundations, and occasionally, healthcare insurers. Investigators apply

for grants in areas that are advertised by these agencies and organizations as being of interest to them.

National Institutes of Health: The various institutes of the NIH fund research in areas prioritized by their respective directors. And while there is typically money for investigator-initiated proposals, considerable money is set aside for particular areas targeted as important by the institute. The NIH OAM (now NCCAM) initially funded 42 small studies in a wide range of CAM-related areas. Subsequently, when its budget increased, the OAM issued requests for proposals in specific areas, such as clinical trials for therapies to treat osteoarthritis, for St. John's wort to treat depression; and for shark cartilage to treat cancer. The NCCAM has encouraged investigators to focus on areas in which there are some pilot data or research results, perhaps from other countries, indicating beneficial effect for the condition of interest.

The result of this process has been that grant applications are tailored to take into account administrative constraints and the desires and priorities of the granting institutions. This, of course, is also true in conventional biomedical research. Grants are often written in response to a specific call for proposal topics. So some of the applying researchers' most interesting ideas and interests may go unfunded.

The complementary and alternative medicine specialty centers that were funded in 1994/1995 by the NIH were encouraged to develop research agendas (1) for conditions that are not treated well by conventional medicine; (2) for conditions for which many patients are already trying alternative therapies that were amenable to easily designed clinical trials, and (3) for therapies which lack proven efficacy in Western scientific terms, but for which substantial number of Americans are paying large sums of money out of their own packets.

Government funding from the NIH, particularly for studies of herbal medicines, brings with it the requirement that the applicant obtain FDA approval for the medicine before initiating the study. This typically adds one to two years to the research process.

In addition, with the growing interest in CAM research, there is increasing pressure from within the NIH for study designs that conform to the conventional clinical trials research paradigm of the randomized, double-blind, placebo-controlled trial, the so-called "gold standard" of clinical research design. Yet for some CAM practices, other clinical research methodology may be more appropriate.

As indicated above, the NIH NCCAM, while expressing interest in traditional systems of medicine, has not to date encouraged research investigating the systems as a whole, perhaps because whole systems cannot be as easily studied in the conventional controlled clinical trial study design. The needed studies are more difficult to conduct, and much pilot work will be needed to refine research methodologies. NCCAM will soon announce a request for proposals for research in traditional systems of medicine, and in doing so, will acknowledge that much exploratory research is needed before larger studies will be initiated.

Another problem faced when trying to obtain funding from the NIH for CAM research is that there has not been a "good fit" between many alternative medicine research projects and the very specific disease-driven structure of the governmental agencies that provide funding for medical research. The individual institutes that comprise the NIH are disease- (or at least topic-) oriented. They include, for example, heart, lung and blood, child health and development, cancer, aging, musculoskeletal system, arthritis and allergy. Grant proposals are assigned for funding to the institute in which they are deemed by the administrative staff to fit best. This is generally determined by the title of the grant proposal.

An even more critical challenge is the "study section" review process, as this is where the grants are scored for scientific merit. Grants are reviewed by groups of scientists with expertise in the topic under review (study sections). These review groups tend to be divided by research areas. In the past, there has been difficulty in applicants receiving appropriate reviews for their grants, since many proposals are tangential to the focus of the standing study

sections. For example, there currently is no study section with a focus on traditional Chinese medicine. However, now that NCCAM is a center, it can appoint its own study sections and choose individual reviewers who have expertise appropriate to any particular grant.

Private foundations and private donors: Some major foundations have greatly increased their giving in the 1990s and are specifically funding science and medicine.[7] While many foundations will fund in areas already well respected and well within established needs, private foundations often take the lead in funding areas that are innovative, on the cutting edge, and that may not yet be acceptable to government funders. Some foundations specifically seek to provide leadership, and are looked to by others for new trends in funding. They may hold their own fact-finding meetings. They may take bold risks in new areas. Private foundations are an important and increasing funding resource in the area of alternative medicine.

Private donor resources continue to be motivating forces for the initiation of CAM centers. The size of the donations are increasing. The Osher Center for Integrative Medicine at the University of California, San Francisco School of Medicine, was established in 1997 with a significant (US$10 million) grant, and the Integrative Medicine Center at Memorial Sloan Kettering Hospital in New York City was initiated in 1999, with funding of similar magnitude from Laurance Rockefeller.

Corporate foundations and Industry: The American pharmaceutical industry has a history of funding biomedical research, particularly studies related to drug development, whether in-house or by underwriting university or other private research efforts. Clearly, pharmaceutical companies stand to benefit from results of the research that they fund. However, issues such as the limited opportunity to patent of many herbal products have contributed to the lack of substantive interest of the pharmaceutical industry in funding herbal research. Yet if people continue to spend billions of dollars out of their own pockets[1] on alternative remedies, especially for vitamins, supplements and herbs, interest in the market is likely to grow.

At this point in time, many US drug companies (many of which are international), are developing products as dietary supplements that do not require an FDA new drug application, and the extensive toxicity, preclinical and clinical research (and associated substantial costs) that would be necessary for such approval. However, it may prove worthwhile for industry to fund research, at least at a level that would validate the efficacy and lack of acute toxicity.

Unlike the pharmaceutical industry, the herbal/vitamin industry has not had the corporate history and tradition of funding extramural research. Nor does the herb industry, in general, have the financial resources that are available to large pharmaceutical companies. This may change in the coming years as large pharmaceutical companies investigate, target and begin to buy small herb companies, as is already beginning to happen.

In Europe, and now in Asian countries such as Japan, some of the larger botanical companies do fund at least some research, and some smaller companies are beginning to follow this example. Company-initiated clinical research generally evaluates their own products. An outside investigator may or may not be interested in studying a particular product. Yet, product-directed research is the focus of a lot of the basic and clinical studies conducted within universities.

Patient advocacy and information groups: Non-profit patient advocacy and information groups, such as the American Heart Association or the American Diabetes Association, have interest in funding studies within their specific disease focus. Although they may not yet have developed research in CAM therapies, it is likely that this will become an area of interest in the near future.

Physicians and organized medicine: If various therapies are proven to work, patients obviously stand to benefit, as do the physicians who treat them or direct them to the appropriate treatments or practitioners. In 1998 and 1999, conventional American medical associations and allied professional groups woke up to the reality that CAM is here to stay. Meetings of medical societies in a wide

variety of disciplines held sessions on CAM. The American Psychological Association, the American Psychiatric Association, and the American Public Health Association (which had already formed a CAM special interest group), the North American Menopause Society, the American Society for Reproductive Medicine, Pediatric Oncology Group (and Children's Cancer Group), all had or are planning sessions on CAM at their annual meetings. Neither physicians nor organized medicine has been a significant funder of CAM research. A few physicians may contribute personal funds to the conduct of research, but these individuals are not typical; most individual physicians are not able to make substantial contributions necessary to fund a research study. However, perhaps groups of individuals should consider initiating such funding.

4. Where Does an Alternative Medicine Program Fit into the Structure and Function of the Conventional American Medical Culture?

Where in academic institutions do alternative medicine programs belong? At Columbia University College of Physicians and Surgeons, for example, the location of the CAM programs is a function of the departmental homes of the faculty members who started each program. The Rosenthal Center (a research and education program) is housed in the Department of Rehabilitation Medicine, where its director is affiliated; the Complementary Care Center is housed in the Department of Surgery where its director is affiliated; the Center for Meditation and Healing is housed in the Department of Psychiatry, where its director is affiliated; the Integrative Therapies for Children with Cancer is in the Department of Pediatrics.

Yet these programs are often broader and more cross-cutting than would logically be housed in any one department, and seem inherently interdisciplinary. In fact, they do not "fit nicely" in any existing structure in an established medical school environment, just as funding for most CAM research does not "fit nicely" within the

NIH funding structure. For this reason, some CAM programs are being developed through departments of family medicine, for example, where there is a broader medical mandate. And, in a few places there is discussion of initiating new, independent departments for CAM. Some alternative medicine clinical programs are developing outside the artificial constraints of hospital or medical school departmental structure, and are being developed as free-standing programs.

Within the NIH, funding of these areas is already becoming more widespread among the NIH institutes, as noted above. While many of the NIH institutes have a history of some modest funding of CAM-related therapies, these are, of necessity, to treat diseases under their institutional mandate. However, there is now, the NCCAM, the Office of Dietary Supplements (ODS), the Office of Research on Women's Health and the Office of Behavioral and Social Science Research (OBSSR). These divisions do not have a disease focus and, as more broadly charged, are appropriate target sites for those seeking funding in CAM.

A congressional mandate directed the OBSSR to lead efforts at the NIH to develop a mind-body medicine initiative. Congress also specifically designated US$10 million for this purpose to the OBSSR. Twelve NIH institutes agreed to co-sponsor the initiative. Five institutes — the NCI, the NHLBI, the National Institute of Child Health and Human Development (NICHD), the National Institute of Dental and Craniofacial Research (NIDCR), and the NIMH — will support the five new centers, which have just been approved for these awards. In addition, the ODS just awarded two grants (September 1999) for the establishment of Centers for Botanical Research.

5. Conclusion

Programs in CAM are growing at academic institutions around the country. The potential funding sources for such programs are

becoming more diverse, more informed and more sophisticated. But a great deal of work remains for researchers and clinicians who are trying to develop the strong evidence base to support the broad use of CAM in the US.

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What Will Influence the Future of Alternative Medicine?

A WORLD PERSPECTIVE

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This book provides an overview of factors that have influenced and will continue to influence the development of "alternative" (traditional) medicine in the world. Traditionally, the lack of relevant good quality scientific research is often the reason why a large number of healthcare practices are labeled "alternative". However, nonscientific factors may be at least as important as the scientific ones. Among such factors are cultural, political, administrative, and economic considerations. The articles in this volume provide an international perspective on how such pervasive factors impact on the development, research, and practice of alternative medicine in the world.

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